

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

**FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933**

Xeris Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)

2834
(Primary Standard Industrial Classification Code Number)

20-3352427
(I.R.S. Employer Identification No.)

Xeris Pharmaceuticals, Inc.
180 N. LaSalle Street, Suite 1800
Chicago, IL 60601
1-844-445-5704

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Paul Edick
President and Chief Executive Officer
Xeris Pharmaceuticals, Inc.
180 N. LaSalle Street, Suite 1800
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1-844-445-5704

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated filer
Non-accelerated filer (Do not check if a smaller reporting company)

Accelerated filer
Smaller reporting company
Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

CALCULATION OF REGISTRATION FEE

TITLE OF EACH CLASS OF SECURITIES TO BE REGISTERED	PROPOSED MAXIMUM AGGREGATE OFFERING PRICE (1)	AMOUNT OF REGISTRATION FEE (2)
Common stock, \$0.0001 par value per share	\$	\$

- (1) Estimated solely for the purpose of computing the registration fee in accordance with Rule 457(o) under the Securities Act of 1933, as amended. Includes the aggregate offering price of shares that the underwriters have the option to purchase to cover over-allotments, if any.
(2) Registration fee will be paid when registration statement is first publicly filed under the Securities Act of 1933, as amended.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant files a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the Securities and Exchange Commission declares our registration statement effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to completion, dated _____, 2018

Preliminary Prospectus

Shares



Common Stock

We are offering _____ shares of common stock. This is our initial public offering and no public market currently exists for our shares. We expect that the initial public offering price will be between \$ _____ and \$ _____ per share. We have applied to list our common stock on the Nasdaq Global Market under the symbol "XERS".

We are an "emerging growth company" under the federal securities laws and, as such, we have elected to comply with certain reduced public company reporting requirements for this prospectus and for filings.

Investing in our common stock involves a high degree of risk. Before buying any shares, you should read carefully the discussion of the material risks of investing in our common stock under the heading "[Risk Factors](#)" starting on page 11 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission approved or disapproved of securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	PER SHARE	TOTAL
Public offering price	\$ _____	\$ _____
Underwriting discount (1)	\$ _____	\$ _____
Proceeds, before expenses, to Xeris Pharmaceuticals, Inc.	\$ _____	\$ _____

(1) We refer you to "Underwriting" beginning on page 155 of this prospectus for additional information regarding underwriting compensation.

Delivery of the shares of common stock is expected to be made on or about _____, 2018. We have granted the underwriters an option for a period of 30 days to purchase an additional _____ shares of our common stock. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable by us will be \$ _____, and the total proceeds to us, before expenses, will be \$ _____.

Joint Book-Running Managers

Jefferies

Leerink Partners

RBC Capital Markets

Mizuho Securities

The date of this prospectus is _____, 2018.

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Neither we nor the underwriters have authorized anyone to provide you with information different from, or in addition to, that contained in this prospectus, any amendment or supplement to this prospectus and any related free writing prospectus. We and the underwriters take no responsibility for, and can provide no assurances as to the reliability of, any information that others may give you. This prospectus is not an offer to sell, nor is it seeking an offer to buy, these securities in any jurisdiction where the offer or sale is not permitted. The information contained in this prospectus or in any free writing prospectus is only accurate as of its date, regardless of its time or delivery or the time of any sale of our common stock. Our business, financial condition, results of operations and future growth prospects may have changed since that date.

Until and including _____, 2018 (25 days after the date of this prospectus), all dealers that buy, sell or trade our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the obligation of dealers to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

PROSPECTUS SUMMARY

This summary highlights information contained in greater detail elsewhere in this prospectus. This summary does not contain all of the information that you should consider in making your investment decision. Before investing in our common stock, you should carefully read this entire prospectus, including our financial statements and the related notes thereto and the information set forth under the sections titled "Risk Factors," "Special Note Regarding Forward-Looking Statements" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," in each case included in this prospectus. Unless the context otherwise requires, we use the terms "Xeris," the "Company," "we," "us," "our" and similar designations in this prospectus to refer to Xeris Pharmaceuticals, Inc.

Our Company

We are a specialty pharmaceutical company leveraging our novel non-aqueous formulation technology platforms, XeriSol and XeriJect, to develop and commercialize ready-to-use injectable and infusible drug formulations. We have developed a ready-to-use, room-temperature stable liquid glucagon formulation that, unlike any currently available products, can be administered without any preparation or reconstitution. Our lead product candidate, Glucagon Rescue Pen, delivers ready-to-use glucagon via a commercially-available auto-injector for the treatment of severe hypoglycemia, a potentially life-threatening condition, in people with diabetes. We have completed three Phase 3 clinical trials for our Glucagon Rescue Pen and expect to submit a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or the FDA, in the third quarter of 2018. If our NDA is submitted and approved in our expected timeframe, we believe we will have the first ready-to-use, room-temperature stable liquid glucagon formulation that can be administered without any preparation or reconstitution. We are also applying our novel ready-to-use, room-temperature stable liquid glucagon formulation for the management of additional conditions associated with hypoglycemia with significant unmet medical need. In addition, we are applying our technology platforms to convert other commercially-available drugs into ready-to-use, room-temperature stable liquid formulations to address the needs in multiple therapeutic areas and conditions, including epilepsy and diabetes.

Our Technology Platforms and Our Pipeline

Our proprietary non-aqueous formulation technology platforms are designed to address solubility and stability challenges presented by current aqueous formulations of certain drugs. Our proprietary XeriSol and XeriJect platforms offer the opportunity to eliminate the need for reconstitution and refrigeration, enable long-term room-temperature stability, significantly reduce injection volume and allow for a more convenient subcutaneous or intramuscular administration as opposed to intravenous infusion, all of which we believe are distinct advantages over existing aqueous formulations of marketed and development-stage products. We believe that our technology platforms can lead to products that will improve outcomes and enable easier administration while reducing costs for payors and the healthcare system. XeriSol is best suited for peptides and small molecules that currently encounter formulation challenges. XeriJect is best suited for drugs and biologics consisting of large molecules, such as proteins, monoclonal antibodies and vaccines.

The following table summarizes key information about our internal product candidates.

	Product Candidate	Indication	Development Stage				Next Milestone	
			Pre-Clinical	Phase 1	Phase 2	Phase 3	Event	Expected Date
Ready-to-Use Glucagon for Hypoglycemia	Glucagon Rescue Pen	Severe Hypoglycemia	Phase 3				Submit NDA	3Q'18
	Self-Administered Glucagon	Post-Bariatric Hypoglycemia*	Phase 2a				Ph 2a Results (Closed Loop Pump) Initiate Ph 2b (Vial/Syringe)	1H'18 2H'18
	Continuous Glucagon	Congenital Hyperinsulinism*	Phase 2				Ph 2 Interim Efficacy Results	2H'18
	Continuous Glucagon	Hypoglycemia-Associated Autonomic Failure	Phase 2a				Ph 2a Results	2H'18
	Self-Administered Glucagon	Exercise-Induced Hypoglycemia	Phase 2a				Initiate Ph 2b	2H'18
Ready-to-Use Products for Epilepsy and Diabetes	Diazepam	Acute Repetitive Seizures*	Pre-Clinical				Ph 1 Results	2H'18
	Pramlintide-Insulin	T1D / T2D Blood Sugar Control	Pre-Clinical				Pre-clinical Results	1H'18

* Received orphan drug designation

Additionally, we expect to commence a proof-of-concept clinical study for our bi-hormonal artificial pancreas program in mid-2018.

We are the sponsor of four active Investigational New Drug, or IND, applications for our Glucagon Rescue Pen and ready-to-use glucagon for the treatment of severe hypoglycemia and the intermittent and chronic conditions listed above.

Severe Hypoglycemia and Limitations of Existing Products

Hypoglycemia, a key concern of people with both Type 1 Diabetes, or T1D, and Type 2 Diabetes, or T2D, occurs when a person has a deficiency of glucose in their bloodstream, often as a result of insulin treatment. Symptoms of hypoglycemia include fatigue, shakiness, anxiety, headache, nausea and vomiting, and in severe cases, hypoglycemia can result in cardiovascular disease, seizure, coma and, if left untreated, death. Treatment-associated hypoglycemia in people with diabetes remains the major limiting factor in the glycemic management of T1D and T2D. In the United States, all of the approximately 1.3 million people with T1D and approximately 4.3 million people with T2D who require insulin therapy to lower their blood glucose levels are at risk for hypoglycemia. Hypoglycemic events of any severity are a daily concern for people with diabetes and represent the greatest barrier to optimal glycemic control. Severe hypoglycemic events are extremely frightening for patients and caregivers and can result in seizure, coma and, if left untreated, death. The American Diabetes Association, or ADA, recommends that glucagon be prescribed for all individuals at increased risk of clinically significant hypoglycemia for use in the event of an emergency.

Because of the urgent nature of severe hypoglycemia, the majority of severe hypoglycemic events are treated on an emergency basis, outside of a healthcare facility. Two emergency glucagon products are currently available to treat severe hypoglycemia. Each product is sold as a vial of lyophilized, glucagon powder with an exposed needle/syringe that contains a liquid diluent. The glucagon powder must be combined with the liquid diluent at the time of use and drawn into a syringe in accordance with a complex multi-step reconstitution and dose calibration procedure. Additionally, once reconstituted, the glucagon must be used immediately because once the lyophilized glucagon is combined with water, the solution becomes unstable and can fibrillate, rendering it inactive and potentially toxic.

In published comparative human factors studies with currently marketed kits, only 6% to 31% of users were able to successfully administer the full dose of glucagon. The complex, unreliable administration of currently marketed products inhibits patient interest in carrying a kit and physician focus on ensuring each clinically

appropriate patient at increased risk has a filled prescription. In 2017, U.S. sales for emergency glucagon kits totaled approximately \$240 million, based on approximately 660,000 total prescriptions written for approximately 960,000 single-dose kits.

Our Glucagon Rescue Pen

We are developing our lead product candidate, Glucagon Rescue Pen, which delivers our ready-to-use glucagon formulation via a commercially-available auto-injector, for the treatment of severe hypoglycemia in people with diabetes. We believe our Glucagon Rescue Pen addresses the administration challenges of currently marketed emergency glucagon kits, and, if approved, has the potential to be the preferred emergency glucagon product. The key features of our Glucagon Rescue Pen are:

- *Ready-to-use:* With its easy two-step administration process, the user simply pulls off the red cap and pushes the Glucagon Rescue Pen down on the skin for five seconds, until the window turns red. There is no reconstitution required at the time of emergency.
- *Easy-to-use:* In our human factors study, 99% of users were able to successfully administer the full dose with our Glucagon Rescue Pen.
- *No dose calibration required:* The Glucagon Rescue Pen will be offered in two pre-measured doses, 0.5 mg for pediatric administration and 1 mg for adolescents and adults.
- *No visible needle:* The needle in the Glucagon Rescue Pen is not visible to the user.
- *Auto-retraction:* The needle auto-retracts after administration for safety.
- *Auto-locks:* The device auto-locks after use for safety.
- *Two-year room-temperature stability:* No refrigeration is required at any time.

As of December 31, 2017, we had completed two Phase 3 clinical trials of our Glucagon Rescue Pen and expect to submit a NDA to the FDA in the third quarter of 2018 utilizing the 505(b)(2) regulatory pathway. To generate additional information regarding the entire treatment episode, including preparation and administration time of our Glucagon Rescue Pen compared to Eli Lilly's Glucagon Emergency Kit, we completed an additional Phase 3b clinical trial of our Glucagon Rescue Pen in the second quarter of 2018. We also intend to offer our Glucagon Rescue Pen in a pre-filled syringe presentation that may be preferred by some healthcare professionals.

Glucagon Rescue Pen Market Potential

Based on current market data, as well as our caregiver and patient and healthcare professional perceptions studies, we believe that our Glucagon Rescue Pen, if approved, has the potential to increase demand for emergency glucagon treatments among people with diabetes.

Despite the risk of experiencing a severe hypoglycemic event, we believe that emergency glucagon therapy is under-appreciated, under-evaluated and under-taught, resulting in a market that is under-penetrated. According to a 2015 study published in the journal *Endocrine Practice*, approximately 50% of people with T1D and approximately 3% of people with T2D with a new insulin prescription had a filled glucagon prescription. We intend to market our Glucagon Rescue Pen to all 3.5 million people that we believe are clinically appropriate for glucagon. We believe by increasing penetration into the market for emergency glucagon kits, and based on the current price per unit for currently marketed kits, the U.S. market potential may total up to \$2.0 billion.

We expect to initially target approximately 8,000 healthcare professionals that are high prescribers of current glucagon kits and/or mealtime insulin products, using an expected initial sales force of 60 individuals. As part of our marketing strategy, we plan to activate patient demand efficiently and effectively through targeted direct-to-patient promotion, as the majority of people with diabetes are concentrated in ten states.

Ready-to-Use Glucagon for Hypoglycemia Associated with Intermittent and Chronic Conditions

We are applying our ready-to-use, liquid-stable glucagon formulation to treat five intermittent and chronic conditions with significant unmet medical need: Post-Bariatric Hypoglycemia, or PBH, syndrome; Congenital Hyperinsulinism, or CHI; Hypoglycemia-Associated Autonomic Failure, or HAAF; Exercise-Induced

Hypoglycemia, or EIH; and management of diabetes via glucagon in a fully-integrated, bi-hormonal artificial pancreas closed-loop system. By applying our ready-to-use glucagon to these conditions, we expect to leverage operating efficiencies across our supply chain, research and development, and commercial and medical organizations.

We also are applying our technology platforms to develop additional product candidates, such as ready-to-use, liquid-stable diazepam delivered via a commercially-available auto-injector for the emergency treatment of epileptic seizures, and a fixed-dose co-formulation of pramlintide and insulin, or Pram-Insulin, for the management of diabetes. We believe that our strong product candidate portfolio, complemented by external expansion opportunities, will support our vision to effectively and efficiently meet the needs of our target markets.

Intellectual Property and Barriers to Entry

We own the worldwide rights to our proprietary formulation technology platforms and our product candidates, with 66 patents issued globally, including a composition of matter patent covering our ready-to-use glucagon formulation that expires in 2036. The FDA has granted orphan drug status to three of our product candidates, which are our ready-to-use glucagon for PBH and CHI, and our ready-to-use, liquid-stable formulation of diazepam for the treatment of acute repetitive seizures in patients with epilepsy.

Management

Our management team includes veterans in drug development, discovery and commercialization, with executive experience in leading global pharmaceutical and healthcare companies, including Durata Therapeutics, Baxter Healthcare, Merck, Searle, Takeda, Warner Chilcott, MedPointe Healthcare, Amylin Pharmaceuticals, PowderJect Technologies, Integra LifeSciences and Alpharma.

Our Strategy

Our strategy is to utilize our proprietary non-aqueous formulation technology platforms to convert marketed and development-stage products that have poor solubility and stability into ready-to-use, user-friendly injectable and infusible drugs for multiple therapeutic areas and conditions, including hypoglycemia, epilepsy and diabetes. We also seek to apply our formulation technology platforms to enhance the formulations of proprietary products and candidates of other pharmaceutical and biotechnology companies. The key elements of our strategy include the following objectives:

- Rapidly secure regulatory approval for our lead product candidate, the Glucagon Rescue Pen, for severe hypoglycemia.
- Maximize the commercial potential for our Glucagon Rescue Pen.
- Advance our ready-to-use glucagon portfolio to address other conditions associated with hypoglycemia.
- Leverage our technology and expertise to develop a portfolio of additional product candidates.
- Collaborate with third party pharmaceutical and biotechnology companies to apply our technology platforms to enhance the formulations of their proprietary products and candidates.

The nature of our product candidates and target conditions provides us with a potentially faster and capital-efficient development and regulatory pathway to approval.

Risks Affecting Our Business

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks are discussed more fully in the "Risk Factors" section of this prospectus immediately following this prospectus summary, and include the following:

- As a company, we have a limited operating history and no history of commercializing pharmaceutical products, and have incurred significant losses since inception. We expect to incur losses over the next several years and may not be able to achieve or sustain revenues or profitability in the future.
- We may not submit our NDA on our expected timeline and, even if we do, the FDA may not accept our NDA for filing.

- We are dependent on the success of our glucagon product candidates, particularly our Glucagon Rescue Pen. We cannot be certain that our Glucagon Rescue Pen or any of our other product candidates will receive marketing approval. Without marketing approval, we will not be able to commercialize our product candidates or generate product revenues.
- Our business depends entirely on the success of our product candidates. Even if approved, our product candidates may not be accepted in the marketplace and our business may be materially harmed.
- The market opportunity for our product candidates may be smaller than we estimate.
- Even if our product candidates receive regulatory approval, we may still face future development and regulatory difficulties. If we fail to comply with continuing U.S. and non-U.S. regulations or new safety data arise, we could lose our marketing approvals and our business would be seriously harmed.
- We operate in a competitive business environment and, if we are unable to compete successfully against our existing or potential competitors, our sales and operating results may be negatively affected and we may not successfully commercialize our product candidates, even if approved.
- Clinical failure may occur at any stage of clinical development, and the results of our clinical trials may not support our proposed indications for our product candidates. If our clinical trials fail to demonstrate efficacy and safety to the satisfaction of the FDA or other regulatory authorities, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of such product candidates.
- Our reliance on third-party suppliers, including single-source suppliers and a limited number of options for alternate sources for our product candidates, including our Glucagon Rescue Pen, could harm our ability to develop our product candidates or to commercialize any product candidates that are approved.
- Reimbursement decisions by third-party payors may have an adverse effect on pricing and market acceptance. If there is not sufficient reimbursement for our products, it is less likely that they will be widely used.
- We drew down \$20.0 million from our loan and security agreement with Oxford Finance LLC and Silicon Valley Bank. The second tranche of an additional \$15.0 million is only available if we submit our NDA for our Glucagon Rescue Pen before September 30, 2018. The third tranche of an additional \$10.0 million is only available if we receive approval of our Glucagon Rescue Pen NDA by the FDA before September 30, 2019.
- Our independent registered public accounting firm has identified a material weakness in our internal control over financial reporting which will require remediation.

Corporate Information

We were incorporated in 2005 under the laws of the state of Delaware. Our principal executive offices are located at 180 N. LaSalle St., Suite 1800, Chicago, Illinois 60601, and our phone number is 1-844-445-5704. Our website address is <http://www.xerispharma.com>. The information contained in or accessible from our website is not incorporated into this prospectus, and you should not consider it part of this prospectus.

The "Xeris" name, and the XeriJect, XeriSol, Glucagon Rescue Pen, and CSI Glucagon names and related images, logos and symbols appearing in this prospectus are our properties, trademarks and service marks. Other marks appearing in this prospectus are the property of their respective owners.

Implications of Being an Emerging Growth Company

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- Only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;

- Reduced disclosure about our executive compensation arrangements;
- No advisory votes on executive compensation or golden parachute arrangements; and
- Exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of \$1.07 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering; (iii) the date on which we have issued more than \$1.0 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission, or SEC. We may choose to take advantage of some but not all of these exemptions. We have taken advantage of reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold stock.

THE OFFERING

Shares of common stock offered by us	shares.
Shares of our common stock outstanding after this offering	shares (or shares assuming full exercise of the underwriters' option to purchase additional shares).
Option to purchase additional shares	We have granted the underwriters a 30-day option to purchase up to additional shares of our common stock.
Use of proceeds	We currently intend to use the net proceeds of this offering, together with our cash and cash equivalents, to support the expected commercial launch of our Glucagon Rescue Pen, including investments in sales and marketing, inventory and our commercial and medical affairs infrastructure; to advance our other pipeline product candidates; and the remainder for working capital and other general corporate purposes. For a more complete description of our intended use of the proceeds from this offering, see "Use of Proceeds."
Proposed Nasdaq Global Market symbol	"XERS".
Risk factors	Investment in our common stock involves substantial risks. You should read this prospectus carefully, including the section entitled "Risk Factors" and the financial statements and the related notes to those statements included in this prospectus, before investing in our common stock.

The number of shares of common stock outstanding after this offering is based on 24,928,991 shares of our common stock outstanding as of December 31, 2017, after giving effect to the automatic conversion of all outstanding shares of convertible preferred stock into an aggregate of 21,083,391 shares of common stock upon the completion of this offering, which consists of 20,375,711 shares of preferred stock outstanding as of December 31, 2017 and reflects the subsequent issuance and sale by us of an aggregate of 707,680 shares of our Series C preferred stock in February 2018, and excludes:

- 3,208,588 shares of common stock issuable upon exercise of options issued under our 2011 Stock Option/Stock Issuance Plan at a weighted-average exercise price of \$0.93 per share;
- 316,880 shares of common stock issued upon the early exercise of stock options issued under our 2011 Stock Option/Stock Issuance Plan, which remain subject to vesting restrictions;
- 35,500 shares of common stock issuable upon the exercise of warrants to purchase common stock at an exercise price of \$3.319 per share as of December 31, 2017, plus 95,686 shares of common stock issuable upon the exercise of warrants to purchase common stock at an exercise price of \$6.2705 per share that we issued in February 2018;
- 801,882 shares of common stock reserved for issuance under our 2011 Stock Option/Stock Issuance Plan as of December 31, 2017, plus an additional 600,000 shares of common stock that we reserved for issuance under such plan in February 2018, which shares will no longer be reserved following this offering;
- shares of common stock to be reserved for future issuance under our 2018 Stock Option and Incentive Plan to be effective upon the effectiveness of the registration statement of which this prospectus forms a part; and

- shares of common stock to be reserved for future issuance under our 2018 Employee Stock Purchase Plan to be effective upon the effectiveness of the registration statement of which this prospectus forms a part.

Except as otherwise noted, all information in this prospectus:

- assumes no exercise of the underwriters' option to purchase additional shares;
- assumes no exercise of the outstanding options and warrants described above;
- gives effect to the automatic conversion upon the completion of this offering of all of our outstanding shares of convertible preferred stock into an aggregate of 21,083,391 shares of common stock; and
- assumes the filing of our amended and restated certificate of incorporation and the effectiveness of our amended and restated bylaws, which will occur upon the closing of this offering.

SUMMARY FINANCIAL INFORMATION

The following tables summarize our financial and operating data for the periods indicated. The summary statements of operations data for the years ended December 31, 2016 and 2017 and the summary balance sheet data as of December 31, 2017 have been derived from our audited financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future for a full year or any interim period.

The summary financial information below should be read in conjunction with the information contained in "Selected Financial Information," "Management's Discussion and Analysis of Financial Condition and Results of Operations," our financial statements and notes thereto, and other financial information included elsewhere in this prospectus.

	YEARS ENDED DECEMBER 31,	
	2016	2017
	(in thousands, except share and per share data)	
Statements of Operations Data:		
Grant income	\$ 1,022	\$ 1,540
Service revenue	53	16
Cost of revenue	8	4
Gross profit	<u>1,067</u>	<u>1,552</u>
Operating expenses:		
Research and development	10,238	20,166
General and administrative	4,060	8,015
Expense from operations	<u>14,298</u>	<u>28,181</u>
Loss from operations	<u>(13,231)</u>	<u>(26,629)</u>
Other income (expense):		
Interest income	5	124
Interest expense	(2)	(2)
Change in fair value of warrants	24	(46)
Other expense	(5)	(1)
Total other income	<u>22</u>	<u>75</u>
Net loss	<u>\$ (13,209)</u>	<u>\$ (26,554)</u>
Net loss per share—basic and diluted (1)	<u>\$ (4.03)</u>	<u>\$ (7.35)</u>
Weighted average number of shares outstanding, basic and diluted (1)	<u>3,281,564</u>	<u>3,612,512</u>
Pro forma net loss per share (unaudited) (1):		
Basic and diluted		<u>\$ (1.31)</u>
Pro forma weighted average shares outstanding (unaudited) (1):		
Basic and diluted		<u>20,231,131</u>

	AS OF DECEMBER 31, 2017		
	ACTUAL	PRO FORMA (2) (Unaudited) (in thousands)	PRO FORMA AS ADJUSTED (3)
Balance Sheet Data:			
Cash and cash equivalents	\$ 42,045	\$ 66,448	
Working capital (4)	39,193	63,596	
Total assets	44,998	69,401	
Deferred rent—long-term	90	90	
Debt, long term	—	20,000	
Total liabilities	4,950	24,950	
Total convertible preferred stock	97,878	—	
Total stockholders' equity (deficit)	(57,830)	44,451	

- (1) See Note 2 to our audited financial statements included elsewhere in this prospectus for an explanation of the calculations of our basic and diluted net loss per share, unaudited basic and diluted pro forma net loss per share and the shares used in computing basic and diluted net loss per share and unaudited basic and diluted pro forma net loss per share.
- (2) Pro forma amounts give effect to (i) the sale and issuance of 707,680 shares of our Series C preferred stock in February 2018 for aggregate net proceeds of \$4.4 million, (ii) the drawdown of \$20.0 million from our Loan Agreement with Oxford Finance, LLC and Silicon Valley Bank in February 2018 and (iii) the automatic conversion of all of our outstanding shares of preferred stock into an aggregate of 21,083,391 shares of common stock upon the closing of this offering.
- (3) Pro forma as adjusted amounts reflect pro forma adjustments described in footnote (2) as well as the sale of _____ shares of our common stock in this offering at the assumed initial public offering price of \$ _____ per share, the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.
- (4) We define working capital as current assets less current liabilities.

The pro forma as adjusted information discussed above is illustrative only and will change based on the actual initial public offering price and other terms of this offering determined at pricing. A \$1.00 increase (decrease) in the assumed initial public offering price of \$ _____ per share, the midpoint of the price range set forth on the cover of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, working capital, total assets and total stockholders' equity by approximately \$ _____ million, assuming that the number of shares offered by us, as set forth on the cover of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1.0 million shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, working capital, total assets and total stockholders' equity by approximately \$ _____ million, assuming the assumed initial public offering price remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the following risks and other information contained in this prospectus, including our financial statements and the related notes and the section of this prospectus titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" before you make an investment decision. If any of the events contemplated by the following discussion of risks were to occur, our business, results of operations and financial condition could suffer significantly. As a result, the market price of our common stock could decline, and you may lose all or part of your investment in our common stock.

Risks Related to our Financial Position and Need for Financing

As a company, we have a limited operating history and no history of commercializing pharmaceutical products, and have incurred significant losses since inception. We expect to incur losses over the next several years and may not be able to achieve or sustain revenues or profitability in the future.

We are a clinical-stage pharmaceutical company with a limited operating history. Pharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We have not generated any product revenues and have financed our operations primarily through private placements of our preferred stock and borrowings under the Loan and Security Agreement, which we refer to as the Loan Agreement, that we entered into with Oxford Finance LLC and Silicon Valley Bank. We do not expect to generate any product revenues unless one or more of our product candidates receives regulatory approval and is commercialized. We have not yet demonstrated an ability to obtain marketing approvals, manufacture a commercial-scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies prior to regulatory approval of any product candidates, especially pharmaceutical companies such as ours. Any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully commercializing pharmaceutical products. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We will need to transition from a company with a development focus to a company capable of supporting commercial activities. We may not be successful in such a transition. We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

We have incurred significant losses in every fiscal year since inception. We incurred net losses of \$13.2 million and \$26.6 million in the years ended December 31, 2016 and 2017, respectively. In addition, our accumulated deficit as of December 31, 2017 was \$60.6 million. Substantially all our operating losses have resulted from costs incurred in connection with research and development of our product candidates and clinical and regulatory initiatives to obtain approvals for our product candidates.

Following this offering, we expect that our operating expenses will continue to increase as we continue to build our commercial infrastructure, develop, enhance and commercialize new products and incur additional operational and reporting costs associated with being a public company.

In particular, we anticipate that our expenses will increase substantially as we:

- continue our research and development efforts;
- seek regulatory approval for new product candidates and product enhancements;
- build commercial infrastructure to support sales and marketing for our product candidates;
- hire and retain additional personnel and add operational, financial and management information systems; and
- operate as a public company.

All of our product candidates are still in development and none have been approved for sale. Our ability to generate revenue from our product candidates, and to transition to profitability and generate positive cash flows is uncertain,

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and depends on the successful development and commercialization of our product candidates. Successful development and commercialization will require achievement of key milestones, including completing clinical trials of our product candidates that are under clinical development, obtaining marketing approval for our product candidates, manufacturing, marketing and selling those products for which we, or any of our future collaborators, may obtain marketing approval, satisfying any post-marketing requirements and obtaining reimbursement for our products from private insurance or government payors. Because of the uncertainties and risks associated with these activities, we are unable to accurately predict the timing and amount of revenues, and if or when we might achieve profitability. We and any future collaborators may never succeed in these activities and, even if we or any future collaborators do, we may never generate revenues that are large enough for us to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

Our failure to become and remain profitable would depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations. If we continue to suffer losses as we have in the past, investors may not receive any return on their investment and may lose their entire investment.

We have not generated any revenue from our product candidates, including our Glucagon Rescue Pen, and may never be profitable.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from any of our product candidates. We do not expect to generate significant revenue unless or until we obtain marketing approval of, and begin to sell, our product candidates. We do not expect to commercialize any of our product candidates before 2019, if ever. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- obtain marketing approval for our product candidates, including our Glucagon Rescue Pen;
- obtain commercial quantities of our product candidates, if approved, at acceptable cost levels;
- commercialize our product candidates, if approved, by developing our own sales force for commercialization in the United States or in other key territories by entering into partnership or co-promotion arrangements with third parties;
- set an acceptable price for our product candidates, if approved;
- obtain and maintain third-party coverage and adequate reimbursement for our product candidates, if approved; and
- achieve an adequate level of market acceptance of our product candidates, if approved, in the medical community and with third-party payors, including placement in accepted clinical guidelines for the conditions for which our product candidates are intended to target.

If any of our product candidates are approved for commercial sale, we expect to incur significant sales and marketing costs as we prepare for its commercialization. Even if we receive marketing approval and expend these costs, our product candidates may not be commercially successful. We may not achieve profitability soon after generating product sales, if ever. If we are unable to generate product revenue, we will not become profitable and may be unable to continue operations without continued funding.

We will require additional capital to sustain our business, and this capital may cause dilution to our stockholders and might not be available on terms favorable to us or at all, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts.

Pharmaceutical development is a time-consuming, expensive and uncertain process that takes years to complete. In addition, if any of our product candidates are approved, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we may be forced to delay, reduce or eliminate our research and development programs. We plan to use the net proceeds of this offering, together with our existing cash and cash equivalents, to support the expected commercial launch of our Glucagon Rescue Pen, including investments in sales and marketing, inventory and our commercial and medical affairs infrastructure, to advance our other pipeline product candidates and for working capital and other general corporate purposes. We will be required to expend significant funds in order to commercialize our Glucagon Rescue Pen, as well as any of our other product candidates that receive marketing

approval. The net proceeds of this offering and our existing cash and cash equivalents may not be sufficient to fund all of the efforts that we plan to undertake.

We may be required to obtain further funding through public or private equity offerings, debt financings, royalty-based financing arrangements, collaborations and licensing arrangements or other sources. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences and privileges superior to those of holders of our common stock, including shares of common stock sold in this offering. Any debt financing obtained by us would be senior to our common stock, would likely cause us to incur interest expenses, and could involve restrictive covenants relating to our capital raising activities and other financial and operational matters, which may increase our expenses and make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions and in-licensing opportunities. We may also be required to secure any such debt obligations with some or all of our assets. For example, our Loan Agreement is secured by substantially all of our existing property and assets other than our intellectual property assets, subject to certain exceptions. Our Loan Agreement also contains a negative pledge on intellectual property owned by us, pursuant to which we have agreed not to encumber any of our intellectual property.

If we raise additional funds through collaborations or marketing, distribution or licensing, or royalty-based financing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. Securing financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the development and commercialization, if approved, of our product candidates. It is also possible that we may allocate significant amounts of capital toward solutions or technologies for which market demand is lower than anticipated and, as a result, abandon such efforts. Adequate additional financing may not be available to us on acceptable terms, or at all. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Any of these negative developments could have a material adverse effect on our business, operating results, financial condition and common stock price.

We may not have cash available to us in an amount sufficient to enable us to make interest or principal payments on our indebtedness when due.

Our Loan Agreement provides for term loans of up to an aggregate of \$45.0 million, of which \$20.0 million was borrowed upon signing. We can become eligible to draw the remaining \$25.0 million upon the achievement of regulatory milestones related to our Glucagon Rescue Pen. Specifically, the second tranche of an additional \$15.0 million is only available if we submit our NDA for our Glucagon Rescue Pen before September 30, 2018, and then only available to be drawn until the earlier of September 30, 2018 or the 30th day following such NDA submission. The third tranche of an additional \$10.0 million is only available if we receive approval of our Glucagon Rescue Pen NDA by the FDA before September 30, 2019, and then only available to be drawn until the earlier of September 30, 2019 or the 30th day following NDA approval by the FDA.

All obligations under our Loan Agreement are secured by substantially all of our existing property and assets other than our intellectual property assets, subject to certain exceptions. This debt financing may create additional financial risk for us, particularly if our business or prevailing financial market conditions are not conducive to paying off or refinancing our outstanding debt obligations at maturity.

Failure to satisfy our current and future debt obligations under our Loan Agreement could result in an event of default and, as a result, our lenders could accelerate all of the amounts due. Events of default include our failure to comply with customary affirmative covenants as well as our breach of customary negative covenants in the Loan Agreement. Affirmative covenants include the maintenance of a \$5.0 million minimum cash balance in the event that we maintain one or more permitted accounts at other institutions. Negative covenants include prohibition on the payment of dividends and distributions, certain mergers and change of control events, and the occurrence of material adverse changes in the company's business or its prospect of repayment of its obligations. In the event of an acceleration of amounts due under our Loan Agreement as a result of an event of default, we may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness while still pursuing our current business strategy. In addition, our lenders could seek to enforce their security interests in any collateral securing such indebtedness.

Risks Related to the Product Development and Regulatory Approval of Our Product Candidates

We are dependent on the success of our glucagon product candidates, particularly our Glucagon Rescue Pen. We may not submit our NDA for our Glucagon Rescue Pen and the FDA may not accept our NDA for filing on our expected timeframe or ever. Even if our NDA is accepted for filing by the FDA, we cannot be certain that our Glucagon Rescue Pen or any of our other product candidates will receive marketing approval. Without marketing approval, we will not be able to commercialize our product candidates or generate product revenues.

We have devoted a significant portion of our financial resources and business efforts to the development of the Glucagon Rescue Pen. While we intend to submit an NDA for the Glucagon Rescue Pen in the third quarter of 2018, we have not received approval from regulatory authorities to market the Glucagon Rescue Pen or any other product candidate in any jurisdiction, and it is possible that neither our Glucagon Rescue Pen nor any other product candidates we may seek to develop in the future will ever obtain the appropriate regulatory approvals necessary for us to commence product sales. We may not submit our NDA for our Glucagon Rescue Pen and the FDA may not accept our NDA for filing on our expected timeframe or ever. Even if our NDA is accepted for filing by the FDA, we cannot be certain that our Glucagon Rescue Pen or any of our other product candidates will receive marketing approval.

The development of a product candidate and issues relating to its approval and marketing are subject to extensive regulation by the Food and Drug Administration, or FDA, in the United States and by comparable regulatory authorities in other countries. We are not permitted to market our product candidates in the United States until we receive approval of a New Drug Application, or NDA, from the FDA. The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions.

NDAs must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and effectiveness for each desired indication. NDAs must also include significant information regarding the chemistry, manufacturing and controls for the product. Obtaining approval of a NDA is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval. If we submit a NDA to the FDA, the FDA must decide whether to accept or reject the submission for filing. We cannot be certain that any submissions will be accepted for filing and review by the FDA. In addition, our Glucagon Rescue Pen is considered to be a drug-device combination product by the FDA, and its NDA will require review and coordination by the FDA's drug and device centers prior to approval. We cannot predict whether we will obtain regulatory approval to commercialize our Glucagon Rescue Pen or any of our other product candidates, and we cannot, therefore, predict the timing of any future revenues from these product candidates, if any. Any delay or setback in the regulatory approval or commercialization of any of these product candidates will adversely affect our business.

The FDA has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. For example, the FDA:

- could determine that we cannot rely on the Section 505(b)(2) regulatory pathway for our product candidates;
- could determine that the information provided by us was inadequate, contained clinical deficiencies or otherwise failed to demonstrate the safety and effectiveness of our Glucagon Rescue Pen or any of our product candidates for any indication;
- may not find the data from bioequivalence studies and/or clinical trials sufficient to support the submission of a NDA or to obtain marketing approval in the United States, including any findings that the clinical and other benefits of our product candidates outweigh their safety risks;
- may disagree with our trial design or our interpretation of data from preclinical studies, bioequivalence studies and/or clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our trials;
- may determine that there are unacceptable risks associated with the device component of our Glucagon Rescue Pen or that there are deficiencies with the information submitted to demonstrate the safety, effectiveness and reliability of the device component;

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- may determine that we have identified the wrong listed drug or drugs or that approval of our Section 505(b)(2) application for our Glucagon Rescue Pen or any of our other product candidates is blocked by patent or non-patent exclusivity of the listed drug or drugs or of other previously-approved drugs with the same conditions of approval as our Glucagon Rescue Pen;
- may identify deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for the manufacturing of our product candidates;
- may audit some or all of our clinical research and human factors study sites to determine the integrity of our data and may reject any or all of such data;
- may approve our product candidates for fewer or more limited indications than we request, or may grant approval contingent on the performance of costly post-approval clinical trials;
- may change its approval policies or adopt new regulations; or
- may not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of our product candidates.

As of December 31, 2017 we had completed two Phase 3 clinical trials evaluating our Glucagon Rescue Pen in patients with T1D. Our first Phase 3 clinical trial was a non-inferiority comparison of the Glucagon Rescue Pen against Eli Lilly's glucagon determined by an increase in plasma glucose concentration from below 50.0 mg/dL to greater than 70.0 mg/dL within 30 minutes after receiving glucagon. In this trial, our Glucagon Rescue Pen did not meet a primary endpoint for noninferiority in the intent-to-treat, or ITT, population due to one response failure in excess of the pre-specified threshold of three response failures. In the same trial, two subjects were censored from the mITT population because of a clinically significant protocol violation, and the remaining subjects were used for the per-protocol analysis. In accordance with FDA and International Council for Harmonisation guidance for evaluation of non-inferiority studies, we presented a series of analyses implementing ITT, mITT, and per-protocol cohorts for all the endpoints for this clinical trial to the FDA at a pre-NDA meeting held in December 2017. In that meeting, the FDA agreed overall that the totality of data for our Glucagon Rescue Pen is sufficient to support NDA review. However, certain of our analyses may be viewed as post-hoc analyses and although we believe that post-hoc analyses can provide additional information regarding results from this trial, retrospective analyses can result in the introduction of bias and may be given less weight by the FDA, including for purposes of determining whether to accept our NDA for filing or approving our NDA.

The FDA provided additional comments to address prior to NDA submission related to the prefilled syringe presentation of our Glucagon Rescue Pen. Based on these comments, we are conducting additional studies, the results from which we intend to include in our Glucagon Rescue Pen submission to the FDA.

In order to generate additional information regarding the entire treatment episode, we completed an additional non-inferiority Phase 3b clinical trial in the second quarter of 2018 comparing our Glucagon Rescue Pen to Eli Lilly's glucagon. We intend to complement our NDA submission with the results of this clinical trial. If this Phase 3b clinical trial produces negative or inconclusive results, or has adverse safety data, the FDA or other regulatory authorities may require us to conduct additional clinical trials prior to approval.

In any event, the FDA may not accept our NDA submission for review, or the FDA may require us to undertake additional activities, such as conducting additional studies or performing other analyses before accepting our NDA for filing or approving our Glucagon Rescue Pen.

Even if a product is approved, the FDA may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming clinical trials and/or reporting as conditions of approval. Regulators of other countries and jurisdictions have their own procedures for approval of product candidates with which we must comply prior to marketing in those countries or jurisdictions.

Obtaining regulatory approval for marketing of a product candidate in one country does not ensure that we will be able to obtain regulatory approval in any other country. In addition, delays in approvals or rejections of marketing applications in the United States or other countries may be based upon many factors, including regulatory requests for additional analyses, reports, data, preclinical studies and clinical trials, regulatory questions regarding different interpretations of data and results, changes in regulatory policy during the period of product development and the emergence of new information regarding our product candidates or other products. Also, regulatory approval for any of our product candidates may be withdrawn.

We intend to utilize the 505(b)(2) pathway for the regulatory approval of certain of our product candidates, including our Glucagon Rescue Pen. If the FDA does not conclude that the Glucagon Rescue Pen or such other product candidates meet the requirements of Section 505(b)(2), final marketing approval of our product candidates by the FDA or other regulatory authorities may be delayed, limited, or denied, any of which would adversely affect our ability to generate operating revenues.

We are pursuing a regulatory pathway pursuant to Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FDCA, for the approval of certain of our product candidates, including our Glucagon Rescue Pen, which allows us to rely on our submissions on existing clinical data for the drug. Section 505(b)(2) was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments, and permits the submission of a NDA where at least some of the information required for approval comes from preclinical studies or clinical trials not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The FDA interprets Section 505(b)(2) of the FDCA to permit the applicant to rely upon the FDA's previous findings of safety and efficacy for an approved product. The FDA requires submission of information needed to support any changes to a previously approved drug, such as published data or new studies conducted by the applicant or clinical trials demonstrating safety and efficacy. The FDA could refuse to file our NDA submissions, request additional information before accepting our submissions for filing or require additional information to sufficiently demonstrate safety and efficacy to support approval.

If the FDA determines that our Glucagon Rescue Pen or our other product candidates do not meet the requirements of Section 505(b)(2), we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for these product candidates, and the complications and risks associated with these product candidates, would likely substantially increase. Moreover, an inability to pursue the Section 505(b)(2) regulatory pathway would likely result in new competitive products reaching the market more quickly than our product candidates, which would likely materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization.

Some pharmaceutical companies and other actors have objected to the FDA's interpretation of Section 505(b)(2) to allow reliance on the FDA's prior findings of safety and effectiveness. If the FDA changes its interpretation of Section 505(b)(2), or if the FDA's interpretation is successfully challenged in court, this could delay or even prevent the FDA from approving any Section 505(b)(2) application that we submit. Moreover, the FDA recently adopted an interpretation of the three-year exclusivity provisions whereby a 505(b)(2) application can be blocked by exclusivity even if it does not rely on the previously-approved drug that has exclusivity (or any safety or effectiveness information regarding that drug). Under the FDA's new interpretation, the approval of one or more of our product candidates may be blocked by exclusivity awarded to a previously-approved drug product that shares certain innovative features with our product candidates, even if our 505(b)(2) application does not identify the previously-approved drug product as a listed drug or rely upon any of its safety or efficacy data. Any failure to obtain regulatory approval of our product candidates would significantly limit our ability to generate revenues, and any failure to obtain such approval for all of the indications and labeling claims we deem desirable could reduce our potential revenues.

Clinical failure may occur at any stage of clinical development, and the results of our clinical trials may not support our proposed indications for our product candidates. If our clinical trials fail to demonstrate efficacy and safety to the satisfaction of the FDA or other regulatory authorities, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of such product candidate.

We cannot be certain that existing clinical trial results will be sufficient to support regulatory approval of our product candidates. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and preclinical testing. Moreover, success in clinical trials in a particular indication, does not ensure that a product candidate will be successful in other indications. A number of companies in the pharmaceutical industry have suffered significant setbacks in clinical trials, even after promising results in earlier preclinical studies or clinical trials or successful later-stage trials in other related indications. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. The results of preclinical and early clinical

trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical and initial clinical trials. A failure of a clinical trial to meet its predetermined endpoints would likely cause us to abandon a product candidate and may delay development of any other product candidates. Any delay in, or termination of, our clinical trials will delay the submission of the NDA to the FDA, the Marketing Authorization Application, or MAA, to the European Medicines Agency, or EMA, or other similar applications with other relevant foreign regulatory authorities and, ultimately, our ability to commercialize our product candidates and generate revenue.

Additional time may be required to obtain regulatory approval for our product candidates because they are combination products.

Certain of our product candidates, including our Glucagon Rescue Pen, are drug and device combination products that require coordination within the FDA and similar foreign regulatory agencies for review of their device and drug components. Medical products containing a combination of new drugs, biological products or medical devices may be regulated as “combination products” in the United States and Europe. A combination product generally is defined as a product comprised of components from two or more regulatory categories (e.g., drug/device, device/biologic, drug/biologic). Each component of a combination product is subject to the requirements established by the FDA for that type of component, whether a new drug, biologic or device. In order to facilitate pre-market review of combination products, the FDA designates one of its centers to have primary jurisdiction for the pre-market review and regulation of the overall product based upon a determination by the FDA of the primary mode of action of the combination product. Where approval of the drug and device is sought under a single application, the increased complexity of the review process may delay approval. The FDA review process and criteria are not well-established areas, which could also lead to delays in the approval process. The EMA has a parallel review process in place for combination products, the potential effects of which in terms of approval and timing could independently affect our ability to market our combination products in Europe.

Delays in conducting clinical trials could result in increased costs to us and delay our ability to obtain regulatory approval for our product candidates.

Any delays in conducting clinical trials and related drug development programs could materially affect our product development costs and delay regulatory approval of our product candidates. We do not know whether planned clinical trials will begin on time, will need to be redesigned, or will be completed on schedule, if at all. A clinical trial can be delayed for a variety of reasons, including:

- delays or failures in obtaining regulatory authorization to commence a trial because of safety concerns of regulators relating to our product candidates or similar product candidates, competitive or comparator products or supportive care products or failure to follow regulatory guidelines;
- delays or failures in obtaining clinical materials and manufacturing sufficient quantities of the product candidate for use in a trial;
- delays or failures in reaching agreement on acceptable terms with prospective study sites or other contract research organizations, or CROs;
- delays or failures in obtaining approval of our clinical trial protocol from an institutional review board, or IRB, to conduct a clinical trial at a prospective study site;
- receipt by a competitor of marketing approval for a product targeting an indication that our product candidate targets, such that we are not “first to market” with our product candidate;
- delays in recruiting or enrolling subjects to participate in a clinical trial, particularly with respect to our product candidates for certain rare indications, including those for which we have obtained, or plan to seek, orphan drug designation;
- failure of a clinical trial or clinical investigators to be in compliance with current Good Clinical Practices, or cGCPs;
- unforeseen safety issues;
- inability to monitor subjects adequately during or after treatment;
- difficulty monitoring multiple study sites;

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- the FDA requiring alterations to any of our study designs, our nonclinical strategy or our manufacturing plans;
- failure of our third-party clinical trial managers to satisfy their contractual duties, comply with regulations, or meet expected deadlines; and
- determination by regulators that the clinical design of a trial is not adequate.

Clinical trials may also be delayed or terminated as a result of ambiguous or negative interim results. In addition, a clinical trial may be suspended or terminated by us, the FDA, the Internal Review Boards, or IRBs, at the sites where the IRBs are overseeing a trial, or a data safety monitoring board overseeing the clinical trial at issue, or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities;
- unforeseen safety issues, including serious adverse events associated with a product candidate, or lack of effectiveness; and
- lack of adequate funding to continue the clinical trial.

Further, conducting clinical trials in foreign countries, as we have done and plan to do for certain of our product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

Our product candidates may have undesirable side effects which may delay or prevent marketing approval, or, if approval is received, require them to include safety warnings, require them to be taken off the market or otherwise limit their sales.

Undesirable side effects that may be caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. The range and potential severity of possible side effects from systemic therapies are significant. The results of future clinical trials may show that our product candidates cause undesirable or unacceptable side effects, which could interrupt, delay or halt clinical trials, and result in delay of, or failure to obtain, marketing approval from the FDA and other regulatory authorities, or result in marketing approval from the FDA and other regulatory authorities with restrictive label warnings. Recent developments in the pharmaceutical industry have prompted heightened government focus on safety reporting during both pre- and post-approval time periods and pharmacovigilance. Global health authorities may impose regulatory requirements to monitor safety that may burden our ability to commercialize our drug products.

To date, patients treated with our ready-to-use glucagon have experienced drug-related side effects typically observed with glucagon products, including nausea, vomiting and headaches. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. It is possible that there may be side effects associated with our other product candidates' use. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects.

Even if any of our product candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products:

- regulatory authorities may require the addition of labeling statements, including "black box" warnings, contraindications or dissemination of field alerts to physicians and pharmacies;
- we may be required to change instructions regarding the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be subject to limitations on how we may promote the product;

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- sales of the product may decrease significantly;
- regulatory authorities may require us to take our approved product off the market;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could also prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from the sale of our products.

We have received orphan drug designation for our product candidates with respect to certain indications and intend to pursue such designation for others, but we may be unable to obtain such designation or to maintain the benefits associated with orphan drug status, including market exclusivity, even if that designation is granted.

We have received orphan drug designation from the FDA for three of our product candidates, which are our ready-to-use glucagon for PBH and congenital hyperinsulinism, and our ready-to-use diazepam for acute repetitive seizures. We intend to pursue such designation for others in specific orphan indications in which there is a medically plausible basis for its use. Under the Orphan Drug Act of 1983, the FDA may designate a product candidate as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as having a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. Orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. Although we intend to seek orphan drug designation for certain additional indications, we may never receive such designation. Moreover, obtaining orphan drug designation for one indication does not mean we will be able to obtain such designation for another indication.

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a NDA, to market the same drug for the same indication for seven years, except in limited circumstances such as if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Similarly, the FDA can subsequently approve a drug with the same active moiety for the same condition during the exclusivity period if the FDA concludes that the later drug is clinically superior, meaning the later drug is safer, more effective or makes a major contribution to patient care. Even with respect to the indications for which we have received orphan designation, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products, and thus approval of our product candidates could be blocked for seven years if another company previously obtained approval and orphan drug exclusivity for the same drug and same condition. If we do obtain exclusive marketing rights in the United States, they may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of the relevant patients. Further, exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition, the same drugs can be approved for different indications and might then be used off-label in our approved indication, and different drugs for the same condition may already be approved and commercially available.

In Europe, the period of orphan drug exclusivity is ten years, although it may be reduced to six years if, at the end of the fifth year, it is established that the criteria for orphan drug designation are no longer met, in other words, when it is shown on the basis of available evidence that the product is sufficiently profitable not to justify maintenance of market exclusivity. We have received orphan drug designation from the EMA for our ready-to-use glucagon for treatment of congenital hyperinsulinism.

Our failure to successfully identify, develop and market additional product candidates could impair our ability to grow.

As part of our growth strategy, we intend to identify, develop and market additional product candidates leveraging our formulation technology platforms. We are exploring various therapeutic opportunities for our pipeline programs. We may spend several years completing our development of any particular current or future internal product candidates, and failure can occur at any stage. The product candidates to which we allocate our resources may not end up being successful. While we identified several potential applications of our ready-to-use glucagon, including our Glucagon Rescue Pen and additional chronic or intermittent conditions, there is no guarantee that we will be able to utilize our formulation technology platforms to advance additional product candidates.

In the future, we may be dependent upon pharmaceutical companies, academic scientists and other researchers to sell or license product candidates, approved products or the underlying technology to us. The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

In addition, future acquisitions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention to develop acquired products or technologies;
- incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions;
- higher than expected acquisition and integration costs;
- difficulty in combining the operations and personnel of any acquired businesses with our operations and personnel;
- increased amortization expenses;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to motivate key employees of any acquired businesses.

Further, any product candidate that we identify internally or acquire would require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and other regulatory authorities.

Risks Related to the Commercialization and Marketing of our Product Candidates

Our business depends entirely on the success of our product candidates. Even if approved, our product candidates may not be accepted in the marketplace and our business may be materially harmed.

To date, we have expended significant time, resources and effort on the development of our product candidates, and a substantial portion of our resources going forward will be focused on seeking marketing approval for and planning for potential commercialization of our lead product candidate, our Glucagon Rescue Pen, in the United States. Our business and future success are substantially dependent on our ability to successfully and timely obtain regulatory approval for and commercialize our Glucagon Rescue Pen. Our other product candidates are in earlier stages of development and subject to the risks of failure inherent in developing drug products. Accordingly, our ability to generate product revenues in the immediate term will depend on our ability to successfully obtain marketing approval for and commercialize our Glucagon Rescue Pen. Any delay or setback in the regulatory approval or commercialization of any of our product candidates will adversely affect our business.

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Even if all regulatory approvals are obtained, the commercial success of our product candidates depends on gaining market acceptance among physicians, patients, patient advocacy groups, healthcare payors and the medical community. The degree of market acceptance of our product candidates will depend on many factors, including:

- the scope of regulatory approvals, including limitations or warnings contained in a product candidate's regulatory-approved labeling;
- our ability to produce, through a validated process, sufficiently large quantities of our product candidates to permit successful commercialization;
- our ability to establish and maintain commercial manufacturing arrangements with third-party manufacturers;
- our ability to build and maintain sales, distribution and marketing capabilities sufficient to launch commercial sales of our product candidates;
- the acceptance in the medical community of the potential advantages of the product candidate, including with respect to our efforts to increase adoption of our product candidates such as our Glucagon Rescue Pen by patients and healthcare providers;
- the incidence, prevalence and severity of adverse side effects of our product candidates;
- the willingness of physicians to prescribe our product candidates and of the target patient population to try these therapies;
- the price and cost-effectiveness of our product candidates;
- the extent to which each product is approved for use at, or included on formularies of, hospitals and managed care organizations;
- any negative publicity related to our or our competitors' products or other formulations of products that we administer, including as a result of any related adverse side effects;
- alternative treatment methods and potentially competitive products;
- the potential advantages of the product candidate over existing and future treatment methods;
- the strength of our sales, marketing and distribution support; and
- the availability of sufficient third-party coverage and reimbursement.

Additionally, if the Glucagon Rescue Pen or any of our other product candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such products, require us to take our approved product off the market or ask us to voluntarily remove the product from the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- regulatory authorities may impose conditions under a risk evaluation and mitigation strategy, or REMS, including distribution of a medication guide to patients outlining the risks of such side effects or imposing distribution or use restrictions;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

If our product candidates are approved but do not achieve an adequate level of acceptance by physicians, patients and third-party payors, we may never generate significant revenue from these products, and our business, financial condition and results of operations may be materially harmed. Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new therapeutics are introduced that are more favorably received than our products or that render our products obsolete, or if significant adverse events occur. If

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our products do not achieve and maintain market acceptance, we will not be able to generate sufficient revenue from product sales to attain profitability.

The market opportunity for our product candidates may be smaller than we estimate.

The potential market opportunity for our product candidates is difficult to precisely estimate. Our estimates of the potential market opportunity for our product candidates include several key assumptions of the current market size and current pricing for commercially available products and is based on industry and market data obtained from industry publications, studies conducted by us, our industry knowledge, third-party research reports and other surveys. Industry publications and third-party research generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. For example, our projections for the potential size of the market for our Glucagon Rescue Pen are based on our belief that we would be able to increase the adoption of emergency glucagon products by patients and care providers. While we believe that our internal assumptions are reasonable, if any of these assumptions proves to be inaccurate, then the actual market for our product candidates, including our Glucagon Rescue Pen, could be smaller than our estimates of our potential market opportunity. If the actual market for our product candidates is smaller than we expect, our product revenue may be limited and it may be more difficult for us to achieve or maintain profitability.

Our company has limited experience marketing and selling drug products and are currently developing an internal sales organization. If we are unable to establish marketing, sales and distribution capabilities or enter into agreements with third parties to market, sell and distribute our product candidates, we may not be able to generate product revenues.

We currently do not have sufficient infrastructure for the sales, marketing or distribution of our product candidates, and the cost of establishing and maintaining such an organization may exceed the benefits of doing so. In order to commercialize our product candidates, we must expand our marketing, sales, distribution, managerial and other non-technical capabilities and/or make arrangements with third parties to perform these services. We intend to establish a sales force to promote our Glucagon Rescue Pen in the United States, if we obtain FDA approval. There are significant expenses and risks involved with establishing our own sales and marketing capabilities, including our ability to hire, retain and appropriately incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could delay any product launch, which would adversely impact the commercialization of our product candidates, including our Glucagon Rescue Pen. We are building out our commercial organization in anticipation of receiving marketing approval of our Glucagon Rescue Pen. If the expected commercial launch of our Glucagon Rescue Pen is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

We cannot be sure that we will be able to hire a sufficient number of sales representatives or that they will be effective at promoting our products that receive regulatory approval, if any. In addition, we will need to commit significant additional management and other resources to establish and grow our sales organization. We may not be able to achieve the necessary development and growth in a cost-effective manner or realize a positive return on our investment. We will also have to compete with other companies to recruit, hire, train and retain sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our products include:

- our inability to recruit and train adequate numbers of sales and marketing personnel;
- the inability of sales personnel to obtain access to or to persuade adequate numbers of physicians to prescribe any of our product candidates that receive regulatory approval; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

In the event that we are unable to effectively implement our sales organization or distribution strategy on a timely and effective basis, if at all, the commercialization of our product candidates could be delayed which would negatively impact our ability to generate product revenues.

We intend to leverage the sales and marketing capabilities that we establish for our Glucagon Rescue Pen to commercialize additional product candidates for the management of other hypoglycemic conditions, if approved by the FDA, in the United States. If we are unable to do so for any reason, we would need to expend additional resources to establish commercialization capabilities for those product candidates, if approved.

In addition, we intend to establish collaborations to commercialize our product candidates outside of the United States, if approved by the relevant regulatory authorities. Therefore, our future success will depend, in part, on our ability to enter into and maintain collaborative relationships for such efforts, the collaborator's strategic interest in the product and such collaborator's ability to successfully market and sell the product. We may not be able to establish or maintain such collaborative arrangements, or if able to do so, that they will have effective sales forces. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and such efforts may not be successful.

Reimbursement decisions by third-party payors may have an adverse effect on pricing and market acceptance. If there is not sufficient reimbursement for our products, it is less likely that they will be widely used.

Our future revenues and profitability will be adversely affected if U.S. and foreign governmental, private third-party insurers and payors and other third-party payors, including Medicare and Medicaid, do not agree to defray or reimburse the cost of our products to the patients. If these entities fail to provide coverage and reimbursement with respect to our products or provide an insufficient level of coverage and reimbursement, our products may be too costly for some patients to afford them and physicians may not prescribe them. In addition, limitations on the amount of reimbursement for our products may also reduce our profitability. In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, actions and proposals to control and reduce healthcare costs. There have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval for our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any of our product candidates for which we obtain marketing approval. Government and other third-party payors are also challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs.

Market acceptance and sales of our products and product candidates that we develop, if approved, will depend on reimbursement policies and may be affected by future healthcare reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will cover and establish payment levels. In the United States, no uniform policy of coverage and reimbursement for drugs exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a drug from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our drugs on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. We cannot be certain that reimbursement will be available for any of our product candidates, or that reimbursement rates will not change for our current products. Also, we cannot be certain that reimbursement policies will not reduce the demand for, or the price paid for, our products. If reimbursement is not available or is available on a limited basis, we may not be able to successfully commercialize any of our product candidates.

The United States and several other jurisdictions are considering, or have already enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that could negatively affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access to healthcare. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. Furthermore, third-party payors are increasingly requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We expect to experience pricing pressures in connection with the sale of our products that we develop due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, the ACA, became law in the United States. The ACA contains

provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, and mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Adoption of general controls and measures, coupled with the tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceutical drugs. While we cannot predict what impact on federal reimbursement policies this legislation will have in general or on our business specifically, the ACA may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of our products and our product candidates. We cannot predict whether these challenges will continue or other proposals will be made or adopted, or what impact these efforts may have on us.

Some patients may require health insurance coverage to afford our products, if approved, and if we are unable to obtain adequate coverage and reimbursement by third-party payors for our products, our ability to successfully commercialize our product candidates may be adversely impacted. Any limitation on the use of our products or any decrease in the price of our products will have a material adverse effect on our ability to achieve profitability.

Pricing pressure from healthcare industry consolidation and our competitors may impact our ability to sell our products at prices necessary to support our current business strategies.

Our market is subject to competitive pricing pressure as a result of product competition and a trend of consolidation in the healthcare industry to aggregate purchasing power as healthcare costs increase and reforms initiated by legislators, regulators and third-party payors to curb these costs are implemented.

For example, Eli Lilly's Glucagon Emergency Kit, or GEK, is covered at or above 94% with unrestricted access across commercial, Medicare, Managed Medicaid and State Medicaid plans. Of our target patient population, approximately 50% are commercially-insured, one-third are covered by Medicare and approximately 15% are covered by Medicaid. However, as the healthcare industry consolidates, competition to provide products and services to industry participants has become more intense and may intensify as the potential purchasers of our products or third-party payors use their purchasing power to exert competitive pricing pressure. We expect that market demand, government regulation, third-party coverage and reimbursement policies and societal pressures will continue to change the healthcare industry worldwide, resulting in further business consolidations and alliances among our potential purchasers. If competitive forces drive down the prices we are able to charge for our products, our profit margins will shrink, which will adversely affect our ability to invest in and grow our business.

Even if we successfully obtain approval for, produce and distribute our Glucagon Rescue Pen, its success will be dependent on its proper use by patients, healthcare practitioners and caregivers.

While we have designed our Glucagon Rescue Pen to be operable by patients, caregivers and healthcare practitioners, we cannot control the successful use of the product by patients, caregivers and healthcare practitioners. Even though our Glucagon Rescue Pen was used correctly by individuals in our human factors study, there is no guarantee that these results will be replicated by users in the future. If we are not successful in promoting the proper use of our Glucagon Rescue Pen, if approved, by patients, healthcare practitioners and caregivers, we may not be able to achieve market acceptance or effectively commercialize our Glucagon Rescue Pen. In addition, even in the event of proper use of our Glucagon Rescue Pen, individual devices may fail. Increasing the scale of production inherently creates increased risk of manufacturing errors, and we may not be able to adequately inspect every device that is produced, and it is possible that individual devices may fail to perform as designed. Manufacturing errors could negatively impact market acceptance of any of our product candidates that receive approval, result in negative press coverage, or increase the risk that we may be sued.

Guidelines and recommendations can reduce the use of our product candidates.

Government agencies and industry associations such as the American Diabetes Association promulgate guidelines applicable to certain drug classes which may include our products and product candidates that we are developing. Recommendations from these organizations may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Regulations or guidelines affecting our products and product candidates that we are developing or the use of competitive or alternative products as the standard of care to be followed by patients and healthcare providers could result in decreased use of our product candidates or negatively impact our ability to gain market acceptance and market share.

Risks Related to our Industry and the Ongoing Legal and Regulatory Requirements to which our Product Candidates are Subject

Even if our product candidates receive regulatory approval, we may still face future development and regulatory difficulties. If we fail to comply with continuing U.S. and non-U.S. regulations or new safety data arise, we could lose our marketing approvals and our business would be seriously harmed.

Our product candidates, if approved, will also be subject to ongoing regulatory requirements for manufacturing, distribution, sale, labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information. In addition, approved products, third-party suppliers and their facilities are required to comply with extensive FDA requirements and requirements of other similar agencies even after approval, including ensuring that quality control and manufacturing procedures conform to current good manufacturing practice, or cGMPs, and applicable Quality System regulations, or QSRs. As such, we and our third-party suppliers are subject to continual review and periodic inspections, both announced and unannounced, to assess compliance with cGMPs and QSRs. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. We will also be required to report certain adverse reactions and production problems, if any, to the FDA and other similar agencies and to comply with certain requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. Accordingly, we may not promote our approved products, if any, for indications or uses for which they are not approved.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, it may impose restrictions on that product or us, including requiring withdrawal of the product from the market. These unknown problems could be discovered as a result of any post-marketing follow-up studies, routine safety surveillance or other reporting required as a condition to approval.

Regulatory agencies may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product. The FDA and other agencies, including the Department of Justice, or DOJ, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we, or any future collaborators, do not market any of our product for which we, or they, receive marketing approval for only their approved indications, we, or they, may be subject to warnings or enforcement action for off-label marketing. Violation of the FDCA and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations or allegations of violations of federal and state healthcare fraud and abuse laws and state consumer protection laws.

If our product candidates fail to comply with applicable regulatory requirements, or if a problem with one of our products or third-party suppliers is discovered, a regulatory agency may:

- restrict the marketing or manufacturing of such products;
- restrict the labeling of a product;
- issue warning letters or untitled letters which may require corrective action;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us to enter into a consent decree or permanent injunction, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- impose other administrative or judicial civil or criminal penalties including fines, imprisonment and disgorgement of profits;
- suspend or withdraw regulatory approval;
- refuse to approve pending applications or supplements to approved applications filed by us;
- close the facilities of our third-party suppliers;

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- suspend ongoing clinical trials;
- impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or recommend or require a product recall.

The FDA's and foreign regulatory agencies' policies are subject to change and additional federal, state, local or non-U.S. governmental regulations may be enacted that could affect our ability to maintain compliance. We cannot predict the likelihood, nature or extent of adverse governmental regulation that may arise from future legislation or administrative action, either in the United States or abroad.

We operate in a competitive business environment and, if we are unable to compete successfully against our existing or potential competitors, our sales and operating results may be negatively affected and we may not successfully commercialize our product candidates, even if approved.

The pharmaceutical and biotechnology industries are characterized by intense competition and significant and rapid technological change as researchers learn more about diseases and develop new technologies and treatments. Any product candidates that we successfully develop and commercialize will compete with existing drugs and new drugs that may become available in the future. While we believe that our product and product candidate platform, development expertise and scientific knowledge provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies and public and private research institutions. Many of our current and potential competitors are major pharmaceutical companies that have substantially greater financial, technical and marketing resources than we do, and they may succeed in developing products that would render our products obsolete or noncompetitive. Our ability to compete successfully will depend on our ability to develop future products that reach the market in a timely manner, are well adopted by patients and healthcare providers and receive adequate coverage and reimbursement from third-party payors. Because of the size of the potential market, we anticipate that companies will dedicate significant resources to developing products competitive to our product candidates.

For example, we have numerous competitors in the severe hypoglycemia market, which currently include Eli Lilly's Glucagon Emergency Kit and Novo Nordisk's GlucaGen, and in the future may include a subcutaneous dasiglucagon auto-injector, being developed by Zealand Pharma and an intranasal glucagon dry powder, being developed by Eli Lilly. At any time, these or other industry participants may develop alternative treatments, products or procedures for the treatment of severe hypoglycemia that compete directly or indirectly with our Glucagon Rescue Pen, if approved. They may also develop and patent processes or products earlier than we can or obtain regulatory clearance or approvals for competing products more rapidly than we can, which could impair our ability to develop and commercialize similar processes or products. If alternative treatments are, or are perceived to be, superior to our products, sales of our products, if approved, could be negatively affected and our results of operations could suffer.

The widespread acceptance of currently available therapies with which our product candidates will compete may limit market acceptance of our product candidates even if commercialized. For example, emergency glucagon products are currently available for hypoglycemia and are widely accepted in the medical community and have a long history of use. These treatments will compete with our Glucagon Rescue Pen, if approved, and may limit the potential for our Glucagon Rescue Pen to receive widespread acceptance if commercialized.

We intend to submit the NDA for our Glucagon Rescue Pen to the FDA for approval under Section 505(b)(2) of the FDCA. If the FDA approves a competitor's application for a product candidate or drug-device combination product before our application for a similar product candidate or drug-device combination product, and grants such competitor a period of exclusivity, the FDA may take the position that it cannot approve our 505(b)(2) application for a similar product candidate until the exclusivity period expires. Additionally, even if our 505(b)(2) application for our Glucagon Rescue Pen is approved first and we receive three-year marketing exclusivity, we may still be subject to competition from other companies with approved products or approved 505(b)(2) NDAs for different conditions of use that would not be restricted by any grant of exclusivity to us.

If the FDA or other applicable regulatory authorities approve generic products that compete with any of our product candidates, the sales of our product candidates, if approved, could be adversely affected.

Once a NDA, including a Section 505(b)(2) application, is approved, the product covered becomes a "listed drug" which can be cited by potential competitors in support of approval of an abbreviated new drug application, or ANDA.

FDA regulations and other applicable regulations and policies provide incentives to manufacturers to create modified versions of a drug to facilitate the approval of an ANDA or other application for similar substitutes. If these manufacturers demonstrate that their product has the same active ingredient(s), dosage form, strength, route of administration, and conditions of use, or labeling, as our product candidate, they might only be required to conduct a relatively inexpensive study to show that their generic product is absorbed in the body at the same rate and to the same extent as, or is bioequivalent to, our product candidate. In some cases, even this limited bioequivalence testing can be waived by the FDA. Competition from generic equivalents to our product candidates could substantially limit our ability to generate revenues and therefore to obtain a return on the investments we have made in our product candidates.

Even if we obtain FDA approval of our lead product candidate, Glucagon Rescue Pen, or our other product candidates in the United States, we may never obtain or maintain foreign regulatory approvals to market our products in other countries.

We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. In order to market products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval or certification by one foreign regulatory authority does not ensure approval or certification by regulatory authorities in other foreign countries or by the FDA. International jurisdictions require separate regulatory approvals and compliance with numerous and varying regulatory requirements. The approval procedures vary among countries and may involve requirements for additional testing, and the time required to obtain approval may differ from country to country and from that required to obtain clearance or approval in the United States. In addition, with respect to our Glucagon Rescue Pen, we are engaged in ongoing interactions with European regulatory authorities regarding our development path in Europe. For our Glucagon Rescue Pen, because Eli Lilly's Glucagon Emergency Kit is not approved in Europe, we may be required to conduct one or more additional clinical trials comparing our Glucagon Rescue Pen to Novo Nordisk's GlucaGen, in addition to our existing clinical trials involving Eli Lilly's Glucagon Emergency Kit. Such requirements may increase our development expenses and delay our regulatory development plans for potential European approval of our Glucagon Rescue Pen. There can be no assurance that the results that we observed from our prior and ongoing clinical trials for our Glucagon Rescue Pen will be replicated in any future clinical trials that we undertake, or that any such results will be sufficient to secure approval in Europe.

In addition, some countries only approve or certify a product for a certain period of time, and we are required to re-approve or re-certify our products in a timely manner prior to the expiration of our prior approval or certification. We may not obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals or certifications and may not receive necessary approvals to commercialize our products in any market. If we fail to receive necessary approvals or certifications to commercialize our products in foreign jurisdictions on a timely basis, or at all, or if we fail to have our products re-approved or re-certified, our business, results of operations and financial condition could be adversely affected. The foreign regulatory approval or certification process may include all of the risks associated with obtaining FDA clearance or approval. In addition, the clinical standards of care may differ significantly such that clinical trials conducted in one country may not be accepted by healthcare providers, third-party payors or regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any drug we develop will be unrealized.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay regulatory approval of our product candidates, including our Glucagon Rescue Pen, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

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Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, President Obama signed into law the ACA, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the ACA of importance to our product candidates are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the federal Anti-Kickback Statute, or AKS, which include, among other things, new government investigative powers and enhanced penalties for non-compliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- the requirements under the federal open payments program and its implementing regulations;
- a requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Since its enactment, some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial, congressional, and executive challenges. As a result, there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of the ACA. The U.S. Supreme Court has upheld certain key aspects of the legislation, including a tax-based shared responsibility payment imposed on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly known as the requirement that all individuals maintain health insurance coverage or pay a penalty, referred to as the "individual mandate." However, as a result of tax reform legislation passed in December 2017, the individual mandate has been eliminated effective January 1, 2019. According to the Congressional Budget Office, the repeal of the individual mandate will cause 13 million fewer Americans to be insured in 2027 and premiums in insurance markets may rise.

Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. One Executive Order directs federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or

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regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The second Executive Order terminates the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. The loss of the cost share reduction payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. In addition, the Centers for Medicare & Medicaid Services, or CMS, has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results. We continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of 2% per fiscal year through 2027. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

The costs of prescription pharmaceuticals in the United States has also been the subject of considerable debate, and members of Congress and the Trump Administration have indicated that each will address such costs through new legislative and administrative measures. To date, there have been several recent U.S. congressional inquiries and proposed state and federal legislation designed to, among other things, improve transparency in drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare, and reform government program reimbursement methodologies for drug products. The pricing of prescription pharmaceuticals is also subject to governmental control outside the United States. In these other countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost effectiveness of our product candidates to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our ability to generate revenues and become profitable could be impaired.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for approved products. In addition, there have been several recent Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare and reform government program reimbursement methodologies for drugs. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent labeling and post-marketing testing and other requirements.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance and review and approval of marketing applications. Notably, on January 30, 2017, President Trump issued an Executive Order, applicable to all executive agencies,

including the FDA, that requires that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This Executive Order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations to offset any incremental cost of a new regulation and approximate the total costs or savings associated with each new regulation or repealed regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within the Office of Management and Budget on February 2, 2017, the Trump administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. Further, on February 24, 2017, President Trump issued an Executive Order requiring each agency to designate a regulatory reform officer and create a regulatory reform task force to evaluate existing regulations and make recommendations regarding their repeal, replacement or modification. It is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Our relationships with customers and payors will be subject to applicable anti-kickback, fraud and abuse, transparency, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our future arrangements with investigators, healthcare practitioners, consultants, third-party payors and customers, if any, will subject us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws and regulations may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute any products for which we obtain marketing approval. These include the following:

- ***Anti-Kickback Statute.*** The federal Anti-Kickback Statute, or AKS, makes it illegal for any person or entity (including a prescription drug manufacturer or a party acting on its behalf) to knowingly and willfully solicit, offer, receive or pay remuneration, directly or indirectly, in cash or in kind, in exchange for or intended to induce or reward either the referral of an individual for, or the purchase, order, prescription or recommendation or arranging of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are several statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, they are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. A person or entity can be found guilty of violating the AKS without actual knowledge of the statute or specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil money penalties statute. Violations of the AKS carry potentially significant civil and criminal penalties, including imprisonment, fines, administrative civil monetary penalties, and exclusion from participation in federal healthcare programs.
- ***False Claims Laws.*** The federal false claims and civil monetary penalties laws, including the federal civil False Claims Act, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or knowingly avoiding, decreasing or concealing an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties.
- ***Anti-Inducement Law.*** The anti-inducement law prohibits, among other things, the offering or giving of remuneration, which includes, without limitation, any transfer of items or services for free or for less than fair market value (with limited exceptions), to a Medicare or Medicaid beneficiary that the person knows or

should know is likely to influence the beneficiary's selection of a particular supplier of items or services reimbursable by a federal or state governmental program.

- **HIPAA.** The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program (including private payors) or making false or fraudulent statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Additionally, HIPAA, as amended by HITECH and its implementing regulations, also imposes obligations on covered entities and their business associates, including mandatory contractual terms and technical safeguards, with respect to maintaining the privacy, security and transmission of individually identifiable health information.
- **Transparency Requirements.** The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the CMS information related to payments or transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as information regarding ownership and investment interests held by the physicians described above and their immediate family members.
- **Analogous State and Foreign Laws.** Analogous state and foreign fraud and abuse laws and regulations, such as state anti-kickback and false claims laws, can apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements, and claims involving healthcare items or services reimbursed by non-governmental third-party payors, and are generally broad and are enforced by many different federal and state agencies as well as through private actions. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties, and our business generally, will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including our arrangements with physicians and other healthcare providers, some of whom receive stock options as compensation for services provided, may not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, reputational harm and the curtailment or restructuring of our operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any.

In some countries, such as the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. In addition, there can be considerable

pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after coverage and reimbursement have been obtained. Reference pricing used by various countries and parallel distribution or arbitrage between low-priced and high-priced countries, can further reduce prices. To obtain reimbursement or pricing approval in some countries, we, or any future collaborators, may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidates to other available therapies, which is time-consuming and costly. If reimbursement of our product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed.

We will need to obtain FDA approval of any proposed product names, and any failure or delay associated with such approval may adversely impact our business.

Any name we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a trademark registration from the U.S. Patent and Trademark Office, or USPTO. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. The FDA may object to any product name we submit if it believes the name inappropriately implies medical claims. If the FDA objects to any of our proposed product names, we may be required to adopt an alternative name for our product candidates. If we adopt an alternative name, we would lose the benefit of any existing trademark applications for such product candidate, and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

Risks Related to our Dependence on Third Parties

We depend on third parties to conduct the clinical trials for our product candidates, and any failure of those parties to fulfill their obligations could harm our development and commercialization plans.

We depend on independent clinical investigators, CROs, academic institutions and other third-party service providers to conduct clinical trials for our product candidates. Although we rely heavily on these parties for successful execution of our clinical trials, we are ultimately responsible for the results of their activities and many aspects of their activities are beyond our control. For example, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial, but the independent clinical investigators may prioritize other projects over ours or may fail to timely communicate issues regarding our

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products to us. Third parties may not complete activities on schedule or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols. The delay or early termination of any of our clinical trial arrangements, the failure of third parties to comply with the regulations and requirements governing clinical trials, or our reliance on results of trials that we have not directly conducted or monitored could hinder or delay the development, approval and commercialization of our product candidates and would adversely affect our business, results of operations and financial condition.

We maintain compliance programs related to our clinical trials through our clinical operations and development personnel working with our finance and legal group's support. Our clinical trial vendors are required to monitor and report to us the possible remedial action required for the conduct of clinical studies; and we are obliged to take the appropriate action. We also monitor clinical trial vendors through our regulatory and quality assurance staff and service providers. However, we cannot assure you that our programs and personnel will timely and fully discover any fraud or abuse that may occur in connection with our clinical trials. Such fraud or abuse, if it occurs, could have a material adverse effect on our research, development, commercialization activities and results.

Our reliance on third-party suppliers, including single-source suppliers and a limited number of options for alternate sources for our product candidates, including our Glucagon Rescue Pen, could harm our ability to develop our product candidates or to commercialize any product candidates that are approved.

We do not currently own or operate manufacturing facilities for the production of any of our product candidates, including our Glucagon Rescue Pen. We rely on third-party suppliers to manufacture and supply our products. We currently rely on a number of single-source suppliers, such as Bachem Americas, Inc., or Bachem, for API, Pyramid Laboratories, Inc., or Pyramid, for drug product and SHL Pharma, LLC, or SHL Pharma, for auto-injector and final product assembly. We have entered into a supply agreement with Bachem and a joint development agreement with SHL Pharma and intend to enter into supply agreements with Pyramid and SHL Pharma. Because we have contracts in place with some but not all of our third-party suppliers, our suppliers may not be required to provide us with any guaranteed minimum production levels or have dedicated capacity for our products. As a result, there can be no assurances that we will be able to obtain sufficient quantities of key materials or products in the future, which could have a material adverse effect on our business.

For us to be successful, our third-party suppliers must be able to provide us with raw materials, components and products in substantial quantities, in compliance with regulatory requirements, in accordance with agreed upon specifications, at acceptable costs and on a timely basis. Reliance on third-party suppliers entails risks to which we would not be subject if we manufactured products ourselves, including reliance on the third-party for regulatory compliance and quality assurance, the possibility that products will not be delivered on a timely basis, the possibility of increases in pricing for our products, the possibility of breach or termination of a manufacturing agreement or purchase order by the third-party.

Our product candidates, including Glucagon Rescue Pen, are drug-device combination products that will be regulated under the drug regulations of the FDCA based on its primary mode of action as a drug. Third-party manufacturers may not be able to comply with the cGMP regulatory requirements applicable to drug-device combination products, including applicable provisions of the FDA's drug cGMP regulations, device cGMP requirements embodied in the QSR or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could significantly affect supplies of our product candidates. The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMPs and QSRs. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product

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candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Contract manufacturers may face manufacturing or quality control problems causing drug substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP and QSR requirements. Any failure to comply with cGMP or QSR requirements or other FDA, EMA and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products following approval.

The FDA and other foreign regulatory authorities require manufacturers to register manufacturing facilities. The FDA and corresponding foreign regulators also inspect these facilities to confirm compliance with applicable cGMPs and QSRs. Contract manufacturers may face manufacturing or quality control problems causing drug substance or device component production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP or QSR requirements. Any failure to comply with cGMP or QSR requirements or other FDA, EMA and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products following approval.

There are a limited number of third-party suppliers that are compliant with cGMP and/or QSRs, as required by the FDA, the European Union, and other regulatory authorities, and that also have the necessary expertise and capacity to manufacture our materials and products. As a result, it may be difficult for us to locate third-party suppliers for our anticipated future needs, and our anticipated growth could strain the ability of our current third-party suppliers to deliver products, raw materials and components to us. If we are unable to arrange for third-party suppliers for our materials and products, or to do so on commercially reasonable terms, we may not be able to complete development of or market our products.

The introduction of new cGMP or QSR regulations or product specific requirements by a regulatory body, may require that we source alternative materials, modify existing manufacturing processes or implement design changes to our products that are subject to prior approval by the FDA or other regulatory authorities. We may also be required to reassess a third-party supplier's compliance with all applicable new regulations and guidelines, which could further impede our ability to manufacture and supply products in a timely manner. As a result, we could incur increased production costs, experience supply interruptions, suffer damage to our reputation and experience an adverse effect on our business and financial results.

In addition, our reliance on third-party suppliers involves a number of additional risks, including, among other things:

- our suppliers may fail to comply with regulatory requirements or make errors in manufacturing raw materials, components or products that could negatively affect the efficacy or safety of our products or cause delays in shipments of our products;
- we may be subject to price fluctuations by suppliers due to terms within a long-term supply arrangements or lack of a long-term supply arrangements for key materials and products;
- our suppliers may lose access to critical services or sustain damage to a facility, including losses due to natural disasters or geopolitical events, that may result in a sustained interruption in the manufacture and supply of our products;
- fluctuations in demand for our products or a supplier's demand from other customers, may affect their ability or willingness to deliver materials or products in a timely manner or may lead to long-term capacity constraints at the supplier;
- we may not be able to find new or alternative sources or reconfigure our products and manufacturing processes in a timely manner, if a necessary raw material or components becomes unavailable; and
- our suppliers may encounter financial or other hardships unrelated to our demand for materials, products and services, which could inhibit their ability to fulfill our orders and meet our requirements.

If any of the above risks materialize and we are unable to satisfy commercial demand for our products in a timely manner, our ability to generate revenue would be impaired, market acceptance of our products could be adversely affected, and customers may instead purchase or use our competitors' products. In addition, we could be forced to

secure new materials or develop alternative third-party suppliers, which can be difficult given our product complexity, long development lead-times and global regulatory review processes.

We may in the future elect to manufacture certain new or existing products ourselves, without the assistance of third-party suppliers. However, in order to make that election, we will need to invest substantial additional funds and recruit qualified personnel in order to operate our own manufacturing facility on a commercial basis. There can be no assurance that we will be able to successfully manufacture our own products and if we are not able to make or obtain adequate supplies of our raw materials, components or products, it will be more difficult for us to launch new products, supply our current markets and compete effectively.

If our third-party manufacturers of our product candidates are unable to increase the scale of their production of our product candidates, or increase the product yield of manufacturing, then our costs to manufacture the product may increase and commercialization may be delayed.

In order to produce sufficient quantities to meet the demand for clinical trials and subsequent commercialization of our Glucagon Rescue Pen or any of our other product candidates in our pipeline or that we may develop, our third-party manufacturers will be required to increase their production and automate and otherwise optimize their manufacturing processes while maintaining the quality of the product. The transition to larger scale production could prove difficult. In addition, if our third-party manufacturers are not able to automate and otherwise optimize their manufacturing process to increase the product yield for our Glucagon Rescue Pen and other components of our product candidates, or if they are unable to produce increased amounts of our product candidates while maintaining quality, then we may not be able to meet the demands of clinical trials or market demands, which could decrease our ability to generate revenues and have a material adverse impact on our business and results of operations.

We enter into various contracts in the normal course of our business in which we indemnify the other party to the contract. In the event we have to perform under these indemnification provisions, it could have a material adverse effect on our business, financial condition and results of operations.

In the normal course of business, we periodically have entered, and in the future may enter, into academic, commercial, service, collaboration, licensing, feasibility, consulting and other agreements that contain indemnification provisions. We have in the past and may in the future agree to indemnify the counterparties from losses arising from claims relating to the products, processes or services made, used, sold or performed. We may also agree to indemnify our vendors from any third-party product liability claims that could result from the production, use or consumption of the product, as well as for alleged infringements of any patent or other intellectual property right by a third party.

Should our obligation under an indemnification provision exceed applicable insurance coverage or if we were denied insurance coverage, our business, financial condition and results of operations could be adversely affected. Similarly, if we are relying on a collaborator to indemnify us and the collaborator is denied insurance coverage or the indemnification obligation exceeds the applicable insurance coverage and does not have other assets available to indemnify us, our business, financial condition and results of operations could be adversely affected.

We expect to seek to establish collaborations and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

We expect to seek one or more collaborators for the development and commercialization of one or more of our product candidates, particularly with respect to our pipeline product candidates or foreign geographies. Likely collaborators may include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the potential differentiation of our product candidate from competing product candidates, design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities and the regulatory pathway for any such approval, the potential market for the product candidate, the costs and complexities of manufacturing and delivering the product to patients and the potential of competing products. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and whether such a collaboration could be more attractive than the one with

us for our product candidate. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Collaborations are complex and time-consuming to negotiate and document. Further, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Any collaboration agreements that we enter into in the future may contain restrictions on our ability to enter into potential collaborations or to otherwise develop specified product candidates. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense.

Risks Related to our Intellectual Property

Our success depends on our ability to protect our intellectual property and proprietary technology, as well as the ability of our collaborators to protect their intellectual property and proprietary technology.

Our success depends in large part on our ability to obtain and maintain patent protection and trade secret protection in the United States and other countries with respect to our proprietary product candidates. If we do not adequately protect our intellectual property rights, competitors may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. To protect our proprietary position, we file patent applications in the United States and abroad related to our novel product candidates that are important to our business; we may in the future also license or purchase patent applications filed by others. The patent application and approval process is expensive and time-consuming. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

If the scope of the patent protection we or our potential licensors obtain is not sufficiently broad, we may not be able to prevent others from developing and commercializing technology and products similar or identical to ours. The degree of patent protection we require to successfully compete in the marketplace may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of our patents have, or that any of our pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect our current and future product candidates or otherwise provide any competitive advantage. In addition, to the extent that we license intellectual property in the future, we cannot assure you that those licenses will remain in force. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Furthermore, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally twenty years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized.

Even if they are unchallenged, our patents and pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our patents by developing similar or alternative technologies or therapeutics in a non-infringing manner. For example, a third party may develop a competitive therapy that provides benefits similar to one or more of our product candidates but that uses a formulation and/or a device that falls outside the scope of our patent protection. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our product candidates could be negatively affected, which would harm our business. Although we currently own all of our patents and our patent applications, similar risks would apply to any patents or patent applications that we may in-license in the future.

We, or any future partners, collaborators, or licensees, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position.

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It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we or our partners, collaborators, licensees or licensors fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our partners, collaborators, licensees or licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. In addition, the determination of patent rights with respect to pharmaceutical compounds commonly involves complex legal and factual questions, which has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

Moreover, because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, our patents or pending patent applications may be challenged in the courts or patent offices in the United States and abroad. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it may be used to invalidate a patent, or may prevent a patent from issuing from a pending patent application. For example, such patent filings may be subject to a third-party preissuance submission of prior art to the USPTO to other patent offices around the world. Alternately or additionally, we may become involved in post-grant review procedures, oppositions, derivations proceedings, reexaminations, inter partes review or interference proceedings, in the United States or elsewhere, challenging patents or patent applications in which we have rights, including patents on which we rely to protect our business. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products.

Pending and future patent applications may not result in patents being issued which protect our business, in whole or in part, or which effectively prevent others from commercializing competitive products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent or in the same manner as the laws of the United States. For example, patent laws in various jurisdictions, including significant commercial markets such as Europe, restrict the patentability of methods of treatment of the human body more than United States law does.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our future development partners will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case;
- patent applications may not result in any patents being issued;
- patents that may be issued may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use, and sell our potential product candidates;

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- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates in such countries.

Issued patents that we have or may in the future obtain or license may not provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our or our future licensors' patents by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may also seek approval to market their own products similar to or otherwise competitive with our products. Alternatively, our competitors may seek to market generic versions of any approved products by submitting ANDAs to the FDA in which they claim that patents owned or in the future licensed by us are invalid, unenforceable or not infringed. In these circumstances, we may need to defend or assert our patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid or unenforceable, or that our competitors are competing in a non-infringing manner. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

In the future, we may enter into license agreements with third parties pursuant to which they have the right, but not the obligation in certain circumstances to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents. Even if we are permitted to pursue such enforcement or defense, we will require the cooperation of those licensors, and cannot guarantee that we would receive it and on what terms. We cannot be certain that those licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. If we cannot obtain patent protection, or enforce existing or future patents against third parties, our competitive position and our financial condition could suffer.

In addition, we rely on the protection of our trade secrets and proprietary know-how. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors, we cannot provide any assurances that all such agreements have been duly executed, and third parties may still obtain this information or may come upon this or similar information independently. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating our trade secrets. If any of these events occurs or if we otherwise lose protection for our trade secrets or proprietary know-how, our business may be harmed.

It is difficult and costly to protect our intellectual property and our proprietary technologies, and we may not be able to ensure their protection.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection for the use, formulation and structure of our product candidates, the methods used to manufacture them, the related therapeutic targets and associated methods of treatment as well as on successfully defending these patents against potential third-party challenges. Our ability to protect our products and product candidates from unauthorized making, using, selling, offering to sell or importing by third parties is dependent on the extent to which we have rights under valid and enforceable patents that cover these activities.

The patent positions of pharmaceutical, biotechnology and other life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Further, the determination that a patent application or patent claim meets all of the requirements for patentability is a subjective determination based on the application of law and jurisprudence. The ultimate determination by the USPTO or by a court or other trier of fact in the United States, or corresponding foreign national patent offices or courts, on whether a claim meets all requirements of patentability cannot be assured. We have not conducted searches for third-party publications, patents and other information that may affect

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the patentability of claims in our various patent applications and patents, so we cannot be certain that all relevant information has been identified. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or patent applications, in any future licensed patents or patent applications or in third-party patents.

We cannot provide assurances that any of our patent applications will be found to be patentable, including over our own prior art patents, or will issue as patents. Neither can we make assurances as to the scope of any claims that may issue from our pending and future patent applications nor to the outcome of any proceedings by any potential third parties that could challenge the patentability, validity or enforceability of our patents and patent applications in the United States or foreign jurisdictions. Any such challenge, if successful, could limit patent protection for our products and product candidates and/or materially harm our business.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- we may not be able to generate sufficient data to support full patent applications that protect the entire breadth of developments in one or more of our programs;
- it is possible that one or more of our pending patent applications will not become an issued patent or, if issued, that the patent(s) will not: (a) be sufficient to protect our technology, (b) provide us with a basis for commercially viable products or (c) provide us with any competitive advantages;
- if our pending applications issue as patents, they may be challenged by third parties as not infringed, invalid or unenforceable under U.S. or foreign laws; or
- if issued, the patents under which we hold rights may not be valid or enforceable.

In addition, to the extent that we are unable to obtain and maintain patent protection for one of our products or product candidates or in the event that such patent protection expires, it may no longer be cost-effective to extend our portfolio by pursuing additional development of a product or product candidate for follow-on indications.

We also may rely on trade secrets to protect our technologies or products, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisers may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third-party entity illegally obtained and is using any of our trade secrets is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications are required to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after a patent has issued. There are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction.

Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Where available, we will seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, which is limited to the approved indication (or any additional indications approved during the period of extension). However, the

applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

Others may challenge inventorship or claim an ownership interest in our intellectual property which could expose it to litigation and have a significant adverse effect on its prospects.

A third party or former employee or collaborator may claim an ownership interest in one or more of our patents or other proprietary or intellectual property rights. A third party could bring legal actions against us and seek monetary damages and/or enjoin clinical testing, manufacturing and marketing of the affected product or products. While we are presently unaware of any claims or assertions by third-parties with respect to our patents or other intellectual property, we cannot guarantee that a third-party will not assert a claim or an interest in any of such patents or intellectual property. If we become involved in any litigation, it could consume a substantial portion of our resources, and cause a significant diversion of effort by our technical and management personnel.

Changes to the patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Recent patent reform legislation in the United States, including the Leahy-Smith America Invents Act, or the America Invents Act, could increase those uncertainties and costs. The America Invents Act was signed into law on September 16, 2011, and many of the substantive changes became effective on March 16, 2013. The America Invents Act reforms United States patent law in part by changing the U.S. patent system from a "first to invent" system to a "first inventor to file" system, expanding the definition of prior art, and developing a post-grant review system. This legislation changes United States patent law in a way that may weaken our ability to obtain patent protection in the United States for those applications filed after March 16, 2013.

Further, the America Invents Act created new procedures to challenge the validity of issued patents in the United States, including post-grant review and inter partes review proceedings, which some third parties have been using to cause the cancellation of selected or all claims of issued patents. For a patent with an effective filing date of March 16, 2013 or later, a petition for post-grant review can be filed by a third party in a nine-month window from issuance of the patent. A petition for inter partes review can be filed immediately following the issuance of a patent if the patent has an effective filing date prior to March 16, 2013. A petition for inter partes review can be filed after the nine-month period for filing a post-grant review petition has expired for a patent with an effective filing date of March 16, 2013 or later. Post-grant review proceedings can be brought on any ground of invalidity, whereas inter partes review proceedings can only raise an invalidity challenge based on published prior art and patents. In these adversarial actions, the USPTO reviews patent claims without the presumption of validity afforded to U.S. patents in lawsuits in U.S. federal courts and uses a lower burden of proof than used in litigation in U.S. federal courts. Therefore, it is generally considered easier for a competitor or third party to have a U.S. patent invalidated in a USPTO post-grant review or inter partes review proceeding than invalidated in a litigation in a U.S. federal court. If any of our patents are challenged by a third party in such a USPTO proceeding, there is no guarantee that we will be successful in defending the patent, which would result in a loss of the challenged patent right to us. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We may not be able to enforce our intellectual property rights throughout the world.

Filing, prosecuting, enforcing and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. The requirements for patentability may differ in certain countries, particularly in developing countries; thus, even in countries where we do pursue patent protection, there can be no assurance that any patents will issue with claims that cover our product candidates.

Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, laws of some countries outside of the United States and Europe do not afford intellectual property protection to the same extent as the laws of the United States and Europe. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, including India, China and other developing countries, do not favor the enforcement of patents and other intellectual property rights. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the United States and Europe. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop and market their own products and, further, may export otherwise infringing products to territories where we have patent protection, if our ability to enforce our patents to stop infringing activities is inadequate. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Agreements through which we may license patent rights may not give us sufficient rights to permit us to pursue enforcement of those licensed patents or defense of any claims asserting the invalidity of these patents (or control of enforcement or defense) of such patent rights in all relevant jurisdictions as requirements may vary.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business. Moreover, such proceedings could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Furthermore, while we intend to protect our intellectual property rights in major markets for our products, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate.

Others may claim an ownership interest in our intellectual property which could expose us to litigation and have a significant adverse effect on our prospects.

A third party may claim an ownership interest in one or more of our patents or other proprietary or intellectual property rights. A third party could bring legal actions against us and seek monetary damages and/or enjoin clinical testing, manufacturing and marketing of the affected product or products. While we are presently unaware of any claims or assertions by third parties with respect to our patents or other intellectual property, we cannot guarantee that a third party will not assert a claim or an interest in any of such patents or intellectual property. If we become involved in any litigation, it could consume a substantial portion of our resources, and cause a significant diversion of effort by our technical and management personnel. If any of these actions are successful, in addition to any potential liability for damages, we could be required to obtain a license to continue to manufacture or market the affected product, in which case we may be required to pay substantial royalties or grant cross-licenses to our patents. We cannot, however, assure you that any such license will be available on acceptable terms, if at all. Ultimately, we could be prevented from commercializing a product candidate, or be forced to cease some aspect of our business operations as a result of claims of patent infringement or violation of other intellectual property rights. Further, the outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of any adverse party. This is especially true in intellectual property cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree.

The pharmaceutical industry is characterized by frequent patent litigation and we could become subject to litigation that could be costly, result in the diversion of management's time and efforts, require us to pay damages or prevent us from marketing our existing or future products.

Our commercial success will depend in part on not infringing the patents or violating the other proprietary rights of third parties. Significant litigation regarding patent rights exists in our industry. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make and sell our products. Generally, we do not conduct

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independent reviews of patents issued to third parties. The large number of patents, the rapid rate of new patent issuances, the complexities of the technology involved, and uncertainty of litigation increase the risk of business assets and management's attention being diverted to patent litigation. We may receive in the future, particularly as a public company, communications from various industry participants alleging our infringement of their patents, trade secrets, or other intellectual property rights and/or offering licenses to such intellectual property. Any lawsuits resulting from such allegations could subject us to significant liability for damages and invalidate our proprietary rights. Any potential intellectual property litigation also could force us to do one or more of the following:

- stop selling products or using technology that contains the allegedly infringing intellectual property;
- lose the opportunity to license our technology to others or to collect royalty payments based upon successful protection and assertion of our intellectual property rights against others;
- incur significant legal expenses;
- pay substantial damages to the party whose intellectual property rights we may be found to be infringing;
- redesign those products that contain the allegedly infringing intellectual property, which could be costly, disruptive and/or infeasible; or
- attempt to obtain a license to the relevant intellectual property from third parties, which may not be available on reasonable terms or at all.

Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business, and harm our reputation. In connection with such litigation or claims, we may be required to obtain licenses or make changes to our products or technologies, and if we fail to do so, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products, all of which could have a material adverse effect on our business, results of operations and financial condition.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

Many of our employees were previously employed at other pharmaceutical companies, including our competitors or potential competitors, in some cases until recently. We may be subject to claims that we or our employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of these former employers or competitors. In addition, we have been and may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defense to those claims fails, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Any litigation or the threat thereof may adversely affect our ability to hire employees. A loss of key personnel or their work product could hamper or prevent our ability to commercialize product candidates, which could have an adverse effect on our business, results of operations and financial condition.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving one or more of our patents could limit our ability to assert those patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Similarly, if

we assert trademark infringement claims, a court may determine that the marks we have asserted are unenforceable, that the alleged infringing mark does not infringe our trademark rights, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this last instance, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could adversely affect the price of shares of our common stock. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Our unpatented trade secrets, know-how, confidential and proprietary information, and technology may be inadequately protected.

We rely in part on unpatented trade secrets, know-how and technology. This intellectual property is difficult to protect, especially in the pharmaceutical industry, where much of the information about a product must be submitted to regulatory authorities during the regulatory approval process. We seek to protect trade secrets, confidential information and proprietary information, in part, by entering into confidentiality and invention assignment agreements with employees, consultants, and others. These parties may breach or terminate these agreements, and we may not have adequate remedies for such breaches. Furthermore, these agreements may not provide meaningful protection for our trade secrets or other confidential or proprietary information or result in the effective assignment to us of intellectual property, and may not provide an adequate remedy in the event of unauthorized use or disclosure of confidential information or other breaches of the agreements. Despite our efforts to protect our trade secrets and our other confidential and proprietary information, we or our collaboration partners, board members, employees, consultants, contractors, or scientific and other advisors may unintentionally or willfully disclose our proprietary information to competitors.

There is a risk that our trade secrets and other confidential and proprietary information could have been, or could, in the future, be shared by any of our former employees with, and be used to the benefit of, any company that competes with us.

If we fail to maintain trade secret protection or fail to protect the confidentiality of our other confidential and proprietary information, our competitive position may be adversely affected. Competitors may also independently discover our trade secrets. Enforcement of claims that a third party has illegally obtained and is using trade secrets is expensive, time consuming and uncertain. If our competitors independently develop equivalent knowledge, methods and know-how, we would not be able to assert our trade secret protections against them, which could have a material adverse effect on our business.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our marks of interest and our business may be adversely affected.

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We rely on both registration and common law protection for our trademarks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During the trademark registration process, we may receive Office Actions from the USPTO objecting to the registration of our trademark. Although we would be given an opportunity to respond to those objections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and/or to seek the cancellation of registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

A NDA submitted under Section 505(b)(2) subjects us to the risk that we may be subject to a patent infringement lawsuit that would delay or prevent the review or approval of our product candidate.

We expect to submit our NDAs for our product candidates, including our Glucagon Rescue Pen, to the FDA for approval under Section 505(b)(2) of the FDCA. Section 505(b)(2) permits the submission of a NDA where at least some of the information required for approval comes from preclinical studies and/or clinical trials that were not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference. A NDA under Section 505(b)(2) would enable us to reference published literature and/or the FDA's previous findings of safety and effectiveness for a previously approved drug.

For NDAs submitted under Section 505(b)(2), the patent certification and related provisions of the Hatch-Waxman Act apply. Accordingly, if we rely for approval on the safety or effectiveness information for a previously approved drug, referred to as a listed drug, we will be required to include patent certifications in our 505(b)(2) application regarding any patents covering the listed drug. If there are patents listed in the FDA publication Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, for the listed drug, and we seek to obtain approval prior to the expiration of one or more of those patents, we will be required to submit a Paragraph IV certification indicating our belief that the relevant patents are invalid, unenforceable or will not be infringed by the manufacture, use or sale of the product that is the subject of our 505(b)(2) application. Otherwise, our 505(b)(2) application cannot be approved by the FDA until the expiration of any patents listed in the Orange Book for the listed drug. While we do not expect to submit any Paragraph IV certifications in connection with our planned 505(b)(2) application for our Glucagon Rescue Pen or our other current product candidates, there can be no assurance that we will not be required to submit a Paragraph IV certification in respect of any future product candidates for which we seek approval under Section 505(b)(2).

If we submit any Paragraph IV certification that may be required, we will be required to provide notice of that certification to the NDA holder and patent owner shortly after our 505(b)(2) application is accepted for filing. Under the Hatch-Waxman Act, the patent owner may file a patent infringement lawsuit after receiving such notice. If a patent infringement lawsuit is filed within 45 days of the patent owner's or NDA holder's receipt of notice (whichever is later), a one-time, automatic stay of the FDA's ability to approve the 505(b)(2) NDA is triggered, which typically extends for 30 months unless patent litigation is resolved in favor of the Paragraph IV filer or the patent expires before that time. Accordingly, we may invest a significant amount of time and expense in the development of one or more product candidates only to be subject to significant delay and patent litigation before such product candidates may be commercialized, if at all.

In addition, a 505(b)(2) application will not be approved until any non-patent exclusivity listed in the Orange Book for the listed drug, or for any other drug with the same, protected conditions of approval as our product, has expired. The FDA also may require us to perform one or more additional clinical trials or measurements to support the change from the listed drug, which could be time consuming and could substantially delay our achievement of regulatory approval. The FDA also may reject any future 505(b)(2) submissions and require us to submit traditional NDAs under Section 505(b)(1), which would require extensive data to establish safety and effectiveness of the product for the proposed use and could cause delay and additional costs. Or the FDA could reject any future 505(b)(2) application and require us to submit an ANDA if, before the submission of our 505(b)(2) application, the FDA approves an application for a product that is pharmaceutically equivalent to ours. These factors, among others, may limit our ability to commercialize our product candidates successfully.

Risks Related to Employee Matters, Managing Growth and Ongoing Operations

If product liability lawsuits are brought against us, our business may be harmed, and we may be required to pay damages that exceed our insurance coverage.

We may face liability claims related to the use or misuse of our product candidates and, if approved, our products. These claims may be expensive to defend and may result in large judgments against us. During the course of treatment, patients using our product candidates could suffer adverse medical effects for reasons that may or may not be related to our product candidates. We will face even greater risks upon any commercialization by us of our product candidates. Any of these events could result in a claim of liability. Any such claims against us, regardless of their merit, could result in significant costs to defend or awards against us that could materially harm our business, financial condition or results of operations. In addition, any such claims against us could result in a distraction to

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management, decreased demand for our products, an adverse effect on our public reputation, and/or difficulties in commercializing our products. To date, we have not received notice of any product liability claims against us. We maintain total products liability insurance coverage of \$5.0 million.

Although we maintain product liability insurance for claims arising from the use of our product candidates in clinical trials prior to FDA approval and for claims arising from the use of our products after FDA approval at levels that we believe are appropriate, we may not be able to maintain our existing insurance coverage or obtain additional coverage on commercially reasonable terms for the use of our other product candidates and products in the future. Also, our insurance coverage and resources may not be sufficient to satisfy any liability resulting from product liability claims, which could materially harm our business, financial condition or results of operations.

Product liability claims could result in an FDA or other regulatory authority investigation of the safety or efficacy of our products, our manufacturing processes and facilities, our marketing programs, our internal safety reporting systems or our staff conduct. A regulatory authority investigation could also potentially lead to a recall of our products or more serious enforcement actions, limitations on the indications for which they may be used, or suspension or withdrawal of approval. Product liability claims could also result in investigation, prosecution or enforcement action by the DOJ or other federal or state government agencies.

Our business could suffer if we lose the services of key members of our senior management, or if we are not able to attract and retain other key employees and consultants.

We are dependent upon the continued services of key members of our executive management and a limited number of key advisors and personnel. In particular, we are highly dependent on the skills and leadership of our executive management team, including Paul Edick, our Chief Executive Officer, Barry Deutsch, our Chief Financial Officer, Steven Prestrelski, our Chief Scientific Officer and Co-Founder, John Shannon, our Chief Operating Officer, Ken Johnson, our Senior Vice President, Clinical Development, Regulatory, Quality Assurance and Medical Affairs, and Beth Hecht, our General Counsel and Corporate Secretary. We have not historically maintained "key person" insurance on all of our executive officers but plan to obtain such insurance in the future. The loss of any one of these individuals could disrupt our operations or our strategic plans. Our industry has experienced a high rate of turnover of management personnel in recent years. Any of our personnel may terminate their employment at will. If we lose one or more of our executive officers or other key employees, our ability to implement our business strategy successfully could be seriously harmed. Furthermore, replacing executive officers or other key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain marketing approval of and commercialize products successfully.

Additionally, our future success will depend on, among other things, our ability to continue to hire and retain the necessary qualified scientific, technical and managerial personnel, for whom we compete with numerous other companies, academic institutions and organizations. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key employees on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions.

We rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by other entities and may have commitments under consulting or advisory contracts with those entities that may limit their availability to us. If we are unable to continue to attract and retain highly qualified personnel, our ability to develop and commercialize our product candidates will be limited.

We will need to increase the size of our organization, and we may encounter difficulties managing our growth.

As of March 1, 2018, we had 46 employees. As our product candidates continue to progress toward potential approval and commercialization, we anticipate the need to hire additional employees as required to add depth and specialized expertise to our team. This growth could place a strain on our administrative and operational infrastructure. If the product candidates that we are developing continue to advance in clinical trials, we will need to expand our development, regulatory, manufacturing, quality, compliance, recordkeeping, information technology, training, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to develop additional relationships with various collaborators, CROs, suppliers, manufacturers and other organizations. We may not be able to establish such relationships or may incur

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significant costs to do so. Our ability to manage our growth will also require us to continue to improve our operational, financial and management controls, reporting systems and procedures, and other compliance programs and processes, which will further increase our operating costs. Failure to manage our growth effectively could cause us to over-invest or under-invest in infrastructure, and result in losses or weaknesses in our infrastructure, which could adversely affect us. Additionally, our anticipated growth will increase the demands placed on our suppliers, resulting in an increased need for us to monitor our suppliers carefully for quality assurance, and our business could suffer.

We may be required to maintain high levels of inventory, which could consume a significant amount of our resources and reduce our cash flows.

As a result of the need to maintain substantial levels of inventory due to single third-party sourcing and long lead-time to develop alternate third-party sources, we intend to carry a high level of inventory for strategic materials and products and are subject to the risk of inventory obsolescence. In the event that a substantial portion of our inventory becomes obsolete, it could have a material adverse effect on our earnings and cash flows due to the resulting costs associated with the inventory impairment charges and costs required to replace such inventory.

We expect to incur significant additional costs as a result of being a public company, which may adversely affect our operating results and financial condition.

We expect to incur costs associated with corporate governance requirements, including requirements under the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules implemented by the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, or the Dodd-Frank Act, the SEC and The Nasdaq Global Market. These rules and regulations are expected to increase our accounting, legal and financial compliance costs and make some activities more time-consuming and costly. In addition, we will incur additional costs associated with our public company reporting requirements and we expect those costs to increase in the future. For example, we will be required to devote significant resources to complete the assessment and documentation of our internal control system and financial process under Section 404 of the Sarbanes-Oxley Act, including an assessment of the design of our information systems associated with our internal controls.

To date, we have never conducted a review of our internal control for the purpose of providing the reports required by these rules. During the course of our review and testing, we may identify deficiencies and be unable to remediate them before we must provide the required reports. Furthermore, if we have a material weakness in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company we will be required to timely file accurate quarterly and annual reports with the SEC under the Securities Exchange Act of 1934, or the Exchange Act, as amended. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from The Nasdaq Global Market or other adverse consequences. We will incur significant costs to remediate any material weaknesses we identify through these efforts. We also expect these rules and regulations to make it more expensive for us to maintain directors' and officers' liability insurance and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees, or as executive officers. We cannot predict or estimate the amount of additional costs we may incur or the timing of such costs.

New laws and regulations, as well as changes to existing laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act, the Dodd-Frank Act and rules adopted by the SEC and The Nasdaq Global Market, would likely result in increased costs to us as we respond to their requirements, which may adversely affect our operating results and financial condition.

We have identified a material weakness in our internal control over financial reporting in our audit for the fiscal year ended December 31, 2017. If we fail to remediate this weakness or experience material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately report our financial condition or results of operations which may adversely affect investor confidence in us and, as a result, the value of our common stock.

As a result of becoming a public company, we will be required, under Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial

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reporting beginning with our Annual Report on Form 10-K for the year ended December 31, 2019. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company's annual and interim financial statements will not be detected or prevented on a timely basis.

We may further enhance the computer systems processes and related documentation necessary to perform the evaluation needed to comply with Section 404. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are effective. The effectiveness of our controls and procedures may be limited by a variety of factors, including:

- faulty human judgment and simple errors, omissions or mistakes;
- fraudulent action of an individual or collusion of two or more people;
- inappropriate management override of procedures; and
- the possibility that any enhancements to controls and procedures may still not be adequate to assure timely and accurate financial control.

For example, for the year ended December 31, 2017, we identified a material weakness in our internal control over financial reporting due to a lack of proper segregation of duties within our finance and accounting function. This weakness was due to our inability to implement the appropriate segregation of duties within our historical enterprise resource planning, or ERP, system. Since August 2017, we have made efforts to design manual controls to mitigate the risk. In addition, in December 2017, we implemented a new ERP system. If we are unable to conclude that our internal control over financial reporting is effective or take effective remedial measures to improve our internal control, we could lose investor confidence in the accuracy and completeness of our financial reports, which would likely cause the price of our common stock to decline.

When we cease to be an "emerging growth company" under the federal securities laws, our auditors will be required to express an opinion on the effectiveness of our internal controls. If we are unable to confirm that our internal control over financial reporting is effective, or if our auditors are unable to express an opinion on the effectiveness of our internal controls, we could lose investor confidence in the accuracy and completeness of our financial reports, which would cause the price of our common stock to decline.

If we experience significant disruptions in our information technology systems, our business may be adversely affected.

We depend on our information technology systems for the efficient functioning of our business, including accounting, data storage, compliance, purchasing and inventory management. Our current systems are not fully redundant. While we will attempt to mitigate interruptions, we may experience difficulties in implementing some upgrades which would impact our business operations, or experience difficulties in operating our business during the upgrade, either of which could disrupt our operations, including our ability to timely ship and track product orders, project inventory requirements, manage our supply chain and otherwise adequately service our customers. In the event we experience significant disruptions as a result of the current implementation of our information technology systems, we may not be able to repair our systems in an efficient and timely manner. Accordingly, such events may disrupt or reduce the efficiency of our entire operation and have a material adverse effect on our results of operations and cash flows.

We are increasingly dependent on sophisticated information technology for our infrastructure. Our information systems require an ongoing commitment of significant resources to maintain, protect and enhance existing systems. Failure to maintain or protect our information systems and data integrity effectively could have a materially adverse effect on our business. For example, third parties may attempt to hack into systems and may obtain our proprietary information.

Fluctuations in insurance cost and availability could adversely affect our profitability or our risk management profile.

We hold a number of insurance policies, including product liability insurance, directors' and officers' liability insurance, general liability insurance, property insurance and workers' compensation insurance. If the costs of

maintaining adequate insurance coverage increase significantly in the future, our operating results could be materially adversely affected. Likewise, if any of our current insurance coverage should become unavailable to us or become economically impractical, we would be required to operate our business without indemnity from commercial insurance providers. If we operate our business without insurance, we could be responsible for paying claims or judgments against us that would have otherwise been covered by insurance, which could adversely affect our results of operations or financial condition.

We may seek to grow our business through acquisitions of or investments in new or complementary businesses, products or technologies, and the failure to manage any acquisitions or investments, or the failure to integrate them with our existing business, could have a material adverse effect on us.

From time to time we expect to consider opportunities to acquire or make investments in other technologies, products and businesses that may enhance our capabilities, complement our current products or expand the breadth of our markets or customer base. Potential acquisitions and strategic investments involve numerous risks, including:

- problems assimilating the purchased technologies, products or business operations;
- issues maintaining uniform standards, procedures, controls and policies;
- unanticipated costs associated with acquisitions;
- diversion of management's attention from our core business;
- adverse effects on existing business relationships with suppliers and customers;
- risks associated with entering new markets in which we have limited or no experience;
- potential loss of key employees of acquired businesses; and
- increased legal and accounting compliance costs.

We have no current commitments with respect to any acquisition or investment and we have never entered into or completed an acquisition. We do not know if we will be able to identify suitable acquisitions, complete any such acquisitions on favorable terms or at all, successfully integrate any acquired business, product or technology into our business or retain any key personnel, suppliers or distributors. Our ability to grow through acquisitions successfully depends upon our ability to identify, negotiate, complete and integrate suitable target businesses and to obtain any necessary financing. These efforts could be expensive and time-consuming, and may disrupt our ongoing business and prevent management from focusing on our operations. If we are unable to integrate any acquired businesses, products or technologies effectively, our business, results of operations and financial condition will be materially adversely affected.

Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain products outside of the United States and require us to develop and implement costly compliance programs.

If we expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as

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certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The Securities and Exchange Commission, or SEC, also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

Our employees, independent contractors, consultants, collaborators and contract research organizations may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could cause significant liability for us and harm to our reputation.

We are exposed to the risk that our employees, independent contractors, consultants, collaborators and contract research organizations may engage in fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable non-U.S. regulatory authorities, to provide accurate information to the FDA or comparable non-U.S. regulatory authorities, to comply with manufacturing standards we have established, to comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable non-U.S. regulatory authorities, to report financial information or data accurately or to disclose unauthorized activities to us. Such misconduct could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of product materials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law new legislation that significantly revises the Internal Revenue Code of 1986, as amended. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for net interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such net operating losses may be carried forward indefinitely), and modifying or repealing many business deductions and credits (including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as "orphan drugs"). We continue to examine the impact this tax reform legislation may have on our business. The overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain how various states will respond to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

Risks Related to Our Common Stock and this Offering

No public market for our common stock currently exists and an active trading market may not develop or be sustained following this offering.

Prior to this initial public offering, there has been no public market for our common stock. Although we have applied to list our common stock on The Nasdaq Global Market, an active trading market may not develop following the completion of this offering or, if developed, may not be sustained. The lack of an active market may impair your

ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value or the trading price of your shares. An inactive market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration. The public offering price for our common stock has been determined by negotiation among us and the underwriters based upon several factors, and the price at which our common stock trades after this offering may decline below the public offering price. You may experience a significant decrease in the value of the common stock you purchase in this offering regardless of our operating performance or prospects.

If you purchase shares of common stock in this offering, you will suffer immediate dilution in the net tangible book value of your investment.

The initial public offering price of our common stock is substantially higher than the net tangible book value per share of our common stock. Therefore, if you purchase shares of our common stock in this offering, you will pay a price per share that substantially exceeds our net tangible book value per share after this offering. Based on the assumed initial public offering price of \$ _____ per share, which is the midpoint of the estimated price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, you will experience immediate dilution of \$ _____ per share, representing the difference between our pro forma as-adjusted net tangible book value per share after giving effect to this offering and the assumed initial public offering price. Purchasers of common stock in this offering will have contributed approximately _____ % of the aggregate price paid by all purchasers of our stock and will own approximately _____ % of our common stock outstanding after this offering, excluding any shares of our common stock that they may have acquired prior to this offering. Furthermore, if the underwriters exercise their option to purchase additional shares or if our previously issued options or warrants to acquire common stock at prices below the initial public offering price are exercised, you will experience further dilution. For additional information on the dilution that you will experience immediately after this offering, see the section titled "Dilution."

Our stock price may be volatile, and you may not be able to resell shares of our common stock at or above the price you paid.

The initial public offering price for our common stock has been determined through our negotiations with the underwriters and may not be representative of the price that will prevail in the open market following the offering. The trading price of our common stock following completion of this offering may be highly volatile and could be subject to wide fluctuations in response to the risk factors discussed in this section, and others beyond our control, including:

- the timing and results of applications for FDA approval of our Glucagon Rescue Pen and other regulatory actions with respect to our product candidates;
- regulatory actions with respect to our competitors' products and product candidates;
- the success of existing or new competitive products or technologies;
- results of clinical trials of product candidates of our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- the timing and results of clinical trials of our pipeline product candidates;
- commencement or termination of collaborations for our development programs;
- the results of our efforts to develop additional product candidates or products;
- the level of expenses related to any of our product candidates or clinical development programs;
- failure or discontinuation of any of our development programs;
- the pricing and reimbursement of our Glucagon Rescue Pen, if approved, and of other product candidates that may be approved;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- actual or anticipated changes in estimates as to financial results or development timelines;

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- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or other stockholders;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

In recent years, the stock markets, and particularly the stock of smaller pharmaceutical and biotechnology companies at times have experienced price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of affected companies. Broad market and industry factors may significantly affect the market price of our common stock unrelated to our actual operating performance. These fluctuations may be even more pronounced in the trading market for our common stock shortly following this offering. If the market price of shares of our common stock after this offering does not ever exceed the initial public offering price, you may not realize any return on your investment in us and may lose some or all of your investment.

In addition, in the past, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Securities litigation brought against us following volatility in our stock price, regardless of the merit or ultimate results of such litigation, could result in substantial costs, which would hurt our financial condition and operating results and divert management's attention and resources from our business.

Securities analysts may publish inaccurate or unfavorable research or reports about our business or may publish no information at all, which could cause our stock price or trading volume to decline.

If a trading market for our common stock develops, the trading market will be influenced by the research and reports that industry or financial analysts publish about us and our business. We do not control these analysts. As a newly public company, we may be slow to attract research coverage and the analysts who publish information about our common stock will have had relatively little experience with our company, which could affect their ability to accurately forecast our results and could make it more likely that we fail to meet their estimates. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us provide inaccurate or unfavorable research or issue an adverse opinion regarding our stock price, our stock price could decline. If one or more of these analysts cease coverage of our company or fail to publish reports covering us regularly, we could lose visibility in the market, which in turn could cause our stock price or trading volume to decline.

The concentration of our capital stock ownership with insiders upon the completion of this offering will likely limit your ability to influence corporate matters.

Based upon shares outstanding as of December 31, 2017, we anticipate that our executive officers, directors, current five percent or greater stockholders and affiliated entities will together beneficially own approximately % of our common stock outstanding after this offering, or % if the underwriters exercise their option to purchase additional shares in full. These stockholders may in some instances exercise their influence in ways that you do not believe are in your best interests as a stockholder. Some of these persons or entities may have interests different than yours. For example, because many of these stockholders purchased their shares at prices substantially below the price at which shares are being sold in this offering and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors or they may want us to pursue strategies that deviate from the interests of other stockholders. In particular, these stockholders, acting together, may be able to control our management and affairs and matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, such as mergers, consolidations or the sale of substantially all of our assets. Consequently, this concentration of ownership could limit your ability to influence corporate matters and may have the effect of delaying or preventing a change of control, including a merger, consolidation or other business combination involving us, or discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control, even if such a change of control would benefit our other stockholders. This significant concentration of share ownership may adversely affect the trading price for our common stock because some investors perceive disadvantages in owning stock in companies with concentrated equity ownership.

We are an “emerging growth company” and the reduced disclosure requirements applicable to “emerging growth companies” may make our common stock less attractive to investors.

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we may take advantage of certain exemptions and relief from various reporting requirements that are applicable to other public companies that are not “emerging growth companies.” In particular, while we are an “emerging growth company” (i) we will not be required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, (ii) we will be exempt from any rules that may be adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotations or a supplement to the auditor’s report on financial statements, (iii) we will be subject to reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (iv) we will not be required to hold nonbinding advisory votes on executive compensation or stockholder approval of any golden parachute payments not previously approved.

As a result, our public filings may not be comparable to companies that are not “emerging growth companies”. We may remain an “emerging growth company” until the fiscal year-end following the fifth anniversary of the completion of this initial public offering, though we may cease to be an “emerging growth company” earlier under certain circumstances, including (i) if the market value of our common stock that is held by nonaffiliates exceeds \$700 million as of any June 30, in which case we would cease to be an “emerging growth company” as of the following January 1, or (ii) if our gross revenue exceeds \$1.07 billion in any fiscal year.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies.

Investors may find our common stock less attractive if we rely on the exemptions and relief granted by the JOBS Act. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may decline and/or become more volatile.

Our management might apply the proceeds of this offering in ways that do not increase the value of your investment.

Although we currently intend to use the net proceeds from this offering in the manner described in the section titled “Use of Proceeds” in this prospectus, our management will have broad discretion as to the use of the net proceeds of this offering and you will be relying on the judgment of our management regarding the application of these proceeds. We might apply the net proceeds of this offering in ways with which you do not agree, or in ways that do not yield a favorable return. You will not have the opportunity to influence our decisions on how to use our net proceeds from this offering or to assess whether proceeds are being used appropriately. If our management applies these proceeds in a manner that does not improve our operating results and yield a significant return, if any, on our investment of these net proceeds, the market price of our common stock could decline. For more information on our management’s planned use of proceeds, please read “Use of Proceeds” elsewhere in this prospectus. Pending their use, we may also invest the net proceeds from this offering in a manner that does not produce income or that loses value.

A significant portion of our total outstanding shares of common stock is restricted from immediate resale but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. Upon the completion of this offering, we expect that entities affiliated with holders of 5% or more of our common stock prior to this offering and our management team will beneficially own, collectively, approximately % of our outstanding common stock. If one or more of them were to sell a substantial portion of the shares they hold, it could cause our stock price to decline. Based on shares outstanding as of December 31, 2017, upon completion of this offering, we will have approximately outstanding shares of common stock, assuming no exercise of the underwriters’ over-allotment option to purchase additional shares. As of the date of this prospectus, approximately shares of common stock will be subject to a 180-day contractual lock-up with the underwriters. The underwriters may, in their sole discretion and without notice, release all or any portion of the shares from these lock-up arrangements, and the lock-up agreements

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are subject to certain exceptions. See “Underwriting” for more information. Of the shares subject to a contractual lock-up with the underwriters, approximately _____ shares of common stock also will be subject to a 180-day contractual lock-up with us.

After this offering, holders of an aggregate of approximately _____ shares of our common stock and _____ shares issuable upon exercise of outstanding warrants will have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders.

In addition, as of December 31, 2017, there were _____ shares subject to outstanding options granted under our 2011 Plan that will become eligible for sale in the public market to the extent permitted by any applicable vesting requirements, the lock-up agreements described above and Rules 144 and 701 under the Securities Act of 1933, as amended. We intend to register the shares of common stock issuable upon exercise of these options. We also intend to register all _____ shares of common stock that we may issue under our 2018 Stock Option and Incentive Plan and 2018 Employee Stock Purchase Plan that we intend to adopt in connection with this offering. Once we register these shares, they can be freely sold in the public market upon issuance and once vested, subject to the 180-day lock-up periods under the lock-up agreements described above and in the “Underwriting” section of this prospectus.

We might not be able to utilize a significant portion of our net operating loss carryforwards and research and development tax credit carryforwards.

As of December 31, 2017, we had federal net operating loss carryforwards of \$55.8 million, and federal research and orphan drug credit carryforwards of \$2.0 million. If not utilized, these carryforwards will expire at various dates between 2025 and 2036. These net operating loss and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the newly enacted federal income tax law, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. It is uncertain how various states will respond to the newly enacted federal tax law. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an “ownership change,” which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. Our existing net operating losses or credits may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change in connection with or after this offering, our ability to utilize our net operating losses or credits could be further limited by Sections 382 and 383 of the Code. In addition, future changes in our stock ownership, many of which may be outside of our control, could result in an ownership change under Sections 382 and 383 of the Code. Accordingly, we may not be able to utilize a material portion of our net operating losses or credits.

We do not anticipate paying any cash dividends in the foreseeable future, and accordingly, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

After the completion of this offering, we do not anticipate declaring any cash dividends to holders of our common stock in the foreseeable future. In addition, under our Loan Agreement, we are restricted from paying any dividends or making any distributions on account of our capital stock. Our ability to pay cash dividends also may be prohibited by future loan agreements. Consequently, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investment. Investors seeking cash dividends should not invest in our common stock.

Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management or hinder efforts to acquire a controlling interest in us.

Provisions in our corporate charter and our bylaws that will become effective upon the closing of this offering may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

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- establish a classified board of directors such that all members of the board are not elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on at stockholder meetings;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call a special meeting of stockholders;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a “poison pill” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors;
- require the approval of the holders of at least two-thirds of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws;
- provide that the Court of Chancery of the State of Delaware will be the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty by one or more of our directors, officers or employees, any action asserting a claim against us pursuant to the Delaware General Corporation Law, or any action asserting a claim against us that is governed by the internal affairs doctrine.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. This could discourage, delay or prevent someone from acquiring us or merging with us, whether or not it is desired by, or beneficial to, our stockholders. This could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

Our bylaws to be effective upon the consummation of this offering designate certain courts as the sole and exclusive forums for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our bylaws that will become effective upon the completion of this offering provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers and employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws, or (iv) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein. In addition, our amended and restated bylaws will further provide that the United States District Court for the Northern District of Illinois will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. In addition, our amended and restated bylaws will provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing provisions. We have chosen the United States Court for the Northern District of Illinois as the exclusive forum for such causes of action because our principal executive offices are located in Chicago, Illinois. Some companies that have adopted similar federal district court forum selection provisions are currently subject to a suit in the Court of Chancery of the State of Delaware brought by stockholders who assert that the federal district court forum selection provision is not enforceable. We recognize that the federal district court forum selection clause may impose additional litigation costs on stockholders who assert the provision is not enforceable and may impose more general additional litigation costs in pursuing any such claims, particularly if the stockholders do not reside in or near the state of Illinois. Additionally, this choice of forum provision may limit a stockholder’s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders.

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Stockholders who do bring a claim in these courts could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near the states in which these courts are located. Such courts may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments or results may be more favorable to us than to our stockholders. Alternatively, if the federal district court forum selection provision is found inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could have an adverse effect on our business, financial condition or results of operations. The U.S. District Court for the Northern District of Illinois may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the sections entitled “Prospectus Summary,” “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business,” contains express or implied forward-looking statements that are based on our management’s belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this prospectus include, but are not limited to, statements about:

- the timing or likelihood of our NDA submission to the FDA for our Glucagon Rescue Pen and its acceptance for filing by the FDA;
- the timing or likelihood of approval by the FDA of our NDA for our Glucagon Rescue Pen;
- our estimates regarding the market opportunities for our product candidates;
- the commercialization, marketing and manufacturing of our product candidates, if approved;
- the pricing and reimbursement of our Glucagon Rescue Pen or any other of our product candidates, if approved;
- the rate and degree of market acceptance and clinical utility of our Glucagon Rescue Pen or any other of our product candidates for which we receive marketing approval;
- the initiation, timing, progress and results of our research and development programs and future preclinical and clinical studies;
- our ability to advance any other product candidates into, and successfully complete, clinical studies and obtain regulatory approval for them;
- our ability to identify additional product candidates;
- the implementation of our strategic plans for our business, product candidates and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- our ability to use the proceeds of this offering in ways that increase the value of your investment;
- our expectations related to the use of proceeds from this offering, and estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- our ability to manufacture, or the ability of third parties to deliver, sufficient quantities of components and drug product for commercialization of our Glucagon Rescue Pen or any other of our product candidates;
- our ability to maintain and establish collaborations;
- our financial performance;
- our ability to effectively manage our anticipated growth;
- developments relating to our competitors and our industry, including the impact of government regulation;
- our ability to remediate the material weakness identified by our independent registered public accounting firm and avoid any findings of material weakness or significant deficiencies in the future; and
- other risks and uncertainties, including those listed under the caption “Risk Factors.”

In some cases, forward-looking statements can be identified by terminology such as “may,” “should,” “expects,” “intends,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “potential,” “continue” or the negative of these terms or other comparable terminology. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the section entitled “Risk Factors” and elsewhere in this prospectus. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those

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implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance. You should read this prospectus and the documents that we reference in this prospectus and have filed with the Securities and Exchange Commission as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements.

The forward-looking statements in this prospectus represent our views as of the date of this prospectus. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this prospectus.

This prospectus also contains estimates, projections and other information concerning our industry, our business and the markets for our product candidates. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from our own internal estimates and research as well as from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

USE OF PROCEEDS

We estimate that the net proceeds to us from the sale of _____ shares of our common stock in this offering will be approximately \$ _____ million, or approximately \$ _____ if the underwriters exercise in full their option to purchase additional shares, assuming an initial public offering price of \$ _____ per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

A \$1.00 increase (decrease) in the assumed initial public offering price of \$ _____ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the net proceeds to us from this offering by \$ _____ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase (decrease) of 1.0 million shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) our net proceeds from this offering by \$ _____ million, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We do not expect that a change in the offering price or the number of shares by these amounts would have a material effect on our intended uses of the net proceeds from this offering, although it may impact the amount of time prior to which we may need to seek additional capital.

As of December 31, 2017, we had cash and cash equivalents of \$42.0 million. In February 2018, we issued additional shares of Series C preferred stock for net proceeds of \$4.4 million and drew down \$20.0 million from our Loan Agreement with Oxford Finance, LLC and Silicon Valley Bank. We currently intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, as follows:

- approximately \$ _____ million to support the expected commercial launch of our Glucagon Rescue Pen, including investments in sales and marketing, inventory and our commercial and medical affairs infrastructure;
- approximately \$ _____ million to advance our other pipeline product candidates, including the _____ for PBH, the _____ for HAAF, CHI and EIH and the _____ for ready-to-use diazepam and pram-insulin; and
- the remainder for working capital and other general corporate purposes.

Based on our current plans, we believe our existing cash and cash equivalents, together with the net proceeds from this offering, will be sufficient to fund our operations and capital expenditure requirements through _____.

This expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. For example, we may use a portion of the net proceeds for the acquisition of businesses or technologies to continue to build our pipeline, our research and development capabilities and our intellectual property position, although we currently have no agreements, commitments or understandings with respect to any such transaction. We cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our research and development, the status of and results from non-clinical studies or clinical trials we may commence in the future, as well as any collaborations that we may enter into with third parties for our product candidates or strategic opportunities that become available to us, and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

Pending our use of proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation instruments, including short-term, investment-grade, interest-bearing instruments and U.S. government securities.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain any future earnings to fund the development and expansion of our business, and therefore we do not anticipate paying cash dividends on our common stock in the foreseeable future. Any future determination to pay dividends will be at the discretion of our board of directors and will depend on our results of operations, financial condition, capital requirements, contractual restrictions and other factors deemed relevant by our board of directors. Under our Loan Agreement with Oxford Finance, LLC and Silicon Valley Bank, we are restricted from paying any dividends or making any distributions on account of our capital stock. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Loan Agreement” for a description of the restrictions on our ability to pay dividends.

CAPITALIZATION

The following table sets forth our capitalization as of December 31, 2017:

- on an actual basis;
- on a pro forma basis to reflect (i) the sale and issuance of 707,680 shares of our Series C preferred stock in February 2018 for aggregate net proceeds of \$4.4 million, (ii) the drawdown in February 2018 of \$20.0 million from our Loan Agreement with Oxford Finance, LLC and Silicon Valley Bank, (iii) the automatic conversion of all outstanding shares of convertible preferred stock into an aggregate of 21,083,391 shares of common stock upon the completion of this offering and (iv) the filing of our amended and restated certificate of incorporation, which will occur upon the closing of this offering;
- on a pro forma as-adjusted basis to give further effect to reflect the sale and issuance by us of shares of our common stock in this offering at an assumed initial public offering price of \$ per share (the midpoint of the range listed on the cover page of this prospectus), after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

You should read the information below in conjunction with the financial statements and the related notes thereto and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this prospectus.

(In thousands, except share and per share data)	AS OF DECEMBER 31, 2017		
	ACTUAL	PRO FORMA	PRO FORMA AS ADJUSTED
			(Unaudited)
Cash and cash equivalents	\$ 42,045	\$ 66,448	\$
Deferred rent—long-term	\$ 90	\$ 90	\$
Debt, long term	—	20,000	
Convertible preferred stock, \$0.0001 par value; 21,950,994 shares authorized and 20,375,711 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma; no shares authorized, issued or outstanding, pro forma as adjusted	97,878	—	
Stockholders' equity:			
Common stock, \$0.0001 par value; 30,450,994 shares authorized, 3,845,600 shares issued and outstanding, actual; shares authorized, 24,928,991 shares issued and outstanding, pro forma; shares authorized, shares issued and outstanding, pro forma as adjusted	1	3	
Preferred stock, \$0.0001 par value; no shares authorized, issued and outstanding, actual; shares authorized and no shares issued and outstanding, pro forma and pro forma as adjusted	—	—	
Additional paid-in capital	2,754	105,033	
Accumulated (deficit)	(60,585)	(60,585)	
Total stockholders' equity (deficit)	(57,830)	44,451	
Total capitalization	\$ 40,138	\$ 64,541	\$

A \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of cash and cash equivalents, additional paid-in capital, total stockholders' equity and total capitalization by approximately \$ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and

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commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1.0 million shares in the number of shares offered by us in this offering would increase (decrease) the pro forma as adjusted amount of cash and cash equivalents, additional paid-in capital, total stockholders' equity and total capitalization by approximately \$ million, assuming the assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The table above excludes each of the following:

- 3,208,588 shares of common stock issuable upon exercise of options issued under our 2011 Stock Option/Stock Issuance Plan at a weighted-average exercise price of \$0.93 per share;
- 316,880 shares of common stock issued upon the early exercise of stock options issued under our 2011 Stock Option/Stock Issuance Plan, which remain subject to vesting restrictions;
- 35,500 shares of common stock issuable upon the exercise of warrants to purchase common stock at an exercise price of \$3.319 per share as of December 31, 2017, plus 95,686 shares of common stock issuable upon the exercise of warrants to purchase common stock at an exercise price of \$6.2705 per share that we issued in February 2018;
- 801,882 shares of common stock reserved for issuance under our 2011 Stock Option/Stock Issuance Plan as of December 31, 2017, plus an additional 600,000 shares of common stock that we reserved for issuance under such plan in February 2018, which shares will no longer be reserved following this offering;
- shares of common stock to be reserved for future issuance under our 2018 Stock Option and Incentive Plan to be effective upon the effectiveness of the registration statement of which this prospectus forms a part; and
- shares of common stock to be reserved for future issuance under our 2018 Employee Stock Purchase Plan to be effective upon the effectiveness of the registration statement of which this prospectus forms a part.

DILUTION

If you invest in our common stock in this offering, your interest will be diluted immediately to the extent of the difference between the public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock after this offering. As of December 31, 2017, our historical net tangible book value was \$(57.8) million, or \$(13.90) per share. Our historical net tangible book value represents total tangible assets less total liabilities and convertible preferred stock, all divided by the number of shares of common stock outstanding on December 31, 2017.

Our pro forma net tangible book value as of December 31, 2017 was \$44.4 million, or \$1.76 per share, after giving effect to (i) the sale and issuance of 707,680 shares of our Series C preferred stock in February 2018 for aggregate net proceeds of \$4.4 million, (ii) the drawdown in February 2018 of \$20.0 million from our Loan Agreement with Oxford Finance, LLC and Silicon Valley Bank and (iii) the conversion of all outstanding shares of our convertible preferred stock into 21,083,391 shares of our common stock upon the completion of this offering. After giving effect to the sale of _____ shares of common stock offered in this offering at an assumed initial public offering price of \$ _____ per share, the midpoint of the range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of December 31, 2017 would have been \$ _____ million, or \$ _____ per share. This represents an immediate increase in pro forma net tangible book value of \$ _____ per share to existing stockholders and an immediate dilution of \$ _____ per share to new investors, or approximately _____ % of the assumed initial public offering price of \$ _____ per share. The following table illustrates this dilution on a per share basis:

Assumed initial public offering price per share		\$
Historical net tangible book value per share as of December 31, 2017		\$(13.90)
Increase per share attributable to the pro forma adjustments described above		15.66
Pro forma net tangible book value per share as of December 31, 2017, before giving effect to this offering		1.76
Increase in pro forma net tangible book value per share attributable to this offering		
Pro forma as adjusted net tangible book value per share after giving effect to this offering		_____
Dilution in pro forma as adjusted net tangible book value per share to new investors in this offering		_____

A \$1.00 increase (decrease) in the assumed initial public offering price of \$ _____ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted net tangible book value by \$ _____ per share and the dilution to investors participating in this offering by \$ _____ per share, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated expenses payable by us. Similarly, each increase (decrease) of 1.0 million shares in the number of shares offered by us in this offering would increase (decrease) the pro forma as adjusted net tangible book value by \$ _____ per share and the dilution to investors participating in this offering by \$ _____ per share, assuming the assumed initial public offering price of \$ _____ per share, the midpoint of the price range set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated expenses payable by us.

The following table summarizes, on a pro forma as adjusted basis as of December 31, 2017, the differences between the number of shares of common stock purchased from us on an as converted basis, the total cash consideration and the average price per share paid to us by existing stockholders and by new investors purchasing shares in this offering, at the assumed initial public offering price of \$ _____ per share, the midpoint of the price range set forth on the cover of this prospectus before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us:

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	SHARES PURCHASED		TOTAL CONSIDERATION		AVERAGE PRICE PER SHARE
	NUMBER	PERCENT	AMOUNT	PERCENT	
Existing stockholders	24,928,991	%	\$105,153,232	%	\$ 4.18
New investors participating in this offering					
Total		100.0%		100.0%	

A \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the total consideration paid by investors in this offering by approximately \$ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1.0 million shares in the number of shares offered by us in this offering would increase (decrease) the total consideration paid by investors in this offering by approximately \$ million, assuming the assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise their option to purchase additional shares of our common stock in full, our existing stockholders would own % and our new investors would own % of the total number of shares of our common stock outstanding after this offering.

The foregoing tables and calculations exclude:

- 3,208,588 shares of common stock issuable upon exercise of options issued under our 2011 Stock Option/Stock Issuance Plan at a weighted-average exercise price of \$0.93 per share;
- 316,880 shares of common stock issued upon the early exercise of stock options issued under our 2011 Stock Option/Stock Issuance Plan, which remain subject to vesting restrictions;
- 35,500 shares of common stock issuable upon the exercise of warrants to purchase common stock at an exercise price of \$3.319 per share as of December 31, 2017, plus 95,686 shares of common stock issuable upon the exercise of warrants to purchase common stock at an exercise price of \$6.2705 per share that we issued in February 2018;
- 801,882 shares of common stock reserved for issuance under our 2011 Stock Option/Stock Issuance Plan as of December 31, 2017, plus an additional 600,000 shares of common stock that we reserved for issuance under such plan in February 2018, which shares will no longer be reserved following this offering;
- shares of common stock to be reserved for future issuance under our 2018 Stock Option and Incentive Plan to be effective upon the effectiveness of the registration statement of which this prospectus forms a part; and
- shares of common stock to be reserved for future issuance under our 2018 Employee Stock Purchase Plan to be effective upon the effectiveness of the registration statement of which this prospectus forms a part.

To the extent that outstanding options are exercised or shares are issued under our equity incentive plans, you will experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities may result in further dilution to our stockholders.

SELECTED FINANCIAL INFORMATION

The statements of operations data for the years ended December 31, 2016 and 2017 and the balance sheet data as of December 31, 2016 and 2017 are derived from our audited financial statements included elsewhere in this prospectus. You should read this data together with our financial statements and related notes included elsewhere in this prospectus and the information under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations." Our historical results are not necessarily indicative of the results to be expected in the future for a full year or any interim period.

	YEARS ENDED DECEMBER 31,	
	2016	2017
	(in thousands, except share and per share data)	
Statements of Operations Data:		
Grant income	\$ 1,022	\$ 1,540
Service revenue	53	16
Cost of revenue	8	4
Gross profit	<u>1,067</u>	<u>1,552</u>
Operating expenses:		
Research and development	10,238	20,166
General and administrative	4,060	8,015
Expense from operations	<u>14,298</u>	<u>28,181</u>
Loss from operations	<u>(13,231)</u>	<u>(26,629)</u>
Other income (expense):		
Interest income	5	124
Interest expense	(2)	(2)
Change in fair value of warrants	24	(46)
Other expense	(5)	(1)
Total other income	<u>22</u>	<u>75</u>
Net loss	<u>\$ (13,209)</u>	<u>\$ (26,554)</u>
Net loss per share—basic and diluted ⁽¹⁾	<u>\$ (4.03)</u>	<u>\$ (7.35)</u>
Weighted average number of shares outstanding, basic and diluted ⁽¹⁾	<u>3,281,564</u>	<u>3,612,512</u>
Pro forma net loss per share (unaudited) ⁽¹⁾ :		
Basic and diluted		<u>\$ (1.31)</u>
Pro forma weighted average shares outstanding (unaudited) ⁽¹⁾ :		
Basic and diluted		<u>20,231,131</u>

	DECEMBER 31,	
	2016	2017
	(in thousands)	
Balance Sheet Data:		
Cash and cash equivalents	\$ 32,269	\$ 42,045
Working capital ⁽²⁾	30,647	39,193
Total assets	33,533	44,998
Deferred rent—long-term	42	90
Convertible preferred stock	62,898	97,878
Accumulated deficit	(34,031)	(60,585)
Total stockholder's deficit	(31,934)	(57,830)

⁽¹⁾ See Note 2 to our audited financial statements included elsewhere in this prospectus for an explanation of the calculations of our basic and diluted net loss per share, basic and diluted pro forma net loss per share and the shares used in computing basic and diluted net loss per share and basic and diluted pro forma net loss per share.

⁽²⁾ We define working capital as current assets less current liabilities.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATION

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and related notes included elsewhere in this prospectus. In addition to financial information, the following discussion contains forward-looking statements that reflect our plans, estimates, and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this prospectus, particularly in "Risk Factors."

Overview

We are a specialty pharmaceutical company leveraging our novel non-aqueous formulation technology platforms, XeriSol and XeriJect, to develop and commercialize ready-to-use injectable and infusible drug formulations. We have developed a ready-to-use, room-temperature stable liquid glucagon formulation that, unlike any currently available products, can be administered without any preparation or reconstitution. Our lead product candidate, Glucagon Rescue Pen, delivers ready-to-use glucagon via a commercially-available auto-injector for the treatment of severe hypoglycemia, a potentially life-threatening condition, in people with diabetes. We have completed three Phase 3 clinical trials for our Glucagon Rescue Pen and expect to submit a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or the FDA, in the third quarter of 2018. If our NDA is submitted and approved in our expected timeframe, we believe we will have the first ready-to-use, room-temperature stable liquid glucagon formulation that can be administered without any preparation or reconstitution. We are also applying our novel room-temperature stable liquid glucagon formulation for the management of additional conditions associated with hypoglycemia with significant unmet medical need. In addition, we are applying our technology platforms to convert other commercially-available drugs into ready-to-use, room-temperature stable liquid formulations to address the needs in multiple therapeutic areas and conditions, including epilepsy and diabetes.

We have begun building out our commercial organization, including individuals in operations and marketing, as well as our medical affairs organization. Outside of the United States, we plan to pursue development and commercialization partnerships. We currently contract with third parties for the manufacture, assembly, testing, packaging, storage and distribution of our products.

Since our inception in 2005, we have devoted substantially all our resources to research and development initiatives, undertaking preclinical studies of our product candidates, conducting clinical trials of our most advanced product candidates, organizing and staffing our company and raising capital. We do not have any products approved for sale and have not generated any revenue from product sales. We have funded our operations to date primarily with proceeds from the sale of preferred stock, bank financings and grant awards received from the National Institute of Health, or NIH, and other philanthropic organizations. As of December 31, 2017, we had received cash proceeds of \$100.5 million from sales of our preferred stock, and \$8.0 million from grant awards from the NIH and other philanthropic organizations. In the first quarter of 2018, we issued additional shares of Series C preferred stock for cash proceeds of \$4.4 million and closed on a \$45.0 million Loan Agreement of which \$20.0 million was drawn in February 2018. An additional \$15.0 million will be available beginning upon the submission of a NDA for our Glucagon Rescue Pen until the earlier of September 30, 2018 or the 30th day following NDA submission. The remaining \$10.0 million will be available beginning upon approval of our Glucagon Rescue Pen NDA by the FDA until the earlier of September 30, 2019 or the 30th day following NDA approval by the FDA.

For the years ended December 31, 2017 and 2016, our net loss was \$26.6 million and \$13.2 million, respectively. We have not been profitable since inception, and as of December 31, 2017, our accumulated deficit was \$60.6 million. We expect to continue to incur net losses for the foreseeable future as we prepare for a potential commercial launch of our Glucagon Rescue Pen, including hiring our sales force. We also expect to incur significant expenses and increasing operating losses in the near term. We expect our expenses will increase substantially in connection with our ongoing activities, as we:

- continue our research and development efforts;
- seek regulatory approval for new product candidates and product enhancements;

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- build commercial infrastructure to support sales and marketing for our product candidates;
- hire and retain additional personnel and add operational, financial and management information systems; and
- operate as a public company.

We do not expect to generate significant product revenue unless or until we obtain marketing approval of, and begin to sell, our product candidates. We expect to continue to seek private or public equity and debt financing to meet our capital requirements. There can be no assurance that such funding may be available to us on acceptable terms, or at all, or that we will be able to commercialize our product candidates. In addition, we may not be profitable even if we commercialize any of our product candidates.

Components of our Results of Operations

Revenue

Grant income is derived from grants that we received from the NIH and other philanthropic organizations to help bring necessary drugs to the market place where there are currently unmet needs. As of December 31, 2017, we are eligible to receive \$2.7 million in grants from the NIH and other philanthropic organizations that will help fund our ongoing clinical development for other chronic glucagon programs as well as our auto-injectable diazepam program for treatment of seizures. These awards will be recognized as grant income when we have performed the services as outlined in the grant agreements.

Service revenue is derived from the feasibility studies we perform for third parties to determine whether our XeriSol and XeriJect technologies may enhance such party's drug offerings.

Cost of revenue includes employees' time, materials and overhead applied to the feasibility studies.

Research and Development

Research and development expense consists of expenses incurred in connection with the discovery and development of our XeriSol and XeriJect product candidates. We expense research and development costs as incurred. Research and development costs that are paid in advance of performance are capitalized until services are provided or goods are delivered. Research and development expenses include:

- expenses incurred under agreements with contract research organizations, or CROs, as well as investigative sites and consultants that conduct our preclinical studies and clinical trials;
- manufacturing scale-up expenses and the cost of acquiring and manufacturing preclinical and clinical trial materials and commercial materials, including manufacturing validation batches;
- outsourced professional scientific development services;
- employee-related expenses, which include salaries, benefits and stock-based compensation;
- expenses relating to regulatory activities, including filing fees paid to regulatory agencies;
- laboratory materials and supplies used to support our research activities; and
- allocated expenses for utilities and other facility-related costs.

Research and development activities are central to our business model. We expect research and development expenses to increase in 2018 as we continue to progress our product candidates through clinical trials. In 2018, we expect to complete a Phase 3b clinical trial for our Glucagon Rescue Pen, complete Phase 2a and Phase 2b clinical trials for PBH, continue a Phase 2 clinical trial for CHI, complete a Phase 2a clinical trial for HAAF, initiate a Phase 2b clinical trial for exercise induced hypoglycemia, or EIH, complete a Phase 1 clinical trial for Diazepam and complete a preclinical study for Pramlintide-Insulin. Our research and development expenses may vary significantly over time due to uncertainties relating to the terms and timing of regulatory approvals and unexpected results of our clinical trials. We expect our research and development expenses to increase significantly over the next several years as we increase personnel costs, including stock-based compensation, conduct clinical trials and prepare regulatory filings for our product candidates.

General and Administrative

General and administrative expenses consist principally of salaries, stock-based compensation and related costs for personnel in executive, marketing and administrative positions, facility costs not otherwise included in research and

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development, marketing expenses, professional fees for legal, audit and accounting services, fees paid for market research and trade shows and travel cost.

We anticipate that, following the completion of this offering, we will incur greater expenses as a public reporting company, including increased payroll, legal and compliance, accounting, insurance and investor relations costs. We also expect selling and marketing costs to increase significantly as we prepare for the expected commercial launch of our Glucagon Rescue Pen, if approved, including the build out of a sales force in 2019.

Interest Expense and Other Income

Other income consists primarily of interest income earned on short term deposits and the change in the fair market value of our preferred stock warrants.

In February 2018, we entered into a \$45.0 million Loan Agreement, of which we drew down \$20.0 million upon closing, and we expect to draw down another \$15.0 million in 2018, assuming submission of our NDA for the Glucagon Rescue Pen. As a result of those borrowings, we expect interest expense to increase beginning in the first quarter of 2018.

Income Tax

We have incurred operating losses since inception and therefore do not have any taxable income. We have \$55.8 million in net operating loss carryforwards and \$2.0 million in federal research credits that begin to expire in 2025. Additionally, we have a California Competes Tax Credit Allocation agreement and Illinois EDGE agreement that will reduce future taxable income in those respective states by up to \$1.5 million and \$1.4 million, respectively.

Results of Operations

The following table summarizes our results of operations for the years ended December 31, 2016 and 2017:

	YEARS ENDED DECEMBER 31,		INCREASE (DECREASE)
	2016	2017 (in thousands)	
Grant income	\$ 1,022	\$ 1,540	\$ 518
Service revenue	53	16	(37)
Cost of revenue	8	4	(4)
Gross profit	1,067	1,552	485
Operating expenses:			
Research and development	10,238	20,166	9,928
General and administrative	4,060	8,015	3,955
Expense from operations	14,298	28,181	13,883
Loss from operations	(13,231)	(26,629)	(13,398)
Other income (expense):			
Interest income	5	124	119
Interest expense	(2)	(2)	—
Change in fair value of warrants	24	(46)	(70)
Other expense	(5)	(1)	4
Total other income	22	75	53
Net loss	<u>\$(13,209)</u>	<u>\$(26,554)</u>	<u>\$ (13,345)</u>

Gross Profit

Gross profit increased by \$485,000 for the year ended December 31, 2017 when compared to the year ended December 31, 2016, primarily driven by an increase in grant income by \$518,000. This increase was primarily driven by several clinical trials and preclinical studies for our CHI, PBH and auto-injector for auto-injectable diazepam formulation for treatment of seizures that were covered by grants awarded to us.

[Table of Contents](#)**Research and Development**

The following table summarizes our research and development expenses by functional area for the years ended December 31, 2016 and 2017:

	FOR THE YEARS ENDED DECEMBER 31,	
	2016	2017
	(in thousands)	
Clinical and preclinical	\$ 2,128	\$ 9,233
Product development	5,406	6,654
Compensation and related personnel costs	2,626	4,217
Stock-based compensation	78	62
Total research and development expenses	<u>\$ 10,238</u>	<u>\$ 20,166</u>

The following table summarizes our research and development expenses by program for the years ended December 31, 2016 and 2017:

	FOR THE YEARS ENDED DECEMBER 31,	
	2016	2017
	(in thousands)	
Glucagon Rescue Pen	\$ 4,687	\$ 10,339
Other ready to use glucagon products	2,088	4,013
Pipeline product candidates	257	60
Overhead (personnel, facilities and other expenses)	3,206	5,754
Total research and development expenses	<u>\$ 10,238</u>	<u>\$ 20,166</u>

Research and development expense increased \$9.9 million for the year ended December 31, 2017 when compared to the year ended December 31, 2016. This increase was primarily driven by expenses associated with clinical trials, product development and an increase in headcount. In 2017, we started and completed two Phase 3 clinical trials for our Glucagon Rescue Pen and started Phase 2 clinical trials for PBH and CHI. We produced two registration batches and one engineering batch for the Glucagon Rescue Pen in 2017 that will be used to support our planned NDA submission in the third quarter of 2018. We also produced clinical supplies for the PBH and CHI programs as well as preclinical material for our chronic glucagon and Diazepam programs. We increased headcount in 2017 from 10 to 24 employees to support our current research and development activities.

General and Administrative

General and administrative costs increased \$4.0 million for the year ended December 31, 2017 when compared to the year ended December 31, 2016. This increase was primarily driven by increased expenses associated with an increase in headcount and marketing and market research expenses. In 2017, we increased our headcount from three to 17, including the addition of marketing, market research and medical affairs departments, and as a result compensation and related benefit expenses increased \$3.4 million. Marketing and market research expenses increased \$0.5 million in 2017 as we performed extensive market research for our existing product candidates as well as evaluated several new potential product candidates.

Other Income

Other income increased \$53,000 to \$75,000 for the year ended December 31, 2017 as a result of the interest income earned on our cash and cash equivalents. This increase was partially offset by the change in the fair market value of our warrants. The change in fair value of warrant liability represents non-cash (expense) income and is driven by the increase in the fair value of the preferred stock that it converts into.

Liquidity and Capital Resources

Our primary uses of cash are to fund product development costs, operating expenses and working capital requirements. Historically, we have funded our operations primarily through private placements of convertible preferred stock, bank financings and grants awarded from the NIH and other philanthropic organizations. As of December 31, 2017, we have \$2.7 million in awarded unused grants that can be utilized to offset program costs for our PBH, CHI and chronic glucagon programs as well as our auto-injectable diazepam program for treatment of seizures, in accordance with the grant agreements.

Capital Resources and Funding Requirements

We have incurred operating losses since inception and we have an accumulated deficit of \$60.6 million at December 31, 2017. We believe that our cash and cash equivalents as of December 31, 2017, together with the proceeds of the sale of Series C preferred stock in February of 2018, the proceeds from the Loan Agreement that closed in February 2018 and the proceeds from this offering will enable us to fund our operating expenses through . We expect to incur substantial additional expenditures in the near term to support our ongoing activities and the expected commercial launch of our Glucagon Rescue Pen. Additionally, we expect to incur additional costs as a result of operating as a public company. We expect to continue to incur net losses for the next several years and we are highly dependent on our ability to find additional sources of funding in the form of debt or equity financing and grant awards to fund our operations. Our ability to fund our product development, clinical operations, including completion of our planned Phase 2 and Phase 3 clinical trials and commercialization of our product candidates will depend on the amount and timing of cash received from planned financing transactions and grant awards. Our future capital requirements will depend on many factors, including:

- the costs, timing and outcome of regulatory review of our Glucagon Rescue Pen;
- the costs, timing and outcomes of clinical trials and regulatory reviews associated with our product candidates;
- the costs of commercialization activities, including product marketing, sales and distribution;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims;
- the emergence of competing technologies and products and other adverse marketing developments;
- the effect on our product development activities of actions taken by the FDA or other regulatory authorities;
- our degree of success in commercializing Glucagon Rescue Pen, if approved; and
- the number and types of future products we develop and commercialize.

Until we obtain regulatory approval to market our product candidates, if ever, we cannot generate revenues from sales of our products. Even if we are able to sell our products, we may not generate a sufficient amount of product revenues to finance our cash requirements. Accordingly, we may need to obtain additional financing in the future which may include public or private debt and equity financings. There can be no assurance that such funding may be available to us on acceptable terms, or at all, or that we will be able to successfully commercialize our product candidates. The issuance of equity securities may result in dilution to stockholders. If we raise additional funds through the issuance of debt securities, these securities may have rights, preferences and privileges senior to those of our common stock and the terms of the debt securities could impose significant restrictions on our operations. The failure to raise funds as and when needed could have a negative impact on our financial condition and ability to pursue our business strategies. If additional funding is not secured when required, the Company may need to delay or curtail its operations until such funding is received, which would have a material adverse impact on our business prospects and results of operations.

Series C Convertible Preferred Stock

In 2017, we sold 5,657,514 shares of our Series C preferred stock for proceeds of \$35.5 million. In February 2018, we sold an additional 707,680 shares of Series C preferred stock for proceeds of \$4.4 million.

Loan Agreement

In February 2018, we entered into a Loan and Security Agreement, which we refer to as the Loan Agreement, with Oxford Finance LLC and Silicon Valley Bank, which we collectively refer to as our Lenders, providing a senior secured loan facility of up to an aggregate principal amount of \$45.0 million, comprised of a \$20.0 million

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drawdown in February 2018, and an additional \$25.0 million which can be borrowed in two additional tranches. The second tranche is \$15.0 million and is available if we submit our NDA for our Glucagon Rescue Pen before September 30, 2018, and then only available to be drawn until the earlier of September 30, 2018 or the 30th day following such NDA submission. The third tranche is \$10.0 million and is available if we receive approval of our Glucagon Rescue Pen NDA by the FDA before September 30, 2019, and then only available to be drawn until the earlier of September 30, 2019 or the 30th day following NDA approval by the FDA.

The interest rate under the Loan Agreement is the thirty-day U.S. LIBOR rate plus 6.75%. Payments on the Loan Agreement are interest only for the first 24 months, which can be extended by an additional twelve months if the third tranche is drawn. The total term of the loan is 59 months and the principal payments will begin in either 36 or 24 months, contingent on the third tranche being drawn.

Pursuant to the Loan Agreement, we provided a first priority security interest in all existing and after-acquired assets, excluding intellectual property and certain other assets, owned by us. Our Loan Agreement contains a negative pledge on intellectual property owned by us.

We also issued warrants to the Lenders to purchase our Series C preferred stock at an exercise price of \$6.2705. The number of warrants issued to Lenders is equal to the total principal of each funded tranche multiplied by 3.0%, which is then divided by \$6.2705. As of March 1, 2018, a total of 95,686 warrants have been issued in connection with the Loan Agreement.

The Loan Agreement allows us to voluntarily prepay the outstanding amounts thereunder, but not less than \$2.0 million of the outstanding principal at any time. A prepayment fee of 1.5% would be assessed on the prepaid principal through the interest-only period. A final payment fee of 6.5% multiplied by the original principal amount of each tranche drawn is due upon the earlier to occur of the maturity date of the Loan Agreement, the acceleration of the Loan Agreement or prepayment of such borrowings. The Loan Agreement includes a non-utilization fee of 2.0% multiplied by the principal amount of tranche three payable to Lenders in October 2019, if we elect not to draw the third tranche.

The Loan Agreement also contains customary indemnification obligations and customary events of default, including, among other things, our failure to fulfill certain of our obligations under the Loan Agreement and the occurrence of a material adverse change in our business, operations or condition, a material impairment of the prospect of repayment of any portion of the loan, or a material impairment in the perfection or priority of the Lenders' lien in the collateral or in the value of such collateral. In the event of default by us under the Loan Agreement, the Lenders would be entitled to exercise their remedies thereunder, including the right to accelerate the debt, upon which we may be required to repay all amounts then outstanding under the Loan Agreement, which could harm our financial condition.

The Loan Agreement includes certain restrictions on, among other things, our ability to incur additional indebtedness, change the name or location of our business, merge with or acquire other entities, pay dividends or make other distributions to holders of our capital stock, make certain investments, engage in transactions with affiliates, create liens, open new deposit accounts, sell assets or pay subordinated debt.

Cash Flows

	FOR THE YEARS ENDED DECEMBER 31,	
	2016	2017
	(in thousands)	
Net cash used in operating activities	\$(16,087)	\$(24,663)
Net cash used in investing activities	(35)	(700)
Net cash provided by financing activities	3,904	35,139
Increase (decrease) in cash and cash equivalents	<u>\$(12,218)</u>	<u>\$ 9,776</u>

Net cash used in operating activities for the year ended December 31, 2017 was \$24.7 million, consisting primarily of a net loss of \$26.6 million offset by non-cash charges of \$0.8 million and an increase in net operating assets and

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liabilities of \$1.1 million. Non-cash charges were primarily for stock compensation expense and depreciation of fixed assets. The increase in net operating assets and liabilities was primarily related to an increase in accrued expenses and accounts payable related to employee costs, clinical and research and development expenses partially offset by an increase in accounts receivable. Net cash used in operating activities for the year ended December 31, 2016 was \$16.1 million, consisting primarily of a net loss of \$13.2 million offset by non-cash charges of \$0.7 million and a decrease in net operating assets and liabilities of \$3.6 million. Non-cash charges were primarily for stock compensation expense and depreciation of fixed assets. The decrease in net operating assets and liabilities was primarily related to the payment of accrued expenses and accounts payable related to employee costs, clinical and research and development expenses.

Net cash used in investing activities for the year ended December 31, 2017 was \$0.7 million, consisting of purchases of additional research laboratory equipment to facilitate our increased research and development activities. In 2016 we purchased \$35,000 of computer and related hardware equipment used in our research and development activities and furniture for the Austin office. We will continue to incur capital expenditures in 2018.

Net cash provided by financing activities for the year ended December 31, 2017 was \$35.1 million due primarily to the sale of \$35.0 million of our Series C Preferred Stock. Net cash provided in financing activities for the year ended December 31, 2016 was \$3.9 million due primarily to the sale of \$4.0 million of our Series C Preferred Stock.

Contractual Obligations and Commitments

As of December 31, 2017, we were obligated to pay the following amounts for our operating leases:

	TOTAL	LESS THAN 1 YEAR	1- 3 YEARS	3- 5 YEARS	MORE THAN 5 YEARS
Operating leases	\$5,395	\$ 730	\$ 1,693	\$ 2,271	\$ 701

We enter into contracts in the normal course of business with clinical trial sites, manufacturing organizations and with vendors for preclinical studies, research supplies and other services and products for operating purposes. These contracts generally provide for termination after a notice period, and, therefore, are cancellable contracts and not included in the table above.

As of December 31, 2017, we have received \$0.8 million out of an expected \$0.9 million in grant proceeds for the development of a stable liquid glucagon for use in an artificial pancreas. Under the terms of the agreement, we will be required to pay up to four times the award received upon commercialization of glucagon for use in the artificial pancreas. If we undergo a change in control, then we will be required to pay a mid-single digit percentage of the gross proceeds, capped at four times the award amount less any amounts already paid. Additionally, if sales of glucagon for use in the artificial pancreas exceed \$750 million in the first five years after the first commercial sale, then we would be required to make an additional payment equal to the original award amount.

As of December 31, 2017, we received \$0.9 million in grant proceeds to help fund our EIH program. Under terms of this agreement, we will be required to pay up to two times the award amount upon the commercialization of an EIH product. These amounts are a low double-digit percentage of annual gross sales of an EIH product, capped at \$0.5 million annually. If we undergo a change in control, then we will pay a mid-single digit percentage of the consideration capped at two times the award amount less any amounts already paid. Additionally, if sales exceed \$1 billion, we will be required to pay an additional amount equal to two times the award amount.

As of December 31, 2017, we received \$1.0 million in grant proceeds to help fund our chronic glucagon programs. Under terms of this agreement we will be required to pay up to two times the award amount upon the commercialization of any chronic glucagon program. These amounts are a low double-digit percentage of annual gross sales of all chronic glucagon programs, capped at \$0.5 million annually. If we undergo a change in control, then we will pay a mid-single digit percentage of the consideration capped at two times the award amount less any amounts already paid. Additionally, for each chronic glucagon program where sales exceed \$500 million, we will be required to pay an additional amount equal to two times the award amount.

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The amount we may have to repay under the grant agreements are contingent upon future events and therefore not included in the table above. We have also received awards from the NIH National Institute of Diabetes and Kidney Diseases, which awards are not subject to any repayment obligations.

Off-Balance Sheet Arrangements:

As of December 31, 2017, we had an unused letter of credit for \$58,000 that is used to secure the San Diego, California lease. In the first quarter of 2018 we entered into another letter of credit for \$85,000 to secure a lease in Chicago, Illinois.

Internal Controls

Our internal policies and procedures relating to control over financial reporting are designed to provide reasonable assurance as to the reliability of our financial reporting. In the year ended December 31, 2017, we identified a material weakness in our internal control over financial reporting due to a lack in the proper segregation of duties within our finance and accounting function, as one individual had control over two or more phases of a transaction or operation. This weakness was due to our inability to implement the appropriate segregation of duties within our historical enterprise resource planning system. Since August 2017, we have made efforts to design manual controls to mitigate the risk. In addition, in December 2017, we implemented a new enterprise resource planning system that allowed for greater segregation of duties.

QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risks related to changes in interest rates.

Interest Rate Risk

Cash and Cash Equivalents—We are exposed to the risk of interest rate fluctuations on the interest income earned on our cash and cash equivalents. A hypothetical 100 basis point movement in interest rates applicable to our cash and cash equivalents outstanding at December 31, 2017 would increase interest income by approximately \$0.4 million on an annual basis. No significant decrease in interest income would be expected as our cash balances are earning interest at rates of less than approximately 100 basis points.

Loan Agreement—Our interest rate risk relates primarily to U.S. dollar LIBOR-indexed borrowings. Based on our outstanding borrowings at , 2018, a one-percentage point increase in interest rates would affect interest expense on the debt by \$0.2 million on an annualized basis. A one-percentage point decrease in interest rates would affect interest expense on the debt by \$0.2 million on an annualized basis.

CRITICAL ACCOUNTING POLICIES AND THE USE OF ESTIMATES

We have based our management's discussion and analysis of our financial condition and results of operations on our financial statements that have been prepared in accordance with generally accepted accounting principles, or GAAP, in the United States. The preparation of these financial statements requires us to make estimates that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments, including those related to clinical trial expenses and stock-based compensation. We base our estimates on historical experience and on various other factors we believe to be appropriate under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully discussed in Note 2 to our audited financial statements included in this prospectus, we believe that the following accounting policies are critical to the process of making significant judgments and estimates in the preparation of our financial statements. We have reviewed these critical accounting policies and estimates with the audit committee of our board of directors.

Research and development costs

Research and development costs are expensed as incurred. Research and development costs include salaries and personnel-related costs, consulting fees, fees paid for contract research services, laboratory equipment and facilities costs, and other external costs.

Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are used or the services are performed.

When preparing our financial statements, we are required to estimate our accrued clinical expenses. This process involves reviewing open contracts and communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. Payments under some of the contracts we have with parties depend on factors, such as successful enrollment of certain numbers of patients, site initiation and the completion of clinical trial milestones. When accruing clinical expenses, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If possible, we obtain information regarding unbilled services directly from our service providers. However, we may be required to estimate the cost of these services based only on information available to us. If we underestimate or overestimate the cost associated with a trial or service at a given point in time, adjustments to research and development expenses may be necessary in future periods. Historically, our estimated accrued clinical expenses have approximated actual expense incurred.

Stock based compensation

The following table summarizes the reporting of total stock-based compensation expense resulting from employee stock options and restricted stock awards:

	YEARS ENDED DECEMBER 31,	
	2016	2017
	(in thousands)	
Research and development	\$ 78	\$ 62
General and administrative	462	437
Total stock based compensation	<u>\$ 540</u>	<u>\$ 499</u>

We account for our stock-based compensation awards in accordance with ASC Topic 718, *Compensation—Stock Compensation*, or ASC 718. ASC 718 requires all stock-based payments to employees, including grants of employee stock options, to be recognized in the statements of operations based on their grant date fair values. We estimate the grant date fair value of each option award using the Black-Scholes option-pricing model. We recognize stock-based compensation expense, net of estimated forfeitures, equal to the grant date fair value of stock options on a straight-line basis over the requisite service period.

Estimating the fair value of options requires the input of subjective assumptions, including the estimated fair value of our common stock, the expected life of the option, stock price volatility, the risk-free interest rate and expected dividends. The assumptions used in our Black-Scholes option-pricing model represent management's best estimates and involve a number of variables, uncertainties and assumptions and the application of management's judgment, as they are inherently subjective. If any assumptions change, our stock-based compensation expense could be materially different in the future.

These assumptions used in our Black-Scholes option-pricing model are estimated as follows:

- *Expected Term.* We do not believe we are able to rely on our historical exercise and post-vesting termination activity to provide accurate data for estimating the expected term for use in determining the fair value-based

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measurement of our options. Therefore, we have opted to use the “simplified method” for estimating the expected term of options, which is the average of the weighted-average vesting period and contractual term of the option.

- *Expected Volatility.* Since there has been no public market for our common stock and lack of company specific historical volatility, we have determined the share price volatility for options granted based on an analysis of the volatility of a peer group of publicly traded companies. In evaluating similarity, we consider factors such as stage of development, risk profile, enterprise value and position within the industry.
- *Risk-Free Interest Rate.* The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of the grant for zero-coupon U.S. Treasury notes with remaining terms similar to the expected term of the options.
- *Expected Dividends.* The expected dividend yield is 0% because we have not historically paid, and do not expect for the foreseeable future to pay, a dividend on our common stock.
- *Fair value of common stock.* As there has been no public market for our common stock to date, the estimated fair value of our common stock has been determined by our board of directors as of the date of each option grant, with input from management, considering our most recently available third-party valuations of common stock. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants’ Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*.

Prior to December 31, 2017 our valuations were performed by a third-party valuation company using a discounted cash flow, or DCF, analysis. This method was chosen based on our sources of historical capital and potential future capital needs. In the fourth quarter of 2017, we went from a DCF valuation technique to a hybrid method, which uses market approaches to estimate our enterprise value. The hybrid method is a probability-weighted expected return method, or PWERM, where the equity value in one or more of the scenarios are calculated using an option-pricing method, or OPM. The OPM treats common stock and preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company’s securities changes. The PWERM is a scenario-based methodology that estimates the fair value of common stock based upon an analysis of future values for the company, assuming various outcomes. The common stock value is based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available as well as the rights of each class of stock. The future value of the common stock under each outcome is discounted back to the valuation date at an appropriate risk-adjusted discount rate and probability weighted to arrive at an indication of value for the common stock. The assumptions underlying these valuations represent management’s best estimates, which involve inherent uncertainties and the application of management judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our stock-based compensation expense could be materially different.

For stock awards after the completion of this offering, our board of directors intends to determine the fair value of each share of underlying common stock based on the closing price of our common stock as reported on the date of grant.

The intrinsic value of all outstanding options as of the date of this prospectus was \$ million based on the estimated fair value of our common stock of \$ per share, which is the midpoint of the price range set forth on the cover of this prospectus for this offering.

If factors change and we employ different assumptions, stock-based compensation expense may differ significantly from what we have recorded in the past. If there are any modifications or cancellations of the underlying unvested securities, we may be required to accelerate, increase or cancel any remaining unearned stock-based compensation expense. To the extent that our assumptions are incorrect, the amount of stock-based compensation recorded will change.

Income Taxes

Income taxes are recorded in accordance with ASC 740, *Accounting for Income Taxes* (“ASC 740”), which provides for deferred taxes using an asset and liability approach. We recognize deferred tax assets and liabilities for the

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expected future tax consequences of events that have been included in the financial statements or tax returns. We determine our deferred tax assets and liabilities based on differences between financial reporting and tax bases of assets and liabilities, which are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Valuation allowances are provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

We account for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, we recognize the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. As of December 31, 2017, we did not have any significant uncertain tax positions.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its NOLs to offset future taxable income. We have not completed a study to assess whether an ownership change has occurred in 2017. Our existing NOLs may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change in connection with or after this offering, our ability to utilize NOLs could be further limited by Section 382 of the Code. Future changes in our stock ownership, some of which are outside of our control, could result in an ownership change under Section 382 of the Code. Our NOLs are also subject to international regulations, which could restrict our ability to utilize our NOLs. Furthermore, our ability to utilize NOLs of companies that we may acquire in the future may be subject to limitations. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities.

Recent accounting pronouncements

See Note 2 to our audited financial statements beginning on page F-1 of this prospectus for a description of recent accounting pronouncements applicable to our financial statements.

JOBS ACT ACCOUNTING ELECTION

In April 2012, the Jumpstart Our Business Startups Act of 2012, or JOBS Act, was enacted. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to take advantage of such extended transition period.

BUSINESS

Overview

We are a specialty pharmaceutical company leveraging our novel non-aqueous formulation technology platforms, XeriSol and XeriJect, to develop and commercialize ready-to-use injectable and infusible drug formulations. We have developed a ready-to-use, room-temperature stable liquid glucagon formulation that, unlike any currently available products, can be administered without any preparation or reconstitution. Our lead product candidate, Glucagon Rescue Pen, delivers ready-to-use glucagon via a commercially-available auto-injector for the treatment of severe hypoglycemia, a potentially life-threatening condition, in people with diabetes. We have completed three Phase 3 clinical trials for our Glucagon Rescue Pen and expect to submit a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or the FDA, in the third quarter of 2018. If our NDA is submitted and approved in our expected timeframe, we believe we will have the first ready-to-use, room-temperature stable liquid glucagon formulation that can be administered without any preparation or reconstitution. We are also applying our novel ready-to-use, room-temperature stable liquid glucagon formulation for the management of additional conditions associated with hypoglycemia with significant unmet medical need. In addition, we are applying our XeriSol and XeriJect technology platforms to convert other commercially-available drugs into ready-to-use, room-temperature stable liquid formulations to address the needs in multiple therapeutic areas and conditions, including epilepsy and diabetes. We own the worldwide rights to our proprietary formulation technology platforms and our product candidates, with 66 patents issued globally, including a composition of matter patent covering our ready-to-use glucagon formulation that expires in 2036.

Our proprietary XeriSol and XeriJect non-aqueous formulation technologies allow for the subcutaneous, or SC, and intramuscular, or IM, delivery of highly-concentrated, ready-to-use formulations of peptides, proteins, antibodies and small molecules using commercially-available syringes, auto-injectors, multi-dose pens and infusion pumps. Current aqueous formulations of certain drugs present numerous challenges for patients and care providers, including multi-step reconstitution, refrigeration requirements, large injection volumes and intravenous, or IV, administration over several hours. Our broadly-applicable platforms offer the opportunity to eliminate reconstitution and refrigeration, enable long-term room-temperature stability, significantly reduce injection volume and allow for a more convenient SC or IM administration as opposed to IV infusion, all of which we believe are distinct advantages over these existing aqueous formulations. We believe that our technology platforms can lead to products that will improve outcomes and enable easier administration while reducing costs for payors and the healthcare system.

We are developing our lead product candidate, the Glucagon Rescue Pen, for the treatment of severe hypoglycemia in people with diabetes to address limitations of currently marketed emergency glucagon kits. Hypoglycemia, a key concern of people with both Type 1 Diabetes, or T1D, and Type 2 Diabetes, or T2D, occurs when a person has a deficiency of glucose in their bloodstream, often as a result of insulin treatment. Symptoms of hypoglycemia include fatigue, shakiness, anxiety, headache, nausea and vomiting, and in severe cases, hypoglycemia can result in cardiovascular disease, seizure, coma, and, if left untreated, death. The current standard of care for severe hypoglycemia in the ambulatory setting is the emergency administration of glucagon, a hormone that raises the concentration of glucose in the bloodstream. Currently marketed emergency glucagon kits consist of a glucagon powder that must be reconstituted with a liquid diluent and drawn into a syringe using a multi-step procedure that can be difficult to successfully administer, particularly in an emergency. In published comparative human factors studies with currently marketed kits, only 6% to 31% of users were able to successfully administer the full dose of glucagon. The underuse or unsuccessful use of currently marketed kits leaves people at risk of experiencing prolonged severe hypoglycemic events, which if left untreated, can lead to serious health consequences and death.

We believe our Glucagon Rescue Pen addresses the administration challenges of currently marketed products, and, if approved, has the potential to be the preferred emergency glucagon product. Our ready-to-use Glucagon Rescue Pen does not require reconstitution or refrigeration and features two-year room-temperature stable liquid glucagon delivered in an auto-injecting device with no visible needle. In our human factors study, 99% of users were able to successfully administer the full dose with our ready-to-use Glucagon Rescue Pen.

Our goal is to establish our Glucagon Rescue Pen, if approved, as the preferred emergency glucagon product and drive greater adoption and penetration of emergency glucagon therapy by offering a glucagon product that better meets the needs of patients and caregivers. The ADA recommends that glucagon be prescribed for all individuals at

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increased risk of clinically significant hypoglycemia for use in the event of an emergency. People with diabetes who are treated with insulin or substances that promote production of insulin are increased risk of clinically significant hypoglycemia. There are an estimated 1.3 million people with T1D who are treated with insulin because their bodies do not naturally produce insulin, all of whom are clinically appropriate for glucagon. Approximately 4.3 million additional people with T2D are treated with insulin because their bodies do not use insulin properly, of which we estimate that approximately 50% are clinically appropriate for glucagon. Therefore, we estimate the potential target population for emergency glucagon therapy totals approximately 3.5 million people in the United States. Our commercial strategy is to penetrate this market efficiently with a concentrated sales force by targeting high prescribers of glucagon and mealtime insulin and activate demand through targeted direct-to-patient promotion.

Due to the limitations of currently marketed products, only approximately 660,000 total prescriptions for emergency glucagon kits were written in 2017 in the United States, resulting in the purchase of approximately 960,000 single-dose kits. Based on our market research, we intend to market two Glucagon Rescue Pens per package and to target all 3.5 million people that we believe are clinically appropriate for glucagon. In 2017, U.S. sales for emergency glucagon kits was approximately \$240 million, but we believe that increasing penetration, including by new entrants that address unmet patient and caregiver needs such as our Glucagon Rescue Pen, may result in a market totaling up to \$2.0 billion. Outside of the United States, we estimate there are an additional 3.5 million people with diabetes in Europe and an additional 12.5 million people with diabetes in Japan and China that are clinically appropriate for emergency glucagon treatment. We plan to pursue development and commercialization collaborations for these markets.

We are also applying our glucagon formulation to five intermittent and chronic use conditions with significant unmet medical need. These additional applications are:

- Post-Bariatric Hypoglycemia, or PBH, syndrome, a serious complication of bariatric surgery that can arise from excessive insulin, or hyperinsulinism, due to the change in gastric anatomy resulting from bariatric surgery.
- Congenital Hyperinsulinism, or CHI, a condition caused by several genetic defects that result in severe, persistent hypoglycemia in infants and children, which can lead to brain damage and death.
- Hypoglycemia-Associated Autonomic Failure, or HAAF, in which chronic hypoglycemia impairs the body's natural response to restore blood sugar levels and can lead to an individual becoming unaware of the onset of a severe hypoglycemic event and result in cardiovascular disease, seizure, coma, and, if left untreated, death.
- Exercise-Induced Hypoglycemia, or EIH, in people with diabetes. Exercise, particularly aerobic exercise, often results in a significant drop in blood glucose levels for people on insulin.
- Management of diabetes via glucagon in a fully-integrated, bi-hormonal artificial pancreas closed-loop system.

By applying our ready-to-use glucagon to treat multiple conditions, we expect to leverage operating efficiencies across our supply chain, research and development, and commercial and medical organizations.

We also are applying our technology platforms to develop additional product candidates, such as ready-to-use, liquid-stable diazepam delivered via a commercially-available auto-injector for the emergency treatment of epileptic seizures and a fixed-dose co-formulation of pramlintide and insulin, or Pram-Insulin, for the management of diabetes. We believe that our strong product candidate portfolio, complemented by external expansion opportunities, will support our vision to effectively and efficiently meet the needs of our target markets.

The nature of our product candidates and target conditions provides us with a potentially faster and capital-efficient development and regulatory pathway to approval. The FDA has granted orphan drug status to three of our product candidates, which are our ready-to-use glucagon for PBH and CHI and our ready-to-use, liquid-stable formulation of diazepam for the treatment of acute repetitive seizures, or ARS, in patients with epilepsy. This designation provides us with research and development tax credits and exemption from FDA user fees, as well as seven years of orphan drug exclusivity upon product approval. In addition, because certain conditions that we intend to target are rare conditions, we believe our clinical trials may be of smaller size than studies for conditions that are not rare conditions. Furthermore, because the product candidates developed using our technology platforms are designed to be reformulations of currently approved products, we expect to utilize the FDA's pathway under Section 505(b)(2) of the U.S. Federal Food, Drug and Cosmetic Act, or the FDCA, which permits submissions to rely, in part, on the

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safety and effectiveness of a previously approved product, which may potentially result in a more expeditious pathway to FDA approval.

Our management team includes veterans in drug development, discovery and commercialization, with executive experience in leading global pharmaceutical and healthcare companies, including Durata Therapeutics, Baxter Healthcare, Merck, Searle, Takeda, Warner Chilcott, MedPointe Healthcare, Amylin Pharmaceuticals, PowderJect Technologies, Integra LifeSciences and Alpharma. We are supported by investors that include private equity, venture capital and public healthcare investment funds. Our investors include Asahi Kasei, Bay City Capital, Deerfield Management, Mérieux Développement, Palmetto Partners, Redmile, Sabby and Wild Basin. As of March 1, 2018, we had raised an aggregate of \$105.2 million from the sale of our equity securities.

Our Pipeline

The following table summarizes key information about our internal product candidates.

	Product Candidate	Indication	Development Stage				Next Milestone	
			Pre-Clinical	Phase 1	Phase 2	Phase 3	Event	Expected Date
Ready-to-Use Glucagon for Hypoglycemia	Glucagon Rescue Pen	Severe Hypoglycemia	Phase 3				Submit NDA	3Q '18
	Self-Administered Glucagon	Post-Bariatric Hypoglycemia*	Phase 2a		Phase 2b		Ph 2a Results (Closed Loop Pump) Initiate Ph 2b (Vial/Syringe)	1H '18 2H '18
	Continuous Glucagon	Congenital Hyperinsulinism*	Phase 2		Phase 2b		Ph 2 Interim Efficacy Results	2H '18
	Continuous Glucagon	Hypoglycemia-Associated Autonomic Failure	Phase 2a		Phase 2b		Ph 2a Results	2H '18
	Self-Administered Glucagon	Exercise-Induced Hypoglycemia	Phase 2a		Phase 2b		Initiate Ph 2b	2H '18
Ready-to-Use Products for Epilepsy and Diabetes	Diazepam	Acute Repetitive Seizures*	Pre-Clinical		Phase 1		Ph 1 Results	2H '18
	Pramlintide-Insulin	T1D / T2D Blood Sugar Control	Pre-Clinical		Phase 1		Pre-clinical Results	1H '18

* Received orphan drug designation

Additionally, we expect to commence a proof-of-concept clinical study for our bi-hormonal artificial pancreas program in mid-2018.

Our Strategy

Our strategy is to utilize our proprietary non-aqueous formulation technology platforms to convert marketed and development-stage products that have poor solubility and stability into ready-to-use, user-friendly injectable and infusible drugs for multiple therapeutic areas and conditions, including hypoglycemia, epilepsy and diabetes. We also seek to apply our formulation technology platforms to enhance the formulations of proprietary products and candidates of other pharmaceutical and biotechnology companies. The key elements of our strategy include:

- **Rapidly secure regulatory approval for our lead product candidate, the Glucagon Rescue Pen, for severe hypoglycemia.** We have completed three Phase 3 clinical trials for our Glucagon Rescue Pen and expect to submit a NDA to the FDA in the third quarter of 2018 utilizing the 505(b)(2) regulatory pathway. Additionally, we are engaged in ongoing interactions with the European Medicines Agency, or EMA, regarding our development path in Europe.
- **Maximize the commercial potential for our Glucagon Rescue Pen.** If approved, we plan to commercially launch our Glucagon Rescue Pen in the United States in the second half of 2019. We expect to initially target approximately 8,000 healthcare professionals who are high prescribers of current glucagon kits and/or mealtime insulin products, using an expected initial sales force of 60 individuals, and activate demand through targeted direct-to-patient promotion. We have started to build our commercial organization, including individuals in operations and marketing, as well as our medical affairs organization. Outside of the United States, we plan to pursue development and commercialization partnerships.

- **Advance our ready-to-use glucagon portfolio to address other conditions associated with hypoglycemia.** We plan to apply our ready-to-use, room-temperature stable liquid glucagon to address multiple conditions that could benefit from intermittent or chronic administration, such as PBH, CHI, HAAF and EIH in diabetes. We are also evaluating our liquid-stable glucagon as the glucagon component of a fully-integrated, bi-hormonal artificial pancreas. We plan to leverage efficiencies across our portfolio, such as our supply chain, research and development, and our commercial and medical organizations. We plan to use commercially available drug delivery devices for our liquid-stable glucagon formulation and associated intermittent and chronic glucagon programs.
- **Leverage our technology and expertise to develop a portfolio of additional product candidates.** We are exploring the application of our formulation technology platforms to other commercially available drugs for multiple conditions. We are developing an improved formulation of diazepam for the treatment of ARS in patients with epilepsy, to be administered through a ready-to-use auto-injector. We have completed formulation development and preclinical pharmacokinetic studies and plan to commence a Phase 1 clinical trial in the first half of 2018. We are also conducting preclinical studies of a fixed-ratio pramlintide-insulin combination product for the treatment of diabetes.
- **Collaborate with third party pharmaceutical and biotechnology companies to apply our technology platforms to enhance the formulations of their proprietary products and candidates.** We are pursuing formulation and development partnerships to apply our XeriSol and XeriJect technology platforms to enhance the formulation, delivery and clinical profile of other companies' proprietary drugs and biologics. We currently are working with several companies on feasibility programs to evaluate the formulation of their therapeutics with, depending on the type of molecule XeriSol or XeriJect. Active programs include a XeriJect monoclonal antibody formulation, a XeriJect blood factor formulation and a XeriSol co-formulation of a peptide and small molecule for T1D. We plan to continue to explore the application of our formulation technology platforms to proprietary drugs and biologics from additional pharmaceutical and biotechnology companies.

Our Technology Platforms

Overview

Our proprietary non-aqueous formulation technology platforms are designed to address the challenges presented by current aqueous formulations of certain drugs. Injectable pharmaceuticals have conventionally used aqueous delivery systems to administer drugs and biologics, but, in the presence of water, many drugs have poor solubility and low stability. To optimize their stability and enable longer-term storage, many of these products are freeze dried into a powder and, when needed, must be reconstituted with a liquid diluent, which is often a challenging multi-step procedure with the potential for error. Furthermore, the drug product begins to break down once combined with water, which requires the drug to be used immediately or otherwise refrigerated. In addition, these products can require complicated formulations and large injection volumes to make them soluble. For many products, these volumes are too large for SC or IM delivery and instead necessitate IV infusion over several hours. These drugs can be difficult or painful to administer and have limited portability, resulting in an overall poor experience for patients and caregivers.

Our proprietary XeriSol and XeriJect platforms offer the opportunity to eliminate the need for reconstitution and refrigeration, enable long-term room-temperature stability, significantly reduce injection volume and allow for a more convenient SC or IM administration as opposed to IV infusion, all of which we believe are distinct advantages over existing aqueous formulations of marketed and development-stage products. We believe that our technology platforms can lead to products that will improve outcomes and enable easier administration while reducing costs for payors and the healthcare system.

Our XeriJect formulation platform is best suited for drugs and biologics consisting of large molecules, such as proteins, monoclonal antibodies and vaccines. XeriSol is best suited for peptides and small molecules that currently encounter formulation challenges. With XeriJect, we have formulated suspensions with a protein concentration in excess of 400 mg/mL, far exceeding current aqueous formulation systems with maximum achievable protein concentrations of 50-250 mg/mL. These biocompatible non-aqueous, injectable solutions or suspensions formulated with our platforms can then be packaged for administration in a commercially-available auto-injector, pre-filled syringe, vial, multi-dose pen or infusion pump.

Ready-to-Use Glucagon

Our novel, room-temperature stable liquid glucagon formulation represents a significant advancement over the current freeze-dried, or lyophilized, glucagon, enabling a ready-to-use solution that can be quickly and easily injected or infused subcutaneously. This formulation is designed to provide the flexibility to dose different volumes of liquid glucagon using a range of delivery devices to suit the needs of people with hypoglycemic conditions. We believe our ready-to-use glucagon has the potential to change the paradigm for treatment or prevention of hypoglycemic conditions and improve the lives of people who experience hypoglycemia.

Our Product Candidates

Glucagon Rescue Pen

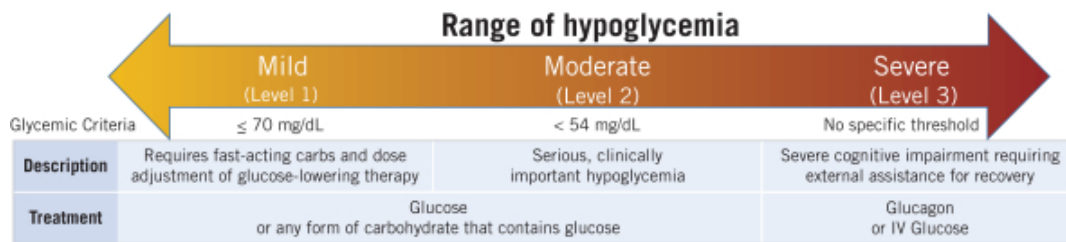
Our Glucagon Rescue Pen offers a ready-to-use, room-temperature stable glucagon that is designed to be administered subcutaneously in a simple two-step process. In our human factors study, 99% of users were able to successfully administer the full dose with our Glucagon Rescue Pen. Conversely, in published human factors studies of currently marketed glucagon kits, only 6% to 31% of users were able to successfully administer the full dose. If approved, we believe we can establish our Glucagon Rescue Pen as the preferred emergency glucagon product and drive greater adoption and penetration of emergency glucagon therapy for patients and caregivers. We have completed three Phase 3 clinical trials for our Glucagon Rescue Pen and expect to submit a NDA to the FDA in the third quarter of 2018. In December 2012, we filed an Investigational New Drug, or IND, application for our Glucagon Rescue Pen for severe hypoglycemia. We are the sponsor of this IND, which is active as of the date of this prospectus.

We intend to develop a clinical development program in the EU for our Glucagon Rescue Pen. We are currently engaging with the EMA to determine the regulatory path for our Glucagon Rescue Pen in the EU for the treatment of severe hypoglycemia. Depending on the guidance we receive, we plan to submit a clinical trial application to the EMA. We have no current plans to submit our Glucagon Rescue Pen for regulatory approval in Canada, but we have submitted a clinical trial application to Health Canada to support the inclusion of Canadian clinical research sites in XSGP-301 and XSGP-303 Phase 3 clinical trials.

Hypoglycemia Background

Diabetes is a widespread condition that affects an estimated 425 million people worldwide. There are an estimated 20.2 million drug-treated people in the United States. Among people with diabetes in the United States, all of the approximately 1.3 million people with T1D and 4.3 million people with T2D require insulin therapy to lower their blood glucose levels to achieve normal blood sugar levels and avoid hyperglycemia. Conversely, insulin treatment in people with diabetes can also lead to hypoglycemia, a deficiency of glucose in the bloodstream, which is more common in people with diabetes who are treated with insulin or substances that promote production of insulin. In 2014, the U.S. Department of Health and Human Services National Action Plan for Adverse Drug Event Prevention highlighted diabetes agent-associated hypoglycemia as one of its three primary concerns because of the severity and increasing prevalence of the problem. In 2017, the American Diabetes Association, or ADA, stated that hypoglycemia remains the major limiting factor in the glycemic management of T1D and T2D.

Hypoglycemia is categorized by level of severity, expressed as mild, moderate or severe hypoglycemic events. Definitions, symptoms and treatment recommendations for hypoglycemia per the ADA and the American Association of Clinical Endocrinologists, or AACE, are summarized in the figure below:



Hypoglycemic events of any severity are a daily concern for people with diabetes. Severe hypoglycemic events are extremely frightening for patients and caregivers and can result in cardiovascular disease seizure, coma, and, if left

untreated, death. Fear of hypoglycemia and the morbidity and mortality risks associated with it is a constant reality for people with diabetes. According to scientific literature, fear of hypoglycemia is a critical impediment to psychological well-being and quality of life and represents the greatest barrier to optimal glycemic control. Studies have shown that only 14% of those aged 18–25 years and 29% of those aged 26–50 years achieved optimal glycemic control by taking insulin.

The ADA recommends that glucagon be prescribed for all individuals at increased risk of clinically significant hypoglycemia, defined as blood glucose <54 mg/dL, for use in the event of an emergency. Glucagon works to raise the glucose levels in a person's blood by inducing the liver to convert glycogen, a type of stored sugar in the body, into glucose.

While patients can take preventive measures, hypoglycemic events still occur. On average, people with T1D experience an episode of mild or moderate hypoglycemia twice per week and 30% to 40% of people with T1D experience one to two episodes of severe hypoglycemia per year. On average, half of people with T2D treated with insulin experience an episode of mild or moderate hypoglycemia twice per month. People with T2D treated with insulin are also at risk of severe hypoglycemia, and approximately 21% of these individuals experience an episode of severe hypoglycemia at least once annually.

Limitations of Existing Products

Because of the urgent nature of severe hypoglycemia, the majority of severe hypoglycemic events are treated on an emergency basis, outside of a healthcare facility. Two emergency glucagon products are currently available to treat severe hypoglycemia: Eli Lilly's Glucagon Emergency Kit, or GEK, which represents approximately 78% of U.S. sales, and Novo Nordisk's GlucaGen, which represents approximately 22% of U.S. sales. Each product is sold as a vial of lyophilized, glucagon powder with an exposed needle/syringe that contains a liquid diluent. The glucagon powder must be combined with the liquid diluent at the time of use and drawn into a syringe in accordance with a complex multi-step reconstitution and dose calibration procedure. Long-term storage of the combined solution is impractical because once the lyophilized glucagon is combined with water, the solution becomes unstable and can fibrillate, rendering it inactive and potentially toxic.

The multi-step reconstitution and dose calibration procedure required for current glucagon kits outlined below can be intimidating, particularly in an emergency situation, for likely glucagon kit users, a group that includes caregivers, co-workers, friends, teachers or other bystanders.

Step-by-Step Instructions for GEK

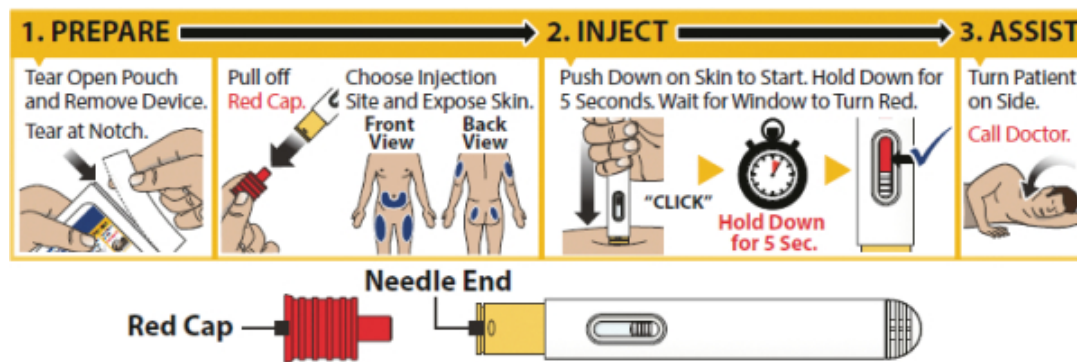
1. Flip off the seal from the vial of Glucagon powder.
 2. Remove the needle cover from the syringe. **DO NOT REMOVE THE PLASTIC CLIP FROM THE SYRINGE**, as this may allow the push rod to come out of the syringe.
 3. Insert the needle into the rubber stopper on the vial, then inject the entire contents of the syringe into the vial of Glucagon powder.
 4. Remove the syringe from the vial, then swirl the vial until the liquid becomes clear. Glucagon should not be used unless the solution is clear and of a water-like consistency.
 5. Insert the same syringe into the vial and slowly withdraw all the liquid. To use on children weighing less than 44 pounds, withdraw half of the liquid (0.5 mark on the syringe).
 6. Cleanse site on buttock, arm or thigh and inject Glucagon immediately after mixing, and then withdraw the needle. Apply light pressure against the injection site.
 7. Turn the person on his/her side. When an unconscious person awakens, he/she may vomit. **Call 911 immediately after administering Glucagon. If the person does not awaken within 15 minutes, you may administer a second dose of Glucagon, if previously instructed to do so by a healthcare professional.**
 8. As soon as the person is awake and able to swallow, give him/her a fast-acting source of sugar (such as fruit juice), followed by a snack or meal containing both protein and carbohydrates (such as cheese and crackers, or a peanut butter sandwich).
 9. Discard any unused reconstituted Glucagon. Remember to notify your healthcare professional that an episode of severe hypoglycemia has occurred. These are not the complete instructions. Go to "Information for the User" for complete instructions on how to administer Glucagon.
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In 2018, we conducted a quantitative study with 700 caregivers and people with diabetes evaluating the market perceptions of current glucagon kits, which we refer to as our Caregiver and Patient Perceptions Study. In that study, only one third of respondents had a highly favorable opinion of the current kits and only half were confident that a glucagon kit user would be able to correctly administer the current emergency glucagon products. Furthermore, in three published comparative human factors studies with currently marketed kits, only 6% to 31% of users were able to successfully administer the full dose of glucagon. Accordingly, a diabetes patient experiencing a severe hypoglycemic episode who relies on a bystander to administer glucagon may not receive the full dose of glucagon needed to restore their blood glucose levels. Failure to promptly treat severe hypoglycemia leaves the person at critical risk of irreversible brain damage and heart problems, especially in people who already have coronary artery disease. If emergency medical treatment is not successful, the severe hypoglycemic event can be fatal.

Xeris Glucagon Rescue Pen Key Features and Benefits

Leveraging our patented XeriSol technology, we believe our Glucagon Rescue Pen offers an important advancement in the treatment of severe hypoglycemia. We are developing the Glucagon Rescue Pen as a ready-to-use, room-temperature stable liquid glucagon delivered via auto-injector available in 1 mg and 0.5 mg pre-measured doses for adult and pediatric use, respectively. We have designed the Glucagon Rescue Pen to be easy to administer, as depicted in the figure below.



The key features of our Glucagon Rescue Pen are:



- **Ready-to-use:** With its easy two-step administration process, the user simply pulls off the red cap and pushes the Glucagon Rescue Pen down on the skin for five seconds, until the window turns red. There is no reconstitution required at the time of emergency.
- **Easy-to-use:** In our human factors study, 99% of users were able to successfully administer the full dose with our Glucagon Rescue Pen.
- **No dose calibration required:** The Glucagon Rescue Pen will be offered in two pre-measured doses, 0.5 mg for pediatric administration and 1 mg for adolescents and adults.
- **No visible needle:** The needle in the Glucagon Rescue Pen is not visible to the user.
- **Auto-retraction:** The needle auto-retracts after administration for safety.
- **Auto-locks:** The device auto-locks after use for safety.
- **Two-year room-temperature stability:** No refrigeration is required at any time.



We also intend to offer our Glucagon Rescue Pen in a pre-filled syringe presentation that may be preferred by some healthcare professionals.



In contrast to currently marketed emergency glucagon kits, our Glucagon Rescue Pen features the following benefits:

	GEK 	Xeris Glucagon Rescue Pen 
No Reconstitution in Emergency	X	✓
Auto-Injection	X	✓
Needle Auto-Retraction and Needle Guard	X	✓
Dose Volume Pre-measured for Pediatrics	X	✓
Room-Temperature Stable as a Liquid	X	✓
Rate of Successful Full Dose Delivery in Human Factors Studies	6 – 31%	99%
Route of Administration	SC or IM	SC

In our Caregiver and Patient Perceptions Study, more than 75% responded that they would prefer our Glucagon Rescue Pen over currently available glucagon kits. In 2018, we conducted a quantitative study of over 400 healthcare professionals, which we refer to as our Healthcare Professional Perceptions Study. In that study, results indicated that glucagon would be prescribed to more people across all clinically appropriate patient segments if our Glucagon Rescue Pen were available. Based on this market research, we believe that the glucagon market will become more penetrated and that our Glucagon Rescue Pen will become the preferred emergency glucagon delivery solution.

Xeris Glucagon Rescue Pen Market Potential

Based on current market data as well as our Caregiver and Patient and Healthcare Professional Perceptions Studies, we believe that our Glucagon Rescue Pen, if approved, has the opportunity to increase penetration of the glucagon market in severe hypoglycemia by increasing the number of diabetes patients who have a filled glucagon prescription and by increasing the number of glucagon products they have on hand.

There are approximately 20.2 million drug-treated people with diabetes in the United States, and the compound annual growth rate in incidence of diagnosed and treated people with diabetes is approximately 4% per year. An additional 84 million people in the United States are pre-diabetic and may progress to T2D. The ADA recommends that glucagon be prescribed for all individuals at increased risk of clinically significant hypoglycemia for use in the event of an emergency. Based on our Healthcare Professional Perceptions Study, we believe almost all people with T1D and approximately 50% of people with T2D on insulin are considered clinically appropriate for glucagon. In the United States, there is an estimated 1.3 million people with T1D who are treated with insulin because their bodies do not naturally produce insulin and approximately 4.3 million additional people with T2D who are treated with insulin because their bodies do not use insulin properly. In the aggregate, we estimate that the potential target population for emergency glucagon therapy totals approximately 3.5 million people in the United States. We intend

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to sell our Glucagon Rescue Pen in a package of two, based on responses from our market research indicating that potential buyers would purchase, on average, two pens per person. We believe by increasing penetration into the market for emergency glucagon kits and based on the current price of approximately \$280 per unit for currently marketed kits, the U.S. market potential may total up to \$2.0 billion.

Despite the risk of experiencing a severe hypoglycemic event, we believe that emergency glucagon therapy is underappreciated, under-evaluated and under-taught, resulting in a market that is under-penetrated. According to a 2015 study published in the journal *Endocrine Practice*, approximately 50% of people with T1D and approximately 3% of people with T2D with a new insulin prescription had a filled glucagon prescription. We believe that the drawbacks of currently marketed products and the lack of conversations regarding glucagon limit their adoption. Two of the top reasons given by people with diabetes for nonrenewal of glucagon prescriptions were that they were not confident that a caregiver or other person would be able to correctly administer the currently available kit, and their healthcare professional did not discuss the need for a new one with them. In the United States, approximately 660,000 total prescriptions for emergency glucagon kits were written in 2017 in the United States, resulting in the purchase of approximately 960,000 single-dose kits. In 2017, U.S. sales for emergency glucagon kit totaled approximately \$240 million.

In our Healthcare Professional Perceptions Study, results indicated that glucagon would be prescribed to more people across all clinically appropriate patient segments if our Glucagon Rescue Pen was available. Similarly, in our Caregiver and Patient Perceptions Study, almost two-thirds of people with T1D and T2D who use insulin said they would proactively ask for a prescription for our Glucagon Rescue Pen if available. Importantly, over half of those same people do not currently have a filled glucagon prescription. During an emergency hypoglycemic event, these individuals would often be required to seek treatment through ambulance calls, hospital admissions or office visits. We believe that these studies show that more people would want to have emergency glucagon on-hand if there was a product that better met their needs. We believe this represents an opportunity for our Glucagon Rescue Pen, if approved, to shift the site of care from the emergency room or hospital to less costly settings such as the home.

We believe that a relevant market analogue for our Glucagon Rescue Pen is the epinephrine auto-injector, including EpiPen, for life-threatening allergic reactions. The table below provides a comparison of the severe allergy and hypoglycemia markets.

	SEVERE ALLERGIC REACTION (EPINEPHRINE)	SEVERE HYPOGLYCEMIA (GLUCAGON)
Clinically Appropriate Patient Population in the United States	5.2 million patients	3.5 million patients
No. of Units Sold in the United States (2017)	~8.2 million auto-injectors	~960,000 kits*

* Single-dose units of Eli Lilly's Glucagon Emergency Kits and Novo Nordisk's GlucaGen

We believe this comparison of the allergy and hypoglycemia markets supports the potential of our Glucagon Rescue Pen, if approved, to increase both the number of clinically appropriate people who have glucagon, as well as the number of glucagon products they have on hand.

Outside the United States, we estimate that an additional 3.5 million people with diabetes in Europe and an additional 12.5 million people with diabetes in Japan and China are clinically appropriate for glucagon treatment. However, only approximately 733,000 emergency glucagon products were sold in the United Kingdom, Germany, France, Italy and Spain combined, and only approximately 414,000 were sold in Japan and China combined, which we believe indicates that the market for emergency glucagon products is significantly under-penetrated in those regions.

Commercial Strategy

If approved, we will seek to replace currently marketed emergency glucagon kits with our Glucagon Rescue Pen, increase the number of at-risk people who carry emergency glucagon and promote access to emergency glucagon products. While our sales force and medical teams expect to focus on driving awareness and adoption of our

Glucagon Rescue Pen by healthcare professionals, we believe accelerated growth and expanded uptake will come from targeted direct-to-patient messaging that, because the majority of people with diabetes are concentrated in ten states, will allow us to efficiently and effectively reach our target audience.

Our plan to execute on our go-to-market strategy for our Glucagon Rescue Pen includes the following:

- **Create awareness and anticipation prior to launch.** Following submission of our NDA, we plan to use the FDA's NDA review period to both better understand the market and create excitement and anticipation for our company and our technology. We expect to hire ten regional medical affairs directors prior to commercial launch to establish additional relationships with key opinion leaders and gain insight into current practice patterns and burdens. We also plan to begin to raise awareness in the market on the incidence, prevalence and impact of severe hypoglycemic events.
- **Drive awareness and adoption of our Glucagon Rescue Pen.** If approved by the FDA, we plan to drive awareness and adoption of our Glucagon Rescue Pen to replace current emergency glucagon kits in the market.
 - **Healthcare Professionals:** At launch, our targets will consist of high glucagon prescribing healthcare professionals. Approximately 3,000 healthcare professionals issue 50% of current glucagon prescriptions. We plan to hire 60 sales representatives initially to reach these professionals.
 - **Patients and Caregivers:** We intend to activate patient advocacy organizations and leverage channels such as direct-to-consumer tactics, social media, digital presence, traditional offline channels and press coverage to drive awareness and communicate our value proposition to patients and caregivers. Epidemiology and census data indicate that ten states account for almost 60% of people with diabetes, allowing us to be efficient and effective with our promotional activities.
- **Penetrate the market.** We believe that the glucagon rescue market is currently significantly underpenetrated due to the lack of, and limitations in, current treatment options. We are designing our Glucagon Rescue Pen to offer healthcare professionals, patients and caregivers a ready-to-use alternative that facilitates administration of the full dose of glucagon every time it is used. We believe this offering, paired with our commercial focus, has the potential to grow the market in two ways:
 - **Healthcare Professionals:** In addition to the 3,000 healthcare professionals who issue about half of the current glucagon prescriptions, we will target approximately 5,000 healthcare professionals who are high meal time insulin prescribers, but who are under-indexed in prescribing glucagon. We intend to reach these professionals using our initial sales representatives.
 - **Patients and Caregivers:** We believe there is an opportunity to activate patient and caregiver demand for our Glucagon Rescue Pen. Our Glucagon Rescue Pen is designed as an easy-to-use solution for a segment of patients and caregivers who currently lack the confidence in administering current emergency glucagon kits and would rather rely on emergency responders for treatment.
- **Promote access:** Current emergency glucagon kits have favorable market access, and current trends indicate a relatively low level of management of these products by payors. For example, Eli Lilly's GEK is covered at or above 94% with unrestricted access across commercial, Medicare, Managed Medicaid and State Medicaid plans. A Diabetes Health Coverage: State Laws and Programs report reviewing state insurance mandated coverage, Medicaid coverage and state-sponsored diabetes programs showed that 46 states and the District of Columbia have a diabetes statutory mandate for coverage, whether as medication or supply. Of our target patient population, approximately 50% are commercially-insured, one-third are covered by Medicare and approximately 15% are covered by Medicaid. To promote access to our Glucagon Rescue Pen, we plan to engage with payors to more fully understand their drivers and barriers and convey the health and pharmacoeconomic value of our Glucagon Rescue Pen.

We plan to establish a distribution channel in the United States for the commercialization of our Glucagon Rescue Pen. We expect to sell our Glucagon Rescue Pens to wholesale pharmaceutical distributors, who, in turn, will sell our Glucagon Rescue Pens to pharmacies and other customers. We expect to use a third-party logistics provider for key services related to logistics, warehousing and inventory management, distribution, contract administration, order management and chargeback processing and accounts receivable management. Outside of the United States, we plan to collaborate with local companies.

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Clinical Experience

We have completed three Phase 3 clinical trials for our Glucagon Rescue Pen. In addition, we have evaluated our Glucagon Rescue Pen in six preclinical studies, one Phase 1 pharmacokinetic, or PK, clinical trial and two Phase 2 clinical trials. We are currently conducting one supplementary Phase 1 clinical trial from which we expect to obtain results in the second quarter of 2018. We expect EMA guidance on the regulatory pathway in Europe in the second quarter of 2018. Depending on EMA feedback, we plan to initiate a Phase 3 study, with topline results expected in the second half of 2018. The following table summarizes the completed and ongoing clinical trials for our Glucagon Rescue Pen.

PROTOCOL NO./TITLE	PHASE OF DEVELOPMENT	DESIGN/OBJECTIVES	STUDY POPULATION AND DEMOGRAPHICS	DOSE (NO. EXPOSED EACH TREATMENT) AND DOSAGE FORM/ PRODUCT CONFIGURATION
Completed XSGP-302 A Phase 3 Study to Evaluate the Glucose Response of Glucagon Rescue Pen (Glucagon Injection) In Pediatric Patients With Type 1 Diabetes	Phase 3a	Non-randomized, open-label, single dose/efficacy, PD, PK, safety and tolerability	Children (2<6, 6<12 and 12<18 years) with T1D n=31	Ages 2<6 years (n=7), single dose of 0.5mg Glucagon Rescue Pen; ages 6<12 years (n=13), single dose of 0.5mg Glucagon Rescue Pen; ages 12<18 years (n=11), single dose of 1mg Glucagon Rescue Pen followed by single dose of 0.5mg Glucagon Rescue Pen 7 to 28 days later/ Rescue Pen
XSGP-301 Glucagon Rescue Pen (Glucagon Injection) Compared To Eli Lilly Glucagon (Glucagon For Injection [rDNA Origin]) For Induced Hypoglycemia Rescue In Adult Patients With T1D: A Phase 3, Randomized, Blinded, 2-Way Crossover Study To Evaluate Efficacy and Safety	Phase 3a	Double-blind, randomized, two-way crossover/efficacy (return to plasma glucose >70.0 mg/dL) of Glucagon Rescue Pen 1 mg to be non-inferior to Eli Lilly's glucagon; compare the PD characteristics of Glucagon Rescue Pen versus Eli Lilly's glucagon; safety and tolerability; PK.	Adult patients with T1D n=80	Glucagon Rescue Pen 1mg (n=78), Eli Lilly's glucagon 1mg (n=79)/Rescue Pen

<u>PROTOCOL NO./TITLE</u>	<u>PHASE OF DEVELOPMENT</u>	<u>DESIGN/OBJECTIVES</u>	<u>STUDY POPULATION AND DEMOGRAPHICS</u>	<u>DOSE (NO. EXPOSED EACH TREATMENT) AND DOSAGE FORM/ PRODUCT CONFIGURATION</u>
XSGP-303 Glucagon Rescue Pen (Glucagon Injection) Compared To Eli Lilly Glucagon (Glucagon For Injection [rDNA Origin]) For Induced Hypoglycemia Rescue In Adults With T1D: A Phase 3B Multi-Centered, Randomized, Controlled, Single-Blind, 2-Way Crossover Study To Evaluate Efficacy And Safety	Phase 3b	Non-inferiority, multi-centered, randomized controlled, single-blind, two-period, two-way crossover efficacy and safety	Adults with T1D n=81	Glucagon Rescue Pen 1 mg, Eli Lilly's glucagon 1 mg/ Rescue Pen
XSGP-202 Glucagon Rescue Pen (Glucagon Injection) For Induced Hypoglycemia Rescue In Adult Patients With T1D: A Phase 2A Pilot Study To Evaluate Protocol Design Issues For An Upcoming Phase 3 Clinical Study	Phase 2	Open-label 2-way crossover Explore safety efficacy in treatment of insulin-induced hypoglycemia	T1D adult male/female patients 18–65 years of age n=7	Glucagon Rescue Pen 0.5 mg (n=6) and 1 mg (n=7), subcutaneous injections given one week apart/Pre-Filled Syringe
XSGP-201 A Randomized, Phase 2, Double-Blind, 3-Way Crossover Study With Glucagon Rescue Pen (Glucagon For Injection) To Evaluate Safety, Tolerability and Comparative Pharmacokinetics and Pharmacodynamics To Eli Lilly Glucagon (Glucagon For Injection [rDNA Origin]) In Healthy Volunteers	Phase 2	Double-blind, Randomized, 3-way crossover/Safety, tolerability, PK and efficacy vs. marketed comparator	Healthy male/female volunteers 18–60 years of age n=28	Subcutaneous injection of: Glucagon Rescue Pen 0.5 (n=29) and 1 mg (n=28); and Eli Lilly's glucagon (rDNA origin) 1 mg/ Pre-Filled Syringe
Ongoing				
XSGP-101 A Two-Way Crossover Comparative PD/PK Study Of Glucagon Rescue Pen (Glucagon Injection) Administered By Auto-Injector And Pre-Filled Syringe	Phase 1	Two-way crossover comparative bioequivalence, safety, tolerability and PD/PK of Glucagon Rescue Pen administered via auto-injector vs. pre-filled syringe	Healthy male/female volunteers 18-64 years of age n=32	Glucagon Rescue Pen 1 mg/Pre-Filled Syringe

Completed Phase 3 Clinical Trials

XSGP-302: A Phase 3 Study to Evaluate the Glucose Response of Glucagon Rescue Pen (Glucagon Injection) In Pediatric Patients With Type 1 Diabetes

In 2017, we conducted a sequential non-randomized, open-label, single dose efficacy and safety Phase 3 clinical trial in pediatric subjects with T1D. This clinical trial included a total of 31 subjects (seven subjects 2 to <6 years, 13 subjects 6 to <12 years and eleven subjects 12 to <18 years). In this clinical trial, we induced hypoglycemia, defined as plasma glucose <80 mg/dL, with administration of insulin and then treated subjects with our Glucagon Rescue Pen. The primary endpoint of this clinical trial was to assess the increase in plasma glucose of subjects from baseline to 30 minutes after injection of an age-appropriate dose of our Glucagon Rescue Pen, defined as 0.5 mg dose for subjects 2 to <12 years and in separate visits both a 0.5 mg and 1.0 mg dose for subjects 12 to <18 years.

All three age groups met the primary endpoint of non-zero glucose response at 30 minutes post-administration of our Glucagon Rescue Pen. All evaluable subjects achieved a target glucose increase of at least 25 mg/dL. Following administration, plasma glucose levels over time showed similar glucose responses for subjects in each age group and in each dose in the 12 to <18 years age group. Further, in each age group the observed effect was statistically significant with increases from baseline in mean plasma glucose at 30 minutes following administration of an age-appropriate dose of our Glucagon Rescue Pen. Administration of 0.5 mg of our Glucagon Rescue Pen in the 12 to <18 years age resulted in a glucose response that was similar to the age-appropriate dose of 1 mg of our Glucagon Rescue Pen.

Overall, our Glucagon Rescue Pen was observed to be well-tolerated. All auto-injectors, or AIs, delivered a full dose. There were no discontinuations due to adverse events, or AEs, no severe AEs, no device-related AEs and no serious adverse events, or SAEs. The majority of treatment-emergent AEs observed were gastrointestinal disorders.

The following table summarizes additional trial design parameters and clinical results that we observed from XSGP-302:

GLUCAGON DOSE	0.5 MG DOSE			1 MG DOSE
	2 TO < 6 YEARS	6 TO < 12 YEARS	12 TO < 18 YEARS	12 TO < 18 YEARS
SUBJECT AGES				
n	7	13	11	11
% with >25 mg/dL rise in glucose within 30 minutes	100	100	100	100
Glucose C _{max} (mg/dL)	207.8 (35.9)	206.9 (49.6)	212.1 (40.6)	198.9 (60.0)
Mean (SD)				
Glucose T _{max} (minutes)	67.7 (11.1)	66.4 (15.7)	78.2 (11.5)	81.8 (15.6)
Mean (SD)				
% with nausea	42.9	53.8	36.4	36.4
% with emesis	14.3	23.1	0	18.2

XSGP-301: Glucagon Rescue Pen (Glucagon Injection) Compared To Eli Lilly Glucagon (Glucagon For Injection [rDNA Origin]) For Induced Hypoglycemia Rescue In Adult Patients With T1D: A Phase 3, Randomized, Blinded, 2-Way Crossover Study To Evaluate Efficacy and Safety

In 2017, we completed a non-inferiority, prospective, randomized, controlled, double-blinded, two-period, two-way crossover, comparative efficacy and safety Phase 3 pivotal clinical trial in male and female patients aged 18 to 75 years with T1D in an inpatient setting. The trial was conducted across seven locations in the United States and enrolled 80 subjects. The objectives of this clinical trial were to compare the safety, tolerability and efficacy of our Glucagon Rescue Pen and Eli Lilly's glucagon, as determined by an increase in plasma glucose concentration from below 50 mg/dL to greater than 70 mg/dL within 30 minutes after receiving glucagon. We also evaluated an additional primary endpoint of plasma glucose > 70 mg/dL or increase by >20 mg/dL within 30 minutes. This additional primary endpoint was defined and pre-specified for analysis prior to unblinding the study. Additional endpoints of interest included plasma glucose of >70 mg/dL or resolution of all induced neuroglycopenic symptoms

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within 30 minutes of glucagon, relief of hypoglycemia symptoms, global feeling of hypoglycemia and glucose elevation 0-90 minutes post-injection.

In this clinical trial, we induced severe hypoglycemia by an IV infusion of regular insulin followed by initial and subsequent bolus doses if plasma glucose after 30 minutes was > 60 mg/dL. Subjects were also administered an IV infusion of regular insulin based on a subject's historical use of basal insulin. The investigator adjusted the IV insulin infusion rate if the rate of glucose change after 30 minutes was < 1 mg/dL/minute. Investigators were instructed to avoid any bolus doses or basal infusion rate increases within 20 minutes of blinded study drug administration. Once the initial plasma glucose measurement < 50 mg/dL was achieved, the IV insulin infusion was stopped. Once the confirmatory plasma glucose reading < 50 mg/dL was achieved, subjects were administered blinded study drug via the subcutaneous route in the upper arm, leg or abdomen.

Subjects were randomized to receive glucagon in one of two sequence groups: our Glucagon Rescue Pen followed by Eli Lilly's glucagon, or Eli Lilly's glucagon followed by our Glucagon Rescue Pen. Following glucagon dosing, plasma glucose was monitored every five minutes until 90 minutes post-dosing. Additional blood samples were collected at regular intervals. Subjects also completed a questionnaire regarding hypoglycemia symptoms at the start of the hypoglycemia induction period and periodically until 45 minutes post-treatment with glucagon. Tolerability was assessed by comparing adverse event reports between the groups. In addition, subjects completed questionnaires concerning injection site discomfort. After a wash-out period of seven to 28 days, subjects returned to the clinic and the study procedures were repeated with each subject crossing over to the other treatment group.

Analyses of the primary endpoints were performed according to pre-specified intent-to-treat, or ITT, modified intent-to-treat, or mITT, and per-protocol methods. The ITT cohort was defined as all subjects randomized to one of the two sequence groups. The mITT cohort was defined as the ITT cohort minus one subject that mistakenly received two doses of Eli Lilly's glucagon. The per-protocol cohort was defined as the mITT cohort minus any subjects adjudicated for at least one major protocol violation. Criteria for major protocol violations were defined and pre-specified prior to unblinding of the trial. Following adjudication of major protocol violations, two subjects, one in each study arm, who received a clinically significant (20%) increase in basal IV insulin rate during the final 20 minutes of the induction procedure were censored to establish the per-protocol cohort.

For the ITT and mITT analysis, three or fewer response failures were defined as the pre-specified threshold demonstrating non-inferiority of our Glucagon Rescue Pen. For the primary endpoint of glucose increase >70 mg/dL within 30 minutes, the total difference in response failures was four, representing one more than the pre-specified threshold of three response failures. For the additional primary endpoint of plasma glucose >70 mg/dL or increase by >20 mg/dL within 30 minutes, the total difference in response failures was two and, therefore, ITT analysis of this additional primary endpoint demonstrated that our Glucagon Rescue Pen was non-inferior to Eli Lilly's glucagon. The per-protocol analysis of both primary endpoints met the pre-specified threshold. Certain of our analyses may be viewed as post-hoc analyses, and although post-hoc analyses can result in the introduction of bias and may be given less weight by the FDA, we believe that this retrospective analysis can provide additional information regarding results from this trial.

We believe the clinical trial results support the potential of our Glucagon Rescue Pen to reverse severe hypoglycemia in a reliable manner. In accordance with FDA and International Council for Harmonisation guidance for evaluation of non-inferiority studies, we presented a series of analyses implementing ITT, mITT and per-protocol cohorts for this clinical trial to the FDA at a pre-NDA meeting held in December 2017. In that meeting, the FDA agreed overall that the totality of data for our Glucagon Rescue Pen is sufficient to support NDA review.

Additionally, a single dose of our Glucagon Rescue Pen increased plasma glucose and improved clinical symptoms such as cognitive impairment and other neuroglycopenic/neurogenic symptoms that are associated with severe hypoglycemia in 100% of subjects. We also observed comparable increases in plasma glucose concentration from below 50 mg/dL to greater than 70 mg/dL within 30 minutes after receiving our Glucagon Rescue Pen and comparable resolution of clinical symptoms to Eli Lilly's glucagon, such as cognitive impairment and other neuroglycopenic/neurogenic symptoms that are associated with severe hypoglycemia, as well as comparable pharmacodynamics.

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The following table summarizes the efficacy outcomes for XSGP-301.

CLINICAL COMPARISON	mITT RESPONSE RATE	
	GLUCAGON RESCUE PEN	ELI LILLY GLUCAGON
Subjects successfully rescued from induced hypoglycemia without other rescue therapy (e.g., intravenous dextrose)	100% (78/78)	100% (79/79)
Plasma glucose >70 mg/dL within 30 minutes of glucagon (primary endpoint)	Intent-to-treat† 94.9% (74/78) Per-protocol 96.1% (74/77)	Intent-to-treat 100% (79/79) Per-protocol 100% (78/78)
Plasma glucose of >70 mg/dL or > 20 mg/dL increase within 30 minutes of glucagon (additional primary endpoint)	Intent-to-treat 97.4% (76/78) Per-protocol 97.4% (75/77)	Intent-to-treat 100% (79/79) Per-protocol 100% (78/78)
Plasma glucose of >70 mg/dL or resolution of all induced neuroglycopenic symptoms within 30 minutes of glucagon	100% (78/78)	100% (79/79)
Resolution of hypoglycemia symptoms	100% (78/78)	100% (79/79)
Global feeling of hypoglycemia improvement pre/post injection	100% (78/78)	100% (79/79)
Sustained glucose elevation from 0-90 minutes post-injection	100% (78/78)	100% (79/79)

† one (1) additional endpoint failure exceeded the non-inferiority threshold of N=3; all other comparisons demonstrate non-inferiority vs. Eli Lilly's glucagon.

Overall, all treatment regimens were well-tolerated. One SAE of hypoglycemia was reported for a participant treated with Eli Lilly's glucagon. The SAE was determined by the study investigator not to be related to the study drug and resolved during the trial. The incidence of AEs was low in both groups, and the most commonly reported AE was nausea: 20.5% for our Glucagon Rescue Pen and 12.7% for Eli Lilly's glucagon (p=not significant), followed by vomiting and headache. AEs were generally mild or moderate in severity, transient and resolved with no treatment.

XSGP-303: Glucagon Rescue Pen (Glucagon Injection) Compared to Eli Lilly Glucagon (Glucagon For Injection [rdDNA Origin]) For Induced Hypoglycemia Rescue in Adult Patients With T1D: A Phase 3b Multi-Centered, Randomized, Controlled, Single Blind, 2-Way Crossover Study To Evaluate Efficacy and Safety.

In the second quarter of 2018, we completed a non-inferiority, prospective, randomized, controlled, single-blinded, two-period, two-way crossover, comparative efficacy and safety Phase 3b clinical trial in male and female patients aged 18 to 75 years with T1D in an inpatient setting. The trial was conducted across six locations in the United States and Canada and enrolled 81 subjects. The objectives of this clinical trial were to compare the safety, tolerability and efficacy of our Glucagon Rescue Pen and Eli Lilly's glucagon, as determined by an increase in plasma glucose concentration from below 50 mg/dL to greater than 70 mg/dL within 30 minutes after receiving glucagon. We also evaluated an additional primary endpoint of plasma glucose > 70 mg/dL or increase by ³ 20 mg/dL within 30 minutes. Additional endpoints of interest also included plasma glucose of >70 mg/dL or resolution of all induced neuroglycopenic symptoms within 30 minutes of glucagon, relief of hypoglycemia symptoms, global feeling of hypoglycemia and total elapsed time required from decision to dose and actual time of injection (e.g. preparation time).

Consistent with our XSGP-301 trial, in XSGP-303 we induced severe hypoglycemia by an IV infusion of regular insulin followed by initial and subsequent bolus doses if plasma glucose after 30 minutes was > 60 mg/dL. The subjects' IV infusion of regular insulin was based upon their historical use of basal insulin. The investigator adjusted the IV insulin infusion rate if the rate of glucose change after 30 minutes was < 1 mg/dL/minute. Investigators were instructed to avoid any bolus doses when a subject's plasma glucose was < 60 mg/dL. Once the initial plasma glucose measurement < 50 mg/dL was achieved, the IV insulin infusion was stopped. Once the confirmatory plasma glucose reading < 50 mg/dL was achieved, subjects were administered blinded study drug via the subcutaneous route in the abdomen.

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Subjects were randomized to receive glucagon in one of two sequence groups: our Glucagon Rescue Pen followed by Eli Lilly's glucagon, or Eli Lilly's glucagon followed by our Glucagon Rescue Pen. Following glucagon dosing, plasma glucose was monitored every five minutes until 90 minutes post-dosing. Additional blood samples were collected at regular intervals. Subjects also completed a questionnaire regarding hypoglycemia symptoms at the start of the hypoglycemia induction period and periodically until 45 minutes post-treatment with glucagon. Tolerability was assessed by comparing adverse event reports between the groups. In addition, subjects completed questionnaires concerning injection site discomfort. After a wash-out period of seven to 28 days, subjects returned to the clinic and the study procedures were repeated with each subject crossing over to the other treatment group.

Analyses of the primary endpoints were performed according to pre-specified intent-to-treat, or ITT, and per-protocol methods. The ITT cohort was defined as all subjects randomized to one of the two sequence groups. The per-protocol cohort was defined as the ITT cohort minus any subjects adjudicated for at least one major protocol violation.

For the ITT analysis, three or fewer response failures were defined as the pre-specified threshold demonstrating non-inferiority of our Glucagon Rescue Pen. For the primary endpoint of glucose increase from below 50 mg/dL to >70 mg/dL within 30 minutes, all subjects who received a study drug experienced successful plasma glucose recovery. As there were no treatment failures observed, the ITT analysis of the primary endpoints demonstrated that our Glucagon Rescue Pen was non-inferior to Eli Lilly's glucagon.

Criteria for major protocol violations were defined and pre-specified prior to starting the trial. Following adjudication of major protocol violations, one subject in the Glucagon Rescue Pen arm was identified who was administered study drug despite not being within a steady state of hypoglycemia. In addition, subjects who did not receive a study drug were considered major protocol violations. These subjects were censored to establish the per-protocol cohort. Despite the major protocol violation in the subject who received Glucagon Rescue Pen, plasma glucose recovery was achieved within 30 minutes and the subject successfully meet the study primary endpoint.

We believe the results of XSGP-303 corroborate the outcomes observed in XSGP-301 and further support the potential of our Glucagon Rescue Pen to reverse severe hypoglycemia in a reliable manner. We intend to incorporate the result of this study into the NDA submission.

The following table summarizes the preliminary efficacy outcomes for XSGP-303.

Clinical Comparison	RESPONSE RATE	
	GLUCAGON RESCUE PEN	ELI LILLY GLUCAGON
Subjects successfully rescued from induced hypoglycemia without other rescue therapy (e.g., intravenous dextrose).	100% (76/76)	100% (78/78)
Plasma glucose from <50 mg/dl to >70 mg/dl in 30 minutes. (primary endpoint)	Intent-to-treat 100% (76/76)	Intent-to-treat 100% (78/78)
	Per-protocol 100% (75/75)	Per-protocol 100% (78/78)
Plasma glucose of >70 mg/dl or > 20 mg/dl increase within 30 minutes of glucagon. (additional primary endpoint)	Intent-to-treat 100% (76/76)	Intent-to-treat 100% (78/78)
	Per-protocol 100% (75/75)	Per-protocol 100% (78/78)

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Plasma glucose of >70 mg/dl or resolution of all induced neuroglycopenic symptoms within 30 minutes of glucagon.	100% (76/76)	100% (78/78)
Resolution of hypoglycemia symptoms.	100% (76/76)	100% (78/78)
Global feeling of hypoglycemia improvement pre/post injection.	100% (76/76)	100% (78/78)
Sustained glucose elevation from 0-90 minutes post-injection.	100% (76/76)	100% (78/78)

Overall, all treatment regimens were well-tolerated. There were no reported SAEs. The incidence of AEs was low in both groups and the most commonly reported AE was nausea, followed by vomiting and headache. AEs were generally mild or moderate in severity, transient and resolved with no treatment.

Ongoing Clinical Trials

XSGP-101: A Two-Way Crossover Comparative PD/PK Study Of Glucagon Rescue Pen (Glucagon Injection) Administered By Auto-Injector And Pre-Filled Syringe

At our pre-NDA meeting in December 2017, the FDA recommended to us that we address three areas of inquiry regarding our pre-filled syringe presentation of our Glucagon Rescue Pen: the characterization of PD/PK data to compare changes in serum plasma glucose levels and serum hormone levels when glucagon is administered by an auto-injector versus hand injection, a human factors validation study for this presentation and device reliability testing for this presentation. As a result of this meeting, with respect to the pre-filled syringe presentation of our Glucagon Rescue Pen, we initiated our XSGP-101 clinical trial in the first quarter of 2018, the results of which, combined with the human factors studies and device reliability testing, we intend to include in our Glucagon Rescue Pen NDA submission to the FDA.

XSGP-101 is a Phase 1 clinical trial two-way crossover comparative PD/PK study of our Glucagon Rescue Pen administered by auto-injector and pre-filled syringe, which we expect to complete in the second quarter of 2018. We expect to enroll approximately 32 healthy male and female volunteers between 18 and 64 years of age. The primary objective of this study is to demonstrate bioequivalence of our Glucagon Rescue Pen 1 mg when injected subcutaneously in the abdomen via auto-injector, versus a pre-filled syringe, in fasted healthy volunteers with low to normal blood glucose. Secondary objectives include safety and tolerability. As of the date of this prospectus, there have been no reported SAEs.

Other Completed Supporting Trials

Phase 2 Clinical Trials

XSGP-201: A Randomized, Phase 2, Double-Blind, 3-Way Crossover Study with Glucagon Rescue Pen (Glucagon For Injection) To Evaluate Safety, Tolerability and Comparative Pharmacokinetics and Pharmacodynamics To Eli Lilly Glucagon (Glucagon For Injection [rDNA Origin]) In Healthy Volunteers

In 2014, we completed a double-blind, randomized, three-way crossover Phase 2 clinical trial of our Glucagon Rescue Pen in 28 healthy male and female subjects 18 to 60 years of age to evaluate the safety, tolerability, PK and efficacy versus Eli Lilly's glucagon. Subjects were subcutaneously injected with our Glucagon Rescue Pen via a pre-filled syringe in doses of 0.5 and 1 mg and with Eli Lilly's glucagon for injection in a dose of 1 mg.

Plasma glucose concentration-time curves showed little separation between treatment groups, and there were no substantial differences between our Glucagon Rescue Pen 1 mg and Eli Lilly's glucagon for injection 1 mg in terms of glucose area under the curve, maximum concentration, or C_{max} , and time to reach maximum concentration, or T_{max} .

Results showed that all treatments were well-tolerated and demonstrated a comparable safety profile. No SAEs were observed, and all AEs were transient and consistent with rescue injections of glucagon.

XSGP-202: Glucagon Rescue Pen (Glucagon Injection) For Induced Hypoglycemia Rescue In Adult Patients With T1D: A Phase 2a Pilot Study To Evaluate Protocol Design Issues For An Upcoming Phase 3 Clinical Study

In 2015, we completed an open-label two-way crossover Phase 2 clinical trial to explore the safety and efficacy of our Glucagon Rescue Pen for the treatment of insulin-induced hypoglycemia in seven adult males and females with T1D 18 to 65 years of age. Subjects were given our Glucagon Rescue Pen injection via the pre-filled syringe 0.5 mg (n=6) and 1 mg (n=7), subcutaneous injections given one week apart.

All subjects in a state of insulin-induced hypoglycemia experienced objective and subjective response to rescue doses of our Glucagon Rescue Pen with return of glucose to > 70 mg/dL and resolution of all hypoglycemia symptoms within 30 minutes of injection.

Results showed AEs were generally mild and corresponded to known effects of rescue doses of glucagon. Vasovagal syncope, or fainting, was observed in one patient, which met the definition of an SAE as an important medical event but was attributed by the investigator to study procedures.

Preclinical Studies

Six preclinical studies, consisting of five studies in rats and one study in rabbits, demonstrated that our concentrated, non-aqueous solution of glucagon was safe in animal models. Studies included PK and PD studies, toxicity and potential impurities studies, toxicokinetic evaluations and local tolerance. We conducted these studies during 2010 to 2018. These studies administered glucagon to a total of 206 rats and 8 rabbits.

Human Factors Summative Validation Study

In 2017, we conducted a human factors summative validation study in users, which confirmed that our Glucagon Rescue Pen can be correctly, safely and effectively used. Of the 75 injections, 74 (99%) were successful. There was a single failure that occurred when an untrained subject prematurely lifted the pen from the injection site within approximately 1.5 seconds of activation, resulting in a partial dose. The subject admitted to not reading the label guide. No mitigation response was needed as the failure was attributed to the participant's noncompliance with reading the label guide while performing the procedure. After reviewing the label guide, the subject successfully administered the injection during an unaided second attempt. The study concluded that the Glucagon Rescue Pen dose label, packaging, device and injection procedure, label guide and instructions for use had been successfully validated.

Ready-to-Use Glucagon for Hypoglycemia Associated with Intermittent and Chronic Conditions

We are applying our ready-to-use liquid-stable glucagon formulation to treat five intermittent and chronic conditions with significant unmet medical need. In particular, our formulation may be applied to conditions requiring continuous doses or smaller or mini-doses of glucagon over a longer administration period. We intend to leverage work across our programs to substantially reduce development costs for each indication and enable expanded uses for intermittent and chronic applications of ready-to-use glucagon to follow our Glucagon Rescue Pen. Aspects include:

- Chemistry, manufacturing and controls, or CMC
- Non-clinical toxicology program
- Clinical supplies manufacturing

For intermittent and chronic conditions, we intend to leverage our preclinical studies across our glucagon portfolio, which consist of two toxicology studies in rats, one toxicology study in pigs, one tolerability study in rabbits, two PK studies in rats and one toxicology and PK study in rats. These preclinical studies supported further development of our ready-to-use glucagon in our target conditions and did not raise safety concerns in animal models. A number of additional toxicology studies are ongoing or planned to support long-term chronic use of ready-to-use glucagon in these additional hypoglycemic conditions. We conducted multiple studies starting in 2010 and these are ongoing. These studies administered glucagon to a total of 320 rats, 54 pigs and 8 rabbits.

For commercialization in our intermittent and chronic conditions, we expect to target endocrinologists, diabetologists and primary care providers that are currently prescribing glucagon and rapid acting insulin. Many of these physicians, particularly endocrinologists, are also currently treating PBH patients and we believe there is significant overlap between these physicians and those who would prescribe ready-to-use glucagon for HAAF and EIH. Furthermore, because there are few CHI patients and they are primarily treated at a handful of centers of excellence in the United States, we believe we can engage these clinicians with a small group of regional medical affairs directors.

In December 2013, we filed an IND application for the use of ready-to-use glucagon delivered via a wearable patch pump. This IND has supported our clinical development efforts in PBH, HAAF and feasibility assessment in a bi-hormonal artificial pancreas closed-loop system. We are the sponsor of this IND, which is active as of the date of this prospectus.

Ready-to-Use Glucagon for Post-Bariatric Hypoglycemia Syndrome

We are developing a ready-to-use glucagon formulation for chronic administration for PBH, a challenging complication of bariatric surgery that may significantly impair quality of life, but for which there are currently no approved treatments. In January 2018, we received orphan drug designation from the FDA for our ready-to-use glucagon for the treatment of patients with hyperinsulinemic hypoglycemia, of which PBH is a category. We plan to meet with the FDA in the first half of 2018 and complete a Phase 2b clinical trial for our ready-to-use glucagon for PBH by the end of 2018. We expect to initiate a pivotal clinical program in the first half of 2019.

Post-Bariatric Hypoglycemia Syndrome Market

Obesity and related comorbidities such as T2D and cardiovascular disease are increasingly recognized as a major threat to individual and public health, with sustained weight loss difficult to achieve. Clinicians and patients alike have embraced the results of recent controlled clinical trials demonstrating the efficacy of surgical procedures performed on the stomach or intestines, known as bariatric surgery, to not only induce sustained weight loss but also to improve or normalize obesity-related comorbidities, including T2D. The number of bariatric surgeries performed in the United States has increased from an estimated 158,000 procedures per year in 2011 to 216,000 in 2016, growing nearly 40% in just five years. While benefits of bariatric surgery are now achieved with a lower risk of surgical complications, longer-term intestinal and nutritional complications can still occur.

One challenging and sometimes severe complication of bariatric surgery is hyperinsulinemic hypoglycemia. Hyperinsulinemic hypoglycemia, and more specifically PBH, is most commonly associated with Roux-en-Y gastric bypass, or RYGB, a procedure in which the small intestine is re-routed to a small resected stomach pouch. However, PBH has also been observed following sleeve gastrectomy, a procedure that reduces the size of the stomach. PBH is defined as documented plasma glucose levels below 70 mg/dL in conjunction with hypoglycemic symptoms and the relief of such symptoms with the normalization of glucose levels. Symptoms include palpitations, lightheadedness and sweating. A subset of post-bariatric patients develops very severe hypoglycemia involving a shortage of glucose in the brain, known as neuroglycopenic symptoms, typically occurring one to three years following bariatric surgery, associated with confusion, decreased attentiveness, seizure and loss of consciousness. For these patients, quality of life can be severely affected as many cannot care for themselves or even be left alone and may ultimately lose their employment due to this disability.

Hypoglycemia typically occurs after meals, particularly those rich in simple carbohydrates. Due to the change in gastric anatomy resulting from bariatric surgery, plasma insulin concentrations are inappropriately high at the time of hypoglycemia in these patients. Treatment of hypoglycemia requires rapid-acting carbohydrates such as glucose tablets, which in PBH patients can contribute to rebound hyperglycemia that triggers further insulin secretion and recurrent hypoglycemia.

There are currently no approved treatments for PBH. Current strategies to manage PBH include dietary modification aimed at reducing intake of high glycemic index carbohydrates. Both diet and off-label administration of pre-meal acarbose, an anti-diabetic drug used to treat T2D, aim to minimize rapid post-meal surges in glucose that trigger insulin secretion. Additional off-label therapies include those aimed at reducing insulin secretion. In severe cases, gastric restriction or banding has been required to slow gastric emptying and gastrostomy tubes have been used to provide the sole source of nutrition. Despite strict adherence to medical nutrition therapy and clinical use of multiple

medical options, patients continue to have frequent hypoglycemia. While hypoglycemia most commonly occurs following meals, it can also occur in response to increased activity and emotional stress. Importantly, patient safety is additionally compromised when hypoglycemia unawareness develops with recurrent hypoglycemia. We believe there is an urgent need for therapeutic options to allow optimal nutrition, maintain health and quality of life and improve safety in patients with PBH.

Because episodes of hypoglycemia normally occur in the ambulatory setting, the reported prevalence of PBH varies, but we estimate that roughly 1% to 2% of bariatric surgery patients experience PBH. As bariatric procedures have been performed for over ten years, market research has estimated a standing population of approximately 30,000 patients with severe PBH in the United States that require additional treatment options. A similar size patient population is estimated to exist in Europe. These patients may require chronic administration of glucagon multiple times a day.

Xeris Offering—Ready-to-Use Glucagon for PBH

We have developed a ready-to-use glucagon formulation that can be easily and quickly injected or infused subcutaneously from a syringe or pump. Injection of small doses of our liquid-stable glucagon after meals may offer a novel mechanism for PBH patients to treat or prevent hypoglycemia. Importantly, these smaller and more physiologic doses are designed to prevent rebound hyperglycemia associated with glucose tablets, carbohydrate intake and rescue doses of glucagon. Further, small doses of glucagon may offer a direct treatment mechanism for PBH, as opposed to indirect methods aimed at preventing hypoglycemia that are currently employed using various off-label therapeutic options.

Primary market research has shown endocrinologists are comfortable with glucagon's mechanism of action and current safety profile and view ready-to-use glucagon as a welcome treatment option for PBH patients. Physicians surveyed reported ready-to-use glucagon utilization of 68% to 97% if the product can prevent half of severe hypoglycemic events in PBH patients.

As there are currently no therapeutic options indicated for treatment of PBH and the condition has been designated a rare disease, we believe that payors will include our ready-to-use glucagon on their formularies, if approved. We intend to conduct additional payor research as product development progresses.

From 2015 to 2017, the NIH National Institute of Diabetes and Digestive and Kidney Diseases awarded us \$1.78 million in Fast-Track Small Business Innovation Research, or SBIR, grants to demonstrate the potential benefits of ready-to-use glucagon in these patients. Collaborators on this grant include endocrinologists at the Joslin Diabetes Center and device engineers at the Harvard University John R. Paulson School of Engineering and Applied Science.

Clinical Experience

We have completed seven preclinical studies in multiple species and a proof-of-concept clinical trial. We are conducting an ongoing randomized controlled Phase 2a clinical trial for our ready-to-use glucagon for PBH, and we expect to conduct a Phase 2b clinical trial in the second half of 2018.

Phase 2 Clinical Trials

XSGO-PB01: A Phase 2 Proof-Of-Concept Study of Sensor Guided, Clinician-Administered Delivery of Glucagon Infusion from a Patch Pump to Prevent Post-Prandial Hypoglycemia in Post-Bariatric Surgery Patients

In 2017, we conducted an iterative design-and-evaluation Phase 2 clinical trial to assess the performance of a novel event-based hypoglycemia prediction algorithm that triggered delivery of mini-doses of ready-to-use glucagon from a patch-pump. For the trial, which was conducted from the first quarter of 2016 through the second quarter of 2017, we recruited seven patients 18 to 65 years of age with a history of RYGB surgery and PBH with neuroglycopenia who were uncontrolled on medical nutrition therapy and medications. In the inpatient setting, subjects received a mixed-meal tolerance test, which is known to cause hypoglycemia in these patients. Upon receipt of an alarm based on continuous glucose monitor data, subjects were given small, subcutaneous infusions of ready-to-use glucagon from a pump, with the aim of preventing hypoglycemia. The primary endpoint of this study was to investigate the ability of the patch-pump to detect and direct timing of glucose administration. The secondary endpoint of this study was to investigate the safety profile of this product candidate.

Ready-to-use glucagon bolus through the infusion pump was observed to rapidly raise serum glucagon levels, and the doses employed were not associated with increased insulin or C-peptide concentrations. Nadir glucose and time spent under 75 mg/dL in the period after the glucagon bolus were reduced progressively with each new stage of protocol development, which involved either earlier hypoglycemia alarms or larger glucagon doses. All seven patients successfully completed nine treatment visits in this trial. Results showed the treatment to be well-tolerated, with discomfort at the infusion site and erythema the most frequent adverse events, and no SAEs.

Since this was the first implementation of the ready-to-use glucagon formulation in mini-doses in PBH, the dosage was chosen with caution to prevent rebound hyperglycemia that has been observed with use of rescue doses of glucagon. Using these results, we determined the dosage required to effectively prevent hypoglycemic events in the postprandial setting. The results of this trial were published in the peer-reviewed journal *Diabetes Technology & Therapeutics*.

XSGO-PB02: Closed-Loop Glucagon Pump for Treatment of Post-Bariatric Hypoglycemia

Following the positive proof-of-concept outcome of XSGO-PB01, in the fourth quarter of 2017, we initiated a randomized, placebo-controlled, double-blind Phase 2 clinical trial to assess the efficacy of ready-to-use glucagon to prevent and treat hypoglycemia occurring in ten patients with PBH in response to meals or exercise. Following a mixed-meal tolerance test, subjects were randomized to either vehicle or glucagon infusion on the first study visit and crossed-over to the other treatment during the second treatment visit. Investigators were masked to subject assignment.

The clinical trial is currently ongoing, with results from ten subjects expected in the first half of 2018. We expect this randomized controlled trial data will help enable the evaluation of ready-to-use glucagon in the outpatient setting in a planned Phase 2b clinical trial using a vial/syringe, which we intend to complete in the second half of 2018. The primary objective of this study is to investigate the efficacy of our closed-loop glucagon pump for PBH measured by real-time continuous glucose monitoring. Secondary objectives include safety and tolerability. As of the date of this prospectus, there have been no reported SAEs.

Ready-to-Use Glucagon for Congenital Hyperinsulinism

We are evaluating our ready-to-use glucagon formulation for chronic management of congenital hyperinsulinism, for which there are currently no approved therapies. In the United States, 80 to 160 infants are born with CHI on an annual basis. We estimate that there are approximately 6,200 patients with CHI in the United States. In September 2014, we received orphan drug designation from the FDA for ready-to-use glucagon for the prevention of chronic, severe hypoglycemia in patients with CHI. In October 2014, we also received orphan drug designation from the EMA for ready-to-use glucagon for the treatment of CHI. We are currently conducting a Phase 2 clinical trial, from which we expect interim efficacy data in the second half of 2018. Based on these interim results, we plan to meet with the FDA and discuss plans for a pivotal program.

Congenital Hyperinsulinism Market

CHI is the result of several genetic defects that present as dysregulated increased insulin secretion, causing severe, persistent hypoglycemia in infants and children. CHI often responds poorly or not at all to current medical approaches and can sometimes lead to surgical removal of the pancreas, or near-total pancreatectomy. In CHI, microscopic abnormalities in the pancreas can result in prolonged severe hypoglycemia which, if untreated, can cause death. Repeated episodes of severe and prolonged hypoglycemia, even if not fatal, can result in permanent neurologic damage, including developmental delay, mental retardation and focal central nervous system deficits.

Management of CHI is aimed at preventing morbidity associated with repeated hypoglycemic episodes, including permanent brain damage, as well as mortality. Currently, there are no approved drugs for CHI. While limited treatment options are available, they have marginal efficacy, are poorly tolerated by patients and negatively impact quality of life. Often, severe cases of CHI are resistant to diazoxide due to the type of genetic mutation. Other drugs, such as octreotide, have been used to reduce insulin secretion but may be ineffective in maintaining normal blood sugar and may cause substantial side effects.

Pancreatectomy is an option if a solitary focal lesion in the pancreas can be identified and surgically removed, typically resulting in a cure without the need for medication or continuous feedings. However, if the disease is not localized, near-total pancreatectomy would be required. Patients who undergo near-total pancreatectomy are at high

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risk for developing insulin-dependent diabetes later in life. This risk increases with the extent of pancreatic removal, but the risk is significant even with conservative surgical procedures. The use of pancreatectomy oftentimes addresses CHI but creates another chronic condition, insulin-dependent diabetes.

Xeris Offering—Continuous Subcutaneous Infusion of Ready-to-Use Glucagon

If approved, we believe our ready-to-use glucagon would enable safe, continuous administration of glucagon from a pump to manage CHI. IV glucagon is routinely used in the hospital and in conjunction with IV glucose to stabilize blood glucose levels in affected infants, but the IV must be changed every 24 hours or less due to the instability of glucagon in aqueous solution. The use of glucagon has historically been limited due to the lack of a stable formulation and convenient delivery system for long-term administration, especially in the home setting where a central catheter is impractical and a gastrostomy-tube is cumbersome.

We believe that the continuous subcutaneous infusion of ready-to-use glucagon, if approved, is superior to the use of off-label drugs because ready-to-use glucagon:

- Offers a direct effect of increasing glucose levels compared to indirect mechanisms of glucose control.
- Enables release of patient's excess glycogen stores.
- Avoids the side effects related to octreotide, nifedipine and diazoxide.

In addition, we believe that the continuous subcutaneous infusion of ready-to-use glucagon, if approved, is superior to the use of infused glucose because ready-to-use glucagon:

- Provides an approach to wean the patient off a central glucose line, such as an IV, to enable discharge from the hospital.
- Eliminates bloating observed with the high-volume glucose infusions often required to maintain normal blood glucose levels.

Finally, we believe that the continuous subcutaneous infusion of ready-to-use glucagon, if approved, is superior to pancreatectomy, because patients may be able to avoid the development of insulin-resistant diabetes as a lifetime condition. CHI patients who progress to adolescence typically normalize or at least no longer require intensive medical management. We believe that avoiding pancreatectomy is likely the most impactful result of management of CHI with ready-to-use glucagon.

In the short-term inpatient setting, we believe our ready-to-use formulation may enable administration of glucagon from a small, wearable, infusion pump. In the long term, we believe the glucagon pump system may enable outpatient administration of glucagon for prevention of hypoglycemia. We expect most patients that are candidates for ready-to-use glucagon would use the product until mid-adolescence and transition out of the standing patient pool.

There are currently no therapeutic options indicated for treatment of CHI, and current standard of care involves near-total pancreatectomy or use of multiple off-label therapeutics. We believe payors will include our ready-to-use glucagon on their formularies because CHI is a rare pediatric disease and ready-to-use glucagon has the potential to reduce time spent in the NICU, avoid expensive pancreatectomies, as well as avoid the long-term costs associated with diabetes treatment resulting from pancreatectomy. We intend to conduct additional payor research as product development progresses.

From 2015 to 2017, we were awarded \$2.1 million in SBIR grants from the NIH National Institute of Diabetes and Digestive and Kidney Diseases to initiate clinical studies in infant patients with CHI.

Clinical Experience

We are currently conducting a Phase 2 proof-of-concept randomized controlled clinical trial and previously completed a number of preclinical studies in multiple species that we are leveraging for all of our chronic glucagon programs.

Ongoing Phase 2 Clinical Trial

XSGO-CH01: A Phase 2 Proof-of-Concept Study of CSI Glucagon (Continuous Subcutaneous Glucagon Infusion) to Prevent Hypoglycemia with Lower Intravenous Glucose Infusion Rates in Children up to One Year of Age with Congenital Hyperinsulinism

In the fourth quarter of 2016, we initiated a randomized controlled Phase 2 clinical trial at four CHI centers of excellence in the United States, with interim efficacy results from twelve subjects expected in the second half of 2018. While the study is blinded, the protocol allows physicians to use continuous subcutaneous infusion glucagon in an open-label extension phase as appropriate. During one observation, the open-label data showed use of continuous subcutaneous infusion of glucagon enabled the reduction of the IV glucose infusion rate by a clinically significant 65%. To date, continuous subcutaneous glucagon has been observed to be well-tolerated and in this clinical trial there have been no unanticipated adverse events or reported SAEs. We expect the randomized controlled data from this clinical trial will help us initiate the pivotal program for continuous subcutaneous infusion of glucagon, which we plan to initiate in the first half of 2019.

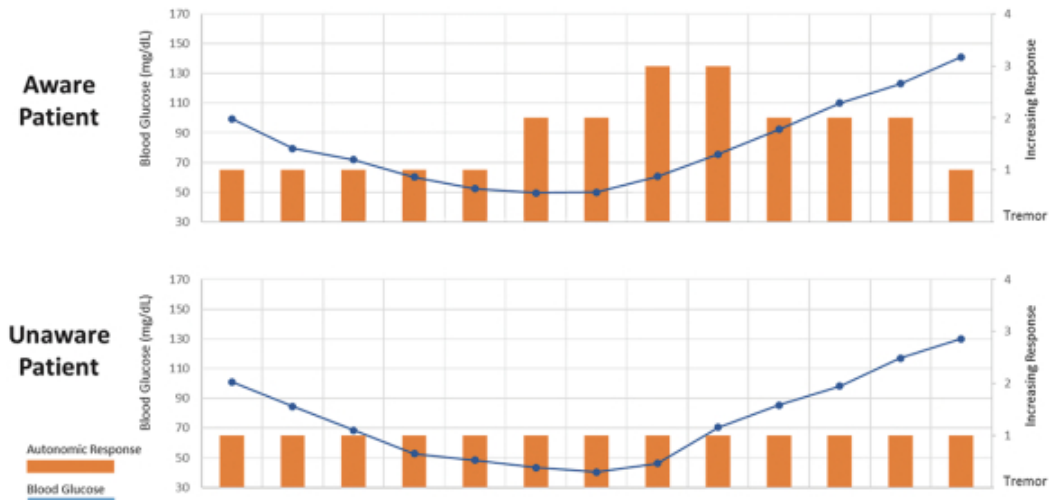
Ready-to-Use Glucagon for Hypoglycemia-Associated Autonomic Failure

We are evaluating our ready-to-use glucagon for HAAF, a condition for which there are currently no therapeutic options. We expect to conduct a Phase 2a clinical trial from which we expect to obtain topline results in the second half of 2018. If clinical development is successful, we expect to submit a NDA under the 505(b)(2) pathway for FDA review. We intend to discuss the registration pathway with the FDA in the second half of 2018.

Hypoglycemia-Associated Autonomic Failure Market

Typically, a decrease in plasma glucose below the normal range triggers defensive counter-regulatory responses that restore blood sugars. However, individuals with HAAF have defects in that counter-regulatory response. These individuals do not experience the physiological symptoms of worsening hypoglycemia and are at risk of being unaware of an impending severe hypoglycemic event. Chronic hypoglycemia is thought to lead to this defective glucose counter-regulation and hypoglycemia unawareness. The lack of awareness of an oncoming hypoglycemic event may result in the inability to treat or prevent it, creating a vicious cycle of recurrent hypoglycemia and possibly leading to the sudden onset of severe hypoglycemia, putting patients at risk for severe hypoglycemia, neuroglycopenia, seizure, coma and, if left untreated, death. As such, hypoglycemia unawareness is a major concern for this subset of people with T1D and T2D and their caregivers.

The figures below depict the effect of hypoglycemic unawareness where symptoms do not signal corresponding blood glucose.



It has been shown that the autonomic response and awareness of hypoglycemia can be restored with scrupulous avoidance of hypoglycemia for two to three weeks. However, this restoration can currently only be achieved with intensive diet and behavior modification, which we believe results in low participation and success rates.

Based on our research, we estimate that approximately 20% of people with T1D and 14% of people with T2D (primarily those on insulin) have HAAF. In primary market research, physicians indicated approximately half of patients with some form of HAAF are moderately to severely affected. However due to the need for better diagnosis procedures and guidelines for HAAF, the physicians surveyed also reported that they currently expect approximately 40% and 50% under-diagnosis rates of HAAF in people with T1D and T2D, respectively. We believe there is a critical unmet need for a therapeutic treatment for insulin deficient diabetes patients with HAAF.

Xeris Offering—Continuous Subcutaneous Infusion of Ready-to-Use Glucagon

We are developing a novel continuous subcutaneous glucagon infusion system incorporating our ready-to-use, liquid-stable glucagon formulation with an infusion pump. Continuous subcutaneous infusion of ready-to-use glucagon could be used to avoid hypoglycemia during a three- to four-week period to restore autonomic response and hypoglycemia awareness. Combined with patient training, the treatment may result in a significant long-term reduction in hypoglycemia rates post-intervention, particularly of severe hypoglycemia. If approved, we believe our ready-to-use glucagon has the potential to be the first product designed to prevent hypoglycemia for extended periods of time to enable re-establishment of hypoglycemia awareness and treat HAAF. We believe our ready-to-use glucagon, if approved, could provide substantial therapeutic benefit to patients who suffer from severe hypoglycemic events and are taken to the emergency room multiple times per year.

The use of glucagon to treat this condition has been hampered due to the lack of a room-temperature stable liquid glucagon formulation and a convenient delivery system for continuous administration. Attempts at off-label treatment with current emergency glucagon products require reconstitution of freeze-dried glucagon powder, and the drug chamber and infusion set would likely require replacement at least every 24 hours due to the instability of glucagon in aqueous solution.

There are currently no therapeutic treatment options for HAAF. However, since at least some payors currently cover diabetes coaching and training services conducted by certified diabetes educators, which are often used to help treat or manage HAAF, we believe payors will cover ready-to-use glucagon if we can demonstrate reversal of hypoglycemia unawareness. We intend to conduct additional payor research as product development progresses.

Clinical Experience

We expect to conduct a Phase 2a proof-of-concept randomized controlled clinical trial and have successfully completed a number of preclinical studies in multiple species that we are leveraging in our other chronic glucagon programs.

Ongoing Phase 2 Clinical Trial

XSGO-AF01: Fixed Rate Continuous Subcutaneous Glucagon Infusion (CSGI) vs Placebo in Type 1 Diabetes Mellitus Patients with Recurrent Severe Hypoglycemia: Effects On Counter Regulatory Responses to Insulin Induced Hypoglycemia

We expect to conduct a randomized, controlled, Phase 2a clinical trial at four sites in the United States, with topline results from 40 subjects expected in the second half of 2018. We believe that our ready-to-use glucagon has the potential to be the first treatment option to prevent the occurrence of hypoglycemia for an entire month in people with T1D. In addition, we seek to evaluate whether epinephrine response and hypoglycemic awareness are restored following the course of treatment and, if so, the duration of the restored response. We expect data from this Phase 2a clinical trial to help outline pivotal study endpoints and enable an FDA discussion in the second half of 2018.

Ready-to-Use Glucagon for Exercise-Induced Hypoglycemia in Diabetes

We are evaluating our ready-to-use glucagon and plan to initiate additional Phase 2 clinical development in the second half of 2018 for EIH, for which there are currently no approved therapies. We intend to discuss the registration pathway with FDA in 2018. In November 2013, we filed an IND application for the use of mini-dose ready-to-use glucagon for EIH. We are the sponsor of this IND, which is active as of the date of this prospectus.

Exercise-Induced Hypoglycemia in Diabetes Market

Exercise-induced hypoglycemia and the complexity of management aimed at its prevention represent major barriers to the adoption of regular physical activity for many individuals with diabetes treated with insulin. Although carbohydrate ingestion, including oral glucose tablets, can help ameliorate hypoglycemia, patients' carbohydrate requirements can be as high as 1 gram per minute of exercise, which can be counterproductive to weight management. Aerobic exercise, in particular, often results in a significant drop in blood glucose concentrations. Qualitative feedback has shown that the challenges in current exercise management strategies and the need to consume carbohydrates is frustrating and may lead to minimized or complete omission of exercise for many patients. People with diabetes who use insulin are at risk of EIH. We believe there is a subset of these individuals that exercises at least three times per week per current guidelines, and who could potentially use a mini-dose of ready-to-use glucagon each time they exercised. If approved, our ready-to-use glucagon would represent a significant market opportunity in the treatment for EIH.

Xeris Offering—Mini-doses of Ready-to-Use Glucagon for Treatment of EIH

We are developing a mini-dose of our ready-to-use, liquid-stable glucagon and have observed appropriate dose-dependent PK and PD responses when administered subcutaneously at doses of 75, 150 and 300 µg in adults with T1D. Our previous proof-of-concept study demonstrated that 150 µg of this mini-dose glucagon corrected non-severe hypoglycemia to a substantially similar degree as oral glucose tablets that are commonly used during exercise in correcting non-severe hypoglycemia in adults with T1D, while enabling avoidance of unnecessary caloric intake.

Modestly increasing glucagon levels at the start of exercise has previously not been possible, since current commercially available glucagon preparations are unstable in aqueous solution. They exist as a lyophilized powder that must be reconstituted in diluent immediately prior to injection and are only indicated at an emergency dose of 1 mg for rescue from severe hypoglycemia. Despite the challenging reconstitution process, there has been significant documented off-label use of the current glucagon kits.

We have been awarded over \$3.0 million in grants from organizations such as the Leona M. and Harry B. Helmsley Charitable Trust and the NIH National Institute of Diabetes and Digestive and Kidney Diseases, and we have worked with institutions including the Joslin Diabetes Center and the University of Pennsylvania for clinical development of our mini-dose glucagon product candidate.

Clinical Experience

We have successfully completed a number of preclinical studies in multiple species to support the safety of mini-dose glucagon, as well as three Phase 2 safety and efficacy clinical trials in subjects with T1D.

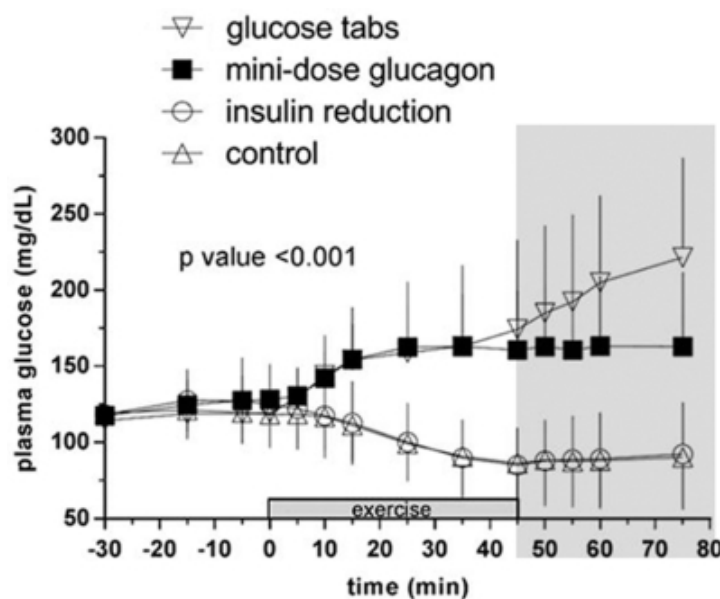
Phase 2 Clinical Trials

XSMP-203: The Use of Mini-Dose Glucagon to Prevent Exercise-Induced Hypoglycemia in Type 1 Diabetes

Based on our previous dose-finding trials (XSMP-201 and XSMP-202), we initiated a third Phase 2 clinical trial of mini-dose glucagon for EIH in the first quarter of 2016. The primary analysis of this trial was comparison of the glycemic response of 150 µg mini-dose glucagon against current standards of care, including basal insulin reduction and glucose tablet consumption, to mitigate exercise-induced hypoglycemia. In particular, this was a four-session, randomized crossover trial involving 15 adults with T1D who exercised at 50-55% VO₂max for 45 minutes under conditions of no intervention (control), 50% basal insulin reduction, 40 g oral glucose tablets, or 150 µg subcutaneous mini-dose glucagon, all administered five minutes before exercise. Secondary endpoints were to investigate the safety profile of this product candidate.

During the exercise sessions conducted in this study, plasma glucose increased slightly with mini-dose glucagon compared to a decrease with control and insulin reduction, as depicted in the figure below. Plasma glucose increased more greatly with glucose tablets. Hypoglycemia (<70 mg/dL) was experienced by six subjects during control, five during insulin reduction and none with glucose tablets or mini-dose glucagon; however, five subjects experienced hyperglycemia (≥250 mg/dL) with glucose tablets and one with mini-dose glucagon. The study was well-controlled, as insulin levels were not different among sessions, while glucagon levels increased only in the mini-dose glucagon arm, as expected.

In a Phase 2a randomized, controlled clinical study, T1D subjects (n=16) administered mini-dose glucagon completed a 45-minute exercise session without adjusting basal insulin or ingesting glucose tabs (calories).



The Phase 2a study concluded that mini-dose glucagon (150 µg) may have the potential to prevent EIH in adults with T1D. In addition, mini-dose glucagon may be more effective at preventing EIH than insulin reduction that was associated with a similar rate and magnitude of hypoglycemia as no intervention. Moreover, while mini-dose glucagon was as effective as glucose tablets for preventing exercise-induced hypoglycemia, mini-dose glucagon may result in less post-intervention hyperglycemia than ingestion of carbohydrates and avoids the consumption of unnecessary calories. The results of this study were presented in 2017 at the American Diabetes Association' Scientific Sessions and the European Association for the Study of Diabetes Annual Meeting and have been accepted for publication.

Ready-to-Use Glucagon for Bi-Hormonal Artificial Pancreas Closed-Loop Systems

We are evaluating our ready-to-use glucagon for use in a bi-hormonal artificial pancreas closed-loop system. We intend to initiate a Phase 2a proof-of-concept randomized three-way crossover clinical trial in mid-2018 to evaluate the utility of such a system. In December 2013, we filed an IND application for the use of ready-to-use glucagon in a bi-hormonal artificial pancreas closed-loop system. We are the sponsor of this IND, which is active as of the date of this prospectus.

Insulin-Dependent Diabetes Market

Continuous subcutaneous insulin infusion from a pump, or CSII, has been shown to improve glycemic control for people with diabetes. However, data from clinical trials indicate that even when used in closed-loop, insulin analogs, pumps and continuous glucose monitoring, or CGM, have generally modest effects in reducing hypoglycemic events because they are capable of only delivering or stopping delivery of insulin. As such, CSII users are still forced to ingest carbohydrate containing foods, over-the-counter glucose products, or utilize emergency glucagon products to counteract hypoglycemia.

We believe the quality of life for patients could be significantly improved by offering a bi-hormonal artificial pancreas that delivers both insulin and glucagon. While significant work has been done developing extensive algorithms and control systems needed for the bi-hormonal pump, a key limitation has been the lack of a glucagon formulation that does not require reconstitution and is stable for at least three days in a pump chamber. We believe the utilization of our ready-to-use glucagon in a bi-hormonal system has the potential to minimize the incidence of hypoglycemia, improve patient quality of life, and drive higher rates of adoption of CSII systems.

All patients utilizing an intensive insulin regimen are candidates for a bi-hormonal pump system. In the United States, this includes all 1.3 million people with T1D as well as approximately 500,000 people with T2D. Of this combined population, approximately one-third is currently utilizing CSII therapy.

Xeris Offering—Liquid-Stable Ready-To-Use Glucagon for a Bi-Hormonal Artificial Pancreas

A liquid-stable glucagon formulation is a critical component to facilitate a bi-hormonal artificial pancreas. Our ready-to-use glucagon has demonstrated stability at body temperature in a patch pump chamber. Collaborators in our bi-hormonal artificial pancreas program include endocrinologists at Oregon Health & Science University (OHSU). In addition, numerous researchers have expressed interest in using our ready-to-use glucagon in research studies with novel bi-hormonal pump systems.

To support development of our ready-to-use glucagon for this application, we have been awarded approximately \$1.9 million in funding from organizations such as the NIH National Institute of Diabetes and Digestive and Kidney Diseases and the JDRF.

Clinical Experience

We have successfully completed a number of preclinical studies in multiple species and a Phase 2a dose-ranging glucagon PK/PD study and are currently conducting a Phase 2a proof-of-concept randomized clinical trial.

Ongoing Phase 2 Clinical Trial

G18002: A Randomized, Three-Way, Cross-Over Outpatient Study to Assess the Efficacy of a Dual-Hormone Closed-Loop System with XeriSol Glucagon vs Closed-Loop System with Insulin Only vs a Predictive Low Glucose Suspend System

We intend to initiate a single center, randomized, three-way, crossover trial in mid-2018 to compare the glucose control resulting from the use of a bi- and single-hormone closed-loop system as compared to a predictive low glucose suspend system. The bi-hormonal closed-loop system is designed to reduce the time spent in the hypoglycemic range and increase the time spent in the target range, even after exercise, as compared to an insulin only closed-loop system and a predictive low glucose suspend system. We intend to enroll 19 subjects in this clinical trial, with results expected in the first half of 2019.

Preclinical Programs

Ready-to-Use Diazepam

Leveraging our XeriSol formulation technology, we are developing a ready-to-use diazepam formulation for the treatment of ARS in patients with epilepsy. Approximately 160,000 people in the United States experience ARS.

Immediate treatment of epileptic seizures is critical to avoid increased risks of morbidity and mortality, including permanent neuronal damage, behavioral abnormalities and an increased probability in the need for life-long care.

Injectable and rectal gel formulations of diazepam are the current standard of care for the emergency treatment of epileptic seizures. In 2017, these diazepam formulations generated total U.S. sales of approximately \$127 million, of which DiaStat Rectal Gel and its generic formulations comprised \$83 million. DiaStat requires a multi-step procedure which makes it more difficult to administer while a patient is experiencing seizures. Additionally, the use of rectal gel in both middle school children and young adults with ARS is reduced because of social stigma. These characteristics are limitations that may diminish the specific demand for rectal diazepam products. Due to this limitation, we believe the market for diazepam in ARS is underpenetrated. We believe that a ready-to-use diazepam rescue pen would improve patient quality of life and drive adoption of diazepam to treat ARS.

Our ready-to-use diazepam rescue pen has demonstrated rapid onset and high bioavailability in preclinical models. We received orphan drug designation for our product candidate from the FDA and were awarded grants totaling \$1.5 million from the Epilepsy Foundation and the NIH for this program. If approved, we believe that our ready-to-use diazepam rescue pen would become the standard of care for the treatment of ARS. We plan to conduct a Phase 1 clinical trial of our ready-to-use diazepam rescue pen in the second half of 2018. If results are positive, we plan to initiate a Phase 2 clinical trial in the first half of 2019.

Pram-Insulin

Leveraging our XeriSol platform, we are developing a ready-to-use fixed dose combination of insulin and pramlintide to be delivered via a vial and syringe. Despite advances in the delivery and pharmacology of insulin, most people with T1D are still unable to achieve glycemic targets with insulin therapy alone, particularly after mealtime. Pramlintide acetate (Symlin), a synthetic analog of the hormone amylin, has been approved by the FDA for use by people with T1D and T2D who use mealtime insulin. Pramlintide is indicated as an adjunct treatment for people who use mealtime insulin therapy and who have failed to achieve glucose control despite optimal insulin therapy. At present, pramlintide must be administered as a separate injection, doubling the number of daily injections for the patient, which we believe has limited the market.

Our fixed dose combination is designed to reduce the number of injections as the pramlintide would not require a separate mealtime injection. If approved, we believe the potential target population for our fixed dose combination may total 350,000 to 390,000 patients. We plan to open an Investigational New Drug, or IND, application for our fixed dose combination of insulin and pramlintide in the second half of 2018.

Manufacturing and Supply

We currently contract with third parties for the manufacture, assembly, testing, packaging, storage and distribution of our products. In our experience, third party contract manufacturing organizations, or CMOs, are generally cost-efficient, high quality and reliable, and we currently have no plans to build our own manufacturing or distribution infrastructure. Our technical team has extensive pharmaceutical development, manufacturing, analytical, quality and distribution experience and is qualified and capable of managing supply chain operations across multiple CMOs. Our Quality System, Standard Operating Procedures and CMO interfaces are designed to promote cGMP compliance and effective regulatory communications. We selected our CMOs for specific competencies, and they have met our development, manufacturing, quality and regulatory requirements and were all involved in manufacturing our clinical supplies and commercial registration batches.

Glucagon is the active pharmaceutical ingredient, or API, used in our Glucagon Rescue Pen and our intermittent and chronic hypoglycemia products in development that utilize ready-to-use glucagon. We intend to use Bachem Americas, Inc., or Bachem, as our primary commercial source for API. Bachem holds a U.S. drug master file for glucagon produced at its facility in Switzerland, and its manufacturing process is fully validated. We have entered into a non-exclusive supply agreement with Bachem. While we believe that Bachem has sufficient capacity to satisfy our long-term requirements for our Glucagon Rescue Pen and other pipeline products utilizing ready-to-use glucagon, we are actively engaged in developing a second API source. An alternate supplier has successfully produced one full scale commercial batch, and we intend to complete development work and register this supplier as a qualified source shortly after NDA approval.

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Manufacturing drug product for our Glucagon Rescue Pen requires an aseptic fill/finish facility capable of handling solvents and a cyclic olefinic polymer syringe. Pyramid Laboratories, Inc., or Pyramid, has been actively involved in the development of our product candidates, and we intend to use its facility in California to be our primary source for drug product. We intend to enter into a non-exclusive supply agreement with Pyramid. While we believe that Pyramid has sufficient capacity to satisfy our demand requirements for at least three to five years, we are evaluating alternate sourcing options.

The auto-injector used to deliver drug product in our Glucagon Rescue Pen is a proprietary multi-product device platform developed by SHL Pharma, LLC, or SHL Pharma. We entered into a joint development agreement in January 2016 to develop an auto-injector suitable for our Glucagon Rescue Pen, and we are in the final stages of assembly equipment process validation. SHL Pharma produces device sub-assemblies in company-owned facilities in Taiwan and performs final drug product/device assembly operations at its facility in Florida. We intend to enter into a non-exclusive supply agreement with SHL Pharma. We intend to source the device from a single supplier over the life of the product.

We believe that a number of CMOs can provide suitable secondary packaging services for our Glucagon Rescue Pen, and we intend to enter into one or more commercial supply agreements. A number of third party logistic providers can provide commercial order processing and finished good distribution services to U.S. wholesale customers, and we expect to enter into one or more commercial distribution agreements in 2018.

Competition

Our industry is characterized by intense competition and a strong emphasis on proprietary products. We believe the key competitive factors that will affect the development and commercial success of our product candidates include likelihood of successful dose delivery, ease of administration, therapeutic efficacy, safety and tolerability profiles and cost. While we believe that our product and product candidate platform, development expertise and scientific knowledge provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies. Many of our potential competitors have substantially greater financial, technical and human resources than we do, as well as more experience in the development of product candidates, obtaining FDA and other regulatory approvals of products, and the commercialization of those products.

Two emergency glucagon products are currently available to treat severe hypoglycemia: Eli Lilly's GEK and Novo Nordisk's GlucaGen. Each kit is sold as a vial of lyophilized, glucagon powder with an exposed syringe/needle that contains a liquid diluent. The glucagon powder must be combined with the liquid diluent at the time of use and drawn into a syringe in accordance with a complex multi-step reconstitution and dose calibration procedure. Additionally, once reconstituted, the glucagon must be used immediately because once the lyophilized glucagon is combined with water, the solution becomes unstable and can fibrillate, rendering it inactive and potentially toxic. We believe that the drawbacks of currently marketed products and the lack of conversations regarding glucagon limit their adoption. In addition to the currently marketed GEK and Novo Nordisk's GlucaGen, we are currently aware of several product candidates that are expected to compete with our Glucagon Rescue Pen, if approved. Eli Lilly is developing an intranasal glucagon dry powder. While healthcare professionals as well as patients and caregivers believe both our Glucagon Rescue Pen and the intranasal dry powder are easy to use, they have expressed concern that the full dose of glucagon may not be delivered via intranasal absorption. Of note, in a Phase 1 clinical trial, a pediatric subject failed to achieve a ≥ 25 mg/dL rise in glucose because he blew his nose immediately after a 2 mg intranasal dose administration.

In our market research, respondents ranked the importance of successful full-dose delivery and ability to tell if the full dose was administered significantly higher than the needleless attribute. In our market research, caregivers and people with diabetes associated our Glucagon Rescue Pen with efficacious and successful dose delivery, as well as ease of ability to tell if the full dose was administered. Similarly, healthcare professionals indicated that one of the most appealing attributes of our Glucagon Rescue Pen is the greater likelihood of successful dose delivery.

In addition, Zealand Pharma is developing an SC dasiglucagon, a stable analog of human glucagon, in an auto-injector. Zealand's dasiglucagon is currently in Phase 3 development and is being studied in adults only. Data

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released to date indicate that Zealand's dasiglucagon will have a room-temperature stable shelf-life up to 12 months.

Additional Phase 1 candidates for severe hypoglycemia include Adocia's BioChaperone Glucagon and Novo Nordisk's NNC9204-1513.

While there are currently no FDA approved products indicated for treatment of PBH, we are aware of a number of product candidates in development. For example, Eiger Biopharma is developing its product candidate exendin 9-39, a glucagon-like peptide-1 receptor antagonist, to be administered subcutaneously, which is currently in Phase 2 development.

Currently, there are no approved drugs for CHI and limited treatment options are available, but we are aware of several product candidates in development. For example, Rezolute is developing RZ358, an IV administered fully human antibody that inhibits the effects of elevated insulin via allosteric modulation of the insulin receptor, which is currently in Phase 2 development. In addition, Zealand Pharma is developing an SC infusion of dasiglucagon, which is currently in Phase 3 clinical development.

There are currently no approved products for the treatment of HAAF. Many other therapeutic compounds have been investigated in academic clinical research for the indirect prevention of hypoglycemia. While none of these interventions have been successful to date, this research shows there is considerable interest in restoring hypoglycemia awareness and HAAF.

Currently, the first-line emergency treatment of epileptic seizures in the outpatient setting is the administration of diazepam in a non-sterile rectal gel marketed by Valeant Pharmaceuticals as DiaStat. We are also aware of several product candidates in development for the treatment of ARS in patients with epilepsy. For example, Neurelis is developing NRL-1, an intranasal formulation of diazepam, for which Neurelis has announced an intention to file a NDA in 2018. In addition, Aquestive is developing AQST-203, a buccal soluble formulation of diazepam, which is currently in Phase 3 development.

Intellectual Property

Proprietary protection

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our drug candidates, manufacturing and process discoveries and other know-how, to operate without infringing the proprietary rights of others, and to prevent others from infringing on our proprietary rights. We have been building and continue to build our intellectual property portfolio relating to our product candidates and technology. Our policy is to seek to protect our proprietary position by, among other methods, filing U.S. and certain foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also intend to rely on trade secrets, know-how, continuing technological innovation and potential in-licensing opportunities to develop and maintain our proprietary position. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us or our partners in the future will be commercially useful in protecting our technology.

Patent rights

As of March 15, 2018, we owned 66 issued patents globally, of which 12 are issued U.S. patents. As of March 15, 2018, we owned over 60 patent applications pending globally, of which 12 are patent applications pending in the United States. As of March 15, 2018, three of our U.S. issued patents have pending continuations or divisionals in process which may provide additional intellectual property protection if issued as U.S. patents. Our issued patents expire between December 22, 2023 and April 22, 2036, subject to payment of required maintenance fees, annuities and other charges. The subset of our patent estate directed specifically to our ready-to-use glucagon consists of one U.S. composition of matter patent that is scheduled to expire in year 2036, one pending U.S. patent application and an international patent application. Patents that issue based on the foregoing international application would expire in year 2036.

Trade secret and other protection

In addition to patented intellectual property, we also rely on trade secrets and proprietary know-how to protect our technology and maintain our competitive position, especially when we do not believe that patent protection is appropriate or can be obtained. Our policy is to require each of our employees, consultants and advisors to execute a confidentiality and inventions assignment agreement before beginning their employment, consulting or advisory relationship with us. The agreements generally provide that the individual must keep confidential and not disclose to other parties any confidential information developed or learned by the individual during the course of the individual's relationship with us except in limited circumstances. These agreements generally also provide that we shall own all inventions conceived by the individual in the course of rendering services to us.

Other intellectual property rights

We file trademark applications and pursue registrations in the United States and abroad when appropriate. We own a registered trademark for the mark Xeris Pharmaceuticals. We also own pending trademark applications for XERISOL, XERIJECT and HYOPEN in the United States; and XERISOL and XERIJECT in the EU for use in connection with our pharmaceutical research and development as well as products, as well as trade names that could be used with our potential products. The USPTO has allowed the following trademark applications which are awaiting Statements of Use: XERISOL, XERIJECT, HYOPEN and GLUCAPEN.

From time to time, we may find it necessary or prudent to obtain licenses from third-party intellectual property holders.

Grant Agreements

Through December 31, 2017, we have received \$0.8 million out of an expected \$0.9 million in grant proceeds for the development of a stable liquid glucagon for use in an artificial pancreas. Under the terms of the agreement, we will be required to pay up to four times the award received upon commercialization of glucagon for use in the artificial pancreas. If we undergo a change in control, then we will be required to pay a mid-single digit percentage of the gross proceeds, capped at four times the award amount less any amounts already paid. Additionally, if sales of glucagon for use in the artificial pancreas exceed \$750 million in the first five years after the first commercial sale, then we would be required to make an additional payment equal to four times the award amount.

Through December 31, 2017, we received \$0.9 million in grant proceeds to help fund our EIH program. Under terms of this agreement, we will be required to pay up to two times the award amount upon the commercialization of an EIH product. These amounts are a low double-digit percentage of annual gross sales of an EIH product, capped at \$0.5 million annually. If we undergo a change in control, then we will pay a mid-single digit percentage of the consideration capped at two times the award amount less any amounts already paid. Additionally, if sales exceed \$1 billion, we will be required to pay an additional amount equal to two times the award amount.

Through December 31, 2017, we received \$1.0 million in grant proceeds to help fund our T1D chronic glucagon programs. Under terms of this agreement we will be required to pay up to two times the award amount upon the commercialization of any chronic glucagon program. These amounts are a low double-digit percentage of annual gross sales of T1D all chronic glucagon programs, capped at \$0.5 million annually. If we undergo a change in control, then we will pay a mid-single digit percentage of the consideration capped at two times the award amount less any amounts already paid. Additionally, for each chronic glucagon program where sales exceed \$500 million, we will be required to pay an additional amount equal to two times the award amount.

We have also received awards from the NIH National Institute of Diabetes and Kidney Diseases, which awards are not subject to any repayment obligations. See "Management's Discussion and Analysis of Financial Condition and Results of Operation—Contractual Obligations and Commitments" for additional details.

Loan and Security Agreement

In February 2018, we entered into a Loan and Security Agreement, which we refer to as the Loan Agreement, with Oxford Finance LLC and Silicon Valley Bank, which we collectively refer to as our Lenders, providing a senior secured loan facility of up to an aggregate principal amount of \$45.0 million, comprised of a \$20.0 million drawdown in February 2018, and an additional \$25.0 million which can be borrowed in two additional tranches. The second tranche is \$15.0 million and is available if we submit our NDA for our Glucagon Rescue Pen before September 30, 2018, and then only available to be drawn until the earlier of September 30, 2018 or the 30th day

following such NDA submission. The third tranche is \$10.0 million and is available if we receive approval of our Glucagon Rescue Pen NDA by the FDA before September 30, 2019, and then only available to be drawn until the earlier of September 30, 2019 or the 30th day following NDA approval by the FDA. See “Management’s Discussion and Analysis of Financial Condition and Results of Operation—Loan Agreement” for additional details.

Government Regulation

United States Drug Development

In the United States, the FDA regulates drugs, medical devices and combinations of drugs and devices, or combination products, under the federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. Drugs are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA’s refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, requests for voluntary product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Our product candidates are subject to regulation as combination products, which means that they are composed of both a drug product and device product. If marketed individually, each component would be subject to different regulatory pathways and reviewed by different Centers within the FDA. A combination product, however, is assigned to a Center that will have primary jurisdiction over its regulation based on a determination of the combination product’s primary mode of action, which is the single mode of action that provides the most important therapeutic action. In the case of our product candidates, the primary mode of action is attributable to the drug component of the product, which means that the FDA’s Center for Drug Evaluation and Research has primary jurisdiction over the premarket development, review and approval of our product candidates. Accordingly, we plan to investigate our products through the IND framework and seek approval through the NDA pathway. Based on our discussions with the FDA to date, we do not anticipate that the FDA will require a separate medical device authorization for the device, but this could change during the course of its review of any marketing application that we may submit. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of extensive preclinical laboratory tests, animal studies and formulation studies in accordance with applicable regulations, including the FDA’s Good Laboratory Practice, or GLP, regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with an applicable IND and other clinical study related regulations, sometimes referred to as good clinical practices, or GCPs, to establish the safety and efficacy of the proposed drug for its proposed indication;
- submission to the FDA of a NDA;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with the FDA’s current good manufacturing practice requirements, or cGMP;
- potential FDA audit of the clinical trial sites that generated the data in support of the NDA and payment of associated user fees;
- review by an FDA advisory committee, where appropriate or if applicable;
- FDA review and approval of the NDA prior to any commercial marketing or sale; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy, or REMS, and the potential requirement to conduct post-approval studies.

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Once a pharmaceutical product candidate is identified for development, it enters the preclinical testing stage. Pre-clinical tests include laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, to the FDA as part of the IND. An IND is an exemption from the FDCA that allows an unapproved product to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA authorization to administer such investigational product to humans. The sponsor must also include a protocol detailing, among other things, the objectives of the initial clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated if the initial clinical trial lends itself to an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions related to a proposed clinical trial and places the trial on a clinical hold within that 30-day period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during clinical trials due to safety concerns or non-compliance, and may be imposed on all drug products within a certain class of drugs. The FDA also can impose partial clinical holds, for example, prohibiting the initiation of clinical trials of a certain duration or for a certain dose.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCP regulations. These regulations include the requirement that all research subjects provide informed consent in writing before their participation in any clinical trial. Further, an institutional review board, or IRB, must review and approve the plan for any clinical trial before it commences at any institution, and the IRB must conduct continuing review and reapprove the study at least annually. An IRB considers, among other things, whether the risks to individuals participating in the clinical trial are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the information regarding the clinical trial and the consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed.

Each new clinical protocol and any amendments to the protocol must be submitted for FDA review and to the IRBs for approval. Protocols detail, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1. The product is initially introduced into a small number of healthy human subjects or patients and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain early evidence on effectiveness. In the case of some products for severe or life-threatening diseases, especially when the product is suspected or known to be unavoidably toxic, the initial human testing may be conducted in patients.
- Phase 2. Involves clinical trials in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage and schedule.
- Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit relationship of the product and provide an adequate basis for product labeling.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 trials. Companies that conduct certain clinical trials also are required to register them and post the results of completed clinical trials on a government-sponsored database, such as ClinicalTrials.gov in the United States, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events, findings from other studies that suggest a significant risk to humans exposed to the product,

findings from animal or in vitro testing that suggest a significant risk to human subjects, and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated check points based on access to certain data from the study. The clinical trial sponsor may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

NDA and FDA Review Process

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the drug, proposed labeling and other relevant information, are submitted to the FDA as part of a NDA for a new drug, requesting approval to market the product. Under federal law, the submission of most NDAs is subject to an application user fee, which for federal fiscal year 2018 is \$2,421,495 for a NDA requiring clinical data. The sponsor of an approved NDA is also subject to an annual program fee, which for fiscal year 2018 is \$304,162. Certain exceptions and waivers are available for some of these fees, such as an exception from the application fee for products with orphan designation and a waiver for certain small businesses.

The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting a NDA for filing. The FDA typically makes a decision on accepting a NDA for filing within 60 days of receipt. The decision to accept the NDA for filing means that the FDA has made a threshold determination that the application is sufficiently complete to permit a substantive review. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA's goal to complete its substantive review of a standard NDA and respond to the applicant is ten months from the receipt of the NDA. The FDA does not always meet its PDUFA goal dates, and the review process is often significantly extended by FDA requests for additional information or clarification and may go through multiple review cycles.

After the NDA submission is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMPs to assure and preserve the product's identity, strength, quality and purity. The FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. The FDA will likely re-analyze the clinical trial data, which could result in extensive discussions between the FDA and us during the review process. The review and evaluation of a NDA by the FDA is extensive and time consuming and may take longer than originally planned to complete, and we may not receive a timely approval, if at all.

Before approving a NDA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMPs. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. In addition, before approving a NDA, the FDA may also audit data from clinical trials to ensure compliance with GCP requirements. After the FDA evaluates the application, manufacturing process and manufacturing facilities, it may issue an approval letter or a Complete

Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes all the specific deficiencies in the NDA identified by the FDA. The Complete Response Letter may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the NDA, addressing all the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive, and the FDA may interpret data differently than we interpret the same data.

There is no assurance that the FDA will ultimately approve a product for marketing in the United States, and we may encounter significant difficulties or costs during the review process. If a product receives marketing approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling or may condition the approval of the NDA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-market testing or clinical trials and surveillance to monitor the effects of approved products. For example, the FDA may require Phase 4 clinical trials to further assess drug safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. The FDA may also place other conditions on approvals including the requirement for a risk evaluation and mitigation strategy, or REMS, to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory requirements or if problems occur following initial marketing.

Section 505(b)(2) NDAs

NDAs for most new drug products are based on two full clinical studies which must contain substantial evidence of the safety and effectiveness of the proposed new product for the proposed use. These applications are submitted under Section 505(b)(1) of the FDCA. The FDA is, however, authorized to approve an alternative type of NDA under Section 505(b)(2) of the FDCA. This type of application allows the applicant to rely, in part, on the FDA's previous findings of safety and effectiveness for a similar product, or published literature. Specifically, Section 505(b)(2) applies to NDAs for a drug for which the investigations relied upon by the applicant for approval of the application "were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted."

Thus, Section 505(b)(2) authorizes the FDA to a NDA based on safety and effectiveness data that were not developed by the applicant. NDAs filed under Section 505(b)(2) may provide an alternate and potentially more expeditious pathway to FDA approval for new or improved formulations or new uses of previously approved products. If the 505(b)(2) applicant can establish that reliance on the FDA's previous approval is scientifically appropriate, the applicant may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new drug candidate for all or some of the labeled indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

Abbreviated New Drug Applications for Generic Drugs

In 1984, with passage of the Hatch-Waxman Amendments to the FDCA, Congress established an abbreviated regulatory scheme authorizing the FDA to approve generic drugs that are shown to contain the same active ingredients as, and to be bioequivalent to, drugs previously approved by the FDA pursuant to NDAs. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application, or ANDA, to the agency. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the

active pharmaceutical ingredient, bioequivalence, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data and quality control procedures. ANDAs are “abbreviated” because they generally do not include preclinical and clinical data to demonstrate safety and effectiveness. Instead, in support of such applications, a generic manufacturer may rely on the preclinical and clinical testing previously conducted for a drug product previously approved under a NDA, known as the reference-listed drug, or RLD.

Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is the same as the RLD with respect to the active ingredients, the route of administration, the dosage form, the strength of the drug and the conditions of use of the drug. At the same time, the FDA must also determine that the generic drug is “bioequivalent” to the innovator drug. Under the statute, a generic drug is bioequivalent to a RLD if the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug. Upon approval of an ANDA, the FDA indicates whether the generic product is “therapeutically equivalent” to the RLD in its publication “Approved Drug Products with Therapeutic Equivalence Evaluations,” also referred to as the “Orange Book.” Physicians and pharmacists consider a therapeutic equivalent generic drug to be fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, the FDA’s designation of therapeutic equivalence often results in substitution of the generic drug without the knowledge or consent of either the prescribing physician or patient.

Under the Hatch-Waxman Amendments, the FDA may not approve an ANDA until any applicable period of non-patent exclusivity for the RLD has expired. The FDCA provides a period of five years of non-patent data exclusivity for a new drug containing a new chemical entity. For the purposes of this provision, a new chemical entity, or NCE, is a drug that contains no active moiety, which is the molecule or ion responsible for the physiological or pharmacological action of the drug substance, that has previously been approved by the FDA in any other NDA. In cases where such NCE exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification, which states that the proposed drug will not infringe the already approved product’s listed patents or that such patents are invalid or unenforceable, in which case the applicant may submit its application four years following the original product approval.

The FDCA also provides for a period of three years of exclusivity if the NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or indication. Three-year exclusivity would be available for a drug product that contains a previously approved active moiety, provided the statutory requirement for a new clinical investigation is satisfied. Unlike five-year NCE exclusivity, an award of three-year exclusivity does not block the FDA from accepting ANDAs seeking approval for generic versions of the drug as of the date of approval of the original drug product. The FDA typically makes decisions about awards of data exclusivity shortly before a product is approved.

Pursuant to the Food and Drug Administration Reauthorization Act of 2017, the FDA must establish a priority review track for certain generic drugs, requiring the FDA to review a drug application within eight (8) months for a drug that has three (3) or fewer approved drugs listed in the Orange Book and is no longer protected by any patent or regulatory exclusivities, or is on the FDA’s drug shortage list. The new legislation also authorizes FDA to expedite review of “competitive generic therapies” or drugs with inadequate generic competition, including holding meetings with or providing advice to the drug sponsor prior to submission of the application.

Hatch-Waxman Patent Certification and the 30-Month Stay

Upon approval of a NDA, including a 505(b)(2) NDA, or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant’s product or an approved method of using the product. Each of the patents listed by the NDA sponsor is published in the Orange Book. When an ANDA applicant files its application with the FDA, the applicant is required to certify to the FDA concerning any patents listed for the reference product in the Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval. To the extent that the Section 505(b)(2) applicant relies on studies conducted for an already

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approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would.

Specifically, the applicant must certify with respect to each patent that:

- the required patent information has not been filed;
- the listed patent has expired;
- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- the listed patent is invalid, unenforceable or will not be infringed by the new product.

A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents or indicates that it is not seeking approval of a patented method of use, the application will not be approved until all the listed patents claiming the referenced product have expired (other than method of use patents involving indications for which the applicant is not seeking approval).

If the ANDA or 505(b)(2) applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA or the 505(b)(2) application has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA or 505(b)(2) application until the earlier of 30 months after the receipt of the Paragraph IV notice, expiration of the patent, or a decision in the infringement case that is favorable to the applicant. The ANDA or 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the branded reference drug has expired.

Regulation of Combination Products in the United States

Certain products may be comprised of components, such as drug components and device components, that would normally be regulated under different types of regulatory authorities, and frequently by different centers at the FDA. These products are known as combination products. Specifically, under regulations issued by the FDA, a combination product may be:

- a product comprised of two or more regulated components that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
- two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products;
- a drug, or device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, or device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or
- any investigational drug, or device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

Under the FDCA and its implementing regulations, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. The designation of a lead center generally eliminates the need to receive approvals from more than one FDA component for combination products, although it does not preclude consultations by the lead center with other components of FDA. The determination of which center will be the lead center is based on the "primary mode of action" of the combination product. Thus, if the primary mode of action of a drug-device combination product is attributable to the drug product, the FDA center responsible for premarket review of the drug product would have primary jurisdiction for the combination product. The FDA has also established an Office of Combination Products to address issues surrounding combination

products and provide more certainty to the regulatory review process. That office serves as a focal point for combination product issues for agency reviewers and industry. It is also responsible for developing guidance and regulations to clarify the regulation of combination products, and for assignment of the FDA center that has primary jurisdiction for review of combination products where the jurisdiction is unclear or in dispute.

A combination product with a drug primary mode of action generally would be reviewed and approved pursuant to the drug approval processes under the FDCA. In reviewing the NDA or 505(b)(2) application for such a product, however, FDA reviewers in the drug center could consult with their counterparts in the device center to ensure that the device component of the combination product met applicable requirements regarding safety, effectiveness, durability and performance. In addition, under FDA regulations, combination products are subject to cGMP requirements applicable to both drugs and devices, including the Quality System, or QS, regulations applicable to medical devices.

Drug-device combination products present unique challenges for competitors seeking approval of Abbreviated New Drug Applications, or ANDA, for generic versions of combination products. Generally, FDA reviews both the drug and device constituents of a proposed generic product to determine whether it is the same as the innovator product, including whether the basic design and operating principles of the device component are the same and whether minor differences require significant differences in labeling for safe and effective use. If FDA determines that the device component of the proposed generic product is not the same in terms of performance and critical design, or that the labeling is not the same, it generally will not approve the ANDA. Likewise, if FDA determines that certain clinical studies, such as clinical usability or human factors studies, are necessary to demonstrate the safety and/or effectiveness of the device component, FDA generally will not accept or approve an ANDA for a combination product and will instead require the submission of a full NDA or 505(b)(2) application.

Post-Marketing Requirements

Any products for which we receive FDA approval are subject to continuing regulation by the FDA, including, among other things, monitoring and recordkeeping activities, reporting to the applicable regulatory authorities of adverse events with the product, providing the applicable regulatory authorities with updated safety and efficacy information, and product sampling and distribution requirements in accordance with the Prescription Drug Marketing Act, or PDMA, a part of the FDCA, as well as the Drug Supply Chain Security Act, or DSCSA. The PDMA, its implementing regulations and state laws limit the distribution of prescription pharmaceutical product samples, and the DSCSA imposes requirements to ensure accountability in distribution and to identify and remove counterfeit and other illegitimate products from the market. Moreover, each component of a combination product retains their regulatory status (as a drug or device, for example) and is subject to the requirements established by the FDA for that type of component. The FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market.

Prescription drug advertising is subject to federal, state and foreign regulations. In the United States, the FDA regulates prescription drug promotion and advertising, including direct-to-consumer advertising. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. In addition, a pharmaceutical company must comply with restrictions on promoting drugs for uses or in patient populations that are not described in the drug's approved labeling (known as "off-label use"), limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although physicians may prescribe legally available drugs for off-label uses, manufacturers typically may not market or promote such off-label uses.

In the United States, once a product is approved, its manufacture is subject to comprehensive and continuing regulation by the FDA. The FDA regulations require that combination products be manufactured in specific approved facilities and in accordance with cGMPs applicable to drugs and devices, including certain QS requirements. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies

for compliance with cGMPs and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. These regulations also impose certain organizational, procedural and documentation requirements with respect to manufacturing and quality assurance activities. NDA holders using contract manufacturers, laboratories or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified suppliers to these firms. These firms and, where applicable, their suppliers are subject to inspections by the FDA at any time, and the discovery of violative conditions, including failure to conform to cGMPs, could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute products manufactured, processed or tested by them. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved NDA, including, among other things, recall or withdrawal of the product from the market.

The FDA also may require post-marketing testing, known as Phase 4 testing, REMS and surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, untitled or warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development and impact approved products already on the market.

Other Regulatory Matters

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The failure to comply with regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, voluntary recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, exclusion from federal healthcare programs, or refusal to allow a firm to enter into supply contracts, including government contracts. In addition, even if a firm complies with FDA and other requirements, new information regarding the safety or effectiveness of a product could lead the FDA to modify or withdraw product approval. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the voluntary recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

Orphan Designation and Exclusivity

The FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States. Alternatively, orphan drug designation may be available if the disease or the condition affects more than 200,000 individuals in the United States and there is no reasonable expectation that the cost of developing and making the drug for this type of disease or condition will be recovered from sales in the United States.

Orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. If a product with orphan designation receives the first FDA approval for the disease or condition for which it has such designation or for a select indication or use within the rare disease or condition for which it was designated, the product generally will receive orphan drug exclusivity. Orphan drug exclusivity means that the FDA may not approve another sponsor's marketing application for the same drug for the same condition for seven years, except in certain limited circumstances. Orphan exclusivity does not block the approval of a different drug for the same rare disease or condition, nor does it block the approval of the same drug

for different conditions. If a drug designated as an orphan drug ultimately receives marketing approval for an indication broader than what was designated in its orphan drug application, it may not be entitled to exclusivity.

Orphan drug exclusivity will not bar approval of another product with the same drug for the same condition under certain circumstances, including if a subsequent product with the same drug for the same condition is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care, or if the company with orphan drug exclusivity cannot assure the availability of sufficient quantities of the drug to meet the needs of persons with the disease or condition for which the drug was designated.

Pediatric Studies and Exclusivity

Under the Pediatric Research Equity Act of 2003, as amended, a NDA or supplement thereto must contain data to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. A sponsor who is planning to submit a marketing application for a drug product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must submit an initial Pediatric Study Plan, or PSP, within sixty days of an end-of-phase 2 meeting or as may be agreed between the sponsor and the FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults or full or partial waivers if certain criteria are met. The FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials, and/or other clinical development programs. The requirements for pediatric data generally do not apply to drugs for an indication for which orphan designation has been granted.

Pediatric exclusivity is another type of non-patent exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent five-year and three-year and orphan exclusivity. This six-month exclusivity may be granted if a NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of FDA-requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

Regulations and Procedures Governing Approval of Medicinal Products in the European Union

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, an applicant will need to obtain the necessary approvals by the comparable non-U.S. regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. Specifically, the process governing approval of medicinal products in the European Union ("EU") generally follows the same lines as in the United States. It entails satisfactory completion of pharmaceutical development, preclinical studies and adequate and well-controlled clinical trials to establish the safety and efficacy of the medicinal product for each proposed indication. It also requires the submission to the relevant competent authorities for clinical trials authorization and to the European Medicines Authority, or EMA, for a marketing authorization application, or MAA, and granting of a marketing authorization by these authorities before the product can be marketed and sold in the EU.

European Orphan Designation and Exclusivity

In the European Union, the EMA's Committee for Orphan Medicinal Products, or COMP, grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of

life-threatening or chronically debilitating conditions that affect not more than five in 10,000 persons in the European Union Community, or when, without incentives, it is unlikely that sales of such products in the European Union would be sufficient to justify the necessary investment in developing the products. Additionally, orphan drug designation is only available where no satisfactory method of diagnosis, prevention, or treatment of the condition has been authorized (or the product would be a significant benefit to those affected).

In the European Union, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and 10 years of market exclusivity is granted following medicinal product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. Market exclusivity would not prevent the approval of a similar drug that is shown to be safer, more effective or otherwise clinically superior.

Other Healthcare Laws and Compliance Requirements

In addition to FDA restrictions on the marketing of pharmaceutical products and medical devices, we may be subject to various federal and state laws targeting fraud and abuse in the healthcare industry. Our activities are also subject to regulation by numerous regulatory authorities include the Centers for Medicare & Medicaid Services, or CMS, other divisions of the Department of Health and Human Services, or DHHS, the Department of Justice, or DOJ, the Drug Enforcement Administration, or DEA, the Consumer Product Safety Commission, or CPSC, the Federal Trade Commission, or FTC, the Occupational Safety & Health Administration, or OSHA, the Environmental Protection Agency, or EPA, and state and local governments. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, or AKS, which makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully solicit, receive, offer, receive or pay any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in exchange for, or intended to induce or reward, including arranging for or recommending, either the referral of an individual, or the purchase, lease, order, prescription or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs; a person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act (see below) or federal civil money penalties statute. Violations of the AKS carry potentially significant civil and criminal penalties, including imprisonment, fines, administrative civil monetary penalties, and exclusion from participation in federal healthcare programs;
- federal civil and criminal false claims laws and civil monetary penalties laws, such as the federal False Claims Act, which imposes criminal and civil penalties and authorizes civil whistleblower or qui tam actions, against individuals or entities (including manufacturers) for, among other things: knowingly presenting, or causing to be presented, to a federal government healthcare program, claims for payment that are false or fraudulent; making, using or causing to be made or used, a false statement or record material to payment of a false or fraudulent claim or obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. The government may deem manufacturers to have "caused" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. Our marketing and activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for our products, and the sale and marketing of our products and any future product candidates, are subject to scrutiny under this law;
- the anti-inducement law, which prohibits, among other things, the offering or giving of remuneration, which includes, without limitation, any transfer of items or services for free or for less than fair market value (with limited exceptions), to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of items or services reimbursable by a federal or state governmental program;

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- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which imposes criminal and civil liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program (including private payors) or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by HITECH, and their respective implementing regulations, which impose specified requirements on certain covered healthcare providers, health plans, and healthcare clearinghouse (“covered entities”) as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information, including mandatory contractual terms and required implementation of technical safeguards of such information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associate with pursuing federal civil actions;
- the federal false statements statute, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal transparency requirements under the Affordable Care Act, including the Physician Payments Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program to report annually to the U.S. Department of Health and Human Services information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;
- federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs; and
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.
- The Foreign Corrupt Practices Act, or FCPA, prohibits companies and their intermediaries from making, or offering or promising to make improper payments to non-U.S. officials for the purpose of obtaining or retaining business or otherwise seeking favorable treatment.

Additionally, we are subject to state and non-U.S. equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor. Many U.S. states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare services reimbursed by any source, not just governmental payors, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America’s Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement we could be subject to penalties. Finally, there are state and non-U.S. laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including penalties, fines, disgorgement, imprisonment and/or exclusion or suspension from federal and state healthcare programs such as Medicare and Medicaid and debarment from contracting with the U.S. government. In addition, private individuals have the ability to bring actions on behalf of the U.S. government under the federal False Claims Act as well as under the false claims laws of several states.

Neither the U.S. government nor the U.S. courts have provided definitive guidance on the application of fraud and abuse laws to our business. Law enforcement authorities are increasingly focused on enforcing these laws, and it is possible that some of our practices may be challenged under these laws. Efforts to ensure that our current and future business arrangements with third parties, and our business generally, will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including our arrangements with physicians and other healthcare providers, some of whom receive stock options as compensation for services provided, may not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our drug candidates outside the United States will also likely subject us to non-U.S. equivalents of the healthcare laws mentioned above, among other non-U.S. laws.

If any of the physicians or other healthcare providers or entities with whom we expect to do business with are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, which may also adversely affect our business.

We may be subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

Healthcare Reform

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products. For example, in March 2010, the Affordable Care Act, or the ACA, was enacted, which, among other things, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; introduced a new methodology by which rebates owed by manufacturers under the Medicaid Drug

Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care plans; imposed mandatory discounts for certain Medicare Part D beneficiaries as a condition for manufacturers' outpatient drugs coverage under Medicare Part D; subjected drug manufacturers to new annual fees based on pharmaceutical companies' share of sales to federal healthcare programs; imposed a new federal excise tax on the sale of certain medical devices; created a new Patient Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; created the Independent Payment Advisory Board, which, if impaneled, would have authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs; and established the a Center for Medicare Innovation at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Since its enactment, some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial, Congressional, and Executive challenges. The U.S. Supreme Court has upheld certain key aspects of the legislation, including a tax-based shared responsibility payment imposed on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly the requirement that all individuals maintain health insurance coverage or pay a penalty, referred to as the "individual mandate. However, the current presidential administration has indicated that enacting changes to the ACA is a legislative priority and has discussed repealing and replacing or amending the ACA. While Congress has not passed repeal legislation to date, the 2017 Tax Reform Act includes a provision repealing the individual mandate, effective January 1, 2019.

Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. One Executive Order directs federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The second Executive Order terminates the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. In addition, CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results. We continue to evaluate the effect that the Affordable Care Act and its possible repeal and replacement could have on our business.

In addition, the Budget Control Act of 2011 and the Bipartisan Budget Act of 2015 led to aggregate reductions of Medicare payments to providers of up to 2% per fiscal year that will remain in effect through 2027 unless additional Congressional action is taken. Further, on January 2, 2013, the American Taxpayer Relief Act was signed into law, which, among other things, reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. More recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which have resulted in several recent Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that additional foreign, federal and state healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our products, once approved, or additional pricing pressures.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidate for which we obtain regulatory approval. In the United States and markets in other countries, sales of any product candidates for which we receive regulatory approval for commercial sale will depend, in part, on the availability of coverage and reimbursement from third-party payors. Third-party payors include government authorities, managed care providers, private health insurers and other organizations. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the reimbursement rate that the payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication. A decision by a third-party payor not to cover our product candidates could reduce physician utilization of our products once approved and have a material adverse effect on our sales, results of operations and financial condition. Moreover, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

In addition, coverage and reimbursement for products can differ significantly from payor to payor. One third-party payor's decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service, or will provide coverage at an adequate reimbursement rate. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payor separately and will be a time-consuming process.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. In order to obtain and maintain coverage and reimbursement for any product, we may need to conduct expensive clinical trials in order to demonstrate the medical necessity and cost-effectiveness of such product, in addition to the costs required to obtain regulatory approvals. Our products may not be considered medically necessary or cost-effective. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit.

The United States government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price-controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, and mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Adoption of general controls and measures, coupled with the tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceutical drugs.

The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the Department of Health and Human Services as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. Effective in 2010, the ACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs from 15.1% of average manufacturer price, or AMP, to 23.1% of AMP, and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, creating a new methodology by which rebates owed by are calculated for drugs that are inhaled, infused, instilled, implanted or injected, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The ACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization as of 2010 and by expanding the population potentially eligible for Medicaid drug benefits (phased-in by 2014). Pricing and rebate programs must also comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990.

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The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Unlike Medicare Parts A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. While all Medicare drug plans must give at least a standard level of coverage set by Medicare, Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for drugs for which we obtain marketing approval. Any negotiated prices for any of our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

For a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer. As of 2010, the ACA expanded the types of entities eligible to receive discounted 340B pricing, although under the current state of the law these newly eligible entities (with the exception of children's hospitals) will not be eligible to receive discounted 340B pricing on orphan drugs. As 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase. The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. The plan for the research was published in 2012 by the Department of Health and Human Services, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures are made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the research will have on the sales of our drug candidates, if any such drug or the condition that they are intended to treat are the subject of a trial. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's drug could adversely affect the sales of our drug candidate. If third-party payors do not consider our drugs to be cost-effective compared to other available therapies, they may not cover our drugs after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our drugs on a profitable basis.

In recent years, additional laws have resulted in direct or indirect reimbursement reductions for certain Medicare providers, including:

- The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2027 unless additional Congressional action is taken.
- The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.
- The Middle Class Tax Relief and Job Creation Act of 2012 required that the Centers for Medicare & Medicaid Services reduce the Medicare clinical laboratory fee schedule by 2% in 2013, which served as a base for 2014 and subsequent years. In addition, effective January 1, 2014, CMS also began bundling the Medicare payments for certain laboratory tests ordered while a patient received services in a hospital outpatient setting.

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These laws, and future state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

As noted above, the marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. We expect that an increasing emphasis on cost containment measures in the United States will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Further, there have been several recent U.S. congressional inquiries and proposed federal and proposed and enacted state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. At the federal level, Congress and the Trump administration have each indicated that it will continue to pursue new legislative and/or administrative measures to control drug costs. Individual state legislatures have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing. Some of these measures include price or patient reimbursement constraints, discounts, restrictions on certain product access, marketing cost disclosure and transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

Outside of the United States, the pricing of pharmaceutical products and medical devices is subject to governmental control in many countries. For example, in the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular therapy to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. Other countries may allow companies to fix their own prices for products, but monitor and control product volumes and issue guidance to physicians to limit prescriptions. Efforts to control prices and utilization of pharmaceutical products and medical devices will likely continue as countries attempt to manage healthcare expenditures.

Employees

As of March 1, 2018, we had 46 employees, 23 of whom were primarily engaged in product development and research, 22 of whom were primarily engaged in administration and finance and, one of whom was primarily engaged in sales and marketing. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

Facilities

Our principal office is located in Chicago, Illinois. Our Chicago office occupies approximately 16,045 square feet of leased space. The lease term expires on November 30, 2024. We also maintain a product development site in San Diego, California. We currently occupy temporary space in San Diego as our permanent space is under construction. We expect that work to be completed by mid-year 2018. Our permanent San Diego office will occupy approximately 17,105 square feet of leased space under a 60-month lease. We believe that the Chicago office coupled with our permanent San Diego office will be suitable and adequate to meet our current needs.

Legal Proceedings

We are not aware of any pending or threatened legal proceeding against us that could have a material adverse effect on our business, operating results or financial condition. The medical device industry is characterized by frequent claims and litigation, including claims regarding patent and other intellectual property rights as well as improper hiring practices. As a result, we may be involved in various additional legal proceedings from time to time.

MANAGEMENT

The following table sets forth information about our directors and executive officers as of _____, 2018.

<u>NAME</u>	<u>AGE</u>	<u>POSITION(S)</u>
Executive Officers		
Paul Edick	62	President, Chief Executive Officer and Director
Barry Deutsch	55	Chief Financial Officer
John Shannon	56	Executive Vice President, Chief Operating Officer
Steven Prestrelski	54	Chief Scientific Officer
Ken Johnson	56	Senior Vice President, Clinical Development, Regulatory, Quality Assurance and Medical Affairs
Non-Employee Directors		
BJ Bormann	59	Director
Dawn Halkuff	47	Director
Marla Persky	62	Director
Jonathan Rigby	51	Director
John Schmid	55	Director
Jeffrey Sherman	63	Director

(1) Member of our audit committee

(2) Member of our compensation committee

(3) Member of our nominating and corporate governance committee

Executive Officers

Paul Edick. Mr. Edick joined our company in January 2017 as President and Chief Executive Officer. Previously, Mr. Edick was a founding partner of 3G Advisors, a consultancy firm to the pharmaceutical, healthcare and healthcare investor communities. From 2010 to 2014, Mr. Edick was the chief executive officer of Durata Therapeutics, Inc. prior to its acquisition in November 2014. Prior to that, Mr. Edick was chief executive officer of Ganic Pharmaceuticals, Inc., a Warburg Pincus investment search vehicle, from 2008 to 2010. Before that, from 2006 to 2008, Mr. Edick was chief executive officer of MedPointe Healthcare, Inc. and served as its president of pharmaceutical operations from 2002 to 2006.

Mr. Edick currently serves on the board of directors for PDL BioPharma, Inc. and Iterum Therapeutics Limited. Mr. Edick has also previously served on a number of pharmaceutical and healthcare company boards including Circassia Pharmaceuticals Plc, Sucampo Pharmaceuticals, Inc., Durata Therapeutics, Amerita, Inc. and Informed Medical Communications, Inc. Mr. Edick received a B.A. degree in psychology from Hamilton College. We believe Mr. Edick is qualified to serve on our board of directors because of his management and industry experience.

Barry Deutsch. Mr. Deutsch joined our company in July 2017 as our vice president, business development. In April 2018, Mr. Deutsch was appointed as our Chief Financial Officer. Previously, from 2007 to 2017, Mr. Deutsch was a vice president for the BioScience Division of Baxter Healthcare Corporation, Baxalta Incorporated following its spinoff from Baxter, and Shire plc following its acquisition of Baxalta. Mr. Deutsch's roles included serving as a member of the Baxter senior management team, vice president of business development at Baxter BioScience and Baxalta and head of business development and public-private partnerships for the intercontinental region at Baxalta and Shire.

Mr. Deutsch received a B.S. in Economics degree in finance and accounting from The Wharton School of the University of Pennsylvania and an M.B.A. from the Kellogg School of Management at Northwestern University.

John Shannon. Mr. Shannon joined our company in February 2017 as Chief Operating Officer. Previously, from 2015 until its acquisition in 2016, Mr. Shannon served as chief executive officer and director for Catheter Connections, Inc. Prior to that, from 2011 to until its acquisition in 2014, Mr. Shannon served as chief commercial officer for Durata Therapeutics. From 2002 to 2014, he served as vice president and general manager of Baxter BioScience.

Mr. Shannon received a B.S. degree in biology with an emphasis in microbiology from Western Illinois University.

Steve Prestrelski, Ph.D. Dr. Prestrelski is one of our co-founders. He has served as our Chief Scientific Officer since 2005 and as our Interim Chief Executive Officer from 2013 to 2014. He also served on our board of directors from 2005 to 2015. Dr. Prestrelski is the inventor of our platform technologies. Prior to joining our company, from 2003 to 2011, Dr. Prestrelski was vice president of pharmaceutical R&D at Amylin Pharmaceuticals. At Amylin, from 2003 to 2005, he was the executive director of the Bydureon program. From 1998 to 2002, Dr. Prestrelski was vice president, biopharmaceuticals at PowderJect Technologies, Inc. Dr. Prestrelski serves on the board of directors of BaroFold, Inc. and on the scientific advisory board of iMEDD, Inc. Dr. Prestrelski served on the scientific advisory board of GIRx Metabolics from 2012 to 2014.

Dr. Prestrelski has a B.S. in nutrition science from Drexel University, a Ph.D. in molecular biophysics from the City University of New York and an M.B.A from Rady School of Management at the University of California, San Diego.

Ken Johnson, Pharm. D. Dr. Johnson joined our company in March 2017. Prior to that, from 2016 to 2017, Dr. Johnson served as executive director, U.S. medical affairs for hospital specialty products at Merck. Previously, Dr. Johnson served as vice president of global medical affairs at Circassia Pharmaceuticals from 2015 to 2016 and as vice president of corporate medical affairs at Durata Therapeutics from 2012 to 2015. Prior to his time at Durata, Mr. Johnson also held senior management positions in medical affairs at Horizon Pharma, Inc., Takeda Pharmaceuticals North America, NeoPharm, Inc., Searle/Pharmacia Pharmaceuticals and Bristol-Myers Squibb.

Dr. Johnson received a B.S. in pharmacy and Pharm. D. from the University of Minnesota and completed a post-doctoral fellowship at the University of Tennessee Health Sciences Center.

Non-Employee Directors

BJ Bormann, Ph.D. Dr. Bormann has served on our board of directors since April 2018. Dr. Bormann has served as chief executive officer and as a member of the board of directors of Pivot Pharmaceuticals Inc. since 2015. Dr. Bormann also serves as the interim chief executive officer of Supportive Therapeutics, LLC and was previously the chief executive officer of Harbour Antibodies from 2015 to 2017 and the chief business advisor for NanoMedical Systems, Inc. From 2007 to 2013, Dr. Bormann was a senior vice president, world-wide alliances, licensing and business development at Boehringer Ingelheim Pharmaceuticals, Inc. Dr. Bormann currently serves on the board of directors of various companies, including Supportive Therapeutics, LLC, the Institute for Pediatric Innovation and Bioline RX.

Dr. Bormann received her Ph.D. in biomedical science from the University of Connecticut Health Center and her B.Sc. from Fairfield University in biology. Dr. Bormann completed postdoctoral training at Yale Medical School in the department of pathology. We believe Dr. Bormann is qualified to serve on our board of directors because of her experience in the industry in which we operate.

Dawn Halkuff. Ms. Halkuff has served on our board of directors since April 2018. Since 2016, Ms. Halkuff has served as the chief commercial officer of TherapeuticsMD, Inc. Prior to that, Ms. Halkuff held numerous senior level positions at Pfizer, Inc., the Pfizer Consumer Healthcare Wellness Organization and a member of its Consumer Global Leadership Team, including roles as senior vice president, global wellness, vice president, women's health sales and marketing and senior director, women's health products. Prior to that, Ms. Halkuff was the commercial lead for sales and marketing of the Pfizer's Women's Health Division. From 2005 to 2010, Ms. Halkuff was head of global innovation at Weight Watchers International.

Ms. Halkuff has a B.A. degree in psychology from University of Connecticut and an M.B.A from Pennsylvania State University. We believe Ms. Halkuff is qualified to serve on our board of directors because of her experience in the industry in which we operate.

Marla S. Persky. Ms. Persky has served on our board of directors since Since 2014, Ms. Persky has served as the chief executive officer and president of WOMN, LLC, a consulting and coaching organization. From 2005 to 2013, Ms. Persky was senior vice president, general counsel and corporate secretary of Boehringer Ingelheim USA, a pharmaceutical company. April 2018. Ms. Persky also serves on the board of directors of Text IQ, Inc. and Ygeia Group, Inc.

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Ms. Persky has a B.S.S. degree in speech sciences from Northwestern University and a J.D. from Washington University School of Law. We believe Ms. Persky is qualified to serve on our board of directors because of her experience in the industry in which we operate.

Jonathan Rigby. Mr. Rigby has served as on our board of directors since March 2016. In 2011, Mr. Rigby founded SteadyMed Therapeutics Inc. and has since served as its president, chief executive officer and director. Prior to founding SteadyMed, Mr. Rigby cofounded Zogenix Inc., a specialty pharmaceutical company focused on the development and commercialization of central nervous system and pain products, where he served as its vice president of business development from 2006 until December 2011.

Mr. Rigby has a B.S. degree in biological sciences from Sheffield University (UK) and an M.B.A. from Portsmouth University (UK). We believe Mr. Rigby is qualified to serve on our board of directors because of his experience in the industry in which we operate.

John Schmid. Mr. Schmid has served on our board of directors since September 2017. Mr. Schmid currently serves as a member of the board of directors of Neos Therapeutics, Inc., AnaptysBio Inc., Forge Therapeutics, Inc., Patara Pharma, Inc. and Speak, Inc. Previously, he was the chief financial officer of Auspex Pharmaceuticals, Inc. from 2013 until its acquisition in 2015. Prior to joining Auspex Pharmaceuticals, Mr. Schmid cofounded Trius Therapeutics, Inc. in 2004, where he served as chief financial officer until its sale in 2013.

Mr. Schmid received a B.A. in economics from Wesleyan University and an M.B.A. from the University of San Diego. We believe Mr. Schmid is qualified to serve on our board of directors because of his experience, including financial experience, in the industry in which we operate.

Jeffrey Sherman, M.D., FACP. Dr. Sherman has served on our board of directors since April 2018. Since 2009, Dr. Sherman has served as the chief medical officer and executive vice president at Horizon Pharma plc. Dr. Sherman serves on the board of directors of Strongbridge Biopharma plc and is a member of a number of professional societies, a diplomat of the National Board of Medical Examiners and the American Board of Internal Medicine, and also serves on the Board of Advisors of the Center for Information and Study on Clinical Research Participation. He previously held positions at IDM Pharma Takeda Global Research and Development, Neopharm, Searle/Pharmacia, Bristol-Myers Squibb, and is past president of the Drug Information Association.

Dr. Sherman received a B.A. in Biology from Lake Forest College and earned his M.D. from the Rosalind Franklin University of Medicine and Science/The Chicago Medical School. Dr. Sherman completed internship and residency programs at Northwestern University Feinberg School of Medicine, where he currently serves as an adjunct assistant professor, and a fellowship program at the University of California San Francisco. We believe Mr. Sherman is qualified to serve on our board of directors because of his experience in the industry in which we operate.

Board Composition

Our board of directors currently consists of seven members, each of whom is a member pursuant to the board composition provisions of our current certificate of incorporation and agreements with our stockholders. These board composition provisions will terminate upon the completion of this offering. Upon the termination of these provisions, there will be no further contractual obligations regarding the election of our directors. Our nominating and corporate governance committee and our board of directors may therefore consider a broad range of factors relating to the qualifications and background of nominees. Our nominating and corporate governance committee's and our board of directors' priority in selecting board members is identification of persons who will further the interests of our stockholders through their established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, knowledge of our business, understanding of the competitive landscape, professional and personal experiences and expertise relevant to our growth strategy. Our directors hold office until their successors have been elected and qualified or until the earlier of their resignation or removal. Our amended and restated certificate of incorporation and amended and restated bylaws that will become effective upon the closing of this offering also provide that our directors may be removed only for cause by the affirmative vote of the holders of at least two-thirds of the votes that all our stockholders would be entitled to cast in an annual election of directors, and that any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

Staggered Board

In accordance with the terms of our amended and restated certificate of incorporation and our amended and restated bylaws that will become effective upon the closing of this offering, our board of directors will be divided into three staggered classes of directors and each will be assigned to one of the three classes. At each annual meeting of the stockholders, a class of directors will be elected for a three-year term to succeed the directors of the same class whose terms are then expiring. The terms of the directors will expire upon the election and qualification of successor directors at the annual meeting of stockholders to be held during the years 2019 for Class I directors, 2020 for Class II directors and 2021 for Class III directors.

- Our Class I directors will be Jonathan Rigby and BJ Bormann;
- Our Class II directors will be Jeffrey Sherman and Dawn Halkuff; and
- Our Class III directors will be Paul Edick, John Schmid and Marla Persky.

Our amended and restated certificate of incorporation and amended and restated bylaws that will become effective upon the closing of this offering will provide that the number of our directors shall be fixed from time to time by a resolution of the majority of our board of directors.

The division of our board of directors into three classes with staggered three-year terms may delay or prevent stockholder efforts to effect a change of our management or a change in control.

Board Independence

We intend to apply to list our common stock on The Nasdaq Global Market. Under the rules of The Nasdaq Global Market, independent directors must comprise a majority of a listed company's board of directors within twelve months from the date of listing. In addition, The Nasdaq Global Market rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and governance committees be independent within twelve months from the date of listing. Audit committee members must also satisfy additional independence criteria, including those set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and compensation committee members must also satisfy the independence criteria set forth in Rule 10C-1 under the Exchange Act. Under The Nasdaq Global Market rules, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3 under the Exchange Act, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee: (1) accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries, other than compensation for board service; or (2) be an affiliated person of the listed company or any of its subsidiaries. In order to be considered independent for purposes of Rule 10C-1, the board of directors must consider, for each member of a compensation committee of a listed company, all factors specifically relevant to determining whether a director has a relationship to such company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to: the source of compensation of the director, including any consulting advisory or other compensatory fee paid by such company to the director, and whether the director is affiliated with the company or any of its subsidiaries or affiliates.

In _____, 2018, our board of directors undertook a review of the composition of our board of directors and its committees and the independence of each director. Based upon information requested from and provided by each director concerning his background, employment and affiliations, including family relationships, our Board of Directors has determined that none of our non-employee directors has a material relationship with us that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" in accordance with the rules of The Nasdaq Global Market. In making that determination, our board of directors considered the relationships that each of those non-employee directors has with us and all other facts and circumstances the board of directors deemed relevant in determining independence, including the potential deemed beneficial ownership of our capital stock by each non-employee director, including non-employee directors that are affiliated with certain of our major stockholders. Mr. Edick is not an independent director under these rules because he is an executive officer of our company.

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Our board of directors does not currently have a process for security holders to send communications to the Board. The Board intends to implement such a process as soon as practicable.

Board Committees

Our board of directors has established an audit committee, a compensation committee, and a nominating and corporate governance committee.

Audit Committee

Upon the effectiveness of the registration statement of which this prospectus forms a part, our audit committee will consist of John Schmid, Jonathan Rigby and Marla Persky and will be chaired by John Schmid. The functions of the audit committee will include:

- appointing, approving the compensation of, and assessing the independence of our independent registered public accounting firm;
- pre-approving auditing and permissible non-audit services, and the terms of such services, to be provided by our independent registered public accounting firm;
- reviewing the overall audit plan with our independent registered public accounting firm and members of management responsible for preparing our financial statements;
- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures as well as critical accounting policies and practices used by us;
- coordinating the oversight and reviewing the adequacy of our internal control over financial reporting;
- establishing policies and procedures for the receipt and retention of accounting-related complaints and concerns;
- recommending based upon the audit committee's review and discussions with management and our independent registered public accounting firm whether our audited financial statements shall be included in our Annual Report on Form 10-K;
- monitoring the integrity of our financial statements and our compliance with legal and regulatory requirements as they relate to our financial statements and accounting matters;
- preparing the audit committee report required by SEC rules to be included in our annual proxy statement;
- reviewing all related person transactions for potential conflict of interest situations and approving all such transactions; and
- reviewing quarterly earnings releases.

All members of our audit committee will meet the requirements for financial literacy under the applicable rules and regulations of the SEC and The Nasdaq Global Market. Our Board of Directors has determined that John Schmid qualifies as an audit committee financial expert within the meaning of applicable SEC regulations. In making this determination, our Board of Directors considered the nature and scope of experience that John Schmid has previously had with public reporting companies. Our Board of Directors has determined that all of the current members of our audit committee satisfy the relevant independence requirements for service on the audit committee set forth in the rules of the SEC and the listing requirements of The Nasdaq Global Market. Both our independent registered public accounting firm and management will periodically meet privately with our audit committee.

In connection with this offering, our board of directors will adopt a written audit committee charter. We believe that the composition of our audit committee, and our audit committee's charter and functioning, will comply with the applicable requirements of The Nasdaq Global Market and SEC rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

Following the consummation of this offering, the full text of our audit committee charter will be posted on the investor relations portion of our website at <https://www.xerispharma.com/>. We do not incorporate the information contained on, or accessible through, our corporate website into this prospectus, and you should not consider it a part of this prospectus.

Compensation Committee

Upon the effectiveness of the registration statement of which this prospectus forms a part, our compensation committee will consist of BJ Bormann, John Schmid, Jeffrey Sherman and Dawn Halkuff, and will be chaired by Barbara-Jean Bormann. The functions of the compensation committee will include:

- annually reviewing and recommending to the board of directors the corporate goals and objectives relevant to the compensation of our Chief Executive Officer;
- evaluating the performance of our Chief Executive Officer in light of such corporate goals and objectives and based on such evaluation (i) reviewing and determining the cash compensation of our Chief Executive Officer and (ii) reviewing and approving grants and awards to our Chief Executive Officer under equity-based plans;
- reviewing and approving the cash compensation of our other executive officers;
- reviewing and establishing our overall management compensation, philosophy and policy;
- overseeing and administering our compensation and similar plans;
- evaluating and assessing potential and current compensation advisors in accordance with the independence standards identified in the applicable Nasdaq rules;
- reviewing and approving our policies and procedures for the grant of equity-based awards;
- reviewing and recommending to the board of directors the compensation of our directors;
- preparing our compensation committee report if and when required by SEC rules;
- reviewing and discussing annually with management our "Compensation Discussion and Analysis," if and when required, to be included in our annual proxy statement; and
- reviewing and approving the retention or termination of any consulting firm or outside advisor to assist in the evaluation of compensation matters.

Each member of our compensation committee will be a non-employee director, as defined in Rule 16b-3 promulgated under the Exchange Act, and an outside director, as defined pursuant to Section 162(m) of the Internal Revenue Code of 1986. Furthermore, we believe that, upon the consummation of this offering, the composition of our compensation committee, and our compensation committee's charter and functioning, will comply with the listing requirements of The Nasdaq Global Market and SEC rules and regulations.

In connection with this offering, our board of directors will adopt a written compensation committee charter. We believe that the composition of our compensation committee, and our compensation committee's charter and functioning, will comply with the applicable requirements of The Nasdaq Global Market and SEC rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

Following the consummation of this offering, the full text of our compensation committee charter will be posted on the investor relations portion of our website at <https://www.xerispharma.com/>. We do not incorporate the information contained on, or accessible through, our corporate website into this prospectus, and you should not consider it a part of this prospectus.

Nominating and Corporate Governance Committee

Upon the effectiveness of the registration statement of which this prospectus forms a part, our nominating and corporate governance committee will consist of Jonathan Rigby, Marla Persky, BJ Bormann and Dawn Halkuff and will be chaired by Jonathan Rigby. The functions of the nominating and corporate governance committee will include:

- developing and recommending to the board of directors criteria for board and committee membership;
- establishing procedures for identifying and evaluating board of director candidates, including nominees recommended by stockholders;
- reviewing the composition of the board of directors to ensure that it is composed of members containing the appropriate skills and expertise to advise us;
- identifying individuals qualified to become members of the board of directors;
- recommending to the board of directors the persons to be nominated for election as directors and to each of the board's committees;

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- developing and recommending to the board of directors a code of business conduct and ethics and a set of corporate governance guidelines; and
- overseeing the evaluation of our board of directors and management.

In connection with this offering, our board of directors will adopt a written nominating and corporate governance committee charter. We believe that the composition of our nominating and corporate governance committee, and our nominating and corporate governance committee's charter and functioning, will comply with the requirements of The Nasdaq Global Market and SEC rules and regulations that will be applicable to us. We intend to comply with future requirements to the extent they become applicable to us.

Following the consummation of this offering, the full text of our nominating and corporate governance committee charter will be posted on the investor relations portion of our website at <https://www.xerispharma.com/>. We do not incorporate the information contained on, or accessible through, our corporate website into this prospectus, and you should not consider it a part of this prospectus.

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee is, or has at any time during the prior three years been, one of our officers or employees. None of our executive officers currently serve, or have in the past fiscal year served, as a member of the board of directors or compensation committee of any entity that has one or more of its executive officers serving as a member of our board of directors or our compensation committee.

Code of Business Conduct and Ethics

Our board of directors intends to adopt, subject to and effective upon the effectiveness of the registration statement of which this prospectus forms a part, a Code of Business Conduct and Ethics in connection with this offering. The Code of Business Conduct and Ethics will apply to all of our employees, officers (including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions), agents and representatives, including directors and consultants.

We intend to disclose future amendments to certain provisions of our Code of Business Conduct and Ethics and our Code of Ethics for our Chief Executive Officer, Chief Financial Officer and Principal Accounting Officer, or waivers of those provisions, applicable to any principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions or our directors on our website identified below or in a current report on Form 8-K. Upon the completion of this offering, the full text of our Code of Business Conduct and Ethics and our Code of Ethics for our Chief Executive Officer, Chief Financial Officer and Principal Accounting Officer will be posted on our website at <http://www.xerispharma.com>. The inclusion of our website address in this prospectus does not include or incorporate by reference the information on our website into this prospectus, and you should not consider that information a part of this prospectus.

Limitations on Liability and Indemnification Agreements

As permitted by Delaware law, provisions in our amended and restated certificate of incorporation and amended and restated bylaws, both of which will become effective upon the consummation of this offering, limit or eliminate the personal liability of directors for a breach of their fiduciary duty of care as a director. The duty of care generally requires that, when acting on behalf of the corporation, a director exercise an informed business judgment based on all material information reasonably available to him or her. Consequently, a director will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any act related to unlawful stock repurchases, redemptions or other distributions or payments of dividends; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not limit or eliminate our rights or any stockholder's rights to seek non-monetary relief, such as injunctive relief or rescission. These provisions will not alter a director's liability under other laws,

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such as the federal securities laws or other state or federal laws. Our amended and restated certificate of incorporation that will become effective upon the completion of this offering also authorizes us to indemnify our officers, directors and other agents to the fullest extent permitted under Delaware law.

As permitted by Delaware law, our amended and restated bylaws to be effective upon the consummation of this offering will provide that:

- we will indemnify our directors, officers, employees and other agents to the fullest extent permitted by law;
- we must advance expenses to our directors and officers, and may advance expenses to our employees and other agents, in connection with a legal proceeding to the fullest extent permitted by law; and
- the rights provided in our amended and restated bylaws are not exclusive.

If Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of a director or officer, then the liability of our directors or officers will be so eliminated or limited to the fullest extent permitted by Delaware law, as so amended. Our bylaws also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in connection with their services to us, regardless of whether our bylaws permit such indemnification. We have obtained such insurance.

In addition to the indemnification that will be provided for in our amended and restated certificate of incorporation and amended and restated bylaws, we will enter into separate indemnification agreements with each of our directors and executive officers, which may be broader than the specific indemnification provisions contained in the Delaware General Corporation Law. These indemnification agreements may require us, among other things, to indemnify our directors and executive officers for some expenses, including attorneys' fees, expenses, judgments, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of his service as one of our directors or executive officers or any other company or enterprise to which the person provides services at our request. We believe that these provisions and agreements are necessary to attract and retain qualified individuals to serve as directors and executive officers.

This description of the indemnification provisions of our amended and restated certificate of incorporation, our amended and restated bylaws and our indemnification agreements is qualified in its entirety by reference to these documents, each of which is attached as an exhibit to the registration statement of which this prospectus forms a part.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable.

There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer

EXECUTIVE COMPENSATION

Executive Compensation Overview

As an emerging growth company, we have opted to comply with the executive compensation disclosure rules applicable to “smaller reporting companies,” as such term is defined in the rules promulgated under the Securities Act. This section provides an overview of the compensation awarded to, earned by, or paid to each individual who served as our principal executive officer at any time during fiscal year 2017, and our next two most highly compensated executive officers in respect of their service to our company for our fiscal year ended December 31, 2017. We refer to these individuals as our named executive officers. Our named executive officers are:

- Paul Edick, our President and Chief Executive Officer effective January 10, 2017;
- Nora Brennan, our Former Chief Financial Officer;
- John Shannon, our Executive Vice President and Chief Operating Officer; and
- Doug Baum, who served as our President and Chief Executive Officer through January 10, 2017.

Our executive compensation program is based on a pay for performance philosophy. Compensation for our executive officers is composed primarily of the following main components: base salary; bonus; and equity incentives in the form of options. Our executive officers, like all full-time employees, are eligible to participate in our health and welfare benefit plans. As we transition from a private company to a publicly traded company, we intend to evaluate our compensation values and philosophy and compensation plans and arrangements as circumstances require.

2017 Summary Compensation Table

The following table sets forth information regarding compensation awarded to, earned by, or paid to our named executive officers for services rendered to us in all capacities during the fiscal year ended December 31, 2017.

NAME AND PRINCIPAL POSITION	YEAR	SALARY (\$)	OPTION AWARDS (\$) ⁽¹⁾	NON-EQUITY PLAN COMPENSATION \$ ⁽²⁾	ALL OTHER COMPENSATION (\$) ⁽³⁾	TOTAL (\$)
Paul Edick, <i>President and Chief Executive Officer</i> ⁽⁴⁾	2017	489,583	657,134	250,000	—	1,396,717
Nora Brennan, <i>Former Chief Financial Officer</i> ⁽⁵⁾	2017	147,917	166,192	64,167	—	378,276
John Shannon, <i>Executive Vice President and Chief Operating Officer</i> ⁽⁶⁾	2017	218,750	168,029	100,834	—	487,613
Doug Baum <i>Former President and Chief Executive Officer</i> ⁽⁷⁾	2017	10,781	—	—	291,949	302,730

(1) Amounts reflect the grant date fair value of option awards granted or modified in 2017 in accordance with the Financial Accounting Standards Board's Accounting Standards Codification Topic 718, or ASC 718. Such grant date fair value does not take into account any estimated forfeitures related to service-vesting conditions. For information regarding assumptions underlying the valuation of equity awards, see Note 2 to our financial statements and the discussion under “Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and the Use of Estimates—Stock based compensation” included elsewhere in this prospectus. These amounts do not correspond to the actual value that may be recognized by the named executive officers upon vesting of applicable awards.

(2) The amounts reported reflect a cash bonus approved by our board of directors based on achievement of individual and company performance goals in 2017, prorated for partial years of service with respect to Ms. Brennan and Mr. Shannon.

(3) The amounts reported reflect severance payments paid in connection with Mr. Baum's separation agreement.

(4) Mr. Edick commenced his employment with us in January 2017.

(5) As of April 2018, Ms. Brennan is no longer employed by us.

(6) Mr. Shannon commenced his employment with us in February 2017.

(7) Mr. Baum entered into a separation agreement with us on December 13, 2016, whereby he stepped down as President and Chief Executive Officer on January 10, 2017. As part of his separation agreement, as modified on January 6, 2017, he received salary

continuation in 2017 for nine months in an aggregate amount equal to \$210,848, COBRA continuation benefits from us for nine months in an amount equal to \$7,873, and forgiveness by us of the outstanding balance under a certain note and pledge agreement dated October 22, 2013 by and between us and Mr. Baum in the amount of \$73,227.

Narrative to the 2017 Summary Compensation Table

Base Salary

We use base salaries to recognize the experience, skills, knowledge and responsibilities required of all our employees, including our named executive officers. Base salaries are reviewed annually, typically in connection with our annual performance review process, and adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance and experience.

Annual Bonus

We do not have a formal performance-based bonus plan. Our employment agreements with our named executive officers provide that the executive may be eligible to earn an annual performance bonus of up to a target percentage of the executive's base salary, as described further below under the section entitled "—Employment Arrangements and Severance Agreements with our Named Executive Officers". From time to time, our board of directors or compensation committee may approve annual bonuses for our named executive officers based on individual performance, company performance or as otherwise determined to be appropriate.

Equity Compensation

Although we do not have a formal policy with respect to the grant of equity incentive awards to our executive officers, or any formal equity ownership guidelines applicable to them, we believe that equity grants provide our executive officers with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executive officers and our stockholders. In addition, we believe that equity grants with a time-based vesting feature promote executive retention because this feature incentivizes our executive officers to remain in our employment during the vesting period. Accordingly, our board of directors periodically reviews the equity incentive compensation of our named executive officers and from time to time may grant equity incentive awards to them in the form of stock options.

We typically grant stock option awards at the start of employment to each executive officer and our other employees as well as on an annual basis for retention purposes. We award our stock options on the date our board of directors approves the grant. We set the option exercise price and grant date fair value based on our per-share estimated valuation on the date of grant.

Employment Arrangements and Severance Agreements with our Named Executive Officers

We have entered into employment agreements with each of our named executive officers. These agreements set forth the initial terms and conditions of each executive's employment with us, including base salary, target annual bonus opportunity and standard employee benefit plan participation. In connection with this offering, we intend to enter into new employment agreements with each of our named executive officers.

These employment agreements provide for "at will" employment. The material terms of these employment agreements with our named executive officers are described below. The terms "cause" and "change in control" used in each existing employment agreement are defined in each employment agreement.

Paul Edick

We entered into an employment agreement with Mr. Paul Edick, our President and Chief Executive Officer, on January 9, 2017, pursuant to which Mr. Edick is entitled to receive an annual base salary of \$500,000, an annual target bonus equal to 50% of his annual base salary based upon our board of directors' assessment of Mr. Edick's performance and our attainment of targeted goals approved by the board of directors, an equity grant and eligibility to participate in our benefit plans generally. This employment agreement also contains provisions related to confidentiality, inventions assignment and non-competition, pursuant to which Mr. Edick agrees to refrain from disclosing our confidential information, re-affirms the obligations contained in his Proprietary Information and Inventions Agreement and agrees not to compete with us during his employment.

Mr. Edick's employment agreement provides that, in the event that his employment is terminated by us without "cause" or by him upon a "material change" (as each term is defined in the employment agreement), subject to the

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execution and effectiveness of a separation agreement and release, he will be entitled to receive (in addition to accrued compensation and benefits through the date of termination) (i) salary continuation based on his then-current base salary for 11 months and (ii) reimbursement of COBRA premiums for health benefit coverage for him and his immediate family in an amount equal to the monthly employer contribution that we would have made to provide health insurance to Mr. Edick had he remained employed with us for up to 11 months following termination.

Upon a "change in control," subject to the execution and effectiveness of a release, Mr. Edick shall be eligible to receive a lump sum amount equal to 18 months of his then-current base salary (but in no event less than \$500,000), his annual target bonus reflective for a period of 18 months and 100% accelerated vesting of his outstanding stock options. Furthermore, the employment agreement provides that our board of directors may, in its sole discretion, consider providing Mr. Edick with a transaction bonus at the time of a "change in control". If he is terminated upon the effectiveness of the "change in control," he shall also receive reimbursement of COBRA premiums for health benefit coverage for him and his immediate family in an amount equal to the monthly employer contribution that we would have made to provide health insurance to Mr. Edick had he remained employed with us for up to 18 months following termination.

Nora Brennan

We entered into an employment agreement with Ms. Nora Brennan, our Chief Financial Officer, on May 11, 2017, pursuant to which Ms. Brennan was entitled to receive an annual base salary of \$275,000, an annual target bonus equal to 40% of her annual base salary based upon our board of directors' assessment of Ms. Brennan's performance and our attainment of targeted goals approved by the board of directors, an equity grant and eligibility to participate in our benefit plans generally. This employment agreement also contained provisions related to confidentiality, inventions assignment and non-competition agreement with us, pursuant to which Ms. Brennan agreed to refrain from disclosing our confidential information, re-affirms the obligations contained in her Proprietary Information and Inventions Agreement and agrees not to compete with us during her employment.

Ms. Brennan's employment agreement provided that, in the event that her employment was terminated by us without "cause" or by her upon a "material change," subject to the execution and effectiveness of a separation agreement and release, she would be entitled to receive (in addition to accrued compensation and benefits through the date of termination) (i) salary continuation based on her then-current base salary for 10 months and (ii) reimbursement of COBRA premiums for health benefit coverage for her and her immediate family in an amount equal to the monthly employer contribution that we would have made to provide health insurance to Ms. Brennan had she remained employed with us for up to 10 months following termination.

Upon a "change in control," subject to the execution and effectiveness of a release, Ms. Brennan would be eligible to receive a lump sum amount equal to 12 months of her then-current base salary (but in no event less than \$275,000), her annual target bonus and 100% accelerated vesting of her outstanding stock options. Furthermore, the employment agreement provided that our board of directors may, in its sole discretion, consider providing Ms. Brennan with a transaction bonus at the time of a "change in control". If she were terminated upon the effectiveness of the "change in control," she would also receive reimbursement of COBRA premiums for health benefit coverage for her and her immediate family in an amount equal to the monthly employer contribution that we would have made to provide health insurance to Ms. Brennan had she remained employed with us for up to 12 months following termination.

John Shannon

We entered into an employment agreement with Mr. John Shannon, our Executive Vice President and Chief Operating Officer, on February 16, 2017 pursuant to which Mr. Shannon is entitled to receive an annual base salary of \$250,000, an annual target bonus equal to 40% of his annual base salary based upon our board of directors' assessment of Mr. Shannon's performance and our attainment of targeted goals as approved by the board of directors, an equity grant and eligibility to participate in our benefit plans generally. This employment agreement

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also contains provisions related to confidentiality, inventions assignment and non-competition agreement with us, pursuant to which Mr. Shannon agrees to refrain from disclosing our confidential information, re-affirms the obligations contained in his Proprietary Information and Inventions Agreement and agrees not to compete with us during his employment.

Mr. Shannon's employment agreement provides that, in the event that his employment is terminated by us without "cause" or by him upon a "material change," subject to the execution and effectiveness of a separation agreement and release, he will be entitled to receive (in addition to accrued compensation and benefits through the date of termination) (i) salary continuation based on his then-current base salary for 10 months and (ii) reimbursement of COBRA premiums for health benefit coverage for him and his immediate family in an amount equal to the monthly employer contribution that we would have made to provide health insurance to Mr. Shannon had he remained employed with us for up to 10 months following termination.

Upon a "change in control," subject to the execution and effectiveness of a release, Mr. Shannon shall be eligible to receive a lump sum amount equal to 12 months of his then-current base salary (but in no event less than \$250,000), his annual target bonus and 100% accelerated vesting of his outstanding stock options. Furthermore, the employment agreement provides that our board of directors may, in its sole discretion, consider providing Mr. Shannon with a transaction bonus at the time of a "change in control". If he is terminated upon the effectiveness of the "change in control," he shall also receive reimbursement of COBRA premiums for health benefit coverage for him and his immediate family in an amount equal to the monthly employer contribution that we would have made to provide health insurance to Mr. Shannon had he remained employed with us for up to 12 months following termination.

Doug Baum

Mr. Baum entered into a separation notice and release agreement with us on December 13, 2016, as modified on January 6, 2017, which provided for his termination as our President and Chief Executive Officer effective January 10, 2017. Pursuant to the separation agreement, Mr. Baum was eligible to receive salary continuation for nine months, COBRA reimbursement for nine months, acceleration of his outstanding equity grants and the extension of the post-termination exercise period for certain portions of his option grants to the earlier of (i) January 9, 2019, (ii) a change in control and (iii) the original expiration dates as set forth in the applicable stock option agreement. Furthermore, we agreed to forgive the outstanding balance under a certain note and pledge agreement dated October 22, 2013 by and between us and Mr. Baum in the amount of \$73,227.

Outstanding Equity Awards at 2017 Fiscal Year-End

The following table sets forth information concerning outstanding equity awards held by our named executive officers as of December 31, 2017.

NAME	OPTION AWARDS ⁽¹⁾					STOCK AWARDS	
	VESTING COMMENCEMENT DATE	NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS (#) EXERCISABLE	NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS (#) UNEXERCISABLE	OPTION EXERCISE PRICE (\$)	OPTION EXPIRATION DATE	NUMBER OF SHARES OR UNITS OF STOCK THAT HAVE NOT VESTED (#)	MARKET VALUE OF SHARES OR UNITS OF STOCK THAT HAVE NOT VESTED (\$) ⁽²⁾
Paul Edick	6/12/2017 ⁽³⁾	114,942	9,421	0.87	6/11/2027	—	—
	1/9/2017 ⁽⁴⁾	1,189,904	—	0.87	1/27/2027	—	—
Nora Brennan	6/19/2017 ⁽⁵⁾	64,942	217,686	0.87	6/11/2027	50,000	—
John Shannon	6/12/2017 ⁽⁶⁾	—	44,771	0.87	6/11/2027	—	—
	2/16/2017 ⁽⁷⁾	114,942	170,635	0.87	2/3/2027	—	—
Doug Baum	12/26/2013 ⁽⁸⁾	11,756	—	0.61	1/9/2019	—	—
	4/5/2013 ⁽⁸⁾	17,817	—	0.61	1/9/2019	—	—

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- (1) Each equity award was granted pursuant to our 2011 Stock Option/Stock Issuance Plan, as amended, or the 2011 Plan. The shares subject to each option vest with respect to 25% of the option on the one year anniversary of the applicable vesting commencement date and the remaining shares subject to each option vest in 36 equal installments on the corresponding day of each calendar month thereafter (or, if such calendar month does not have a corresponding day, on the last day of such month), in all cases subject to the optionee's continuous service to us through each vesting date. In addition, each option becomes exercisable as described in the footnotes below, where any unvested portion subject to a right of repurchase upon the optionee's termination of continuous service. Upon a change in control of the Company while the optionee is providing services to us, 100% of the shares subject to the option shall vest and become exercisable immediately prior to the effective date of the change in control.
- (2) The market value for our common stock is based on the assumed initial public offering price of \$ per share, the midpoint of the estimated price range set forth on the cover page of this prospectus.
- (3) 114,942 of the shares subject to the option became exercisable as of June 12, 2017, and the remaining 9,421 shares became exercisable on January 1, 2018.
- (4) The shares subject to this option are early exercisable.
- (5) Ms. Brennan departed from her position as Chief Financial Officer in April 2018. On December 29, 2017, Ms. Brennan early exercised 50,000 shares subject to the option, all of which were unvested as of December 31, 2017.
- (6) The option shall become exercisable on January 1, 2019.
- (7) 114,942 of the shares subject to the option became exercisable as of the grant date, an additional 114,942 shares became exercisable on January 1, 2018, and the remaining 55,693 shares shall become exercisable on January 1, 2019.
- (8) Mr. Baum departed from his position as President and Chief Executive Officer on January 10, 2017. As part of his separation agreement, as modified on January 6, 2017, certain vested shares subject to outstanding stock options shall remain exercisable through the earlier of (i) January 9, 2019, (ii) a change in control, and (iii) the original expiration dates as set forth in the applicable stock option agreement.

Compensation Risk Assessment

We believe that although a portion of the compensation provided to our executive officers and other employees is performance-based, our executive compensation program does not encourage excessive or unnecessary risk taking.

This is primarily due to the fact that our compensation programs are designed to encourage our executive officers and other employees to remain focused on both short-term and long-term strategic goals. As a result, we do not believe that our compensation programs are reasonably likely to have a material adverse effect on us.

Employee Benefit and Equity Compensation Plans

2011 Stock Option/Stock Issuance Plan

Our 2011 Plan was adopted by our board of directors and our stockholders in March 2011. The 2011 Plan was most recently amended in January 2018 with the approval of both our board of directors and our stockholders. Under the 2011 Plan, we have reserved for issuance an aggregate of 8,397,950 shares of our common stock. The number of shares of common stock reserved for issuance is subject to adjustment in the event of any merger, consolidation, sale of all or substantially all of our assets, reorganization, recapitalization, reclassification, stock dividend, stock split, reverse stock split or other similar transaction.

The shares of common stock underlying awards that (i) expire, are terminated or are canceled for any reason prior to the issuance of the underlying shares or (ii) are unvested and then repurchased at a price not greater than the option exercise or direct issue price paid per share shall be added back to the shares of common stock available for issuance under the 2011 Plan.

Our board of directors has acted as administrator of the 2011 Plan. The administrator has full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted, and to determine the specific terms and conditions of each award, subject to the provisions of the 2011 Plan. Persons eligible to participate in the 2011 Plan are those employees, officers and directors of, and consultants and advisors to, our company as selected from time to time by the administrator in its discretion.

The 2011 Plan permits the granting of (1) options to purchase common stock, including options intended to qualify as incentive stock options under Section 422 of the Internal Revenue Code of 1986, as amended, or the Code, and (2) shares of common stock directly, either through the immediate purchase of such shares or as a bonus for services rendered or pursuant to restricted stock units or other share right awards which vest upon the completion of designated

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service periods of pre-established performance milestones. In addition, the 2011 Plan permits the granting of restricted shares of common stock. The per share option exercise price of each option will be determined by the administrator but may not be less than par value of the common stock on the date of grant. The term of each option will be fixed by the administrator. The administrator will determine at what time or times each option may be exercised.

The 2011 Plan provides that upon the occurrence of a "change in control," as defined in the 2011 Plan, 100% of the shares subject to outstanding options shall vest and become exercisable immediately prior to the effective date of the change in control unless such option is assumed or continued or replaced with a cash retention program which preserves the spread existing on the unvested option shares at the time of the change in control. Immediately following the change in control, all outstanding options shall terminate and cease to be outstanding unless assumed or continued by the successor entity. Our board of directors has discretion to provide that all or some of the outstanding options shall vest and become exercisable in full immediately prior to a change in control event, even if such awards are not going to be assumed or continued. The 2011 Plan also provides that, upon the occurrence of a "change in control," the right of repurchase and vesting conditions for restricted stock and restricted stock units shall immediately vest in full prior to the "change in control" unless such awards are assigned to a successor entity or continued pursuant to the terms of the transaction. Our board of directors has discretion to provide that all or some of the outstanding restricted stock or restricted stock units shall vest and become exercisable in full immediately prior to a change in control event, even if such awards are not going to be assumed or continued.

The administrator may amend or modify the 2011 Plan at any time, subject to stockholder approval where such approval is required by applicable law. The administrator of the 2011 Plan may also amend or modify any outstanding award, provided that no amendment to an award may adversely affect a participant's rights without his or her consent.

The 2011 Plan will terminate automatically upon the earlier of (i) 10 years from the date on which the 2011 Plan was adopted by our board of directors, (ii) the date on which all shares available for issuance under the 2011 Plan shall have been issued as vested shares or (iii) the action of board to terminate of all outstanding options in connection with a "change in control." As of December 31, 2017, options to purchase 3,208,588 shares of common stock were outstanding under the 2011 Plan. Our board of directors has determined not to make any further awards under the 2011 Plan following the closing of this offering.

2018 Stock Option and Incentive Plan

Our 2018 Stock Option and Incentive Plan, or the 2018 Plan, was adopted by our board of directors on _____ and approved by our stockholders on _____ and will become effective upon the effectiveness of the registration statement of which this prospectus is part. The 2018 Plan will replace the 2011 Plan as our board of directors has determined not to make additional awards under the 2011 Plan following the closing of our initial public offering. The 2018 Plan allows the compensation committee to make equity-based and cash-based incentive awards to our officers, employees, directors and other key persons (including consultants).

We have initially reserved _____ shares of our common stock, or the Initial Limit, for the issuance of awards under the 2018 Plan. The 2018 Plan provides that the number of shares reserved and available for issuance under the plan will automatically increase each January 1, beginning on January 1, 2019, by _____ % of the outstanding number of shares of our common stock on the immediately preceding December 31, or such lesser number of shares as determined by our compensation committee, or the Annual Increase. This number is subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization.

The shares we issue under the 2018 Plan will be authorized but unissued shares or shares that we reacquire. The shares of common stock underlying any awards that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by us prior to vesting, satisfied without any issuance of stock, expire or are otherwise terminated (other than by exercise) under the 2018 Plan and the 2011 Plan will be added back to the shares of common stock available for issuance under the 2018 Plan.

The maximum aggregate number of shares that may be issued in the form of incentive stock options shall not exceed the Initial Limit cumulatively increased on January 1, 2019 and on each January 1 thereafter by the lesser of the Annual Increase for such year or _____ shares of common stock.

The 2018 Plan will be administered by our compensation committee. Our compensation committee has full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted, to make any

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combination of awards to participants, and to determine the specific terms and conditions of each award, subject to the provisions of the 2018 Plan. Persons eligible to participate in the 2018 Plan will be those full or part-time officers, employees, non-employee directors and other key persons (including consultants) as selected from time to time by our compensation committee in its discretion.

The 2018 Plan permits the granting of both options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Code, and options that do not so qualify. The option exercise price of each option will be determined by our compensation committee but may not be less than 100% of the fair market value of our common stock on the date of grant. The term of each option will be fixed by our compensation committee and may not exceed 10 years from the date of grant. Our compensation committee will determine at what time or times each option may be exercised.

Our compensation committee may award stock appreciation rights subject to such conditions and restrictions as it may determine. Stock appreciation rights entitle the recipient to shares of common stock, or cash, equal to the value of the appreciation in our stock price over the exercise price. The exercise price of each stock appreciation right may not be less than 100% of the fair market value of the common stock on the date of grant.

Our compensation committee may award restricted shares of common stock and restricted stock units to participants subject to such conditions and restrictions as it may determine. These conditions and restrictions may include the achievement of certain performance goals and/or continued employment with us through a specified vesting period. Our compensation committee may also grant shares of common stock that are free from any restrictions under the 2018 Plan. Unrestricted stock may be granted to participants in recognition of past services or other valid consideration and may be issued in lieu of cash compensation due to such participant. Our compensation committee may grant cash bonuses under the 2018 Plan to participants, subject to the achievement of certain performance goals.

The 2018 Plan provides that in the case of, and subject to, the consummation of a "sale event" as defined in the 2018 Plan, all outstanding awards may be assumed, substituted or otherwise continued by the successor entity. To the extent that the successor entity does not assume, substitute or otherwise continue such awards, then (i) all stock options and stock appreciation rights will automatically become fully exercisable and the restrictions and conditions on all other awards with time-based conditions will automatically be deemed waived, and awards with conditions and restrictions relating to the attainment of performance goals may become vested and non-forfeitable in connection with a sale event in the compensation committee's discretion and (ii) upon the effectiveness of the sale event, the 2018 Plan and all awards will automatically terminate. In the event of such termination, (i) individuals holding options and stock appreciation rights will be permitted to exercise such options and stock appreciation rights (to the extent exercisable) prior to the sale event; or (ii) we may make or provide for a cash payment to participants holding options and stock appreciation rights equal to the difference between the per share cash consideration payable to stockholders in the sale event and the exercise price of the options or stock appreciation rights (to the extent then exercisable).

Our board of directors may amend or discontinue the 2018 Plan and our compensation committee may amend the exercise price of options and amend or cancel outstanding awards for purposes of satisfying changes in law or any other lawful purpose but no such action may adversely affect rights under an award without the holder's consent. Certain amendments to the 2018 Plan require the approval of our stockholders. No awards may be granted under the 2018 Plan after the date that is 10 years from the date of stockholder approval. No awards under the 2018 Plan have been made prior to the date of this prospectus.

2018 Employee Stock Purchase Plan

Our board of directors adopted on _____, 2018, and our stockholders approved on _____, 2018, the 2018 Employee Stock Purchase Plan, or ESPP, which will become effective upon the effectiveness of the registration statement of which this prospectus is a part. The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423(b) of the Code. The ESPP initially reserves and authorizes the issuance of up to a total of shares of common stock to participating employees. The ESPP provides that the number of shares reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2019 and each January 1 thereafter through January 1, 2028, by the least of (i) _____ % of the outstanding number of shares of our common stock on the immediately preceding December 31; (ii) shares or (iii) such number of shares as determined by the ESPP administrator. The number of shares reserved under the ESPP is subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization.

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All employees who have completed at least three months of employment and whose customary employment is for more than 20 hours per week are eligible to participate in the ESPP. However, any employee who owns 5% or more of the total combined voting power or value of all classes of stock is not eligible to purchase shares under the ESPP.

We will make one or more offerings each year to our employees to purchase shares under the ESPP. Unless otherwise determined by the compensation committee, offerings will usually begin on each January 1 and July 1 and will continue for six-month periods, referred to as offering periods. Each eligible employee may elect to participate in any offering by submitting an enrollment form at least 15 business days before the relevant offering date.

Each employee who is a participant in the ESPP may purchase shares by authorizing payroll deductions of up to % of his or her base compensation during an offering period. Unless the participating employee has previously withdrawn from the offering, his or her accumulated payroll deductions will be used to purchase shares on the last business day of the offering period at a price equal to 85% of the fair market value of the shares on the first business day or the last business day of the offering period, whichever is lower. Under applicable tax rules, an employee may purchase no more than \$25,000 worth of shares of common stock, valued at the start of the purchase period, under the ESPP in any calendar year.

The accumulated payroll deductions of any employee who is not a participant on the last day of an offering period will be refunded. An employee's rights under the ESPP terminate upon voluntary withdrawal from the plan or when the employee ceases employment with us for any reason.

The ESPP may be terminated or amended by our board of directors at any time. An amendment that increases the number of shares of common stock authorized under the ESPP and certain other amendments require the approval of our stockholders.

Senior Executive Cash Incentive Bonus Plan

In 2018, our board of directors adopted the Senior Executive Cash Incentive Bonus Plan, or the Bonus Plan. The Bonus Plan provides for cash bonus payments based upon the attainment of performance targets established by our compensation committee. The payment targets will be related to financial and operational measures or objectives with respect to our company, or corporate performance goals, as well as individual performance objectives.

Our compensation committee may select corporate performance goals from among the following:

Each executive officer who is selected to participate in the Bonus Plan will have a target bonus opportunity set for each performance period. The bonus formulas will be adopted in each performance period by the compensation committee and communicated to each executive. The corporate performance goals will be measured at the end of each performance period after our financial reports have been published or such other appropriate time as the compensation committee determines. If the corporate performance goals and individual performance objectives are met, payments will be made as soon as practicable following the end of each performance period. Subject to the rights contained in any agreement between the executive officer and us, an executive officer must be employed by us on the bonus payment date to be eligible to receive a bonus payment. The Bonus Plan also permits the compensation committee to approve additional bonuses to executive officers in its sole discretion and provides the compensation committee with discretion to adjust the size of the award as it deems appropriate to account for unforeseen factors beyond management's control that affected corporate performance.

401(k) Plan

We maintain the Xeris Pharmaceuticals, Inc. 401(k) Plan, a tax-qualified retirement plan for our employees. The 401(k) plan is intended to qualify under Section 401(k) of the Code, so that contributions to the 401(k) plan by employees or by us, and the investment earnings thereon, are not taxable to the employees until withdrawn from the 401(k) plan, and so that contributions by us, if any, will be deductible by us when made. All employees are eligible to participate in the 401(k) plan as of the first day of the first full month of their employment. Participants have the option to make two kinds of Elective Deferral Contributions: Pre-Tax Elective Deferrals and Roth Elective Deferrals. Any initial election or change of election by an eligible employee may be made at any time. Participants are always 100% vested in their contributions. While we have discretion to make matching contributions, we have historically not provided such contributions.

DIRECTOR COMPENSATION

The following table presents the total compensation for each person who served as a non-employee member of our board of directors and received compensation for such service during the fiscal year ended December 31, 2017. Other than as set forth in the table and described more fully below, we did not pay any compensation, make any equity awards to, or pay any other compensation to any of the non-employee members of our board of directors in 2017. Mr. Baum, our former President and Chief Executive Officer, did not receive any compensation for his service as a member of our board of directors during 2017. Mr. Baum's compensation for service as an employee for fiscal year 2017 is presented in "Executive Compensation – 2017 Summary Compensation Table." In addition, Paul Edick, our current President and Chief Executive Officer does not receive any compensation for his service as a member of our board of directors. Mr. Edick's compensation for service as an employee for fiscal year 2017 is presented in "Executive Compensation – 2017 Summary Compensation Table." We reimburse non-employee members of our board of directors for reasonable travel expenses.

Director Compensation Table—2017

NAME	FEES EARNED OR PAID IN CASH (\$)	OPTION AWARDS (\$) ⁽¹⁾	TOTAL (\$)
Robert C. Faulkner (2)	—	—	—
Cary McNair (2)	—	—	—
Jonathan Rigby (3)	38,750	7,157	45,907
John Schmid (4)	10,000	7,157	17,157

- (1) Each equity award was granted pursuant to our 2011 Plan and, unless otherwise described in the footnotes, the shares vest in 24 equal installments commencing as of May 14, 2017 for Mr. Rigby and September 30, 2017 for Mr. Schmid (or, if such calendar month does not have a corresponding day, on the last day of such month), in all cases subject to the optionee's continuous service to us through each vesting date. The shares subject to the options are early exercisable. Upon a change in control of the Company while the optionee is providing services to us and where the option is not assumed, continued, or substituted, 100% of the shares subject to the option shall vest and become exercisable immediately prior to the effective date of the change in control.
- (2) Investor-appointed directors did not receive fees or other compensation for their service on our board of directors. Messrs. Faulkner and McNair departed from our board of directors in April 2018.
- (3) The amounts reported were granted pursuant to the offer agreement, dated September 15, 2017, by and between Mr. Rigby and us. As of December 31, 2017, Mr. Rigby held unexercised options to purchase 50,080 shares of our common stock.
- (4) The amounts reported were granted pursuant to the offer agreement, dated August 31, 2017, by and between Mr. Schmid and us. On December 29, 2017, Mr. Schmid early exercised all 10,080 shares subject to his option, all of which remained unvested as of December 31, 2017, and he did not hold any other unexercised options.

Non-Employee Director Compensation Policy

Our board of directors has adopted a non-employee director compensation policy, effective upon effectiveness of the registration statement of which this prospectus forms a part, that is designed to enable us to attract and retain, on a long-term basis, highly qualified non-employee directors. Under the policy, each director who is not an employee will be paid cash compensation from and after the completion of this offering, as set forth below:

	MEMBER ANNUAL FEE (\$)	CHAIRMAN ADDITIONAL ANNUAL FEE (\$)
Board of Directors	35,000	20,000
Audit Committee	8,000	8,000
Compensation Committee	6,000	6,000
Nominating and Corporate Governance Committee	4,000	4,000

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In addition, each non-employee director elected or appointed to our board of directors following the completing of this offering will be granted options with a grant date fair value of \$ _____ on the date of such director's election or appointment to the board of directors, which will vest in the following manner, subject to continued service through such vesting date(s): _____. On the date of each annual meeting of stockholders of our company, each non-employee director will be granted options with a grant date fair value of \$ _____, which will vest in the following manner, subject to continued service as a director through such vesting date(s): _____.

CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

The following is a description of transactions or series of transactions since January 1, 2015, to which we were or will be a party, in which:

- the amount involved in the transaction exceeds \$120,000; and
- in which any of our executive officers, directors and principal stockholders, including their immediate family members, had or will have a direct or indirect material interest.

Compensation arrangements for our named executive officers and our directors are described elsewhere in this prospectus under “Management—Director Compensation” and “Executive Compensation.”

Private Placements of Securities

Series C Preferred Stock Financing

In December 2015, with subsequent closings in December 2016, May 2017, December 2017 and February 2018, we sold an aggregate of 13,542,592 shares of our Series C preferred stock at a purchase price of \$6.2705 per share for an aggregate principal amount of \$84.9 million. The following table summarizes purchases of our Series C preferred stock by related persons:

STOCKHOLDER	SHARES OF SERIES C PREFERRED STOCK	TOTAL PURCHASE PRICE
Entities affiliated with Palmetto Partners, Ltd.	1,833,983	\$ 11,499,996.41
Entities affiliated with Deerfield Management Company	3,114,584	\$ 19,529,998.98
Entities affiliated with Redmile Group, LLC (1)	3,109,796	\$ 19,499,995.82
Mérieux Participations 2 S.A.S.	1,562,873	\$ 9,799,995.15
Paul Edick(2)	23,922	\$ 150,002.91
Nora Brennan(3)	16,000	\$ 100,328.00
John Shannon	16,000	\$ 100,328.00
Ken Johnson	4,000	\$ 25,082.00

(1) Robert Faulkner was a member of our board of directors from December 2015 to April 2018 and is a partner at Redmile Group, LLC.

(2) Represents 23,922 shares of Series C preferred stock held by the Paul R. Edick 2008 Revocable Trust.

(3) Ms. Brennan departed from her position as our Chief Financial Officer on April 1, 2018.

Agreements with Stockholders

In connection with our Series C preferred stock financing, we entered into investors' rights, voting and right of first refusal and co-sale agreements containing registration rights, information rights, voting rights and rights of first refusal, among other things, with certain holders of our preferred stock and certain holders of our common stock. These stockholder agreements will terminate upon the closing of this offering, except for the registration rights granted under our investors' rights agreement, as more fully described in “Description of Capital Stock—Registration Rights.”

Indemnification Agreements

In connection with this offering, we intend to enter into new agreements to indemnify our directors and executive officers. These agreements will, among other things, require us to indemnify these individuals for certain expenses (including attorneys' fees), judgments, fines and settlement amounts reasonably incurred by such person in any action or proceeding, including any action by or in our right, on account of any services undertaken by such person on behalf of our company or that person's status as a member of our board of directors to the maximum extent allowed under Delaware law.

Policies for Approval of Related Party Transactions

Our board of directors reviews and approves transactions with directors, officers and holders of five percent or more of our voting securities and their affiliates, each a related party. Prior to this offering, the material facts as to the

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related party's relationship or interest in the transaction are disclosed to our board of directors prior to their consideration of such transaction, and the transaction is not considered approved by our board of directors unless a majority of the directors who are not interested in the transaction approve the transaction. Further, when stockholders are entitled to vote on a transaction with a related party, the material facts of the related party's relationship or interest in the transaction are disclosed to the stockholders, who must approve the transaction in good faith.

In connection with this offering, we have adopted a written related party transactions policy that such transactions must be approved by our audit committee. This policy will become effective on the date on which the registration statement of which this prospectus is part is declared effective by the SEC. Pursuant to this policy, the audit committee has the primary responsibility for reviewing and approving or disapproving "related party transactions," which include transactions between us and related persons in which the aggregate amount involved exceeds or may be expected to exceed \$120,000 and in which a related person has or will have a direct or indirect material interest. For purposes of this policy, a related person will be defined as a director, executive officer, nominee for director, or greater than 5% beneficial owner of our common stock, in each case since the beginning of the most recently completed year, and their immediate family members.

PRINCIPAL STOCKHOLDERS

The following table sets forth, as of _____, 2018, information regarding the beneficial ownership of our common stock by:

- each person, or group of affiliated persons, who is known by us to be the beneficial owner of five percent or more of our outstanding common stock (on an as-converted to common stock basis);
- each of our directors;
- each of our named executive officers; and
- all our directors and executive officers as a group (nine persons).

The information in the following table is calculated based on 25,255,297 shares of common stock outstanding before this offering as of _____, 2018 (which includes 316,880 shares of common stock issued upon the early exercise of stock options, which remain subject to vesting restrictions) and _____ shares of common stock outstanding after this offering. The number of shares outstanding is based on the number of shares of common stock outstanding on _____, 2018 as adjusted to give effect to:

- the automatic conversion of all outstanding shares of our convertible preferred stock into 21,083,391 shares of common stock upon the completion of this offering; and
- the sale of _____ shares of common stock in this offering (assuming no exercise of the underwriters' option to purchase additional shares).

Each individual or entity shown on the table has furnished information with respect to beneficial ownership. Except as otherwise indicated below, the address of each officer, director and five percent stockholder listed below is c/o Xeris Pharmaceuticals, Inc., 180 N. LaSalle Street, Suite 1800, Chicago, IL 60601.

We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of common stock issuable pursuant to the exercise of stock options that are either immediately exercisable or exercisable within 60 days of _____, 2018. These shares are deemed to be outstanding and beneficially owned by the person holding those options for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them.

	SHARES OF COMMON STOCK BENEFICIALLY OWNED	PERCENTAGE OF SHARES BENEFICIALLY OWNED	
		BEFORE OFFERING	AFTER OFFERING
5% Stockholders			
Entities affiliated with Palmetto Partners, Ltd. (1)	3,511,108	13.90%	%
Entities affiliated with Deerfield Management Company (2)	3,114,584	12.33%	%
Entities affiliated with Redmile Group, LLC (3)	3,109,796	12.31%	%
Mérieux Participations 2 S.A.S. (4)	1,562,873	6.19%	%
John Kinzell (5)	1,337,891	5.30%	%
Directors, Named Executive Officers and Other Executive Officers			
Paul Edick (6)	1,513,189	5.99%	%
Steven Prestrelski (7)	1,014,617	4.02%	%
Douglas Baum (8)	672,399	2.66%	%
John Shannon (9)	396,348	1.57%	%
Nora Brennan (10)	373,628	1.48%	%
Barry Deutsch (11)	103,987	*	%
Ken Johnson (12)	144,000	*	%
BJ Bormann	—	—	
Jeffrey Sherman	—	—	
Jonathan Rigby	50,080	*	
John Schmid	10,080	*	%
Marla Persky	—	—	
Dawn Halkuff	—	—	
All current executive officers and directors as a group (11 persons) (13)	3,228,314	12.78%	%

* Less than one percent.

- (1) Consists of (i) 1,657,125 shares of common stock issuable upon conversion of preferred stock held by Palmetto Partners 2014, LP., (ii) 1,036,599 shares of common stock issuable upon conversion of preferred stock held by Palmetto Partners 2015, LP, (iii) 797,384 shares of common stock issuable upon conversion of preferred stock held by Palmetto Partners, Ltd. and (iv) 20,000 shares of common stock underlying options exercisable within 60 days of _____, 2018 held by Palmetto Partners 2015, LP. Palmetto Partners, Ltd. is the general partner of each of Palmetto Partners 2014, LP and Palmetto Partners 2015, LP and may be deemed to beneficially own the securities held by such funds. The address of Palmetto Partners, Ltd. is 109 N Post Oak Ln., Suite 600, Houston, TX 77024.
- (2) Consists of (i) 1,557,292 shares of common stock issuable upon conversion of preferred stock held by Deerfield Private Design Fund III, L.P. and (ii) 1,557,292 shares of common stock issuable upon conversion of preferred stock held by Deerfield Special Situations Fund, L.P. Deerfield Mgmt, L.P. is the general partner of Deerfield Special Situations Fund, L.P., and Deerfield Mgmt III, L.P. is the general partner of Deerfield Private Design Fund III, L.P. (collectively with Deerfield Special Situations Fund, L.P., the "Deerfield Funds"). Deerfield Management Company, L.P. is the investment manager of each of the Deerfield Funds. James E. Flynn is the sole member of the general partner of Deerfield Mgmt, L.P., Deerfield Mgmt III, L.P. and Deerfield Management Company, L.P. Deerfield Mgmt, L.P., Deerfield Management Company, L.P. and as such shares voting and investment control over the shares held by the Deerfield Funds. Mr. James E. Flynn may be deemed to beneficially own the securities held by Deerfield Special Situations Fund, L.P. Deerfield Mgmt III, L.P., Deerfield Management Company, L.P. and Mr. James E. Flynn may be deemed to beneficially own the securities held by Deerfield Private Design Fund III, L.P. The address of the Deerfield Funds is 780 Third Avenue, 37th Floor, New York, NY 10017.
- (3) Consists of (i) 556,135 shares of common stock issuable upon conversion of preferred stock held by Redmile Biopharma Investments I, L.P., (ii) 402,161 shares of common stock issuable upon conversion of preferred stock held by Redmile Capital Fund, LP, (iii) 653,678 shares of common stock issuable upon conversion of preferred stock held by Redmile Capital Offshore Fund II, Ltd., (iv) 127,764 shares of common stock issuable upon conversion of preferred stock held by Redmile Capital Offshore Fund, Ltd., (v) 1,270,392 shares of common stock issuable upon conversion of preferred stock held by Redmile Private Investments II, LP and (vi) 99,666 shares of common stock issuable upon conversion of preferred stock held by Redmile Strategic Master Fund, LP. Redmile Group, LLC is the investment manager of each of Redmile Biopharma Investments I, L.P., Redmile Capital Fund, LP, Redmile Capital Offshore Fund II, Ltd., Redmile Capital Offshore Fund, Ltd., Redmile Private Investments II, L.P. and Redmile Strategic Master Fund, LP (the "Redmile Funds"). Redmile Group, LLC may be deemed to beneficially own the securities held by the Redmile Funds. Jeremy C. Green serves as the managing member of Redmile Group, LLC and as such shares voting and dispositive power over the shares held by the Redmile Funds. Redmile Group, LLC and Mr. Green each disclaim beneficial ownership of these shares, except to the extent of its or his pecuniary interest in such shares, if any. The address of Redmile Group, LLC is One Letterman Drive, Building D, Suite D3-300, San Francisco, CA 94129.

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- (4) Consists of 1,562,873 shares of common stock issuable upon conversion of preferred stock held by Mérieux Participants 2 S.A.S. Voting and investment power over the securities held by Mérieux Participants 2 S.A.S. is exercised by its board of directors. The address of Mérieux Participants 2 S.A.S. is 17 Rue Bourgelat, Lyon, France 69002.
- (5) Consists of (i) 1,135,597 shares of common stock, (ii) 134,475 shares of common stock issuable upon conversion of preferred stock, (iii) 31,250 shares of common stock held by the John H. Kinzell and Ann J. Kinzell 2011 Trust (the "Trust Shares") and (iv) 36,569 shares of common stock issuable upon conversion of preferred stock held by Ann Kinzell (the "Kinzell Shares"). Mr. Kinzell may be deemed to beneficially own both the Trust Shares and the Kinzell Shares, which are held in a shared trust and by Ann Kinzell, Mr. Kinzell's wife, respectively. Mr. Kinzell disclaims beneficial ownership of the Trust Shares and the Kinzell Shares and this shall not be deemed an admission that he is the beneficial owner of the Trust Shares and the Kinzell Shares.
- (6) Consists of (i) 1,489,267 shares of common stock underlying options exercisable within 60 days of _____, 2018 and (ii) 23,922 shares of common stock issuable upon conversion of preferred stock held by the Paul R. Edick 2008 Revocable Trust (the "2008 Trust Shares"). Mr. Edick may be deemed to beneficially own the 2008 Trust Shares. Mr. Edick disclaims beneficial ownership of the 2008 Trust Shares and this shall not be deemed an admission that he is the beneficial owner of the 2008 Trust Shares.
- (7) Consists of (i) 775,000 shares of common stock, (ii) 24,509 shares of common stock issuable upon conversion of preferred stock, (iii) 173,067 shares of common stock underlying options exercisable within 60 days of _____, 2018 and (iv) 42,041 shares of common stock issuable upon conversion of preferred stock held by Steven Prestrelski and Tracy Yeo.
- (8) Consists of (i) 658,682 shares of common stock, (ii) 13,717 shares of common stock issuable upon conversion of preferred stock.
- (9) Consists of (i) 16,000 shares of common stock issuable upon conversion of preferred stock and (ii) 380,348 shares of common stock underlying options exercisable within 60 days of _____, 2018.
- (10) Consists of (i) 50,000 shares of common stock, (ii) 16,000 shares of common stock issuable upon conversion of preferred stock and (iii) 307,628 shares of common stock underlying options exercisable within 60 days of _____, 2018.
- (11) Consists of (i) 37,500 shares of common stock, (ii) 3,987 shares of common stock issuable upon conversion of preferred stock and (iii) 62,500 shares of common stock underlying options exercisable within 60 days of _____, 2018.
- (12) Consists of (i) 4,000 shares of common stock issuable upon conversion of preferred stock and (ii) 140,000 shares of common stock underlying options exercisable within 60 days of _____, 2018.
- (13) Includes an aggregate of 2,540,390 shares of common stock underlying options exercisable within 60 days of _____, 2018 held by nine executive officers and directors.

DESCRIPTION OF CAPITAL STOCK

The following descriptions are summaries of the material terms of our amended and restated certificate of incorporation and amended and restated bylaws, which will be effective upon the closing of this offering. The descriptions of the common stock and preferred stock give effect to changes to our capital structure that will occur upon the completion of this offering. We refer in this section to our amended and restated certificate of incorporation as our certificate of incorporation, and we refer to our amended and restated bylaws as our bylaws.

General

Upon completion of this offering, our authorized capital stock will consist of _____ shares of common stock, par value \$0.0001 per share, and _____ shares of preferred stock, par value \$0.0001 per share, all of which shares of preferred stock will be undesignated.

As of December 31, 2017, 4,162,480 shares of our common stock (which includes 316,880 shares of common stock issued upon the early exercise of stock options, which remain subject to vesting restrictions), 1,843,965 shares of Series A preferred stock, 5,696,834 shares of Series B preferred stock were outstanding, and 12,834,912 shares of Series C preferred stock were outstanding and held. This amount does not take into account the conversion of all outstanding shares of our preferred stock into common stock upon the closing of this offering.

Common Stock

The holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of the stockholders. The holders of our common stock do not have any cumulative voting rights. Holders of our common stock are entitled to receive ratably any dividends declared by our board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. Our common stock has no preemptive rights, conversion rights or other subscription rights or redemption or sinking fund provisions.

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock. The shares to be issued by us in this offering will be, when issued and paid for, validly issued, fully paid and non-assessable.

Preferred Stock

Upon the completion of this offering, all outstanding shares of our preferred stock will be converted into shares of our common stock. Upon the consummation of this offering, our board of directors will have the authority, without further action by our stockholders, to issue up to _____ shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our company or other corporate action. Immediately after consummation of this offering, no shares of preferred stock will be outstanding, and we have no present plan to issue any shares of preferred stock.

Options

As of _____, 2018, options to purchase 3,208,588 shares of common stock were outstanding under our 2011 Plan (which excludes options to purchase 316,880 shares of common stock that were early exercised).

Warrants

As of December 31, 2017, we had outstanding warrants to purchase 35,500 shares of Series B convertible preferred stock at an exercise price of \$3.319 per share.

Registration Rights

Upon the completion of this offering, the holders of 24,614,512 shares of our common stock, including those issuable upon the conversion of preferred stock, will be entitled to rights with respect to the registration of these securities under the Securities Act. These rights are provided under the terms of an investors' rights agreement between us, certain holders of our common stock and holders of our preferred stock. The investors' rights agreement includes demand registration rights, short-form registration rights and piggyback registration rights. All fees, costs and expenses of underwritten registrations under this agreement will be borne by us and all selling expenses, including underwriting discounts and selling commissions, will be borne by the holders of the shares being registered.

Demand Registration Rights

Beginning 180 days after the effective date of this registration statement, the holders of 24,614,512 shares of our common stock, including those issuable upon the conversion of shares of our preferred stock upon closing of this offering, are entitled to demand registration rights. Under the terms of the investors' rights agreement, we will be required, upon the written request of holders of at least 20% of the securities eligible for registration then outstanding or such lesser percentage that would result in an aggregate offering price of at least \$10.0 million, to file a registration statement and use commercially reasonable efforts to effect the registration of all or a portion of these shares for public resale. We are required to effect only two registrations pursuant to this provision of the investors' rights agreement.

Short-Form Registration Rights

Pursuant to the investors' rights agreement, if we are eligible to file a registration statement on Form S-3, upon the written request of majority in interest of these holders to sell registrable securities at an aggregate price of at least \$1.0 million, we will be required to use commercially reasonable efforts to effect a registration of such shares. We are not required to effect more than registrations that have been declared or ordered effective by the SEC pursuant to this provision of the investors' rights agreement. The right to have such shares registered on Form S-3 is further subject to other specified conditions and limitations.

Piggyback Registration Rights

Pursuant to the investors' rights agreement, if we register any of our securities either for our own account or for the account of other security holders, the holders of 24,614,512 shares of our common stock, including those issuable upon the conversion of our preferred stock, are entitled to include their shares in the registration. Subject to certain exceptions contained in the investors' rights agreement, we and the underwriters may limit the number of shares included in the underwritten offering to the number of shares which we and the underwriters determine in our sole discretion will not jeopardize the success of the offering.

Indemnification

Our investors' rights agreement contains customary cross-indemnification provisions, under which we are obligated to indemnify holders of registrable securities in the event of material misstatements or omissions in the registration statement attributable to us, and they are obligated to indemnify us for material misstatements or omissions attributable to them.

Expiration of Registration Rights

The demand registration rights and short form registration rights granted under the investors' rights agreement will terminate on the fifth anniversary of the completion of this offering or at such time after this offering when the holders' shares may be sold without restriction pursuant to Rule 144 within a three-month period.

Anti-Takeover Effects of Delaware Law and Certain Provisions of our Certificate of Incorporation Amended and Restated Bylaws

Our certificate of incorporation and bylaws include a number of provisions that may have the effect of delaying, deferring or preventing another party from acquiring control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions include the items described below.

Board Composition and Filling Vacancies

Our certificate of incorporation provides for the division of our board of directors into three classes serving staggered three-year terms, with one class being elected each year. Our certificate of incorporation also provides that directors may be removed only for cause and then only by the affirmative vote of the holders of two-thirds or more of the shares then entitled to vote at an election of directors. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board, may only be filled by the affirmative vote of a majority of our directors then in office even if less than a quorum. The classification of directors, together with the limitations on removal of directors and treatment of vacancies, has the effect of making it more difficult for stockholders to change the composition of our board of directors.

No Written Consent of Stockholders

Our certificate of incorporation provides that all stockholder actions are required to be taken by a vote of the stockholders at an annual or special meeting, and that stockholders may not take any action by written consent in lieu of a meeting. This limit may lengthen the amount of time required to take stockholder actions and would prevent the amendment of our bylaws or removal of directors by our stockholders without holding a meeting of stockholders.

Meetings of Stockholders

Our certificate of incorporation and bylaws provide that only a majority of the members of our board of directors then in office may call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our bylaws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

Advance Notice Requirements

Our bylaws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. Our bylaws specify the requirements as to form and content of all stockholders' notices. These requirements may preclude stockholders from bringing matters before the stockholders at an annual or special meeting.

Amendment to Certificate of Incorporation and Bylaws

Any amendment of our certificate of incorporation must first be approved by a majority of our board of directors, and if required by law or our certificate of incorporation, must thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment and a majority of the outstanding shares of each class entitled to vote thereon as a class, except that the amendment of the provisions relating to stockholder action, board composition, limitation of liability and the amendment of our bylaws and certificate of incorporation must be approved by not less than two-thirds of the outstanding shares entitled to vote on the amendment, and not less than two-thirds of the outstanding shares of each class entitled to vote thereon as a class. Our bylaws may be amended by the affirmative vote of a majority of the directors then in office, subject to any limitations set forth in the bylaws; and may also be amended by the affirmative vote of at least two-thirds of the outstanding shares entitled to vote on the amendment, or, if our board of directors recommends that the stockholders approve the amendment, by the affirmative vote of the majority of the outstanding shares entitled to vote on the amendment, in each case voting together as a single class.

Undesignated Preferred Stock

Our certificate of incorporation that will become effective upon the completion of the offering provides for 10,000,000 authorized shares of preferred stock. The existence of authorized but unissued shares of preferred stock may enable our board of directors to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of our stockholders, our board of directors could cause shares of preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, our certificate of incorporation grants our board of directors broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of

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shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

Choice of Forum

Our amended and restated bylaws that will become effective upon the completion of this offering will provide that the Court of Chancery of the State of Delaware will be the exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a breach of fiduciary duty by one or more of our directors, officers or employees, (iii) any action asserting a claim against us arising pursuant to the Delaware General Corporation Law or (iv) any action asserting a claim against us that is governed by the internal affairs doctrine. Our amended and restated bylaws will further provide that, unless we consent in writing to an alternate forum, the United States District Court for the Northern District of Illinois will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and consented to the forum provisions in our amended and restated bylaws. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation and bylaws has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable.

Stock Exchange Listing

We have applied to list our common stock on the Nasdaq Global Market under the proposed trading symbol "XERS."

Transfer Agent and Registrar

The Transfer Agent and Registrar for our common stock will be .

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our shares. Future sales of our common stock in the public market, or the availability of such shares for sale in the public market, could adversely affect market prices prevailing from time to time. As described below, only a limited number of shares will be available for sale shortly after this offering due to contractual and legal restrictions on resale. Nevertheless, sales of shares of our common stock in the public market after such restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price at such time and our ability to raise equity capital in the future.

Based on the number of shares outstanding as of _____, 2018, upon the completion of this offering, _____ shares of our common stock will be outstanding, assuming the issuance of shares offered by us in this offering, no exercise of the underwriters' option to purchase additional shares and no exercise of outstanding options. Of the outstanding shares, all of the shares sold in this offering will be freely tradable, except that any shares held by our affiliates, as that term is defined in Rule 144 under the Securities Act, may only be sold in compliance with the limitations described below, and restricted shares of common stock are subject to time-based vesting terms. All remaining shares of common stock held by existing stockholders immediately prior to the completion of this offering will be "restricted securities" as such term is defined in Rule 144. These restricted securities were issued and sold by us, or will be issued and sold by us, in private transactions and are eligible for public sale only if registered under the Securities Act or if they qualify for an exemption from registration under the Securities Act, including the exemptions provided by Rule 144 or Rule 701, summarized below.

Rule 144

In general, a person who has beneficially owned restricted stock for at least six months would be entitled to sell their securities provided that (i) such person is not deemed to have been one of our affiliates at the time of, or at any time during the 90 days preceding, a sale and (ii) we are subject to the periodic reporting requirements of the Exchange Act for at least 90 days before the sale. Persons who have beneficially owned restricted shares for at least six months but who are our affiliates at the time of, or any time during the 90 days preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period only a number of securities that does not exceed the greater of either of the following:

- 1% of the number of shares then outstanding, which will equal approximately _____ shares immediately after this offering, assuming no exercise of the underwriters' option to purchase additional shares, based on the number of shares outstanding as of _____, 2018; or
- the average weekly trading volume of our common stock on The Nasdaq Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale;

provided, in each case, that we are subject to the periodic reporting requirements of the Exchange Act for at least 90 days before the sale. Such sales both by affiliates and by non-affiliates must also comply with the manner of sale, current public information and notice provisions of Rule 144.

Rule 701

Rule 701 under the Securities Act, as in effect on the date of this prospectus, permits resales of shares in reliance upon Rule 144 but without compliance with certain restrictions of Rule 144, including the holding period requirement. Most of our employees, executive officers or directors who purchased shares under a written compensatory plan or contract may be entitled to rely on the resale provisions of Rule 701, but all holders of Rule 701 shares are required to wait until 90 days after the date of this prospectus before selling their shares.

However, substantially all Rule 701 shares are subject to lock-up agreements as described below and under "Underwriting" included elsewhere in this prospectus and will become eligible for sale upon the expiration of the restrictions set forth in those agreements.

Lock-Up Agreements

We, all of our directors and officers and substantially all of our stockholders have agreed not to sell or otherwise transfer or dispose of any of our securities for a period of 180 days from the date of this prospectus, subject to

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certain exceptions. The representatives of the underwriters in this offering may, in their sole discretion, permit early release of shares subject to the lock-up agreements. See the section entitled “Underwriting” appearing elsewhere in this prospectus for more information.

Registration Rights

Upon completion of this offering, certain holders of our securities will be entitled to various rights with respect to registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act immediately upon the effectiveness of the registration. See the section entitled “Description of Capital Stock—Registration Rights” appearing elsewhere in this prospectus for more information.

Equity Incentive Plans

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all of our shares issued or reserved for issuance under our equity incentive plans. The first such registration statement is expected to be filed soon after the date of this prospectus and will automatically become effective upon filing with the SEC. Accordingly, shares registered under such registration statement will be available for sale in the open market, unless such shares are subject to vesting restrictions with us or the lock-up restrictions described above.

MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS FOR NON-U.S. HOLDERS

The following discussion is a summary of the material U.S. federal income tax considerations applicable to non-U.S. holders (as defined below) with respect to their ownership and disposition of shares of our common stock issued pursuant to this offering. For purposes of this discussion, a non-U.S. holder means a beneficial owner of our common stock that is for U.S. federal income tax purposes:

- a non-resident alien individual;
- a corporation or other organization taxable as a corporation for U.S. federal income tax purposes that is created or organized in or under laws other than the laws of the United States, any state thereof, or the District of Columbia;
- an estate the income of which is not subject to U.S. federal income tax on a net income basis; or
- a trust the income of which is not subject to U.S. federal income tax on a net income basis and that (1) is not subject to the primary supervision of a court within the United States or over which no U.S. persons have authority to control all substantial decisions and (2) has not made an election to be treated as a U.S. person.

This discussion does not address the tax treatment of partnerships or other entities that are pass-through entities for U.S. federal income tax purposes or persons that hold their common stock through partnerships or other pass-through entities. A partner in a partnership or other pass-through entity that will hold our common stock should consult his, her or its tax advisor regarding the tax consequences of acquiring, holding and disposing of our common stock through a partnership or other pass-through entity, as applicable.

This discussion is based on current provisions of the U.S. Internal Revenue Code of 1986, as amended, which we refer to as the Code, existing and proposed U.S. Treasury Regulations promulgated thereunder, current administrative rulings and judicial decisions, all as in effect as of the date of this prospectus and, all of which are subject to change or to differing interpretation, possibly with retroactive effect. Any such change or differing interpretation could alter the tax consequences to non-U.S. holders described in this prospectus. There can be no assurance that the Internal Revenue Service, which we refer to as the IRS, will not challenge one or more of the tax consequences described herein. We assume in this discussion that a non-U.S. holder holds shares of our common stock as a capital asset within the meaning of Section 1221 of the Code, generally property held for investment.

This discussion does not address all aspects of U.S. federal income taxation that may be relevant to a particular non-U.S. holder in light of that non-U.S. holder's individual circumstances nor does it address any U.S. state, local or non-U.S. taxes, the alternative minimum tax, the Medicare tax on net investment income, the rules regarding qualified small business stock within the meaning of Section 1202 of the Code, or any other aspect of any U.S. federal tax other than the income tax. This discussion also does not consider any specific facts or circumstances that may apply to a non-U.S. holder and does not address the special tax rules applicable to particular non-U.S. holders, such as:

- insurance companies;
- tax-exempt or governmental organizations;
- financial institutions;
- brokers or dealers in securities;
- regulated investment companies;
- pension plans;
- "controlled foreign corporations," "passive foreign investment companies," and corporations that accumulate earnings to avoid U.S. federal income tax;
- "qualified foreign pension funds," or entities wholly owned by a "qualified foreign pension fund";
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons that hold our common stock as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment; and
- certain U.S. expatriates.

This discussion is for general information only and is not tax advice. Accordingly, all prospective non-U.S. holders of our common stock should consult their tax advisors with respect to the U.S. federal, state, local and non-U.S. tax consequences of the purchase, ownership and disposition of our common stock.

Distributions on Our Common Stock

Distributions, if any, on our common stock will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder's investment, up to such holder's tax basis in the common stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below in "Gain on Sale, or Other Taxable Disposition of Our Common Stock." Any such distributions will also be subject to the discussions below under the sections titled "Backup Withholding and Information Reporting" and "Withholding and Information Reporting Requirements—FATCA."

Subject to the discussion in the following two paragraphs in this section, dividends paid to a non-U.S. holder generally will be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence.

Dividends that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States and, if an applicable income tax treaty so provides, that are attributable to a permanent establishment or a fixed base maintained by the non-U.S. holder within the United States, are generally exempt from the 30% withholding tax if the non-U.S. holder satisfies applicable certification and disclosure requirements. However, such U.S. effectively connected income, net of specified deductions and credits, is taxed at the same graduated U.S. federal income tax rates applicable to United States persons (as defined in the Code). Any U.S. effectively connected income received by a non-U.S. holder that is a corporation may also, under certain circumstances, be subject to an additional "branch profits tax" at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence.

A non-U.S. holder of our common stock who claims the benefit of an applicable income tax treaty between the United States and such holder's country of residence generally will be required to provide a properly executed IRS Form W-8BEN or W-8BEN-E (or successor form) to the applicable withholding agent and satisfy applicable certification and other requirements. Non-U.S. holders are urged to consult their tax advisors regarding their entitlement to benefits under a relevant income tax treaty. A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty may obtain a refund or credit of any excess amounts withheld by timely filing a U.S. tax return with the IRS.

Gain on Sale or Other Taxable Disposition of Our Common Stock

Subject to the discussions below under "Backup Withholding and Information Reporting" and "Withholding and Information Reporting Requirements—FATCA," a non-U.S. holder generally will not be subject to any U.S. federal income tax on any gain realized upon such holder's sale or other taxable disposition of shares of our common stock unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a U.S. trade or business and, if an applicable income tax treaty so provides, is attributable to a permanent establishment or a fixed-base maintained by such non-U.S. holder in the United States, in which case the non-U.S. holder generally will be taxed on a net income basis at the graduated U.S. federal income tax rates applicable to United States persons (as defined in the Code) and, if the non-U.S. holder is a foreign corporation, the branch profits tax described above in "Distributions on Our Common Stock" also may apply;
- the non-U.S. holder is a nonresident alien individual who is present in the United States for 183 days or more in the taxable year of the disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence) on the net gain derived from the disposition, which may be offset by certain U.S. source capital losses of the non-U.S. holder, if any (even though the individual is not considered a resident of the United States), provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses; or

- we are, or have been, at any time during the five-year period preceding such sale of other taxable disposition (or the non-U.S. holder's holding period, if shorter) a "U.S. real property holding corporation," unless our common stock is regularly traded on an established securities market and the non-U.S. holder holds no more than 5% of our outstanding common stock, directly or indirectly, actually or constructively, during the shorter of the 5-year period ending on the date of the disposition or the period that the non-U.S. holder held our common stock. Generally, a corporation is a U.S. real property holding corporation only if the fair market value of its U.S. real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance, we do not believe that we are, or have been, a U.S. real property holding corporation, or that we are likely to become one in the future. No assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rules described above.

Backup Withholding and Information Reporting

We must report annually to the IRS and to each non-U.S. holder the gross amount of the distributions on our common stock paid to such holder and the tax withheld, if any, with respect to such distributions. Non-U.S. holders may have to comply with specific certification procedures to establish that the holder is not a United States person (as defined in the Code) in order to avoid backup withholding at the applicable rate with respect to dividends on our common stock. Dividends paid to non-U.S. holders subject to withholding of U.S. federal income tax, as described above in "Distributions on Our Common Stock," generally will be exempt from U.S. backup withholding.

Information reporting and backup withholding will generally apply to the proceeds of a disposition of our common stock by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the holder certifies its status as a non-U.S. holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker.

Non-U.S. holders should consult their tax advisors regarding the application of the information reporting and backup withholding rules to them. Copies of information returns may be made available to the tax authorities of the country in which the non-U.S. holder resides or is incorporated under the provisions of a specific treaty or agreement. Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder can be refunded or credited against the non-U.S. holder's U.S. federal income tax liability, if any, provided that an appropriate claim is filed with the IRS in a timely manner.

Withholding and Information Reporting Requirements—FATCA

Provisions of the Code commonly referred to as the Foreign Account Tax Compliance Act, or FATCA, generally impose a U.S. federal withholding tax at a rate of 30% on payments of dividends on, or gross proceeds from the sale or other disposition of, our common stock paid to a foreign entity unless (i) if the foreign entity is a "foreign financial institution," such foreign entity undertakes certain due diligence, reporting, withholding, and certification obligations, (ii) if the foreign entity is not a "foreign financial institution," such foreign entity identifies certain of its U.S. investors, if any, or (iii) the foreign entity is otherwise exempt under FATCA. Under applicable U.S. Treasury regulations, withholding under FATCA currently applies to payments of dividends on our common stock, but will only apply to payments of gross proceeds from a sale or other disposition of our common stock made after December 31, 2018. Under certain circumstances, a non-U.S. holder may be eligible for refunds or credits of this withholding tax. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this paragraph. Non-U.S. holders should consult their tax advisors regarding the possible implications of this legislation on their investment in our common stock and the entities through which they hold our common stock, including, without limitation, the process and deadlines for meeting the applicable requirements to prevent the imposition of the 30% withholding tax under FATCA.

UNDERWRITING

Subject to the terms and conditions set forth in the underwriting agreement, dated _____, 2018, among us and Jefferies LLC and Leerink Partners LLC, as the representatives of the underwriters named below, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the respective number of shares of common stock shown opposite its name below:

UNDERWRITER	NUMBER OF SHARES
Jefferies LLC	
Leerink Partners LLC	
RBC Capital Markets, LLC	
Mizuho Securities USA LLC	
Total	

The underwriting agreement provides that the obligations of the several underwriters are subject to certain conditions precedent such as the receipt by the underwriters of officers' certificates and legal opinions and approval of certain legal matters by their counsel. The underwriting agreement provides that the underwriters will purchase all of the shares of common stock if any of them are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated. We have agreed to indemnify the underwriters and certain of their controlling persons against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make in respect of those liabilities.

The underwriters have advised us that, following the completion of this offering, they currently intend to make a market in the common stock as permitted by applicable laws and regulations. However, the underwriters are not obligated to do so, and the underwriters may discontinue any market-making activities at any time without notice in their sole discretion. Accordingly, no assurance can be given as to the liquidity of the trading market for the common stock, that you will be able to sell any of the common stock held by you at a particular time or that the prices that you receive when you sell will be favorable.

The underwriters are offering the shares of common stock subject to their acceptance of the shares of common stock from us and subject to prior sale. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Commission and Expenses

The underwriters have advised us that they propose to offer the shares of common stock to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers, which may include the underwriters, at that price less a concession not in excess of \$ _____ per share of common stock. The underwriters may allow, and certain dealers may reallow, a discount from the concession not in excess of \$ _____ per share of common stock to certain brokers and dealers. After the offering, the initial public offering price, concession and reallowance to dealers may be reduced by the representatives. No such reduction will change the amount of proceeds to be received by us as set forth on the cover page of this prospectus.

The following table shows the public offering price, the underwriting discounts and commissions that we are to pay the underwriters and the proceeds, before expenses, to us in connection with this offering. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	PER SHARE		TOTAL	
	WITHOUT OPTION TO PURCHASE ADDITIONAL SHARES	WITH OPTION TO PURCHASE ADDITIONAL SHARES	WITHOUT OPTION TO PURCHASE ADDITIONAL SHARES	WITH OPTION TO PURCHASE ADDITIONAL SHARES
Public offering price	\$	\$	\$	\$
Underwriting discounts and commissions paid by us	\$	\$	\$	\$
Proceeds to us, before expenses	\$	\$	\$	\$

We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately \$. We have also agreed to pay the filing fees incident to, and the fees and disbursements of counsel for the underwriters in connection with, the required review by the Financial Industry Regulatory Authority, Inc.

Determination of Offering Price

Prior to this offering, there has not been a public market for our common stock. Consequently, the initial public offering price for our common stock will be determined by negotiations between us and the representatives. Among the factors to be considered in these negotiations will be prevailing market conditions, our financial information, market valuations of other companies that we and the underwriters believe to be comparable to us, estimates of our business potential, the present state of our development and other factors deemed relevant.

We offer no assurances that the initial public offering price will correspond to the price at which the common stock will trade in the public market subsequent to the offering or that an active trading market for the common stock will develop and continue after the offering.

Listing

We have applied to have our common stock listed on The Nasdaq Global Market under the trading symbol "XERS".

Stamp Taxes

If you purchase shares of common stock offered in this prospectus, you may be required to pay stamp taxes and other charges under the laws and practices of the country of purchase, in addition to the offering price listed on the cover page of this prospectus.

Option to Purchase Additional Shares

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase, from time to time, in whole or in part, up to an aggregate of shares from us at the public offering price set forth on the cover page of this prospectus, less underwriting discounts and commissions. If the underwriters exercise this option, each underwriter will be obligated, subject to specified conditions, to purchase a number of additional shares proportionate to that underwriter's initial purchase commitment as indicated in the table above. This option may be exercised only if the underwriters sell more shares than the total number set forth on the cover page of this prospectus.

No Sales of Similar Securities

We, our officers, directors and holders of all or substantially all our outstanding capital stock and other securities have agreed, subject to specified exceptions, not to directly or indirectly:

- sell, offer, contract or grant any option to sell (including any short sale), pledge, transfer, establish an open "put equivalent position" within the meaning of Rule 16a-1(h) under the Securities Exchange Act of 1934, as amended, or

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- otherwise dispose of any shares of common stock, options or warrants to acquire shares of common stock, or securities exchangeable or exercisable for or convertible into shares of common stock currently or hereafter owned either of record or beneficially, or
- publicly announce an intention to do any of the foregoing for a period of 180 days after the date of this prospectus without the prior written consent of the representatives.

This restriction terminates after the close of trading of the common stock on and including the 180th day after the date of this prospectus.

The representatives may, in their sole discretion and at any time or from time to time before the termination of the 180-day period release all or any portion of the securities subject to lock-up agreements. There are no existing agreements between the underwriters and any of our shareholders who will execute a lock-up agreement, providing consent to the sale of shares prior to the expiration of the lock-up period.

Stabilization

The underwriters have advised us that they, pursuant to Regulation M under the Securities Exchange Act of 1934, as amended, certain persons participating in the offering may engage in short sale transactions, stabilizing transactions, syndicate covering transactions or the imposition of penalty bids in connection with this offering. These activities may have the effect of stabilizing or maintaining the market price of the common stock at a level above that which might otherwise prevail in the open market. Establishing short sales positions may involve either "covered" short sales or "naked" short sales.

"Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares of our common stock in this offering. The underwriters may close out any covered short position by either exercising their option to purchase additional shares of our common stock or purchasing shares of our common stock in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option to purchase additional shares.

"Naked" short sales are sales in excess of the option to purchase additional shares of our common stock. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the shares of our common stock in the open market after pricing that could adversely affect investors who purchase in this offering.

A stabilizing bid is a bid for the purchase of shares of common stock on behalf of the underwriters for the purpose of fixing or maintaining the price of the common stock. A syndicate covering transaction is the bid for or the purchase of shares of common stock on behalf of the underwriters to reduce a short position incurred by the underwriters in connection with the offering. Similar to other purchase transactions, the underwriter's purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. A penalty bid is an arrangement permitting the underwriters to reclaim the selling concession otherwise accruing to a syndicate member in connection with the offering if the common stock originally sold by such syndicate member are purchased in a syndicate covering transaction and therefore have not been effectively placed by such syndicate member.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. The underwriters are not obligated to engage in these activities and, if commenced, any of the activities may be discontinued at any time.

Electronic Distribution

A prospectus in electronic format may be made available by e-mail or on the web sites or through online services maintained by one or more of the underwriters or their affiliates. In those cases, prospective investors may view offering terms online and may be allowed to place orders online. The underwriters may agree with us to allocate a

specific number of shares of common stock for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters' web sites and any information contained in any other web site maintained by any of the underwriters is not part of this prospectus, has not been approved and/or endorsed by us or the underwriters and should not be relied upon by investors.

Other Activities and Relationships

The underwriters and certain of their affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriters and certain of their affiliates have, from time to time, performed, and may in the future perform, various commercial and investment banking and financial advisory services for us and our affiliates, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and certain of their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments issued by us and our affiliates. If the underwriters or their respective affiliates have a lending relationship with us, they routinely hedge their credit exposure to us consistent with their customary risk management policies. The underwriters and their respective affiliates may hedge such exposure by entering into transactions which consist of either the purchase of credit default swaps or the creation of short positions in our securities or the securities of our affiliates, including potentially the common stock offered hereby. Any such short positions could adversely affect future trading prices of the common stock offered hereby. The underwriters and certain of their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Selling Restrictions

Canada

Resale Restrictions

The distribution of our shares of common stock in Canada is being made only in the provinces of Ontario, Quebec, Manitoba, Alberta and British Columbia on a private placement basis exempt from the requirement that we prepare and file a prospectus with the securities regulatory authorities in each province where trades of these securities are made. Any resale of the shares of common stock in Canada must be made under applicable securities laws which may vary depending on the relevant jurisdiction, and which may require resales to be made under available statutory exemptions or under a discretionary exemption granted by the applicable Canadian securities regulatory authority. Purchasers are advised to seek legal advice prior to any resale of the securities.

Representations of Canadian Purchasers

By purchasing our shares of common stock in Canada and accepting delivery of a purchase confirmation, a purchaser is representing to us and the dealer from whom the purchase confirmation is received that:

- the purchaser is entitled under applicable provincial securities laws to purchase the shares without the benefit of a prospectus qualified under those securities laws as it is an "accredited investor" as defined under National Instrument 45-106—*Prospectus Exemptions*,
- the purchaser is a "permitted client" as defined in National Instrument 31-103—*Registration Requirements, Exemptions and Ongoing Registrant Obligations*,
- where required by law, the purchaser is purchasing as principal and not as agent, and
- the purchaser has reviewed the text above under Resale Restrictions.

Conflicts of Interest

Canadian purchasers are hereby notified that the underwriters are relying on the exemption set out in section 3A.3 or 3A.4, if applicable, of National Instrument 33-105—*Underwriting Conflicts* from having to provide certain conflict of interest disclosure in this document.

Statutory Rights of Action

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if the prospectus (including any amendment thereto) such as this document contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser of these securities in Canada should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Enforcement of Legal Rights

All of our directors and officers as well as the experts named herein may be located outside of Canada and, as a result, it may not be possible for Canadian purchasers to effect service of process within Canada upon us or those persons. All or a substantial portion of our assets and the assets of those persons may be located outside of Canada and, as a result, it may not be possible to satisfy a judgment against us or those persons in Canada or to enforce a judgment obtained in Canadian courts against us or those persons outside of Canada.

Taxation and Eligibility for Investment

Canadian purchasers of our shares of common stock should consult their own legal and tax advisors with respect to the tax consequences of an investment in the shares in their particular circumstances and about the eligibility of the shares for investment by the purchaser under relevant Canadian legislation.

Australia

This prospectus is not a disclosure document for the purposes of Australia's Corporations Act 2001 (Cth) of Australia, or Corporations Act, has not been lodged with the Australian Securities & Investments Commission and is only directed to the categories of exempt persons set out below. Accordingly, if you receive this prospectus in Australia:

You confirm and warrant that you are either:

- a "sophisticated investor" under section 708(8)(a) or (b) of the Corporations Act;
- a "sophisticated investor" under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant's certificate to the company which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made; or
- a "professional investor" within the meaning of section 708(11)(a) or (b) of the Corporations Act.

To the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor or professional investor under the Corporations Act any offer made to you under this prospectus is void and incapable of acceptance.

You warrant and agree that you will not offer any of the shares issued to you pursuant to this prospectus for resale in Australia within 12 months of those securities being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

European Economic Area

In relation to each member state of the European Economic Area which has implemented the Prospectus Directive, each referred to herein as a Relevant Member State, with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State, referred to herein as the Relevant Implementation Date, no offer of any securities which are the subject of the offering contemplated by this prospectus has been or will be made to the public in that Relevant Member State other than any offer where a prospectus has been or will be published in relation to such securities that has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the relevant competent authority in that Relevant Member State in accordance with the Prospectus

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Directive, except that with effect from and including the Relevant Implementation Date, an offer of such securities may be made to the public in that Relevant Member State:

- to any legal entity which is a “qualified investor” as defined in the Prospectus Directive;
- to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives of the underwriters for any such offer; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of securities shall require the Company or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

For the purposes of this provision, the expression an “offer to the public” in relation to any securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the securities to be offered so as to enable an investor to decide to purchase or subscribe the securities, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State and the expression “Prospectus Directive” means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State and the expression “2010 PD Amending Directive” means Directive 2010/73/EU.

Hong Kong

No securities have been offered or sold, and no securities may be offered or sold, in Hong Kong, by means of any document, other than to persons whose ordinary business is to buy or sell shares or debentures, whether as principal or agent; or to “professional investors” as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong, or SFO, and any rules made under that Ordinance; or in other circumstances which do not result in the document being a “prospectus” as defined in the Companies Ordinance (Cap. 32) of Hong Kong, or CO, or which do not constitute an offer to the public for the purpose of the CO or the SFO. No document, invitation or advertisement relating to the securities has been issued or may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted under the securities laws of Hong Kong) other than with respect to securities which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” as defined in the SFO and any rules made under that Ordinance.

This prospectus has not been registered with the Registrar of Companies in Hong Kong. Accordingly, this prospectus may not be issued, circulated or distributed in Hong Kong, and the securities may not be offered for subscription to members of the public in Hong Kong. Each person acquiring the securities will be required, and is deemed by the acquisition of the securities, to confirm that he is aware of the restriction on offers of the securities described in this prospectus and the relevant offering documents and that he is not acquiring, and has not been offered any securities in circumstances that contravene any such restrictions.

Israel

This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968, or the Securities Law, and has not been filed with or approved by the Israel Securities Authority. In the State of Israel, this document is being distributed only to, and is directed only at, and any offer of the shares is directed only at, (i) a limited number of persons in accordance with section 15A of the Securities Law and (ii) investors listed in the first addendum, or the Addendum, to the Israeli Securities Law, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and “qualified individuals”, each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors (in each case purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors will be required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it.

Japan

The offering has not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948 of Japan, as amended), or FIEL, and the Initial Purchaser will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means, unless otherwise provided herein, any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the FIEL and any other applicable laws, regulations and ministerial guidelines of Japan.

Singapore

This prospectus has not been and will not be lodged or registered with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or the invitation for subscription or purchase of the securities may not be issued, circulated or distributed, nor may the securities be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to the public or any member of the public in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (ii) to a relevant person as defined under Section 275(2), or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions, specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of any other applicable provision of the SFA.

Where the securities are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- a corporation (which is not an accredited investor as defined under Section 4A of the SFA) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary is an accredited investor,

securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares of common stock pursuant to an offer made under Section 275 of the SFA except:

- to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- where no consideration is or will be given for the transfer;
- where the transfer is by operation of law;
- as specified in Section 276(7) of the SFA; or
- as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

Switzerland

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This prospectus has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this prospectus nor any other offering or marketing material relating to the securities or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this prospectus nor any other offering or marketing material relating to the offering, the Company or the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this prospectus will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, or FINMA, and the offer of securities has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of securities.

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United Kingdom

This prospectus is only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive that are also (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, referred to herein as the Order, and/or (ii) high net worth entities falling within Article 49(2)(a) to (d) of the Order and other persons to whom it may lawfully be communicated. Each such person is referred to herein as a Relevant Person.

This prospectus and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other persons in the United Kingdom. Any person in the United Kingdom that is not a Relevant Person should not act or rely on this document or any of its contents.

LEGAL MATTERS

The validity of the shares of common stock offered by this prospectus will be passed upon for us by Goodwin Procter LLP, Boston, Massachusetts. Certain legal matters relating to this offering will be passed upon for the underwriters by Wilmer Cutler Pickering Hale and Dorr LLP, New York, New York.

EXPERTS

The financial statements of Xeris Pharmaceuticals, Inc. as of December 31, 2016 and 2017, and for each of the years in the two-year period ended December 31, 2017, have been included herein in reliance upon the report of KPMG LLP, an independent registered public accounting firm, appearing elsewhere herein, and upon the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 (File Number 333-) under the Securities Act with respect to the common stock we are offering by this prospectus. This prospectus does not contain all of the information included in the registration statement. For further information pertaining to us and our common stock, you should refer to the registration statement and to its exhibits. Whenever we make reference in this prospectus to any of our contracts, agreements or other documents, the references are not necessarily complete, and you should refer to the exhibits attached to the registration statement for copies of the actual contract, agreement or other document.

Upon the completion of the offering, we will be subject to the informational requirements of the Exchange Act and will file annual, quarterly and current reports, proxy statements and other information with the SEC. You can read our SEC filings, including the registration statement, at the SEC's website at www.sec.gov. You may also read and copy any document we file with the SEC at its public reference facility at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. We also maintain a website at www.xerispharma.com. Upon completion of the offering, you may access, free of charge, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to those reports, as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC.

You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Stockholders and Board of Directors
Xeris Pharmaceuticals, Inc.:

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Xeris Pharmaceuticals, Inc. (the Company) as of December 31, 2017 and 2016, the related statements of operations, convertible preferred stock and stockholders' deficit, and cash flows for the years then ended, and the related notes (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

We have served as the Company's auditor since 2016

Chicago, Illinois
March 21, 2018

XERIS PHARMACEUTICALS, INC.**Balance Sheets**December 31, 2016 and 2017
(In thousands except share and par value data)

	2016	2017
Assets:		
Current assets:		
Cash and cash equivalents	\$ 32,269	\$ 42,045
Accounts receivable	101	1,199
Prepaid expenses and other current assets	804	809
Total current assets	33,174	44,053
Property and equipment, net	312	788
Other assets	47	157
Total assets	<u>\$ 33,533</u>	<u>\$ 44,998</u>
Liabilities, Convertible Preferred Stock and Stockholders' Deficit:		
Current liabilities:		
Accounts payable	\$ 1,315	\$ 1,976
Accrued expenses	902	2,557
Deferred grant award	263	234
Preferred stock warrants	47	93
Total current liabilities	2,527	4,860
Deferred rent—long term	42	90
Total liabilities	2,569	4,950
Convertible Preferred Stock:		
Series A Convertible Preferred Stock—par value \$0.0001 1,864,797 shares authorized; 1,843,965 shares issued and outstanding as of December 31, 2016 and 2017, respectively; (Liquidation preference of \$1,881 at December 31, 2017)	1,945	1,945
Series B Convertible Preferred Stock—par value \$0.0001 5,732,338 authorized; 5,696,834 issued and outstanding as of December 31, 2016 and 2017, respectively; (Liquidation preference of \$18,908 at December 31, 2017)	18,536	18,536
Series C Convertible Preferred Stock—par value \$0.0001 7,973,845 and 14,353,859 shares authorized; 7,177,398 and 12,834,912 issued and outstanding as of December 31, 2016 and 2017, respectively; (Liquidation preference of \$80,481 at December 31, 2017)	42,417	77,397
Total convertible preferred stock	62,898	97,878
Stockholders' Deficit		
Common stock—par value \$0.0001, 21,247,980 and 30,450,994 shares authorized; 3,432,642 and 3,845,600 shares issued and outstanding as of December 31, 2016 and 2017, respectively.	1	1
Additional-paid-in-capital	2,096	2,754
Accumulated deficit	(34,031)	(60,585)
Total stockholders' deficit	(31,934)	(57,830)
Total liabilities, convertible preferred stock and stockholders' deficit	<u>\$ 33,533</u>	<u>\$ 44,998</u>

See Notes to Financial Statements.

XERIS PHARMACEUTICALS, INC.
Statements of Operations
Years Ended December 31, 2016 and 2017
(In thousands except share and per share data)

	2016	2017
Grant income	\$ 1,022	\$ 1,540
Service revenue	53	16
Cost of revenue	8	4
Gross profit	<u>1,067</u>	<u>1,552</u>
Operating expenses:		
Research and development	10,238	20,166
General and administrative	4,060	8,015
Expense from operations	<u>14,298</u>	<u>28,181</u>
Loss from operations	<u>(13,231)</u>	<u>(26,629)</u>
Other income (expense):		
Interest income	5	124
Interest expense	(2)	(2)
Change in fair value of warrants	24	(46)
Other expense	(5)	(1)
Total other income	<u>22</u>	<u>75</u>
Net loss	<u>\$ (13,209)</u>	<u>\$ (26,554)</u>
Net loss per share—basic and diluted	<u>\$ (4.03)</u>	<u>\$ (7.35)</u>
Weighted average shares outstanding, basic and diluted	<u>3,281,564</u>	<u>3,612,512</u>
Pro forma net loss per share basic and diluted—unaudited		<u>\$ (1.31)</u>
Pro forma weighted average shares outstanding basic and diluted—unaudited		<u>20,231,131</u>

See Notes to Financial Statements.

XERIS PHARMACEUTICALS, INC.

Statements of Convertible Preferred Stock and of Stockholders' Deficit

Years Ended December 31, 2016 and 2017

(In thousands except share data)

	CONVERTIBLE PREFERRED STOCK						STOCKHOLDERS' DEFICIT					
	SERIES A		SERIES B		SERIES C		COMMON STOCK		ADDITIONAL PAID IN CAPITAL	SHAREHOLDER NOTES RECEIVABLE	ACCUMULATED DEFICIT	TOTAL
	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT				
Balance, January 1, 2016	1,796,174	\$ 1,787	5,696,834	\$18,536	6,539,490	\$38,569	3,233,894	\$ 1	\$ 1,534	\$ (90)	\$ (20,822)	\$ (19,377)
Net loss	—	—	—	—	—	—	—	—	—	—	(13,209)	(13,209)
Exercise of Series A Warrants	47,791	49	—	—	—	—	—	—	—	—	—	—
Fair market value of preferred stock warrants charged to Series A Preferred stock	—	109	—	—	—	—	—	—	—	—	—	—
Issuance of Series C Preferred Stock, net of cost \$152	—	—	—	—	637,908	3,848	—	—	—	—	—	—
Repayments on shareholder notes	—	—	—	—	—	—	—	—	—	17	—	17
Allowance on shareholder notes	—	—	—	—	—	—	—	—	—	73	—	73
Exercise and vesting of stock based awards	—	—	—	—	—	—	198,748	—	22	—	—	22
Stock based compensation	—	—	—	—	—	—	—	—	540	—	—	540
Balance, December 31, 2016	1,843,965	\$ 1,945	5,696,834	\$18,536	7,177,398	\$42,417	3,432,642	\$ 1	\$ 2,096	\$ —	\$ (34,031)	\$ (31,934)
Net loss	—	—	—	—	—	—	—	—	—	—	(26,554)	(26,554)
Issuance of Series C Preferred Stock, net of cost \$395	—	—	—	—	5,657,514	34,980	—	—	—	—	—	—
Exercise and vesting of stock based awards	—	—	—	—	—	—	412,958	—	159	—	—	159
Stock based compensation	—	—	—	—	—	—	—	—	499	—	—	499
Balance, December 31, 2017	<u>1,843,965</u>	<u>\$ 1,945</u>	<u>5,696,834</u>	<u>\$18,536</u>	<u>12,834,912</u>	<u>\$77,397</u>	<u>3,845,600</u>	<u>\$ 1</u>	<u>\$ 2,754</u>	<u>\$ —</u>	<u>\$ (60,585)</u>	<u>\$ (57,830)</u>

See Notes to Financial Statements.

XERIS PHARMACEUTICALS, INC.
Statements of Cash Flows
Years Ended December 31, 2016 and 2017
(In thousands)

	<u>2016</u>	<u>2017</u>
Cash flows from operating activities:		
Net loss	\$(13,209)	\$(26,554)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	116	177
Impairment of fixed assets	—	48
Stock-based compensation	540	499
Change in fair value of warrants	(24)	46
Allowance for shareholder note receivable	73	—
Changes in operating assets and liabilities:		
Accounts receivable	204	(1,098)
Prepaid expenses and other current assets	(294)	(5)
Other assets	1	(111)
Accounts payable	(2,909)	661
Accrued expenses	(552)	1,703
Deferred grant award	(33)	(29)
Net cash used in operating activities	<u>(16,087)</u>	<u>(24,663)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(35)	(700)
Net cash used in investing activities	<u>(35)</u>	<u>(700)</u>
Cash flows from financing activities:		
Proceeds from sale of Series C Preferred Stock	4,000	35,475
Payments of Series C Preferred Stock offering costs	(152)	(495)
Proceeds from exercise of preferred stock warrants	49	—
Proceeds from shareholder notes receivable	17	—
Repayments of capital lease	(32)	—
Proceeds from exercise of stock awards	22	159
Net cash provided by financing activities	<u>3,904</u>	<u>35,139</u>
Increase (decrease) in cash and cash equivalents	(12,218)	9,776
Cash and cash equivalents, beginning of year	44,487	32,269
Cash and cash equivalents, end of year	<u>\$ 32,269</u>	<u>\$ 42,045</u>
Supplemental cash flow information:		
Income taxes paid	\$ —	\$ —
Interest paid	<u>\$ 2</u>	<u>\$ 2</u>
Supplemental schedule of noncash investing and financing activities:		
Change in fair market value of expired warrants	<u>\$ 109</u>	<u>\$ —</u>

See Notes to Financial Statements.

XERIS PHARMACEUTICALS, INC.

Note 1. Organization and Nature of the Business

Nature of business

Xeris Pharmaceuticals, Inc. ("Xeris" or the "Company") is a specialty pharmaceutical company that was incorporated in Delaware in 2005. Xeris is dedicated to the development of ready-to-use injectable and infusible drug formulations to address important unmet medical needs and that are easier to use by patients, caregivers and health practitioners, and reduce costs for payors and the healthcare system.

Basis of presentation

The financial statements are prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP").

Since its inception, the Company has devoted substantially all of its efforts to research and development, regulatory and technical activities. The Company has financed its operation through the issuance of convertible preferred stock and other equity instruments and grants from the National Institute of Health and other philanthropic organizations.

The Company has not generated any revenue from product sales. The Company has incurred operating losses since inception and had an accumulated deficit of \$34.0 million and \$60.6 million as of December 31, 2016 and 2017, respectively. The Company expects to continue to incur net losses for the next several years and is highly dependent on its ability to find additional sources of funding in the form of debt and/or equity financing and grant awards to fund its operations. The Company's ability to fund its planned clinical operations, including completion of its planned trials, and commercialization of its product candidates is expected to depend on the amount and timing of cash receipts from financing transactions and grant awards. Adequate additional funding may not be available to the Company on acceptable terms or at all. The failure to raise funds as and when needed could have a negative impact on the Company's financial condition and ability to pursue its business strategies. Based on the Company's current operating plans, existing working capital at December 31, 2017 combined with the \$35.0 million in expected proceeds from the Loan and Security Agreement (the "Loan Agreement") with Oxford Finance LLC (Oxford) and Silicon Valley Bank (SVB) (collectively, the "Lenders") and \$4.4 million in Series C Convertible Preferred Stock sold in February 2018, cash is sufficient to sustain operations beyond March 21, 2019. If additional funding is not secured when required, the Company may need to delay or curtail its operations until such funding is received. The Company is subject to a number of risks similar to other specialty pharmaceutical companies, including, but not limited to, successful development and commercialization of its drug candidates, raising additional capital, the development of new technological innovations by its competitors, protection of intellectual property and market acceptance of the Company's products.

Note 2. Summary of Significant Accounting Policies

Use of estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities and contingent liabilities and expenses included in the financial statements and accompanying notes. Actual results could differ from those estimates.

Grant Income

The Company has received several grants from the National Institute of Health and other philanthropic organizations for certain research and development projects the Company is currently performing. Grant income is recognized when these research and development activities are performed, and the Company has met criteria for reimbursement per the grant agreements. The Company also has grants where cash is received upfront. The Company defers these awards until the research and development expenses are incurred.

Revenue

The Company recognizes revenue when persuasive evidence of an arrangement exists, the related services have been performed, the price is fixed and determinable and collectability is reasonably assured. The Company generates revenue through the performance of research and development activities on behalf of others.

Research and development costs

Research and development costs are expensed as incurred. Research and development costs include salaries, stock compensation and other personnel-related costs, consulting fees, fees paid for contract research services, laboratory equipment and facilities costs, and other external costs.

Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are received or the services are performed.

Stock based compensation

The Company accounts for its stock-based compensation awards in accordance with ASC Topic 718, *Compensation—Stock Compensation* (“ASC 718”). ASC 718 requires all stock-based payments to employees, including grants of employee stock options, to be recognized in the statements of operations based on their grant date fair values. The Company estimates the grant date fair value of each option award using the Black-Scholes option-pricing model. The use of the Black-Scholes option-pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the common stock consistent with the expected life of the option, risk-free interest rates and expected dividend yields of the common stock. The Company recognizes stock-based compensation expense, net of estimated forfeitures, equal to the grant date fair value of stock options on a straight-line basis over the requisite service period. Restricted stock awards are valued based on the fair market value of the Company’s common stock on the date they were granted. Restricted stock that vests and stock options that are authorized are issued out of authorized available shares.

The Company accounts for stock-based awards issued to non-employees by recognizing compensation expense based on the fair value of such awards when the services are completed over the vesting period of the award.

Income Taxes

Income taxes are recorded in accordance with ASC 740, *Accounting for Income Taxes* (“ASC 740”), which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. The Company determines its deferred tax assets and liabilities based on differences between financial reporting and tax bases of assets and liabilities, which are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Valuation allowances are provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. As of December 31, 2017, the Company does not have any significant uncertain tax positions.

Cash and cash equivalents

Cash and cash equivalents includes demand deposits with financial institutions and liquid investments with original maturities of three months or less.

Concentrations of risk

The Company has no off-balance sheet concentrations of credit risk, such as foreign currency exchange contracts, option contracts or other hedging arrangements.

The Company is dependent on several key suppliers and third-party manufacturers. A failure or disruption by one of the Company’s key suppliers or third-party manufacturers may have a material impact to its planned operations.

Prepaid expenses and other current assets

Prepaid expenses and other current assets include prepaid expenses for general business purposes, which are stated at cost and are amortized on a straight-line basis over the related period of benefit. Prepaid expenses also include supplies and materials used in several research projects. These supplies are expensed as they are consumed.

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Property and equipment

Property and equipment are carried at cost less accumulated depreciation. Depreciation is calculated utilizing the straight-line method over the estimated useful lives of the respective assets:

Lab equipment	5 years
Computer equipment	5 years
Leasehold improvements	Lesser of useful life or lease term
Software	3-5 years
Furniture and fixtures	5 years
Office equipment	5 years

Costs of major additions and betterments are capitalized; maintenance and repairs, which do not improve or extend the life of the respective assets, are charged to expense as incurred. Upon retirement or sale, the cost of the disposed asset and the related accumulated depreciation are removed from the accounts and the resulting gain or loss is recognized.

Impairment of long-lived assets

The Company periodically evaluates its long-lived assets for potential impairment in accordance with ASC Topic 360, *Property, Plant and Equipment*. Potential impairment is assessed when there is evidence that events or changes in circumstances indicate that the carrying amount of an asset may not be recovered. Recoverability of these assets is assessed based on undiscounted expected future cash flows from the assets, considering a number of factors, including past operating results, budgets and economic projections, market trends and product development cycles. If impairments are identified, assets are written down to their estimated fair value. The Company recognized impairment charges of \$0 and \$48,000 for the years ended December 31, 2016 and 2017, respectively. The impairment charge in 2017 was related to equipment that is no longer used in the Company's manufacturing of the glucagon rescue pen due to process and formulation improvements.

Deferred rent

Certain of the Company's lease agreements provide for scheduled rent increases during the lease term and for rental payments commencing at a date after the initial occupancy date. Provisions are made for the excess of operating lease rentals, computed on a straight-line basis throughout the lease term, over cash rentals paid.

Preferred stock

The Company's Series A, B and C Convertible Preferred Stock (collectively known as "Preferred Stock") allows the holders to redeem their shares upon a change in control in the Company. As a result, the Company classifies its Preferred Stock as mezzanine equity. The Company charges specific incremental issuance costs incurred in the offering of Preferred Stock against the gross proceeds of the Preferred Stock.

Warrants

Warrants for the Company's convertible preferred stock are liability classified as they represent a financial instrument for a share of convertible preferred stock. The warrants are revalued each reporting period with the change in fair value recorded in the accompanying statements of operations until the warrants are exercised, expire, reclassified to permanent equity, or otherwise settled.

Fair value of financial instruments

Fair value is the price that could be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. Fair value determination in accordance with applicable accounting guidance requires that a number of significant judgments are made. Additionally, fair value is used on a nonrecurring basis to evaluate assets for impairment or as required for disclosure purposes by applicable accounting guidance on disclosures about fair value of financial instruments. Depending on the nature of the assets and liabilities, various valuation techniques and assumption are used when estimating fair value. Items measured at fair value on a recurring basis include the Company's preferred stock warrants. The warrants are carried at their estimated fair value.

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Segments

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker ("CODM") in making decisions regarding resource allocation and assessing performance. The Company's chief executive officer uses summary financial information in determining how to allocate resources and assess performance. The Company has determined that it operates in one segment and all of the Company's assets are located in the United States.

Net loss per share

Basic and diluted net loss per common share is determined by dividing net loss applicable to common stockholders by the weighted-average common shares during the period. For all periods presented, the outstanding shares of the Preferred Stock, preferred stock warrants, and stock awards have been excluded from the calculation because their effects would be anti-dilutive. Therefore the weighted-average shares used to calculate both basic and diluted loss per share are the same.

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares outstanding as of December 31, 2016 and 2017, as they would be antidilutive:

	YEARS ENDED DECEMBER 31,	
	2016	2017
Convertible preferred stock	14,718,197	20,375,711
Preferred stock warrants	35,500	35,500
Stock options and unvested restricted stock awards	1,095,431	3,525,468
	<u>15,849,128</u>	<u>23,936,679</u>

Amounts in the table above reflect the common stock equivalents of the noted instruments.

The unaudited pro forma net loss per common share is computed using the weighted-average number of common shares outstanding and assumes the issuance of 20,411,211 shares of common stock issued to the holders of the Company's Preferred Stock and preferred stock warrants upon an initial public offering as if such conversion had occurred at the beginning of the period presented or the date of original issuance, if later.

The following table summarizes the calculation of unaudited pro forma basic and diluted net loss per common share:

(In thousands except share and per share data)	2017
Pro forma net loss per common share (unaudited)	
Numerator	
Net Loss attributable to common stockholders	\$ (26,554)
Pro forma adjustments to eliminate changes in fair value of preferred stock warrant liability	46
Net loss used to compute pro forma net loss per share	\$ (26,508)
Denominator	
Weighted average of common shares outstanding	3,612,512
Pro forma adjustment to reflect the automatic conversion of all Convertible Preferred Stock and the related preferred stock warrants to common stock upon an initial public offering	16,618,619
Pro forma weighted average number of shares outstanding—Basic and diluted	20,231,131
Pro forma net loss per share—basic and diluted	\$ (1.31)

Recent accounting pronouncements

In March 2016, the Financial Accounting Standards Board (FASB) issued ASU 2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share Based Payment Accounting* (“ASU 2016-09”) as part of the FASB simplification initiative. The new standard provides for changes to accounting for stock compensation including 1) excess tax benefits and tax deficiencies related to share-based payment awards will be recognized as income tax expense in the reporting period in which they occur; 2) excess tax benefits will be classified as an operating activity in the statement of cash flow; 3) the option to elect to estimate forfeitures or account for them when they occur; and 4) increase tax withholding requirements threshold to qualify for equity classification. ASU 2016-09 is effective for public companies with annual periods and interim periods beginning after December 15, 2016. Early adoption is permitted. The Company intends to adopt this standard on January 1, 2018 and continues to analyze and assess the impact, if any, of this standard on its financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*. The new standard requires the recognition of assets and liabilities arising from lease transactions on the balance sheet and the disclosure of key information about leasing arrangements. Accordingly, a lessee will recognize a lease asset for its right to use the underlying asset and a lease liability for the corresponding lease obligation. Both the asset and liability will initially be measured at the present value of the future minimum lease payments over the lease term. Subsequent measurement, including the presentation of expenses and cash flows, will depend on the classification of the lease as either a finance or an operating lease. Initial costs directly attributable to negotiating and arranging the lease will be included in the asset. For leases with a term of twelve months or less, a lessee can make an accounting policy election by class of underlying asset to not recognize an asset and corresponding liability. Lessees will also be required to provide additional qualitative and quantitative disclosures regarding the amount, timing and uncertainty of cash flows arising from leases. These disclosures are intended to supplement the amounts recorded in the financial statements and provide additional information about the nature of an organization's leasing activities. The new standard will be effective for public companies with annual periods and interim periods beginning after December 15, 2018. Early adoption is permitted. In transition, lessees are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. The transition guidance also provides specific guidance for sale and leaseback transactions, build-to-suit leases and amounts previously recognized in accordance with the business combinations guidance for leases. The Company intends to adopt this standard on January 1, 2020 and continues to analyze and assess the impact, if any, of this standard on its financial statements.

In May 2014, the FASB issued ASU 2014-09 (ASC606), *Revenue from Contracts with Customers*. This ASU, as amended by ASU 2015-14, affects any entity that either enters into contracts with customers to transfer goods and services or enters into contracts for the transfer of nonfinancial assets. ASU 2014-09 will replace most existing revenue recognition guidance in GAAP when it becomes effective. The standard's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In doing so, companies will need to use more judgment and make more estimates than under the currently effective guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. ASU 2014-09 is effective for public companies with annual periods beginning after December 15, 2018 and for interim periods beginning after December 15, 2019. Early adoption is permitted. The Company intends to adopt this standard on January 1, 2019 and continues to analyze and assess the impact, if any, of this standard on its financial statements.

In May 2017, the FASB issued ASU 2017-09, *Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting*. ASU 2017-09 clarifies when changes to the terms or conditions of a share-based payment award must be accounted for as modifications. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award changes as a result of the change in terms or conditions. ASU 2017-09 will be applied prospectively to awards modified on or after the adoption date. ASU 2017-09 is effective for public companies for annual and interim periods beginning after December 15, 2017. Early adoption is permitted. The Company intends to adopt this standard on January 1, 2019, and continues to analyze and assess the impact, if any, of this standard on its financial statements.

Note 3. Property and Equipment

Property and equipment consisted of the following:

(In thousands)	DECEMBER 31,	
	2016	2017
Lab equipment	\$ 375	\$ 860
Furniture and fixtures	103	128
Computer equipment	50	100
Office equipment	26	78
Software	16	52
Leasehold improvements	10	10
	<u>580</u>	<u>1,228</u>
Less accumulated depreciation and amortization	(268)	(440)
Property and equipment, net	<u>\$ 312</u>	<u>\$ 788</u>

Depreciation and amortization expense relating to property and equipment was \$116,000 and \$177,000 for the years ended December 31, 2016 and 2017, respectively.

Note 4. Accrued Expenses

Accrued expenses consist of the following:

(In thousands)	DECEMBER 31,	
	2016	2017
Accrued employee costs	\$ 744	\$ 1,581
Accrued research costs	70	566
Other	88	410
Accrued expenses	<u>\$ 902</u>	<u>\$ 2,557</u>

Note 5. Convertible Preferred Stock

The holders of the Company's Preferred Stock will be entitled to receive non-cumulative dividends at the rate of 8% of the purchase price per annum in preference to any dividends to the holders of the common stock, payable as and if when declared by the Board of Directors. The Board has not declared any dividends as of December 31, 2017. The holders of the Preferred Stock also will be entitled to participate pro rata in any dividends paid to the holders of the common stock on an as-converted basis.

Upon the liquidation of the Company, the holders of Preferred Stock will be entitled to receive, in preference to the holders of the common stock, an amount equal to \$1.02 per share for Series A Convertible Preferred Stock, \$3.319 per share for Series B Convertible Preferred Stock and \$6.2705 per share for Series C Convertible Preferred Stock plus any declared but unpaid dividends (the "Liquidation Preference"). After the payment of the Liquidation Preference in full, the remaining assets or other property of the Company will be distributed ratably to the holders of the common stock and the Preferred Stock on an as converted basis. A merger or consolidation involving the Company, a sale of voting control of the Company or the sale of all or substantially all of the assets of the Company will be deemed to be a liquidation for this purpose.

The holders of the Preferred Stock will have the right to convert their shares (including declared, but unpaid dividends thereon) into shares of the Company's common stock at any time. The initial conversion rate will be 1:1 subject to customary anti-dilution provisions.

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The Preferred Stock will convert automatically into common stock upon the election of the holders of a majority of the outstanding Preferred Stock holders; or the closing of a firmly underwritten public offering of shares of the Company's common stock at a public offering price per share (prior to underwriter commissions and expenses) that is not less than \$9.40 per share in an offering with aggregate proceeds to the Company of not less than \$30,000,000.

Prior to completion of the Company's initial public offering, the holders of the Series C Convertible Preferred Stock are entitled to elect two board members and the holders of Series A and B Convertible Preferred Stock are entitled to elect two board members.

Note 6. Warrants

In 2013 the Company issued 69,000 Series A Convertible Preferred Stock warrants ("Series A Warrants"). The holder of each Series A Warrant was entitled to purchase one share of Series A Convertible Preferred Stock for \$1.02. In 2016 47,791 warrants were exercised and the remaining Series A Warrants expired. There were no Series A Warrants outstanding as of December 31, 2016 and 2017.

In 2014 the Company issued 35,500 warrants ("Series B Warrants") to certain investors. The Series B Warrants allow each holder to purchase one share of Series B Preferred stock for \$3.319 and they expire in August of 2020. There have been no exercises of Series B Warrants as of December 31, 2017 and as such all 35,500 warrants were outstanding as of December 31, 2016 and 2017.

Note 7. Commitments and Contingencies

Commitments

The Company has non-cancellable operating leases for office space and equipment, which expire at various times through 2024. The non-cancellable office lease agreements provide for monthly lease payments, which increase during the term of the lease. Future minimum lease payments under operating leases at December 31, 2017 are as follows:

(In thousands)	
2018	\$ 730
2019	859
2020	834
2021	1,123
2022	1,148
Thereafter	701
Total minimum lease payments	<u>\$5,395</u>

Total rent expense under these operating leases was approximately \$268,000 and \$526,000 for the years ended December 31, 2016 and 2017, respectively.

The Company has an outstanding letter of credit for \$58,000 used to secure a lease in San Diego, California.

Through December 31, 2017, the Company has received \$760,000 out of an expected \$872,000 in grant proceeds for the development of a stable liquid glucagon for use in an artificial pancreas. Under the terms of the agreement, the Company will be required to pay up to four times the award received upon the commercialization of glucagon for use in the artificial pancreas. If the Company undergoes a change in control, then the Company will be required to pay a mid-single digit percentage of the gross proceeds, capped at four times the award amount less any amounts already paid. Additionally, if sales of glucagon for use in the artificial pancreas exceed \$750 million in the first five years after the first commercial sale, then the Company would be required to make an additional payment equal to the original award amount.

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The Company has received a grant for \$929,000 to help fund its exercise induced hypoglycemia (“EIH”) program. Under terms of this agreement and upon the commercialization of an EIH product, the Company will be required to make royalty payments based on a low double-digit percentage of annual gross sales of an EIH product, capped at \$500,000 annually. If the Company undergoes a change in control, the Company will pay a mid-single digit percentage of the consideration capped at two times the award amount less any amounts already paid. Additionally, if sales exceed \$1 billion, the Company will be required to make a milestone payment equal to two times the award amount.

The Company has received a grant for \$1,004,000 to help fund its Type 1 Diabetes chronic glucagon programs. Under terms of this agreement the Company will be required to pay up to two times the award amount upon the commercialization of any chronic glucagon program. These amounts are a low double-digit percentage of annual gross sales of all Type 1 Diabetes chronic glucagon programs, capped at \$500,000 annually. If the Company undergoes a change in control, then it will pay a mid-single digit percentage of the consideration capped at two times the award amount less any amounts already paid. Additionally, for each chronic glucagon program where sales exceed \$500 million, the Company will be required to pay an additional amount equal to two times the award amount.

Litigation

From time to time, the Company may become involved in various legal actions arising in the ordinary course of business. As of December 31, 2016 and 2017, management was not aware of any existing, pending or threatened legal actions that would have a material impact on the financial position or results of operations of the Company.

Note 8. Shareholder Notes Receivables

In November 2014, the Company accepted Notes Receivables totaling \$107,000 from its then Chief Executive Officer (CEO) and a member of the Company’s Board of Directors, to exercise certain stock options. The Notes Receivables carried an interest rate of 1.93%, were payable in equal installments over 60 months and were collateralized by the underlying common stock purchased as a part of the stock option exercise and thus were recorded as a deduction to stockholder’s equity. The Board member paid his Note Receivable in full upon his resignation from the Board in 2016. The Company agreed to forgive the unpaid portion of the CEO’s Note Receivable as part of his severance package in connection with this separation from the Company in January 2017. As a result, the CEO’s Note Receivable of \$73,000 was fully reserved at December 31, 2016 and written off in January 2017.

Note 9. Stock Compensation Plan

In 2011 the Company adopted the 2011 Stock/Option Issuance Plan (“2011 Plan”) and subsequently amended to authorize the Board of Directors to issue up to 7,797,950 incentive grant and non-statutory awards. Options and restricted stock granted to employees under the 2011 Plan typically vest over a 48-month period and options and restricted stock granted to non-employee directors vest over a 24-month period. All stock awards typically expire 10 years after they were issued. Subsequent to December 31, 2017 the shareholders approved an increase of 600,000 incentive grant and non-statutory awards allowed to be granted under the 2011 Plan.

The fair value of stock options was estimated with the following weighted average assumptions:

	YEARS ENDED DECEMBER 31,	
	2016	2017
Expected term	5.88	6.06
Expected volatility	61.46%	61.10%
Risk-free interest rate	1.48%	2.06%
Expected dividends	—	—

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Stock option activity for employee awards for the year ended December 31, 2016 and 2017 is as follows:

	UNITS	WEIGHTED AVERAGE EXERCISE PRICE	WEIGHTED AVERAGE CONTRACTUAL LIFE (YEARS)
Outstanding—January 1, 2016	649,418	\$ 0.74	6.33
Issued	246,000	1.52	
Exercised	(22,332)	0.49	
Forfeited	(16,655)	0.69	
Outstanding—December 31, 2016	856,431	0.95	6.71
Issued	2,925,607	0.92	
Exercised	(208,958)	0.89	
Forfeited	(23,612)	1.03	
Expired	(83,000)	0.86	
Outstanding—December 31, 2017	3,466,468	\$ 0.93	8.71
Exercisable—December 31, 2017	3,045,590	\$ 0.92	8.70
Vested and expected to vest at December 31, 2017	3,091,081	\$ 0.93	8.70

The weighted average grant date fair value of awards granted during the years ended December 31, 2016 and 2017 was \$0.87 and \$0.53 per share, respectively. The total intrinsic value of options exercised during the years ended December 31, 2016 and 2017 was \$9,000 and \$1,258,000 respectively. The aggregate intrinsic value of awards vested and expected to vest as of December 31, 2016 and 2017 was \$122,000 and \$7,422,000, respectively.

Restricted stock awards for employees for the 2011 Plan for the years ended December 31, 2016 and 2017 is as follows:

	SHARES
Outstanding—January 1, 2016	172,500
Granted	185,000
Vested	(177,395)
Outstanding—December 31, 2016	180,105
Vested	(180,105)
Outstanding—December 31, 2017	—

The weighted average grant date fair value of awards issued in 2016 was \$294,000 and the intrinsic fair value of shares vested and expected to vest during the year ended December 31, 2016 was \$157,000. There were no awards granted during 2017 or outstanding as of December 31, 2017.

The following table summarizes the reporting of total stock-based compensation expense resulting from employee and non-employee stock options and restricted stock awards:

(In thousands)	YEARS ENDED DECEMBER 31,	
	2016	2017
Research and development	\$ 78	\$ 62
General and administrative	462	437
Total stock based compensation	\$ 540	\$ 499

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There was a total of \$1,311,000 of unrecognized compensation expense that is expected to be recognized over a weighted average period of 1.34 years.

The Company also granted stock options to non-employees. These awards are marked to fair-value at the end of each reporting period. Stock option activity for these awards for the years ended December 31, 2016 and 2017 is as follows:

	<u>UNITS</u>	<u>WEIGHTED AVERAGE EXERCISE PRICE</u>	<u>WEIGHTED AVERAGE CONTRACTUAL LIFE (YEARS)</u>
Outstanding—January 1, 2016	49,000	\$ 0.50	7.15
Issued	25,000	1.59	
Exercised	(22,916)	0.46	
Forfeited	(2,084)	0.46	
Outstanding—December 31, 2016	49,000	1.07	7.75
Issued	10,000	0.87	
Outstanding—December 31, 2017	59,000	\$ 1.07	6.75
Exercisable—December 31, 2017	49,000	\$ 1.07	6.75
Vested and expected to vest at December 31, 2017	49,000	\$ 1.07	6.74

The aggregate intrinsic value of awards vested and expected to vest at December 31, 2016 and 2017 was \$8,000 and \$110,000 respectively. The aggregate intrinsic value of awards exercisable as of December 31, 2016 and 2017 was \$8,000 and \$111,000, respectively. The company recognized expense associated with these awards of \$8,000 and \$35,000 for the years ended December 31, 2016 and 2017, respectively.

Note 10. Defined Contribution Plan

The Company sponsors an employee retirement plan qualifying under Section 401(k) of the Internal Revenue Code for all eligible employees in the United States. Employees become eligible to contribute to the plan upon meeting certain age requirements and 30 days of service. Currently the company does not make any contributions to the plan.

Note 11. Income Taxes

Due to reported losses, the Company recorded no income tax expense for the years ended December 31, 2016 and 2017. A reconciliation of the expected income tax benefit computed using the federal statutory income tax rate of 34% to the Company's effective income tax rate is as follows:

(In thousands)	<u>DECEMBER 31,</u>	
	<u>2016</u>	<u>2017</u>
Income tax using the federal statutory tax rate	\$(4,491)	\$(9,028)
Impact of rate change	—	7,478
Research and development and orphan drug credit	(655)	(517)
Permanent adjustments to expenses	(3)	76
Stock compensation	145	42
Prior year adjustment	—	(100)
Changes in valuation allowance	5,004	2,049
Total income taxes	\$ —	\$ —

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During the years ended December 31, 2016 and 2017, the Company had no interest and penalties related to income taxes.

Deferred income taxes reflect the net tax effects of temporary difference between the carrying amount of the assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The Company has established a valuation allowance due to the uncertainties regarding the realization of the deferred tax assets based on the Company's lack of earning's history. Significant components of the Company's deferred tax assets and liabilities are as follows:

(In thousands)	DECEMBER 31,	
	2016	2017
Deferred tax assets		
Net operating losses	\$ 10,547	\$ 11,715
Research credits	1,462	2,045
Stock compensation	5	49
Other temporary differences	202	349
Valuation allowance	(12,157)	(14,124)
Total assets	59	34
Deferred tax liabilities		
Fixed and intangible assets	(59)	(34)
Total liabilities	(59)	(34)
Net deferred tax assets	\$ —	\$ —

As of December 31, 2016 and 2017, the Company had federal net operating loss carryforwards ("NOL") of \$31,011,000 and \$55,786,000, respectively. As of December 31, 2016 and 2017, the Company had federal research and orphan drug credit carryforwards of \$1,462,000 and \$2,045,000, respectively. If not utilized, these NOLs and research and orphan drug credit carryforwards will expire between 2025 and 2036.

Impacts of the Tax Cuts and Jobs Act

On December 22, 2017, the Tax Cuts and Jobs Act (H.R. 1) (the "Tax Act") was signed into law. The Tax Act contains significant changes to corporate taxation, including (i) the reduction of the corporate income tax rate to 21%, (ii) the acceleration of expensing for certain business assets, (iii) the one-time transition tax related to the transition of U.S. international tax from a worldwide tax system to a territorial tax system, (iv) the repeal of the domestic production deduction, (v) additional limitations on the deductibility of interest expense, and (vi) expanded limitations on executive compensation. The key impacts of the Tax Act on the Company's financial statement for the year ended December 31, 2017, were the re-measurement of deferred tax balances to the new corporate tax rate. While the Company has not yet completed the assessment of the effects of the Tax Act, the Company was able to determine reasonable estimates for the impacts of the key items specified above, thus it reported provisional amounts for these items. In accordance with Staff Accounting Bulletin No. 118 ("SAB 118"), the Company is providing additional disclosures related to these provisional amounts. In order to calculate the effects of the new corporate tax rate on its deferred tax balances, ASC 740 "Income Taxes" ("ASC 740") required the re-measurement of the Company's deferred tax balances as of the enactment date of the Tax Act, based on the rates at which the balances were expected to reverse in the future. The provisional amount determined, and recorded, for the re-measurement of its deferred tax balances resulted in a net reduction in deferred tax assets of \$7,478,000 and a corresponding reduction in the valuation allowance of \$7,478,000.

The aforementioned provisional amounts related to the deferred tax balances are based on information available at this time and may change due to a variety of factors, including, among others, (i) anticipated guidance from the U.S. Department of Treasury about implementing the Tax Act, (ii) potential additional guidance from the Securities and Exchange Commission or the FASB related to the Tax Act and (iii) management's further assessment of the Tax Act and related regulatory guidance. The Company is not complete in its assessment of the impact of the Tax Act on its

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business and financial statements. While the effective date of most of the provisions of the Tax Act do not apply until the Company's tax year beginning January 1, 2018 it will continue the assessment of the impact of the Tax Act on its business and financial statements throughout the one-year measurement period as provided by SAB 118.

Note 12. Fair Value Measurement

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Fair value measurements are classified and disclosed in one of the following categories:

Level 1: Measured using unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.

Level 2: Measured using quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability.

Level 3: Measured based on prices or valuation models that required inputs that are both significant to the fair value measurement and less observable from objective sources (i.e., supported by little or no market activity).

Fair value measurements are classified based on the lowest level of input that is significant to the measurement. The Company's assessment of the significance of a particular input to the fair value measurement requires judgment, which may affect the valuation of the assets and liabilities and their placement within the fair value hierarchy levels. The determination of the fair values stated below takes into account the market for its financial assets and liabilities, the associated credit risk and other factors as required. The Company considers active markets as those in which transactions for the assets or liabilities occur in sufficient frequency and volume to provide pricing information on an ongoing basis.

The carrying amounts of cash and cash equivalents, grants receivable, and accounts payables approximate their fair values due to the short-term maturities of these instruments.

The fair value of the Company's warrant liabilities at inception and for subsequent mark-to-market fair value measurements, are based on management's valuation model and expected methods and timing of settlement. These estimates are prepared using models that consider various inputs including: (a) the Company's estimated future cash flows, (b) time value, and (c) current market conditions, as well as other relevant economic measures. The Company has determined that the warrant liabilities fair values are Level 3 items within the fair value hierarchy. The following table presents the changes in the warrant liabilities:

(In thousands)	
Balance at January 1, 2016	\$ 180
Fair value of Series A warrants expired/exercised	(109)
Changes in fair value of warrants	(24)
Balance at December 31, 2016	47
Changes in fair value of warrants	46
Balance at December 31, 2017	<u>\$ 93</u>

Note 13. Related Party Transaction

During 2017 the Company paid a spouse of an officer \$37,000 to help with the development of the Company's website.

Note 14. Subsequent Events

Management reviews events and transactions occurring after the balance sheet date for potential recognition and disclosure in the financial statements. Management has evaluated subsequent events through March 21, 2018, the date on which the financial statements were available to be issued.

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In February 2018, the Company entered into a sublease for office space in Chicago, Illinois that expires in November 2024, and entered into a letter of credit for \$85,000 to secure the sublease. Annual minimum lease payments for the next five years are included in the table below:

(In thousands)	
2018	\$ 163
2019	202
2020	210
2021	219
2022	228
Thereafter	462
Total minimum lease payments	<u>\$1,484</u>

In February 2018, the Company sold 707,680 shares of Series C Convertible Preferred Stock for \$6.2705 per share resulting in proceeds of \$4.4 million with the same rights and preferences as the Series C Preferred Stock disclosed in Note 5.

In February 2018, the Company entered into the Loan Agreement, providing a senior secured loan facility of up to an aggregate principal amount of \$45.0 million, comprising a \$20.0 million drawdown in February 2018, and an additional \$25.0 million which can be borrowed in two additional tranches. The second tranche is \$15.0 million and is available beginning upon our submission of our NDA for our Glucagon Rescue Pen until the earlier of September 30, 2018 or the 30th day following such NDA submission. The third tranche is \$10.0 million and is available beginning upon approval of our Glucagon Rescue Pen NDA by the FDA until the earlier of September 30, 2019 or the 30th day following NDA approval by the FDA.

The interest rate under the Loan Agreement is the thirty-day U.S. LIBOR rate plus 6.75%. Payments on the Loan Agreement are interest only for the first 24 months, which can be extended by an additional twelve months if the third tranche is drawn. The total term of the loan is 59 months and the principal payments will begin in either 36 or 24 months, contingent on the third tranche being drawn.

Pursuant to the Loan Agreement, the Company provided a first priority security interest in all existing and after-acquired assets, excluding intellectual property and certain other assets, owned by us. There is a negative pledge on intellectual property owned by the Company.

The Company also issued warrants to the Lenders to purchase the Company's Series C Preferred stock at an exercise price of \$6.2705. The number of warrants issued to Lenders is equal to the total principal of each funded tranche multiplied by 3.0%, which is then divided by \$6.2705. As of March 1, 2018, a total of 95,686 warrants have been issued in connection with the Loan Agreement.

The Loan Agreement allows the Company to voluntarily prepay the outstanding amounts thereunder, but not less than \$2.0 million of the outstanding principal at any time. A prepayment fee of 1.5% would be assessed on the prepaid principal through the interest-only period. A final payment fee of 6.5% multiplied by the original principal amount of each tranche drawn is due upon the earlier to occur of the maturity date of the Loan Agreement, the acceleration of the Loan Agreement or prepayment of such borrowings. The Loan Agreement includes a non-utilization fee of 2.0% multiplied by the principal amount of tranche three payable to lenders in October 2019, if the Company does not elect to draw the third Tranche.

Shares

Common Stock

PROSPECTUS

Joint Book-Running Managers

Jefferies

Leerink Partners

RBC Capital Markets

Mizuho Securities

Until _____, 2018 all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

, 2018

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution

The following table sets forth the estimated costs and expenses, other than underwriting discounts and commissions, to be paid by us in connection with the sale of the shares of common stock being registered hereby.

SEC registration fee	\$	*
FINRA filing fee		*
Listing fee		*
Printing and engraving expenses		*
Legal fees and expenses		*
Accounting fees and expenses		*
Blue Sky fees and expenses (including legal fees)		*
Transfer agent and registrar fees and expenses		*
Miscellaneous		*
Total		*

* To be provided by amendment.

Item 14. Indemnification of Directors and Officers

Section 145 of the Delaware General Corporation Law, or the DGCL, authorizes a corporation to indemnify its directors and officers against liabilities arising out of actions, suits and proceedings to which they are made or threatened to be made a party by reason of the fact that they have served or are currently serving as a director or officer to a corporation. The indemnity may cover expenses (including attorneys' fees) judgments, fines and amounts paid in settlement actually and reasonably incurred by the director or officer in connection with any such action, suit or proceeding. Section 145 permits corporations to pay expenses (including attorneys' fees) incurred by directors and officers in advance of the final disposition of such action, suit or proceeding. In addition, Section 145 provides that a corporation has the power to purchase and maintain insurance on behalf of its directors and officers against any liability asserted against them and incurred by them in their capacity as a director or officer, or arising out of their status as such, whether or not the corporation would have the power to indemnify the director or officer against such liability under Section 145.

We have adopted provisions in our certificate of incorporation and bylaws to be in effect upon the closing of this offering that limit or eliminate the personal liability of our directors to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended. Consequently, a director will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any unlawful payments related to dividends or unlawful stock purchases, redemptions or other distributions; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not alter director liability under the federal securities laws and do not affect the availability of equitable remedies such as an injunction or rescission.

In addition, our bylaws provide that:

- we will indemnify our directors, officers and, in the discretion of our board of directors, certain employees to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended; and

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- we will advance reasonable expenses, including attorneys' fees, to our directors and, in the discretion of our board of directors, to our officers and certain employees, in connection with legal proceedings relating to their service for or on behalf of us, subject to limited exceptions.

We intend to enter into indemnification agreements with each of our directors and executive officers. These agreements provide that we will indemnify each of our directors, certain of our executive officers and, at times, their affiliates to the fullest extent permitted by Delaware law. We will advance expenses, including attorneys' fees (but excluding judgments, fines and settlement amounts), to each indemnified director or executive officer in connection with any proceeding in which indemnification is available and we will indemnify our directors and officers for any action or proceeding arising out of that person's services as a director or officer brought on behalf of us or in furtherance of our rights. Additionally, certain of our directors or officers may have certain rights to indemnification, advancement of expenses or insurance provided by their affiliates or other third parties, which indemnification relates to and might apply to the same proceedings arising out of such director's or officer's services as a director referenced herein. Nonetheless, we have agreed in the indemnification agreements that our obligations to those same directors or officers are primary and any obligation of such affiliates or other third parties to advance expenses or to provide indemnification for the expenses or liabilities incurred by those directors are secondary.

We also maintain general liability insurance which covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers, including liabilities under the Securities Act of 1933, as amended, or the Securities Act.

The underwriting agreement filed as Exhibit 1.1 to this registration statement provides for indemnification of us and our directors and officers by the underwriters against certain liabilities under the Securities Act and the Securities Exchange Act of 1934.

Item 15. Recent Sales of Unregistered Securities

In the three years preceding the filing of this registration statement, we have issued the following securities that were not registered under the Securities Act:

(a) Issuances of Capital Stock

In December 2015, with subsequent closings in December 2016, May 2017, December 2017 and February 2018, we sold an aggregate of 13,542,592 shares of our Series C preferred stock at a purchase price of \$6.2705 per share.

No underwriters were involved in the foregoing sales of securities. The sales of securities described above were deemed to be exempt from registration pursuant to Section 4(a)(2) of the Securities Act, including Regulation D and Rule 506 promulgated thereunder, as transactions by an issuer not involving a public offering. All of the purchasers in these transactions represented to us in connection with their purchase that they were acquiring the securities for investment and not distribution, that they could bear the risks of the investment and could hold the securities for an indefinite period of time. Such purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration or an available exemption from such registration. All of the foregoing securities are deemed restricted securities for the purposes of the Securities Act.

(b) Grants and Exercises of Stock Options

Between March 1, 2015 and March 1, 2018, we have granted stock options to purchase an aggregate of 4,019,951 shares of our common stock, with exercise prices ranging from \$0.87 to \$3.33 per share, to employees, directors and consultants pursuant to the 2011 Stock Option Plan, or the 2011 Plan. Since December 31, 2017, and through the date of filing, shares of common stock have been issued upon the exercise of stock options pursuant to the 2011 Plan.

The issuances of the securities described above were deemed to be exempt from registration pursuant to Section 4(a)(2) of the Securities Act or Rule 701 promulgated under the Securities Act as transactions pursuant to compensatory benefit plans. The shares of common stock issued upon the exercise of options are deemed to be restricted securities for purposes of the Securities Act.

(c) Issuances of Warrants

On March 1, 2015, the Company issued warrants to purchase 35,500 shares of Series B preferred stock at an exercise price of \$3.319 per share. On February 28, 2018, the Company issued warrants to purchase 95,686 shares of its Series C preferred stock at an exercise price of \$6.2705 per share.

Item 16. Exhibits and Financial Statement Schedules

(a) Exhibits

<u>EXHIBIT NUMBER</u>	<u>EXHIBIT TABLE</u>
1.1*	Form of Underwriting Agreement
3.1**	Amended and Restated Certificate of Incorporation of the Registrant, as currently in effect
3.2*	Amendment to Amended and Restated Certificate of Incorporation of the Registrant
3.3*	Form of Amended and Restated Certificate of Incorporation of the Registrant (to be effective upon the closing of this offering)
3.4**	Amended and Restated By-laws of the Registrant , as currently in effect
3.5*	Form of Amended and Restated By-laws (to be effective upon the closing of this offering)
4.1**	Amended and Restated Investors' Rights Agreement among the Registrant and certain of its stockholders, dated December 31, 2015
4.2*	Form of Specimen Common Stock Certificate
5.1*	Opinion of Goodwin Procter LLP
10.1*#	2011 Stock Option and Incentive Plan and forms of award agreements thereunder
10.2*#	2018 Stock Option and Incentive Plan and forms of award agreements thereunder
10.3*#	Senior Executive Cash Incentive Bonus Plan
10.4*#	Form of Director Indemnification Agreement
10.5*#	Form of Officer Indemnification Agreement
10.6**	Lease Agreement, dated as of September 29, 2017, by and between Are-SD Region No. 30, LLC and the Registrant
10.7*#	Form of Amended and Restated Employment Agreement, by and between the Registrant and Paul Edick (to be entered into in connection with this offering)
10.8*#	Form of Amended and Restated Employment Agreement, by and between the Registrant and John Shannon (to be entered into in connection with this offering)
10.9*#	Form of Amended and Restated Employment Agreement, by and between the Registrant and Steven Prestrelski (to be entered into in connection with this offering)
10.10*#	Form of Amended and Restated Employment Agreement, by and between the Registrant and Ken Johnson (to be entered into in connection with this offering)
10.11+	API Supply Agreement, dated as of January 1, 2018, by and between the Registrant and Bachem Americas, Inc.
10.12+	Quality Assurance Agreement, dated as of November 20, 2015, by and between Bachem AG and the Registrant, as amended by (i) Amendment 1 to the Quality Assurance Agreement, dated as of October 31, 2016, by and between Bachem AG and the Registrant and (ii) Amendment 2 to the Quality Assurance Agreement, dated as of January 26, 2017, by and between Bachem AG and the Registrant.

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<u>EXHIBIT NUMBER</u>	<u>EXHIBIT TABLE</u>
10.13+	Master Service Agreement, dated as of November 1, 2016, by and between Pyramid Laboratories and the Registrant
10.14*+	Joint Development Agreement, dated as of January 29, 2016, by and between the Registrant and Scandinavian Health Limited
10.15	Loan and Security Agreement, dated as of February 28, 2018, by and between Oxford Finance, LLC, Silicon Valley Bank and the Registrant
23.1*	Consent of KPMG LLP, Independent Registered Public Accounting Firm
23.2*	Consent of Goodwin Procter LLP (included in Exhibit 5.1)
24.1*	Power of Attorney (included on signature page)
*	To be filed by amendment.
**	Previously filed.
+	Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from the Registration Statement and submitted separately to the Securities and Exchange Commission.
#	Indicates a management contract or any compensatory plan, contract or arrangement

(b) Financial Statement Schedules.

No financial statement schedules have been submitted because they are not required or are not applicable or because the information required is included in the consolidated financial statements or the notes thereto.

Item 17. Undertakings

The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the Underwriting Agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes that:

- (1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
- (2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, Xeris Pharmaceuticals, Inc. has duly caused this registration statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Chicago, State of Illinois, on the day of , 2018.

Xeris Pharmaceuticals, Inc.

By: _____
Paul Edick
President and Chief Executive Officer

SIGNATURES AND POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Paul Edick and Barry Deutsch, and each of them, either of whom may act without the joinder of the other, as his true and lawful attorneys-in-fact and agents with full power of substitution and re-substitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement, and to sign any registration statement for the same offering covered by the registration statement that is to be effective upon filing pursuant to Rule 462(b) promulgated under the Securities Act, and all post-effective amendments thereto, and to file the same, with all exhibits thereto and all documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or his or their substitute or substitutes, may lawfully do or cause to be done or by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended this registration statement has been signed by the following persons in the capacities indicated on the day of , 2018.

<u>SIGNATURE</u>	<u>TITLE</u>
_____	_____
Paul Edick	President and Chief Executive Officer (Principal Executive Officer)
_____	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)
Barry Deutsch	Director
_____	Director
John Schmid	Director
_____	Director
BJ Bormann	Director
_____	Director
Jeffrey Sherman	Director
_____	Director
Jonathan Rigby	Director
_____	Director
Marla Persky	Director
_____	Director
Dawn Halkuff	Director

[***] INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 PROMULGATED UNDER THE SECURITIES ACT OF 1933, AS AMENDED

API SUPPLY AGREEMENT

This API Supply Agreement (“**Agreement**”) is made as of the January 1, 2018 (“**Effective Date**”), by and between Xeris Pharmaceuticals, Inc., a Delaware Corporation, with a place of business at 180 N. LaSalle Street, Suite 1800, Chicago, Illinois 60601, USA (“**XERIS**”), and Bachem Americas, Inc., a California Corporation, with a place of business at 3132 Kashiwa Street, Torrance, CA 90505, USA (“**BACHEM**”). XERIS and BACHEM may be referred to individually as a “**Party**” or collectively as the “**Parties**.”

Background

XERIS is engaged in the business of developing and commercializing pharmaceutical products;

BACHEM is engaged in the manufacture and supply of active pharmaceutical ingredients for research and development purposes and commercial use;

XERIS desires to purchase from **BACHEM**, and **BACHEM** desires to supply to **XERIS**, the active pharmaceutical ingredient or drug substance known as Glucagon (as further defined below, the “**API**”) for use by **XERIS** in manufacturing finished drug products incorporating such active pharmaceutical ingredient, all in accordance with the terms and conditions of this Agreement.

NOW, THEREFORE, in consideration of the mutual covenants and premises herein contained, the Parties hereto agree as follows:

ARTICLE 1 DEFINITIONS

1.1 “**Affiliate**” or “**Affiliates**” shall mean, with respect to a Party, any corporation, limited liability company or other business entity controlling, controlled by or under common control with such Party, for so long as such relationship exists. For the purposes of this definition, control means: (a) to possess, directly or indirectly, the power to direct affirmatively the management and policies of such corporation, limited liability company or other business entity, whether through ownership of voting securities or by contract relating to voting rights or corporate governance; or (b) ownership of more than fifty percent (50%) of the voting stock in such corporation, limited liability company or other business entity (or such lesser percent as may be the maximum that may be owned pursuant to Applicable Laws of the country of incorporation or domicile, as applicable).

1.2 “**API**” shall mean Glucagon, Pharma Grade Material, as currently defined under **BACHEM** product code [***] Specifications, and as subsequently amended from time to time as required and as mutually agreed to between the Parties and attached to the Quality Agreement.

1.3 “**Applicable Laws**” shall mean: (a) all relevant federal, state and local laws, statutes, rules, codes of practice, regulations, and ordinances in the United States, Europe and any other countries, as mutually agreed upon in advance by the Parties, as well as industry standards and regulatory guidelines applicable to the manufacture and supply of API, including,

[***] INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 PROMULGATED UNDER THE SECURITIES ACT OF 1933, AS AMENDED

the United States Federal Food, Drug, and Cosmetic Act; (b) cGMPs; and (c) all applicable regulations and guidelines of any Regulatory Authority; in each case, together, with any and all amendments thereto.

1.4 “**cGMPs**” shall mean current good manufacturing practices, as provided for (and as amended from time to time) in: (a) the Current Good Manufacturing Practice regulations promulgated by the FDA under the United States Food, Drug and Cosmetic Act; (b) the European Community Directive 91/356/EEC (Principles and guidelines of good manufacturing practice for medicinal products), as well as applicable documents developed by the International Conference on Harmonization (ICH) Q7 Guideline: Good Manufacturing Practice Guide for Active Pharmaceutical ingredients; (c) the Swissmedic Therapeutic Product Guidelines for authorization and supervision of therapeutic products; and (d) similar requirements of other Regulatory Authorities; subject to any arrangements, additions or clarifications, and the respective roles and responsibilities, agreed from time to time between the Parties.

1.5 “**Drug Master File**” or “**DMF**” shall mean a drug master file filed with the FDA or the EMA which includes confidential detailed information relating to the facilities, processes, or articles used in manufacturing, processing, packaging, testing and storing of the API, or any equivalent filing in any jurisdiction outside the United States or Europe.

1.6 “**EMA**” shall mean the European Medicines Agency, or any successor entity thereto performing substantially similar functions.

1.7 “**Facility**” shall mean BACHEM’s cGMP-compliant manufacturing facilities located at Hauptstrasse 144,4416 Bubendorf, Switzerland

1.8 “**FDA**” shall mean the United States Food and Drug Administration, or any successor entity thereto performing substantially similar functions.

1.9 “**Latent Defect**” shall mean, with respect to API, a hidden or latent defect not detected by the analytical test methods in operation at the date of shipment to XERIS by BACHEM and which was not detected by XERIS during the inspection period defined in [Section 4.3.1](#).

1.10 “**Major Change**” shall mean a change that may adversely impact quality, safety, efficacy, stability, regulatory compliance, or regulatory registration of the API or Product.

1.11 “**Product**” shall mean a finished pharmaceutical drug product incorporating the API.

1.12 “**Regulatory Authority**” shall mean the FDA, EMA or any other governmental or regulatory authority responsible for the regulation of API used in pharmaceutical products intended for human use in an applicable.

1.13 “**Specifications**” shall mean those specifications and release requirements, as defined in the current Quality Agreement.

[***] INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 PROMULGATED UNDER THE SECURITIES ACT OF 1933, AS AMENDED

1.14 “**Quality Agreement**” shall mean the Quality Assurance Agreement between the Parties dated November 20, 2015, and as amended on October 31, 2016 and January 26, 2017, and as may be further amended from time to time, which contains the current Specifications and specifies the Parties’ respective responsibilities regarding the manufacture, storage, release, quality control and quality assurance of API in accordance with requirements of Regulatory Authorities and cGMP’s. In the event that any conflict shall arise between the terms of this Agreement and the Quality Agreement, the terms of this Agreement shall take precedence over the terms of the Quality Agreement in all respects except matters of quality and pharmacovigilance, in which case the Quality Agreement shall take precedence.

1.15 “**Warehouse**” shall mean BACHEM’s cGMP-compliant warehousing facilities located at 3132 Kashiwa Street, Torrance, California, USA.

ARTICLE 2 SUPPLY

2.1 API Supply. Subject to the terms and conditions of this Agreement, BACHEM shall supply to XERIS, such quantities of the API as may be specified in purchase orders submitted by XERIS pursuant to Section 2.3 below from time to time during the Term. All API to be supplied under this Agreement shall be manufactured by BACHEM at the Facility, in conformance with Applicable Laws, the Specifications and the Quality Agreement.

2.2 Forecasts.

2.2.1 At the beginning of each [***] during the Term, XERIS shall provide BACHEM with a [***] forecast of the gross weight quantities of the API estimated to be required (each, a “**Rolling Forecast**”). The Rolling Forecast from the beginning of the first [***] in any given year shall be the calendar year forecast (each, a “**Calendar Year Forecast**”). Subject to provisions in Sections 2.3 and, the first [***] of such Rolling Forecasts and Calendar Year Forecasts shall be binding and all remaining quarters of such forecasts are non-binding and serve only to facilitate BACHEM’s production scheduling. BACHEM shall inform XERIS within [***] of receiving a Rolling Forecast, in writing by email, if such forecast cannot be met or is at risk of not being met due to capacity or shelf-life constraints as defined herein. Failure of BACHEM to accept or reject a forecast within [***] of receipt shall be deemed an acceptance of the Rolling Forecast and confirmation of suitable available capacity.

2.2.2 At the beginning of each [***] during the Term, BACHEM shall provide an estimate of their total production capacity available for XERIS API, above and beyond the requirements of the Rolling Forecast if any, (“**Toted Capacity Constraints**”) for the next [***] period.

2.3 Orders.

2.3.1 Orders. Together with each Rolling Forecast provided under Section 2.2 above, XERIS shall place a firm order for the applicable calendar quarter or multiple smaller orders throughout the applicable calendar quarter with BACHEM for the gross weight quantity of API required for delivery. For each calendar year of this Agreement, XERIS shall use commercially reasonable efforts to order a gross weight quantity of API for delivery at least

equal to the gross weight quantity of API contained in the applicable Calendar Year Forecast. For the avoidance of doubt, XERIS may order quantities of API in addition to those specified in the then current Calendar Year Forecast and Rolling Forecast for delivery hereunder in accordance with the lead times therefor and subject to BACHEM's Purchase Order acceptance and Total Capacity Constraints. Unless otherwise limited by BACHEM's Total Capacity Constraints, BACHEM agrees to provide up to [***] of any forecast if ordered by XERIS, unless Parties agree to a higher quantity in writing. BACHEM shall use commercially reasonable efforts to accept and fulfill all orders for API provided by XERIS under this Agreement and endeavor to hold stock sufficient to meet the next [***] of each Rolling Forecast.

2.3.2 Form of Orders. XERIS's orders shall be made pursuant to a written purchase order (each, a "**Purchase Order**") that specifies, at a minimum, quantity of API ordered, date of order, date of delivery, addresses for delivery, contact information at delivery sites, and required carriers with account numbers, one of which must be utilized for delivery to the specified destinations. BACHEM shall use commercially reasonable efforts to achieve a maximum lead time of no more than [***] to complete and deliver an order. BACHEM shall accept all orders XERIS submits to BACHEM in accordance with this Article 2. BACHEM shall provide to XERIS written notice of BACHEM's acceptance (each, an "**Acceptance Notice**" of each Purchase Order within [***] of BACHEM's receipt of such Purchase Order and each such Acceptance Notice shall include confirmation of the delivery date of the applicable quantity of API; provided that to the extent no delivery date is included in an Acceptance Notice issued by BACHEM or BACHEM fails to issue an Acceptance Notice within the applicable time period, the order shall be deemed accepted by BACHEM and the applicable delivery date shall be deemed to be the delivery date specified by XERIS in the corresponding Purchase Order. Except as to the quantity of API, delivery date and delivery location specified in a Purchase Order which shall be binding on the Parties, NO TERMS OR CONDITIONS CONTAINED IN ANY PURCHASE ORDER, ORDER ACKNOWLEDGMENT OR SIMILAR STANDARDIZED FORM SHALL BE CONSTRUED TO AMEND OR MODIFY THE TERMS OF THIS AGREEMENT, AND ALL SUCH TERMS AND CONDITIONS ARE HEREBY EXCLUDED.

2.3.3 Retest Date. API supplied by BACHEM under this Agreement shall have a retest date that is at least [***]% of the original re-test date at the time of delivery of such API to XERIS, unless otherwise agreed to by XERIS in writing in advance of the delivery. If BACHEM cannot supply API with the required re-test Date, XERIS shall have the [***]. If XERIS agrees in writing to accept API with a [***] and if requested by XERIS, BACHEM agrees to re-test any such API and extend the retest date to a minimum of [***] within cGMP, ICH and DMF guidelines and complete such testing prior to shipment.

2.4 Shipping and Warehousing. BACHEM shall deliver quantities of API ordered by XERIS in accordance with Section 2.3 above, to the locations specified in the applicable Purchase Order. Shipments may be shipped DDP (*Incoterms 2010*) direct to XERIS locations specified on a Purchase Order, or, FCA (*Incoterms 2010*) to BACHEM's Warehouse in Torrance, CA USA. While in-transit and during storage at the Warehouse, BACHEM shall ensure API is shipped and stored according to cGMP's and Specifications. BACHEM shall request advance import and customs information from XERIS as required and ship API, together with all relevant documentation relating to the API, including, but not limited to those documents listed in Exhibit 2, in accordance with any agreed-upon shipment specifications or as

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otherwise reasonably directed by XERIS in writing and in accordance with this Agreement. XERIS shall only be obligated to pay for quantities of API actually delivered in compliance with the applicable Purchase Order and the terms of this Agreement.

2.5 Shortage of Supply. If BACHEM is unable, or anticipates that it will not be able, to supply XERIS's requirements for the API in accordance with Sections 2.2 and 2.3 above fa "**Shortage of Supply**"). BACHEM shall notify XERIS in writing of the same within [***] of receipt of applicable Purchase Orders, Rolling Forecast or determination that a Shortage of Supply will exist, and shall include in such notice its best estimate of the duration of the delay, the reasons for the delay, and whether the reason impacts the validated state of the process. BACHEM shall, at its own cost, use commercially reasonable efforts to remedy any Shortage of Supply and resume supplying API meeting the requirements of this Agreement to XERIS as soon as possible. In addition to the foregoing measures, if BACHEM is unable to supply XERIS's requirements of API, BACHEM shall allocate the quantities of the API that BACHEM has in inventory, and that BACHEM is able to produce, on a reasonable worldwide basis (based upon sales history and realistic forecasted demand). In the event of a Shortage of Supply exceeding [***] ([***]%), in addition to any other rights or remedies that XERIS may have under this Agreement, or at law or in equity, XERIS shall be relieved from its obligations to purchase any quantities of API identified in any outstanding Purchase Order, Calendar Year Forecast or Rolling Forecast.

ARTICLE 3 PAYMENTS

3.1 Price. The Price for the API subject to this Agreement shall be based on annual calendar year volume as listed in the schedule in Exhibit 1.

3.2 Mid-year Price Adjustment. XERIS shall notify BACHEM as soon as reasonably possible, in writing by email, if it does not intend to order the total gross weight quantity of API contained in a Calendar Year Forecast; and to the extent the lower annual quantity would affect Price, XERIS shall pay [***]. XERIS shall notify BACHEM as soon as reasonably possible, in writing by email, if it intends to order a total gross weight quantity of API greater than contained in a Calendar Year Forecast; and subject to BACHEM accepting the additional order quantities as provided for in Section 2.3.1 and to the extent the higher annual quantity would affect Price, BACHEM shall [***].

3.3 Invoicing: Payment. BACHEM shall submit an invoice to XERIS upon shipment of API ordered by XERIS hereunder. All invoices shall be sent to the address specified in the Purchase Order therefor, and each invoice shall state the Price for the gross weight quantity of API in a given shipment, plus any documented taxes and other costs incident to the purchase or shipment initially paid by BACHEM but to be borne by XERIS hereunder. All payments shall be made by direct bank transfer to an account designated in BACHEM's invoice. In connection with an order, XERIS may provide BACHEM with a reseller certificate, in which case, XERIS will be exempt from all relevant sales taxes. Payments shall be due [***] from invoice date. Payment by XERIS shall not constitute acceptance of any shipment of API or impair XERIS's right of inspection and rejection under Article 4 below.

ARTICLE 4 QUALITY

4.1 Quality Assurance. All API supplied by BACHEM shall meet the agreed current Specifications and shall be manufactured and stored in accordance with all Applicable Laws relevant to the Facility, Warehouse and the Quality Agreement. BACHEM agrees that, prior to each shipment of API hereunder, it shall perform quality assurance and quality control procedures reasonably necessary to ensure that the API to be shipped conforms fully with the Specifications and in compliance with cGMP's. Each shipment of API shall be accompanied by a certificate of analysis, which will include a signed certification of cGMP compliance and such additional documents as may be specified in the Quality Agreement or as otherwise reasonably required by XERIS from time to time.

4.2 Quality Agreement. Prior to XERIS issuing its first Purchase Order to BACHEM pursuant to this Agreement, the Parties shall review and may update the existing Quality Agreement as agreed to in writing, if required.

4.3 Rejection and Replacement of API.

4.3.1 Inspection by XERIS. XERIS, or its designee, shall have [***] following its receipt of a shipment of API to reject such API on the grounds that all or part of the shipment fails to conform to the applicable Specifications or otherwise fails to conform to the warranties given by BACHEM in Section 9.2, which rejection shall be accomplished by giving written notice to BACHEM summarizing the manner in which all or part of such shipment fails to meet the foregoing requirements. The foregoing inspection obligation will not prevent XERIS from enforcing any rights under this Agreement if Latent Defects in the API are discovered after the [***] inspection period as set forth herein, so long as XERIS informs BACHEM in writing immediately, but no later than [***] after its discovery and within the original retest date for any API delivered. XERIS shall be responsible for storage and handling the API in accordance with the Specifications upon delivery.

4.3.2 Resolution of Disputes. BACHEM shall acknowledge receipt in writing to a rejection notice from XERIS within [***] from the date of receipt of such rejection notice in accordance with Section 4.3.1 above. If BACHEM does not agree with XERIS's determination that such API fails to conform to the Specifications or the warranties provided by BACHEM in Section 9.2, then BACHEM and XERIS shall use reasonable efforts to resolve such disagreement as promptly as possible. Without limiting the foregoing, either party may submit the API to a nationally recognized testing laboratory (the "**Laboratory**") which shall be agreed upon by the parties in advance, to test whether or not the API conforms to the Specifications or the warranties provided by BACHEM in Section 9.2. The Laboratory's determination will be final. If the Laboratory determines that the API does not conform to the Specifications or the warranties provided by BACHEM in Section 9.2, BACHEM will be responsible for all expenses related to the Laboratory testing, otherwise XERIS will be responsible for those expenses.

4.3.3 Replacement of API. API accepted by BACHEM as not meeting the applicable requirements or the Specifications, or which is determined by the Laboratory not to meet such requirements or the Specifications, shall be returned by XERIS to BACHEM, or

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disposed of, as directed by BACHEM, at BACHEM's expense. BACHEM shall replace all such rejected API within the shortest possible time, but in any event, within a reasonable timeframe, as agreed to by the Parties, after its receipt of notice of such rejection (or, if applicable, the Laboratory's determination that such API was non-conforming). Without limiting any other provision in this Agreement, XERIS may withhold payment for such shipment or the portion thereof that has been rejected by XERIS, or, if Parties cannot agree on a suitable timeframe to replace such rejected API, XERIS shall be entitled to a full refund of prior payments for such shipment or the portion thereof that has been rejected by XERIS, pursuant to this Section 4.3. The warranties given by BACHEM in Section 9.2 below shall survive any failure to reject by XERIS under this Section 4.3.

4.4 Changes.

4.4.1 BACHEM shall maintain change control systems that ensure that XERIS is notified in a timely manner regarding all Major Changes as agreed to by the Parties in accordance with the Quality Agreement.

4.4.2 BACHEM shall promptly inform XERIS in writing of any proposed Major Change to the raw materials, intermediates, manufacturing process, equipment, packaging, labeling, testing, specifications, storage or shipping, if such item is specifically mentioned in the DMF. Notwithstanding the foregoing, in no event will BACHEM implement any Major Change with respect to quantities of API to be supplied to XERIS, without giving XERIS prior written notice, and prior to all necessary filings with and approvals by applicable Regulatory Authorities have been made or obtained by BACHEM or XERIS, as applicable.

ARTICLE 5 RECORDS: INSPECTIONS

5.1 Record Keeping. BACHEM shall generate and maintain complete and accurate records in the language of the Facility and Warehouse as required by the GMP guidelines and samples as necessary to evidence compliance with this Agreement and all Applicable Laws and other requirements of applicable governmental authorities relating to the raw materials, intermediates, manufacturing process, packaging, labeling, testing, specifications, storage or shipping activities relating to the API. All such records and samples shall be maintained by BACHEM in accordance with the procedures set out in the Quality Agreement for the applicable time period specified therein.

5.2 Inspection. During the term of this Agreement, and for [***] thereafter, or as otherwise required by Applicable Laws, XERIS (or an agreed upon designee) shall have the right to inspect and audit, during regular business hours: (a) any facility at which any of the raw material receiving, manufacturing or processing, packaging, labeling, testing, storage or shipping activities relating to the API are performed, including the Facility and Warehouse, with the exception of some analytical testing, which may be sub-contracted out to other facilities; and (b) any of BACHEM's manufacturing and quality control records and all other documentation relating to the manufacturing and processing activities with respect to the API (including any internal quality assurance/control audits or reviews conducted by BACHEM), with the understanding that executed manufacturing batch records may only be reviewed onsite. During

any such audit, BACHEM shall use reasonable efforts to provide an oral or written translation and explanation of original documents of critical portions of any manufacturing or quality control record to XERIS as may be reasonably requested by XERIS, in accordance with the Quality Agreement. Such inspections and audits shall be conducted annually and with reasonable notice in accordance with any procedures for audits specified in the Quality Agreement; provided however that XERIS shall have the right to conduct additional inspections and audits under this Section 5.2 if there has been a replacement of API under Section 4.3.3 or any other cause-related dispute related hereto.

ARTICLE 6 REGULATORY MATTERS

6.1 Regulatory Actions. BACHEM shall permit the FDA and other Regulatory Authorities, as applicable, to conduct such inspections of the Facility, and any other facility at which any of the raw material receiving, manufacturing or processing, packaging, labeling, testing, storage or shipping activities relating to the API are performed, with the exception of some analytical testing which may be sub-contracted out to other facilities, as such Regulatory Authorities may request, including pre-approval inspections, and shall cooperate with such Regulatory Authorities with respect to such inspections and any related matters, in each case that is related to the manufacture and supply of API. BACHEM shall notify XERIS about such regulatory actions or inspections as further described, and in accordance with the Quality Agreement.

6.2 Regulatory Cooperation. BACHEM has registered the API with the FDA as a Generic product and, during the Term, BACHEM will timely perform all necessary filings and pay all required fees to maintain the Generic status. BACHEM agrees to provide to XERIS or directly to the applicable Regulatory Authority, as requested by such Regulatory Authority, with all reasonable information and data in BACHEM's possession or control reasonably necessary for XERIS (or its designees) to apply for, obtain and maintain regulatory approvals for any Product in the United States, Europe and any other countries, as mutually agreed upon in advance by the Parties. In addition, BACHEM agrees to reasonably cooperate with XERIS (or its designees) with respect to obligations to submit or report information relevant to API pursuant to FDA and other Regulatory Authorities or to comply with Applicable Laws relevant to the Facility and the Warehouse.

6.3 Drug Master Files. BACHEM shall provide, or cooperate with XERIS to provide, the appropriate authorizations to each applicable Regulatory Authority allowing XERIS (or its designee) the right to reference all Drug Master Files to support any mutually agreed to regulatory filing for any Product developed, manufactured or commercialized by XERIS, its Affiliates and licensees. If the Drug Master File filed with the FDA or applicable Regulatory Authority(ies) as of the Effective Date is not sufficient to support the applicable regulatory filing for a Product, Parties agree to use commercially reasonable efforts to develop a corrective action plan agreeable to both Parties, and BACHEM shall use commercially reasonable efforts to correct any deficiencies of such Drug Master File(s) identified by any Regulatory Authority in a prompt and efficient manner so as to prevent any delay in XERIS (or any of its Affiliates or licensees) obtaining regulatory approval for a Product based on such Drug Master File(s). In addition, BACHEM shall be responsible for maintaining such Drug Master File(s) in accordance

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with Applicable Laws relevant to the Facility and ensuring that all data and information incorporated therein is accurate and current as necessary to support obtaining and maintaining the applicable regulatory filings) and regulatory approval(s) by XERIS (or its designees).

6.4 Recall. Any recalls of any of XERIS's Products shall, as between the Parties, be controlled solely by XERIS; provided, however, that if BACHEM reasonably believes a recall may be necessary with respect to any API provided under this Agreement, BACHEM shall immediately notify XERIS in writing. BACHEM shall provide assistance to XERIS (or its designee), as reasonably requested, in conducting such recall, including providing all pertinent records as may be required by Regulatory Authorities in the region affected, to assist XERIS in effecting such recall. Except as otherwise provided for under Article 10, BACHEM shall reimburse XERIS for reasonable and documented recall expenses directly related to an API quality defect proven by XERIS to have been solely caused by BACHEM's negligence or error and which, in no event, shall exceed \$[***], and BACHEM shall also reimburse XERIS for the cost of the API used to manufacture Product involved in the recall.

ARTICLE 7 TERM AND TERMINATION

7.1 Term. The term of this Agreement shall commence on the Effective Date and shall continue for an initial term of [***] ("**Initial Term**"), Thereafter, this Agreement shall automatically be renewed for successive [***] periods (each, a "**Renewal Term**;" and all such Renewal Terms together with the Initial Term, collectively, the "**Term**"'), unless either Party notifies the other Party in writing at least [***] prior to the expiration of the then-current Term that such Party does not wish to renew this Agreement for an additional Renewal Term.

7.2 Termination for Material Breach. If either Party materially breaches this Agreement or the Quality Agreement at any time, the non-breaching Party shall have the right to terminate this Agreement by written notice to the breaching Party, if such breach is not cured within [***] days after written notice is given by the non-breaching Party to the breaching Party specifying the breach.

7.3 Termination for Failure to Supply. Without limiting any other provision of this Agreement, including Sections 2.5 and 7.2 above, if [***] (a) Late Shipments of API or (b) Shortages of Supply of API occur during any [***] period, then XERIS shall have the right to terminate this Agreement immediately by written notice to BACHEM. For purposes of this Section 7.3, a Late Shipment shall mean any shipment of a BACHEM confirmed Purchase Order that is delivered more than [***] days past the delivery date specified in the applicable Purchase Order (each a "**Late Shipment**")

7.4 Termination by XERIS. XERIS may terminate this Agreement immediately upon written notice to BACHEM if: (a) XERIS, in its sole discretion, determines that Products will not be marketed by XERIS (or its designee); or (b) the FDA or EMA withdraws approval of, or fails to approve, the manufacturing or marketing by XERIS (or its designee) of all Products then in development.

7.5 Effects of Termination. It is understood that termination or expiration of this Agreement shall not relieve a Party from any liability that, at the time of such termination or

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expiration, has already accrued to the other Party, except as specified in this Section 7.5. Upon expiration or termination of this Agreement for any reason (other than by XERIS pursuant to Section 7.2 or 7.3 above), to the extent BACHEM so notifies XERIS, XERIS shall have the obligation to purchase all API ordered under any outstanding Purchase Orders and will pay the applicable price differential for the lower annual volume, if any, for the volume of API ordered and delivered to XERIS year-to-date. To the extent XERIS notifies BACHEM of expiration or termination of this Agreement according to provisions provided herein, XERIS shall have the option to purchase additional transitional stock of API from BACHEM, in addition to quantities contained in outstanding Purchase Orders, of less than or equal to ***% of the most recent Rolling Forecast at the applicable price and according to a delivery schedule mutually agreeable to both Parties.

7.6 Survival. The provisions of Sections 1,2,4,3-6,7.5,7.6,8-11 shall survive the expiration or termination of this Agreement for any reason. In addition, the provisions of the Quality Agreement shall survive expiration or termination of this Agreement until the date of expiration of the last-to-expire batch of API delivered by BACHEM to XERIS hereunder. All other Tights and obligations of the Parties shall cease upon termination of this Agreement. Except as otherwise expressly provided in this Section 7.6, all other rights and obligations of the Parties shall terminate.

ARTICLE 8 CONFIDENTIALITY

8.1 Confidential Information. Except as otherwise provided in this Article 8, during the Term and for a period of [***] years thereafter, each Party shall maintain in confidence and only use for the purposes of this Agreement any confidential information, data and materials supplied to such Party by the other Party (“**Confidential Information**”) A receiving Party’s obligations under this Article 8 shall not apply to any information, data or material that, in each case as demonstrated by written documentation: (a) was already known to the receiving Party, other than under an obligation of confidentiality, at the time of disclosure; (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party; (c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement; (d) was subsequently lawfully disclosed to the receiving Party by a person other than the disclosing Party; or (e) was independently developed by the receiving Party without reference to any Confidential Information of the disclosing Party.

8.2 Confidentiality: Non-Disclosure. Each Party agrees not to disclose any Confidential Information of the other Party except to those employees and consultants who have a need to know and provided that each person to whom Confidential Information is disclosed agrees to be bound by the same terms regarding the disclosure and use of Confidential Information as set forth in this Article 8. Each Party further agrees not to use or disclose the Confidential Information of the other Party except as otherwise permitted by this Agreement, or as may be necessary to exercise its rights or perform its obligations under this Agreement. Nothing contained in this Article 8 shall prevent either Party from disclosing any Confidential Information of the other Party to: (a) regulatory agencies for the purpose of obtaining approval to distribute and market Products; provided, however, that all reasonable steps are taken to

maintain the confidentiality of such Confidential Information to be disclosed; (b) to accountants, lawyers or other professional advisors or in connection with a merger, acquisition, securities offering or other strategic transaction, subject in each case, to the recipient entering into an agreement to protect such Confidential Information from disclosure; or (c) is required by law or regulation to be disclosed; provided, however, that the Party subject to such disclosure requirement has provided written notice to the other Party promptly upon receiving notice of such requirement in order to enable the other Party to seek a protective order or otherwise prevent disclosure of such Confidential Information.

ARTICLE 9 REPRESENTATIONS AND WARRANTIES

9.1 Mutual Warranties. Each Party represents and warrants to the other Party that: (a) it has the power and authority to enter into this Agreement and to perform its obligations hereunder and to grant to the other Party the rights granted to such other Party under this Agreement; (b) it has obtained all necessary corporate approvals to enter into and execute this Agreement and to perform its obligations hereunder; and (c) the execution, delivery and performance of this Agreement does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor will it enter into or assume during the Term, any contract or other obligation with a third party that would in any way limit the performance of its obligations under this Agreement.

9.2 BACHEM Warranties. BACHEM represents and warrants that:

9.2.1.1 API. All API supplied hereunder shall (a) comply with all Applicable Laws and the Quality Agreement and meet all Specifications and cGMP's, and (b) BACHEM shall perform and document all manufacturing and supply activities contemplated herein in compliance with all Applicable Laws.

9.2.1.2 Facilities and Equipment. The Facility, all equipment used for the manufacture of API within the Facility and the activities contemplated herein, and any other facility at which any of the manufacturing or processing, packaging, labeling, testing or storage activities relating to the API are performed will comply with all Applicable Laws and cGMP's, and BACHEM shall obtain and maintain all governmental registrations, permits, licenses and approvals necessary for BACHEM to manufacture and supply API to XERIS, and otherwise to perform its obligations, under this Agreement

9.2.1.3 No Encumbrance. Title to all API provided to XERIS under this Agreement shall pass as provided in this Agreement, free and clear of any security interest, lien, or other encumbrance.

9.2.1.4 Personnel. Neither BACHEM, nor any of its Affiliates, nor, to the best of BACHEM's knowledge, any of their respective employees have been "debarred" by the FDA, or subject to a similar sanction from any Regulatory Authority in any jurisdiction outside the United States, nor have debarment proceedings against BACHEM, any of its Affiliates, or any of their respective employees been commenced. BACHEM will promptly notify XERIS in Writing if any such proceedings have commenced or if BACHEM, any of its Affiliates, or any of their respective employees are debarred by the FDA or any other Regulatory Authority.

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9.3 XERIS Warranties. XERIS represents and warrants that it shall comply in all material respects with all Applicable Laws pertaining to the distribution, sale, and marketing of Product.

9.4 DISCLAIMER. EXCEPT AS PROVIDED IN THIS ARTICLE 9, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES (EXPRESS, IMPLIED, STATUTORY OR OTHERWISE) WITH RESPECT TO THE SUBJECT MATTER HEREOF AND EACH PARTY EXPRESSLY DISCLAIMS ANY SUCH ADDITIONAL REPRESENTATIONS AND WARRANTIES, INCLUDING ANY IMPLIED WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE, MERCHANTABILITY OR NON-INFRINGEMENT OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS.

ARTICLE 10 INDEMNIFICATION AND LIMITATION OF LIABILITY

10.1 XERIS. it is understood that BACHEM has no control over the ultimate use of the API or Products. XERIS shall indemnify, defend and hold harmless BACHEM, its directors, officers, employees, agents, successors and assigns from and against any liabilities, expenses or costs (including reasonable attorneys' fees and court costs) arising out of or relating to XERIS' (a) use of the API, other than as set forth herein, (b) use, sale, manufacturing, distribution or other disposal of the Products, (c) breach of its representations and warranties herein, Or (d) gross negligence or willful misconduct.

10.2 BACHEM. BACHEM shall indemnify, defend and hold harmless XERIS, its directors, officers, employees, agents, successors and assigns from and against all liabilities, expenses, and costs (including reasonable attorneys' fees and court costs) arising out of or relating to BACHEM's (a) breach of its representations and warranties herein and XERIS' use of the API, as set forth herein, (b) gross negligence or willful misconduct, or (c) subject to Section 6.4, API defects that result in a Product recall up to a maximum amount.

10.3 Indemnification Procedure. Any Party seeking indemnification under this Article 10 (the "**Indemnitee**") shall: (a) promptly notify the Indemnifying Party (the "**Indemnitor**") of such claim; (b) provide the Indemnitor sole control over the defense and settlement thereof; and (c) at the Indemnitor's request and expense, provide full information and reasonable assistance to Indemnitor with respect to such claims. Without limiting the foregoing, with respect to claims brought under Section 10.1 or 10.2 above, the Indemnitee, at its own expense, shall have the right to participate with counsel of its own choosing in the defense and settlement of any such claim. The indemnification under this Article 10 shall not apply to amounts paid in settlement of any claim if such settlement is effected without the consent of the Indemnitor.

10.4 Insurance. During the Term and for a period of [***] thereafter, BACHEM shall maintain, with financially sound and reputable insurers, insurance reasonably sufficient to cover BACHEM's activities and obligations under this Agreement. Without limiting the foregoing, BACHEM shall maintain, at its sole cost and expense (i) general liability insurance (ii)

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contractual liability insurance and (iii) product liability insurance, such insurances covering at least bodily injury, death, and property damage limits, in such amounts and with such scope of coverage as is consistent with pharmaceutical industry standards to insure BACHEM's indemnification and other obligations hereunder. At the reasonable request of XERIS, BACHEM shall provide to XERIS copies of certificates of insurance evidencing coverage in accordance with this [Section 10.4](#).

10.5 **LIMITATION OF LIABILITY**. EXCEPT FOR A PARTY'S INDEMNIFICATION OBLIGATIONS, GROSS NEGLIGENCE OR WILLFUL MISCONDUCT, EACH PARTY'S LIABILITY SHALL BE LIMITED AS SET FORTH HEREIN AND IN NO EVENT SHALL EITHER PARTY BE LIABLE FOR (I) ANY SPECIAL, INCIDENTAL, INDIRECT, PUNITIVE, CONSEQUENTIAL OR EXEMPLARY OR PUNITIVE DAMAGES; INCLUDING LOST PROFITS, OR OPPORTUNITY OR GOODWILL, HOWEVER CAUSED, UNDER ANY THEORY OF LIABILITY AND EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, OR (II) FOR EACH EVENT GIVING RISE TO ANY INJURIES, CLAIMS, LOSSES, EXPENSES, OR DAMAGES, AN AMOUNT EXCEEDING \$[***]. To the extent that this clause conflicts with any other clause of this Agreement, this clause shall take precedence over such conflicting clause. If applicable law prevents enforcement of this [Section 10.5](#), then this Section shall be deemed modified to provide the maximum protection to each Party as is allowable under applicable law.

ARTICLE 11 GENERAL PROVISIONS

11.1 **Assignment**. The Parties agree that their rights and obligations under this Agreement may not be assigned or otherwise transferred to a third party without the prior written consent of the other Party hereto. Notwithstanding the foregoing, either Party may transfer or assign its rights and Obligations under this Agreement to a successor to all or substantially all of its business or assets relating to this Agreement whether by sale, merger, operation of law or otherwise; provided that such assignee or transferee has agreed to be bound by the terms and conditions of this Agreement. Subject to the foregoing, this Agreement shall be binding upon and inure to the benefit of the Parties hereto, their successors and assigns.

11.2 **Governing Law**. This Agreement shall be governed by, and construed and interpreted in accordance with, the laws of the State of New York, as if entered into by New York residents and executed and wholly performed within the State of New York.

11.3 **Disputes**. Except for any disputes with respect to non-conforming API, which shall be resolved in accordance with [Section 4.3](#) above, if BACHEM and XERIS are unable to resolve any dispute between them, either BACHEM or XERIS may, by written notice to the other, have such dispute referred to the senior management of BACHEM and XERIS for attempted resolution by good faith negotiations within [***] after such notice is received. If the Parties are unable to resolve such dispute in accordance with the aforementioned procedure or within such [***] period, subject to [Section 11.4](#) below, either Party shall have the right to pursue any and all other remedies available to such Party.

[***] INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 PROMULGATED UNDER THE SECURITIES ACT OF 1933, AS AMENDED

11.4 Arbitration. Except for any disputes with respect to non-conforming API, which shall be resolved in accordance with Section 4.3 above, any dispute or claim arising out of or in connection with this Agreement or the performance, breach or termination thereof which is unable to be resolved pursuant to discussions between the Parties in accordance with Section 11.3 above, shall, upon notice by either Party to the other, be submitted to binding arbitration in New York City, New York under the Rules of the American Arbitration Association (or any successor entity thereto, collectively, "AAA") by one arbitrator appointed in accordance with said rules. The arbitrator may engage an independent expert with experience in the subject matter of the dispute to advise the arbitrator. The decision and award rendered by the arbitrator shall be written, final and non-appealable and may be entered in any court of competent jurisdiction. The Parties agree that, any provision of applicable law notwithstanding, they will not request, and the arbitrator shall have no authority to award, punitive or exemplary damages against any Party. The costs of any arbitration, including administrative fees and fees of the arbitrator, shall be shared equally by the Parties, unless otherwise determined by the arbitrator. Each Party shall bear the cost of its own attorneys' and expert fees. Notwithstanding the foregoing, either Party may apply to any court of competent jurisdiction for injunctive relief without breach of this arbitration provision.

11.5 Notices. Any notice or report required or permitted to be given or made under this Agreement by either Party shall be in writing and in English and delivered to the other Party at its address indicated below (or to such other address as a Party may specify by like notice) by courier or by registered or certified airmail, postage prepaid, or by facsimile; provided, however, that all facsimile notices shall be promptly confirmed, in writing, by courier or by registered or certified airmail, postage prepaid. All notices shall be effective as of the date received by the addressee.

If to XERIS:

Xeris Pharmaceuticals, Inc.
180 N. LaSalle Street, Suite 1800
Chicago, IL 60601

Attn: Paul Edick, CEO

If to BACHEM:

Bachem Americas, Inc.
3132 Kashiwa Street
Torrance, CA 90505

Attn: Brian Gregg, COO

11.6 Force Majeure. Neither Party will be liable for its failure to perform any of its obligations hereunder during any period in which such performance is delayed by acts of God, fire, war, embargo, riots, or other similar cause outside the reasonable control of such Party ("**Force Majeure Event**"). A Party affected by a Force Majeure Event will promptly notify the other Party, explaining the nature and expected duration thereof and such Party shall use all reasonable efforts to remedy or mitigate such Force Majeure Event and the effects thereof. Notwithstanding the foregoing, if a Party is unable to perform any of its obligations under this Agreement for a period of more than [***] as a result of a Force Majeure Event, the other Party may terminate this Agreement upon written notice to the affected Party.

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11.7 Interpretation. The headings to the several Articles and Sections of this Agreement are not a part of this Agreement, but are included for convenience of reference only and shall not affect its meaning or interpretation.

11.8 Waiver. Any waiver of the terms and conditions hereof must be explicitly in writing and executed by a duly authorized officer of the Party waiving compliance. The waiver by either of the Parties of any breach of any provision hereof by the other shall not be construed to be a waiver of any succeeding breach of such provision or a waiver of the provision itself. The delay or failure of any Party at any time to require performance of any provision of this Agreement shall in no manner affect such Party's rights at a later time to enforce the same.

11.9 Severability. Should any section, or portion thereof, of this Agreement be held invalid or unenforceable in any jurisdiction by any court of competent authority or by a legally enforceable directive of any governmental body, such section or portion thereof shall be validly reformed so as to approximate the intent of the Parties as nearly as possible and, if unreformable, shall be deemed divisible and deleted with respect to such jurisdiction, but the Agreement shall not otherwise be affected.

11.10 Independent Contractors. The relationship of XERIS and BACHEM established by this Agreement is that of independent contractors. Nothing in this Agreement shall be construed to create a partnership, joint venture, agency or other fiduciary relationship between XERIS and BACHEM. Neither Party shall have any right, power or authority to assume, create or incur any expense, liability or obligation, express or implied, on behalf of the other.

11.11 Entire Agreement: Amendment. The terms and provisions contained in the Agreement (including the Exhibits hereto and any Purchase Orders issued pursuant hereto) and the Quality Agreement constitute the entire agreement between the Parties and Shall supersede all previous communications, representations, agreements or understandings, either oral or written, between the Parties with respect to the subject matter hereof. No agreement or understanding varying or extending this Agreement shall be binding upon either Party hereto, unless set forth in a writing which specifically refers to the Agreement signed by duly authorized officers or representatives of the respective Parties, and the provisions hereof not specifically amended thereby shall remain in full force and effect.

11.12 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but which together shall constitute one and the same instrument.

[Remainder of page intentionally left blank; signature page follows]

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IN WITNESS WHEREOF, the Parties hereto have caused their duly authorized representatives to execute this API Supply Agreement as of the Effective Date.

XERIS PHARMACEUTICALS, INC.

By: /s/ Paul R. Edick

Name: Paul R. Edick

Title: CEO

BACHEM AMERICAS, INC.

By: /s/ Brian Gregg

Name: Brian Gregg

Title: COO

[***] INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 PROMULGATED UNDER THE SECURITIES ACT OF 1933, AS AMENDED

Exhibit 1

API PRICING

Annual Price/Volume

<u>Price (per gram)</u>	<u>Annual Grams</u>
\$_____/g	[***]g
\$_____/g	[***]g
\$_____/g	[***] – [***]g
\$_____/g	>[***]g

*** INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 PROMULGATED UNDER THE SECURITIES ACT OF 1933, AS AMENDED

EXHIBIT 2

RELEVANT SHIPPING DOCUMENTATION

Certificate of Analysis
Certificate of Conformance
TSE/BSE Safety Certificate
Packing List invoice
Temperature data logger for BBU/TOR and/or BBU/XERIS shipments

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Xeris/Bachem

Quality Assurance Agreement

This Quality Assurance Agreement (the “**Quality Assurance Agreement**”) is made as of November 20, 2015 (“**Effective Date**”) between **Bachem AG**, an entity organized under the laws of Switzerland, with its principal place of business at Hauptstrasse 144, CH-4416 Bubendorf, Switzerland (“**Bachem**”), and **Xeris Pharmaceuticals, Inc.** an entity organized under the laws of Texas with its principal place of business at 3208 Red River Street, Suite 300, Austin, TX 78705, USA (“**Xeris**”).

PREAMBLE

WHEREAS, Bachem is engaged in the business of manufacturing of active pharmaceutical ingredients (API) and has a broad proprietary know-how in the development of the manufacturing process for peptides including related analytical methods as well as in the manufacturing of peptides:

WHEREAS, Xeris is a company engaged in research, development and eventual commercialization and sale of medicinal products.

WHEREAS, the Parties now desire to set forth in this Quality Assurance Agreement a plan, prepared by Xeris and Bachem, for determining the conformity of Product supplied by Bachem to Xeris under this Agreement to the Specifications (as defined below).

NOW THEREFORE, in consideration of premises and mutual promises herein made, and in consideration of representations, warranties, and covenants herein contained, Bachem and Xeris agree as follows:

**ARTICLE 1
PREAMBLE AND DEFINITIONS**

Section 1.1 Preamble. The preamble to this Quality Assurance Agreement forms an integral part hereof.

Section 1.2 Definitions. Unless the context otherwise requires, the following terms as used in this Quality Assurance Agreement shall have the following meaning:

“**Annex**” means an exhibit annexed to and forming part of this Quality Assurance Agreement.

“**Competent Authorities**” mean the FDA in the United States or any other applicable national, supranational, federal, state or local regulatory agency or entity having the responsibility, jurisdiction, and authority to approve the clinical manufacture, use, importation, packaging, labeling, marketing, and sale of Product or Xeris’ Pharmaceutical Products in any country where Bachem has authorized Xeris to access Bachem’s DMF.

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“**Xeris’ Pharmaceutical Products**” means Xeris’ pharmaceutical medications or formulations, including those in any manner arising or resulting from the use of the Product in connection with the above medications.

“**Certificate of Analysis**” means a certificate in writing for each batch of Product, signed by a Qualified Person or its deputy, that provides full analytical results of the batch of Product, a TSE-Safely-Certificate and certifies (a) the conformity of the batch of Product to the Specifications and (b) that manufacturing and release records of the respective batch of Product were reviewed by Bachem and manufacturing and release of the respective batch of Product is in accordance with all applicable cGMP requirements. All Product batches delivered to Xeris or its designee shall comply with provisions of this Quality Assurance Agreement.

“**Confidential Information**” means, with respect to a Party, all information of a confidential nature which may be disclosed by or on behalf of that Party to the other Party including, but not limited to, the Product Information and information relating to the disclosing Party’s business or scientific strategies, research, product development, marketing, customers, opportunities, finances, sales and pricing of products, processes, and all other written information clearly identified as “Confidential” when submitted by the disclosing Party to the receiving Party.

“**DMF**” means Drug Master File maintained with the FDA or its equivalent maintained with a Competent Authority in any other country mutually agreed between the Parties.

“**GMP or cGMP**” means the (a) current regulations for Good Manufacturing Practice as outlined in the US Code of Federal Regulations and applicable FDA guidance documents as amended and (b) the ICH 07 guideline for the production and release of active substances and in EC Directive 2003/94/EC as amended from time to time and transposed into the respective national laws at the member states of the European Union and the equivalent US (FDA) laws and regulations.

“**Latent Defect**” means, with respect to Product, a hidden or latent defect not detected by the analytical test methods in operation at the date of shipment to Xeris of the relevant Product by Bachem and which was not detected by Xeris during the initial Testing Period.

“**Manufacture**” means the manufacture, processing, packing, or holding of a product including packaging and labelling operations, testing, and quality control and QA release.

“**Major Deviation**” means a deviation with the potential to have an impact on Product quality, safety, efficacy or stability.

“**Minor Deviation**” means any deviation that will not have an impact on Product quality, safety, efficacy or stability.

“**Major Change**” means a change that may adversely impact quality, safety, efficacy, stability, or regulatory compliance of the Product. Any change that will require regulatory authority approval is also defined as a Major Change.

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“**Minor Change**” means a change that will not have any adverse impact on Product quality, safety, efficacy, stability, or regulatory compliance, and will not require authority approval.

“**OOS**” means out of specification and, with respect to a Product or testing of a Product, means that the Product does not conform to the Specifications or the results of testing of the Product indicate non-conformance of the Product to the Specifications.

“**Party**” or “**Parties**” shall mean Bachem or Xeris, Individually or collectively as the context requires.

“**Product**” means synthetically manufactured human Glucagon as described in more detail in the Specifications in Annex 1 of this Quality Assurance Agreements non-sterile active pharmaceutical ingredient(s) in bulk form, manufactured under GMP requirements.

“**Qualified Person**” has the meaning ascribed to it in EC Directive 2003/94/EEC as amended or as in any other applicable GMP regulation.

“**Specifications**” means the specifications for the Product, as more specifically described in Annex 1 of this Quality Assurance Agreement. Annex 1 may be modified from time to time by written amendment to this Quality Assurance Agreement in accordance with Section 12.4.

“**Testing Period**” means the time after Xeris’ receipt of any shipment of Product to subject such Shipment, on a sample basis, to quality control testing to determine conformity with the relevant Specifications (including COAs and COCs), and whether or not a Product is free from defects in workmanship or materials, and manufactured according to cGMP.

“**TSE-Safety-Certificate**” means a certificate certifying that a batch of the Products) complies with or is outside the scope of monograph 5.2.8 of the European Pharmacopeia.

“**USP**” means current United States Pharmacopeia official compendia of standards.

“**EP**” means current European Pharmacopoeia official compendia of standards.

Section 1.3 Interpretation. Words denoting the singular include the plural and vice versa, words denoting a gender include all genders, and words denoting persons include corporations and all other legal entities.

ARTICLE 2
SUBJECT OF THIS QUALITY ASSURANCE AGREEMENT

Section 2.1 The purpose of this Quality Assurance Agreement is to define and to establish the obligations and responsibilities of Bachem and Xeris relating to the quality assurance requirements of the manufacture, release and supply of the Product pursuant to the Agreement by Bachem in accordance with GMP guidelines for active pharmaceutical ingredients (APIs), namely the US Code of Federal Regulation, Parts 11, 210, 211, applicable

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FDA guidance documents and ICH 07 GMP Guide for APIs as accepted and implemented by the national and international regulations of the European Community, the United States of America, Japan and the member states of the Pharmaceutical inspection Convention (PIC) scheme.

**ARTICLE 3
QUALITY ASSURANCE AGREEMENT CONTACT INFORMATION**

Section 3.1 Notices. Any notice, request, delivery, approval or consent required or permitted to be given under this Quality Assurance Agreement shall be in writing and shall be deemed to have been sufficiently given if delivered in person, transmitted by telecopy with a confirming copy, by e-mail with a confirming copy, sent by Overnight courier or registered mail to the Party to whom it is directed at its address shown in Section 3.02 and Section 3.03 or such other address as such Party shall have last given by notice 10 the other Party.

Section 3.2 Notices to Bachem. Any notice to Bachem under this Quality Assurance Agreement shall be addressed to:

Bachem AG, Hauptstrasse 144
4410 Bubendorf, Switzerland

[***]
[***]
[***]
[***]

Section 3.3 Notices to Xeris. Any notice to Xeris Shall be addressed to:

Xeris Pharmaceuticals Inc., 3208 Red River Street, Suite 300
Austin, TX 78705

[***]
[***]
[***]

**ARTICLE 4
THE PRODUCT**

Section 4.1 Product. The Product covered by this Quality Assurance Agreement, together with the related Specifications, is listed in Annex 1.

**ARTICLE 5
SUPPLY AND MANUFACTURE**

Section 5.1 Premises and Subcontracting. Bachem will manufacture and release the Product at its Site in Bubendorf, Switzerland. Bachem may subcontract quality control work provided that the respective contract laboratories have been qualified by Bachem. In case Bachem subcontracts any work, Bachem is solely responsible for the fulfillment of the obligations of this Quality Assurance Agreement by its subcontractors Bachem agrees to only use qualified laboratory resources listed in Annex I Any modification to the approved contract laboratories list will require prior notice to Xeris.

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Section 5.2 GMP Guidelines. The premises, equipment and systems used to manufacture and release the Product must be in compliance with all applicable GMP requirements for APIs, including the principles detailed in the US Code of Federal Regulations, Parts 11, 210, 211, and ICH Q7 GMP Guide for APIs, as accepted and implemented by the national and international regulations of the European Community, the United States of America, Japan and the member states of the PIC scheme.

Section 5.3 Materials. Bachem shall be responsible for procuring all materials for manufacturing, release and supply of the Product. Bachem shall also be responsible for the specifications and the release of such materials. Upon Xeris' request, Bachem shall provide access to such specifications and release documents for such materials to Xeris for review at Bachem's Site in Bubendorf.

Section 5.4 Manufacturing Batch Records. Bachem shall maintain the manufacturing process and method information in its own formal in manufacturing batch records. COAs including a CoC in English shall be sent to Xeris in a PDF file or equivalent.

Section 5.5 Manufacturing Process. Product must be manufactured, tested, released and packed in compliance with the requirements of the provisions of this Quality Assurance Agreement and CGMPs. Any changes made to the established manufacturing process are subject to Bachem's change control process as described in Article 7 of this Quality Assurance Agreement hereunder. Xeris shall be notified in advance of any Major Changes associated with the manufacture and quality control of Product.

Section 5.6 Facilities. Bachem shall manufacture the Product in facilities which are regularly monitored by Bachem to demonstrate compliance with applicable cGMP guidelines and codes of practice for the type of production.

Section 5.7 Batch Numbering. Bachem shall implement and use a unique batch numbering system for numbering each batch of Product. This number shall appear on all documents relating to the particular batch of Product. Bachem is responsible for maintaining an associated lot genealogy, where the final lot number may be traced back to the intermediates and starting materials used in the specified batch.

Section 5.8 Date of Manufacture. Bachem shall allocate the date of manufacture as the date when all manufacturing work has been completed and the batch is ready for release testing. Bachem shall ensure that stability and retest dates are aligned with Bachem's assigned Date of Manufacture.

Section 5.9 Re-Test Date. The re-test date for Product shall be allocated based on the date of manufacture together with the retest period established by stability data generated using Product produced by the validated manufacturing process.

Section 5.10 Rework and Reprocessing. Reprocessing and rework of Product is permitted with rework steps that have been validated as part of the manufacturing process and in accordance with the provisions of the ICH Q7 guideline Bachem will notify Xeris prior to any reworking.

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Section 5.11 Manufacturing and Equipment Data. Bachem shall be responsible for keeping records of equipment usage, cleaning, raw material batch numbers and certification as well as in process results and parameters. Such documentation shall be retained by Bachem as described in Section 6.9 hereunder.

Section 5.12 Training and Personnel. Bachem shall maintain a GMP compliant training program. Bachem will ensure and document that employees have and maintain education, naming, and experience appropriate to their job duties. Bachem will not employ any person or GMP service provider listed in the DMF that has been debarred by any Competent Authorities or, to Bachem's knowledge, is currently under any investigation which could lead to such debarment. Bachem will provide upon request the required statement supporting the claim that none of the employees or service providers listed in the DMF have been debarred or, to Bachem's knowledge, are under investigation by any Competent Authorities.

Section 5.13 Drug Master File. In mutually agreed countries, Bachem will maintain the Product DMF according to requirements defined by each local Competent Authority. Bachem will provide a letter to the specified Competent Authority at Xeris' request in accordance with Section 5.2 of the Agreement allowing such Competent Authority to review Bachem's Product DMF relative to any Xeris submission.

**ARTICLE 6
QUALITY ASSURANCE AND QUALITY CONTROL**

Section 6.1 Sampling and Samples. Bachem shall ensure that representative samples of Product are taken in accordance with GMP guidelines. Bachem will store API retention samples for all lots produced, sufficient to perform at least [***] full specification analyses, in containers that are equivalent to or more protective than the commercial packaging in accordance with the applicable GMP guidelines API samples will be retained for a minimum of [***] as of batch release. These retain samples will not be specific to Xeris. Xeris shall retain sufficient samples of Product for [***]. A quantity sufficient to perform [***] tests of Products shall be retained by Xeris.

Section 6.2 Testing of Raw Materials. Bachem shall ensure that materials and packaging components used to manufacture the Product's) are in compliance with the specifications as defined by Bachem and, if applicable, disclosed to Xeris for on-site review in Bubendorf. Reduced testing shall be permitted for vendors that have been formally qualified by Bachem and have a demonstrated history of meeting all test specifications, per an approved Bachem SOP. In this case raw materials for use in the manufacture of the Product shall be tested at a minimum for identity on each shipment delivered. Bachem will store retention samples of all STARTING MATERIALS and INTERMEDIATES used sufficient to perform at least [***] full specification analyses and meaningful use tests, in containers that are equivalent to or more protective than the commercial packaging. In all cases, sample packaging and storage conditions shall maintain the physical and chemical integrity of the sample. Samples are to be retained for [***]. However, there will be no retains (or compressed gasses and extremely hazardous materials).

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Section 6.3 In-Process Testing. Bachem shall be responsible for ensuring that all required in-process testing is completed using suitable methods, when applicable, and documented. This will include environmental controls where required. Bachem shall also be responsible for defining appropriate tests and criteria.

Section 6.4 Specifications. Bachem shall implement Specifications for the Product as mutually agreed in this Quality Assurance Agreement. It will remain the responsibility of Xeris to ensure that the Specifications are appropriate for The intended use of Product.

Section 6.5 Approval to ship the Product. Bachem shall be responsible for ensuring that the Product conforms to the Specifications and has been made and tested in accordance with the manufacturing procedure and with all provisions of this Quality Assurance Agreement This will be carried out by Bachem's Qualified Person or deputy before any shipment of Product to Xeris.

Section 6.6 Certificate of Analysis. Bachem shall issue a Certificate of Analysis serving as a confirmation that The Product has been manufactured and tested in accordance with the GMP requirements and with all provisions of this Quality Assurance Agreement The Certificate of Analysis will be signed by Bachem's Qualified Person or deputy and provide full analytical results for each batch. It will be supplied with each delivery of each batch of Product.

Section 6.7 Release of Product for use by Xeris. Bachem shall release Products under their quality system ensuring compliance with applicable regulations Release documentation shall accompany a CoA / CoC as described in this document. Xeris shall be responsible for release of the Products for further use. Xeris shall also be responsible for ensuring that all further medicinal use of Product is in accordance with the relevant laws and regulations.

Section 6.8 Documentation. Bachem shall create and maintain complete manufacturing and control documentation that is at minimum comprised of (i) a completed batch production record including in-process controls; and (ii) a completed analytical batch record; and (iii) equipment charts and print-cuts, and (iv) any documentation on investigations, deviations, OOS or failures as applicable (v) employee training files and records to support manufacturing (vi) cleaning, maintenance and validation records to support manufacturing.

Section 6.9 Document Retention. Bachem shall retain all documentation relevant to the manufacture and release of the Product securely and for a minimum of [***]. The documentation will be available to Xeris and Competent Authorities for on-site review at Bachem in Bubendorf.

Section 6.10 Retained Samples. Bachem Shall retain sufficient samples of Product for [***] years after batch release A quantity sufficient to perform at least [***] shall be retained. Xeris Shall retain Product samples as described in Section 6.1 above.

Section 6.11 Stability Studies. Bachem will run stability testing under ICH conditions according to the relevant Bachem's SOP.

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Section 6.12 Rejection of Product by Xeris. Any problem likely to cause rejection (excluding Latent Defects as defined above) of Product shall promptly be notified to Bachem after It Is identified and in any event within [***] of receipt of Products by Xeris.

Section 6.13 Reference Standards. Bachem will use a fully qualified internal reference standard which is qualified according to expectations of Competent Authorities and as detailed in current guidance documents which may be amended from time to time. Bachem and Xeris will collaborate to consider implementation of USP methods and reference standard when appropriate and practical.

Section 6.14 Conflict Resolution of Analytical Issues. In the event that a dispute arises between Bachem and Xeris in the analysis of the Product, the resolution shall conform with GMP rules on OOS results and shall proceed in stages. The first stage requires direct communication between analytical experts from the Parties to determine that the methods of analysis are the same and are being executed in the same manner at both sites. In a second stage, carefully controlled and split samples shall be exchanged to attempt to reach agreement. Should there be a failure to achieve a common set of results, analytical experts from the Parties shall be required to meet to work through the analysis of a mutually agreed sample, if these actions fail to achieve a common set of results a qualified, independent, third party referee laboratory shall be used to achieve resolution. This laboratory shall be selected mutually by the Parties. The results from this referee laboratory shall be binding on both Parties. Whatever the outcome, Xeris retains the right to decide whether the Product will be used to manufacture Xeris's Pharmaceutical Product. Nothing in this Section 6.14 shall be construed to limit Bachem's or Xeris' rights.

Section 6.15 Conflict Resolution in Quality Assurance Issues. In the event that a dispute arises between Bachem and Xeris concerning the acceptability of a batch of Product, the resolution shall proceed in stages The first stage requires direct communication between The responsible quality assurance personnel from the Parties to determine the facts of the matter and to produce an investigation report. This report shall contain complete details of the problem together with any discussion on the validity and weight to be applied to any results The investigation report shall be reviewed by the senior quality personnel from the Parties and the Parties shall determine together the action to lake It these actions fail to achieve resolution, a qualified, independent external quality consultant shall be used to decide the appropriate action This consultant shall be selected mutually by the Parties. The results from this consultant shall be binding on both Parties. Whatever the outcome, Xeris retains the right to decide whether the Product will be used to manufacture Xeris's Pharmaceutical Product. Nothing in this Section 6.15 shall be construed to limit Bachem's or Xeris's rights.

Section 6.16 Right to Audit. Bachem shall allow representatives of Xeris to have access to is manufacturing, warehousing and laboratory premises and to the associated records including inspection reports, Bachem responses and corrective actions generated from the inspection by any Competent Authority, related to Product or Quality Systems if adversely impacting quality and supply of Product and redacted as necessary to preserve the confidential information of third parties, with prior written reasonable notice for audit purposes. Xeris shall follow Bachem systems and procedures to ensure the safety, confidentiality and security of

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Bachem processes, facilities and personnel during any audit Responses to audit findings will be provided by Bachem within [***] of Bachem's receipt of an audit findings report from Xeris. Initial responses to critical observations that have the potential to impact safety, identity, strength purity or quality (SIS PQ) of the Product will be provided to Xeris within [***].

Section 6.17 Audit Schedule. Without limiting Xeris's rights, Bachem agrees to support Xeris audits according the following schedule:

1. [***] per year;
2. [***] additional technical meeting associated with the NOA review as agreed between the parties;
3. For cause audits may be conducted by Xeris with reasonable notice.

Section 6.18 Audit of Competent Authorities. Bachem shall permit inspection by applicable Competent Authorities Bachem shall notify Xeris, in advance to the extent practical, of any inspections by a Competent Authority specifically related to the Product If results of an unrelated inspection by a Competent Authority may impact Product. Bachem shall notify Xeris promptly, this includes unrelated inspectional findings that may impact the process, facilities, equipment, laboratories or personnel used to manufacture, test and store Xeris Products.

Interactions with Competent Authorities. In the cases of responses to findings by inspectors representing Competent Authorities, Bachem will meet mandatory response timelines and in the case where time is needed to provide a complete response. Bachem will notify the Competent Authority and work aggressively to ensure the complete responses meet timelines specified by the Competent Authorities Bachem will provide Xeris with copies of all correspondence including corrective actions for those observations impacting Xeris products. In the case when DMF queries received by Bachem from Competent Authorities are associated with third parties' applications, Bachem will notify Xeris if the regulatory queries may impact Xeris's Pharmaceutical Products and program timelines. In the case when queries or requested changes from regulators may produce a conflict between Xeris's Pharmaceutical Products and program(s) and Bachem's' changes relative to a third party's application. Bachem will reasonably cooperate with Xeris in order to limit impact on Xeris's Pharmaceutical Products and programs. Xeris will also cooperate in good faith to support the intended change.

Section 6.19 Latent Defects. Upon discovery that any batch, previously approved by Bachem and delivered to Xeris, fails to conform to its Specifications or the regulatory dossier or has in any way been adulterated. Bachem shall promptly notify Xeris of such failure and of the nature thereof in detail, including supplying Xeris with all relevant investigation reports and data. If Xeris notices any Latent Defects. Xeris shall inform Bachem in writing immediately, but no later than [***] alter their discovery and within [***] after receipt of the respective batch of Product. Xeris shall simultaneously send samples of the alleged faulty Product to Bachem. Bachem shall investigate all such failures promptly, at its expense, and co-operate with Xeris in determining the cause for the failure and the corrective action required.

Section 6.20 Product Complaints. Xeris shall be responsible for coordinating The investigation of any complaints about the Xeris' Pharmaceutical Product made from Product(s) and shall notify Bachem of any complaint which may be related to The quality of Product Bachem shall investigate and provide a rapid initial response and a report as soon as possible.

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Section 6.21 Product Recall. Xeris shall be responsible for instituting a medical product recall scheme for Xeris' Pharmaceutical Product. Bachem will inform Xeris as soon as possible, but no later than [***] after Bachem becomes aware of such information. In case Xeris does not agree then Xeris releases Bachem from all consequent financial and liability obligations. Xeris shall notify Bachem of any recall of Xeris' Pharmaceutical Product, which may be due to manufacture, components or tests performed on Product(s) by Bachem. Bachem shall provide a rapid initial response and then a full report as soon as possible. The Parties shall cooperate on the response to the authorities.

**ARTICLE 7
DEVIATIONS AND INVESTIGATIONS**

Section 7.1 Deviations. (Major) Bachem shall ensure that any Major Deviation is carefully investigated, evaluated and documented by quality assurance of Bachem. Investigations shall include root cause determination and corrective actions, where applicable which must be reviewed and approved by Bachem's quality assurance personnel. Bachem will provide access to all documentation with respect to Major Deviations to Xeris on-site at Bachem's facility.

Section 7.2 Deviations. (Minor) Bachem shall ensure that any Minor Deviation is carefully evaluated and documented by quality assurance of Bachem. In the case of Minor Deviations Bachem quality assurance and regulatory affairs will evaluate the acceptability regarding GMP, and the impact on conformity with regulatory submissions. Each investigation must give rise to an explanation and for corrective action, which must be reviewed and approved by Bachem's quality assurance personnel. Bachem will ensure investigation closeout and corrective actions are completed prior to release of Product, if applicable. Bachem will provide access to all documentation with respect to Minor Deviations to Xeris on-site at Bachem's facility.

Section 7.3 OOS Results, and Failure Investigations. Bachem shall be responsible for investigating any OOS results that occur with testing of the Product. According to Bachem's OOS procedure, an initial investigation will clarify whether the OOS result was caused by a lab error or by a batch failure. In case of a batch failure the investigation will be expanded at minimum to evaluate the cause of the failure and its impact on earlier and later production lots. Each investigation must give rise to an explanation and/or corrective action which must be reviewed and approved by Bachem's quality assurance. OOS and failure investigations must be completed prior to Product release.

**ARTICLE 8
CHANGE CONTROL**

Section 8.1 Change Control. Bachem shall maintain a local Change control system that ensures compliance with GMP regulatory submissions and with all provisions of this Quality Assurance Agreement. All changes will be evaluated by competent management personnel.

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regarding the technical implications Bachem's quality assurance and regulatory affairs will evaluate the acceptability of the changes to Product regarding GMPs, the impact on Product quality end stability as well as on conformity with regulatory submissions. Bachem will notify Xeris of any/all proposed Major Changes to the manufacturing process, quality controls, specifications, methods of control, prior to initiation.

**ARTICLE 9
VALIDATION AND QUALIFICATION**

Section 9.1 Process Validation. Bachem will ensure that the manufacturing process used is fully validated, approved by Bachem's Quality Assurance and Regulatory Affairs groups and meets Competent Authorities requirements. Bachem will document the process validation, and at Xeris' request, disclose such documentation to Xeris for on-site review at Bachem.

Section 9.2 Equipment Calibration. Bachem shall be responsible for ensuring that manufacturing is carried out according to Competent Authorities requirements and ICH Q7 rules using calibrated equipment Bachem shall be solely responsible for the equipment calibration and equipment maintenance program including record retention, recall bra lion, and preventive maintenance

Section 9.3 Cleaning Validation. Bachem shall be responsible for ensuring that adequate cleaning is carried out between batches of different products to prevent cross contamination Bachem shall also be responsible for conducting cleaning verification or validation as appropriate (to ensure the integrity of all products, including critical carry-over from similar batches).

Section 9.4 Facility and Utility Qualification (IQ, OQ, PQ). Bachem Shall be responsible for The qualification and maintenance as appropriate of all relevant utilities, equipment, computer systems and facilities associated with the manufacture, storage or testing of Product according to Competent Authorities requirements.

**ARTICLE 10
SPECIFIC RESPONSIBILITIES**

Without limiting each Party's rights and obligations as otherwise set forth in this Quality Assurance Agreement, the following chart sets forth each Party's specific responsibilities in connection with quality assurance matters relating to the manufacture of Product:

<u>RESPONSIBILITY</u>	<u>Bachem</u>	<u>Xeris</u>
Manufacture		—
Manufacture of the API	[***]	[***]
Development of manufacturing process for the API	[***]	[***]
Manufacturing documentation for the API	[***]	[***]
Ownership of manufacturing process and documentation for the API	[***]	[***]

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<u>RESPONSIBILITY</u>	<u>Bachem</u>	<u>Xeris</u>
Procurement of the API raw and starting materials	***	***
Analytical, Laboratory, Sampling and Control		
Retain and store samples of all materials and the API	***	***
Sampling, analysis and release of materials for API	***	***
In-process analyses for manufacture of the API	***	***
Reference standards for laboratory analysis performed by Bachem	***	***
Incoming material testing of the API upon receipt and keeping retained samples as required by competent authorities	***	***
Quality Assurance Activities for API		
Batch numbering _	***	***
Approval of master batch documents	***	***
Preparation and review of the batch production, analytical and packaging records as well as of associated documents	***	***
Assurance of correct storage conditions for the API prior to shipment to Xeris	***	***
Release of API to Xeris	***	***
Release of API for Xeris' Pharmaceutical Product manufacture	***	***
Shipping documentation	***	***
Material safety data sheet provision	***	***
Maintain a change control system	***	***
Provide API Specification as maintained in DMF	***	***
Approve API Specifications and ensure that Specifications are appropriate for further use	***	***
Change Control for Specifications (Bachem for technical feasibility, Xeris for further use)	***	***
Failure investigation in case of batch failure	***	***
Regulatory Documentation for API		
Scheduling and ordering the regulatory work documentation and submissions for API section of Xeris' Drug Products, as needed	***	***
Submission and maintenance of DMF for API	***	
Stability studies for The API	***	***
NDA or MAA submission and maintenance (or Xeris1 Drug Products	***	***
Hosting GMP Inspections for the API by the Competent Authorities	***	***
Maintain site registration licenses	***	***
Validation for API		
Qualification of equipment for manufacturing and analysis	***	***

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<u>RESPONSIBILITY</u>	<u>Bachem</u>	<u>Xeris</u>
Cleaning validation and cleaning verification	[***]	[***]
Validation of test methods	[***]	[***]
validation of manufacturing process	[***]	[***]
Validation of computerized systems	[***]	[***]
Complaint Handling, Drug Safety		
Review and resolution of Xeris' Pharmaceutical Product quality complaints when applicable to API	[***]	[***]
Decisions regarding the notification of critical API quality issues to Swissmedic and Xeris	[***]	[***]
Decisions regarding recalls and field alerts of Xeris' Pharmaceutical Product	[***]	[***]

**ARTICLE 11
CONFIDENTIALITY**

Section 11.1 Confidentiality Restriction of Use. The Confidential Information communicated by one Party to The other Party under this Quality Assurance Agreement through written documents or by any other means or any pan thereof shall be kept in confidence by the receiving Party which agrees to use the Confidential Information solely for The purpose of implementing this Quality Assurance Agreement. This confidentiality shall survive the termination of this Quality Assurance Agreement for [***] years

**ARTICLE 12
MISCELLANEOUS**

Section 12.1 Review terms of QAA. Bachem and Xeris shall evaluate in good faith the validity of the provisions defined in this Quality Assurance Agreement every [***] years (or sooner, to the extent required by applicable laws of the manufacturing site) starting at the Effective Date.

Section 12.2 Governing Law, Dispute Resolution. Any dispute a using cut of or in connection with this Quality Assurance Agreement, including any question regarding its existence, validity or termination, shall be referred lo and finally resolved by arbitration under the London Court of International Arbitration Rules, which Rules are deemed to be incorporated herein by reference. The number of arbitrators shall be one. The seal, or legal place, of arbitration shall be London, England. The language to be used in the arbitral proceedings shall be English. The governing law of the contract shall be the substantive law of Switzerland.

Section 12.3 Annexes. The Annexes referenced in this Quality Assurance Agreement are specifically made a part hereto.

Section 12.4 Amendment. Any amendment or modification of this Quality Assurance Agreement must be in writing and signed by authorized representatives of both Parties.

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Section 12.5 Prevailing Agreement. To the extent that there is a conflict between, or ambiguity relating to this Quality Assurance Agreement and any other Agreement, the wording of this Quality Assurance Agreement shall govern any and all quality matters.

Section 12.6 Language. This Quality Assurance Agreement is made in the English language.

Section 12.7 Number of Copies. Two master copies exist, one with each of the Parties.

Section 12.8 Term. This Quality Assurance Agreement shall commence as of the Effective Date and shall terminate *** years after shipment of the final Batch of Product. For clarity, this Quality Assurance Agreement shall be terminated automatically, if no shipments of the Product to Xeris have been made over a period of *** consecutive years. Termination of this Quality Assurance Agreement shall not relieve the Parties of any obligation accruing prior to termination and shall not extinguish any antecedent breach of any provisions thereof, and such provisions of this Quality Assurance Agreement which, by their terms, survive shall continue in full force and effect after such termination.

Section 12.9 Assignment. Neither of the Parties shall assign or transfer this Quality Assurance Agreement or any of their respective rights or obligations hereunder without the prior written consent of the other Party, which shall not be unreasonably withheld or delayed, except that either Party may assign this Agreement and The rights and obligations hereunder without the consent of the other Party to any person succeeding to all or substantially all of the business or assets of The Party relating to the Product

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IN WITNESS WHEREOF, the Parties have caused this Quality Assurance Agreement to be duly executed by their authorized representatives on the Effective Date.

Bubendorf .Switzerland

Bachem AG

By /s/ Gerard Haas December 9, 2015

Dr Gerhard Haas
VP QAVRA

By: /s/ Jan van Bebber December 9, 2015

Dr. Jan van Bebber
Director QA/RA

Austin. TX USA

Xeris Inc.

By /s/ Yash Sabharwal November 20, 2015

Yash Sabharwal
Chief Operating Officer

By /s/ Banir Ruano November 20, 2015

Banir Ruano
VP of Global Manufacturing & Tech Ops

By /s/ Rebecca Waterbury December 2, 2015

Rebecca Waterbury
VP of Quality

*** INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 PROMULGATED UNDER THE SECURITIES ACT OF 1933, AS AMENDED

CONFIDENTIAL

ANNEX 1

Xeris / Bachem Quality Assurance Agreement

Glucagon

SPECIFICATIONS

The Product shall be released against the following Specifications:

*** INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 PROMULGATED UNDER THE SECURITIES ACT OF 1933, AS AMENDED

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Product: Glucagon, Pharma Grade Material

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ANNEX 2

Xeris / Bachem Quality Assurance Agreement

Glucagon

APPROVED CONTRACT LABORATORIES

Certain analytical services are provided (or Bachem AG by contract laboratories. Following please find the list of these institutes / companies including their potential service(s). All listed subcontractors are appropriately Qualified by Bachem Alternatively to using a contract laboratory these tests may be performed in house at Bachem provided that the specific technique is available.

<u>Contract laboratory</u>	<u>Description of typical service(s)</u>
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

[***] INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 PROMULGATED UNDER THE SECURITIES ACT OF 1933, AS AMENDED

Amendment 1 to the Quality Assurance Agreement

This Amendment 1 (the “**Amendment 1**”) is made as of October 31, 2016 (the “**Effective Date**”) by and between Bachem AG, an entity organized under the laws of Switzerland, with its principal place of business at Hauptstrasse 144, CH-4416 Bubendorf, Switzerland (“**Bachem**”), and Xeris Pharmaceuticals, Inc., an entity organized under the laws of Texas, with its principal place of business at 3208 Red River Street, Suite 300, Austin, TX 78705, USA (“**Xeris**”).

PREAMBLE

WHEREAS, Bachem and Xeris have entered into a Quality Assurance Agreement between the Parties effective as of November 20, 2015 the “Quality Assurance Agreement”;

WHEREAS, Bachem and Xeris now mutually desire to amend, modify and restate certain terms and conditions of the Quality Assurance Agreement.

NOW THEREFORE, the Parties hereto, intending to be legally bound, agree as follows:

1. Definitions

The capitalized terms used in this Amendment 1 shall have the meaning ascribed to such terms in the Quality Assurance Agreement, unless otherwise stated.

2. Amendments

The Parties agree that, as of the Effective Date, the Quality Assurance Agreement is amended as set forth in this Section 2.

2.1 Section 3.3 (Notices to Xeris) of the Quality Assurance Agreement shall be deleted in its entirety and replaced by the following:

Section 3.3 Notices to Xeris. Any notice to Xeris shall be addressed to:

Xeris Pharmaceuticals, Inc., 3208 Red River Street, Suite 300
Austin, TX 78705
[***]

3. MISCELLANEOUS

3.1 The Parties agree that the provisions of this Amendment 1 shall be applied with immediate effect. For the avoidance of doubt it is acknowledged that the provisions of this Amendment 1 shall be valid for future manufacturing and release of the Product.

3.2 In the event of any conflict between the terms of this Amendment 1 and the terms of the Quality Assurance Agreement the terms of this Amendment 1 shall prevail.

*** INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 PROMULGATED UNDER THE SECURITIES ACT OF 1933, AS AMENDED

3.3 Except as expressly modified by this Amendment 1, the terms and provisions of the Quality Assurance Agreement remain and shall remain in full force and effect.

IN WITNESS WHEREOF, the Parties have caused this Amendment 1 to the Quality Assurance Agreement to be duly executed by their authorized representatives on the Effective Date.

Bubendorf, November 3, 2016

Bachem AG

By: /s/ Gerard Haas

Dr. Gerhard Haas
Vice President QA/RA

By: /s/ Jan van Bebber

Dr. Jan van Bebber
Director QA/RA

Austin, TX USA, November 7, 2016

Xeris Inc.

By: /s/ Benir Ruano

Benir Ruano
VP of Global Manufacturing & Tech Ops

By: /s/ Leslie Osmera

Leslie Osmera
VP of QA

*** INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 PROMULGATED UNDER THE SECURITIES ACT OF 1933, AS AMENDED

**Amendment 2 to the
Quality Assurance Agreement**

This Amendment 2 (the “**Amendment 2**”) is made as of **January 26, 2017** (the “**Effective Date**”) by and between **Bachem AG**, an entity organized under the laws of Switzerland, with its principal place of business at Hauptstrasse 144, CH-4416 Bubendorf, Switzerland (“**Bachem**”), and **Xeris Pharmaceuticals, Inc.**, an entity organized under the laws of Texas, with its principal place of business at 3208 Red River Street, Suite 300, Austin, TX 78705, USA (“**Xeris**”).

PREAMBLE

WHEREAS, Bachem and Xeris have entered into a Quality Assurance Agreement between the Parties effective as of November 20, 2015, an amendment to the Quality Assurance Agreement dated October 31, 2016 (“**Amendment 1**”) collectively comprising the “**Quality Assurance Agreement**”;

WHEREAS, Bachem and Xeris now mutually desire to amend, modify and restate certain terms and conditions of the Quality Assurance Agreement.

NOW THEREFORE, the Parties hereto, intending to be legally bound, agree as follows:

1. DEFINITIONS

The capitalized terms used in this Amendment 2 shall have the meaning ascribed to such terms in the Quality Assurance Agreement, unless otherwise stated.

2. AMENDMENTS

The Parties agree that, as of the Effective Date, the Quality Assurance Agreement is amended as set forth in this Section 2.

2.1 Exhibit A (Specifications) of the Quality Assurance Agreement shall be deleted in its entirety and replaced by the following:

(The remainder of this page is intentionally left blank)

[***] INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 PROMULGATED UNDER THE SECURITIES ACT OF 1933, AS AMENDED

Xeris / Bachem Quality Assurance Agreement

ANNEX 1

Glucagon

SPECIFICATIONS

The Product shall be released against the following Specifications:

[***]

<u>Tests</u>	<u>Specifications</u>	<u>Controls</u>
Appearance R	[***]	
Appearance of solution R	[***]	
Identification (HPLC)	[***]	
Identification (HPLC) ^{1,2}	[***]	
Identification (amino acid analysis)	[***]	
	[***]	
	[***]	
	[***]	
	[***]	
	[***]	
	[***]	
	[***]	
Identification (MS) ²	[***]	
Specific optical rotation	[***]	
Related substances (HPLC) R	[***]	
Peptide content R (elemental analysis)	[***]	
Assay (HPLC) ^{1,2,R}	[***]	
Bioassay	[***]	
Mass balance	[***]	
Water content (Karl Fischer) ^R	[***]	
Residue on ignition	[***]	
Acetic acid content (HPLC)	[***]	
Ammonium content (IC)	[***]	
Chloride content (titration)	[***]	
Residual organic solvents (GC)	[***]	

[***] INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 PROMULGATED UNDER THE SECURITIES ACT OF 1933, AS AMENDED

	[***]
Nitrogen content R (elemental analysis)	[***]
Zinc content (ICP-OES)	[***]
Bacterial endotoxins (USP <85>)	[***]
Microbial limit test (USP <61>) Total aerobic microbial count (TAMC)	[***]
Total yeasts and moulds count (TYMC)	[***]

R performed for retest
1 the analytical test method is based on the Glucagon monograph of [***]
2 report separately as Additional Data

To be analyzed according to [***]

Product: Glucagon, Pharma Grade Material

Bachem No.: [***]

Peptide Sequence: [***]

3. MISCELLANEOUS

3.1 The Parties agree that the provisions of this Amendment 2 shall be applied with immediate effect. For the avoidance of doubt it is acknowledged that the provisions of this Amendment 2 shall be valid for future manufacturing and release of the Product.

3.2 Both Parties acknowledge and Xeris agrees that there will be a Major Change to the existing Quality Assurance Agreement within the next months (Change request letter dated February 22, 2016) and therefore the Agreement will be amended with the new Quality Standard reflecting such Change as soon as available.

3.3 In the event of any conflict between the terms of this Amendment 2 and the terms of the Quality Assurance Agreement or the terms of the Amendment 1, the terms of this Amendment 2 shall prevail.

3.4 Except as expressly modified by this Amendment 2, the terms and provisions of the Quality Assurance Agreement and Amendment 1 remain and shall remain in full force and effect.

IN WITNESS WHEREOF, the Parties have caused this Amendment 2 to the Quality Assurance Agreement to be duly executed by their authorized representatives on the Effective Date.

***] INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 PROMULGATED UNDER THE SECURITIES ACT OF 1933, AS AMENDED

Bubendorf, February 8, 2017

Bachem AG

By: /s/ Gerard Haas
Dr. Gerhard Haas
Vice President QA/RA

/s/ Jan van Bebber
Dr. Jan van Bebber
Director QA/RA

Austin, TX USA, February 16, 2017

Xeris Inc.

By: /s/ Benir Ruano
Benir Ruano
VP of Global Manufacturing & Tech Ops

/s/ Leslie Osmera
Leslie Osmera
VP of QA

[***] INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 PROMULGATED UNDER THE SECURITIES ACT OF 1933, AS AMENDED



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MASTER SERVICE AGREEMENT

This Master Service Agreement (“Agreement”) is made and entered into as of November 1, 2016 (“Effective Date”) by and between:

PYRAMID Laboratories Inc. (“PYRAMID”), a California Corporation, having its principal place of business at 3598 Cadillac Avenue, Costa Mesa, CA 92626 and *Xeris Pharmaceuticals, Inc.* (“XERIS”), located at 3208 Red River, Suite 300, Austin, TX 78705.

PURPOSE

XERIS wishes to engage PYRAMID to perform the GMP manufacture of Product and PYRAMID wishes to provide such services to XERIS subject to the terms and conditions of this Agreement:

AGREEMENT

1. DEFINITIONS

1.1 “*Affiliates*” means any corporation, firm, partnership, or other entity which directly or indirectly controls, is controlled by, or is under common control with XERIS.

1.2 “*cGMP*” means the current Good Manufacturing Practices for manufacturing finished pharmaceutical products as set forth in 21 CFR 210 and 211, the guidelines to GMP (under directive 2003/94/EC) as detailed in “The Rules Governing Medicinal Products in the European Union”- Column IV Good Manufacturing Practice for Medicinal Products and in accordance with the Quality Responsibilities detailed in the relevant EC Directive or any foreign equivalent specified in the applicable Work Order,

1.3 “*cGMP Grade*” means Product that has been produced and manufactured in accordance with the Specifications and Regulatory Standards.

1.4 “*Product*” means the intermediates, formulations, or finished products to be tested and/or manufactured by PYRAMID under any Work Order.

1.6 “*Proposal*” is defined as the offer PYRAMID submits to XERIS for the proposed manufacture of Product by PYRAMID. Once it is signed and authorized by XERIS, it will be the “Work Order”, which is defined in Section 3.

1.7 “*Quality Agreement*” is defined in Section 8.



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1.8 “Regulatory Standards” means requirements of the United States FDA (Food and Drug Administration) or foreign equivalent requirements for PYRAMID’S facility, cGMP and all other regulations applicable to PYRAMID, PYRAMID’S facility, and PYRAMID’S manufacture, storage, packaging, labeling, testing, control, and shipment of Product.

1.9 “Services” is defined in Section 2.

1.10 “Specifications” means (a) for any Product, the manufacturing, handling, and storage specifications set out in the Work Order or otherwise specified by XERIS in writing; and (b) any standard operating procedures or guidelines for the manufacture of Product provided to PYRAMID by XERIS in writing.

1.11 “Work Order” is defined in Section 3.

1.12 “XERIS Materials” means any raw materials, active pharmaceutical ingredient(s), or components supplied to PYRAMID by XERIS for testing and/or the manufacture of Products under any Work Order.

2. SCOPE OF AGREEMENT

Under this Agreement XERIS may request PYRAMID to perform cGMP manufacture, fill and finish, and/or testing of Product from time to time (“Services”).

3. WORK ORDERS

The Services detailed in an executed signed Proposal to be performed by PYRAMID under this Agreement, will be considered Work Orders (“Work Orders”), and will be subject to the terms and conditions of this Agreement. In the event of any conflict between the terms of any Work Order and the terms of this Agreement, the terms of this Agreement will take precedence over any Work Order.

4. MANUFACTURE AND SUPPLY

PYRAMID will manufacture the Products in strict accordance with the Specifications and the Regulatory Standards. PYRAMID will supply cGMP Grade Product to XERIS in the quantities, on the schedule, and at the price stated in the Work Order. PYRAMID will store all starting materials and in-process products in accordance with cGMP.



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5. SHIPPING

PYRAMID will package, insure, and ship the Product in accordance with the instructions stated in the Work Order and the applicable Specifications (*i.e.*, applicable batch record), at *XERIS* expense.

6. PAYMENT

6.1 PYRAMID requires [***] ([***]%) down payment upon receipt of a signed Work Order (for development, manufacturing, and analytical), with the exception of stability studies, in order to initiate any project phase. The final balance including all consumables will be due [***] after submittal of the corresponding production records and/or project related documents, reports, etc., as applicable. Product will be available thereafter for delivery at *XERIS*' request. All late payments shall bear interest at a rate of [***] ([***]%) per month, if not prohibited by law, otherwise at the highest lawful contract rate. PYRAMID shall not initiate any phase of the Work Order unless PYRAMID receives a signed Work Order and down payment from *XERIS* to proceed with such phase.

6.2 *XERIS* will pay PYRAMID for the Services as stated in the Work Order. *XERIS* shall be responsible for payment of freight, insurance, customs duties, and related charges for delivery of packaged Products to *XERIS*, unless otherwise specified in the Work Order.

6.3 Except as otherwise provided in the applicable Work Order, *XERIS* will pay to PYRAMID any federal, state, and local sales taxes, if applicable, based on or measured by the sale or use of packaged Products, exclusive of any taxes based on PYRAMID'S income.

6.4 Unless otherwise stated in the applicable Work Order, PYRAMID will invoice *XERIS* on completion of the Work Order and *XERIS* will pay any and all undisputed invoices within [***] of its receipt by *XERIS*. All invoices must reference *XERIS* Work Order number and must be sent to the address specified in the applicable Work Order.

6.5 PYRAMID shall arrange for hazardous waste disposal, if any, at *XERIS* expense after written notification and authorization.

6.6 Executed Work Orders must be received by PYRAMID within [***] of the mutually agreed scheduled commencement date for manufacture of Product in order to reserve the necessary Research & Development resources and/or manufacturing time, and *XERIS* will endeavor to provide any required *XERIS* Materials according to the timelines mutually agreed by the parties under such Work Order.



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6.7 Cancellation or Rescheduling

6.7.1 Cancellation or rescheduling of a manufacturing event by XERIS within:

- 6.7.1.1 Greater than [***] of the scheduled event will incur no charge.
- 6.7.1.2 Less than or equal to [***] of the scheduled event will incur a charge of [***] ([***]%) of the total project cost plus pre-production costs (labor and materials for processed components) specifically for XERIS per Process Lot.
- 6.7.1.3 Less than or equal to [***] of the scheduled event will incur a charge of [***] ([***]%) of the total project cost plus pre-production costs (labor and materials for processed components) specifically for XERIS per Process Lot.
- 6.7.1.4 Less than or equal to [***] of manufacturing of the scheduled event will incur a charge of [***] ([***]%) of the total project cost plus pre-production costs (labor and materials for processed components) specifically for XERIS per Process Lot.
- 6.7.1.5 Less than or equal to [***] of manufacturing of the scheduled event will incur a charge of [***] ([***]%) of the total project cost.

6.7.2 In the event of cancellation of any initiated stability study, a [***] (\$[***]) fee will be applied for the reconciliation and close out of the stability study.

6.7.3 It is recognized that all or part of any formulation development and/or analytical development Services may be terminated upon notification from XERIS. It is PYRAMID'S policy to assess a fee for studies terminated after the initiation of its Work Order. The fee will be prorated based upon the stage of completion of the Phase, and in any event PYRAMID will only be paid for Services completed up to the effective date of such termination,

6.8 In the event of default in the payment of Services rendered or expenses incurred by PYRAMID for XERIS, pursuant to this Agreement, XERIS shall be responsible for all collection fees and reasonable expenses incurred by PYRAMID, including attorney's fees.

7. XERIS MATERIALS AND PRODUCT

7.1 XERIS Materials will remain XERIS' property at all times and will only be used by PYRAMID for the purposes of manufacturing Product under the relevant Work Order.



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7.2 PYRAMID will store and maintain XERIS Materials in accordance with the terms of the applicable Work Order and in such a way that they are clearly identifiable as XERIS property.

7.3 XERIS Materials will be insured by XERIS against any damages that may occur during the storage at the premises of PYRAMID. PYRAMID will not be liable for destruction or deterioration of these materials unless destruction or deterioration is due to the negligence or willful misconduct on the part of PYRAMID.

7.4 XERIS shall provide to PYRAMID the most current technical data relating to XERIS Materials including, but not limited to, specifications, material data safety sheets together with pertinent environmental health and safety information necessary to assure safe handling and disposal of XERIS Materials by PYRAMID employees.

8. QUALITY ASSURANCE

The parties will enter into a quality agreement (the "Quality Agreement"). Any breach of the Quality Agreement will be deemed a breach of this Agreement. In the event of any conflict between the terms of the Quality Agreement and this Agreement, the terms of this Agreement will take precedence over the Quality Agreement. The parties may mutually agree from time to time to update the Quality Agreement.

9. REGULATORY INSPECTIONS

PYRAMID'S obligations to notify and cooperate with XERIS regarding any audit or inspection by a competent regulatory authority with respect to the manufacture and/or testing of Products will be as set out in the Quality Agreement. All reasonable costs associated with PYRAMID'S compliance with any official requests for information or documents relating to Services performed or goods provided by PYRAMID under the Work Order (including XERIS or regulatory authority audits) shall be paid by XERIS, unless any such audit is the result of PYRAMID'S failure to comply with any Regulatory Standards, in which case PYRAMID will solely bear such costs. XERIS shall reimburse PYRAMID for all such reasonable costs including, but not limited to, hourly charge for persons responding to requests, travel, lodging, meals, mileage, incidental expenses, reasonable attorney's fees for preparation of any person called to testify, and associated fees and all other reasonable expenses associated with any such requests.

10. ON SITE REVIEW AND AUDIT

10.1 XERIS may conduct [***] of Quality Assurance Site Compliance Audit each calendar year on a date mutually agreed upon by the parties. The Quality Assurance Audit will take such form as set out in the Quality Agreement and includes the right to inspect any facility



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being used by PYRAMID for the Services and to inspect all relevant records. Any additional audits will be charged at [***] (\$[***]) per day. Qualified Person (QP) audits will be charged [***] (\$[***]) per day. FDA Audits will be charged at [***] (\$[***]) per day, to be limited to no more than [***] total.

10.2 PYRAMID will co-operate fully with XERIS during audits performed under this Section, including furnishing to XERIS copies of all requested documents.

10.3 PYRAMID will provide to XERIS access to PYRAMID'S facilities during execution of the manufacturing Services under any WORK ORDER, upon reasonable notice for the purpose of observing performance of the services, conducting a for-cause audit or investigation and providing technical assistance, where required.

11. RECORDS

11.1 Unless stated otherwise in the Quality Agreement or the Specifications, PYRAMID will, at its expense, store all testing and quality control records relating to a particular Work Order onsite for [***]; and for a period of [***] offsite following completion of the Work Order. At the end of the [***], XERIS will be notified to determine whether the records may be destroyed, provided to XERIS, or continue to be stored at XERIS request or expense.

11.2 PYRAMID will maintain, in accordance with Generally Accepted Accounting Principles and Practices, records reflecting the accuracy of PYRAMID'S charges, including invoices for compensation, and other information as XERIS may reasonably require in connection with this Agreement ("Financial Records"). PYRAMID will preserve such Financial Records, without receipt of additional compensation, for at least [***] years after the date of the final payment.

12. REJECTION OF PRODUCT

12.1 XERIS will have the right to reject any Product that has not been manufactured in compliance with the Quality Agreement, PYRAMID'S warranty in Section 16, or does not meet the established Specification, without invalidating the remainder of the relevant order.

12.2 XERIS' right of rejection will be exercised by delivery of written notice to PYRAMID in accordance with the procedures set out in the Quality Agreement or Work Order. Any quantities of Product that are rejected pursuant to this section will be returned to PYRAMID at PYRAMID'S expense and either (a) will be promptly replaced by PYRAMID at PYRAMID'S sole cost and expense if requested by XERIS not to exceed the paid amount or (b) PYRAMID will return the fees for that portion of the Services that is determined to be nonconforming or made of limited, nominal, or no value to XERIS due to the said nonconforming portion. PYRAMID will be responsible for the replacement cost of any XERIS Materials rendered unusable by PYRAMID'S failure to comply with its warranty in Section 16.



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12.3 If PYRAMID disputes XERIS basis for rejecting Product, then the rejected Product will be tested by an independent cGMP laboratory mutually agreed upon by the PARTIES. The independent laboratory's determination will be final and binding on the parties. The cost of such testing will be borne by PYRAMID if the independent laboratory confirms that the Product in question does not comply with PYRAMID'S warranty in Section 16. Otherwise the costs will be borne by XERIS.

13. INTELLECTUAL PROPERTY

13.1 XERIS will retain ownership of any and all of XERIS' Information and intellectual property in the Specifications, Product Formulation, Product Manufacturing Process, and XERIS Materials. Except for the limited purpose of performing its obligations under this Agreement, PYRAMID is not granted any right, title, or interest in any intellectual property owned or controlled by XERIS.

13.2 All intellectual property produced by PYRAMID in performance of Services, including formulation development, analytical testing, and/or the manufacture of Products under a Work Order will belong to XERIS. PYRAMID agrees to complete, at XERIS expense, but without further compensation to PYRAMID, any documents necessary for XERIS to file patent applications and to prosecute patents with respect to such intellectual property in XERIS' name or PYRAMID'S name, or both. PYRAMID will, if deemed necessary or desirable by XERIS, on the same terms, execute an assignment of rights to XERIS with respect to such patent applications or patents.

14. CONFIDENTIALITY

The parties agree that the Mutual Confidential Disclosure Agreement dated August 26, 2014 entered into by the parties will govern any and all disclosures of confidential information between the parties under this Agreement.

15. RELATIONSHIP WITH XERIS

15.1 PYRAMID is an independent contractor and PYRAMID acknowledges that its personnel or employees are not employees of XERIS. Accordingly, neither PYRAMID nor its employees or personnel will (a) participate in XERIS employee benefit plans nor receive any other compensation beyond that stated below, (b) have the power or authority to bind XERIS or to assume or create any obligation or responsibility, express or implied, on XERIS part or in XERIS, except as otherwise set forth in this Agreement, or (c) represent to any person or entity that PYRAMID, its personnel or any employee of PYRAMID has such power or authority.



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PYRAMID will remain solely liable for all aspects of the employment of such persons including, without limitation, recruitment, hiring, firing, training, promotion, compensation, all payroll taxes and other deductions and all premiums or payments made for worker's compensation coverage, unemployment benefits, or any other payments required by law to be made by employers for or on behalf of employees.

15.2 PYRAMID represents and warrants that it and its personnel and employees are authorized to perform the Services and that neither it nor its personnel or employees will act in violation of any applicable immigration laws or regulations. PYRAMID will indemnify XERIS against any and all claims, fines, penalties, and/or attorney's fees incurred by XERIS for breach by PYRAMID of any immigration laws or regulations and of this warranty.

16. PYRAMID WARRANTIES

PYRAMID represents, warrants and covenants that:

- (a) all Product supplied to XERIS under this Agreement will be of cGMP Grade;
- (b) it is a corporation duly organized and existing in good standing under the laws of the state of its incorporation;
- (c) it has the right and authority to enter into and perform its obligations under this Agreement;
- (d) it will perform all of its obligations under this Agreement in accordance with all applicable governmental laws, rules, and regulations;
- (e) it and its employees, affiliates, and agents have never been debarred or convicted of a crime for which a person can be debarred (i) under Section 306(a) or (b) of the Generic Drug Enforcement Act of 1992 or (ii) for the award of United States of America Federal contracts; and
- (f) none of PYRAMID'S employees, affiliates, or agents, according to PYRAMID'S best knowledge after due inquiry, has ever been threatened to be debarred or indicted for a crime or otherwise engaged in conduct for which a person can be debarred, (i) under Section 306(a) or (b) or (ii) for the award of United States of America Federal contracts. PYRAMID agrees that it will promptly notify XERIS upon learning of any such debarment, conviction, threat, or indictment; and

(g) the foregoing warranty is made to XERIS only and is not transferable to any agents or assigns of XERIS except in accordance with Section 24.1. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THESE TERMS AND CONDITIONS, PYRAMID



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MAKES NO REPRESENTATION AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING ANY EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

17. XERIS WARRANTIES

XERIS represents warrants and covenants that:

(a) it is a corporation duly organized and existing in good standing under the laws of the state of its incorporation;

(b) *XERIS* Materials and PYRAMID'S use of the processes or procedures described in the Specifications will not infringe the intellectual property rights of third parties;

(c) it has the right and authority to enter into and perform its obligations under this Agreement; and

(d) it will perform all of its obligations under this Agreement in accordance with all applicable governmental laws, rules, and regulations.

18. INDEMNIFICATION BY PYRAMID

18.1 PYRAMID will defend, indemnify, and hold harmless *XERIS* and its Affiliates, and its or their officers, directors, shareholders, employees, agents, and representatives from and against any and all liability, damage, loss, cost, or expense (including reasonable attorney's fees, costs, and amounts paid in settlement) (collectively, "Losses") resulting from any third party claim made or suit brought against *XERIS* or any such persons arising out of (a) PYRAMID'S breach of any of its representations, warranties, or covenants in Section 16; or (b) the use by *XERIS* of any Product supplied by PYRAMID under this Agreement that does not comply with its applicable Specifications.

18.2 Upon receipt of notice of any such claim or suit, *XERIS* will promptly notify PYRAMID thereof and will permit PYRAMID, at its cost, to handle and control such claim or suit. *XERIS* will have the right to participate in the defense of such claim or suit at its own expense. *XERIS* shall afford PYRAMID all reasonable assistance (at PYRAMID'S cost and expense), will make no admission prejudicial to the defense of such claim or suit, and agrees not to compromise or settle such claim or demand without PYRAMID'S prior written consent.

18.3 The foregoing indemnification obligation will not apply to any claim or suit to the extent it arises directly out of *XERIS* negligence, willful misconduct, or breach of any term, representation, warranty, or covenant contained in this Agreement or is otherwise covered by *XERIS*' indemnification obligations under Section 19 below.



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19. INDEMNIFICATION BY XERIS

19.1 XERIS will defend, indemnify, and hold harmless PYRAMID and its Affiliates, and its or their officers, directors, shareholders, employees, agents, and representatives from and against any and all liability, damage, loss, cost, or expense (including reasonable attorney's fees, costs, and amounts paid in settlement) (collectively, "Losses") resulting from any third party claim made or suit brought against PYRAMID or any such persons arising out of (a) XERIS breach of any of its representations, warranties, or covenants in Section 17; or (b) the use by XERIS of any Product supplied by PYRAMID under this Agreement that complies with its applicable Specifications.

19.2 Upon receipt of notice of any such claim or suit, PYRAMID will promptly notify XERIS thereof and will permit XERIS, at its cost, to handle and control such claim or suit. PYRAMID will have the right to participate in the defense of such claim or suit at its own expense. PYRAMID will afford XERIS all reasonable assistance (at XERIS cost and expense), will make no admission prejudicial to the defense of such claim or suit, and agrees not to compromise or settle such claim or demand without XERIS' prior written consent.

19.3 The foregoing indemnification obligation will not apply to any claim or suit to the extent it arises directly out of PYRAMID'S negligence, willful misconduct, or breach of any term, representation, warranty, or covenant contained in this Agreement or is otherwise covered by PYRAMID'S indemnification obligations under Section 18 above.

20. INSURANCE

At all times commencing with the date of the signed Work Order, XERIS shall maintain adequate product or general liability insurance as determined by insurance industry standards. At all times commencing with the date of a signed Work Order, PYRAMID shall carry insurance adequate to cover its interest or liabilities hereunder including, but not limited to, worker's compensation and general liability.

21. LIMITATION OF LIABILITY

Both parties shall be limited to the amount paid under this Agreement and shall not be liable under this Agreement, whether in tort, contract or otherwise, for any indirect, incidental, or consequential losses or any punitive or exemplary damages.

22. PUBLICITY

22.1 No press releases or other statements in connection with this Agreement intended for use in the public or private media shall be made by XERIS or PYRAMID without the prior written consent of the other party. If either party is required by law or governmental regulation to describe its relationship to the other, it will promptly give the other party notice with a copy of any disclosure it proposes to make.



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22.2 In addition, PYRAMID will not use *XERIS* in connection with any products, services, promotion, or advertising without *XERIS* prior written permission.

23. TERM AND TERMINATION

23.1 This Agreement will end on completion of the Services under the last Work Order placed within [***] from the Effective Date.

Either Party may terminate any Work Order or this Agreement without cause by giving [***] notice to the other Party in writing. In addition to Section 6.6, if *XERIS* terminates this Agreement or any Work Order without cause, *XERIS*' only obligation will be to pay PYRAMID for the Services completed under the Agreement or the terminated Work Order, as the case may be, up to the date of termination, at the rates provided in the Work Order. All payments paid to PYRAMID in excess of those due to it under this Section will be returned to *XERIS*

23.2 If either party breaches this Agreement, the other party may terminate this agreement if the breaching party does not cure the breach within [***] of written notice of the same. Termination will be without prejudice to any rights that may have been accrued to either party before termination.

23.3 On termination of this Agreement for any reason, PYRAMID will return, at *XERIS* expense, all *XERIS* Materials. In addition, the parties will return to each all copies of the other party's information except for one copy that may be retained for the sole purpose of determining continuing obligations under Section 14.

24. GENERAL

24.1 Assignment; Subcontractors. PYRAMID will not transfer or assign its rights or obligations under this Agreement, in whole or in part, without *XERIS*' prior written permission. *XERIS* may assign its rights and obligations under this Agreement to any Affiliate without PYRAMID'S prior consent, but must give PYRAMID written notice of such assignment within [***] following the assignment. PYRAMID may not utilize subcontractors to perform any part of the Services without prior written authorization by *XERIS*.

24.2 Entire Agreement; Amendments. The provisions, terms, and conditions of this Agreement (including its schedules and any subsequent Work Orders) constitute the entire agreement of the parties with regard to the subject matter of this Agreement and supersede any prior agreements whether oral or written. No waiver, modification, change, or amendment of any of the provisions of this Agreement shall be valid unless in writing and signed by the party



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against whom such claimed waiver, modification, change, or amendment is sought to be enforced. The terms of this Agreement shall supersede any subsequent schedules or Work Orders in the event of inconsistencies with the terms of this Agreement.

24.3 Notices. All notices, requests, demands and other communications required or permitted to be given hereunder will be in writing and will be deemed to have been given (a) when received, if delivered in person, or (b) when sent, if sent by facsimile with receipt confirmed, or (c) three (3) business days following the mailing thereof, if mailed by certified first class mail, postage prepaid, return receipt requested, in any such case as follows:

If to PYRAMID:

PYRAMID Laboratories, Inc.
3598 Cadillac Ave.
Costa Mesa, California 92626
Attn.: Medhat Gorgy
President & CEO

If to XERIS:

XERIS
Xeris Pharmaceuticals, Inc.
3208 Red River Road, Suite 300
Austin, TX 78705
Attn: Peter Knauer, VP of CMC

24.4 Severability. If any term or provision of this Agreement is invalid or unenforceable, the remainder of this Agreement shall be unaffected thereby and each remaining term or provision of this Agreement is valid and will be enforceable to the fullest extent permitted by law.

24.5 Waiver. The failure of either party to insist upon strict observation or performance of any provision of this Agreement, or to exercise any right or remedy shall not impair or waive any such right or remedy in the future. Every right and remedy given by this Agreement to the parties may be exercised from time to time as often as appropriate. All remedies, either under this Agreement or by law or otherwise afforded, will be cumulative and not alternative.

24.6 Force Majeure. Neither party will be liable nor deemed to be in default for any delay or failure in performance under this Agreement or other interruption of service or employment deemed resulting directly or indirectly from Acts of God, civil or military authority, acts of public enemy, war, accident, fire, explosion, earthquake, flood, failure of transportation, strike, or other work interruption by either party's employees or any similar or dissimilar cause beyond the reasonable control of either party.



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24.7 Binding Effect. This Agreement will be binding upon and will inure to the benefit of XERIS and PYRAMID, their respective successors and permitted assigns.

24.8 Arbitration. Any dispute, controversy, or claim arising out of or related to this Agreement, or the breach thereof, shall be settled by binding arbitration in accordance with the Commercial Rules of the American Arbitration Association, and judgment upon any arbitration award rendered hereunder may be entered in any court having jurisdiction. Each party shall select one (1) neutral arbitrator from a list provided by the American Arbitration Association and those two arbitrators shall select a third arbitrator from the list- The arbitration process shall take place in Orange County, California, or such other place as the parties may hereafter agree. The prevailing party shall have the costs for the arbitration, including attorney's fees, paid by the non-prevailing party.

24.9 Governing Law. This Agreement is to be construed and determined under the laws of the State of Delaware.

24.10 Headings. The headings of this Agreement are inserted merely for convenience and ease of reference and will not affect or modify the meaning of any of the terms, covenants or conditions of this Agreement.

[***] INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 PROMULGATED UNDER THE SECURITIES ACT OF 1933, AS AMENDED



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IN WITNESS WHEREOF, the parties have executed this Agreement in duplicate originals by their duly authorized representatives.

PYRAMID Laboratories Inc.

XERIS Pharmaceuticals, Inc.

By: /s/ Medhat Gorgy

By: /s/ Douglas R. Baum

Name: Medhat Gorgy

Name: Douglas R. Baum

Title: President & CEO

Title: President & CEO

Date: November 1, 2016

Date: November 1, 2016

3598 Cadillac Avenue • Costa Mesa, CA 92626 • 714-435-9800 • 714-435-9585 (Fax)

LOAN AND SECURITY AGREEMENT

THIS LOAN AND SECURITY AGREEMENT (as the same may from time to time be amended, modified, supplemented or restated, this “**Agreement**”) dated as of February 28, 2018 (the “**Effective Date**”) among OXFORD FINANCE LLC, a Delaware limited liability company with an office located at 133 North Fairfax Street, Alexandria, Virginia 22314 (“**Oxford**”), as collateral agent (in such capacity, “**Collateral Agent**”), the Lenders listed on Schedule 1.1 hereof or otherwise a party hereto from time to time including Oxford in its capacity as a Lender and SILICON VALLEY BANK, a California corporation with an office located at 3003 Tasman Drive, Santa Clara, CA 95054 (“**Bank**” or “**SVB**”) (each a “**Lender**” and collectively, the “**Lenders**”), and XERIS PHARMACEUTICALS, INC., a Delaware corporation with offices located at 180 North LaSalle Street, Suite 1800, Chicago, IL 60601 (“**Borrower**”), provides the terms on which the Lenders shall lend to Borrower and Borrower shall repay the Lenders. The parties agree as follows:

1. ACCOUNTING AND OTHER TERMS

1.1 Accounting terms not defined in this Agreement shall be construed in accordance with GAAP. Calculations and determinations must be made in accordance with GAAP. Capitalized terms not otherwise defined in this Agreement shall have the meanings set forth in Section 13. All other terms contained in this Agreement, unless otherwise indicated, shall have the meaning provided by the Code to the extent such terms are defined therein. All references to “**Dollars**” or “**\$**” are United States Dollars, unless otherwise noted.

2. LOANS AND TERMS OF PAYMENT

2.1 Promise to Pay. Borrower hereby unconditionally promises to pay each Lender, the outstanding principal amount of all Term Loans advanced to Borrower by such Lender and accrued and unpaid interest thereon and any other amounts due hereunder as and when due in accordance with this Agreement.

2.2 Term Loans.

(a) Availability. (i) Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, to make term loans to Borrower on the Effective Date in an aggregate amount of Twenty Million Dollars (\$20,000,000.00) according to each Lender’s Term A Loan Commitment as set forth on Schedule 1.1 hereto (such term loans are hereinafter referred to singly as a “**Term A Loan**”, and collectively as the “**Term A Loans**”). After repayment, no Term A Loan may be re-borrowed.

(i) Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, during the Second Draw Period, to make term loans to Borrower in an aggregate amount equal to Fifteen Million Dollars (\$15,000,000.00) according to each Lender’s Term B Loan Commitment as set forth on Schedule 1.1 hereto (such term loans are hereinafter referred to singly as a “**Term B Loan**”, and collectively as the “**Term B Loans**”). After repayment, no Term B Loan may be re-borrowed.

(ii) Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, during the Third Draw Period, to make term loans to Borrower in an aggregate amount equal to Ten Million Dollars (\$10,000,000.00) according to each Lender’s Term C Loan Commitment as set forth on Schedule 1.1 hereto (such term loans are hereinafter referred to singly as a “**Term C Loan**”, and collectively as the “**Term C Loans**”; each Term A Loan, Term B Loan or Term C

Loan is hereinafter referred to singly as a “**Term Loan**” and the Term A Loans, the Term B Loans and the Term C Loans are hereinafter referred to collectively as the “**Term Loans**”). After repayment, no Term C Loan may be re-borrowed.

(b) Repayment. Borrower shall make monthly payments of interest only commencing on the first (1st) Payment Date following the Funding Date of each Term Loan, and continuing on the Payment Date of each successive month thereafter through and including the Payment Date immediately preceding the Amortization Date. Borrower agrees to pay, on the Funding Date of each Term Loan, any initial partial monthly interest payment otherwise due for the period between the Funding Date of such Term Loan and the first Payment Date thereof. Commencing on the Amortization Date, and continuing on the Payment Date of each month thereafter, Borrower shall make consecutive equal monthly payments of principal, together with applicable interest, in arrears, to each Lender, as calculated by Collateral Agent (which calculations shall be deemed correct absent manifest error) based upon: (1) the amount of such Lender’s Term Loan, (2) the effective rate of interest, as determined in Section 2.3(a), and (3) a repayment schedule equal to thirty-five (35) months; provided, that if the Borrower draws a Term C Loan, then the foregoing clause (3) shall be based upon a repayment schedule equal to twenty-three (23) months. All unpaid principal and accrued and unpaid interest with respect to each Term Loan is due and payable in full on the Maturity Date. Each Term Loan may only be prepaid in accordance with Sections 2.2(c) and 2.2(d).

(c) Mandatory Prepayments. If the Term Loans are accelerated following the occurrence of an Event of Default, Borrower shall immediately pay to Lenders, payable to each Lender in accordance with its respective Pro Rata Share, an amount equal to the sum of: (i) all outstanding principal of the Term Loans plus accrued and unpaid interest thereon through the prepayment date, (ii) the Final Payment, (iii) the Prepayment Fee, if applicable, (iv) any unpaid facility fee, if applicable, plus (v) all other Obligations that are due and payable, including Lenders’ Expenses and interest at the Default Rate with respect to any past due amounts. Notwithstanding (but without duplication with) the foregoing, on the Maturity Date, if the Final Payment had not previously been paid in full in connection with the prepayment of the Term Loans in full, Borrower shall pay to Collateral Agent, for payment to each Lender in accordance with its respective Pro Rata Share, the Final Payment in respect of the Term Loan(s).

(d) Permitted Prepayment of Term Loans.

(i) Borrower shall have the option to prepay all, but not less than all, of the Term Loans advanced by the Lenders under this Agreement, provided Borrower (i) provides written notice to Collateral Agent of its election to prepay the Term Loans at least thirty (30) days prior to such prepayment, and (ii) pays to the Lenders on the date of such prepayment, payable to each Lender in accordance with its respective Pro Rata Share, an amount equal to the sum of (A) all outstanding principal of the Term Loans plus accrued and unpaid interest thereon through the prepayment date, (B) the Final Payment, (C) the Prepayment Fee, plus (D) any unpaid facility fee, if applicable, plus (E) all other Obligations that are due and payable, including Lenders’ Expenses and interest at the Default Rate with respect to any past due amounts.

(ii) Notwithstanding anything herein to the contrary, Borrower shall also have the option to prepay part of Term Loans advanced by the Lenders under this Agreement, provided Borrower (i) provides written notice to Collateral Agent of its election to prepay the Term Loans at least thirty (30) days prior to such prepayment, (ii) prepays such part of the Term Loans in a denomination that is not less than Two Million Dollars (\$2,000,000.00) or, if in excess thereof, in integral whole number multiples of One Million Dollars (\$1,000,000.00) in excess thereof, and (iii) pays to the Lenders on the date of such prepayment, payable to each Lender in accordance with its respective Pro Rata Share, an

amount equal to the sum of (A) the portion of outstanding principal of such Term Loans plus all accrued and unpaid interest thereon through the prepayment date, (B) the applicable Final Payment, and (C) all other Obligations that are then due and payable, including Lenders' Expenses and interest at the Default Rate with respect to any past due amounts, and (D) the applicable Prepayment Fee with respect to the portion of such Term Loans being prepaid; provided, further however, that, unless the Lenders have provided their prior written consent to Borrower, which may be withheld in the Lenders' sole discretion, Borrower shall not be permitted to make more than four (4) partial prepayments in any anniversary year of the Term Loan. For the purposes of clarity, any partial prepayment shall be applied pro-rata to all outstanding amounts under each Term Loan, and shall be applied pro-rata within each Term Loan tranche to reduce amortization payments under Section 2.2(b) on a pro-rata basis.

2.3 Payment of Interest on the Credit Extensions.

(a) Interest Rate. Subject to Section 2.3(b), the principal amount outstanding under the Term Loans shall accrue interest at a floating per annum rate equal to the Basic Rate, determined by Collateral Agent on the Funding Date of the applicable Term Loan, which interest shall be payable monthly in arrears in accordance with Sections 2.2(b) and 2.3(e). Interest shall accrue on each Term Loan commencing on, and including, the Funding Date of such Term Loan, and shall accrue on the principal amount outstanding under such Term Loan through and including the day on which such Term Loan is paid in full.

(b) Default Rate. Immediately upon the occurrence and during the continuance of an Event of Default, Obligations shall accrue interest at a floating per annum rate equal to the rate that is otherwise applicable thereto plus five percentage points (5.00%) (the "**Default Rate**"). Payment or acceptance of the increased interest rate provided in this Section 2.3(b) is not a permitted alternative to timely payment and shall not constitute a waiver of any Event of Default or otherwise prejudice or limit any rights or remedies of Collateral Agent.

(c) 360-Day Year. Interest shall be computed on the basis of a three hundred sixty (360) day year, and the actual number of days elapsed.

(d) Debit of Accounts. Collateral Agent and each Lender may debit (or ACH) any deposit accounts, maintained by Borrower or any of its Subsidiaries, including the Designated Deposit Account, for principal and interest payments or any other amounts Borrower owes the Lenders under the Loan Documents when due. Any such debits (or ACH activity) shall not constitute a set-off.

(e) Payments. Except as otherwise expressly provided herein, all payments by Borrower under the Loan Documents shall be made to the respective Lender to which such payments are owed, at such Lender's office in immediately available funds on the date specified herein. Unless otherwise provided, interest is payable monthly on the Payment Date of each month. Payments of principal and/or interest received after 2:00 P.M. Eastern time are considered received at the opening of business on the next Business Day. When a payment is due on a day that is not a Business Day, the payment is due the next Business Day and additional fees or interest, as applicable, shall continue to accrue until paid. All payments to be made by Borrower hereunder or under any other Loan Document, including payments of principal and interest, and all fees, expenses, indemnities and reimbursements, shall be made without set-off, recoupment or counterclaim, in lawful money of the United States and in immediately available funds.

2.4 Secured Promissory Notes. The Term Loans shall be evidenced by a Secured Promissory Note or Notes in the form attached as Exhibit D hereto (each a "**Secured Promissory Note**"), and shall be repayable as set forth in this Agreement. Borrower irrevocably authorizes each Lender to

make or cause to be made, on or about the Funding Date of any Term Loan or at the time of receipt of any payment of principal on such Lender's Secured Promissory Note, an appropriate notation on such Lender's Secured Promissory Note Record reflecting the making of such Term Loan or (as the case may be) the receipt of such payment. The outstanding amount of each Term Loan set forth on such Lender's Secured Promissory Note Record shall be prima facie evidence of the principal amount thereof owing and unpaid to such Lender, but the failure to record, or any error in so recording, any such amount on such Lender's Secured Promissory Note Record shall not limit or otherwise affect the obligations of Borrower under any Secured Promissory Note or any other Loan Document to make payments of principal of or interest on any Secured Promissory Note when due. Upon receipt of an affidavit of an officer of a Lender as to the loss, theft, destruction, or mutilation of its Secured Promissory Note, Borrower shall issue, in lieu thereof, a replacement Secured Promissory Note in the same principal amount thereof and of like tenor.

2.5 Fees. Borrower shall pay to Collateral Agent:

(a) Good Faith Deposit. An amount of Fifty Thousand Dollars (\$50,000.00), which amount has been received by Collateral Agent as a good faith deposit from Borrower on or about December 1, 2017, to be applied towards Lenders' Expenses incurred through the Effective Date payable pursuant to Section 2.5(f) hereof, and the balance left over, if any, shall be applied towards the facility fee due on the Effective Date pursuant to Section 2.5(b) hereof. For the purposes of clarity, Borrower shall be responsible for all Lender's Expenses payable pursuant to Section 2.5(f) hereof and the facility fee payable pursuant to Section 2.5(b) hereof;

(b) Facility Fee. Subject to funding of the Term A Loans, a fully earned, non refundable facility fee of Two Hundred Twenty-Five Thousand Dollars (\$225,000.00) to be shared between the Lenders pursuant to their respective Commitment Percentages payable as follows: (i) One Hundred Thousand Dollars (\$100,000.00) of the facility fee shall be due and payable on the Effective Date, (ii) Seventy-Five Thousand Dollars (\$75,000.00) of the facility fee shall be due and payable on the earliest of the Funding Date of the Term B Loan, the termination date of the Second Draw Period, September 30, 2018, and the occurrence of an Event of Default, and (iii) the remaining Fifty Thousand Dollars (\$50,000.00) of the facility fee shall be due and payable on the earliest of the Funding Date of the Term C Loan, the termination date of the Third Draw Period, September 30, 2019, and the occurrence of an Event of Default;

(c) Final Payment. The Final Payment, when due hereunder, to be shared between the Lenders in accordance with their respective Pro Rata Shares;

(d) Prepayment Fee. The Prepayment Fee, if and when due hereunder, to be shared between the Lenders in accordance with their respective Pro Rata Shares;

(e) Non-Utilization Fee. A fully earned, non-refundable non-utilization fee to be shared between the Lenders pursuant to their respective Commitment Percentages payable as follows: (i) following the commencement of the Third Draw Period, if Borrower has elected not to request a draw of the full Term C Loan amount, then, within thirty (30) days following the termination date of the Third Draw Period, Borrower shall pay to the Lenders an amount equal to two percent (2.0%) of the aggregate undrawn principal amount of the Term C Loan to be shared between the Lenders pursuant to their respective Pro Rata Shares. For the purposes of clarity, Borrower shall be responsible for the non-utilization fee even if Borrower elects to prepay during the Third Draw Period; and

(f) **Lenders' Expenses.** All Lenders' Expenses (including reasonable attorneys' fees and expenses for documentation and negotiation of this Agreement) incurred through and after the Effective Date, when due.

2.6 Withholding. Payments received by the Lenders from Borrower hereunder will be made free and clear of and without deduction for any and all present or future taxes, levies, imposts, duties, deductions, withholdings, assessments, fees or other charges imposed by any governmental authority (including any interest, additions to tax or penalties applicable thereto). Specifically, however, if at any time any Governmental Authority, applicable law, regulation or international agreement requires Borrower to make any withholding or deduction from any such payment or other sum payable hereunder to the Lenders, Borrower hereby covenants and agrees that the amount due from Borrower with respect to such payment or other sum payable hereunder will be increased to the extent necessary to ensure that, after the making of such required withholding or deduction, each Lender receives a net sum equal to the sum which it would have received had no withholding or deduction been required and Borrower shall pay the full amount withheld or deducted to the relevant Governmental Authority; provided, that Borrower shall not be required to make such increased payment to a Lender who is not a United States Person (as defined in Section 7701(a)(30) of the Internal Revenue Code of 1986, as amended) or who has not provided a duly executed original IRS Form W-9 certifying that such Lender is exempt from U.S. federal backup withholding tax. Borrower will, upon request, furnish the Lenders with proof reasonably satisfactory to the Lenders indicating that Borrower has made such withholding payment; provided, however, that Borrower need not make any withholding payment if the amount or validity of such withholding payment is contested in good faith by appropriate and timely proceedings and as to which payment in full is bonded or reserved against by Borrower. The agreements and obligations of Borrower contained in this Section 2.6 shall survive the termination of this Agreement.

3. CONDITIONS OF LOANS

3.1 Conditions Precedent to Initial Credit Extension. Each Lender's obligation to make a Term A Loan is subject to the condition precedent that Collateral Agent and each Lender shall consent to or shall have received, in form and substance satisfactory to Collateral Agent and each Lender, such documents, and completion of such other matters, as Collateral Agent and each Lender may reasonably deem necessary or appropriate, including, without limitation:

(a) original Loan Documents, each duly executed by Borrower and each Subsidiary, if any, as applicable;

(b) duly executed original Control Agreements with respect to any Collateral Accounts maintained by Borrower or any of its Subsidiaries, if any, as required pursuant to Section 6.6;

(c) duly executed original Secured Promissory Notes in favor of each Lender according to its Term A Loan Commitment Percentage;

(d) reserved;

(e) the Operating Documents and good standing certificates of Borrower and its Subsidiaries, if any, certified by the Secretary of State (or equivalent agency) of Borrower's and such Subsidiaries', if any, jurisdiction of organization or formation and each jurisdiction in which Borrower and each Subsidiary, if any, is qualified to conduct business, each as of a date no earlier than thirty (30) days prior to the Effective Date;

(f) a completed Perfection Certificate for Borrower and each of its Subsidiaries, if any;

(g) the Annual Projections, for the current calendar year;

(h) duly executed original officer's certificate for Borrower and each Subsidiary, if any, that is a party to the Loan Documents, in a form acceptable to Collateral Agent and the Lenders;

(i) certified copies, dated as of date no earlier than thirty (30) days prior to the Effective Date, of financing statement searches, as Collateral Agent shall request, accompanied by written evidence (including any UCC termination statements) that the Liens indicated in any such financing statements either constitute Permitted Liens or have been or, in connection with the initial Credit Extension, will be terminated or released;

(j) subject to the terms of the Post Closing Letter, a landlord's consent executed in favor of Collateral Agent in respect of all of Borrower's and each Subsidiaries', if any, leased locations;

(k) a bailee waiver executed in favor of Collateral Agent in respect of each third party bailee where Borrower or any Subsidiary maintains Collateral having a book value in excess of One Hundred Thousand Dollars (\$100,000.00);

(l) a duly executed legal opinion of counsel to Borrower dated as of the Effective Date;

(m) evidence satisfactory to Collateral Agent and the Lenders that the insurance policies required by Section 6.5 hereof are in full force and effect, together with appropriate evidence showing loss payable and/or additional insured clauses or endorsements in favor of Collateral Agent, for the ratable benefit of the Lenders;

(n) a copy of any applicable Registration Rights Agreement or Investors' Rights Agreement and any amendments thereto; and

(o) payment of the fees and Lenders' Expenses then due as specified in Section 2.5 hereof.

3.2 Conditions Precedent to all Credit Extensions. The obligation of each Lender to make each Credit Extension, including the initial Credit Extension, is subject to the following conditions precedent:

(a) receipt by (i) the Lenders of an executed Disbursement Letter in the form of Exhibit B-1 attached hereto; and (ii) SVB of an executed Loan Payment/Advance Request Form in the form of Exhibit B-2 attached hereto;

(b) the representations and warranties in Section 5 hereof shall be true, accurate and complete in all material respects on the date of the Disbursement Letter (and the Loan Payment/Advance Request Form) and on the Funding Date of each Credit Extension; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date, and no Event of Default shall have occurred and be continuing or result from the Credit Extension. Each Credit Extension is Borrower's representation and warranty on that date that the

representations and warranties in Section 5 hereof are true, accurate and complete in all material respects; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date;

(c) in such Lender's sole discretion, there has not been any Material Adverse Change or any material adverse deviation by Borrower from the Annual Projections of Borrower presented to and accepted by Collateral Agent and each Lender;

(d) to the extent not delivered at the Effective Date, duly executed original Secured Promissory Notes and Warrants, in number, form and content acceptable to each Lender, and in favor of each Lender according to its Commitment Percentage, with respect to each Credit Extension made by such Lender after the Effective Date; and

(e) payment of the fees and Lenders' Expenses then due as specified in Section 2.5 hereof.

3.3 Covenant to Deliver. Borrower agrees to deliver to Collateral Agent and the Lenders each item required to be delivered to Collateral Agent under this Agreement as a condition precedent to any Credit Extension. Notwithstanding the foregoing, Borrower shall not be required to make duplicative payments to the Lenders if Borrower has already paid Collateral Agent for fees and/or expenses incurred by or on behalf of Collateral Agent pursuant to any Loan Documents, but, for the avoidance of doubt, Borrower shall continue to be responsible for the payment of all fees and Lenders' Expenses in accordance with the terms of this Agreement and the other Loan Documents. Borrower expressly agrees that a Credit Extension made prior to the receipt by Collateral Agent or any Lender of any such item shall not constitute a waiver by Collateral Agent or any Lender of Borrower's obligation to deliver such item, and any such Credit Extension in the absence of a required item shall be made in each Lender's sole discretion.

3.4 Procedures for Borrowing. Subject to the prior satisfaction of all other applicable conditions to the making of a Term Loan set forth in this Agreement, to obtain a Term Loan, Borrower shall notify the Lenders (which notice shall be irrevocable) by electronic mail, facsimile, or telephone by 12:00 noon Eastern time five (5) Business Days prior to the date the Term Loan is to be made. Together with any such electronic, facsimile or telephonic notification, Borrower shall deliver to the Lenders by electronic mail or facsimile a completed Disbursement Letter (and the Loan Payment/Advance Request Form, with respect to SVB) executed by a Responsible Officer or his or her designee. The Lenders may rely on any telephone notice given by a person whom a Lender reasonably believes is a Responsible Officer or designee. On the Funding Date, each Lender shall credit and/or transfer (as applicable) to the Designated Deposit Account, an amount equal to its Term Loan Commitment.

4. CREATION OF SECURITY INTEREST

4.1 Grant of Security Interest. Borrower hereby grants Collateral Agent, for the ratable benefit of the Lenders, to secure the payment and performance in full of all of the Obligations, a continuing security interest in, and pledges to Collateral Agent, for the ratable benefit of the Lenders, the Collateral, wherever located, whether now owned or hereafter acquired or arising, and all proceeds and products thereof. Borrower represents, warrants, and covenants that the security interest granted herein is and shall at all times continue to be a first priority perfected security interest in the Collateral, subject only to Permitted Liens that are permitted by the terms of this Agreement to have priority to Collateral Agent's Lien. If Borrower shall acquire a commercial tort claim (as defined in the Code), Borrower, shall

promptly notify Collateral Agent in a writing signed by Borrower, as the case may be, of the general details thereof (and further details as may be required by Collateral Agent) and grant to Collateral Agent, for the ratable benefit of the Lenders, in such writing a security interest therein and in the proceeds thereof, all upon the terms of this Agreement, with such writing to be in form and substance reasonably satisfactory to Collateral Agent.

Borrower acknowledges that it previously has entered, and/or may in the future enter, into Bank Services Agreements with Bank. Regardless of the terms of any Bank Services Agreement, Borrower agrees that any amounts Borrower owes Bank thereunder shall be deemed to be Obligations hereunder and that it is the intent of Borrower and Bank to have all such Obligations secured by the first priority perfected security interest in the Collateral granted herein (subject only to Permitted Liens that may have superior priority to Collateral Agent's Lien in this Agreement).

If this Agreement is terminated, Collateral Agent's Lien in the Collateral shall continue until the Obligations (other than inchoate indemnity obligations) are repaid in full in cash. Upon payment in full in cash of the Obligations (other than inchoate indemnity obligations) and at such time as the Lenders' obligation to make Credit Extensions has terminated, Collateral Agent shall, at the sole cost and expense of Borrower, release its Liens in the Collateral and all rights therein shall revert to Borrower. In the event (x) all Obligations (other than inchoate indemnity obligations), except for Bank Services, are satisfied in full, and (y) this Agreement is terminated, Collateral Agent shall terminate the security interest granted herein upon Borrower providing cash collateral acceptable to Bank in its good faith business judgment for Bank Services, if any. In the event such Bank Services consist of outstanding Letters of Credit, Borrower shall provide to Bank cash collateral in an amount equal to (x) if such Letters of Credit are denominated in Dollars, then one hundred five percent (105%); and (y) if such Letters of Credit are denominated in a Foreign Currency, then one hundred ten percent (110%), of the Dollar Equivalent of the face amount of all such Letters of Credit plus all interest, fees, and costs due or to become due in connection therewith (as estimated by Bank in its good faith business judgment), to secure all of the Obligations relating to such Letters of Credit.

4.2 Authorization to File Financing Statements. Borrower hereby authorizes Collateral Agent to file financing statements or take any other action required to perfect Collateral Agent's security interests in the Collateral, without notice to Borrower, with all appropriate jurisdictions to perfect or protect Collateral Agent's interest or rights under the Loan Documents, including a notice that any disposition of the Collateral, except to the extent permitted by the terms of this Agreement, by Borrower, or any other Person, shall be deemed to violate the rights of Collateral Agent under the Code.

4.3 Pledge of Collateral. Borrower hereby pledges, assigns and grants to Collateral Agent, for the ratable benefit of the Lenders, a security interest in all the Shares, together with all proceeds and substitutions thereof, all cash, stock and other moneys and property paid thereon, all rights to subscribe for securities declared or granted in connection therewith, and all other cash and noncash proceeds of the foregoing, as security for the performance of the Obligations. On the Effective Date, or, to the extent not certificated as of the Effective Date, within ten (10) days of the certification of any Shares, the certificate or certificates for the Shares will be delivered to Collateral Agent, accompanied by an instrument of assignment duly executed in blank by Borrower. To the extent required by the terms and conditions governing the Shares, Borrower shall cause the books of each entity whose Shares are part of the Collateral and any transfer agent to reflect the pledge of the Shares. Upon the occurrence and during the continuance of an Event of Default hereunder, Collateral Agent may effect the transfer of any securities included in the Collateral (including but not limited to the Shares) into the name of Collateral Agent and cause new (as applicable) certificates representing such securities to be issued in the name of Collateral Agent or its transferee. Borrower will execute and deliver such documents, and take or cause to be taken such actions, as Collateral Agent may reasonably request to perfect or continue the perfection of

Collateral Agent's security interest in the Shares. Unless an Event of Default shall have occurred and be continuing, Borrower shall be entitled to exercise any voting rights with respect to the Shares and to give consents, waivers and ratifications in respect thereof, provided that no vote shall be cast or consent, waiver or ratification given or action taken which would be inconsistent with any of the terms of this Agreement or which would constitute or create any violation of any of such terms. All such rights to vote and give consents, waivers and ratifications shall terminate upon the occurrence and continuance of an Event of Default.

5. REPRESENTATIONS AND WARRANTIES

Borrower represents and warrants to Collateral Agent and the Lenders as follows:

5.1 Due Organization, Authorization: Power and Authority. Borrower and each of its Subsidiaries is duly existing and in good standing as a Registered Organization in its jurisdiction of organization or formation and Borrower and each of its Subsidiaries is qualified and licensed to do business and is in good standing in any jurisdiction in which the conduct of its businesses or its ownership of property requires that it be qualified except where the failure to do so could not reasonably be expected to have a Material Adverse Change. In connection with this Agreement, Borrower and each of its Subsidiaries has delivered to Collateral Agent a completed perfection certificate signed by an officer of Borrower or such Subsidiary (each a "**Perfection Certificate**" and collectively, the "**Perfection Certificates**"). Borrower represents and warrants that (a) Borrower and each of its Subsidiaries' exact legal name is that which is indicated on its respective Perfection Certificate and on the signature page of each Loan Document to which it is a party; (b) Borrower and each of its Subsidiaries is an organization of the type and is organized in the jurisdiction set forth on its respective Perfection Certificate; (c) each Perfection Certificate accurately sets forth each of Borrower's and its Subsidiaries' organizational identification number or accurately states that Borrower or such Subsidiary has none; (d) each Perfection Certificate accurately sets forth Borrower's and each of its Subsidiaries' place of business, or, if more than one, its chief executive office as well as Borrower's and each of its Subsidiaries' mailing address (if different than its chief executive office); (e) except as may be set forth on its respective Perfection Certificate, Borrower and each of its Subsidiaries (and each of its respective predecessors) have not, in the past five (5) years, changed its jurisdiction of organization, organizational structure or type, or any organizational number assigned by its jurisdiction; and (f) all other information set forth on the Perfection Certificates pertaining to Borrower and each of its Subsidiaries, is accurate and complete (it being understood and agreed that Borrower and each of its Subsidiaries may from time to time update certain information in the Perfection Certificates (including the information set forth in clause (d) above) after the Effective Date to the extent Borrower is permitted to take such action resulting in the applicable update by one or more specific provisions in this Agreement, and Borrower complies with the terms of this Agreement in connection with such action); such updated Perfection Certificates subject to the review and approval of Collateral Agent unless such facts, events or circumstances being updated first arose or occurred after the Effective Date and do not constitute a breach, default, or Event of Default under this Agreement or any other Loan Document. If Borrower or any of its Subsidiaries is not now a Registered Organization but later becomes one, Borrower shall notify Collateral Agent of such occurrence and provide Collateral Agent with such Person's organizational identification number within five (5) Business Days of receiving such organizational identification number.

The execution, delivery and performance by Borrower and each of its Subsidiaries of the Loan Documents to which it is a party have been duly authorized, and do not (i) conflict with any of Borrower's or such Subsidiaries' organizational documents, including its respective Operating Documents, (ii) contravene, conflict with, constitute a default under or violate any material Requirement of Law applicable thereto, (iii) contravene, conflict or violate any applicable order, writ, judgment, injunction, decree, determination or award of any Governmental Authority by which Borrower or such

Subsidiary, or any of their property or assets may be bound or affected, (iv) require any action by, filing, registration, or qualification with, or Governmental Approval from, any Governmental Authority (except such Governmental Approvals which have already been obtained and are in full force and effect) or are being obtained pursuant to Section 6.1(b), or (v) constitute an event of default under any material agreement by which Borrower or any of such Subsidiaries, or their respective properties, is bound. Neither Borrower nor any of its Subsidiaries is in default under any agreement to which it is a party or by which it or any of its assets is bound in which such default could reasonably be expected to have a Material Adverse Change.

5.2 Collateral.

(a) Borrower and each its Subsidiaries have good title to, have rights in, and the power to transfer each item of the Collateral upon which it purports to grant a Lien under the Loan Documents, free and clear of any and all Liens except Permitted Liens, and neither Borrower nor any of its Subsidiaries have any Deposit Accounts, Securities Accounts, Commodity Accounts or other investment accounts other than the Collateral Accounts or the other investment accounts, if any, described in the Perfection Certificates delivered to Collateral Agent in connection herewith with respect of which Borrower or such Subsidiary has given Collateral Agent notice and taken such actions as are necessary to give Collateral Agent a perfected security interest therein unless otherwise provided pursuant to Section 6.6. The Accounts are bona fide, existing obligations of the Account Debtors.

(b) On the Effective Date, and except as disclosed on the Perfection Certificate (i) the Collateral is not in the possession of any third party bailee (such as a warehouse), and (ii) no such third party bailee possesses components of the Collateral in excess of One Hundred Thousand Dollars (\$100,000.00). None of the components of the Collateral shall be maintained at locations other than as disclosed in the Perfection Certificates on the Effective Date or as permitted pursuant to Section 6.11.

(c) All Inventory is in all material respects of good and marketable quality, free from material defects.

(d) Borrower and each of its Subsidiaries is the sole owner of the Intellectual Property each respectively purports to own, free and clear of all Liens other than Permitted Liens. Except as noted on the Perfection Certificates, neither Borrower nor any of its Subsidiaries is a party to, nor is bound by, any material license or other material agreement with respect to which Borrower or such Subsidiary is the licensee that (i) prohibits or otherwise restricts Borrower or its Subsidiaries from granting a security interest in Borrower's or such Subsidiaries' interest in such material license or material agreement or any other property, or (ii) for which a default under or termination of could interfere with Collateral Agent's or any Lender's right to sell any Collateral. Borrower shall provide written notice to Collateral Agent and each Lender within ten (10) days of Borrower or any of its Subsidiaries entering into or becoming bound by any license or agreement with respect to which Borrower or any Subsidiary is the licensee (other than over-the-counter software that is commercially available to the public).

5.3 Litigation. Except as disclosed (i) on the Perfection Certificates, or (ii) in accordance with Section 6.9 hereof, there are no actions, suits, investigations, or proceedings pending or, to the knowledge of the Responsible Officers, threatened in writing by or against Borrower or any of its Subsidiaries involving more than One Hundred Thousand Dollars (\$100,000.00).

5.4 No Material Deterioration in Financial Condition; Financial Statements. All consolidated financial statements for Borrower and its Subsidiaries, delivered to Collateral Agent fairly present, in conformity with GAAP, in all material respects the consolidated financial condition of

Borrower and its Subsidiaries, and the consolidated results of operations of Borrower and its Subsidiaries. There has not been any material deterioration in the consolidated financial condition of Borrower and its Subsidiaries since the date of the most recent financial statements submitted to any Lender.

5.5 Solvency. Borrower and Borrower and each of its Subsidiaries, taken as a whole, is Solvent.

5.6 Regulatory Compliance. Neither Borrower nor any of its Subsidiaries is an “investment company” or a company “controlled” by an “investment company” under the Investment Company Act of 1940, as amended. Neither Borrower nor any of its Subsidiaries is engaged as one of its important activities in extending credit for margin stock (under Regulations X, T and U of the Federal Reserve Board of Governors). Borrower and each of its Subsidiaries has complied in all material respects with the Federal Fair Labor Standards Act. Neither Borrower nor any of its Subsidiaries is a “holding company” or an “affiliate” of a “holding company” or a “subsidiary company” of a “holding company” as each term is defined and used in the Public Utility Holding Company Act of 2005. Neither Borrower nor any of its Subsidiaries has violated any laws, ordinances or rules, the violation of which could reasonably be expected to have a Material Adverse Change. Neither Borrower’s nor any of its Subsidiaries’ properties or assets has been used by Borrower or such Subsidiary or, to Borrower’s knowledge, by previous Persons, in disposing, producing, storing, treating, or transporting any hazardous substance other than in material compliance with applicable laws. Borrower and each of its Subsidiaries has obtained all consents, approvals and authorizations of, made all declarations or filings with, and given all notices to, all Governmental Authorities that are necessary to continue their respective businesses as currently conducted.

None of Borrower, any of its Subsidiaries, or any of Borrower’s or its Subsidiaries’ Affiliates or any of their respective agents acting or benefiting in any capacity in connection with the transactions contemplated by this Agreement is (i) in violation of any Anti-Terrorism Law, (ii) engaging in or conspiring to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding or attempts to violate, any of the prohibitions set forth in any Anti-Terrorism Law, or (iii) is a Blocked Person. None of Borrower, any of its Subsidiaries, or to the knowledge of Borrower and any of their Affiliates or agents, acting or benefiting in any capacity in connection with the transactions contemplated by this Agreement, (x) conducts any business or engages in making or receiving any contribution of funds, goods or services to or for the benefit of any Blocked Person, or (y) deals in, or otherwise engages in any transaction relating to, any property or interest in property blocked pursuant to Executive Order No. 13224, any similar executive order or other Anti-Terrorism Law.

5.7 Investments. Neither Borrower nor any of its Subsidiaries owns any stock, shares, partnership interests or other equity securities except for Permitted Investments.

5.8 Tax Returns and Payments; Pension Contributions. Borrower and each of its Subsidiaries has timely filed all required tax returns and reports, and Borrower and each of its Subsidiaries, has timely paid all foreign, federal, state, and local taxes, assessments, deposits and contributions owed by Borrower and such Subsidiaries, in all jurisdictions in which Borrower or any such Subsidiary is subject to taxes, including the United States, unless such taxes are being contested in accordance with the following sentence. Borrower and each of its Subsidiaries, may defer payment of any contested taxes, provided that Borrower or such Subsidiary, (a) in good faith contests its obligation to pay the taxes by appropriate proceedings promptly and diligently instituted and conducted, (b) notifies Collateral Agent in writing of the commencement of, and any material development in, the proceedings, and (c) posts bonds or takes any other steps required to prevent the Governmental Authority levying such contested taxes from obtaining a Lien upon any of the Collateral that is other than a “Permitted Lien.” Neither Borrower nor any of its Subsidiaries is aware of any claims or adjustments proposed for any of

Borrower's or such Subsidiaries', prior tax years which could result in additional taxes, in excess of Twenty-Five Thousand Dollars (\$25,000) in the aggregate, becoming due and payable by Borrower or its Subsidiaries. Borrower and each of its Subsidiaries have paid all amounts necessary to fund all present pension, profit sharing and deferred compensation plans in accordance with their terms, and neither Borrower nor any of its Subsidiaries have, withdrawn from participation in, and have not permitted partial or complete termination of, or permitted the occurrence of any other event with respect to, any such plan which could reasonably be expected to result in any liability of Borrower or its Subsidiaries, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other Governmental Authority.

5.9 Use of Proceeds. Borrower shall use the proceeds of the Credit Extensions solely as working capital and to fund its general business requirements in accordance with the provisions of this Agreement, and not for personal, family, household or agricultural purposes.

5.10 Shares. Borrower has full power and authority to create a first lien on the Shares and no disability or contractual obligation exists that would prohibit Borrower from pledging the Shares pursuant to this Agreement. To Borrower's knowledge, there are no subscriptions, warrants, rights of first refusal or other restrictions on transfer relative to, or options exercisable with respect to the Shares. The Shares have been and will be duly authorized and validly issued, and are fully paid and non-assessable. To Borrower's knowledge, the Shares are not the subject of any present or threatened suit, action, arbitration, administrative or other proceeding, and Borrower knows of no reasonable grounds for the institution of any such proceedings.

5.11 Full Disclosure. No written representation, warranty or other statement of Borrower or any of its Subsidiaries in any certificate or written statement given to Collateral Agent or any Lender, as of the date such representation, warranty, or other statement was made, taken together with all such written certificates and written statements given to Collateral Agent or any Lender, contains any untrue statement of a material fact or omits to state a material fact necessary to make the statements contained in the certificates or statements not misleading (it being recognized that the projections and forecasts provided by Borrower in good faith and based upon reasonable assumptions are not viewed as facts and that actual results during the period or periods covered by such projections and forecasts may differ from the projected or forecasted results).

5.12 Definition of "Knowledge." For purposes of the Loan Documents, whenever a representation or warranty is made to Borrower's knowledge or awareness, to the "best of" Borrower's knowledge, or with a similar qualification, knowledge or awareness means the actual knowledge, after reasonable investigation, of the Responsible Officers.

6. AFFIRMATIVE COVENANTS

Borrower shall, and shall cause each of its Subsidiaries to, do all of the following:

6.1 Government Compliance.

(a) Maintain its and all its Subsidiaries' legal existence and good standing in their respective jurisdictions of organization and maintain qualification in each jurisdiction in which the failure to so qualify could reasonably be expected to have a Material Adverse Change. Comply with all laws, ordinances and regulations to which Borrower or any of its Subsidiaries is subject, the noncompliance with which could reasonably be expected to have a Material Adverse Change.

(b) Obtain and keep in full force and effect, all of the material Governmental Approvals necessary for the performance by Borrower and its Subsidiaries of their respective businesses and obligations under the Loan Documents and the grant of a security interest to Collateral Agent for the ratable benefit of the Lenders, in all of the Collateral. Borrower shall promptly provide copies to Collateral Agent of any material Governmental Approvals obtained by Borrower or any of its Subsidiaries.

6.2 Financial Statements, Reports, Certificates.

(a) Deliver to each Lender:

(i) (A) prior to Borrower's initial public offering and sale of its common stock or other common voting equity securities pursuant to an effective registration statement under the Securities Act of 1933, as amended ("**IPO**"), as soon as available, but no later than thirty (30) days after the last day of each month, a company prepared consolidated and consolidating, if applicable, balance sheet, income statement and cash flow statement covering the consolidated operations of Borrower and its Subsidiaries for such month certified by a Responsible Officer and in a form reasonably acceptable to Collateral Agent; and (B) after Borrower's IPO, as soon as available, but no later than forty-five (45) days after the last day of each quarter, a company prepared consolidated and consolidating, if applicable, balance sheet, income statement and cash flow statement covering the consolidated operations of Borrower and its Subsidiaries for such quarter certified by a Responsible Officer and in a form reasonably acceptable to Collateral Agent;

(ii) (ii) as soon as available, but no later than one hundred eighty (180) days after the last day of Borrower's fiscal year or within five (5) days of filing with the SEC, audited consolidated financial statements prepared under GAAP, consistently applied, together with an unqualified opinion on the financial statements from an independent certified public accounting firm acceptable to Collateral Agent in its reasonable discretion;

(iii) as soon as available after approval thereof by Borrower's Board of Directors, but no later than thirty (30) days after the last day of each of Borrower's fiscal years, Borrower's annual financial projections for the entire current fiscal year as approved by Borrower's Board of Directors, which such annual financial projections shall be set forth in a quarter-by-quarter format (such annual financial projections as originally delivered to Collateral Agent and the Lenders are referred to herein as the "**Annual Projections**"); provided that, any revisions of the Annual Projections approved by Borrower's Board of Directors shall be delivered to Collateral Agent and the Lenders no later than seven (7) days after such approval);

(iv) within five (5) days of delivery, copies of all statements, reports and notices made available to Borrower's security holders or holders of Subordinated Debt;

(v) in the event that Borrower becomes subject to the reporting requirements under the Securities Exchange Act of 1934, as amended, within five (5) days of filing, all reports on Form 10-K, 10-Q and 8-K filed with the Securities and Exchange Commission,

(vi) prompt notice of any amendments of or other changes to the capitalization table of Borrower and to the Operating Documents of Borrower or any of its Subsidiaries, together with any copies reflecting such amendments or changes with respect thereto;

(vii) prompt notice of any event that could reasonably be expected to materially and adversely affect the value of the Intellectual Property;

(viii) as soon as available, but no later than thirty (30) days after the last day of each month, copies of the month-end account statements for each Collateral Account maintained by Borrower or its Subsidiaries, which statements may be provided to Collateral Agent and each Lender by Borrower or directly from the applicable institution(s), and

(ix) other information as reasonably requested by Collateral Agent or any Lender.

Notwithstanding the foregoing, documents required to be delivered pursuant to the terms hereof (to the extent any such documents are included in materials otherwise filed with the SEC) may be delivered electronically and if so delivered, shall be deemed to have been delivered on the date on which Borrower posts such documents, or provides a link thereto, on Borrower's website on the internet at Borrower's website address.

(b) Concurrently with the delivery of the financial statements specified in Section 6.2(a)(i) above but no later than thirty (30) days after the last day of each month, or forty-five (45) days after the last day of each quarter, as applicable, deliver to each Lender, a duly completed Compliance Certificate signed by a Responsible Officer.

(c) Keep proper books of record and account in accordance with GAAP in all material respects, in which full, true and correct entries shall be made of all dealings and transactions in relation to its business and activities. Borrower shall, and shall cause each of its Subsidiaries to, allow, at the sole cost of Borrower, Collateral Agent or any Lender, during regular business hours upon reasonable prior notice (provided that no notice shall be required when an Event of Default has occurred and is continuing), to visit and inspect any of its properties, to examine and make abstracts or copies from any of its books and records, and to conduct a collateral audit and analysis of its operations and the Collateral. Such audits shall be conducted no more often than twice every year unless (and more frequently if) an Event of Default has occurred and is continuing.

(d) Deliver to Collateral Agent and Alexandria Real Estate, as soon as available, but no later than (i) thirty (30) days after the end of each fiscal quarter during which any of the following are in effect: Borrower's lease or license agreement for such premises and/or Collateral Agent's agreement with the landlord of such premises, and (ii) thirty (30) days after the last day of each month in which Borrower has delivered in excess of One Hundred Thousand Dollars (\$100,000) worth of new Collateral to the properties located at 3033 Science Park Road, San Diego, CA 92121 and/or 3985 Sorrento Valley Boulevard, San Diego, CA 92121, an updated, fully comprehensive, Exhibit A to the applicable landlord lien waiver among Alexandria Real Estate, Borrower and Collateral Agent.

(e) Deliver to Collateral Agent and the landlord of the leased premises located at 3208 Red River Street, Austin, Texas 78705, as soon as available, but no later than (i) thirty (30) days after the end of each fiscal quarter during which any of the following are in effect: Borrower's lease or license agreement for such premises and/or Collateral Agent's agreement with the landlord of such premises, and (ii) thirty (30) days after the last day of each month in which Borrower has delivered in excess of One Hundred Thousand Dollars (\$100,000) worth of new Collateral to such leased premises, an updated, fully comprehensive, Exhibit A to the applicable landlord lien waiver among such landlord, Borrower and Collateral Agent.

6.3 Inventory; Returns. Keep all Inventory in good and marketable condition, free from material defects. Returns and allowances between Borrower, or any of its Subsidiaries, and their respective Account Debtors shall follow Borrower's, or such Subsidiary's, customary practices as they exist at the Effective Date. Borrower must promptly notify Collateral Agent and the Lenders of all returns, recoveries, disputes and claims that involve more than Two Hundred Fifty Thousand Dollars (\$250,000.00) individually or in the aggregate in any calendar year.

6.4 Taxes; Pensions. Timely file and require each of its Subsidiaries to timely file, all required tax returns and reports and timely pay, and require each of its Subsidiaries to timely file, all foreign, federal, state, and local taxes, assessments, deposits and contributions owed by Borrower or its Subsidiaries, except for deferred payment of any taxes contested pursuant to the terms of Section 5.8 hereof, and shall deliver to Lenders, on demand, appropriate certificates attesting to such payments, and pay all amounts necessary to fund all present pension, profit sharing and deferred compensation plans in accordance with the terms of such plans.

6.5 Insurance. Keep Borrower's and its Subsidiaries' business and the Collateral insured for risks and in amounts standard for companies in Borrower's and its Subsidiaries' industry and location and as Collateral Agent may reasonably request. Insurance policies shall be in a form, with companies, and in amounts that are reasonably satisfactory to Collateral Agent and Lenders. All property policies shall have a lender's loss payable endorsement showing Collateral Agent as lender loss payee and waive subrogation against Collateral Agent, and all liability policies shall show, or have endorsements showing, Collateral Agent, as additional insured. The Collateral Agent shall be named as lender loss payee and/or additional insured with respect to any such insurance providing coverage in respect of any Collateral, and each provider of any such insurance shall agree, by endorsement upon the policy or policies issued by it or by independent instruments furnished to the Collateral Agent, that it will give the Collateral Agent thirty (30) days prior written notice before any such policy or policies shall be materially altered or canceled. At Collateral Agent's request, Borrower shall deliver certified copies of policies and evidence of all premium payments. Proceeds payable under any policy shall, at Collateral Agent's option, be payable to Collateral Agent, for the ratable benefit of the Lenders, on account of the Obligations. Notwithstanding the foregoing, (a) so long as no Event of Default has occurred and is continuing, Borrower shall have the option of applying the proceeds of any casualty policy up to Five Hundred Thousand Dollars (\$500,000.00) with respect to any loss, but not exceeding Five Hundred Thousand Dollars (\$500,000.00), in the aggregate for all losses under all casualty policies in any one year, toward the replacement or repair of destroyed or damaged property; provided that any such replaced or repaired property (i) shall be of better, equal or like value or usefulness as the replaced or repaired Collateral, (ii) shall have fair market value equal to, or in excess of, the amount of casualty proceeds applied to the acquisition of such property, and (iii) shall be deemed Collateral in which Collateral Agent has been granted a first priority security interest, and (b) after the occurrence and during the continuance of an Event of Default, all proceeds payable under such casualty policy shall, at the option of Collateral Agent, be payable to Collateral Agent, for the ratable benefit of the Lenders, on account of the Obligations. If Borrower or any of its Subsidiaries fails to obtain insurance as required under this Section 6.5 or to pay any amount or furnish any required proof of payment to third persons, Collateral Agent and/or any Lender may make, at Borrower's expense, all or part of such payment or obtain such insurance policies required in this Section 6.5, and take any action under the policies Collateral Agent or such Lender deems prudent.

6.6 Operating Accounts.

(a) Maintain all of Borrower's and its Subsidiaries' Collateral Accounts with Bank or its Affiliates in accounts which are subject to a Control Agreement in favor of Collateral Agent; provided, however, that Borrower and its Subsidiaries may maintain (i) cash collateral deposit accounts at JPM Chase in accordance with the terms of clause (j) of the definition of Permitted Lien that are not required to be subject to a Control Agreement, (ii) deposit accounts at JPM Chase, which are existing on the Effective Date and disclosed on the Perfection Certificate, that are not required to be subject to a Control Agreement, so long as, in the case of clause (ii), (A) Borrower and its Subsidiaries maintain an aggregate minimum cash balance equal to the outstanding Obligations hereunder plus Five Million

Dollars (\$5,000,000.00) in Borrower's and its Subsidiaries' Collateral Accounts with Bank or its Affiliates subject to Control Agreements in favor of Collateral Agent, and (B) such accounts are either closed or subject to Control Agreements in favor of Collateral Agent within sixty (60) days after the Effective Date, and (iii) Borrower's and its Subsidiaries' other deposit accounts not with Bank, so long as, in the case of clause (iii), (A) Borrower and its Subsidiaries maintain an aggregate minimum cash balance equal to the outstanding Obligations hereunder plus Five Million Dollars (\$5,000,000.00) in Borrower's and its Subsidiaries' Collateral Accounts with Bank or its Affiliates subject to Control Agreements in favor of Collateral Agent, and (B) such accounts are subject to Control Agreements in favor of Collateral Agent.

(b) Borrower shall provide Collateral Agent five (5) days' prior written notice before Borrower or any of its Subsidiaries establishes any Collateral Account at or with any Person other than Bank or its Affiliates. In addition, except as otherwise provided in Section 6.6(a), for each Collateral Account that Borrower or any of its Subsidiaries, at any time maintains, Borrower or such Subsidiary shall cause the applicable bank or financial institution at or with which such Collateral Account is maintained to execute and deliver a Control Agreement or other appropriate instrument with respect to such Collateral Account to perfect Collateral Agent's Lien in such Collateral Account in accordance with the terms hereunder prior to the establishment of such Collateral Account, which Control Agreement may not be terminated without prior written consent of Collateral Agent. The provisions of the previous sentence shall not apply to deposit accounts exclusively used for payroll, payroll taxes and other employee wage and benefit payments to or for the benefit of Borrower's, or any of its Subsidiaries', employees and identified to Collateral Agent by Borrower as such in the Perfection Certificates.

(c) Neither Borrower nor any of its Subsidiaries shall maintain any Collateral Accounts except Collateral Accounts maintained in accordance with Sections 6.6(a) and (b).

6.7 Protection of Intellectual Property Rights. Borrower and each of its Subsidiaries shall: (a) use commercially reasonable efforts to protect, defend and maintain the validity and enforceability of its Intellectual Property that is material to Borrower's business; (b) promptly advise Collateral Agent in writing of material infringement by a third party of its Intellectual Property; and (c) not allow any Intellectual Property material to Borrower's business to be abandoned, forfeited or dedicated to the public without Collateral Agent's prior written consent.

6.8 Litigation Cooperation. Commencing on the Effective Date and continuing through the termination of this Agreement, make available to Collateral Agent and the Lenders, without expense to Collateral Agent or the Lenders, Borrower and each of Borrower's officers, employees and agents and Borrower's Books, to the extent that Collateral Agent or any Lender may reasonably deem them necessary to prosecute or defend any third-party suit or proceeding instituted by or against Collateral Agent or any Lender with respect to any Collateral or relating to Borrower.

6.9 Notices of Litigation and Default. Borrower will give prompt written notice to Collateral Agent and the Lenders of any litigation or governmental proceedings pending or threatened (in writing) against Borrower or any of its Subsidiaries, which could reasonably be expected to result in damages or costs to Borrower or any of its Subsidiaries of One Hundred Thousand Dollars (\$100,000.00) or more or which could reasonably be expected to have a Material Adverse Change. Without limiting or contradicting any other more specific provision of this Agreement, promptly (and in any event within three (3) Business Days) upon Borrower becoming aware of the existence of any Event of Default or event which, with the giving of notice or passage of time, or both, would constitute an Event of Default, Borrower shall give written notice to Collateral Agent and the Lenders of such occurrence, which such notice shall include a reasonably detailed description of such Event of Default or event which, with the giving of notice or passage of time, or both, would constitute an Event of Default.

6.10 Intentionally Omitted.

6.11 Landlord Waivers; Bailee Waivers. In the event that Borrower or any of its Subsidiaries, after the Effective Date, intends to add any new offices or business locations, including warehouses, or otherwise store any portion of the Collateral with, or deliver any portion of the Collateral to, a bailee, in each case pursuant to Section 7.2, then Borrower or such Subsidiary will first provide written notice to Collateral Agent and, in the event that the new location is the chief executive office of the Borrower or such Subsidiary or the Collateral at any such new location is valued in excess of Two Hundred Fifty Thousand Dollars (\$250,000.00) in the aggregate, such bailee or landlord, as applicable, must execute and deliver a bailee waiver or landlord waiver, as applicable, in form and substance reasonably satisfactory to Collateral Agent prior to the addition of any new offices or business locations, or any such storage with or delivery to any such bailee, as the case may be.

6.12 Creation/Acquisition of Subsidiaries. In the event Borrower, or any of its Subsidiaries creates or acquires any Subsidiary, Borrower shall provide prior written notice to Collateral Agent and each Lender of the creation or acquisition of such new Subsidiary and take all such action as may be reasonably required by Collateral Agent or any Lender to cause each such Subsidiary to become a co-Borrower hereunder or to guarantee the Obligations of Borrower under the Loan Documents and, in each case, grant a continuing pledge and security interest in and to the assets of such Subsidiary (substantially as described on Exhibit A hereto); and Borrower (or its Subsidiary, as applicable) shall grant and pledge to Collateral Agent, for the ratable benefit of the Lenders, a perfected security interest in the stock, units or other evidence of ownership of each such newly created Subsidiary.

6.13 Further Assurances.

(a) Execute any further instruments and take further action as Collateral Agent or any Lender reasonably requests to perfect or continue Collateral Agent's Lien in the Collateral or to effect the purposes of this Agreement.

(b) Deliver to Collateral Agent and Lenders, within five (5) days after the same are sent or received, copies of all material correspondence, reports, documents and other filings with any Governmental Authority that could reasonably be expected to have a material adverse effect on any of the Governmental Approvals material to Borrower's business or otherwise could reasonably be expected to have a Material Adverse Change.

7. NEGATIVE COVENANTS

Borrower shall not, and shall not permit any of its Subsidiaries to, do any of the following without the prior written consent of the Required Lenders:

7.1 Dispositions. Convey, sell, lease, transfer, assign, or otherwise dispose of (collectively, "**Transfer**"), or permit any of its Subsidiaries to Transfer, all or any part of its business or property, except for Transfers (a) of Inventory in the ordinary course of business; (b) of worn out or obsolete Equipment or other Equipment which is being replaced by Equipment of reasonably equivalent or better value or usefulness; and (c) in connection with Permitted Liens, Permitted Investments and Permitted Licenses.

7.2 Changes in Business, Management, Ownership, or Business Locations. (a) Engage in or permit any of its Subsidiaries to engage in any business other than the businesses engaged in by Borrower as of the Effective Date or reasonably related thereto; (b) liquidate or dissolve; or (c) (i) any Key Person shall cease to be actively engaged in the management of Borrower unless written notice

thereof is provided to Collateral Agent within five (5) Business Days of such change, or (ii) enter into any transaction or series of related transactions in which the stockholders of Borrower who were not stockholders immediately prior to the first such transaction own more than forty nine percent (49%) of the voting stock of Borrower immediately after giving effect to such transaction or related series of such transactions (other than by the sale of Borrower's equity securities in a public offering, a private placement of public equity or to venture capital investors so long as Borrower identifies to Collateral Agent the venture capital investors prior to the closing of the transaction). Borrower shall not, without at least thirty (30) days' prior written notice to Collateral Agent: (A) add any new offices or business locations, including warehouses (unless such new offices or business locations (ii) contain less than Two Hundred Fifty Thousand Dollars (\$250,000.00) in assets or property of Borrower or any of its Subsidiaries and (ii) are not Borrower's or its Subsidiaries' chief executive office); (B) change its jurisdiction of organization, (C) change its organizational structure or type, (D) change its legal name, or (E) change any organizational number (if any) assigned by its jurisdiction of organization.

7.3 Mergers or Acquisitions. Merge or consolidate, or permit any of its Subsidiaries to merge or consolidate, with any other Person, or acquire, or permit any of its Subsidiaries to acquire, all or substantially all of the capital stock, shares or property of another Person; provided, however, nothing herein shall prohibit Borrower from effecting such a transaction to the extent it qualifies as a "Permitted Acquisition". A Subsidiary may merge or consolidate into another Subsidiary (provided such surviving Subsidiary is a "co-Borrower" hereunder or has provided a secured Guaranty of Borrower's Obligations hereunder) or with (or into) Borrower provided Borrower is the surviving legal entity, and as long as no Event of Default is occurring prior thereto or arises as a result therefrom. Without limiting the foregoing, Borrower shall not, without Collateral Agent's prior written consent, enter into any binding contractual arrangement with any Person to attempt to facilitate a merger or acquisition of Borrower, unless (i) no Event of Default exists when such agreement is entered into by Borrower, (ii) such agreement does not give such Person the right to claim any fees, payments or damages from Borrower in excess of Two Hundred Fifty Thousand Dollars (\$250,000.00), and (iii) Borrower notifies Collateral Agent in advance of entering into such an agreement.

7.4 Indebtedness. Create, incur, assume, or be liable for any Indebtedness, or permit any Subsidiary to do so, other than Permitted Indebtedness.

7.5 Encumbrance. Create, incur, allow, or suffer any Lien on any of its property, or assign or convey any right to receive income, including the sale of any Accounts, or permit any of its Subsidiaries to do so, except for Permitted Liens, or permit any Collateral not to be subject to the first priority security interest granted herein (except for Permitted Liens that are permitted by the terms of this Agreement to have priority over Collateral Agent's Lien), or enter into any agreement, document, instrument or other arrangement (except with or in favor of Collateral Agent, for the ratable benefit of the Lenders) with any Person which directly or indirectly prohibits or has the effect of prohibiting Borrower, or any of its Subsidiaries, from assigning, mortgaging, pledging, granting a security interest in or upon, or encumbering any of Borrower's or such Subsidiary's Intellectual Property, except as is otherwise permitted in Section 7.1 hereof and the definition of "Permitted Liens" herein.

7.6 Maintenance of Collateral Accounts. Maintain any Collateral Account except pursuant to the terms of Section 6.6 hereof.

7.7 Distributions; Investments. (a) Pay any dividends (other than dividends payable solely in capital stock) or make any distribution or payment in respect of or redeem, retire or purchase any capital stock (other than repurchases pursuant to the terms of employee stock purchase plans, employee restricted stock agreements, stockholder rights plans, director or consultant stock option plans, or similar plans, provided such repurchases do not exceed Two Hundred Fifty Thousand Dollars (\$250,000.00) in the aggregate per fiscal year) or (b) directly or indirectly make any Investment other than Permitted Investments, or permit any of its Subsidiaries to do so.

7.8 Transactions with Affiliates. Directly or indirectly enter into or permit to exist any material transaction with any Affiliate of Borrower or any of its Subsidiaries, except for (a) transactions that are in the ordinary course of Borrower's or such Subsidiary's business, upon fair and reasonable terms that are no less favorable to Borrower or such Subsidiary than would be obtained in an arm's length transaction with a non-affiliated Person, and (b) Subordinated Debt or equity investments by Borrower's investors in Borrower or its Subsidiaries.

7.9 Subordinated Debt. (a) Make or permit any payment on any Subordinated Debt, except under the terms of the subordination, intercreditor, or other similar agreement to which such Subordinated Debt is subject, or (b) amend any provision in any document relating to the Subordinated Debt which would increase the amount thereof or adversely affect the subordination thereof to Obligations owed to the Lenders.

7.10 Compliance. Become an "investment company" or a company controlled by an "investment company", under the Investment Company Act of 1940, as amended, or undertake as one of its important activities extending credit to purchase or carry margin stock (as defined in Regulation U of the Board of Governors of the Federal Reserve System), or use the proceeds of any Credit Extension for that purpose; fail to meet the minimum funding requirements of ERISA, permit a Reportable Event or Prohibited Transaction, as defined in ERISA, to occur; fail to comply with the Federal Fair Labor Standards Act or violate any other law or regulation, if the violation could reasonably be expected to have a Material Adverse Change, or permit any of its Subsidiaries to do so; withdraw or permit any Subsidiary to withdraw from participation in, permit partial or complete termination of, or permit the occurrence of any other event with respect to, any present pension, profit sharing and deferred compensation plan which could reasonably be expected to result in any liability of Borrower or any of its Subsidiaries, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other Governmental Authority.

7.11 Compliance with Anti-Terrorism Laws. Collateral Agent hereby notifies Borrower and each of its Subsidiaries that pursuant to the requirements of Anti-Terrorism Laws, and Collateral Agent's policies and practices, Collateral Agent is required to obtain, verify and record certain information and documentation that identifies Borrower and each of its Subsidiaries and their principals, which information includes the name and address of Borrower and each of its Subsidiaries and their principals and such other information that will allow Collateral Agent to identify such party in accordance with Anti-Terrorism Laws. Neither Borrower nor any of its Subsidiaries shall, nor shall Borrower or any of its Subsidiaries permit any Affiliate to, directly or indirectly, knowingly enter into any documents, instruments, agreements or contracts with any Person listed on the OFAC Lists. Borrower and each of its Subsidiaries shall immediately notify Collateral Agent if Borrower or such Subsidiary has knowledge that Borrower, or any Subsidiary or Affiliate of Borrower, is listed on the OFAC Lists or (a) is convicted on, (b) pleads *nolo contendere* to, (c) is indicted on, or (d) is arraigned and held over on charges involving money laundering or predicate crimes to money laundering. Neither Borrower nor any of its Subsidiaries shall, nor shall Borrower or any of its Subsidiaries, permit any Affiliate to, directly or indirectly, (i) conduct any business or engage in any transaction or dealing with any Blocked Person, including, without limitation, the making or receiving of any contribution of funds, goods or services to or for the benefit of any Blocked Person, (ii) deal in, or otherwise engage in any transaction relating to, any property or interests in property blocked pursuant to Executive Order No. 13224 or any similar executive order or other Anti-Terrorism Law, or (iii) engage in or conspire to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding, or attempts to violate, any of the prohibitions set forth in Executive Order No. 13224 or other Anti-Terrorism Law.

8. EVENTS OF DEFAULT

Any one of the following shall constitute an event of default (an “**Event of Default**”) under this Agreement:

8.1 Payment Default. Borrower fails to (a) make any payment of principal or interest on any Credit Extension on its due date, or (b) pay any other Obligations within three (3) Business Days after such Obligations are due and payable (which three (3) Business Day grace period shall not apply to payments due on the Maturity Date or the date of acceleration pursuant to Section 9.1 (a) hereof). During the cure period, the failure to cure the payment default is not an Event of Default (but no Credit Extension will be made during the cure period);

8.2 Covenant Default.

(a) Borrower or any of its Subsidiaries fails or neglects to perform any obligation in Sections 6.2 (Financial Statements, Reports, Certificates), 6.4 (Taxes), 6.5 (Insurance), 6.6 (Operating Accounts), 6.7 (Protection of Intellectual Property Rights), 6.9 (Notice of Litigation and Default), 6.11 (Landlord Waivers; Bailee Waivers), 6.12 (Creation/Acquisition of Subsidiaries) or 6.13 (Further Assurances) or Borrower violates any covenant in Section 7; or

(b) Borrower, or any of its Subsidiaries, fails or neglects to perform, keep, or observe any other term, provision, condition, covenant or agreement contained in this Agreement or any Loan Documents, and as to any default (other than those specified in this Section 8) under such other term, provision, condition, covenant or agreement that can be cured, has failed to cure the default within ten (10) days after the occurrence thereof; provided, however, that if the default cannot by its nature be cured within the ten (10) day period or cannot after diligent attempts by Borrower be cured within such ten (10) day period, and such default is likely to be cured within a reasonable time, then Borrower shall have an additional period (which shall not in any case exceed thirty (30) days) to attempt to cure such default, and within such reasonable time period the failure to cure the default shall not be deemed an Event of Default (but no Credit Extensions shall be made during such cure period). Grace periods provided under this Section shall not apply, among other things, to financial covenants or any other covenants set forth in subsection (a) above;

8.3 Material Adverse Change. A Material Adverse Change occurs;

8.4 Attachment; Levy; Restraint on Business.

(a) (i) The service of process seeking to attach, by trustee or similar process, any funds of Borrower or any of its Subsidiaries or of any entity under control of Borrower or its Subsidiaries on deposit with any Lender or any Lender’s Affiliate or any bank or other institution at which Borrower or any of its Subsidiaries maintains a Collateral Account, or (ii) a notice of lien, levy, or assessment is filed against Borrower or any of its Subsidiaries or their respective assets by any government agency, and the same under subclauses (i) and (ii) hereof are not, within ten (10) days after the occurrence thereof, discharged or stayed (whether through the posting of a bond or otherwise); provided, however, no Credit Extensions shall be made during any ten (10) day cure period; and

(b) (i) any material portion of Borrower’s or any of its Subsidiaries’ assets is attached, seized, levied on, or comes into possession of a trustee or receiver, or (ii) any court order enjoins, restrains, or prevents Borrower or any of its Subsidiaries from conducting any part of its business;

8.5 Insolvency. (a) Borrower or any of its Subsidiaries is or becomes Insolvent; (b) Borrower or any of its Subsidiaries begins an Insolvency Proceeding; or (c) an Insolvency Proceeding is begun against Borrower or any of its Subsidiaries and not dismissed or stayed within forty-five (45) days (but no Credit Extensions shall be made while Borrower or any Subsidiary is Insolvent and/or until any Insolvency Proceeding is dismissed);

8.6 Other Agreements. There is a default in any agreement to which Borrower or any of its Subsidiaries is a party with a third party or parties resulting in a right by such third party or parties, whether or not exercised, to accelerate the maturity of any Indebtedness in an amount in excess of One Hundred Thousand Dollars (\$100,000.00) or that could reasonably be expected to have a Material Adverse Change; provided, however, that the Event of Default under this Section 8.6 caused by the occurrence of a breach or default under such other agreement shall be cured or waived for purposes of this Agreement upon Collateral Agent receiving written notice from the party asserting such breach or default of such cure or waiver of the breach or default under such other agreement, if at the time of such cure or waiver under such other agreement (x) Collateral Agent or any Lender has not declared an Event of Default under this Agreement and/or exercised any rights with respect thereto; (y) any such cure or waiver does not result in an Event of Default under any other provision of this Agreement or any Loan Document; and (z) in connection with any such cure or waiver under such other agreement, the terms of any agreement with such third party are not modified or amended in any manner which could in the good faith business judgment of Collateral Agent be materially less advantageous to Borrower;

8.7 Judgments. One or more judgments, orders, or decrees for the payment of money in an amount, individually or in the aggregate, of at least One Hundred Thousand Dollars (\$100,000.00) (not covered by independent third-party insurance as to which liability has been accepted by such insurance carrier) shall be rendered against Borrower or any of its Subsidiaries and shall remain unsatisfied, unvacated, or unstayed for a period of ten (10) days after the entry thereof (provided that no Credit Extensions will be made prior to the satisfaction, vacation, or stay of such judgment, order or decree);

8.8 Misrepresentations. Borrower or any of its Subsidiaries or any Person acting for Borrower or any of its Subsidiaries makes any representation, warranty, or other statement now or later in this Agreement, any Loan Document or in any writing delivered to Collateral Agent and/or Lenders or to induce Collateral Agent and/or the Lenders to enter this Agreement or any Loan Document, and such representation, warranty, or other statement is incorrect in any material respect when made;

8.9 Subordinated Debt. A default or breach occurs under any agreement between Borrower or any of its Subsidiaries and any creditor of Borrower or any of its Subsidiaries that signed a subordination, intercreditor, or other similar agreement with Collateral Agent or the Lenders, or any creditor that has signed such an agreement with Collateral Agent or the Lenders breaches any terms of such agreement;

8.10 Guaranty. (a) Any Guaranty terminates or ceases for any reason to be in full force and effect; (b) any Guarantor does not perform any obligation or covenant under any Guaranty; (c) any circumstance described in Sections 8.3, 8.4, 8.5, 8.7, or 8.8 occurs with respect to any Guarantor, or (d) the liquidation, winding up, or termination of existence of any Guarantor;

8.11 Governmental Approvals. Any Governmental Approval shall have been revoked, rescinded, suspended, modified in an adverse manner, or not renewed in the ordinary course for a full term *and* such revocation, rescission, suspension, modification or non-renewal has resulted in or could reasonably be expected to result in a Material Adverse Change; or

8.12 Lien Priority. Any Lien created hereunder or by any other Loan Document shall at any time fail to constitute a valid and perfected Lien on any of the Collateral purported to be secured thereby, subject to no prior or equal Lien, other than Permitted Liens which are permitted to have priority in accordance with the terms of this Agreement.

9. RIGHTS AND REMEDIES

9.1 Rights and Remedies.

(a) Upon the occurrence and during the continuance of an Event of Default, Collateral Agent may, and at the written direction of Required Lenders shall, without notice or demand, do any or all of the following: (i) deliver notice of the Event of Default to Borrower, (ii) by notice to Borrower declare all Obligations immediately due and payable (but if an Event of Default described in Section 8.5 occurs all Obligations shall be immediately due and payable without any action by Collateral Agent or the Lenders) or (iii) by notice to Borrower suspend or terminate the obligations, if any, of the Lenders to advance money or extend credit for Borrower's benefit under this Agreement or under any other agreement between Borrower and Collateral Agent and/or the Lenders (but if an Event of Default described in Section 8.5 occurs all obligations, if any, of the Lenders to advance money or extend credit for Borrower's benefit under this Agreement or under any other agreement between Borrower and Collateral Agent and/or the Lenders shall be immediately terminated without any action by Collateral Agent or the Lenders).

(b) Without limiting the rights of Collateral Agent and the Lenders set forth in Section 9.1(a) above, upon the occurrence and during the continuance of an Event of Default, Collateral Agent shall have the right, without notice or demand, to do any or all of the following:

(i) foreclose upon and/or sell or otherwise liquidate, the Collateral;

(ii) apply to the Obligations any (a) balances and deposits of Borrower that Collateral Agent or any Lender holds or controls, or (b) any amount held or controlled by Collateral Agent or any Lender owing to or for the credit or the account of Borrower; and/or

(iii) commence and prosecute an Insolvency Proceeding or consent to Borrower commencing any Insolvency Proceeding.

(c) Without limiting the rights of Collateral Agent and the Lenders set forth in Sections 9.1(a) and (b) above, upon the occurrence and during the continuance of an Event of Default, Collateral Agent shall have the right, without notice or demand, to do any or all of the following:

(i) settle or adjust disputes and claims directly with Account Debtors for amounts on terms and in any order that Collateral Agent considers advisable, notify any Person owing Borrower money of Collateral Agent's security interest in such funds, and verify the amount of such account;

(ii) make any payments and do any acts it considers necessary or reasonable to protect the Collateral and/or its security interest in the Collateral. Borrower shall assemble the Collateral if Collateral Agent requests and make it available in a location as Collateral Agent reasonably designates. Collateral Agent may enter premises where the Collateral is located, take and maintain possession of any part of the Collateral, and pay, purchase, contest, or compromise any Lien which appears to be prior or superior to its security interest and pay all expenses incurred. Borrower grants Collateral Agent a license to enter and occupy any of its premises, without charge, to exercise any of Collateral Agent's rights or remedies;

(iii) ship, reclaim, recover, store, finish, maintain, repair, prepare for sale, and/or advertise for sale, the Collateral. Collateral Agent is hereby granted a non-exclusive, royalty-free license or other right to use, without charge, Borrower's and each of its Subsidiaries' labels, patents, copyrights, mask works, rights of use of any name, trade secrets, trade names, trademarks, service marks, and advertising matter, or any similar property as it pertains to the Collateral, in completing production of, advertising for sale, and selling any Collateral and, in connection with Collateral Agent's exercise of its rights under this Section 9.1, Borrower's and each of its Subsidiaries' rights under all licenses and all franchise agreements inure to Collateral Agent, for the benefit of the Lenders;

(iv) place a "hold" on any account maintained with Collateral Agent or the Lenders and/or deliver a notice of exclusive control, any entitlement order, or other directions or instructions pursuant to any Control Agreement or similar agreements providing control of any Collateral;

(v) demand and receive possession of Borrower's Books;

(vi) appoint a receiver to seize, manage and realize any of the Collateral, and such receiver shall have any right and authority as any competent court will grant or authorize in accordance with any applicable law, including any power or authority to manage the business of Borrower or any of its Subsidiaries;

(vii) subject to clauses 9.1(a) and (b), exercise all rights and remedies available to Collateral Agent and each Lender under the Loan Documents or at law or equity, including all remedies provided under the Code (including disposal of the Collateral pursuant to the terms thereof);

(viii) any Letters of Credit, demand that Borrower (i) deposit cash with Bank in an amount equal to (x) if such Letters of Credit are denominated in Dollars, then one hundred five percent (105%); and (y) if such Letters of Credit are denominated in a Foreign Currency, then one hundred ten percent (110%), of the Dollar Equivalent of the aggregate face amount of all Letters of Credit remaining undrawn (plus all interest, fees, and costs due or to become due in connection therewith (as estimated by Bank in its good faith business judgment)), to secure all of the Obligations relating to such Letters of Credit, as collateral security for the repayment of any future drawings under such Letters of Credit, and Borrower shall forthwith deposit and pay such amounts, and (ii) pay in advance all letter of credit fees scheduled to be paid or payable over the remaining term of any Letters of Credit; and

(ix) terminate any FX Contracts.

Notwithstanding any provision of this Section 9.1 to the contrary, upon the occurrence of any Event of Default, Collateral Agent shall have the right to exercise any and all remedies referenced in this Section 9.1 without the written consent of Required Lenders following the occurrence of an Exigent Circumstance. As used in the immediately preceding sentence, "**Exigent Circumstance**" means any event or circumstance that, in the reasonable judgment of Collateral Agent, imminently threatens the ability of Collateral Agent to realize upon all or any material portion of the Collateral, such as, without limitation, fraudulent removal, concealment, or abscondment thereof, destruction or material waste thereof, or failure of Borrower or any of its Subsidiaries after reasonable demand to maintain or reinstate adequate casualty insurance coverage, or which, in the judgment of Collateral Agent, could reasonably be expected to result in a material diminution in value of the Collateral.

9.2 Power of Attorney. Borrower hereby irrevocably appoints Collateral Agent as its lawful attorney-in-fact, exercisable upon the occurrence and during the continuance of an Event of Default, to: (a) endorse Borrower's or any of its Subsidiaries' name on any checks or other forms of payment or security; (b) sign Borrower's or any of its Subsidiaries' name on any invoice or bill of lading for any Account or drafts against Account Debtors; (c) settle and adjust disputes and claims about the Accounts directly with Account Debtors, for amounts and on terms Collateral Agent determines reasonable; (d) make, settle, and adjust all claims under Borrower's insurance policies; (e) pay, contest or settle any Lien, charge, encumbrance, security interest, and adverse claim in or to the Collateral, or any judgment based thereon, or otherwise take any action to terminate or discharge the same; and (f) transfer the Collateral into the name of Collateral Agent or a third party as the Code or any applicable law permits. Borrower hereby appoints Collateral Agent as its lawful attorney-in-fact to sign Borrower's or any of its Subsidiaries' name on any documents necessary to perfect or continue the perfection of Collateral Agent's security interest in the Collateral regardless of whether an Event of Default has occurred until all Obligations (other than inchoate indemnity obligations and Obligations for Bank Services secured by cash collateral in accordance with the terms of Section 4.1 of this Agreement) have been satisfied in full and Collateral Agent and the Lenders are under no further obligation to make Credit Extensions hereunder. Collateral Agent's foregoing appointment as Borrower's or any of its Subsidiaries' attorney in fact, and all of Collateral Agent's rights and powers, coupled with an interest, are irrevocable until all Obligations (other than inchoate indemnity obligations and Obligations for Bank Services secured by cash collateral in accordance with the terms of Section 4.1 of this Agreement) have been fully repaid and performed and Collateral Agent's and the Lenders' obligation to provide Credit Extensions terminates.

9.3 Protective Payments. If Borrower or any of its Subsidiaries fail to obtain the insurance called for by Section 6.5 or fails to pay any premium thereon or fails to pay any other amount which Borrower or any of its Subsidiaries is obligated to pay under this Agreement or any other Loan Document, Collateral Agent may obtain such insurance or make such payment, and all amounts so paid by Collateral Agent are Lenders' Expenses and immediately due and payable, bearing interest at the Default Rate, and secured by the Collateral. Collateral Agent will make reasonable efforts to provide Borrower with notice of Collateral Agent obtaining such insurance or making such payment at the time it is obtained or paid or within a reasonable time thereafter. No such payments by Collateral Agent are deemed an agreement to make similar payments in the future or Collateral Agent's waiver of any Event of Default.

9.4 Application of Payments and Proceeds. Notwithstanding anything to the contrary contained in this Agreement, upon the occurrence and during the continuance of an Event of Default, (a) Borrower irrevocably waives the right to direct the application of any and all payments at any time or times thereafter received by Collateral Agent from or on behalf of Borrower or any of its Subsidiaries of all or any part of the Obligations, and, as between Borrower on the one hand and Collateral Agent and Lenders on the other, Collateral Agent shall have the continuing and exclusive right to apply and to reapply any and all payments received against the Obligations in such manner as Collateral Agent may deem advisable notwithstanding any previous application by Collateral Agent, and (b) the proceeds of any sale of, or other realization upon all or any part of the Collateral shall be applied: first, to the Lenders' Expenses; second, to accrued and unpaid interest on the Obligations (including any interest which, but for the provisions of the United States Bankruptcy Code, would have accrued on such amounts); third, to the principal amount of the Obligations outstanding; and fourth, to any other indebtedness or obligations of Borrower owing to Collateral Agent or any Lender under the Loan Documents. Any balance remaining shall be delivered to Borrower or to whoever may be lawfully entitled to receive such balance or as a court of competent jurisdiction may direct. In carrying out the foregoing, (x) amounts received shall be applied in the numerical order provided until exhausted prior to the application to the next succeeding category, and (y) each of the Persons entitled to receive a payment in any particular category shall receive an amount equal to its pro rata share of amounts available to be applied pursuant thereto for such

category. Any reference in this Agreement to an allocation between or sharing by the Lenders of any right, interest or obligation “ratably,” “proportionally” or in similar terms shall refer to Pro Rata Share unless expressly provided otherwise. Collateral Agent, or if applicable, each Lender, shall promptly remit to the other Lenders such sums as may be necessary to ensure the ratable repayment of each Lender’s portion of any Term Loan and the ratable distribution of interest, fees and reimbursements paid or made by Borrower. Notwithstanding the foregoing, a Lender receiving a scheduled payment shall not be responsible for determining whether the other Lenders also received their scheduled payment on such date; provided, however, if it is later determined that a Lender received more than its ratable share of scheduled payments made on any date or dates, then such Lender shall remit to Collateral Agent or other Lenders such sums as may be necessary to ensure the ratable payment of such scheduled payments, as instructed by Collateral Agent. If any payment or distribution of any kind or character, whether in cash, properties or securities, shall be received by a Lender in excess of its ratable share, then the portion of such payment or distribution in excess of such Lender’s ratable share shall be received by such Lender in trust for and shall be promptly paid over to the other Lender for application to the payments of amounts due on the other Lenders’ claims. To the extent any payment for the account of Borrower is required to be returned as a voidable transfer or otherwise, the Lenders shall contribute to one another as is necessary to ensure that such return of payment is on a pro rata basis. If any Lender shall obtain possession of any Collateral, it shall hold such Collateral for itself and as agent and bailee for Collateral Agent and other Lenders for purposes of perfecting Collateral Agent’s security interest therein.

9.5 Liability for Collateral. So long as Collateral Agent and the Lenders comply with reasonable banking practices regarding the safekeeping of the Collateral in the possession or under the control of Collateral Agent and the Lenders, Collateral Agent and the Lenders shall not be liable or responsible for: (a) the safekeeping of the Collateral; (b) any loss or damage to the Collateral; (c) any diminution in the value of the Collateral; or (d) any act or default of any carrier, warehouseman, bailee, or other Person. Borrower bears all risk of loss, damage or destruction of the Collateral.

9.6 No Waiver; Remedies Cumulative. Failure by Collateral Agent or any Lender, at any time or times, to require strict performance by Borrower of any provision of this Agreement or any other Loan Document shall not waive, affect, or diminish any right of Collateral Agent or any Lender thereafter to demand strict performance and compliance herewith or therewith. No waiver hereunder shall be effective unless signed by Collateral Agent and the Required Lenders and then is only effective for the specific instance and purpose for which it is given. The rights and remedies of Collateral Agent and the Lenders under this Agreement and the other Loan Documents are cumulative. Collateral Agent and the Lenders have all rights and remedies provided under the Code, any applicable law, by law, or in equity. The exercise by Collateral Agent or any Lender of one right or remedy is not an election, and Collateral Agent’s or any Lender’s waiver of any Event of Default is not a continuing waiver. Collateral Agent’s or any Lender’s delay in exercising any remedy is not a waiver, election, or acquiescence.

9.7 Demand Waiver. Borrower waives, to the fullest extent permitted by law, demand, notice of default or dishonor, notice of payment and nonpayment, notice of any default, nonpayment at maturity, release, compromise, settlement, extension, or renewal of accounts, documents, instruments, chattel paper, and guarantees held by Collateral Agent or any Lender on which Borrower or any Subsidiary is liable.

10. NOTICES

All notices, consents, requests, approvals, demands, or other communication (collectively, “**Communication**”) by any party to this Agreement or any other Loan Document must be in writing and shall be deemed to have been validly served, given, or delivered: (a) upon the earlier of actual receipt and three (3) Business Days after deposit in the U.S. mail, first class, registered or certified mail return receipt

requested, with proper postage prepaid; (b) upon transmission, when sent by facsimile transmission; (c) one (1) Business Day after deposit with a reputable overnight courier with all charges prepaid; or (d) when delivered, if hand-delivered by messenger, all of which shall be addressed to the party to be notified and sent to the address, facsimile number, or email address indicated below. Any of Collateral Agent, Lender or Borrower may change its mailing address or facsimile number by giving the other party written notice thereof in accordance with the terms of this Section 10.

If to Borrower:	XERIS PHARMACEUTICALS, INC. 180 North LaSalle Street, Suite 1800 Chicago, IL 60601 Attn: Nora Brennan Email: nbrennan@xerispharma.com
with a copy (which shall not constitute notice) to:	XERIS PHARMACEUTICALS, INC. 180 North LaSalle Street, Suite 1800 Chicago, IL 60601 Attn: Steve Pieper Email: spieper@xerispharma.com
with a copy (which shall not constitute notice) to:	ANDREWS KURTH KENYON LLP 111 Congress Ave., Suite 1700 Austin, TX 78701 Attn: J. Matthew Lyons Email: mlyons@andrewskurth.com
If to Collateral Agent:	OXFORD FINANCE LLC 133 North Fairfax Street Alexandria, Virginia 22314 Attention: Legal Department Fax: (703) 519-5225 Email: LegalDepartment@oxfordfinance.com
with a copy to	SILICON VALLEY BANK 4370 La Jolla Village Drive, Suite 1050 San Diego, CA 92122 Attn: Anthony Flores Fax: (858) 622-1424 Email: aflores@svb.com
with a copy (which shall not constitute notice) to:	Troutman Sanders LLP 401 9 th Street, NW, Suite 1000 Washington, DC 20004 Attn: Charles Charpentier Fax: (202) 274-2994 Email: charles.charpentier@troutman.com

11. CHOICE OF LAW, VENUE AND JURY TRIAL WAIVER

New York law governs the Loan Documents without regard to principles of conflicts of law. Borrower, Lenders and Collateral Agent each submit to the exclusive jurisdiction of the State and Federal courts in the City of New York, Borough of Manhattan. NOTWITHSTANDING THE FOREGOING,

COLLATERAL AGENT AND THE LENDERS SHALL HAVE THE RIGHT TO BRING ANY ACTION OR PROCEEDING AGAINST BORROWER OR ITS PROPERTY IN THE COURTS OF ANY OTHER JURISDICTION WHICH COLLATERAL AGENT AND THE LENDERS (IN ACCORDANCE WITH THE PROVISIONS OF SECTION 9.1) DEEM NECESSARY OR APPROPRIATE TO REALIZE ON THE COLLATERAL OR TO OTHERWISE ENFORCE COLLATERAL AGENT'S AND THE LENDERS' RIGHTS AGAINST BORROWER OR ITS PROPERTY. Borrower expressly submits and consents in advance to such jurisdiction in any action or suit commenced in any such court, and Borrower hereby waives any objection that it may have based upon lack of personal jurisdiction, improper venue, or forum non conveniens and hereby consents to the granting of such legal or equitable relief as is deemed appropriate by such court. Borrower hereby waives personal service of the summons, complaints, and other process issued in such action or suit and agrees that service of such summons, complaints, and other process may be made by registered or certified mail addressed to Borrower at the address set forth in, or subsequently provided by Borrower in accordance with, Section 10 of this Agreement and that service so made shall be deemed completed upon the earlier to occur of Borrower's actual receipt thereof or three (3) days after deposit in the U.S. mails, first class, registered or certified mail return receipt requested, proper postage prepaid.

TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, BORROWER, COLLATERAL AGENT, AND THE LENDERS EACH WAIVE THEIR RIGHT TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION ARISING OUT OF OR BASED UPON THIS AGREEMENT, THE LOAN DOCUMENTS OR ANY CONTEMPLATED TRANSACTION, INCLUDING CONTRACT, TORT, BREACH OF DUTY AND ALL OTHER CLAIMS. THIS WAIVER IS A MATERIAL INDUCEMENT FOR EACH PARTY TO ENTER INTO THIS AGREEMENT. EACH PARTY HAS REVIEWED THIS WAIVER WITH ITS COUNSEL.

12. GENERAL PROVISIONS

12.1 Successors and Assigns. This Agreement binds and is for the benefit of the successors and permitted assigns of each party. Borrower may not transfer, pledge or assign this Agreement or any rights or obligations under it without Collateral Agent's and each Lender's prior written consent (which may be granted or withheld in Collateral Agent's and each Lender's discretion, subject to Section 12.6). The Lenders have the right, without the consent of or notice to Borrower, to sell, transfer, assign, pledge, negotiate, or grant participation in (any such sale, transfer, assignment, negotiation, or grant of a participation, a "**Lender Transfer**") all or any part of, or any interest in, the Lenders' obligations, rights, and benefits under this Agreement and the other Loan Documents; *provided, however*, that any such Lender Transfer (other than a transfer, pledge, sale or assignment to an Eligible Assignee) of its obligations, rights, and benefits under this Agreement and the other Loan Documents shall require the prior written consent of the Required Lenders (such approved assignee, an "**Approved Lender**"). Borrower and Collateral Agent shall be entitled to continue to deal solely and directly with such Lender in connection with the interests so assigned until Collateral Agent shall have received and accepted an effective assignment agreement in form satisfactory to Collateral Agent executed, delivered and fully completed by the applicable parties thereto, and shall have received such other information regarding such Eligible Assignee or Approved Lender as Collateral Agent reasonably shall require. Notwithstanding anything to the contrary contained herein, so long as no Event of Default has occurred and is continuing, no Lender Transfer (other than a Lender Transfer (i) in respect of the Warrants or (ii) in connection with (x) assignments by a Lender due to a forced divestiture at the request of any regulatory agency; or (y) upon the occurrence of a default, event of default or similar occurrence with respect to a Lender's own financing or securitization transactions) shall be permitted, without Borrower's consent, to any Person which is an Affiliate or Subsidiary of Borrower, a direct competitor of Borrower or a vulture hedge fund, each as determined by Collateral Agent.

12.2 Indemnification. Borrower agrees to indemnify, defend and hold Collateral Agent and the Lenders and their respective directors, officers, employees, agents, attorneys, or any other Person affiliated with or representing Collateral Agent or the Lenders (each, an “**Indemnified Person**”) harmless against: (a) all obligations, demands, claims, and liabilities (collectively, “**Claims**”) asserted by any other party in connection with; related to; following or arising from, out of or under, the transactions contemplated by the Loan Documents; and (b) all losses or Lenders’ Expenses incurred, or paid by Indemnified Person in connection with; related to; following; or arising from, out of or under, the transactions contemplated by the Loan Documents between Collateral Agent, and/or the Lenders and Borrower (including reasonable attorneys’ fees and expenses), except for Claims and/or losses directly caused by such Indemnified Person’s gross negligence or willful misconduct. Borrower hereby further indemnifies, defends and holds each Indemnified Person harmless from and against any and all liabilities, obligations, losses, damages, penalties, actions, judgments, suits, claims, costs, expenses and disbursements of any kind or nature whatsoever (including the fees and disbursements of counsel for such Indemnified Person) in connection with any investigative, response, remedial, administrative or judicial matter or proceeding, whether or not such Indemnified Person shall be designated a party thereto and including any such proceeding initiated by or on behalf of Borrower, and the reasonable expenses of investigation by engineers, environmental consultants and similar technical personnel and any commission, fee or compensation claimed by any broker (other than any broker retained by Collateral Agent or Lenders) asserting any right to payment for the transactions contemplated hereby which may be imposed on, incurred by or asserted against such Indemnified Person as a result of or in connection with the transactions contemplated hereby and the use or intended use of the proceeds of the loan proceeds except for liabilities, obligations, losses, damages, penalties, actions, judgments, suits, claims, costs, expenses and disbursements directly caused by such Indemnified Person’s gross negligence or willful misconduct.

12.3 Time of Essence. Time is of the essence for the performance of all Obligations in this Agreement.

12.4 Severability of Provisions. Each provision of this Agreement is severable from every other provision in determining the enforceability of any provision.

12.5 Correction of Loan Documents. Collateral Agent and the Lenders may correct patent errors and fill in any blanks in this Agreement and the other Loan Documents consistent with the agreement of the parties. Following such correction, Collateral Agent shall endeavor to provide Borrower with notice, and a copy, of such correction, but failure of Collateral Agent to provide such notice or copy shall not invalidate such correction or result in any breach of this Agreement by Collateral Agent or any Lender.

12.6 Amendments in Writing; Integration. (a) No amendment, modification, termination or waiver of any provision of this Agreement or any other Loan Document, no approval or consent thereunder, or any consent to any departure by Borrower or any of its Subsidiaries therefrom, shall in any event be effective unless the same shall be in writing and signed by Borrower, Collateral Agent and the Required Lenders provided that:

(i) no such amendment, waiver or other modification that would have the effect of increasing or reducing a Lender’s Term Loan Commitment or Commitment Percentage shall be effective as to such Lender without such Lender’s written consent;

(ii) no such amendment, waiver or modification that would affect the rights and duties of Collateral Agent shall be effective without Collateral Agent’s written consent or signature;

(iii) no such amendment, waiver or other modification shall, unless signed by all the Lenders directly affected thereby, (A) reduce the principal of, rate of interest on or any fees with respect to any Term Loan or forgive any principal, interest (other than default interest) or fees (other than late charges) with respect to any Term Loan (B) postpone the date fixed for, or waive, any payment of principal of any Term Loan or of interest on any Term Loan (other than default interest) or any fees provided for hereunder (other than late charges or for any termination of any commitment); (C) change the definition of the term “**Required Lenders**” or the percentage of Lenders which shall be required for the Lenders to take any action hereunder; (D) release all or substantially all of any material portion of the Collateral, authorize Borrower to sell or otherwise dispose of all or substantially all or any material portion of the Collateral or release any Guarantor of all or any portion of the Obligations or its guaranty obligations with respect thereto, except, in each case with respect to this clause (D), as otherwise may be expressly permitted under this Agreement or the other Loan Documents (including in connection with any disposition permitted hereunder); (E) amend, waive or otherwise modify this Section 12.6 or the definitions of the terms used in this Section 12.6 insofar as the definitions affect the substance of this Section 12.6; (F) consent to the assignment, delegation or other transfer by Borrower of any of its rights and obligations under any Loan Document or release Borrower of its payment obligations under any Loan Document, except, in each case with respect to this clause (F), pursuant to a merger or consolidation permitted pursuant to this Agreement; (G) amend any of the provisions of Section 9.4 or amend any of the definitions of Pro Rata Share, Term Loan Commitment, Commitment Percentage or that provide for the Lenders to receive their Pro Rata Shares of any fees, payments, setoffs or proceeds of Collateral hereunder; (H) subordinate the Liens granted in favor of Collateral Agent securing the Obligations; or (I) amend any of the provisions of Section 12.10. It is hereby understood and agreed that all Lenders shall be deemed directly affected by an amendment, waiver or other modification of the type described in the preceding clauses (C), (D), (E), (F), (G) and (H) of the preceding sentence;

(iv) the provisions of the foregoing clauses (i), (ii) and (iii) are subject to the provisions of any interlender or agency agreement among the Lenders and Collateral Agent pursuant to which any Lender may agree to give its consent in connection with any amendment, waiver or modification of the Loan Documents only in the event of the unanimous agreement of all Lenders.

(b) Other than as expressly provided for in Section 12.6(a)(i)-(iii), Collateral Agent may, if requested by the Required Lenders, from time to time designate covenants in this Agreement less restrictive by notification to a representative of Borrower.

(c) This Agreement and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Agreement and the Loan Documents merge into this Agreement and the Loan Documents.

12.7 Counterparts. This Agreement may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Agreement.

12.8 Survival. All covenants, representations and warranties made in this Agreement continue in full force and effect until this Agreement has terminated pursuant to its terms and all Obligations (other than inchoate indemnity obligations and any other obligations which, by their terms, are to survive the termination of this Agreement) have been satisfied. Without limiting the foregoing, except as otherwise provided in Section 4.1, the grant of security interest by Borrower in Section 4.1 shall survive until the termination of all Bank Services Agreements. The obligation of Borrower in Section 12.2 to indemnify each Lender and Collateral Agent, as well as the confidentiality provisions in Section 12.9 below, shall survive until the statute of limitations with respect to such claim or cause of action shall have run.

12.9 Confidentiality. In handling any confidential information of Borrower and its Subsidiaries, if any, the Lenders and Collateral Agent shall exercise the same degree of care that it exercises for their own proprietary information, but disclosure of information may be made: (a) subject to the terms and conditions of this Agreement, to the Lenders' and Collateral Agent's Subsidiaries or Affiliates, or in connection with a Lender's own financing or securitization transactions and upon the occurrence of a default, event of default or similar occurrence with respect to such financing or securitization transaction; (b) to prospective transferees (other than those identified in (a) above) or purchasers of any interest in the Credit Extensions (provided, however, the Lenders and Collateral Agent shall, except upon the occurrence and during the continuance of an Event of Default, obtain such prospective transferee's or purchaser's agreement to the terms of this provision or to similar confidentiality terms); (c) as required by law, regulation, subpoena, or other order; (d) to Lenders' or Collateral Agent's regulators or as otherwise required in connection with an examination or audit; (e) as Collateral Agent reasonably considers appropriate in exercising remedies under the Loan Documents; and (f) to third party service providers of the Lenders and/or Collateral Agent so long as such service providers have executed a confidentiality agreement with the Lenders and Collateral Agent with terms no less restrictive than those contained herein. Confidential information does not include information that either: (i) is in the public domain or in the Lenders' and/or Collateral Agent's possession when disclosed to the Lenders and/or Collateral Agent, or becomes part of the public domain after disclosure to the Lenders and/or Collateral Agent; or (ii) is disclosed to the Lenders and/or Collateral Agent by a third party, if the Lenders and/or Collateral Agent does not know that the third party is prohibited from disclosing the information. Collateral Agent and the Lenders may use confidential information for any purpose relating to the administration of this Agreement and for the development of client databases, reporting purposes required by law or by governmental authorities, and market analysis. The provisions of the immediately preceding sentence shall survive the termination of this Agreement. The agreements provided under this Section 12.9 supersede all prior agreements, understanding, representations, warranties, and negotiations between the parties about the subject matter of this Section 12.9.

12.10 Right of Set Off. Borrower hereby grants to Collateral Agent and to each Lender, a lien, security interest and right of set off as security for all Obligations to Collateral Agent and each Lender hereunder, whether now existing or hereafter arising upon and against all deposits, credits, collateral and property, now or hereafter in the possession, custody, safekeeping or control of Collateral Agent or the Lenders or any entity under the control of Collateral Agent or the Lenders (including a Collateral Agent affiliate) or in transit to any of them. At any time after the occurrence and during the continuance of an Event of Default, without demand or notice, Collateral Agent or the Lenders may set off the same or any part thereof and apply the same to any liability or obligation of Borrower even though unmatured and regardless of the adequacy of any other collateral securing the Obligations. **ANY AND ALL RIGHTS TO REQUIRE COLLATERAL AGENT TO EXERCISE ITS RIGHTS OR REMEDIES WITH RESPECT TO ANY OTHER COLLATERAL WHICH SECURES THE OBLIGATIONS, PRIOR TO EXERCISING ITS RIGHT OF SETOFF WITH RESPECT TO SUCH DEPOSITS, CREDITS OR OTHER PROPERTY OF BORROWER ARE HEREBY KNOWINGLY, VOLUNTARILY AND IRREVOCABLY WAIVED.**

12.11 Silicon Valley Bank as Agent. Collateral Agent hereby appoints Silicon Valley Bank ("SVB") as its agent (and SVB hereby accepts such appointment) for the purpose of perfecting Collateral Agent's Liens in assets which, in accordance with Article 8 or Article 9, as applicable, of the Code can be perfected by possession or control, including without limitation, all deposit accounts maintained at SVB.

12.12 Cooperation of Borrower. If necessary, Borrower agrees to (i) execute any documents (including new Secured Promissory Notes) reasonably required to effectuate and acknowledge each assignment of a Term Loan Commitment or Loan to an assignee in accordance with Section 12.1, (ii) make Borrower's management available to meet with Collateral Agent and prospective participants and assignees of Term Loan Commitments or Credit Extensions (which meetings shall be conducted no more often than twice every twelve months unless an Event of Default has occurred and is continuing), and (iii) assist Collateral Agent or the Lenders in the preparation of information relating to the financial affairs of Borrower as any prospective participant or assignee of a Term Loan Commitment or Term Loan reasonably may request. Subject to the provisions of Section 12.9, Borrower authorizes each Lender to disclose to any prospective participant or assignee of a Term Loan Commitment, any and all information in such Lender's possession concerning Borrower and its financial affairs which has been delivered to such Lender by or on behalf of Borrower pursuant to this Agreement, or which has been delivered to such Lender by or on behalf of Borrower in connection with such Lender's credit evaluation of Borrower prior to entering into this Agreement.

13. **DEFINITIONS**

13.1 Definitions. As used in this Agreement, the following terms have the following meanings:

"Account" is any "account" as defined in the Code with such additions to such term as may hereafter be made, and includes, without limitation, all accounts receivable and other sums owing to Borrower.

"Account Debtor" is any "account debtor" as defined in the Code with such additions to such term as may hereafter be made.

"Affiliate" of any Person is a Person that owns or controls directly or indirectly the Person, any Person that controls or is controlled by or is under common control with the Person, and each of that Person's senior executive officers, directors, partners and, for any Person that is a limited liability company, that Person's managers and members.

"Agreement" is defined in the preamble hereof.

"Alexandria Real Estate" means ARE-SD Region No. 35, LLC, a Delaware limited liability company.

"Amortization Date" is, with respect to any Term Loan, April 1, 2020; provided, however, that if a Term C Loan is funded, then the Amortization Date with respect to any Term Loan shall be extended to April 1, 2021.

"Annual Projections" is defined in Section 6.2(a).

"Anti-Terrorism Laws" are any laws relating to terrorism or money laundering, including Executive Order No. 13224 (effective September 24, 2001), the USA PATRIOT Act, the laws comprising or implementing the Bank Secrecy Act, and the laws administered by OFAC.

"Approved Fund" is any (i) investment company, fund, trust, securitization vehicle or conduit that is (or will be) engaged in making, purchasing, holding or otherwise investing in commercial loans and similar extensions of credit in the ordinary course of its business or (ii) any Person (other than a natural person) which temporarily warehouses loans for any Lender or any entity described in the

preceding clause (i) and that, with respect to each of the preceding clauses (i) and (ii), is administered or managed by (a) a Lender, (b) an Affiliate of a Lender or (c) a Person (other than a natural person) or an Affiliate of a Person (other than a natural person) that administers or manages a Lender.

“**Approved Lender**” is defined in Section 12.1.

“**Bank**” is defined in the preamble hereof.

“**Bank Services**” are any products, credit services, and/or financial accommodations previously, now, or hereafter provided to Borrower or any of its Subsidiaries by Bank or any Bank Affiliate, including, without limitation, any letters of credit, cash management services (including, without limitation, merchant services, direct deposit of payroll, business credit cards, and check cashing services), interest rate swap arrangements, and foreign exchange services as any such products or services may be identified in Bank’s various agreements related thereto (each, a “**Bank Services Agreement**”).

“**Basic Rate**” is, with respect to a Term Loan, the per annum rate of interest (based on a year of three hundred sixty (360) days) equal to the sum of (a) the thirty (30) day U.S. LIBOR rate reported in The Wall Street Journal on the last Business Day of the month that immediately precedes the month in which the interest will accrue, plus (b) six and three-quarters of one percent (6.75%). If The Wall Street Journal (or another nationally recognized rate reporting source acceptable to Collateral Agent) no longer reports the U.S. LIBOR Rate or if such interest rate no longer exists or if The Wall Street Journal no longer publishes the U.S. LIBOR Rate or ceases to exist, Collateral Agent may in good faith select a replacement interest rate or replacement publication, as the case may be. Notwithstanding the foregoing, the Basic Rate for the Term Loan for the period from the Effective Date through and including February 28, 2018 shall be 8.32970%.

“**Blocked Person**” is any Person: (a) listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (b) a Person owned or controlled by, or acting for or on behalf of, any Person that is listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (c) a Person with which any Lender is prohibited from dealing or otherwise engaging in any transaction by any Anti-Terrorism Law, (d) a Person that commits, threatens or conspires to commit or supports “terrorism” as defined in Executive Order No. 13224, or (e) a Person that is named a “specially designated national” or “blocked person” on the most current list published by OFAC or other similar list.

“**Borrower**” is defined in the preamble hereof.

“**Borrower’s Books**” are Borrower’s or any of its Subsidiaries’ books and records including ledgers, federal, and state tax returns, records regarding Borrower’s or its Subsidiaries’ assets or liabilities, the Collateral, business operations or financial condition, and all computer programs or storage or any equipment containing such information.

“**Business Day**” is any day that is not a Saturday, Sunday or a day on which Collateral Agent is closed.

“**Cash Equivalents**” are (a) marketable direct obligations issued or unconditionally guaranteed by the United States or any agency or any State thereof having maturities of not more than one (1) year from the date of acquisition; (b) commercial paper maturing no more than one (1) year after its creation and having the highest rating from either Standard & Poor’s Ratings Group or Moody’s Investors Service, Inc., and (c) certificates of deposit maturing no more than one (1) year after issue provided that the account in which any such certificate of deposit is maintained is subject to a Control Agreement in favor of Collateral Agent. For the avoidance of doubt, the direct purchase by Borrower or any of its

Subsidiaries of any Auction Rate Securities, or purchasing participations in, or entering into any type of swap or other derivative transaction, or otherwise holding or engaging in any ownership interest in any type of Auction Rate Security by Borrower or any of its Subsidiaries shall be conclusively determined by the Lenders as an ineligible Cash Equivalent, and any such transaction shall expressly violate each other provision of this Agreement governing Permitted Investments. Notwithstanding the foregoing, Cash Equivalents does not include and Borrower, and each of its Subsidiaries, are prohibited from purchasing, purchasing participations in, entering into any type of swap or other equivalent derivative transaction, or otherwise holding or engaging in any ownership interest in any type of debt instrument, including, without limitation, any corporate or municipal bonds with a long-term nominal maturity for which the interest rate is reset through a dutch auction and more commonly referred to as an auction rate security (each, an “**Auction Rate Security**”).

“**Claims**” are defined in Section 12.2.

“**Code**” is the Uniform Commercial Code, as the same may, from time to time, be enacted and in effect in the State of New York; provided, that, to the extent that the Code is used to define any term herein or in any Loan Document and such term is defined differently in different Articles of the Code, the definition of such term contained in Article 9 shall govern; provided further, that in the event that, by reason of mandatory provisions of law, any or all of the attachment, perfection, or priority of, or remedies with respect to, Collateral Agent’s Lien on any Collateral is governed by the Uniform Commercial Code in effect in a jurisdiction other than the State of New York, the term “Code” shall mean the Uniform Commercial Code as enacted and in effect in such other jurisdiction solely for purposes of the provisions thereof relating to such attachment, perfection, priority, or remedies and for purposes of definitions relating to such provisions.

“**Collateral**” is any and all properties, rights and assets of Borrower described on Exhibit A.

“**Collateral Account**” is any Deposit Account, Securities Account, or Commodity Account, or any other bank account maintained by Borrower or any Subsidiary at any time.

“**Collateral Agent**” is, Oxford, not in its individual capacity, but solely in its capacity as agent on behalf of and for the benefit of the Lenders.

“**Commitment Percentage**” is set forth in Schedule 1.1, as amended from time to time.

“**Commodity Account**” is any “commodity account” as defined in the Code with such additions to such term as may hereafter be made.

“**Communication**” is defined in Section 10.

“**Compliance Certificate**” is that certain certificate in the form attached hereto as Exhibit C.

“**Contingent Obligation**” is, for any Person, any direct or indirect liability, contingent or not, of that Person for (a) any indebtedness, lease, dividend, letter of credit or other obligation of another such as an obligation directly or indirectly guaranteed, endorsed, co-made, discounted or sold with recourse by that Person, or for which that Person is directly or indirectly liable; (b) any obligations for undrawn letters of credit for the account of that Person; and (c) all obligations from any interest rate, currency or commodity swap agreement, interest rate cap or collar agreement, or other agreement or arrangement designated to protect a Person against fluctuation in interest rates, currency exchange rates or commodity prices; but “Contingent Obligation” does not include endorsements in the ordinary course of business. The amount of a Contingent Obligation is the stated or determined amount of the primary obligation for

which the Contingent Obligation is made or, if not determinable, the maximum reasonably anticipated liability for it determined by the Person in good faith; but the amount may not exceed the maximum of the obligations under any guarantee or other support arrangement.

“**Control Agreement**” is any control agreement entered into among the depository institution at which Borrower or any of its Subsidiaries maintains a Deposit Account or the securities intermediary or commodity intermediary at which Borrower or any of its Subsidiaries maintains a Securities Account or a Commodity Account, Borrower and such Subsidiary, and Collateral Agent pursuant to which Collateral Agent obtains control (within the meaning of the Code) for the benefit of the Lenders over such Deposit Account, Securities Account, or Commodity Account.

“**Copyrights**” are any and all copyright rights, copyright applications, copyright registrations and like protections in each work or authorship and derivative work thereof, whether published or unpublished and whether or not the same also constitutes a trade secret.

“**Credit Extension**” is any Term Loan or any other extension of credit by Collateral Agent or Lenders for Borrower’s benefit.

“**Default Rate**” is defined in Section 2.3(b).

“**Deposit Account**” is any “deposit account” as defined in the Code with such additions to such term as may hereafter be made.

“**Designated Deposit Account**” is Borrower’s deposit account, account number [***], maintained with Bank.

“**Disbursement Letter**” is that certain form attached hereto as Exhibit B-1.

“**Dollar Equivalent**” is, at any time, (a) with respect to any amount denominated in Dollars, such amount, and (b) with respect to any amount denominated in a Foreign Currency, the equivalent amount therefor in Dollars as determined by Bank at such time on the basis of the then-prevailing rate of exchange in San Francisco, California, for sales of the Foreign Currency for transfer to the country issuing such Foreign Currency.

“**Dollars,**” “**dollars**” and “**\$**” each mean lawful money of the United States.

“**Effective Date**” is defined in the preamble of this Agreement.

“**Eligible Assignee**” is (i) a Lender, (ii) an Affiliate of a Lender, (iii) an Approved Fund and (iv) any commercial bank, savings and loan association or savings bank or any other entity which is an “accredited investor” (as defined in Regulation D under the Securities Act of 1933, as amended) and which extends credit or buys loans as one of its businesses, including insurance companies, mutual funds, lease financing companies and commercial finance companies, in each case, which either (A) has a rating of BBB or higher from Standard & Poor’s Rating Group and a rating of Baa2 or higher from Moody’s Investors Service, Inc. at the date that it becomes a Lender or (B) has total assets in excess of Five Billion Dollars (\$5,000,000,000.00), and in each case of clauses (i) through (iv), which, through its applicable lending office, is capable of lending to Borrower without the imposition of any withholding or similar taxes; provided that notwithstanding the foregoing, “Eligible Assignee” shall not include, unless an Event of Default has occurred and is continuing, (i) Borrower or any of Borrower’s Affiliates or Subsidiaries or (ii) a direct competitor of Borrower or a vulture hedge fund, each as determined by Collateral Agent. Notwithstanding the foregoing, (x) in connection with assignments by a Lender due to a forced divestiture

at the request of any regulatory agency, the restrictions set forth herein shall not apply and Eligible Assignee shall mean any Person or party and (y) in connection with a Lender's own financing or securitization transactions, the restrictions set forth herein shall not apply and Eligible Assignee shall mean any Person or party providing such financing or formed to undertake such securitization transaction and any transferee of such Person or party upon the occurrence of a default, event of default or similar occurrence with respect to such financing or securitization transaction; provided that no such sale, transfer, pledge or assignment under this clause (y) shall release such Lender from any of its obligations hereunder or substitute any such Person or party for such Lender as a party hereto until Collateral Agent shall have received and accepted an effective assignment agreement from such Person or party in form satisfactory to Collateral Agent executed, delivered and fully completed by the applicable parties thereto, and shall have received such other information regarding such Eligible Assignee as Collateral Agent reasonably shall require.

"Equipment" is all "equipment" as defined in the Code with such additions to such term as may hereafter be made, and includes without limitation all machinery, fixtures, goods, vehicles (including motor vehicles and trailers), and any interest in any of the foregoing.

"ERISA" is the Employee Retirement Income Security Act of 1974, as amended, and its regulations.

"Event of Default" is defined in Section 8.

"Excluded Governmental Approvals" means (i) those certain US Federal grant approvals issued to Borrower from the National Institute of Health issued on July 6, 2017, August 17, 2017 and September 7, 2017, (ii) those certain certificates of occupancy issued to Borrower by the City of Austin, Texas, and (iii) that certain clean water certificate issued to Borrower by the City of Austin, Texas, in each case if the granting of a Lien in such grant approval or certificate is prohibited by or would constitute a default under the documents governing such grant approval or certificate or ordinances, regulations or laws applicable thereto (but (A) only to the extent such prohibition is enforceable under applicable law and (B) other than to the extent that any such term would be rendered ineffective pursuant to Sections 9-406, 9-408 or 9-409 (or any other Section) of Article 9 of the Code); provided that upon the termination, lapsing or expiration of any such prohibition, such grant approval or certificate, as applicable, shall automatically be subject to the security interest granted in favor of Secured Party hereunder and become part of the "Collateral."

"Final Payment" is a payment (in addition to and not a substitution for the regular monthly payments of principal plus accrued interest) due on the earliest to occur of (a) the Maturity Date, or (b) the acceleration of any Term Loan, or (c) the prepayment of a Term Loan pursuant to Section 2.2(c) or (d), equal to the original principal amount of such Term Loan multiplied by the Final Payment Percentage, payable to Lenders in accordance with their respective Pro Rata Shares.

"Final Payment Percentage" is six and one half of one percent (6.50%).

"Foreign Currency" means lawful money of a country other than the United States.

"Foreign Subsidiary" is a Subsidiary that is not an entity organized under the laws of the United States or any territory thereof.

"Funding Date" is any date on which a Credit Extension is made to or on account of Borrower which shall be a Business Day.

“FX Contract” is any foreign exchange contract by and between Borrower and Bank under which Borrower commits to purchase from or sell to Bank a specific amount of Foreign Currency on a specified date.

“GAAP” is generally accepted accounting principles set forth in the opinions and pronouncements of the Accounting Principles Board of the American Institute of Certified Public Accountants and statements and pronouncements of the Financial Accounting Standards Board or in such other statements by such other Person as may be approved by a significant segment of the accounting profession in the United States, which are applicable to the circumstances as of the date of determination.

“General Intangibles” are all “general intangibles” as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made, and includes without limitation, all copyright rights, copyright applications, copyright registrations and like protections in each work of authorship and derivative work, whether published or unpublished, any patents, trademarks, service marks and, to the extent permitted under applicable law, any applications therefor, whether registered or not, any trade secret rights, including any rights to unpatented inventions, payment intangibles, royalties, contract rights, goodwill, franchise agreements, purchase orders, customer lists, route lists, telephone numbers, domain names, claims, income and other tax refunds, security and other deposits, options to purchase or sell real or personal property, rights in all litigation presently or hereafter pending (whether in contract, tort or otherwise), insurance policies (including without limitation key man, property damage, and business interruption insurance), payments of insurance and rights to payment of any kind.

“Governmental Approval” is any consent, authorization, approval, order, license, franchise, permit, certificate, accreditation, registration, filing or notice, of, issued by, from or to, or other act by or in respect of, any Governmental Authority.

“Governmental Authority” is any nation or government, any state or other political subdivision thereof, any agency, authority, instrumentality, regulatory body, court, central bank or other entity exercising executive, legislative, judicial, taxing, regulatory or administrative functions of or pertaining to government, any securities exchange and any self-regulatory organization.

“Guarantor” is any Person providing a Guaranty in favor of Collateral Agent.

“Guaranty” is any guarantee of all or any part of the Obligations, as the same may from time to time be amended, restated, modified or otherwise supplemented.

“Indebtedness” is (a) indebtedness for borrowed money or the deferred price of property or services, such as reimbursement and other obligations for surety bonds and letters of credit, (b) obligations evidenced by notes, bonds, debentures or similar instruments, (c) capital lease obligations, and (d) Contingent Obligations.

“Indemnified Person” is defined in Section 12.2.

“Insolvency Proceeding” is any proceeding by or against any Person under the United States Bankruptcy Code, or any other bankruptcy or insolvency law, including assignments for the benefit of creditors, compositions, extensions generally with its creditors, or proceedings seeking reorganization, arrangement, or other relief.

“Insolvent” means not Solvent.

“Intellectual Property” means all of Borrower’s or any Subsidiary’s right, title and interest in and to the following:

(a) its Copyrights, Trademarks and Patents;

(b) any and all trade secrets and trade secret rights, including, without limitation, any rights to unpatented inventions, know-how, operating manuals;

(c) any and all source code;

(d) any and all design rights which may be available to Borrower;

(e) any and all claims for damages by way of past, present and future infringement of any of the foregoing, with the right, but not the obligation, to sue for and collect such damages for said use or infringement of the Intellectual Property rights identified above; and

(f) all amendments, renewals and extensions of any of the Copyrights, Trademarks or Patents.

“Inventory” is all “inventory” as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made, and includes without limitation all merchandise, raw materials, parts, supplies, packing and shipping materials, work in process and finished products, including without limitation such inventory as is temporarily out of any Person’s custody or possession or in transit and including any returned goods and any documents of title representing any of the above.

“Investment” is any beneficial ownership interest in any Person (including stock, partnership interest or other securities), and any loan, advance, payment or capital contribution to any Person.

“Key Person” is each of Borrower’s (i) Chief Executive Officer, who is Paul Edick as of the Effective Date, (ii) Chief Financial Officer, who is Nora Brennan as of the Effective Date, and (iii) Chief Science Officer, who is Steve Prestrelski as of the Effective Date.

“Lender” is any one of the Lenders.

“Lenders” are the Persons identified on Schedule 1.1 hereto and each assignee that becomes a party to this Agreement pursuant to Section 12.1.

“Lenders’ Expenses” are all audit fees and expenses, costs, and expenses (including reasonable attorneys’ fees and expenses, as well as appraisal fees, fees incurred on account of lien searches, inspection fees, and filing fees) for preparing, amending, negotiating, administering, defending and enforcing the Loan Documents (including, without limitation, those incurred in connection with appeals or Insolvency Proceedings) or otherwise incurred by Collateral Agent and/or the Lenders in connection with the Loan Documents.

“Letter of Credit” is a standby or commercial letter of credit issued by Bank upon request of Borrower based upon an application, guarantee, indemnity, or similar agreement.

“Lien” is a claim, mortgage, deed of trust, levy, charge, pledge, security interest, or other encumbrance of any kind, whether voluntarily incurred or arising by operation of law or otherwise against any property.

“**Loan Documents**” are, collectively, this Agreement, the Warrants, the Perfection Certificates, each Compliance Certificate, each Disbursement Letter, each Loan Payment/Advance Request Form and any Bank Services Agreement, the Post Closing Letter, any subordination agreements, any note, or notes or guaranties executed by Borrower or any other Person, and any other present or future agreement entered into by Borrower, any Guarantor or any other Person for the benefit of the Lenders and Collateral Agent in connection with this Agreement; all as amended, restated, or otherwise modified.

“**Loan Payment/Advance Request Form**” is that certain form attached hereto as Exhibit B-2.

“**Material Adverse Change**” is (a) a material impairment in the perfection or priority of Collateral Agent’s Lien in the Collateral or in the value of such Collateral; (b) a material adverse change in the business, operations or condition (financial or otherwise) of Borrower or any Subsidiary; or (c) a material impairment of the prospect of repayment of any portion of the Obligations.

“**Maturity Date**” is, for each Term Loan, February 1, 2023.

“**Obligations**” are all of Borrower’s obligations to pay when due any debts, principal, interest, Lenders’ Expenses, the Prepayment Fee, the Final Payment, the facility fees, and other amounts Borrower owes the Lenders now or later, in connection with, related to, following, or arising from, out of or under, this Agreement or, the other Loan Documents (other than the Warrants), or otherwise, including, without limitation, all obligations relating to letters of credit (including reimbursement obligations for drawn and undrawn letters of credit), cash management services, and foreign exchange contracts, if any, and including interest accruing after Insolvency Proceedings begin (whether or not allowed) and debts, liabilities, or obligations of Borrower assigned to the Lenders and/or Collateral Agent, and the performance of Borrower’s duties under the Loan Documents (other than the Warrants).

“**OFAC**” is the U.S. Department of Treasury Office of Foreign Assets Control.

“**OFAC Lists**” are, collectively, the Specially Designated Nationals and Blocked Persons List maintained by OFAC pursuant to Executive Order No. 13224, 66 Fed. Reg. 49079 (Sept. 25, 2001) and/or any other list of terrorists or other restricted Persons maintained pursuant to any of the rules and regulations of OFAC or pursuant to any other applicable Executive Orders.

“**Operating Documents**” are, for any Person, such Person’s formation documents, as certified by the Secretary of State (or equivalent agency) of such Person’s jurisdiction of organization on a date that is no earlier than thirty (30) days prior to the Effective Date, and, (a) if such Person is a corporation, its bylaws in current form, (b) if such Person is a limited liability company, its limited liability company agreement (or similar agreement), and (c) if such Person is a partnership, its partnership agreement (or similar agreement), each of the foregoing with all current amendments or modifications thereto.

“**Patents**” means all patents, patent applications and like protections including without limitation improvements, divisions, continuations, renewals, reissues, extensions and continuations-in-part of the same.

“**Payment Date**” is the first (1st) calendar day of each calendar month, commencing on March 1, 2018.

“**Perfection Certificate**” and “**Perfection Certificates**” is defined in Section 5.1.

“**Permitted Acquisition**” means an acquisition pursuant to which Borrower acquires a Person or an ownership interest in a Person through the issuance of Borrower’s capital stock, so long as the number

of shares or the voting power of Borrower's capital stock issued with respect to any one Person is less than twenty percent (20%) of the total shares or voting power of Borrower's capital stock outstanding before the issuance, to the extent that each of the following conditions shall have been satisfied:

(a) immediately prior to, and after giving effect thereto, no Event of Default shall have occurred and be continuing or would result therefrom;

(b) all transactions in connection therewith shall be consummated, in all material respects, in accordance with applicable law;

(c) such acquired Person or assets shall be in the same line of business as is conducted by Borrower as of the Effective Date (or a line of business reasonably related thereto);

(d) such acquisition shall not cause the focus or locations of Borrower's and its Subsidiaries' operations (when taken as a whole) to be located outside of the United States;

(e) in the case of the purchase or other acquisition of Shares, all of the Shares acquired or otherwise issued by such Person or any newly formed Subsidiary in connection with such acquisition shall be wholly owned by Borrower or a Subsidiary;

(f) in connection with such acquisition, neither Borrower nor any of its Subsidiaries (including for this purpose, the target of the acquisition) shall acquire or be subject to any Indebtedness or Liens that are not otherwise permitted hereunder;

(g) all of the consideration paid in connection with such acquisition shall be in the form of stock of Borrower, except that Borrower shall be permitted to pay reasonable closing costs in cash;

(h) Borrower shall have delivered to the Collateral Agent and Lenders at least five (5) Business Days (or such shorter period as may be acceptable to Collateral Agent and Lenders) prior to such proposed acquisition (i) a copy of the purchase agreement related to the proposed acquisition (and any related documents reasonably requested by the Collateral Agent and Lenders), (ii) a general description of the acquired assets or acquired business line or unit or division and the competitive position of such business line or unit or division within the industry, (iii) the sources and uses of funds to finance the proposed acquisition, and (iv) to the extent available, quarterly and annual audited financial statements of the Person whose Shares or assets are being acquired for the twelve (12) month period immediately prior to such proposed acquisition;

(i) such Permitted Acquisition shall only involve assets located in the United States;

(j) Collateral Agent and the Lenders have received a certificate from a Responsible Officer together with Board approved projections certifying and setting forth in reasonable detail that Borrower has enough cash on hand to pay its projected expenses and all debt service when due for a period of twelve (12) months after the consummation of such transaction (after giving effect to such transaction); and

(k) such Permitted Acquisition shall be consensual and shall have been approved by the target's board of directors.

Notwithstanding anything to the contrary contained herein, in order for any acquisition of Shares or assets of another Person to constitute a Permitted Acquisition, Borrower must comply with all of the following:

(a) within five (5) Business Days of the closing of such Permitted Acquisition, the applicable Borrower (or Subsidiary) making such Permitted Acquisition and the target shall have executed such documents and taken such actions as may be required under Section 6.12; (b) the applicable Borrower shall have delivered to Collateral Agent and Lenders, in form and substance satisfactory to the Collateral Agent and Lenders and sufficiently in advance (and in any case no later than five (5) Business Days prior to such Permitted Acquisition), such other financial information, financial analysis, documentation or other information relating to such Permitted Acquisition and the pro forma certifications required by clause (c) below, in each case, as Collateral Agent and Lenders shall reasonably request; (c) on or prior to the date of such Permitted Acquisition, the Collateral Agent and Lenders shall have received, in form and substance reasonably satisfactory to the Collateral Agent and Lenders, a certificate of the chief financial officer of Borrower certifying compliance with the requirements contained in this definition of "Permitted Acquisition" and with the other terms of the Loan Documents (before and after giving effect to such Permitted Acquisition); and (d) Borrower shall provide to the Collateral Agent and Lenders as soon as available but in any event not later than five (5) Business Days after the execution thereof, a copy of the executed purchase agreement or similar agreement with respect to any such acquisition.

"Permitted Indebtedness" is:

- (a) Borrower's Indebtedness to the Lenders and Collateral Agent under this Agreement and the other Loan Documents;
- (b) Indebtedness existing on the Effective Date and disclosed on the Perfection Certificate(s);
- (c) Subordinated Debt;
- (d) unsecured Indebtedness to trade creditors incurred in the ordinary course of business;

(e) Indebtedness consisting of capitalized lease obligations and purchase money Indebtedness, in each case incurred by Borrower or any of its Subsidiaries to finance the acquisition, repair, improvement or construction of fixed or capital assets of such person, provided that (i) the aggregate outstanding principal amount of all such Indebtedness does not exceed One Hundred Thousand Dollars (\$100,000.00) at any time and (ii) the principal amount of such Indebtedness does not exceed the lower of the cost or fair market value of the property so acquired or built or of such repairs or improvements financed with such Indebtedness (each measured at the time of such acquisition, repair, improvement or construction is made);

(f) Indebtedness incurred as a result of endorsing negotiable instruments received in the ordinary course of Borrower's business;

(g) Other unsecured Indebtedness in an aggregate amount outstanding at any time not to exceed Twenty-Five Thousand Dollars (\$25,000.00);

and

(h) extensions, refinancings, modifications, amendments and restatements of any items of Permitted Indebtedness (a) through (e) above, provided that the principal amount thereof is not increased or the terms thereof are not modified to impose materially more burdensome terms upon Borrower, or its Subsidiary, as the case may be.

“Permitted Investments” are:

(a) Investments disclosed on the Perfection Certificate(s) and existing on the Effective Date;

(b) (i) Investments consisting of cash and Cash Equivalents, and (ii) any other Investments permitted by Borrower’s investment policy, as amended from time to time, provided that such investment policy (and any such amendment thereto) has been approved in writing by Collateral Agent;

(c) Investments consisting of the endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of Borrower’s business;

(d) Investments consisting of deposit accounts in which Collateral Agent has a perfected security interest or which are otherwise maintained in compliance with Section 6.6;

(e) Investments in connection with Transfers permitted by Section 7.1;

(f) Investments consisting of (i) travel advances and employee relocation loans and other employee loans and advances in the ordinary course of business, and (ii) loans to employees, officers or directors relating to the purchase of equity securities of Borrower or its Subsidiaries pursuant to employee stock purchase plans or agreements approved by Borrower’s Board of Directors; not to exceed Twenty-Five Thousand Dollars (\$25,000.00) in the aggregate for (i) and (ii) in any fiscal year;

(g) Investments (including debt obligations) received in connection with the bankruptcy or reorganization of customers or suppliers and in settlement of delinquent obligations of, and other disputes with, customers or suppliers arising in the ordinary course of business;

(h) Investments consisting of notes receivable of, or prepaid royalties and other credit extensions, to customers and suppliers who are not Affiliates, in the ordinary course of business; provided that this paragraph (h) shall not apply to Investments of Borrower in any Subsidiary;

(i) non-cash Investments in joint ventures or strategic alliances in the ordinary course of Borrower’s business consisting of the non-exclusive licensing of technology, the development of technology or the providing of technical support;

(j) non-cash Investments in connection with Permitted Acquisitions; and

(k) Investments by Borrower or any Subsidiary in Borrower or any other Subsidiary of Borrower which is a “co-Borrower” hereunder or a Guarantor.

“Permitted Licenses” are (A) licenses of over-the-counter software that is commercially available to the public, and (B) non-exclusive and exclusive licenses for the use of the Intellectual Property of Borrower or any of its Subsidiaries entered into in the ordinary course of business, provided, that, with respect to each such license described in clause (B), (i) no Event of Default has occurred or is continuing at the time of such license; (ii) the license constitutes an arms-length transaction, the terms of which, on their face, do not provide for a sale or assignment of any Intellectual Property and do not restrict the ability of Borrower or any of its Subsidiaries, as applicable, to pledge, grant a security interest in or lien on, or assign or otherwise Transfer any Intellectual Property; (iii) in the case of any exclusive license, (x) Borrower delivers ten (10) days’ prior written notice and a brief summary of the terms of the proposed license to Collateral Agent and the Lenders and delivers to Collateral Agent and the Lenders

copies of the final executed licensing documents in connection with the exclusive license promptly upon consummation thereof, and (y) any such license could not result in a legal transfer of title of the licensed property but may be exclusive in respects other than territory and may be exclusive as to territory only as to discrete geographical areas outside of the United States; and (iv) all upfront payments, royalties, milestone payments or other proceeds arising from the licensing agreement that are payable to Borrower or any of its Subsidiaries are paid to a Deposit Account that is governed by a Control Agreement.

“Permitted Liens” are:

(a) Liens existing on the Effective Date and disclosed on the Perfection Certificates or arising under this Agreement and the other Loan Documents;

(b) Liens for taxes, fees, assessments or other government charges or levies, either (i) not due and payable or (ii) being contested in good faith and for which Borrower maintains adequate reserves on its Books, provided that no notice of any such Lien has been filed or recorded under the Internal Revenue Code of 1986, as amended, and the Treasury Regulations adopted thereunder;

(c) liens securing Indebtedness permitted under clause (e) of the definition of **“Permitted Indebtedness,”** provided that (i) such liens exist prior to the acquisition of, or attach substantially simultaneous with, or within twenty (20) days after the, acquisition, lease, repair, improvement or construction of, such property financed or leased by such Indebtedness and (ii) such liens do not extend to any property of Borrower other than the property (and proceeds thereof) acquired, leased or built, or the improvements or repairs, financed by such Indebtedness;

(d) Liens of carriers, warehousemen, suppliers, or other Persons that are possessory in nature arising in the ordinary course of business so long as such Liens attach only to Inventory, securing liabilities in the aggregate amount not to exceed Fifty Thousand Dollars (\$50,000.00), and which are not delinquent or remain payable without penalty or which are being contested in good faith and by appropriate proceedings which proceedings have the effect of preventing the forfeiture or sale of the property subject thereto;

(e) Liens to secure payment of workers’ compensation, employment insurance, old-age pensions, social security and other like obligations incurred in the ordinary course of business (other than Liens imposed by ERISA);

(f) Liens incurred in the extension, renewal or refinancing of the indebtedness secured by Liens described in (a) through (c), but any extension, renewal or replacement Lien must be limited to the property encumbered by the existing Lien and the principal amount of the indebtedness may not increase;

(g) leases or subleases of real property granted in the ordinary course of Borrower’s business (or, if referring to another Person, in the ordinary course of such Person’s business), and leases, subleases, non-exclusive licenses or sublicenses of personal property (other than Intellectual Property) granted in the ordinary course of Borrower’s business (or, if referring to another Person, in the ordinary course of such Person’s business), if the leases, subleases, licenses and sublicenses do not prohibit granting Collateral Agent or any Lender a security interest therein;

(h) banker’s liens, rights of setoff and Liens in favor of financial institutions incurred in the ordinary course of business arising in connection with Borrower’s deposit accounts or securities accounts held at such institutions solely to secure payment of fees and similar costs and expenses and provided such accounts are maintained in compliance with Section 6.6(b) hereof;

(i) Liens arising from judgments, decrees or attachments in circumstances not constituting an Event of Default under Section 8.4 or 8.7;

(j) Liens on Borrower's deposit accounts held at JPM Chase securing Borrower's obligations with respect to certain undrawn letters of credit in an aggregate amount not to exceed the lesser of (i) \$143,000, and (ii) the then current face amount of such letters of credit;

(k) Liens consisting of landlord liens, so long as each such landlord is party to a landlord agreement in favor of Collateral Agent, in form and substance reasonably satisfactory to Collateral Agent; and

(l) Liens consisting of Permitted Licenses.

"Person" is any individual, sole proprietorship, partnership, limited liability company, joint venture, company, trust, unincorporated organization, association, corporation, institution, public benefit corporation, firm, joint stock company, estate, entity or government agency.

"Post Closing Letter" is that certain Post Closing Letter dated as of the Effective Date by and between Collateral Agent and Borrower.

"Prepayment Fee" is, with respect to any funded Term Loan subject to prepayment prior to the Amortization Date, whether by mandatory or voluntary prepayment, acceleration or otherwise, an additional fee payable to the Lenders in amount equal to:

(i) for a prepayment made on or after the Funding Date of such Term Loan through the Amortization Date, one and one half of one percent (1.50%) of the principal amount of such Term Loan prepaid; and

(ii) for a prepayment made on or after the Amortization Date, no Prepayment Fee shall be applicable.

"Pro Rata Share" is, as of any date of determination, with respect to each Lender, a percentage (expressed as a decimal, rounded to the ninth decimal place) determined by dividing the outstanding principal amount of Term Loans held by such Lender by the aggregate outstanding principal amount of all Term Loans.

"Registered Organization" is any "registered organization" as defined in the Code with such additions to such term as may hereafter be made.

"Required Lenders" means (i) for so long as all of the Persons that are Lenders on the Effective Date (each an **"Original Lender"**) have not assigned or transferred any of their interests in their Term Loan, Lenders holding one hundred percent (100%) of the aggregate outstanding principal balance of the Term Loan, or (ii) at any time from and after any Original Lender has assigned or transferred any interest in its Term Loan, Lenders holding at least sixty six percent (66%) of the aggregate outstanding principal balance of the Term Loan and, in respect of this clause (ii), (A) each Original Lender that has not assigned or transferred any portion of its Term Loan, (B) each assignee or transferee of an Original Lender's interest in the Term Loan, but only to the extent that such assignee or transferee is an Affiliate or Approved Fund of such Original Lender, and (C) any Person providing financing to any Person described in clauses (A) and (B) above; provided, however, that this clause (C) shall only apply upon the occurrence of a default, event of default or similar occurrence with respect to such financing.

“Requirement of Law” is as to any Person, the organizational or governing documents of such Person, and any law (statutory or common), treaty, rule or regulation or determination of an arbitrator or a court or other Governmental Authority, in each case applicable to or binding upon such Person or any of its property or to which such Person or any of its property is subject.

“Responsible Officer” is any of the President, Chief Executive Officer, Chief Financial Officer, Corporate Controller, or Senior Director of Finance of Borrower acting alone.

“Second Draw Condition” is the NDA submission of G-Pen.

“Second Draw Period” is the period commencing on the date of the occurrence of the Second Draw Condition and ending on the earliest of (i) September 30, 2018, (ii) the thirtieth day following the occurrence of the Second Draw Condition, and (iii) the occurrence of an Event of Default; provided, however, that the Second Draw Period shall not commence if on the date of the occurrence of the Second Draw Condition an Event of Default has occurred and is continuing.

“Secured Promissory Note” is defined in Section 2.4.

“Secured Promissory Note Record” is a record maintained by each Lender with respect to the outstanding Obligations owed by Borrower to Lender and credits made thereto.

“Securities Account” is any “securities account” as defined in the Code with such additions to such term as may hereafter be made.

“Shares” is one hundred percent (100%) of the issued and outstanding capital stock, membership units or other securities owned or held of record by Borrower or Borrower’s Subsidiary, in any Subsidiary.

“Solvent” is, with respect to any Person: the fair salable value of such Person’s consolidated assets (including goodwill minus disposition costs) exceeds the fair value of such Person’s liabilities; such Person is not left with unreasonably small capital after the transactions in this Agreement; and such Person is able to pay its debts (including trade debts) as they mature.

“Subordinated Debt” is indebtedness incurred by Borrower or any of its Subsidiaries subordinated to all Indebtedness of Borrower and/or its Subsidiaries to the Lenders (pursuant to a subordination, intercreditor, or other similar agreement in form and substance satisfactory to Collateral Agent and the Lenders entered into between Collateral Agent, Borrower, and/or any of its Subsidiaries, and the other creditor), on terms acceptable to Collateral Agent and the Lenders.

“Subsidiary” is, with respect to any Person, any Person of which more than fifty percent (50%) of the voting stock or other equity interests (in the case of Persons other than corporations) is owned or controlled, directly or indirectly, by such Person or through one or more intermediaries.

“Term Loan” is defined in Section 2.2(a)(iii) hereof.

“Term A Loan” is defined in Section 2.2(a)(i) hereof.

“Term B Loan” is defined in Section 2.2(a)(ii) hereof.

“Term C Loan” is defined in Section 2.2(a)(iii) hereof.

“**Term Loan Commitment**” is, for any Lender, the obligation of such Lender to make a Term Loan, up to the principal amount shown on Schedule 1.1.

“**Term Loan Commitments**” means the aggregate amount of such commitments of all Lenders.

“**Third Draw Condition**” is the NDA approval of G-Pen.

“**Third Draw Period**” is the period commencing on the date of the occurrence of the Third Draw Condition and ending on the earliest of (i) September 30, 2019, (ii) the thirtieth day following the occurrence of the Third Draw Condition, and (iii) the occurrence of an Event of Default; provided, however, that the Third Draw Period shall not commence if on the date of the occurrence of the Third Draw Condition an Event of Default has occurred and is continuing.

“**Trademarks**” means any trademark and servicemark rights, whether registered or not, applications to register and registrations of the same and like protections, and the entire goodwill of the business of Borrower connected with and symbolized by such trademarks.

“**Transfer**” is defined in Section 7.1.

“**Warrants**” are those certain Warrants to Purchase Stock dated as of the Effective Date, or any date thereafter, issued by Borrower in favor of each Lender or such Lender’s Affiliates.

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IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the Effective Date.

BORROWER:

XERIS PHARMACEUTICALS, INC.

By: /s/ Nora Brennan
Name: Nora Brennan
Title: CFO

COLLATERAL AGENT AND LENDER:

OXFORD FINANCE LLC

By: /s/ Colette H. Featherly
Name: Colette H. Featherly
Title: Senior Vice President

LENDER:

SILICON VALLEY BANK..

By: /s/ Michael White
Name: Michael White
Title: Managing Director, Head of BD

[Signature Page to Loan and Security Agreement]

SCHEDULE 1.1

Lenders and Commitments

Term A Loans

<u>Lender</u>	<u>Term Loan Commitment</u>	<u>Commitment Percentage</u>
OXFORD FINANCE LLC	\$ 11,111,111.11	55.55555555%
SILICON VALLEY BANK	\$ 8,888,888.89	44.44444445%
TOTAL	\$20,000,000.00	100.00%

Term B Loans

<u>Lender</u>	<u>Term Loan Commitment</u>	<u>Commitment Percentage</u>
OXFORD FINANCE LLC	\$ 8,333,333.33	55.55555555%
SILICON VALLEY BANK	\$ 6,666,666.67	44.44444445%
TOTAL	\$15,000,000.00	100.00%

Term C Loans

<u>Lender</u>	<u>Term Loan Commitment</u>	<u>Commitment Percentage</u>
OXFORD FINANCE LLC	\$ 5,555,555.55	55.55555555%
SILICON VALLEY BANK	\$ 4,444,444.45	44.44444445%
TOTAL	\$10,000,000.00	100.00%

Aggregate (all Term Loans)

<u>Lender</u>	<u>Term Loan Commitment</u>	<u>Commitment Percentage</u>
OXFORD FINANCE LLC	\$24,999,999.99	55.55555555%
SILICON VALLEY BANK	\$20,000,000.01	44.44444445%
TOTAL	\$45,000,000.00	100.00%

EXHIBIT A

Description of Collateral

The Collateral consists of all of Borrower's right, title and interest in and to the following personal property:

All goods, Accounts (including health-care receivables), Equipment, Inventory, contract rights or rights to payment of money, leases, license agreements, franchise agreements, General Intangibles (except as noted below), commercial tort claims, documents, instruments (including any promissory notes), chattel paper (whether tangible or electronic), cash, deposit accounts and other Collateral Accounts, all certificates of deposit, fixtures, letters of credit rights (whether or not the letter of credit is evidenced by a writing), securities, and all other investment property, supporting obligations, and financial assets, whether now owned or hereafter acquired, wherever located; and All Borrower's Books relating to the foregoing, and any and all claims, rights and interests in any of the above and all substitutions for, additions, attachments, accessories, accessions and improvements to and replacements, products, proceeds and insurance proceeds of any or all of the foregoing.

Notwithstanding the foregoing, the Collateral does not include (i) any Intellectual Property; provided, however, the Collateral shall include all Accounts and all proceeds of Intellectual Property; provided that if a judicial authority (including a U.S. Bankruptcy Court) would hold that a security interest in the underlying Intellectual Property is necessary to have a security interest in such Accounts and such property that are proceeds of Intellectual Property, then the Collateral shall automatically, and effective as of the Effective Date, include the Intellectual Property to the extent necessary to permit perfection of Collateral Agent's security interest in such Accounts and such other property of Borrower that are proceeds of the Intellectual Property; (ii) any Equipment or other property financed by a third party, provided that such third party's Liens are Liens of the type described in subsection (c) of the definition of Permitted Liens if the granting of a Lien in such Equipment or other property financed is prohibited by or would constitute a default under any agreement or document governing such Equipment or property financed; provided that the aggregate value of all such Equipment or property financed does not exceed One Hundred Thousand Dollars (\$100,000.00); provided further that upon the termination, lapsing or expiration of any such prohibition, such Equipment or other property financed, as applicable, shall automatically be subject to the security interest granted in favor of Collateral Agent hereunder and become part of the "Collateral"; (iii) any Excluded Governmental Approvals; and (iv) any lease, license or contract, in each case if the granting of a Lien in such lease, license or contract is prohibited by or would constitute a default under the agreement governing such lease, license or contract (but (A) only to the extent such prohibition is enforceable under applicable law and (B) other than to the extent that any such term would be rendered ineffective pursuant to Sections 9-406, 9-408 or 9-409 (or any other Section) of Article 9 of the Code); provided that upon the termination, lapsing or expiration of any such prohibition, such lease, license or contract, as applicable, shall automatically be subject to the security interest granted in favor of Collateral Agent hereunder and become part of the "Collateral."

Pursuant to the terms of a certain negative pledge arrangement with Collateral Agent and the Lenders, Borrower has agreed not to encumber any of its Intellectual Property.

EXHIBIT B-1

Form of Disbursement Letter

[see attached]

DISBURSEMENT LETTER

[DATE]

The undersigned, being the duly elected and acting _____ of _____ XERIS PHARMACEUTICALS, INC., a Delaware corporation with offices located at 180 North LaSalle Street, Suite 1800, Chicago, IL 60601 ("**Borrower**"), does hereby certify to **OXFORD FINANCE LLC** ("**Oxford**" and "**Lender**"), as collateral agent (the "**Collateral Agent**") in connection with that certain Loan and Security Agreement dated as of February 28, 2018, by and among Borrower, Collateral Agent and the Lenders from time to time party thereto (the "**Loan Agreement**"; with other capitalized terms used below having the meanings ascribed thereto in the Loan Agreement) that:

1. The representations and warranties made by Borrower in Section 5 of the Loan Agreement and in the other Loan Documents are true and correct in all material respects as of the date hereof.
2. No event or condition has occurred that would constitute an Event of Default under the Loan Agreement or any other Loan Document.
3. Borrower is in compliance with the covenants and requirements contained in Sections 4, 6 and 7 of the Loan Agreement.
4. All conditions referred to in Section 3 of the Loan Agreement to the making of the Loan to be made on or about the date hereof have been satisfied or waived by Collateral Agent.
5. No Material Adverse Change has occurred.
6. The undersigned is a Responsible Officer.

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7. The proceeds of the Term [A][B][C] Loan shall be disbursed as follows:

Disbursement from Oxford:		
Loan Amount		\$
Plus:		
—Deposit Received		\$
Less:		
—Facility Fee		(\$)
[—Interim Interest		(\$)]
—Lender’s Legal Fees		(\$)*
Net Proceeds due from Oxford:		\$
Disbursement from SVB:		
Loan Amount		\$
Plus:		
—Deposit Received		\$
Less:		
—Facility Fee		(\$)
[—Interim Interest		(\$)]
Net Proceeds due from SVB:		\$
TOTAL TERM [A] [B] [C] LOAN NET PROCEEDS FROM LENDERS		\$

8. The [Term A Loan][Term B Loan][Term C Loan] shall amortize in accordance with the Amortization Table attached hereto.

9. The aggregate net proceeds of the Term Loans shall be transferred to the Designated Deposit Account as follows:

[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

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* Legal fees and costs are through the Effective Date. Post-closing legal fees and costs, payable after the Effective Date, to be invoiced and paid post-closing.

Dated as of the date first set forth above.

BORROWER:

XERIS PHARMACEUTICALS, INC.

By: _____
Name:
Title:

COLLATERAL AGENT AND LENDER:

OXFORD FINANCE LLC

By: _____
Name:
Title:

LENDER:

SILICON VALLEY BANK

By: _____
Name:
Title:

[Signature Page to Disbursement Letter]

AMORTIZATION TABLE

(Term [A][B][C] Loan)

[see attached]

[Signature Page to Disbursement Letter]

EXHIBIT B-2

Loan Payment/Advance Request Form

DEADLINE FOR SAME DAY PROCESSING IS 2:00 P.M. EASTERN TIME*

Fax To:

Date: _____

LOAN PAYMENT:

XERIS PHARMACEUTICALS, INC.

From Account # _____ To Account # _____
 (Deposit Account #) (Loan Account #)

Principal \$ _____ and/or Interest \$ _____

Authorized Signature: _____ Phone Number: _____

Print Name/Title: _____

LOAN ADVANCE:

Complete *Outgoing Wire Request* section below if all or a portion of the funds from this loan advance are for an outgoing wire.

From Account # _____ To Account # _____
 (Loan Account #) (Deposit Account #)

Amount of Advance \$ _____

All Borrower's representations and warranties in the Loan and Security Agreement are true, correct and complete in all material respects on the date of the request for an advance; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date:

Authorized Signature: _____ Phone Number: _____

Print Name/Title: _____

OUTGOING WIRE REQUEST:

Complete only if all or a portion of funds from the loan advance above is to be wired.

Deadline for same day processing is noon, Pacific Time

Beneficiary Name: _____ Amount of Wire: \$ _____
 Beneficiary Bank: _____ Account Number: _____
 City and State: _____

Beneficiary Bank Transit (ABA) #: _____ Beneficiary Bank Code (Swift, Sort, Chip, etc.): _____
(For International Wire Only)
 Intermediary Bank: _____ Transit (ABA) #: _____

For Further Credit to: _____

Special Instruction: _____

By signing below, I (we) acknowledge and agree that my (our) funds transfer request shall be processed in accordance with and subject to the terms and conditions set forth in the agreements(s) covering funds transfer service(s), which agreements(s) were previously received and executed by me (us).

Authorized Signature: _____ 2nd Signature (if required): _____
 Print Name/Title: _____ Print Name/Title: _____
 Telephone #: _____ Telephone #: _____

EXHIBIT C

Compliance Certificate

TO: OXFORD FINANCE LLC, as Collateral Agent and Lender
SILICON VALLEY BANK, as Lender

FROM: XERIS PHARMACEUTICALS, INC.

The undersigned authorized officer (“**Officer**”) of XERIS PHARMACEUTICALS, INC. (“**Borrower**”), hereby certifies that in accordance with the terms and conditions of the Loan and Security Agreement by and among Borrower, Collateral Agent, and the Lenders from time to time party thereto (the “**Loan Agreement**,” capitalized terms used but not otherwise defined herein shall have the meanings given them in the Loan Agreement),

(a) Borrower is in complete compliance for the period ending _____ with all required covenants except as noted below;

(b) There are no Events of Default, except as noted below;

(c) Except as noted below, all representations and warranties of Borrower stated in the Loan Documents are true and correct in all material respects on this date and for the period described in (a), above; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date.

(d) Borrower, and each of Borrower’s Subsidiaries, has timely filed all required tax returns and reports, Borrower, and each of Borrower’s Subsidiaries, has timely paid all foreign, federal, state, and local taxes, assessments, deposits and contributions owed by Borrower, or Subsidiary, except as otherwise permitted pursuant to the terms of Section 5.8 of the Loan Agreement;

(e) No Liens have been levied or claims made against Borrower or any of its Subsidiaries relating to unpaid employee payroll or benefits of which Borrower has not previously provided written notification to Collateral Agent and the Lenders.

Attached are the required documents, if any, supporting our certification(s). The Officer, on behalf of Borrower, further certifies that the attached financial statements are prepared in accordance with Generally Accepted Accounting Principles (GAAP) and are consistently applied from one period to the next except as explained in an accompanying letter or footnotes and except, in the case of unaudited financial statements, for the absence of footnotes and subject to year-end audit adjustments as to the interim financial statements.

Please indicate compliance status since the last Compliance Certificate by circling Yes, No, or N/A under "Complies" column.

	Reporting Covenant	Requirement	Actual	Complies		
1)	Financial statements	Monthly within 30 days, or Quarterly within 45 days, as applicable	Yes	No	N/A	
2)	Annual (CPA Audited) statements	Within 180 days after FYE	Yes	No	N/A	
3)	Annual Financial Projections/Budget (prepared on a quarterly basis)	Annually (within 30 days of FYE), and when revised	Yes	No	N/A	
4)	A/R & A/P agings	If applicable	Yes	No	N/A	
5)	8-K, 10-K and 10-Q Filings	If applicable, within 5 days of filing	Yes	No	N/A	
6)	Compliance Certificate	Monthly within 30 days, or Quarterly within 45 days, as applicable	Yes	No	N/A	
7)	IP Report	When required	Yes	No	N/A	
8)	Total amount of Borrower's cash and cash equivalents at the last day of the measurement period		\$	Yes	No	N/A
9)	Total amount of Borrower's Subsidiaries' cash and cash equivalents at the last day of the measurement period		\$	Yes	No	N/A
10)	Updated Exhibit A to Landlord Waiver	Quarterly within 30 days, and in any month where new Collateral in excess of \$100,000 was delivered to 3033 Science Park Road, San Diego, CA 92121	Yes	No	N/A	

Deposit and Securities Accounts

(Please list all accounts; attach separate sheet if additional space needed)

	Institution Name	Account Number	New Account?		Account Control	Agreement in Place?
1)			Yes	No	Yes	No
2)			Yes	No	Yes	No
3)			Yes	No	Yes	No
4)			Yes	No	Yes	No

Other Matters

- 1) Have there been any changes in management since the last Compliance Certificate? Yes No
- 2) Have there been any transfers/sales/disposals/retirement of Collateral or IP prohibited by the Loan Agreement? Yes No

- 3) Have there been any new or pending claims or causes of action against Borrower that involve more than One Hundred Thousand Dollars (\$100,000.00)? Yes No
- 4) Have there been any amendments of or other changes to the capitalization table of Borrower and to the Operating Documents of Borrower or any of its Subsidiaries? If yes, provide copies of any such amendments or changes with this Compliance Certificate. Yes No

Exceptions

Please explain any exceptions with respect to the certification above: (If no exceptions exist, state "No exceptions." Attach separate sheet if additional space needed.)

XERIS PHARMACEUTICALS, INC.

By: _____
Name:
Title:

Date:

LENDER USE ONLY

Received by: _____ Date: _____
Verified by: _____ Date: _____
Compliance Status: Yes No

EXHIBIT D

Form of Secured Promissory Note

[see attached]

SECURED PROMISSORY NOTE
(Term [A][B][C] Loan)

\$

Dated: [DATE]

FOR VALUE RECEIVED, the undersigned, XERIS PHARMACEUTICALS, INC., a Delaware corporation with offices located at 180 North LaSalle Street, Suite 1800, Chicago, IL 60601 (“**Borrower**”) HEREBY PROMISES TO PAY to the order of [OXFORD FINANCE LLC][SILICON VALLEY BANK] (“**Lender**”) the principal amount of [] MILLION DOLLARS (\$) or such lesser amount as shall equal the outstanding principal balance of the Term [A][B][C] Loan made to Borrower by Lender, plus interest on the aggregate unpaid principal amount of such Term [A][B][C] Loan, at the rates and in accordance with the terms of the Loan and Security Agreement dated February 28, 2018 by and among Borrower, Lender, Oxford Finance LLC, as Collateral Agent, and the other Lenders from time to time party thereto (as amended, restated, supplemented or otherwise modified from time to time, the “**Loan Agreement**”). If not sooner paid, the entire principal amount and all accrued and unpaid interest hereunder shall be due and payable on the Maturity Date as set forth in the Loan Agreement. Any capitalized term not otherwise defined herein shall have the meaning attributed to such term in the Loan Agreement.

Principal, interest and all other amounts due with respect to the Term [A][B][C] Loan, are payable in lawful money of the United States of America to Lender as set forth in the Loan Agreement and this Secured Promissory Note (this “**Note**”). The principal amount of this Note and the interest rate applicable thereto, and all payments made with respect thereto, shall be recorded by Lender and, prior to any transfer hereof, endorsed on the grid attached hereto which is part of this Note.

The Loan Agreement, among other things, (a) provides for the making of a secured Term [A][B][C] Loan by Lender to Borrower, and (b) contains provisions for acceleration of the maturity hereof upon the happening of certain stated events.

This Note may not be prepaid except as set forth in Section 2.2 (c) and Section 2.2(d) of the Loan Agreement.

This Note and the obligation of Borrower to repay the unpaid principal amount of the Term [A][B][C] Loan, interest on the Term [A][B][C] Loan and all other amounts due Lender under the Loan Agreement is secured under the Loan Agreement.

Presentment for payment, demand, notice of protest and all other demands and notices of any kind in connection with the execution, delivery, performance and enforcement of this Note are hereby waived.

Borrower shall pay all reasonable fees and expenses, including, without limitation, reasonable attorneys’ fees and costs, incurred by Lender in the enforcement or attempt to enforce any of Borrower’s obligations hereunder not performed when due.

This Note shall be governed by, and construed and interpreted in accordance with, the internal laws of the State of New York.

The ownership of an interest in this Note shall be registered on a record of ownership maintained by Lender or its agent. Notwithstanding anything else in this Note to the contrary, the right to the principal of, and stated interest on, this Note may be transferred only if the transfer is registered on such record of ownership and the transferee is identified as the owner of an interest in the obligation. Borrower shall be entitled to treat the registered holder of this Note (as recorded on such record of ownership) as the owner in fact thereof for all purposes and shall not be bound to recognize any equitable or other claim to or interest in this Note on the part of any other person or entity.

[Balance of Page Intentionally Left Blank]

IN WITNESS WHEREOF, Borrower has caused this Note to be duly executed by one of its officers thereunto duly authorized on the date hereof.

BORROWER:

XERIS PHARMACEUTICALS, INC.

By: _____
Name:
Title:

LOAN INTEREST RATE AND PAYMENTS OF PRINCIPAL

Date

Principal Amount

Interest Rate

Scheduled
Payment Amount

Notation By

CORPORATE BORROWING CERTIFICATE

BORROWER: XERIS PHARMACEUTICALS, INC.

DATE: February , 2018

LENDERS: OXFORD FINANCE LLC, as Collateral Agent and Lender
SILICON VALLEY BANK, as Lender

I hereby certify as follows, as of the date set forth above:

1. I am the Secretary, Assistant Secretary or other officer of Borrower. My title is as set forth below.
2. Borrower's exact legal name is set forth above. Borrower is a corporation existing under the laws of the State of Delaware.
3. Attached hereto as Exhibit A and Exhibit B, respectively, are true, correct and complete copies of (i) Borrower's Certificate of Incorporation (including amendments), as filed with the Secretary of State of the state in which Borrower is incorporated as set forth in paragraph 2 above; and (ii) Borrower's Bylaws. Neither such Certificate of Incorporation nor such Bylaws have been amended, annulled, rescinded, revoked or supplemented, and such Certificate of Incorporation and such Bylaws remain in full force and effect as of the date hereof.
4. The following resolutions were duly and validly adopted by Borrower's Board of Directors at a duly held meeting of such directors (or pursuant to a unanimous written consent or other authorized corporate action). Such resolutions are in full force and effect as of the date hereof and have not been in any way modified, repealed, rescinded, amended or revoked, and the Lenders may rely on them until each Lender receives written notice of revocation from Borrower.

[Balance of Page Intentionally Left Blank]

RESOLVED, that **any one** of the following officers or employees of Borrower, whose names, titles and signatures are below, may act on behalf of Borrower:

<u>Name</u>	<u>Title</u>	<u>Signature</u>	<u>Authorized to Add or Remove Signatories</u>
Paul Edick	Chief Executive Officer		
Nora Brennan	Chief Financial Officer		
John Shannon	Chief Operating Officer		

RESOLVED FURTHER, that **any one** of the persons designated above with a checked box beside his or her name may, from time to time, add or remove any individuals to and from the above list of persons authorized to act on behalf of Borrower.

RESOLVED FURTHER, that such individuals may, on behalf of Borrower:

Borrow Money. Borrow money from the Lenders.

Execute Loan Documents. Execute any loan documents any Lender requires.

Grant Security. Grant Collateral Agent a security interest in any of Borrower's assets.

Negotiate Items. Negotiate or discount all drafts, trade acceptances, promissory notes, or other indebtedness in which Borrower has an interest and receive cash or otherwise use the proceeds.

Issue Warrants. Issue warrants for Borrower's capital stock.

Further Acts. Designate other individuals to request advances, pay fees and costs and execute other documents or agreements (including documents or agreement that waive Borrower's right to a jury trial) they believe to be necessary to effectuate such resolutions.

RESOLVED FURTHER, that all acts authorized by the above resolutions and any prior acts relating thereto are ratified.

[Balance of Page Intentionally Left Blank]

5. The persons listed above are Borrower's officers or employees with their titles and signatures shown next to their names.

By: _____
Name:
Title:

**** If the Secretary, Assistant Secretary or other certifying officer executing above is designated by the resolutions set forth in paragraph 4 as one of the authorized signing officers, this Certificate must also be signed by a second authorized officer or director of Borrower.*

I, the _____ of Borrower, hereby certify as to paragraphs 1 through 5 above, as of the date set forth above.
[print title]

By: _____
Name:
Title:

EXHIBIT A

Certificate of Incorporation (including amendments)

[see attached]

EXHIBIT B

Bylaws

[see attached]

DEBTOR:
SECURED PARTY:

XERIS PHARMACEUTICALS, INC.
OXFORD FINANCE LLC,
as Collateral Agent

EXHIBIT A TO UCC FINANCING STATEMENT

Description of Collateral

The Collateral consists of all of Debtor's right, title and interest in and to the following personal property:

All goods, Accounts (including health-care receivables), Equipment, Inventory, contract rights or rights to payment of money, leases, license agreements, franchise agreements, General Intangibles (except as noted below), commercial tort claims, documents, instruments (including any promissory notes), chattel paper (whether tangible or electronic), cash, deposit accounts and other Collateral Accounts, all certificates of deposit, fixtures, letters of credit rights (whether or not the letter of credit is evidenced by a writing), securities, and all other investment property, supporting obligations, and financial assets, whether now owned or hereafter acquired, wherever located; and All Debtor's Books relating to the foregoing, and any and all claims, rights and interests in any of the above and all substitutions for, additions, attachments, accessories, accessions and improvements to and replacements, products, proceeds and insurance proceeds of any or all of the foregoing.

Notwithstanding the foregoing, the Collateral does not include (i) any Intellectual Property; provided, however, the Collateral shall include all Accounts and all proceeds of Intellectual Property; provided that if a judicial authority (including a U.S. Bankruptcy Court) would hold that a security interest in the underlying Intellectual Property is necessary to have a security interest in such Accounts and such property that are proceeds of Intellectual Property, then the Collateral shall automatically, and effective as of the Effective Date, include the Intellectual Property to the extent necessary to permit perfection of Secured Party's security interest in such Accounts and such other property of Debtor that are proceeds of the Intellectual Property; (ii) any Equipment or other property financed by a third party, provided that such third party's Liens are Liens of the type described in subsection (c) of the definition of Permitted Liens if the granting of a Lien in such Equipment or other property financed is prohibited by or would constitute a default under any agreement or document governing such Equipment or property financed; provided that the aggregate value of all such Equipment or property financed does not exceed One Hundred Thousand Dollars (\$100,000.00); provided further that upon the termination, lapsing or expiration of any such prohibition, such Equipment or other property financed, as applicable, shall automatically be subject to the security interest granted in favor of Collateral Agent hereunder and become part of the "Collateral"; (iii) any Excluded Governmental Approvals; and (iv) any lease, license or contract, in each case if the granting of a Lien in such lease, license or contract is prohibited by or would constitute a default under the agreement governing such lease, license or contract (but (A) only to the extent such prohibition is enforceable under applicable law and (B) other than to the extent that any such term would be rendered ineffective pursuant to Sections 9-406, 9-408 or 9-409 (or any other Section) of Article 9 of the Code); provided that upon the termination, lapsing or expiration of any such prohibition, such lease, license or contract, as applicable, shall automatically be subject to the security interest granted in favor of Secured Party hereunder and become part of the "Collateral."

Pursuant to the terms of a certain negative pledge arrangement with Secured Party and the Lenders, Debtor has agreed not to encumber any of its Intellectual Property.

Capitalized terms used but not defined herein have the meanings ascribed in the Uniform Commercial Code in effect in the State of New York as in effect from time to time (the "Code") or, if not defined in the Code, then in the Loan and Security Agreement by and between Debtor, Secured Party and the other Lenders party thereto (as modified, amended and/or restated from time to time).