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

FORM 10-Q

(Mark One)

☑ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2018

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 001-38536

XERIS PHARMACEUTICALS, INC.

(Exact Name of the Registrant as Specified in Its Charter)

Delaware	**20-3352427**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification Number)
180 N. LaSalle Street, Suite 1810 Chicago, Illinois	**60601**
(Address of Principal Executive Offices)	(Zip Code)

(844) 445-5704

(Registrant's Telephone Number, Including Area Code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☐ No ☑

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☑ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting 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 ☐	Accelerated filer ☐
Non-accelerated filer ☑ (Do not check if a smaller reporting company)	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. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Class	Shares Outstanding at June 30, 2018
Common Stock, $0.0001 par value per share	20,817,313

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

XERIS PHARMACEUTICALS, INC.
Condensed Balance Sheets
(in thousands, except share and par value)

	June 30, 2018	December 31, 2017
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 134,528	$ 42,045
Accounts receivable, net	1,065	1,199
Prepaid expenses and other current assets	1,439	809
Total current assets	137,032	44,053
Property and equipment, net	1,136	788
Other assets	88	157
Total assets	$ 138,256	$ 44,998
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 556	$ 1,976
Accrued expenses	7,542	2,557
Warrant liabilities	807	93
Deferred grant award	284	234
Total current liabilities	9,189	4,860
Long-term debt, net of unamortized deferred costs	18,167	—
Other long-term liabilities	1,563	90
Total liabilities	28,919	4,950
Commitments and Contingencies (Note 8)		
Convertible Preferred Stock:		
Series A Convertible Preferred Stock—par value $0.0001, 1,864,797 shares authorized and 1,843,965 shares issued and outstanding as of December 31, 2017	—	1,945
Series B Convertible Preferred Stock—par value $0.0001, 5,732,338 shares authorized and 5,696,834 shares issued and outstanding as of December 31, 2017	—	18,536
Series C Convertible Preferred Stock—par value $0.0001, 14,353,859 shares authorized and 12,834,912 shares issued and outstanding as of December 31, 2017	—	77,397
Total convertible preferred stock	—	97,878
Stockholders' Equity (Deficit)		
Preferred stock—par value $0.0001, 10,000,000 shares authorized as of June 30, 2018 and no shares issued and outstanding as of June 30, 2018	—	—
Common stock—par value $0.0001, 150,000,000 and 30,450,994 shares authorized as of June 30, 2018 and December 31, 2017, respectively; 20,688,457 and 2,159,068 shares issued and outstanding as of June 30, 2018 and December 31, 2017, respectively	2	1
Additional paid in capital	194,813	2,754
Accumulated deficit	(85,478)	(60,585)
Total stockholders' equity (deficit)	109,337	(57,830)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 138,256	$ 44,998

The accompanying notes are an integral part of the condensed financial statements.

XERIS PHARMACEUTICALS, INC.
Condensed Statements of Operations
(in thousands, except share and per share data; unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	**2017**	**2018**	**2017**
Grant income	$ 819	$ 549	$ 1,029	$ 903
Service revenue	—	16	53	16
Cost of revenue	—	4	42	4
Gross profit	819	561	1,040	915
Operating expenses:				
Research and development	8,677	4,201	17,389	7,863
General and administrative	4,499	1,559	7,738	2,900
Expense from operations	13,176	5,760	25,127	10,763
Loss from operations	(12,357)	(5,199)	(24,087)	(9,848)
Other (expense) income:				
Interest income	238	—	334	—
Interest expense	(562)	(1)	(753)	(1)
Change in fair value of warrants	(306)	(32)	(388)	(32)
Total other expense	(630)	(33)	(807)	(33)
Net loss	$ (12,987)	$ (5,232)	$ (24,894)	$ (9,881)
Net loss per common share - basic and diluted	$ (3.07)	$ (2.59)	$ (7.76)	$ (4.92)
Weighted average common shares outstanding, basic and diluted	4,231,054	2,022,240	3,205,998	2,010,236

The accompanying notes are an integral part of the condensed financial statements.

XERIS PHARMACEUTICALS, INC.
Condensed Statements of Cash Flows
(in thousands; unaudited)

	Six Months Ended June 30,	
	2018	**2017**
Cash flows from operating activities:		
Net loss	$ (24,894)	$ (9,881)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	141	71
Amortization of debt issuance costs	156	—
Stock-based compensation	605	247
Change in fair value of warrants	388	32
Changes in operating assets and liabilities		
Accounts receivable	134	(490)
Prepaid expenses and other current assets	(629)	437
Other assets	69	(43)
Accounts payable	(1,420)	(926)
Accrued expenses	3,261	555
Deferred grant award	50	—
Deferred rent	112	12
Net cash used in operating activities	(22,027)	(9,986)
Cash flows from investing activities:		
Purchases of property and equipment	(489)	(439)
Net cash used in investing activities	(489)	(439)
Cash flows from financing activities:		
Proceeds from Initial Public Offering	98,325	—
Payments for Initial Public Offering costs	(7,588)	—
Proceeds from sale of Series C Preferred Stock	4,438	30,050
Payments of Series C Preferred Stock offering costs	(24)	(428)
Proceeds from issuance of long-term debt	20,000	—
Payment of debt issuance costs	(238)	—
Proceeds from exercise of stock awards	86	31
Net cash provided by financing activities	114,999	29,653
Increase in cash and cash equivalents	92,483	19,228
Cash and cash equivalents, beginning of period	42,045	32,269
Cash and cash equivalents, end of period	$ 134,528	$ 51,497
Supplemental schedule of cash flow information:		
Cash paid for interest	$ 451	$ —
Supplemental schedule of non-cash investing and financing activities:		
Allocation of debt proceeds to warrants	$ 326	$ —
Deferred Initial Public Offering costs within accrued expenses	$ 1,735	$ —
Accrued debt issuance costs	$ 1,425	$ —
Vesting of early exercised awards	$ 75	$ —

The accompanying notes are an integral part of the condensed financial statements.

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 that address important unmet medical needs, 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 operations through the issuance of common stock in its June 2018 initial public offering ("IPO"), issuance of convertible preferred stock and other equity instruments, issuance of debt and grant funding from the National Institutes of Health ("NIH") and other philanthropic organizations.

The Company has not generated any revenue from product sales. The Company has incurred operating losses since inception and has an accumulated deficit of $85.5 million as of June 30, 2018. The Company expects to continue to incur net losses for the next several years. Based on the Company's current operating plans and existing working capital at June 30, 2018 combined with the $15.0 million in additional expected proceeds from the second tranche of the Loan and Security Agreement, cash is sufficient to sustain operations and capital expenditure requirements through at least the first quarter of 2021. 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, 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

The accompanying unaudited interim financial statements have been prepared in conformity with GAAP. Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

In the opinion of management, the accompanying unaudited interim financial statements include all normal and recurring adjustments (which consist primarily of accruals and estimates that impact the financial statements) considered necessary to present fairly the Company's financial position as of June 30, 2018 and its results of operations and cash flows for the six months ended June 30, 2018 and 2017. Operating results for the three and six month periods ended June 30, 2018 are not necessarily indicative of the results that may be expected for the year ending December 31, 2018. The unaudited interim financial statements, presented herein, do not contain the required disclosures under GAAP for annual financial statements. The accompanying unaudited interim financial statements should be read in conjunction with the audited financial statements and the related notes thereto for the year ended December 31, 2017 included in the prospectus (Registration No. 333-225191) filed pursuant to Rule 424(b) on June 21, 2018 with the U.S. Securities and Exchange Commission.

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, contingent liabilities and expenses included in the financial statements and accompanying notes. Actual results could differ from those estimates.

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 statements 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 impact of the key items specified above and thus it reported provisional amounts for these items. In accordance with Staff Accounting Bulletin No. 118 ("SAB 118"), the Company provides 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 as of December 31, 2017, 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 U.S. 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 business and financial statements. The effective date of most of the provisions of the Tax Act applies to the Company's tax year beginning January 1, 2018. The Company 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.

Debt issuance costs

Long-term debt is accounted for at amortized cost. Debt issuance costs incurred in connection with financing arrangements are amortized to interest expense over the life of the respective financing arrangement using the effective interest method. Debt issuance costs, net of related amortization, are deducted from the carrying value of the related debt.

IPO costs

The Company capitalizes costs that are directly associated with in-process equity financings until such financings are consummated, at which time such costs are recorded in the additional paid in capital line on the balance sheet against the gross proceeds of the IPO. As of June 30, 2018, the Company capitalized approximately $9.3 million in IPO costs.

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 be made. Additionally, fair value is used on a non-recurring 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 assumptions are used when estimating fair value. The carrying amounts of certain of the Company's financial instruments, including cash and cash equivalents, accounts receivable, prepaid expenses and other current assets, and accounts payable, are shown at cost, which approximates fair value due to the short-term nature of these instruments. The debt outstanding under the Loan and Security Agreement approximates fair value due to the variable interest rate on the debt. Items measured at fair value on a recurring basis include the Company's warrants.

Net loss per common 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 outstanding during the period. For all periods presented, the outstanding shares of the preferred stock, warrants, and stock awards have been excluded from the calculation because their effects would be anti-dilutive. Therefore, the weighted average common shares outstanding used to calculate both basic and diluted loss per common share are the same.

The following potentially dilutive securities (shown below in common stock equivalent shares) were excluded from the computation of diluted weighted average common shares outstanding due to their anti-dilutive effect:

	As of June 30,	
	2018	2017
Convertible preferred stock	—	10,954,012
Warrants	73,651	19,931
Stock awards and unvested stock awards	2,541,262	1,957,432

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 being recognized as income tax expense in the reporting period in which they occur; 2) excess tax benefits being 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 adopted this standard on January 1, 2018 and did not have an impact on the financial statements.

Note 3. Reverse Stock Split and Initial Public Offering

On June 8, 2018, the Company effectuated a 1-for-1.78112 reverse stock split of its outstanding common stock, which was approved by the Company's board of directors on May 22, 2018 and by the Company's stockholders on June 8, 2018. The reverse stock split resulted in an adjustment to the preferred stock conversion prices to reflect a proportional decrease in the number of shares of common stock to be issued upon conversion. The accompanying financial statements and notes to the financial statements give retroactive effect to the reverse stock split for all periods presented. The shares of common stock retained a par value of $0.0001 per share. Accordingly, the stockholders' deficit reflects the reverse stock split by reclassifying from common stock to additional paid in capital an amount equal to the par value of the decreased shares resulting from the reverse stock split.

On June 25, 2018, the Company closed the IPO of its common stock pursuant to a registration statement on Form S-1, as amended. The Company sold an aggregate of 6,555,000 shares of common stock under the registration statement at a public offering price of $15.00 per share, including 855,000 shares of common stock pursuant to the exercise of the underwriters' option to purchase additional shares. Net proceeds from the offering were approximately $89.0 million, after deducting underwriting discounts and commissions, as well as other offering expenses.

Upon closing the IPO, all outstanding shares of the Company's Series A, B and C convertible preferred stock were converted into 11,837,073 shares of common stock.

Note 4. Accrued Expenses

Accrued expenses consist of the following:

(in thousands)	June 30, 2018	December 31, 2017
Accrued research costs	$ 2,500	$ 566
Accrued employee costs	1,995	1,581
Accrued IPO costs	1,735	—
Accrued other costs	1,312	410
Accrued expenses	$ 7,542	$ 2,557

Note 5. Long-term Debt

Senior Secured Loan Facility

In February 2018, the Company entered into the Loan and Security Agreement that provides a senior secured loan facility of up to an aggregate principal amount of $45.0 million. The first tranche was $20.0 million and was drawn down in February 2018 ("Term A Loan"). The second tranche is $15.0 million and is available to us through the 30th day following our submission of a New Drug Application ("NDA") for our Glucagon Rescue Pen. The third tranche is $10.0 million and is available beginning upon approval of the Company's Glucagon Rescue Pen NDA by the U.S. Food & Drug Administration ("FDA") until the earlier of September 30, 2019 or the 30th day following NDA approval by the FDA.

The interest rate under the Loan and Security Agreement is the thirty-day U.S. LIBOR rate plus 6.75%, which was approximately 8.75% as of June 30, 2018. Payments on the Loan and Security 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 fifty-nine months, and the principal payments will begin in either 36 months or 24 months, contingent on the third tranche being drawn.

Pursuant to the Loan and Security Agreement, the Company provided a first priority security interest in all existing and future-acquired assets, excluding intellectual property and certain other assets, owned by the Company. The Loan and Security Agreement contains a negative pledge on intellectual property owned by the Company. The Company also issued warrants to the Lenders to purchase common stock, which is further discussed in Note 7, "Warrants," of the notes to unaudited condensed financial statements.

The Loan and Security 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. Prior to April 1, 2020, the Company is subject to a prepayment penalty equal to 1.50% of the principal amount being prepaid. In the event the Company draws on the third tranche, the period subject to 1.50% prepayment is extended to April 1, 2021. No prepayment fee exists for prepayments made after April 1, 2020, or April 1, 2021 in the event the third tranche is issued. 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 and Security Agreement, the acceleration of the Loan and Security Agreement or prepayment of such borrowings. The Loan and Security 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 elects not to draw the third tranche.

The Loan and Security Agreement also contains customary indemnification obligations and customary events of default, including, among other things, failure to fulfill certain obligations under the Loan and Security Agreement and the occurrence of a material adverse change in the Company's 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 under the Loan and Security Agreement, the Company would be required to pay interest on principal and all other due and unpaid obligations at the current rate in effect plus 5%. All such interest would be payable on demand and in cash. Further, the Lenders would be entitled to exercise their remedies thereunder, including the right to accelerate the debt, upon which the Company may be required to repay all amounts then outstanding under the Loan and Security Agreement.

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

The components of debt are as follows:

(in thousands)	**June 30, 2018**	**December 31, 2017**
Term A Loan	$ 20,000	$ —
Less unamortized deferred cost	(1,833)	—
Long-term debt	$ 18,167	$ —

The following table sets forth the Company's future principal payments:

2018	$	—
2019		—
2020		4,680
2021		6,725
2022		7,315
2023		1,280
	$	20,000

The Company incurred debt issuance costs of $1.9 million, which are reflected as a direct reduction to the term loan balance and are being amortized into interest expense over the life of the loan using the effective interest method. For the three and six months ended June 30, 2018, the Company recognized interest expense of $562,000 and $753,000, respectively, of which $116,000 and $156,000, respectively, was related to the amortization of debt issuance costs.

Note 6. Convertible Preferred Stock

In February 2018, the Company issued an additional 707,680 shares of Series C convertible preferred stock for net proceeds of $4.4 million.

During the second quarter of 2018, a majority of the holders of the Company's convertible preferred stock elected to have their shares converted into common stock, therefore, all outstanding shares of preferred stock were converted into 11,837,073 shares of common stock at a conversion rate of 1:1.78112 upon the closing of the Company's IPO on June 25, 2018. Refer to Note 3, "Reverse Stock Split and Initial Public Offering," of the notes to unaudited condensed financial statements for additional information.

Prior to the conversion of the convertible preferred stock into common stock, the holders of the Company's convertible preferred stock were 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. No such dividends were declared by the Company's Board of Directors. The holders of the convertible preferred stock also were entitled to participate pro rata in any dividends paid to the holders of the common stock on an as-converted basis. No dividends were declared by the Company's Board of Directors.

Note 7. Warrants

In 2014 the Company issued 19,931 warrants ("2014 Warrants") to certain investors. The 2014 Warrants allow each holder to purchase one share of common stock for $5.912. There have been no exercises of 2014 Warrants and as such all 19,931 warrants were outstanding as of June 30, 2018.

As part of the Loan and Security Agreement discussed in Note 5, "Long-term Debt," in the notes to unaudited condensed financial statements, the Lenders shall receive warrant coverage equal to 3.0% of the principal borrowing amounts. The warrants will represent a right for the lender to purchase shares of the Company's common stock at an initial exercise price of $11.169 per share. The Company issued 53,720 warrants ("Term A Warrants") upon the drawdown of the Term A Loan in February 2018. There have been no exercises of Term A Warrants and as such all 53,720 warrants were outstanding as of June 30, 2018.

Because the warrants are a freestanding instrument, indexed to the Company's stock, they do not meet the criteria for equity classification. Therefore warrants are liability classified and subject to remeasurement at each reporting period until they are exercised, expired, or otherwise settled. The initial fair value of the warrant liability was recorded with a corresponding offset to deferred debt cost which is a reduction to the notional value of the debt.

The Company recognized a loss of $133,000 and $173,000 upon the change in fair value of the warrants during the three months ended June 30, 2018 related to the 2014 Warrants and the Term A Warrants, respectively. The Company recognized a loss of $178,000 and $210,000 upon the change in fair value of the warrants during the six months ended June 30, 2018 related to the 2014 Warrants and the Term A Warrants, respectively. The Company recognized a loss of $32,000 upon the change in fair value of the 2014 Warrants during the three months and six months ended June 30, 2017.

As of June 30, 2018, the following warrants were outstanding:

	Outstanding Shares	Exercise Price per Share	Expiration Date
2014 Warrants	19,931	$5.912	August 2020
Term A Warrants	53,720	$11.169	February 2025
	73,651		

Note 8. Commitments and Contingencies

Commitments

The Company has non-cancellable operating leases for office space, which expire at various times through 2024. The non-cancellable office lease agreements provide for monthly lease payments, which increase during the term of each lease agreement. In the first quarter of 2018, the Company signed a new lease for office space in Chicago, Illinois with remaining future minimum lease payments of approximately $98,000 in 2018, $202,000 in 2019, $210,000 in 2020, $219,000 in 2021, $228,000 in 2022, $462,000 in 2023 and thereafter.

Total rent expense under these operating leases was approximately $229,000 and $131,000 for the three months ended June 30, 2018 and 2017, respectively, and $420,000 and $171,000 for the six months ended June 30, 2018 and 2017, respectively.

Note 9. Stock Compensation Plan

In 2011 the Company adopted the 2011 Stock Option Issuance Plan (“2011 Plan”) and subsequently amended it to authorize the Board of Directors to issue up to 4,714,982 incentive grant and non-statutory awards. Options and restricted stock granted to employees under the 2011 Plan typically vest over a 48 months period. Options and restricted stock granted to non-employee directors vest over a 24 months period. All stock awards typically expire 10 years after they were issued.

The 2018 Stock Option and Incentive Plan ("2018 Plan") was adopted by our Board of Directors in April 2018 and approved by our stockholders in June 2018 to award up to 1,822,000 shares of our common stock. This plan became effective on the date immediately prior to the effectiveness of the Company's IPO registration statement. The 2018 Plan replaced the 2011 Plan as our Board of Directors determined not to make additional awards under the 2011 Plan following the closing of our IPO, which occurred in June 2018. 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). As of June 30, 2018, there were 1,822,000 awards available for future issuance.

Stock options are granted with an exercise price equal to the market price of the Company’s stock at the date of grant. Stock option awards typically vest between two and four years after the grant date and expire ten years from the grant date.

The fair value of each option is estimated on the date of grant using a Black-Scholes option valuation model that uses the assumptions noted in the following table. The expected life of options represents the period of time that options granted are expected to be outstanding. The risk-free interest rate for periods during the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant. For fiscal 2018, the expected volatility is based on the historical volatility of certain peer companies over the most recent period corresponding to the expected life as of the grant date. The expected dividend yield is based on the expected annual dividend as a percentage of the market value of the Company’s ordinary shares as of the grant date. The Company uses historical data to estimate option exercises and employee terminations within the valuation model.

The fair value of stock options granted was estimated with the following weighted average assumptions:

	Six Months Ended June 30,	
	2018	2017
Expected term	6.00	6.07
Risk-free interest rate	2.77 %	2.05 %
Expected volatility	63.22 %	61.23 %
Expected dividends	—	—

Stock option activity for employee awards for the six months ended June 30, 2018 is as follows:

	UNITS	WEIGHTED AVERAGE EXERCISE PRICE	WEIGHTED AVERAGE CONTRACTUAL LIFE (YEARS)
Outstanding - January 1, 2018	1,946,230	$ 1.66	8.70
Issued	868,620	9.18	
Exercised	(121,869)	1.64	
Forfeited	(169,403)	1.90	
Outstanding - June 30, 2018	2,523,578	4.36	8.76
Exercisable - June 30, 2018	2,365,024	4.40	8.76
Vested and expected to vest at June 30, 2018	2,232,758	4.26	8.72

The weighted-average fair value of awards granted during the six months ended June 30, 2018 was $3.80 per share. The total intrinsic value of options exercised during the six months ended June 30, 2018 was $1.2 million. The aggregate intrinsic value of awards vested and expected to vest as of June 30, 2018 was $32.9 million.

The Company also granted stock options to non-employees. These awards are marked to fair value at the end of each reporting period until they vest. Stock option activity for these awards for the six months ended June 30, 2018 is as follows:

	UNITS	WEIGHTED AVERAGE EXERCISE PRICE	WEIGHTED AVERAGE CONTRACTUAL LIFE (YEARS)
Outstanding - January 1, 2018	33,125	$ 1.91	6.75
Issued	—	—	
Exercised	(17,699)	2.83	
Forfeited	—	—	
Outstanding - June 30, 2018	15,426	4.74	4.63
Exercisable - June 30, 2018	13,474	0.95	4.63
Vested and expected to vest at June 30, 2018	13,474	0.95	4.63

The aggregate intrinsic value of awards vested and expected to vest at June 30, 2018 was $243,000. The aggregate intrinsic value of awards exercisable as of June 30, 2018 was $227,000. The company recognized expense associated with these awards of $50,000 and $2,000 for the three months ended June 30, 2018 and 2017, respectively. The company recognized expense associated with these awards of $106,000 and $9,000 for the six months ended June 30, 2018 and 2017, respectively.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	**2018**	**2017**	**2018**	**2017**
Research and development	$ 161	$ 15	$ 282	$ 30
General and administrative	200	74	323	217
Total stock-based compensation	$ 361	$ 89	$ 605	$ 247

At June 30, 2018, there was a total of $4.8 million of unrecognized compensation expense that is expected to be recognized over a weighted average period of 1.47 years.

Note 10. 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 active markets for similar assets or liabilities, quoted prices for identical or similar assets or liabilities in markets that are not active, or inputs, other than quoted prices in active markets, that are observable either directly or indirectly; and

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 is 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, (c) current market conditions, and (d) 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 December 31, 2017	$	93
Fair value of Term A Warrants issued under the Loan and Security Agreement		326
Change in fair value of warrants		82
Balance at March 31, 2018		501
Change in fair value of warrants		306
Balance at June 30, 2018	$	807

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Cautionary Statements for Forward-Looking Information

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 Quarterly Report on Form 10-Q and with the audited financial statements and the related notes thereto for the year ended December 31, 2017 included in the prospectus (Registration No. 333-225191) filed pursuant to Rule 424(b) on June 21, 2018 with the U.S. Securities and Exchange Commission. In addition to financial information, the following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. All statements in this document other than statements of historical fact are, or could be, "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "will," "would," and "continue" and terms of similar meaning are also generally intended to identify forward-looking statements. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include, but are not limited to, those discussed in Item 1A of Part II of this Quarterly Report on Form 10-Q. Any forward-looking statements contained in this press release speak only as of the date hereof, and Xeris expressly disclaims any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

Overview

Unless otherwise indicated, references to "Xeris," the "Company," "we," "our" and "us" in this Quarterly Report on Form 10-Q refer to Xeris Pharmaceuticals, Inc.

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 have submitted a New Drug Application, or NDA, to the U.S. Food & Drug Administration, or the FDA, in the third quarter of 2018. If our NDA is 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.

We have begun building out our commercial organization, including individuals in operations and marketing as well as medical affairs in preparation for a commercial launch of the Glucagon Rescue Pen in the United States in the second half of 2019. Outside 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 of 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 Institutes of Health ("NIH") and other philanthropic organizations. In particular, we have received cash proceeds of $104.9 million from sales of our preferred stock, $20.0 million from the issuance of a drawdown of the Loan and Security Agreement, and $10.0 million from grant awards from the NIH and other philanthropic organizations. In addition, in June 2018, we completed an initial public offering ("IPO") of our common stock pursuant to a registration statement on Form S-1, as amended. We sold an aggregate of 6,555,000 shares of our common stock under the registration statement at a public offering price of $15.00 per share, including 855,000 shares of our common stock pursuant to the exercise of the underwriters' option to purchase additional shares. Net proceeds were approximately $89.0 million, after deducting underwriting discounts and commissions as well as other offering expenses. The Loan and Security Agreement includes an additional $15.0 million that is available to us through the 30th day following our submission of an NDA for our Glucagon Rescue Pen and $10.0 million that 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 three months ended June 30, 2018 and 2017, our net loss was $13.0 million and $5.2 million, respectively. For the six months ended June 30, 2018 and 2017, our net loss was $24.9 million and $9.9 million, respectively. We have not been profitable since inception, and as of June 30, 2018, our accumulated deficit was $85.5 million. In the near term, we expect to continue to incur significant expenses, operating losses and net losses as we:

- prepare for a potential commercial launch of our Glucagon Rescue Pen, including hiring our sales force;
- continue our research and development efforts;
- seek regulatory approval for new product candidates and product enhancements;
- 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 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 and cost of 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 June 30, 2018, we are eligible to receive $1.9 million in grants from the NIH and other philanthropic organizations that will help fund our ongoing clinical development for intermittent and chronic glucagon programs as well as our auto-injectable diazepam program for the treatment of epileptic 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 the formulation of such parties' proprietary drugs.

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 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 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 (i) complete clinical development of our Glucagon Rescue Pen; (ii) progress our intermittent and chronic glucagon programs for Post-Bariatric Hypoglycemia, Congenital Hyperinsulinism, Hypoglycemia-Associated Autonomic Failure and Exercise-Induced Hypoglycemia; (iii) initiate clinical development for our ready-to-use diazepam rescue pen; and (iv) conduct additional preclinical work for our Pramlintide-Insulin program. 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 conduct new clinical trials and prepare regulatory filings for our product candidates and add headcount to support these efforts.

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

As a public company, we anticipate that 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 in the United States, if approved, including the build out of a sales force in 2019.

Interest Expense and Other Income

Other income consists primarily of interest expense related to our Loan and Security Agreement, interest income earned on short term deposits and the change in the fair market value of our warrants. We expect to draw down another $15.0 million in 2018 from our existing Loan and Security Agreement, and as a result of those borrowings, we expect interest expense to increase in 2018.

Results of Operations

The following table summarizes our results of operations for the three and six months ended June 30, 2018 and 2017:

(in thousands)	Three Months Ended June 30,			Six Months Ended June 30,		
	2018	2017	(Decrease) Increase	2018	2017	(Decrease) Increase
Grant income	$ 819	$ 549	$ 270	$ 1,029	$ 903	$ 126
Service revenue	—	16	(16)	53	16	37
Cost of revenue	—	4	(4)	42	4	38
Gross profit	819	561	258	1,040	915	125
Operating expenses:						
Research and development	8,677	4,201	4,476	17,389	7,863	9,526
General and administrative	4,499	1,559	2,940	7,738	2,900	4,838
Expense from operations	13,176	5,760	7,416	25,127	10,763	14,364
Loss from operations	(12,357)	(5,199)	(7,158)	(24,087)	(9,848)	(14,239)
Other income (expense):						
Interest income	238	—	238	334	—	334
Interest expense	(562)	(1)	(561)	(753)	(1)	(752)
Change in fair value of warrants	(306)	(32)	(274)	(388)	(32)	(356)
Total other expense	(630)	(33)	(597)	(807)	(33)	(774)
Net loss	$ (12,987)	$ (5,232)	$ (7,755)	$ (24,894)	$ (9,881)	$ (15,013)

Gross Profit

Gross profit increased for the three and six month periods ended June 30, 2018 in comparison with the three and six month periods ended June 30, 2017 due to increased grant-funded activities performed during the current period.

Research and Development

The following table summarizes our research and development expenses by functional area for the three and six months ended June 30, 2018 and 2017:

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Clinical and preclinical	$ 2,165	$ 1,677	$ 6,038	$ 2,651
Product development	4,415	1,925	7,866	3,854
Compensation and related personnel costs	1,936	584	3,203	1,328
Stock-based compensation	161	15	282	30
Total research and development expenses	$ 8,677	$ 4,201	$ 17,389	$ 7,863

The following table summarizes our research and development expenses by program for the three and six months ended June 30, 2018 and 2017:

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Glucagon Rescue Pen	$ 3,942	$ 2,228	$ 9,032	$ 4,157
Intermittent and chronic glucagon programs	773	682	1,770	1,503
Additional pipeline programs	528	—	930	—
Overhead (personnel, facilities and other expenses)	3,434	1,291	5,657	2,203
Total research and development expenses	$ 8,677	$ 4,201	$ 17,389	$ 7,863

Research and development expense increased $4.5 million for the three months ended June 30, 2018 in comparison to the three months ended June 30, 2017 and $9.5 million for the six months ended June 30, 2018 in comparison to the six months ended June 30, 2017. These increases were primarily driven by an increase in expenses associated with our clinical and preclinical trials, increased personnel expenses due to additional headcount, an increase in expenses related to product development, and professional service costs incurred supporting the preparation of our Glucagon Rescue Pen NDA filing.

General and Administrative

General and administrative costs increased $2.9 million for the three months ended June 30, 2018 in comparison to the three months ended June 30, 2017. These increases were primarily driven by increases in personnel expenses due to additional headcount and other employee related costs of $1.3 million as well as marketing and market research expenses of $0.7 million.

General and administrative costs increased $4.8 million for the six months ended June 30, 2018 in comparison to the six months ended June 30, 2017. These increases were primarily driven by increases in personnel expenses due to additional headcount and other employee related costs of $2.9 million as well as marketing and market research expenses of $1.3 million.

Other Income (Expense)

For the three and six months ended June 30, 2018, interest expense related to our debt issuance in February 2018 was $562,000 and $753,000, respectively. Interest income for the three and six months ended June 30, 2018, was $238,000 and $334,000, respectively, as excess cash has been held in interest bearing accounts. In addition, the fair market value of our warrants increased for the three and six months ended June 30, 2018 by $274,000 and $356,000, respectively. The change in fair value of warrants increases as the fair value of the stock that it converts into increases.

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, issuance of debt, and grants awarded from the NIH and other philanthropic organizations. On June 25, 2018, we completed our IPO of 6,555,000 shares of our common stock at a price of $15.00 per share for aggregate gross proceeds of approximately $98.3 million, including 855,000 shares of our common

stock pursuant to the exercise of the underwriters' option to purchase additional shares. We received aggregate net proceeds from the offering of approximately $89.0 million, after deducting underwriting discounts and commissions as well as other offering expenses. As of June 30, 2018, we have $1.9 million in awarded unused grants that can be utilized to offset program costs for several of our intermittent and chronic glucagon programs as well as our diazepam program, 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 $85.5 million at June 30, 2018. We believe that our cash and cash equivalents together with the available proceeds from our credit facilities and the proceeds from our IPO will enable us to sustain operations and capital expenditure requirements through at least the first quarter of 2021. 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. Our ability to fund our product development and clinical operations, including completion of our planned Phase 2 and Phase 3 clinical trials, as well as commercialization of our product candidates will depend on the amount and timing of cash received from planned financings. 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, we may need to delay or curtail our operations until such funding is received, which would have a material adverse impact on our business prospects and results of operations.

Cash Flows

	Six Months Ended June 30,	
(in thousands)	**2018**	**2017**
Net cash used in operating activities	$ (22,027)	$ (9,986)
Net cash used in investing activities	(489)	(439)
Net cash provided by financing activities	114,999	29,653
Increase in cash and cash equivalents	$ 92,483	$ 19,228

The increase in cash used in operating activities for the six month period ended June 30, 2018 was primarily due to our net loss adjusted for non-cash charges. The increase in net cash used in operating activities primarily related to increased spending in research and development and general and administrative operating expenses. For a discussion regarding the increase in spending, refer to "Results of Operations" included in Item 2, "Management's Discussion and Analysis of Financial Condition and Results of Operations."

The increase in cash provided by financing activities for the six month period ended June 30, 2018 was primarily due to the net proceeds from the IPO of approximately $90.7 million after deducting payments for IPO costs, net proceeds from the Loan and Security Agreement of $19.8 million and net proceeds from the sale of Series C Preferred Stock of $4.4 million, partially offset by net proceeds from the sale of Series C Preferred Stock of $29.6 million in the prior year.

Contractual Obligations and Commitments

As of June 30, 2018, we were obligated to pay the following amounts:

(in thousands)	TOTAL	2018	2019-2020	2021-2023	2024 and Beyond
Operating leases	$ 6,603	$ 573	$ 2,106	$ 3,556	$ 368
Future principal payments under Loan and Security Agreement	$ 20,000	$ —	$ 4,680	$ 15,320	$ —

We enter into contracts in the normal course of business with clinical trial sites, manufacturing organizations and 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.

Off-Balance Sheet Arrangements

As of June 30, 2018, we had unused letters of credit of $143,000 that are used to secure leases.

CRITICAL ACCOUNTING POLICIES AND THE USE OF ESTIMATES

Our management's discussion and analysis of our financial condition and results of operations on our financial statements 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.

Our significant accounting policies are described in Note 2, "Summary of Significant Accounting Policies," in the notes to unaudited condensed financial statements.

New Accounting Standards

Refer to Note 2, "Summary of Significant Accounting Policies," of the notes to unaudited condensed financial statements, for a description of recent accounting pronouncements applicable to our financial statements.

ITEM 3. 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 one-percentage point increase or decrease in interest rates applicable to our cash and cash equivalents outstanding at June 30, 2018 would increase or decrease interest income by approximately $1.3 million on an annual basis.

Loan and Security Agreement—Our interest rate risk relates primarily to U.S. dollar LIBOR-indexed borrowings. Based on our outstanding borrowings at June 30, 2018, a one-percentage point increase or decrease in interest rates would affect interest expense on the debt by $0.2 million on an annualized basis.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended ("Exchange Act"). Based upon their evaluation of these disclosure controls and procedures, the principal executive officer and principal financial officer concluded that the disclosure controls and procedures were effective as of June 30, 2018 to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time period specified in the U.S. Securities and Exchange Commission's ("SEC") rules and forms, and to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding disclosure.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the three months ended June 30, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not currently subject to any material legal proceedings. From time to time, we may be subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Although the results of litigation and claims cannot be predicted with certainty, as of the date of this report, we do not believe we are party to any claim or litigation the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

ITEM 1A. RISK FACTORS

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, borrowings under the Loan and Security Agreement that we entered into with Oxford Finance LLC and Silicon Valley Bank, and our initial public offering in June 2018, or our IPO. 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. For the three months ended June 30, 2018 and 2017, we reported a net loss of $13.0 million and $5.2 million, respectively. For the six months ended June 30, 2018 and 2017, we reported a net loss of $24.9 million and $9.9 million, respectively. In addition, our accumulated deficit as of June 30, 2018 was $85.5 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.

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. We only recently submitted a New Drug Application, or NDA, for our Glucagon Rescue Pen in the third quarter of 2018, and there is no guarantee that the U.S. Food and Drug Administration, or FDA, will accept our application or approve our Glucagon Rescue Pen. Our ability to generate revenue from our product candidates and to transition to profitability and generate positive cash flows is uncertain 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 may 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 may 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 our current cash resources 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. Our current cash resources 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 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. 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 and Security Agreement is secured by substantially all of our existing property and assets other than our intellectual property assets, subject to certain exceptions. Our Loan and Security 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 and Security 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 available to us through the 30th day following our submission of an NDA for our Glucagon Rescue Pen. 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 and Security 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 and Security 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 and Security 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 and Security 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. The FDA may not accept our Glucagon Rescue Pen NDA 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. We submitted an NDA for the Glucagon Rescue Pen in the third quarter of 2018, however, 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. 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 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 an 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 an NDA is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval. As we submitted an 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 an 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;
- 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 those of our Glucagon Rescue Pen or any of our other product candidates (as applicable);
- 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.

In December 2017 we presented to the FDA at our pre-NDA meeting the results from our two Phase 3 Glucagon Rescue Pen clinical trials that had been completed as of that meeting. 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 modified ITT ("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 this pre-NDA meeting. 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 pre-filled syringe presentation of our Glucagon Rescue Pen. Based on these comments, we conducted additional studies, the results from which were included 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, the results of which were included in our NDA submission. Even though we completed this Phase 3b clinical trial, 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 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 an 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, there could be delays in the approval process due to the increased complexity of the review process and the lack of a well-established review process and criteria. 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;
- 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;
- 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 four indications for our product candidates, which are our ready-to-use glucagon for Post-Bariatric Hypoglycemia and congenital hyperinsulinism, and our ready-to-use diazepam for acute repetitive seizures and Dravet Syndrome. 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 an 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 the 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 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.

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 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 are 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 is 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 market 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 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 we are able to do so, such collaborators may not 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 products 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;
- 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.

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. We submitted the NDA for our Glucagon Rescue Pen to the FDA for approval under Section 505(b)(2) of the FDCA in the third quarter of 2018. Eli Lilly submitted an NDA to the FDA and a Marketing Authorization Application to the European Medicines Agency for its intranasal glucagon in 2018. 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 an 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.

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 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 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.* 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 some state laws 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 may 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 and 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 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 groups' 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, and 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 active pharmaceutical ingredient ("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 supply agreements with Bachem and Pyramid and a joint development agreement with SHL Pharma and intend to enter into a supply agreement with 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, and 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 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 long-term supply arrangements or lack of 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 geo-political 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.

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 and/or 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;
- 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 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 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.

An 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 submitted our NDA for our Glucagon Rescue Pen in the third quarter of 2018 under Section 505(b)(2) of the FDCA, and we expect to submit NDAs for our other product candidates, to the FDA for approval under that section. Section 505(b)(2) permits the submission of an 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. An 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 did not submit any Paragraph IV certifications in connection with our 505(b)(2) NDA for our Glucagon Rescue Pen, and do not expect to submit any Paragraph IV certifications for 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. In addition, 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 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. 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 June 30, 2018, we had 60 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 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 Select 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.

Prior to our IPO, we had 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 Select 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 or 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 Select 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.

We are 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 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. Despite our implementation of security measures, our information systems, like those of other companies, are vulnerable to damages from computer viruses, natural disasters, unauthorized access, cyber attack and other similar disruptions. Any system failure, accident or security breach could result in disruptions to our operations. For example, third parties may attempt to hack into systems and may obtain our proprietary information, which could cause significant damage to our reputation, lead to claims against the Company and ultimately harm our business.

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 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 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

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

Prior to our IPO in June 2018, there was no public market for our common stock. Although our common stock is listed on The Nasdaq Global Select Market, an active trading market may not develop, 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 price at which our common stock trades may decline below the price at which you purchase our shares, and you may experience a significant decrease in the value of the common stock you purchase regardless of our operating performance or prospects.

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 trading price of our common stock 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 review and 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;
- 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 after our IPO. If the market price of shares of our common stock does not ever exceed the price at which you purchased them, 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, 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. 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 will likely limit your ability to influence corporate matters.

Based upon shares outstanding as of June 30, 2018, we estimate that our executive officers, directors, and current 5% or greater stockholders and affiliated entities will together beneficially own approximately 45% of our common stock outstanding. 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. 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 our IPO, 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.

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. As of June 30, 2018, stockholders holding approximately 14,262,313 shares of our common stock were subject to restrictions on their ability to sell their shares, including as a result of the lock-up agreements entered into with the underwriters for our IPO. 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 are subject to certain exceptions. If one or more stockholders were to sell a substantial portion of the shares they hold, it could cause our stock price to decline.

In addition, holders of an aggregate of approximately 11,837,073 shares of our common stock will be entitled, 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 June 30, 2018, there were 2,539,004 shares subject to outstanding options granted under our equity incentive plans 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 have registered the shares of common stock issuable upon exercise of these options under a Registration Statement on Form S-8. We have also registered all 1,822,000 shares of common stock that we may issue under our 2018 Stock Option and Incentive Plan and 193,000 shares of common stock we may issue under our 2018 Employee Stock Purchase Plan. These shares 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.

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 our IPO, 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.

We do not anticipate declaring any cash dividends to holders of our common stock in the foreseeable future. In addition, under our Loan and Security 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 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:

- 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 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 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. 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.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Recent Sales of Unregistered Securities

Set forth below is information regarding securities sold by us during the three months ended June 30, 2018, that were not registered under the Securities Act of 1933, as amended, or the Securities Act. Also included is the consideration, if any, received by us for the securities and information relating to the section of the Securities Act, or rule of the U.S. Securities and Exchange Commission, under which exemption from registration was claimed.

Issuances of securities

None.

Stock option and other equity awards

During the three months ended June 30, 2018, we issued to certain employees, directors and consultants options to purchase an aggregate of 428,882 shares of common stock at a weighted average exercise price of $12.50 per share.

The issuance of stock options and the common stock issuable upon the exercise of such options, and the issuance of restricted stock upon the early exercise of stock options, were issued pursuant to written compensatory plans or arrangements with our employees, directors and consultants, in reliance on the exemption from the registration requirements of the Securities Act provided by Rule 701 promulgated under the Securities Act or the exemption set forth in Section 4(2) under the Securities Act and Regulation D promulgated thereunder relative to transactions by an issuer not involving any public offering. All recipients either received adequate information about us or had access, through employment or other relationships, to such information.

Purchase of Equity Securities

We did not purchase any of our registered equity securities during the three months ended June 30, 2018.

Use of Proceeds from Registered Securities

On June 25, 2018, we completed our initial public offering ("IPO") of 6,555,000 shares of our common stock at a price of $15.00 per share for an aggregate offering price of approximately $98.3 million, including 855,000 shares of our common stock pursuant to the exercise of the underwriters' option to purchase additional shares. Jefferies LLC, Leerink Partners LLC, RBC Capital Markets, LLC and Mizuho Securities USA LLC served as the underwriters of the IPO. The offer and sale of all of the shares in the offering were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-225191), which was declared effective by the SEC on June 20, 2018.

We received aggregate net proceeds from the offering of approximately $89.0 million, after deducting underwriting discounts and commissions, as well as other offering expenses. As of June 30, 2018, we have not used any of the net proceeds from the IPO.

In addition, we have not used any of the net proceeds from the offering to make payments, directly or indirectly, to any director or officer, or any of their associates, to any person owning 10 percent or more of our common stock or to any affiliate. There has been no material change in our planned use of the net proceeds from the offering as described in the final prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act.

ITEM 6. EXHIBITS

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Index to Exhibits, which is incorporated herein by reference.

INDEX TO EXHIBITS

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of Xeris Pharmaceuticals, Inc. dated June 25, 2018 (Incorporated by reference to Exhibit 3.1 to the registrant's Current Report on Form 8-K filed on June 28, 2018).
3.2	Amended and Restated By-Laws of Xeris Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 3.2 to the registrant's Current Report on Form 8-K filed on June 28, 2018).
4.1	Form of Specimen Common Stock Certificate (Incorporated by reference to Exhibit 4.1 to the registrant's Registration Statement on Form S-1 filed May 24, 2018).
10.1#	2018 Stock Option and Incentive Plan and forms of award agreements thereunder (Incorporated by reference to Exhibit 10.2 to the registrant's Registration Statement on Form S-1 Amendment No.2 filed on June 14, 2018).
10.2#	Xeris Pharmaceuticals, Inc. 2018 Employee Stock Purchase Plan (Incorporated by reference to Exhibit 10.18 to the registrant's Registration Statement on Form S-1 Amendment No.2 filed on June 14, 2018).
10.3#	Form of Amended and Restated Employment Agreement, by and between the Registrant and Paul Edick (Incorporated by reference to Exhibit 10.7 to the registrant's Registration Statement on Form S-1 Amendment No.1 filed on June 11, 2018).
10.4#	Form of Amended and Restated Employment Agreement, by and between the Registrant and John Shannon (Incorporated by reference to Exhibit 10.8 to the registrant's Registration Statement on Form S-1 Amendment No.1 filed on June 11, 2018).
10.5#	Form of Amended and Restated Employment Agreement, by and between the Registrant and Steven Prestrelski (Incorporated by reference to Exhibit 10.9 to the registrant's Registration Statement on Form S-1 Amendment No.1 filed on June 11, 2018).
10.6#	Form of Amended and Restated Employment Agreement, by and between the Registrant and Ken Johnson (Incorporated by reference to Exhibit 10.10 to the registrant's Registration Statement on Form S-1 Amendment No.1 filed on June 11, 2018).
10.7#	Form of Employment Agreement, by and between the Registrant and Barry Deutsch (Incorporated by reference to Exhibit 10.11 to the registrant's Registration Statement on Form S-1 Amendment No.1 filed on June 11, 2018).
10.8+	Commercial Supply Agreement dated as of May 14, 2018 by and between Pyramid Laboratories Inc. and the Registrant (Incorporated by reference to Exhibit 10.14 to the registrant's Registration Statement on Form S-1 Amendment No.2 filed on June 14, 2018).
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1*	Certification of Periodic Financial Report by the Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following materials from Xeris Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q for the quarter ended June 30, 2018, formatted in XBRL (Extensible Business Reporting Language): (i) the Condensed Balance Sheets, (ii) the Condensed Statements of Operations, (iii) the Condensed Statements of Cash Flows and (iv) Notes to Unaudited Condensed Financial Statements.

+ Portions of this exhibit (indicated by asterisks) have been omitted pursuant to confidential treatment order and this exhibit has been submitted separately to the U.S. Securities and Exchange Commission.

# Indicates a management contract or any compensatory plan, contract or arrangement.

* The certifications furnished in Exhibit 32.1 hereto are deemed to accompany this report and will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended. Such certifications will not be deemed to be incorporated by reference into any filings under the Securities Act of 1933, as amended, or the Securities Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Xeris Pharmaceuticals, Inc.

Date: August 14, 2018

/s/ Paul Edick

Paul Edick
President, Chief Executive Officer and Chairman
(Principal Executive Officer)

Date: August 14, 2018

/s/ Barry Deutsch

Barry Deutsch
Chief Financial Officer
(Principal Financial Officer)

Exhibit 31.1

CERTIFICATION PURSUANT TO RULE 13a-14(a) OR 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Paul Edick, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Xeris Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 14, 2018

By: /s/ Paul Edick
Paul Edick
President, Chief Executive Officer and Chairman
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO RULE 13a-14(a) OR 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Barry Deutsch, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Xeris Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 14, 2018

By: /s/ Barry Deutsch
Barry Deutsch
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

We, Paul Edick and Barry Deutsch, of Xeris Pharmaceuticals, Inc., certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to our knowledge:

1. the quarterly report on Form 10-Q for the quarter ended June 30, 2018 (Periodic Report) to which this statement is an exhibit fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and

2. information contained in the Periodic Report fairly presents, in all material aspects, the financial condition and results of operations of Xeris Pharmaceuticals, Inc.

Date: August 14, 2018

/s/ Paul Edick
Paul Edick
President, Chief Executive Officer and Chairman
(Principal Executive Officer)

/s/ Barry Deutsch
Barry Deutsch
Chief Financial Officer
(Principal Financial Officer)