

ALIMERA SCIENCES INC  
Form 424B5  
August 11, 2016  
Table of Contents

Filed Pursuant to Rule 424(b)(5)  
Registration No. 333-198044

**PROSPECTUS SUPPLEMENT**

(to Prospectus dated August 20, 2014)

**18,000,000 Shares**

**Common Stock**

We are offering 18,000,000 shares of our common stock pursuant to this prospectus supplement and the accompanying prospectus. Our common stock is listed for trading on The NASDAQ Global Market under the symbol ALIM. On August 10, 2016, the last reported sale price of our common stock was \$1.63 per share.

**Our business and an investment in our common stock involves significant risks. These risks are described under the caption Risk Factors beginning on page S-5 of this prospectus supplement and in the documents incorporated by reference into this prospectus supplement.**

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

	<b>Per Share</b>	<b>Total</b>
Public offering price	\$ 1.40	\$ 25,200,000
Underwriting discount(1)	\$ 0.056	\$ 1,008,000
Proceeds, before expenses, to Alimera Sciences, Inc.	\$ 1.344	\$ 24,192,000

(1) See Underwriting for a description of the compensation payable to the underwriters.

The underwriters may also purchase up to an additional 900,000 shares from us at the public offering price, less underwriting discounts, within 30 days from the date of this prospectus to cover over-allotments.

The underwriters expect to deliver the shares against payment in New York, New York on or about August 16, 2016.

*Sole Book-Running Manager*

**Cowen and Company**

*Co-Manager*

**Laidlaw & Company (UK) Ltd.**

**August 11, 2016.**

**Table of Contents**

**TABLE OF CONTENTS**

**Prospectus Supplement**

	<b>Page</b>
<u>ABOUT THIS PROSPECTUS SUPPLEMENT</u>	S-ii
<u>PROSPECTUS SUPPLEMENT SUMMARY</u>	S-1
<u>THE OFFERING</u>	S-3
<u>RISK FACTORS</u>	S-5
<u>FORWARD-LOOKING STATEMENTS</u>	S-8
<u>USE OF PROCEEDS</u>	S-9
<u>DIVIDEND POLICY</u>	S-10
<u>PRICE RANGE OF OUR COMMON STOCK</u>	S-11
<u>DILUTION</u>	S-12
<u>UNDERWRITING</u>	S-14
<u>MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS</u>	S-18
<u>LEGAL MATTERS</u>	S-21
<u>EXPERTS</u>	S-21
<u>WHERE YOU CAN FIND MORE INFORMATION</u>	S-21
<u>INCORPORATION OF CERTAIN INFORMATION BY REFERENCE</u>	S-22

**Prospectus**

	<b>Page</b>
<u>ABOUT THIS PROSPECTUS</u>	1
<u>WHERE YOU CAN FIND MORE INFORMATION</u>	1
<u>INCORPORATION OF CERTAIN INFORMATION BY REFERENCE</u>	2
<u>SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS</u>	3
<u>THE COMPANY</u>	3
<u>OUR CORPORATE INFORMATION</u>	6
<u>RISK FACTORS</u>	7
<u>DESCRIPTION OF SECURITIES</u>	34
<u>USE OF PROCEEDS</u>	47
<u>RATIO OF FIXED CHARGES AND PREFERENCE DIVIDENDS TO EARNINGS</u>	47
<u>DIVIDEND POLICY</u>	47
<u>PLAN OF DISTRIBUTION</u>	47
<u>LEGAL MATTERS</u>	49
<u>EXPERTS</u>	49

**Table of Contents**

**ABOUT THIS PROSPECTUS SUPPLEMENT**

This document is in two parts. The first part is the prospectus supplement, including the documents incorporated by reference herein, which describes the specific terms of this offering. The second part, the accompanying prospectus, including the documents incorporated by reference therein, provides more general information. Generally, when we refer to this prospectus, we are referring to both parts of this document combined. Before you invest, you should carefully read this prospectus supplement, the accompanying prospectus, all information incorporated by reference herein and therein, as well as the additional information described under **Where You Can Find More Information**. These documents contain information you should consider when making your investment decision. This prospectus supplement may add, update or change information contained in the accompanying prospectus. To the extent that any statement we make in this prospectus supplement is inconsistent with statements made in the accompanying prospectus or any documents incorporated by reference therein, the statements made in this prospectus supplement will be deemed to modify or supersede those made in the accompanying prospectus and such documents incorporated by reference therein.

You should rely only on the information contained or incorporated by reference in this prospectus supplement, the accompanying prospectus and in any free writing prospectuses we may provide to you in connection with this offering. Neither we nor the underwriters have authorized any other person to provide you with any information that is different. If anyone provides you with different or inconsistent information, you should not rely on it. We are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The distribution of this prospectus supplement and the offering of the common stock in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus supplement must inform themselves about, and observe any restrictions relating to, the offering of the common stock and the distribution of this prospectus supplement outside the United States. This prospectus supplement does not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus supplement by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

This prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein and therein include trademarks, service marks and trade names owned by us or other companies. The term **ILUVIEN** is our registered trademark. All other trademarks, service marks and trade names included or incorporated by reference into this prospectus supplement or the accompanying prospectus are the property of their respective owners.

**Table of Contents**

**PROSPECTUS SUPPLEMENT SUMMARY**

*This summary highlights selected information about us, this offering and information appearing elsewhere in this prospectus supplement, in the accompanying prospectus and in the documents incorporated by reference herein and therein. This summary is not complete and does not contain all the information you should consider before investing in our common stock pursuant to this prospectus supplement and the accompanying prospectus. Before making an investment decision, to fully understand this offering and its consequences to you, you should carefully read this entire prospectus supplement and the accompanying prospectus, including Risk Factors, the financial statements, and related notes, and the other information that we incorporated by reference herein and therein.*

**Alimera Sciences, Inc.**

**Overview**

Alimera Sciences, Inc., and its subsidiaries (we, Alimera or the Company) is a pharmaceutical company that specializes in the research, development and commercialization of prescription ophthalmic pharmaceuticals. We are presently focused on diseases affecting the back of the eye, or retina, because we believe these diseases are not well treated with current therapies and represent a significant market opportunity.

Our only commercial product is ILUVIEN<sup>®</sup>, which has been developed to treat diabetic macular edema (DME). DME is a disease of the retina that affects individuals with diabetes and can lead to severe vision loss and blindness. ILUVIEN has received marketing authorization in the United States (U.S.), Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, the Netherlands, Norway, Poland, Portugal, Spain, Sweden and the United Kingdom. In the U.S., ILUVIEN is indicated for the treatment of DME in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure (IOP). In the European Economic Area (EEA) countries in which ILUVIEN has received marketing authorization, it is indicated for the treatment of vision impairment associated with DME considered insufficiently responsive to available therapies. As part of the approval process in the EEA, we have committed to conduct a five-year, post-authorization, open label registry study in 800 patients of ILUVIEN per the labeled indication. Through June 30, 2016, we have enrolled over 380 patients.

We launched ILUVIEN in Germany and the United Kingdom in the second quarter of 2013 and in the U.S. and Portugal in the first quarter of 2015.

In addition, we have entered into various agreements under which distributors will provide regulatory, reimbursement or sales and marketing support for future commercialization of ILUVIEN in numerous countries in the Middle East, Canada, Italy, Australia and New Zealand.

We commenced operations in June 2003. Since our inception we have incurred significant losses. As of June 30, 2016, we have accumulated a deficit of \$361.9 million. We expect to continue to incur losses as we:

continue the commercialization of ILUVIEN in the U.S. and the EEA;

continue to seek regulatory approval of ILUVIEN in other jurisdictions;

evaluate the use of ILUVIEN for the treatment of other diseases; and

advance the clinical development of any future products or product candidates either currently in our pipeline, or that we may license or acquire in the future.

As of June 30, 2016, we had approximately \$16.6 million in cash and cash equivalents.

As of June 30, 2016, we did not meet the liquidity threshold under the financial covenants in our loan and security agreement, as may be amended or modified from time to time (the Term Loan), with Hercules Capital, Inc. (Hercules). While this violation was subsequently waived by Hercules, our current financial forecast for the remainder of 2016 projects that we must obtain additional or alternative financing or it is probable that we will not be able to comply with the financial covenants under the Term Loan. We are currently pursuing alternative or additional equity or debt financing (including this offering). In an event of default, all amounts may become due under the Term Loan and there would be substantial doubt about our ability to continue as a going concern.

S-1

**Table of Contents**

Further, due to the limited revenue generated by ILUVIEN to date, even if we are able to refinance the Term Loan and maintain compliance with its financial covenants, we will need to raise additional capital to fund the continued commercialization of ILUVIEN. If we are unable to raise additional financing, we will need to adjust our commercial plans so that we can continue to operate with our existing cash resources or there may be substantial doubt about our ability to continue as a going concern.

**Corporate Information**

We were incorporated in Delaware on June 4, 2003. Our headquarters are located at 6120 Windward Parkway, Suite 290, Alpharetta, GA 30005. Our telephone number is (678) 990-5740. We maintain an internet site at [www.alimerasciences.com](http://www.alimerasciences.com). The reference to our internet address does constitute incorporation by reference of the information contained on our website.

**Table of Contents**

**THE OFFERING**

Common stock offered by us	18,000,000 shares.
Common stock to be outstanding after this offering	63,375,439 shares (or 64,275,439 shares if the underwriters exercise in full their option to purchase additional shares).
Option to purchase additional shares	We have granted the underwriters an option for a period of up to 30 days from the date of this prospectus supplement to purchase up to 900,000 additional shares of common stock at the public offering price less the underwriting discounts and commissions.
Offering price	\$1.40 per share of common stock.
Use of proceeds	We estimate that our net proceeds from this offering, after deducting underwriting fees and expenses and our estimated offering expenses, will be approximately \$23.9 million. We anticipate that we will use the proceeds from this offering to fund the continued commercialization of our lead product, ILUVIEN, and for general corporate purposes. See Use of Proceeds.
Risk Factors	Investing in our common stock involves significant risks. See Risk Factors for a discussion of factors that you should read and consider before investing in our securities.

NASDAQ Global Market symbol ALIM

The number of shares of common stock that will be outstanding immediately after this offering as shown above is based on 45,375,439 shares of common stock outstanding as of June 30, 2016 and excludes (each as of June 30, 2016):

9,294,919 shares of common stock issuable upon the exercise of outstanding options under our 2010 Equity Incentive Plan (the 2010 Plan), with a weighted average exercise price of \$3.45 per share;

1,001,628 shares of common stock reserved for future grants under the 2010 Plan (subject to automatic annual adjustment in accordance with the terms of the plan);



Edgar Filing: ALIMERA SCIENCES INC - Form 424B5

1,285,593 shares of common stock issuable upon the exercise of outstanding options under our 2005 Equity Incentive Plan (the 2005 Plan), with a weighted average exercise price of \$2.18 per share;

68,190 shares of common stock issuable upon the exercise of outstanding options under our 2004 Equity Incentive Plan (the 2004 Plan), with a weighted average exercise price of \$4.02 per share;

453,009 shares reserved for future issuance under our 2010 Employee Stock Purchase Plan (the 2010 ESPP) (subject to automatic annual adjustment in accordance with the terms of the plan);

1,282,857 shares issuable upon the exercise of warrants outstanding at a weighted average exercise price of \$1.57 per share (including an increase in the number of shares of common stock issuable upon the exercise of a warrant to Hercules from 862,069 shares to 1,258,993 shares in July 2016);

21,950,086 shares of common stock issuable upon the conversion of our preferred stock, consisting of (i) 13,533,835 shares of common stock issuable upon the conversion of shares of Series A Convertible Preferred Stock (including warrants to purchase shares of Series A Convertible Preferred Stock); and (ii) 8,416,251 shares of common stock issuable upon the conversion of shares of Series B Convertible Preferred Stock;

900,000 shares of Series A Convertible Preferred Stock (including warrants to purchase shares of Series A Convertible Preferred Stock); and

8,416.251 shares of Series B Convertible Preferred Stock.

**Table of Contents**

To the extent that any of these options are exercised, new options are issued under our equity incentive plans and subsequently exercised, we issue additional shares of common stock in the future, or the outstanding preferred stock converts to common stock, there will be further dilution to the investor participating in this offering.

Unless otherwise indicated, all information in this prospectus assumes:

that the underwriters do not exercise their option to purchase up to 900,000 additional shares of our common stock; and

no options, restricted stock units, warrants, or shares of common stock were issued after June 30, 2016, other than 383,814 shares of common stock sold and issued pursuant to our sales agreement with Cowen and Company, LLC (Cowen) as part of an at-the-market offering (which we anticipate suspending or terminating following consummation of this offering) after June 30, 2016, and no outstanding options or warrants were exercised after June 30, 2016.

**Table of Contents**

**RISK FACTORS**

*Investing in our securities involves a high degree of risk. You should carefully review the risks and uncertainties described under the heading Risk Factors contained in our Quarterly Report on Form 10-Q for the period ended June 30, 2016, which are incorporated by reference into this prospectus supplement and accompanying prospectus in their entirety, as updated or superseded by the risks and uncertainties described under similar headings in the other documents that are filed after the date hereof and incorporated by reference into this prospectus supplement and accompanying prospectus, together with the other information in this prospectus supplement and accompanying prospectus, the documents incorporated by reference herein and any free writing prospectus that we may authorize for use in connection with this offering. The risks described in these documents are not the only ones we face, but those that we consider to be material. Each of the risk factors could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our securities, and the occurrence of any of these risks might cause you to lose all or part of your investment.*

**Risks Related to this Offering**

***Our stock price has been highly volatile and may be volatile in the future, and purchasers of our common stock could incur substantial losses.***

The realization of any of the risks described in these risk factors or other unforeseen risks could have a dramatic and adverse effect on the market price of our common stock. Between January 1, 2014 and July 31, 2016, the high and low sales prices of our common stock as reported on The NASDAQ Global Market varied between \$1.01 and \$8.44 per share. Additionally, market prices for securities of biotechnology and pharmaceutical companies, including ours, have historically been very volatile. The market for these securities has from time to time experienced significant price and volume fluctuations for reasons that were unrelated to the operating performance of any one company.

The following factors, in addition to the other risk factors described in this section, may also have a significant impact on the market price of our common stock:

uncertainty as to our ability to achieve profitability through the commercialization of ILUVIEN in the EEA and the U.S.;

the ability of ILUVIEN to be approved in any additional jurisdiction;

our ability to operate our business in compliance with the covenants and restrictions that we are subject to under our credit facility;

the ability of ILUVIEN or any future products or product candidates, if approved in additional jurisdictions, to achieve commercial success;

U.S. Food and Drug Administration or international regulatory actions, including failure to receive or maintain regulatory approval for ILUVIEN or any future products or product candidates;

quarterly variations in our results of operations or those of our competitors;

third-party manufacturers ability to manufacture ILUVIEN or any future products or product candidates in sufficient quantities and quality.

announcements by us or our competitors of acquisitions, regulatory approvals, clinical milestones, new products, significant contracts, commercial relationships or capital commitments;

third-party coverage and reimbursement policies;

our ability to meet our repayment and other obligations under our loan agreements;

additions or departures of key personnel;

commencement of, or our involvement in, litigation;

changes in governmental regulations or in the status of our regulatory approvals;

S-5

**Table of Contents**

changes in earnings estimates or recommendations by securities analysts;

any major change in our board of directors or management;

results from our clinical trial programs;

our ability to develop and market new and enhanced products or product candidates on a timely basis;

general economic conditions and slow or negative growth of our markets; and

political instability, natural disasters, war and/or events of terrorism.

From time to time, we estimate the timing of the accomplishment of various regulatory, scientific, clinical and other product development goals or milestones. These milestones may include the submission of regulatory filings, the notification of the results of regulatory filings and the anticipated commercial launch of ILUVIEN in various new jurisdictions or for new or expanded indications, or any future products or product candidates and the commencement or completion of scientific studies and clinical trials. Also, from time to time, we expect that we will publicly announce the anticipated timing of some of these milestones. All of these milestones are based on a variety of assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, our stock price may decline and the further commercialization of ILUVIEN or any future products or product candidates may be delayed.

In addition, the stock market has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of publicly traded companies. Broad market and industry factors may seriously affect the market price of companies' stock, including ours, regardless of actual operating performance. These fluctuations may be even more pronounced in the trading market for our stock. In addition, in the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been initiated against these companies. This litigation, if brought against us, could result in substantial costs and a diversion of our management's attention and resources.

***We have broad discretion in how we use the net proceeds of this offering, and we may not use these proceeds effectively or in ways with which you agree.***

Our management will have broad discretion as to the application of the net proceeds of this offering and could use them for purposes other than those contemplated at the time of this offering. Our stockholders may not agree with the manner in which our management chooses to allocate and spend the net proceeds. Moreover, our management may use the net proceeds for corporate purposes that may not increase the market price of our common stock.

***You will experience immediate and substantial dilution.***

The offering price per share in this offering exceeds the net tangible book value per share of our common stock outstanding prior to this offering. Based on the sale of 18,000,000 shares of our common stock at the public offering price of \$1.40 per share, for aggregate gross proceeds of approximately \$25.2 million, and after deducting estimated aggregate offering expenses payable by us, you will experience immediate dilution of \$1.18 per share, representing

the difference between our as adjusted net tangible book value per share as of June 30, 2016 after giving effect to this offering and the offering price. In addition, we are not restricted from issuing additional securities in the future, including shares of common stock, securities that are convertible into or exchangeable for, or that represent the right to receive, common stock or substantially similar securities. The issuance of these securities may cause further dilution to our stockholders. The exercise of outstanding stock options and the vesting of outstanding restricted stock units may also result in further dilution of your investment. See the section entitled Dilution elsewhere in this prospectus supplement for a more detailed illustration of the dilution you may incur as a result of this offering. You may experience future dilution as a result of future equity offerings.

In order to raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may not be the same as the price per share in this offering. We may sell shares or other securities in any other offering at a price per share that is less than the price per share paid by investors in this offering, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by investors in this offering.

**Table of Contents**

***Our business could be negatively affected as a result of the actions of activist stockholders.***

Proxy contests have been waged against many companies in the biopharmaceutical industry, including us, over the last few years. If faced with a proxy contest or other type of shareholder activism, we may not be able to respond successfully to the contest or dispute, which would be disruptive to our business. Even if we are successful, our business could be adversely affected by a proxy contest or shareholder dispute involving us or our partners because:

responding to proxy contests and other actions by activist stockholders can be costly and time-consuming, disrupting operations and diverting the attention of management and employees;

perceived uncertainties as to future direction may result in the loss of potential acquisitions, collaborations or in-licensing opportunities, and may make it more difficult to attract and retain qualified personnel and business partners; and

if individuals are elected to a board of directors with a specific agenda, it may adversely affect our ability to effectively and timely implement our strategic plan and create additional value for our stockholders.

These actions could cause our stock price to experience periods of volatility.

***Anti-takeover provisions in our charter and bylaws, and in Delaware law, and our rights plan could prevent or delay a change in control of our company.***

We are a Delaware corporation and the anti-takeover provisions of Section 203 of the Delaware General Corporation Law may discourage, delay or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change of control would be beneficial to our existing stockholders. In addition, our amended and restated certificate of incorporation and bylaws may discourage, delay or prevent a change in our management or control over us that stockholders may consider favorable. Our amended and restated certificate of incorporation and bylaws:

authorize the issuance of blank check preferred stock that could be issued by our board of directors to thwart a takeover attempt;

do not provide for cumulative voting in the election of directors, which would allow holders of less than a majority of the stock to elect some directors;

establish a classified board of directors, as a result of which the successors to the directors whose terms have expired will be elected to serve from the time of election and qualification until the third annual meeting following their election;

require that directors only be removed from office for cause;

provide that vacancies on the board of directors, including newly-created directorships, may be filled only by a majority vote of directors then in office;

contain certain protective provisions in favor of the holders of Series A Convertible Preferred Stock;

limit who may call special meetings of stockholders;

prohibit action by written consent of the holders of our common stock, requiring all actions to be taken at a meeting of the stockholders for such holders (holders of Series A Convertible Preferred Stock may act by written consent); and

establish advance notice requirements for nominating candidates for election to the board of directors or for proposing matters that can be acted upon by stockholders at stockholder meetings.

S-7



**Table of Contents**

**FORWARD-LOOKING STATEMENTS**

This prospectus supplement, the accompanying prospectus and the documents incorporated by reference in these documents contain forward-looking statements. Words such as, but not limited to, believe, expect, anticipate, estimate, intend, plan, project, target, goal, likely, will, would, and could, or the negative of these terms and similar words, identify forward-looking statements. Forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. Important factors that could cause actual results to differ materially from those reflected in our forward-looking statements include, among others:

uncertainty as to our ability to achieve profitability through the commercialization of ILUVIEN in the EEA and the U.S.;

our ability to operate our business in compliance with the covenants and restrictions that we are subject to under our credit facility;

our ability to raise sufficient additional financing and our need to raise such financing;

our limited sales and marketing infrastructure;

uncertainty as to the pricing and reimbursement guidelines for ILUVIEN or any future products or product candidates, including ILUVIEN in new markets;

delay in or failure to obtain regulatory approval of ILUVIEN in additional countries or any future products or product candidates;

our ability to successfully commercialize ILUVIEN following regulatory approval in additional markets;

the extent of government regulations; and

dependence on third-party manufacturers to manufacture ILUVIEN or any future products or product candidates in sufficient quantities and quality.

All written and verbal forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. We caution investors not to rely too heavily on the forward-looking statements we make or that are made on our behalf. We undertake no obligation, and specifically decline any obligation, to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

In addition, you should refer to the section of this prospectus supplement entitled "Risk Factors" as well as the documents we have incorporated by reference for a discussion of other important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this prospectus supplement will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all.

S-8

**Table of Contents**

**USE OF PROCEEDS**

We estimate that the net proceeds of this offering, after deducting underwriting discounts and commissions and estimated offering expenses, will be approximately \$23.9 million, or \$25.1 million if the underwriters' option to purchase additional shares is exercised in full. We cannot assure you that this offering will be completed.

We intend to use the proceeds from this offering to fund the continued commercialization of our lead product, ILUVIEN, in the United States and European Union and for other general corporate purposes. We may also use a portion of the net proceeds to acquire or invest in businesses, products or technologies that we believe are complementary to our own. We have not yet determined the amount of proceeds to be used specifically for any of the foregoing purposes. Accordingly, our management will have significant discretion and flexibility in applying the net proceeds from the sale of these securities. Pending any use, as described above, we intend to invest the net proceeds in high-quality, short-term, interest-bearing securities.

S-9

**Table of Contents**

**DIVIDEND POLICY**

We have not declared or paid cash dividends on our common stock since our inception. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any cash dividends in the foreseeable future. Any future determination to declare cash dividends will be made at the discretion of our board of directors, subject to compliance with certain covenants under the Term Loan, which may restrict or limit our ability to declare of pay dividends, and will depend on our financial condition, results of operations, capital requirements, general business conditions and other factors that our board of directors may deem relevant. Further, for so long as at least 37.5% of the shares of Series A Convertible Preferred Stock originally issued to the investors at the closing of our Series A Convertible Preferred Stock financing in October 2012 are held by the initial investors or their affiliates, we may not, without first obtaining the approval of the holders of at least 70% of the then outstanding shares of Series A Convertible Preferred Stock, declare or pay any dividend or distribution on any shares of capital stock; provided, however, that this restriction shall not apply to (A) dividends payable to holders of common stock that consist solely of shares of common stock for which adjustment to the conversion price of the Series A Convertible Preferred Stock is made pursuant to the certificate of designation or (B) dividends or distributions issued pro rata to all holders of capital stock (on an as-converted basis) in connection with the implementation of a poison pill rights plan or similar plan by us. Accordingly, realization of a gain on your investment will depend on the appreciation of the price of our common stock, which may never occur. Consequently, stockholders will need to sell our securities to realize a return on their investment, if any.

**Table of Contents****PRICE RANGE OF OUR COMMON STOCK**

Our common stock is traded on The NASDAQ Global Market under the symbol ALIM. The following table summarizes the high and low closing sales prices for our common stock as reported by The NASDAQ Global Market for the period indicated:

	<b>High</b>	<b>Low</b>
<b>2014</b>		
First Quarter	\$ 7.89	\$ 4.40
Second Quarter	7.81	5.09
Third Quarter	6.37	4.72
Fourth Quarter	6.36	4.77
<b>2015</b>		
First Quarter	\$ 5.86	\$ 4.38
Second Quarter	5.10	4.11
Third Quarter	4.96	2.04
Fourth Quarter	3.34	2.02
<b>2016</b>		
First Quarter	\$ 2.65	\$ 1.65
Second Quarter	2.57	1.23
Third Quarter (through August 10, 2016)	2.08	1.06

The last reported sale price for our common stock on The NASDAQ Global Market on August 10, 2016 was \$1.63.

**Table of Contents****DILUTION**

Our net tangible book value as of June 30, 2016 was approximately \$(10.0) million, or \$(0.22) per share. Net tangible book value per share is determined by dividing our total tangible assets, less total liabilities, by the number of shares of our common stock outstanding as of June 30, 2016. Our historical net tangible book value excludes \$21.8 million of intangible assets. Dilution with respect to net tangible book value per share represents the difference between the amount per share paid by purchasers of shares of common stock in this offering and the net tangible book value per share of our common stock immediately after this offering.

After giving effect to the sale of 18,000,000 shares of our common stock at the public offering price of \$1.40 per share, after deducting underwriting discounts and commissions and estimated offering expenses, our as adjusted net tangible book value as of June 30, 2016 would have been approximately \$13.9 million, or \$0.22 per share. This represents an immediate increase in net tangible book value of \$0.44 per share to existing stockholders and immediate dilution of \$1.18 per share to investors purchasing our common stock in this offering at the public offering price. The following table illustrates this dilution on a per share basis.

The following table illustrates this per share dilution:

Public offering price per share		\$ 1.40
Historical net tangible book value per share as of June 30, 2016	\$ (0.22)	
Increase in net tangible book value per share after this offering	\$ 0.44	
Net tangible book value per share after this offering		\$ 0.22
Dilution per share to investors participating in this offering		\$ 1.18

If the underwriters exercise their option to purchase additional shares in full, the as adjusted net tangible book value per share of our common stock after giving effect to this offering would be \$0.24 per share, and the dilution in net tangible book value per share to investors purchasing common stock in this offering would be \$1.16 per share.

The above discussion and tables also exclude (each as of June 30, 2016):

9,294,919 shares of common stock issuable upon the exercise of outstanding options under the 2010 Plan, with a weighted average exercise price of \$3.45 per share;

1,001,628 shares of common stock reserved for future grants under the 2010 Plan (subject to automatic annual adjustment in accordance with the terms of the plan);

1,285,593 shares of common stock issuable upon the exercise of outstanding options under the 2005 Plan, with a weighted average exercise price of \$2.18 per share;

68,190 shares of common stock issuable upon the exercise of outstanding options under the 2004 Plan, with a weighted average exercise price of \$4.02 per share;

453,009 shares reserved for future issuance under the 2010 ESPP (subject to automatic annual adjustment in accordance with the terms of the plan);

1,282,857 shares issuable upon the exercise of warrants outstanding at a weighted average exercise price of \$1.57 per share (including an increase in the number of shares of common stock issuable upon the exercise of a warrant to Hercules from 862,069 shares to 1,258,993 shares in July 2016);

21,950,086 shares of common stock issuable upon the conversion of our preferred stock, consisting of (i) 13,533,835 shares of common stock issuable upon the conversion of shares of Series A Convertible Preferred Stock (including warrants to purchase shares of Series A Convertible Preferred Stock); and (ii) 8,416,251 shares of common stock issuable upon the conversion of shares of Series B Convertible Preferred Stock;

900,000 shares of Series A Convertible Preferred Stock (including warrants to purchase shares of Series A Convertible Preferred Stock); and

8,416.251 shares of Series B Convertible Preferred Stock.

**Table of Contents**

To the extent that any of these options are exercised, new options are issued under our equity incentive plans and subsequently exercised, we issue additional shares of common stock in the future, or the outstanding preferred stock converts to common stock, there will be further dilution to investors participating in this offering.

S-13



**Table of Contents****UNDERWRITING**

We and Cowen and Company, LLC (Cowen) have entered into an underwriting agreement with respect to the common stock being offered. Subject to the terms and conditions of the underwriting agreement, each underwriter has severally agreed to purchase from us the number of shares of our common stock set forth opposite its name below. Cowen is the representative of the underwriters.

<b>Underwriter</b>	<b>Number of Shares</b>
Cowen and Company, LLC	16,650,000
Laidlaw & Company (UK) Ltd.	1,350,000
<b>Total</b>	<b>18,000,000</b>

The underwriting agreement provides that the obligations of the underwriters are subject to certain conditions precedent and that the underwriters, have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased, other than those shares covered by the overallotment option described below. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the non-defaulting underwriters may be increased or the underwriting agreement may be terminated. We have agreed to indemnify the underwriters against specified liabilities, including liabilities under the Securities Act of 1933, as amended (the Securities Act), and to contribute to payments the underwriters may be required to make in respect thereof.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel and other conditions specified in the underwriting agreement. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

**Overallotment Option to Purchase Additional Shares**

We have granted to the underwriters an option to purchase up to additional 900,000 shares of common stock at the public offering price, less the underwriting discount. This option is exercisable for a period of 30 days. The underwriters may exercise this option solely for the purpose of covering overallotments, if any, made in connection with the sale of common stock offered hereby. To the extent that the underwriters exercise this option, the underwriters will purchase additional shares from us in approximately the same proportion as shown in the table above.

**Discounts and Commissions**

The following table shows the public offering price, underwriting discount and proceeds, before expenses to us. These amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

We estimate that the total expenses of the offering, excluding underwriting discount, will be approximately \$287,500, which includes \$25,000 that we have agreed to reimburse the underwriters for the fees incurred by them in connection with this offering and \$75,000 that we have agreed to pay Laidlaw & Company (UK) Ltd. as an advisory fee.

	<b>Per Share</b>	<b>Total</b>	
		<b>Without Option</b>	<b>With Option</b>
Public offering price	\$ 1.40	\$ 25,200,000	\$ 26,460,000
Underwriting discount	0.056	1,008,000	1,058,400
Proceeds, before expenses, to Alimera Sciences, Inc.	1.344	24,192,000	25,401,600

The underwriters propose to offer the shares of common stock to the public at the public offering price set forth on the cover of this prospectus. The underwriters may offer the shares of common stock to securities dealers at the public offering price less a concession not in excess of \$0.336 per share. If all of the shares are not sold at the public offering price, the underwriters may change the offering price and other selling terms.

### **Discretionary Accounts**

The underwriters do not intend to confirm sales of the shares to any accounts over which it has discretionary authority.

### **Stabilization**

In connection with this offering, the underwriters may engage in stabilizing transactions, overallotment transactions, syndicate covering transactions, and purchases to cover positions created by short sales.

Stabilizing transactions permit bids to purchase shares of common stock so long as the stabilizing bids do not exceed a specified maximum, and are engaged in for the purpose of preventing or retarding a decline in the market price of the common stock while the offering is in progress.

## **Table of Contents**

Over-allotment transactions involve sales by the underwriters of shares of common stock in excess of the number of shares the underwriters are obligated to purchase. This creates a syndicate short position which may be either a covered short position or a naked short position. In a covered short position, the number of shares over-allotted by the underwriters is not greater than the number of shares that they may purchase in the over-allotment option. In a naked short position, the number of shares involved is greater than the number of shares in the over-allotment option. The underwriters may close out any short position by exercising their over-allotment option and/or purchasing shares in the open market.

Syndicate covering transactions involve purchases of common stock in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of shares to close out the short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared with the price at which it may purchase shares through exercise of the over-allotment option. If the underwriters sell more shares than could be covered by exercise of the over-allotment option and, therefore, have a naked short position, the position can be closed out only by buying shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that after pricing there could be downward pressure on the price of the shares in the open market that could adversely affect investors who purchase in the offering.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock in the open market may be higher than it would otherwise be in the absence of these transactions. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of our common stock. These transactions may be effected on the NASDAQ Stock Market, in the over-the-counter market or otherwise and, if commenced, may be discontinued at any time.

## **Passive Market Making**

In connection with this offering, underwriters and selling group members may engage in passive market making transactions in our common stock on the NASDAQ Stock Market in accordance with Rule 103 of Regulation M under the Securities Exchange Act of 1934, as amended (the Exchange Act), during a period before the commencement of offers or sales of common stock and extending through the completion of the distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, that bid must then be lowered when specified purchase limits are exceeded.

## **Lock-Up Agreements**

Pursuant to certain lock-up agreements, we and our executive officers and directors have agreed, subject to certain exceptions, not to offer, sell, assign, transfer, pledge, contract to sell, or otherwise dispose of or announce the intention to otherwise dispose of, or enter into any swap, hedge or similar agreement or arrangement that transfers, in whole or in part, the economic consequence of ownership of, directly or indirectly, or make any demand or request or exercise any right with respect to the registration of, or file with the Securities and Exchange Commission (SEC) a registration statement under the Securities Act relating to, any common stock or securities convertible into or exchangeable or exercisable for any common stock without the prior written consent of Cowen, for a period of 90 days after the date of the pricing of the offering.

Cowen, in its sole discretion, may release our common stock and other securities subject to the lock-up agreements described above in whole or in part at any time. When determining whether or not to release our common stock and other securities from lock-up agreements, Cowen will consider, among other factors, the holder's reasons for requesting the release, the number of shares for which the release is being requested and market conditions at the time of the request.

## **Canada**

The common stock may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the common stock must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus supplement (including any amendment thereto) contains a misrepresentation, provided that

## **Table of Contents**

the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 *Underwriting Conflicts* (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

## **United Kingdom**

Each of the underwriters has represented and agreed that:

it has not made or will not make an offer of the securities to the public in the United Kingdom within the meaning of section 102B of the Financial Services and Markets Act 2000 (as amended) (FSMA) except to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities or otherwise in circumstances which do not require the publication by us of a prospectus pursuant to the Prospectus Rules of the Financial Services Authority (FSA);

it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of section 21 of FSMA) to persons who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 or in circumstances in which section 21 of FSMA does not apply to us; and

it has complied with and will comply with all applicable provisions of FSMA with respect to anything done by it in relation to the securities in, from or otherwise involving the United Kingdom.

## **Switzerland**

The securities will not be offered, directly or indirectly, to the public in Switzerland and this prospectus does not constitute a public offering prospectus as that term is understood pursuant to article 652a or 1156 of the Swiss Federal Code of Obligations.

## **European Economic Area**

In relation to each Member State of the EEA which has implemented the European Prospectus Directive (each, a Relevant Member State), an offer of our shares may not be made to the public in a Relevant Member State other than:

to any legal entity which is a qualified investor, as defined in the European Prospectus Directive;

to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150 natural or legal persons (other than qualified investors as defined in the European Prospectus Directive), subject to obtaining the prior consent of the relevant dealer or dealers nominated by us for any such offer, or;

in any other circumstances falling within Article 3(2) of the European Prospectus Directive; provided that no such offer of our shares shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the European Prospectus Directive or supplement prospectus pursuant to Article 16 of the European Prospectus Directive.

For the purposes of this description, the expression an offer to the public in relation to the securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the securities to be offered so as to enable an investor to decide to purchase or subscribe for the securities, as the expression may be varied in that Relevant Member State by any measure implementing the European Prospectus Directive in that member state, and the expression European Prospectus Directive means Directive 2003/71/EC (and amendments hereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State) and includes any relevant implementing measure in each Relevant Member State. The expression 2010 PD Amending Directive means Directive 2010/73/EU.

## **Table of Contents**

We have not authorized and do not authorize the making of any offer of securities through any financial intermediary on our behalf, other than offers made by the underwriters and their respective affiliates, with a view to the final placement of the securities as contemplated in this document. Accordingly, no purchaser of the shares is authorized to make any further offer of shares on our behalf or on behalf of the underwriters.

## **Electronic Offer, Sale and Distribution of Shares**

A prospectus in electronic format may be made available on the websites maintained by one or more of the underwriters or selling group members, if any, participating in this offering and one or more of the underwriters participating in this offering may distribute prospectuses electronically. Cowen may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the underwriters and selling group members that will make internet distributions on the same basis as other allocations. Other than the prospectus in electronic format, the information on these websites is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or any underwriter in its capacity as underwriter, and should not be relied upon by investors.

## **Other Relationships**

Cowen and its affiliates have provided, and may in the future provide, various investment banking, commercial banking and other financial services for us and our affiliates for which they have received, and may in the future receive, customary fees.

## **Listing on The NASDAQ Global Market**

Our common shares are traded on The NASDAQ Global Market under the symbol ALIM. The transfer agent for our common stock is American Stock Transfer & Trust Company.

---

**Table of Contents****MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS**

The following discussion describes the material U.S. federal income tax consequences of the acquisition, ownership and disposition of our common stock acquired in this offering by Non-U.S. Holders (as defined below). This discussion does not address all aspects of U.S. federal income taxes that may be relevant to Non-U.S. Holders in light of their particular circumstances, nor does it address any U.S. federal estate or gift tax, or any state, local or non-U.S. tax consequences. Rules different from those described below may apply to certain Non-U.S. Holders that are subject to special treatment under the Internal Revenue Code of 1986, as amended (the Code), such as financial institutions, insurance companies, tax-exempt organizations, tax-qualified retirement plans, broker-dealers and traders in securities, commodities or currencies, U.S. expatriates, controlled foreign corporations, passive foreign investment companies, corporations that accumulate earnings to avoid U.S. federal income tax, persons that hold our common stock as part of a straddle, conversion transaction, or other risk reduction strategy, holders deemed to sell our common stock under the constructive sale provisions of the Code, holders who are subject to the alternative minimum tax or the Medicare contribution tax, partnerships and other pass-through entities, and investors in such pass-through entities or entities that are treated as disregarded entities for U.S. federal income tax purposes (regardless of their places of organization or formation). Such Non-U.S. Holders are urged to consult their own tax advisors to determine the U.S. federal, state, local and other tax consequences that may be relevant to them. Furthermore, the discussion below is based upon the provisions of the Code and Treasury regulations, published administrative pronouncements, rulings and judicial decisions thereunder as of the date hereof. Such authorities may be repealed, revoked or modified, perhaps retroactively, so as to result in U.S. federal income tax consequences different from those discussed below. We have not requested a ruling from the U.S. Internal Revenue Service (the IRS), with respect to the statements made and the conclusions reached in the following summary. This discussion assumes that the Non-U.S. Holder holds our common stock as a capital asset within the meaning of Section 1221 of the Code (generally, property held for investment).

The following discussion is for general information only. Persons considering the purchase of our common stock pursuant to this offering should consult their own tax advisors concerning the U.S. federal income consequences of acquiring, owning and disposing of our common stock in light of their particular situations as well as any consequences arising under the laws of any other taxing jurisdiction, including any state, local and non-U.S. tax consequences and any U.S. federal non-income tax consequences.

For the purposes of this discussion, a Non-U.S. Holder is, for U.S. federal income tax purposes, a beneficial owner of common stock that is not a U.S. Holder or an entity treated as a partnership for U.S. federal income tax purposes. A U.S. Holder means a beneficial owner of our common stock that is for U.S. federal income tax purposes (a) an individual who is a citizen or resident of the United States, (b) a corporation or other entity treated as a corporation created or organized in or under the laws of the United States, any state thereof or the District of Columbia, (c) an estate the income of which is subject to U.S. federal income taxation regardless of its source or (d) a trust if it (1) is subject to the primary supervision of a court within the United States and one or more U.S. persons have the authority to control all substantial decisions of the trust or (2) has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person.

**Distributions on our common stock**

Distributions, if any, made on our common stock to a Non-U.S. Holder of our common stock generally will constitute dividends for U.S. tax purposes to the extent made out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles) and will be subject to withholding tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty, subject to the discussion below regarding backup withholding and foreign accounts.



To obtain a reduced rate of withholding under a treaty, a Non-U.S. Holder generally will be required to provide the applicable withholding agent with a properly executed IRS Form W-8BEN or W-8BEN-E, or other appropriate form, certifying the Non-U.S. Holder's entitlement to benefits under that treaty. In the case of a Non-U.S. Holder that is an entity, Treasury regulations and the relevant tax treaty provide rules to determine whether, for purposes of determining the applicability of a tax treaty, dividends will be treated as paid to the entity or to those holding an interest in that entity. If a Non-U.S. Holder holds stock through a financial institution or other agent acting on the holder's behalf, the holder will be required to provide appropriate documentation to such agent. The holder's agent will then be required to provide certification to the applicable withholding agent, either directly or through other intermediaries. If you are eligible for a reduced rate of U.S. federal withholding tax under an income tax treaty, you should consult with your own tax advisor to determine if you are able to obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim for a refund with the IRS.

---

**Table of Contents**

Subject to the discussion below regarding foreign accounts, the applicable withholding agent generally will not be required to withhold tax on dividends paid to a Non-U.S. Holder that are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, are attributable to a permanent establishment that such holder maintains in the United States) if a properly executed IRS Form W-8ECI, stating that the dividends are so connected, is furnished to the applicable withholding agent (or, if stock is held through a financial institution or other agent, to such agent). In general, such effectively connected dividends will be subject to U.S. federal income tax, on a net income basis at the regular graduated rates, unless a specific treaty exemption applies. A corporate Non-U.S. Holder receiving effectively connected dividends may also be subject to an additional branch profits tax, which is imposed, under certain circumstances, at a rate of 30% (or such lower rate as may be specified by an applicable treaty) on the corporate Non-U.S. Holder's effectively connected earnings and profits, subject to certain adjustments.

To the extent distributions on our common stock, if any, exceed our current and accumulated earnings and profits, they will first reduce a Non-U.S. Holder's basis in our common stock as a non-taxable return of capital, but not below zero, and then any excess will be treated as gain and taxed in the same manner as gain realized from a sale or other disposition of common stock as described in the next section.

**Gain on disposition of our common stock**

Subject to the discussion below regarding backup withholding and foreign accounts, a Non-U.S. Holder generally will not be subject to U.S. federal income tax with respect to gain realized on a sale or other disposition of our common stock unless (a) the gain is effectively connected with a trade or business of such holder in the United States (and, if required by an applicable income tax treaty, is attributable to a permanent establishment that such holder maintains in the United States), (b) the Non-U.S. Holder is a nonresident alien individual and is present in the United States for 183 or more days in the taxable year of the disposition and certain other conditions are met, or (c) we are or have been a United States real property holding corporation (a USRPHC), within the meaning of Code Section 897(c)(2) at any time within the shorter of the five-year period preceding such disposition or such holder's holding period.

If you are a Non-U.S. Holder described in (a) above, you will be required to pay tax on the net gain derived from the sale at regular graduated U.S. federal income tax rates, unless a specific treaty exemption applies, and corporate Non-U.S. Holders described in (a) above may be subject to the additional branch profits tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty. If you are an individual Non-U.S. Holder described in (b) above, you will be required to pay a flat 30% tax on the gain derived from the sale, which gain may be offset by U.S. source capital losses (even though you are not considered a resident of the United States). With respect to (c) above, in general, we would be a USRPHC if interests in U.S. real estate constituted (by fair market value) at least half of our assets. We believe that we are not, and do not anticipate becoming, a USRPHC, however, there can be no assurance that we are not currently or will not become a USRPHC in the future. Even if we are treated as a USRPHC, gain realized by a Non-U.S. Holder on a disposition of our common stock will not be subject to U.S. federal income tax so long as (1) the Non-U.S. Holder owned, directly, indirectly and constructively, no more than 5% of our common stock at all times within the shorter of (a) the five-year period preceding the disposition or (b) the holder's holding period and (2) our common stock is regularly traded on an established securities market. There can be no assurance that our common stock will continue to qualify as regularly traded on an established securities market.

**Information reporting requirements and backup withholding**

Generally, we or certain financial middlemen must report information to the IRS with respect to any dividends we pay on our common stock including the amount of any such dividends, the name and address of the recipient, and the amount, if any, of tax withheld. A similar report is sent to the holder to whom any such dividends are paid. Pursuant to

tax treaties or certain other agreements, the IRS may make its reports available to tax authorities in the recipient's country of residence.

Dividends paid by us (or our paying agents) to a Non-U.S. Holder may also be subject to U.S. backup withholding. U.S. backup withholding generally will not apply to a Non-U.S. Holder who provides a properly executed IRS Form W-8BEN or W-8BEN-E or otherwise establishes an exemption.

Under current U.S. federal income tax law, U.S. information reporting and backup withholding requirements generally will apply to the proceeds of a disposition of our common stock effected by or through a U.S. office of any broker, U.S. or non-U.S., unless the holder provides a properly executed IRS Form W-8BEN or W-8BEN-E or otherwise establishes an exemption. Generally, U.S. information reporting and backup withholding requirements will not apply to a payment of disposition proceeds to a Non-U.S. Holder where the transaction is effected outside the United States through a non-U.S. office of a non-U.S. broker. For information reporting purposes, certain brokers with substantial U.S. ownership or operations will generally be treated in a manner similar to U.S. brokers.

**Table of Contents**

If backup withholding is applied to you, you should consult with your own tax advisor to determine if you are able to obtain a tax refund or credit with respect to the amount withheld.

**Foreign accounts**

A U.S. federal withholding tax of 30% may apply to dividends and the gross proceeds of a disposition of our common stock paid to a foreign financial institution (as specifically defined by applicable rules), including when the foreign financial institution holds our common stock on behalf of a Non-U.S. Holder, unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding U.S. account holders of such institution (which may include certain equity holders of such institution, as well as certain account holders that are foreign entities with U.S. owners). Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing these withholding and reporting requirements may be subject to different rules. This U.S. federal withholding tax of 30% may also apply to dividends and the gross proceeds of a disposition of our common stock paid to a non-financial foreign entity unless such entity provides the withholding agent with either a certification that it does not have any substantial direct or indirect U.S. owners or provides information regarding direct and indirect U.S. owners of the entity. The withholding tax described above will not apply if the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from the rules. Under certain circumstances, a Non-U.S. Holder might be eligible for refunds or credits of such tax. Holders are encouraged to consult with their own tax advisors regarding the possible implications of this withholding on their investment in our common stock.

The withholding provisions described above generally apply to payments of dividends on our common stock and will apply to payments of gross proceeds from a sale or other disposition of common stock on or after January 1, 2019.

EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS OWN TAX ADVISOR REGARDING THE TAX CONSEQUENCES OF PURCHASING, HOLDING AND DISPOSING OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAW, AS WELL AS TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL, NON-U.S. OR U.S. FEDERAL NON-INCOME TAX LAWS OR APPLICABLE TREATIES.

**Table of Contents**

**LEGAL MATTERS**

The validity of the shares of common stock being offered by this prospectus will be passed upon for us by Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP, Boston, Massachusetts. Certain intellectual property matters will be passed upon for us by Brinks Gilson & Lione, a Professional Corporation, Durham, North Carolina. The underwriters are being represented by Goodwin Procter LLP, New York, New York.

**EXPERTS**

The financial statements incorporated by reference in this prospectus supplement, the accompanying prospectus and elsewhere in the registration statement have been so incorporated by reference in reliance upon the report of Grant Thornton LLP, independent registered public accountants, upon the authority of said firm as experts in accounting and auditing.

**WHERE YOU CAN FIND MORE INFORMATION**

We have filed with the SEC a registration statement on Form S-3 under the Securities Act with respect to the securities offered by this prospectus supplement and the accompanying prospectus. This prospectus supplement, which is part of the registration statement, omits certain information, exhibits, schedules and undertakings set forth in the registration statement, as permitted by the SEC. For further information pertaining to us and the securities offered in this prospectus supplement, reference is made to that registration statement and the exhibits and schedules to the registration statement. Statements contained in this prospectus supplement as to the contents or provisions of any documents referred to in this prospectus supplement are not necessarily complete, and in each instance where a copy of the document has been filed as an exhibit to the registration statement, reference is made to the exhibit for a more complete description of the matters involved.

We file annual, quarterly and current reports, proxy statements and other information with the SEC. Our SEC filings can be read and copied at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. The public may obtain information on the operation of the public reference room by calling the SEC at 1-800-SEC-0330. Also, the SEC maintains an Internet website at [www.sec.gov](http://www.sec.gov) that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC, including us.

General information about our company, including our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, as well as any amendments and exhibits to those reports, are available free of charge through our website at [www.alimerasciences.com](http://www.alimerasciences.com) as soon as reasonably practicable after we file them with, or furnish them to, the SEC. Information on, or than can be accessed through, our website is not incorporated into this prospectus or other securities filings and is not a part of these filings.

**Table of Contents**

**INCORPORATION OF CERTAIN INFORMATION BY REFERENCE**

The SEC allows us to incorporate by reference into this prospectus supplement the information we file with it, which means that we can disclose important information to you by referring you to those documents. The information we incorporate by reference is an important part of this prospectus supplement, and later information that we file with the SEC will automatically update and supersede some of this information. We incorporate by reference the documents listed below and any future filings we make with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Exchange Act (other than Current Reports on Form 8-K containing only information furnished under Item 2.02 or Item 7.01 of Form 8-K, unless otherwise indicated therein or below), including filings made after the date of the initial registration statement, until we sell all of the securities covered by this prospectus supplement or the sale of securities by us pursuant to this prospectus supplement is terminated. The documents we incorporate by reference are:

our Annual Report on Form 10-K for the year ended December 31, 2015;

our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2016 and June 30, 2016;

our Proxy Statement on Schedule 14A filed with the SEC on April 27, 2016;

our Current Reports on Form 8-K filed on February 5, 2016, March 3, 2016, March 7, 2016, March 8, 2016, March 14, 2016, May 5, 2016, May 27, 2016, June 27, 2016, July 12, 2016 (including the information furnished in Item 7.01 thereto as if filed therewith), July 26, 2016, August 4, 2016, August 10, 2016 and August 11, 2016; and

the description of our common stock contained in our registration statement on Form 8-A (File No. 001-34703) filed under the Exchange Act on April 19, 2010, including any amendment or reports filed for the purpose of updating such descriptions.

Any statement contained in a document incorporated or deemed to be incorporated by reference into this prospectus supplement will be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus supplement or any other subsequently filed document that is deemed to be incorporated by reference into this prospectus supplement modifies or supersedes the statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus supplement.

We will provide each person to whom a prospectus supplement is delivered a copy of all of the information that has been incorporated by reference in this prospectus but not delivered with the prospectus supplement. You may obtain copies of these filings, at no cost, through the Investor Relations section of our website ([www.alimerasciences.com](http://www.alimerasciences.com)) and you may request a copy of these filings (other than an exhibit to any filing unless we have specifically incorporated that exhibit by reference into the filing), at no cost, by writing or telephoning us at the following address:

Corporate Secretary

Alimera Sciences, Inc.

Edgar Filing: ALIMERA SCIENCES INC - Form 424B5

6120 Windward Parkway, Suite 290

Alpharetta, GA 30005

(678) 990-5740

Information on, or that can be accessed through, our website is not incorporated into this prospectus supplement or other securities filings and is not a part of these filings.

In accordance with Section 412 of the Exchange Act, any statement contained in a document incorporated by reference herein shall be deemed modified or superseded to the extent that a statement contained herein or in any other subsequently filed document which also is or is deemed to be incorporated by reference herein modifies or supersedes such statement.

S-22

**Table of Contents**

**PROSPECTUS**

**\$100,000,000**

**Preferred Stock**

**Common Stock**

**Debt Securities**

**Warrants**

From time to time, we may offer and sell shares of preferred stock, common stock, debt securities or warrants to purchase preferred stock, common stock or any combination of these securities, either separately or in units, in one or more offerings in amounts, at prices and on terms that we will determine at the time of the offering. The debt securities and warrants may be convertible into or exercisable or exchangeable for preferred stock, common stock or debt securities and the preferred stock may be convertible into or exchangeable for common stock. The aggregate initial offering price of all securities sold by us under this prospectus will not exceed \$100,000,000.

Each time we offer securities, we will provide you with specific terms of the securities offered in supplements to this prospectus. The prospectus supplement may also add, update or change information contained in this prospectus. You should read this prospectus, the information incorporated by reference in this prospectus, any applicable prospectus supplement and the additional information described below under the heading **Where You Can Find More Information** carefully before you invest in any securities.

The securities offered by this prospectus may be sold directly by us to investors, through agents designated from time to time or to or through underwriters or dealers. We will set forth the names of any underwriters or agents in an accompanying prospectus supplement. For additional information on the methods of sale, you should refer to the section entitled **Plan of Distribution**. The price to the public of such securities and the net proceeds we expect to receive from such sale will also be set forth in a prospectus supplement.

Our common stock is listed on The NASDAQ Global Market under the symbol **ALIM**. The last reported sale price of our common stock on August 8, 2014 was \$5.63 per share.

**INVESTING IN OUR SECURITIES INVOLVES A HIGH DEGREE OF RISKS. SEE RISK FACTORS ON PAGE 7 OF THIS PROSPECTUS AND IN THE OTHER DOCUMENTS INCORPORATED BY REFERENCE IN THIS PROSPECTUS AND THE APPLICABLE PROSPECTUS SUPPLEMENT TO READ ABOUT FACTORS YOU SHOULD CONSIDER BEFORE BUYING OUR SECURITIES.**

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

The date of this prospectus is August 11, 2014.



Table of Contents

**TABLE OF CONTENTS**

	<b>Page</b>
<u>ABOUT THIS PROSPECTUS</u>	1
<u>WHERE YOU CAN FIND MORE INFORMATION</u>	1
<u>INCORPORATION OF CERTAIN INFORMATION BY REFERENCE</u>	2
<u>SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS</u>	3
<u>THE COMPANY</u>	3
<u>OUR CORPORATE INFORMATION</u>	6
<u>RISK FACTORS</u>	7
<u>DESCRIPTION OF SECURITIES</u>	34
<u>USE OF PROCEEDS</u>	47
<u>RATIO OF FIXED CHARGES AND PREFERENCE DIVIDENDS TO EARNINGS</u>	47
<u>DIVIDEND POLICY</u>	47
<u>PLAN OF DISTRIBUTION</u>	47
<u>LEGAL MATTERS</u>	49
<u>EXPERTS</u>	49

**You should rely only on the information contained or incorporated by reference in this prospectus or any applicable prospectus supplement. We have not authorized anyone to provide you with information in addition to or different from that contained in this prospectus or any applicable prospectus supplement. We will be offering to sell, and seeking offers to buy, the securities only in jurisdictions where offers and sales are permitted. You should not assume that the information in this prospectus or any applicable prospectus supplement is accurate as of any date other than the date on the front of those documents.**

Unless the context otherwise requires, throughout this prospectus and any applicable prospectus supplement, the words Alimera we, us, the registrant or the company refer to Alimera Sciences, Inc.; the term securities refers collectively to our preferred stock, common stock, debt securities or warrants to purchase preferred stock, common stock or debt securities, or any combination of the foregoing securities.

**Table of Contents**

**ABOUT THIS PROSPECTUS**

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or the SEC, using a shelf registration process. Using this process, we may, from time to time, sell any combination of the securities described in this prospectus in one or more offering transactions up to a total dollar amount of \$100,000,000. This prospectus provides you with a general description of the securities we may offer. Each time we sell any securities under this prospectus, we will provide a prospectus supplement that will contain more specific information about the specific terms of that particular offering. Each such prospectus supplement may also add, update or change information contained in this prospectus or in documents we have incorporated by reference into this prospectus. To the extent that any statements that we make in a prospectus supplement are inconsistent with statements made in this prospectus, the statements made in this prospectus will be deemed modified or superseded by those made in the prospectus supplement. This prospectus, together with the applicable prospectus supplements and the documents incorporated by reference into this prospectus, includes all material information relating to the offering of the securities described in this prospectus. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sales of securities. To obtain additional information that may be important to you, you should read the exhibits filed by us with the registration statement of which this prospectus is a part or our other filings with the SEC. You should read this prospectus, any applicable prospectus supplement and the additional information described below under **Where You Can Find More Information** before making any investment decision with respect to the securities offered hereby.

**WHERE YOU CAN FIND MORE INFORMATION**

We have filed with the SEC a registration statement on Form S-3 under the Securities Act with respect to the securities offered by this prospectus. This prospectus, which is part of the registration statement, omits certain information, exhibits, schedules and undertakings set forth in the registration statement, as permitted by the SEC. For further information pertaining to us and the securities offered in this prospectus, reference is made to that registration statement and the exhibits and schedules to the registration statement. Statements contained in this prospectus as to the contents or provisions of any documents referred to in this prospectus are not necessarily complete, and in each instance where a copy of the document has been filed as an exhibit to the registration statement, reference is made to the exhibit for a more complete description of the matters involved.

We file annual, quarterly and current reports, proxy statements and other information with the SEC. Our SEC filings can be read and copied at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. The public may obtain information on the operation of the public reference room by calling the SEC at 1-800-SEC-0330. Also, the SEC maintains an Internet website at [www.sec.gov](http://www.sec.gov) that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC, including us.

Our common stock is listed on The NASDAQ Global Market under the symbol **ALIM**. General information about our company, including our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, as well as any amendments and exhibits to those reports, are available free of charge through our website at [www.alimerasciences.com](http://www.alimerasciences.com) as soon as reasonably practicable after we file them with, or furnish them to, the SEC. Information on, or that can be accessed through, our website is not incorporated into this prospectus or other securities filings and is not a part of these filings.

**Table of Contents**

**INCORPORATION OF CERTAIN INFORMATION BY REFERENCE**

The SEC allows us to incorporate by reference into this prospectus the information we file with it, which means that we can disclose important information to you by referring you to those documents. The information we incorporate by reference is an important part of this prospectus, and later information that we file with the SEC will automatically update and supersede some of this information. We incorporate by reference the documents listed below and any future filings we make with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended (the Exchange Act ) (other than Current Reports on Form 8-K containing only information furnished under Item 2.02 or Item 7.01 of Form 8-K, unless otherwise indicated therein), including filings made after the date of the initial registration statement, until we sell all of the securities covered by this prospectus or the sale of securities by us pursuant to this prospectus is terminated. The documents we incorporate by reference are:

our Annual Report on Form 10-K for the year ended December 31, 2013;

our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2014 and June 30, 2014;

our Proxy Statement on Schedule 14A filed with the SEC on April 16, 2014;

our Current Reports on Form 8-K filed on January 28, 2014, February 3, 2014, February 27, 2014, April 25, 2014, May 8, 2014, May 16, 2014, June 9, 2014, June 30, 2014 and August 7, 2014 in each case only to the extent filed and not furnished; and

the description of our common stock contained in our registration statement on Form 8-A (File No. 001-34703) filed under the Exchange Act on April 19, 2010, including any amendment or reports filed for the purpose of updating such descriptions.

Any statement contained in a document incorporated or deemed to be incorporated by reference into this prospectus will be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus or any other subsequently filed document that is deemed to be incorporated by reference into this prospectus modifies or supersedes the statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

We will provide each person to whom a prospectus is delivered a copy of all of the information that has been incorporated by reference in this prospectus but not delivered with the prospectus. You may obtain copies of these filings, at no cost, through the Investor Relations section of our website ([www.alimerasciences.com](http://www.alimerasciences.com)) and you may request a copy of these filings (other than an exhibit to any filing unless we have specifically incorporated that exhibit by reference into the filing), at no cost, by writing or telephoning us at the following address:

Corporate Secretary

Alimera Sciences, Inc.

6120 Windward Parkway, Suite 290

Edgar Filing: ALIMERA SCIENCES INC - Form 424B5

Alpharetta, GA 30005

(678) 990-5740

Information on, or that can be accessed through, our website is not incorporated into this prospectus or other securities filings and is not a part of these filings.

2

**Table of Contents**

**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus, any applicable prospectus supplement and the documents incorporated by reference contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this prospectus, any applicable prospectus supplement and the documents incorporated by reference regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. These statements are subject to risks and uncertainties and are based on information currently available to our management. Words such as, but not limited to, anticipate, believe, estimate, expect, intend, may, plan, contemplates, predict, project, target, continue, ongoing, will, would, should, could, or the negative of these terms and similar expressions or words are forward-looking statements. The events and circumstances reflected in our forward-looking statements may not occur and actual results could differ materially from those projected in our forward-looking statements. Meaningful factors which could cause actual results to differ include, but are not limited to:

uncertainty as to our ability to commercialize ILUVIEN in the European Union (EU);

our limited sales and marketing infrastructure;

delay in or failure to obtain regulatory approval of ILUVIEN or any future products or product candidates;

our inability to successfully market and sell ILUVIEN following regulatory approval in additional markets;

uncertainty as to the pricing and reimbursement guidelines for ILUVIEN or any future products or product candidates, including ILUVIEN in the various EU countries;

uncertainty as to the relationship between the benefits of ILUVIEN or any future products or product candidates and the risks of their side-effect profiles;

dependence on third-party manufacturers to manufacture ILUVIEN or any future products or product candidates in sufficient quantities and quality;

the extent of government regulations;

uncertainty of clinical trial results;

our ability to operate our business in compliance with the covenants and restrictions that we are subject to under our credit facility; and

our ability to raise sufficient additional financing.

All written and verbal forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. We caution investors not to rely too heavily on the forward-looking statements we make or that are made on our behalf. We undertake no obligation, and specifically decline any obligation, to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise. You are advised, however, to consult any further disclosures we make on related subjects in any annual, quarterly or current reports that we may file with the Securities and Exchange Commission.

We encourage you to read the discussion and analysis of our financial condition and our unaudited consolidated interim financial statements contained in or incorporated by reference in this prospectus, and any prospectus supplement. We also encourage you to read the statements under **Risk Factors**, and other sections of this prospectus, which contains a more complete discussion of the risks and uncertainties associated with our business. In addition to the risks described above and in the section entitled **Risk Factors** of this prospectus, other unknown or unpredictable factors also could affect our results. There can be no assurance that the actual results or developments anticipated by us will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, us. Therefore, no assurance can be given that the outcomes stated in such forward-looking statements and estimates will be achieved.

## **THE COMPANY**

Alimera Sciences, Inc., and its wholly-owned subsidiaries (we, Alimera or the Company), is a biopharmaceutical company that specializes in the research, development and commercialization of prescription ophthalmic pharmaceuticals. We are presently focused on diseases affecting the back of the eye, or retina, because we believe these diseases are not well

## **Table of Contents**

treated with current therapies and represent a significant market opportunity. We were formed on June 4, 2003 under the laws of the State of Delaware.

Our only commercial product is ILUVIEN<sup>®</sup>, which has received marketing authorization in the United Kingdom, Austria, Portugal, France, Germany, Spain, Italy, Norway and Denmark, and has been recommended for marketing authorization in eight additional European Union (EU) countries, for the treatment of vision impairment associated with chronic diabetic macular edema (DME) considered insufficiently responsive to available therapies. DME is a disease of the retina that affects individuals with diabetes and can lead to severe vision loss and blindness. ILUVIEN is the first product approved for chronic DME in the EU. As part of the approval process in these countries, we have committed to conduct a five-year, post-authorization, open label registry study of ILUVIEN in 800 patients treated per the labeled indication. ILUVIEN has not been approved by the U.S. Food and Drug Administration (FDA), but a New Drug Application (NDA) is currently under review with the FDA.

We launched ILUVIEN in the United Kingdom and Germany, in April and May of 2013, respectively, and currently plans to launch ILUVIEN in France and Portugal in late 2014. We were able to launch in Germany without price restriction, but continue to work with the statutory health insurance funds in Germany to streamline reimbursement for ILUVIEN.

In January 2013, the United Kingdom's National Institute for Health and Care Excellence (NICE) published final guidance for England and Wales indicating that ILUVIEN does not satisfy NICE's definition of cost effectiveness for the treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies given the cost of £5,500. We submitted a simple patient access scheme (PAS) for ILUVIEN to NICE for consideration under its rapid review facility. In October 2013, the NICE Appraisal Committee issued a positive Final Appraisal Determination recommending ILUVIEN funding for the treatment of pseudophakic eyes (eyes with an artificial lens) in chronic DME patients considered insufficiently responsive to available therapies and the final technology appraisal guidance was published in November 2013. The technology appraisal guidance reverses the published guidance issued by NICE in January 2013, and takes into consideration the PAS. NICE requires clinical commissioning groups, National Health Service (NHS) England and Wales and local public health authorities to comply with the recommendations in the final guidance within three months of its date of publication. We began receiving orders for ILUVIEN from several NHS facilities in January 2014, indicating early implementation of the NICE guidance in certain NHS facilities. Further, in February 2014, the Scottish Medicines Consortium, after completing its assessment and review of a similar simple PAS, announced that it has accepted ILUVIEN for restricted use within the NHS Scotland.

In July 2013, the Transparency Commission (Commission de la Transparence or CT) of the French National Health Authority (Haute Autorite de Sante) issued a favorable opinion for the reimbursement and hospital listing of ILUVIEN for the treatment of chronic DME considered insufficiently responsive to available therapies. In the opinion, ILUVIEN was deemed as providing a moderate medical benefit as defined by the Service Medical Rendu. We have not yet agreed on a price with the French authorities. When we agree on a price with the French authorities, patients will be reimbursed for 100% of the cost of ILUVIEN under the Affection de Longue Duree, a specific program for severe chronic diseases such as diabetes. When comparing the clinical benefit of ILUVIEN to existing therapies, the CT rated the product at level IV (Amelioration du Service Medical Rendu or ASMR) which will be used in considering the price and any reimbursement conditions for ILUVIEN in France.

In September 2013, we submitted an application to the Medicines and Healthcare Products Regulatory Agency in the United Kingdom, as the Reference Member State, for ten additional EU country approvals through the Mutual Recognition Procedure (MRP). In June 2014, we received a positive outcome from the Repeat-Use Procedure for ILUVIEN for the treatment of chronic DME in Ireland, the Netherlands, Belgium, Luxembourg, Sweden, Denmark,

Finland, Norway, Poland and the Czech Republic. The regulatory process in these countries has entered the national phase in which each country grants marketing authorization. In July 2014, we received the first marketing authorizations resulting from the MRP in Norway and Denmark.



## Table of Contents

We submitted a NDA in June 2010 for ILUVIEN in the U.S. with the FDA. We resubmitted our NDA with revisions in May 2011 and April 2013 to address matters raised in the FDA's Complete Response Letters (CRLs) relating to the NDA. In October 2013, we received a third CRL from the FDA stating that the NDA could not be approved in its current form. In the third CRL, the FDA identified clinical and statistical deficiencies and indicated that the benefits of ILUVIEN did not outweigh its risks. Further, the FDA also indicated that results from a new clinical trial would need to be submitted, together with at least 12 months of follow-up data for all enrolled patients, to support certain indications previously discussed with the FDA. The FDA suggested that a meeting with the Dermatologic and Ophthalmic Drugs Advisory Committee may be of assistance in addressing the deficiencies identified above and providing advice whether a patient population can be identified in which the benefits of the drug product might outweigh the risks.

We were notified of a January 2014 meeting of the Advisory Committee shortly after the issuance of the third CRL. In a subsequent communication with the FDA, we believe we clarified that the purpose of the Advisory Committee meeting was to consider the benefits and risks of ILUVIEN based on existing data available from our two completed Phase 3 pivotal clinical trials (collectively, our FAME Study). A meeting with the FDA in preparation for the Advisory Committee resulted in labeling discussions for ILUVIEN, and we and the FDA agreed that the Advisory Committee was no longer necessary.

In March 2014, we resubmitted our NDA for ILUVIEN in response to the third CRL. In the resubmission, we responded to questions raised in the third CRL, addressed deficiencies noted in the methods and controls used for the drug product at the facility where ILUVIEN is manufactured and provided a safety update, which included commercial experience with ILUVIEN in Europe. In April 2014, we were notified by the FDA that the resubmission of our NDA for ILUVIEN had been acknowledged as received by the FDA as a complete class 2 response to the third CRL, and that a Prescription Drug User Fee Act (PDUFA) goal date of September 26, 2014 had been established. We do not plan to conduct any new clinical trials in connection with the FDA's review of this submission.

In the third CRL, the FDA also referenced deficiencies in the methods and controls used for the drug product at the third party facility where ILUVIEN is manufactured. In July 2014, the third party facility received a notification from the Los Angeles District of the Department of Health and Human Services (LA District) after their pre-approval and good manufacturing practice inspection of the facility in connection with our NDA. In that notification, the LA District recommended approval of the NDA by the FDA. This is only a recommendation which the FDA is not obligated to follow. Only the FDA can issue an official approval of the NDA.

In July 2014, we reached agreement with INFARMED, the marketing authorization body of the Portuguese Ministry of Health, for the pricing and reimbursement of ILUVIEN for the public sector in Portugal. We currently plan to make ILUVIEN commercially available in Portugal in late 2014.

We commenced operations on June 4, 2003. Since our inception we have incurred significant losses. As of June 30, 2014, we have accumulated a deficit of \$297.0 million. We expect to incur substantial losses as we:

continue the commercialization of ILUVIEN in the EU;

continue to seek regulatory approval of ILUVIEN in the U.S. and other jurisdictions;

commercialize ILUVIEN in the U.S. if approved by the FDA;

evaluate the use of ILUVIEN for the treatment of other diseases; and

advance the clinical development of any future products or product candidates either currently in our pipeline, or that we may license or acquire in the future.

As of June 30, 2014, we had approximately \$42.0 million in cash and cash equivalents.

We launched ILUVIEN in the United Kingdom and Germany, in April and May of 2013, respectively, and currently plan to launch ILUVIEN in France and Portugal in late 2014. We do not expect to have positive cash flow from operations

**Table of Contents**

until late 2015, if at all. Due to the limited revenue generated by ILUVIEN to date, we may not be able to maintain compliance with covenants under our loan agreements. In an event of default, our lender may call the 2014 Loan Agreement, and we would most likely need to raise additional financing. If we are unable to obtain additional financing, we will need to adjust our commercial plans so that we can continue to operate with our existing cash resources or there may be substantial doubt about our ability to continue as a going concern.

**OUR CORPORATE INFORMATION**

We were incorporated in Delaware in June 2003 and commenced operations on that date. Our principal executive office is located at 6120 Windward Parkway, Suite 290, Alpharetta, Georgia 30005 and our telephone number is (678) 990-5740. Our website address is [www.alimerasciences.com](http://www.alimerasciences.com). The information contained on, or that can be accessed through, our website is not part of this prospectus.

Alimera Sciences and ILUVIEN are trademarks of Alimera Sciences, Inc. This prospectus may also include other registered and unregistered trademarks of Alimera Sciences, Inc. and other persons.

---

**Table of Contents****RISK FACTORS**

An investment in our securities involves a high degree of risk. You should carefully consider the following information, together with the other information contained in this prospectus, any applicable prospectus supplement and other documents that are incorporated by reference into this prospectus and any applicable prospectus supplement, including the section entitled **Risk Factors** in our most recent annual report on Form 10-K as revised and supplemented by our most recent quarterly report on Form 10-Q, each of which are on file with the SEC and are incorporated herein by reference, and which may be amended, supplemented or superseded from time to time by other reports we file with the SEC in the future before buying our securities. These risks are not the only risks facing Alimera. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results. If any of these risks actually occurs, our business, financial condition, results of operations and future prospects would likely be materially and adversely affected. In that event, the market price of our common stock could decline and you could lose all or part of your investment. The risks discussed below also include forward-looking statements and our actual results may differ substantially from those discussed in these forward-looking statements.

**Risks Related to Our Dependence on ILUVIEN**

*We are heavily dependent on the commercial success of our lead product, ILUVIEN, which has received marketing authorizations in Austria, the United Kingdom, Portugal, France, Germany, Spain, Italy, Norway and Denmark, and on the regulatory approval of ILUVIEN for the treatment of chronic diabetic macular edema (DME) in the U.S. and other countries, which may never occur.*

We are a pharmaceutical company with only one product available for commercial sale in a limited number of markets. As a result, our future success is currently dependent upon the commercial and regulatory success of ILUVIEN. ILUVIEN has received marketing authorization from governing regulatory bodies in Austria, the United Kingdom, Portugal, France, Germany, Spain, Italy, Norway and Denmark and has been recommended for marketing authorization in eight additional European Union (EU) countries to treat vision impairment associated with chronic DME considered insufficiently responsive to available therapies. We cannot be certain if, or when, ILUVIEN will receive marketing authorization in the eight additional EU countries. ILUVIEN has not been approved by the FDA in the U.S. and may never receive such approval. We launched ILUVIEN in the United Kingdom and Germany in April and May of 2013, respectively, and currently plan to launch ILUVIEN in Portugal and France in late 2014. The timing of the commercial launch of ILUVIEN in the EU countries is dependent upon each specific EU country's pricing and reimbursement timelines. Because we do not currently have any products or product candidates available for sale or in clinical development other than ILUVIEN, our future success is dependent upon building a commercial operation in the EU to successfully commercialize ILUVIEN in the EU, and/or obtaining regulatory approval from the FDA to market ILUVIEN for the treatment of DME in the U.S., and if approved by the FDA, successfully commercializing ILUVIEN in the U.S.

We anticipate that in the near term our ability to generate revenues will depend solely on our ability to successfully commercialize ILUVIEN on our own in Germany, the United Kingdom, Portugal and France. If we do not successfully commercialize ILUVIEN in these countries or other countries in the EU or receive regulatory approval in the U.S. for ILUVIEN for the treatment of DME, our ability to generate revenue may be jeopardized and, consequently, our business may be seriously harmed. We may not succeed in our commercial efforts in the EU; we may not receive regulatory approval in the U.S. for ILUVIEN; and if we do receive regulatory approval in the U.S. for ILUVIEN, we may not be able to commercialize ILUVIEN successfully, all of which would have a material adverse effect on our business and prospects. In the near term, we may experience delays and unforeseen difficulties in the launch of ILUVIEN in one or more of the EU countries, including obtaining unfavorable pricing and/or

reimbursement, which could negatively affect our stock price. We may continue to experience delays in obtaining regulatory approval in the U.S. for ILUVIEN, if it is approved at all, and our stock price may be negatively affected.

In addition, we have incurred and expect to continue to incur significant expenses and to utilize a substantial portion of our cash resources for the commercial launch of ILUVIEN in Germany, the United Kingdom, Portugal and France, continue to pursue the approval of ILUVIEN in the U.S. and other EU countries and continue to grow our operational capabilities. This represents a significant investment in the commercial and regulatory success of ILUVIEN, which is uncertain.

We may also fail to develop future products or product candidates for the reasons stated in Risks Related to Our Business and Industry. If this were to occur, we will continue to be dependent on the successful commercialization of ILUVIEN, our development costs may increase and our ability to generate revenue could be impaired.

---

**Table of Contents**

***Our revenue from sales of ILUVIEN in the EU countries in which it has received or been recommended for marketing authorization is dependent upon the pricing and reimbursement guidelines adopted in each of such countries, which levels may fall well below our current expectations.***

We have established list pricing or developed estimates of anticipated pricing in countries in which ILUVIEN has received or been recommended for marketing authorization. These estimates are our expectations, which are based upon the burden of DME, the lack of any approved therapies for chronic DME, our perception of the overall cost to benefit ratio of ILUVIEN and the current pricing in the EU of therapies to treat DME and other retinal diseases such as age related macular degeneration and retinal vein occlusion. However, due to numerous factors beyond our control, including efforts to provide for containment of health care costs, one or more EU countries may not support our estimated level of governmental pricing and reimbursement for ILUVIEN, particularly in light of the ongoing budget crises faced by a number of countries in the EU, which would negatively impact anticipated revenue from ILUVIEN in the EU.

***Expansion of our commercial infrastructure in the EU is a significant undertaking that requires substantial financial and managerial resources, and we may not be successful in our efforts. We may also encounter unexpected or unforeseen delays in connection with our continued expansion of our commercial infrastructure in the EU, which may negatively impact our commercial efforts for ILUVIEN.***

We anticipate that in the near term our ability to generate revenues will depend solely on our ability to successfully commercialize ILUVIEN on our own in Germany, the United Kingdom, Portugal and France. We launched ILUVIEN in the United Kingdom and Germany, in April and May of 2013, respectively, and currently plan to launch ILUVIEN in Portugal and France in late 2014. A commercial launch of this size is a significant undertaking that requires substantial financial and managerial resources.

Although we have engaged Quintiles Commercial Europe Limited (together with its affiliates, Quintiles Commercial) to provide services to help facilitate the launch of ILUVIEN in the EU, expansion of our business into the EU continues to require significant management attention and additional financial resources. We may not be able to maintain and expand our commercial operation in a cost-effective manner or realize a positive return on this investment even with the assistance of Quintiles Commercial. In addition, we have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel. Factors that may inhibit our efforts to commercialize our products include:

our or Quintiles Commercial's inability to recruit and retain adequate numbers of effective personnel;

the inability of sales personnel to obtain access to or persuade adequate numbers of ophthalmologists to prescribe our products;

the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;

the inability of market access personnel to obtain sufficient levels of pricing and reimbursement in each jurisdiction; and

unforeseen costs and expenses associated with creating a commercial organization in the EU.

If we or Quintiles Commercial are not successful in recruiting and retaining sales and marketing personnel or in expanding our sales and marketing infrastructure or if we do not successfully enter into additional collaboration arrangements with third-parties, we will have difficulty commercializing ILUVIEN or any future products or product candidates, which would adversely affect our business, operating results and financial condition.

Even with the assistance of Quintiles Commercial or other third-party collaborators, we may not be successful in maintaining and expanding our commercial operation in the EU for numerous reasons, including, but not limited to, failing to attract, retain and motivate the necessary skilled personnel and failing to develop a successful marketing strategy. Failure to maintain and expand our commercial operation in the EU will have a negative outcome on our ability to commercialize ILUVIEN and generate revenue.

Additionally, we, Quintiles Commercial and/or other third-party collaborators may encounter unexpected or unforeseen delays in expanding our commercial operations that delay the commercial launch in one or more EU countries in which ILUVIEN

**Table of Contents**

has received or been recommended for marketing authorization. These delays may increase the cost of and the resources required for successful commercialization of ILUVIEN in the EU. We do not have experience in a commercial operation of this size in the EU or elsewhere.

***ILUVIEN may not be commercially successful.***

Market acceptance of and demand for ILUVIEN will depend on many factors, including, but not limited to:

cost of treatment;

pricing and availability of alternative products;

our ability to obtain third-party coverage or reimbursement for ILUVIEN;

perceived efficacy relative to other available therapies;

shifts in the medical community to new treatment paradigms or standards of care;

relative convenience and ease of administration; and

prevalence and severity of adverse side effects associated with treatment.

Because we only recently initiated the commercialization of ILUVIEN, we have limited information with regard to the market acceptance of ILUVIEN in the EU or elsewhere. As a result, we may have to revise our estimates regarding the acceptance of ILUVIEN under our anticipated pricing structure, reevaluate and/or change the anticipated pricing for ILUVIEN.

***The activities of competitive drug companies, or others, may limit ILUVIEN's revenue potential or render it obsolete.***

Our commercial opportunities for ILUVIEN will be reduced or eliminated if our competitors develop or market products that:

are more effective;

have fewer or less severe adverse side effects;



are better tolerated;

receive better reimbursement terms;

are more accepted by physicians;

are more adaptable to various modes of dosing;

have better distribution channels;

are easier to administer; or

are less expensive, including but not limited to a generic version of ILUVIEN.

We expect that ILUVIEN may compete in the EU, and, if approved by the FDA, in the U.S., with other products that have been or are being developed for the treatment of diabetic macular edema (DME). There are three biological products, Lucentis, Eylea and Avastin, expected to provide competition for ILUVIEN. Lucentis is currently approved for the treatment of DME, the treatment of neovascular wet age-related macular degeneration (AMD) and the treatment of macular edema following retinal vein occlusion (RVO) in the U.S. and the EU. Lucentis is marketed in the U.S. by Genentech and in the EU by Novartis. Eylea is currently approved for the treatment of DME, the treatment of neovascular wet AMD and the treatment of macular edema following RVO in the U.S. and the EU. Eylea is marketed in the U.S. by Regeneron and in the EU by Bayer. Avastin, an oncology product marketed by the Roche Group, is used by retinal specialists in both the U.S. and in certain countries of the EU in the treatment of numerous retinal diseases but is not formulated or approved for any ophthalmic use.

Within the corticosteroid class, Ozurdex is expected to provide competition for ILUVIEN. Ozurdex has recently been approved by the FDA for use in adult patients with DME who have had an artificial lens implant or are scheduled for cataract

**Table of Contents**

surgery. In Europe, the CHMP has recommended extending the Marketing Authorization for Ozurdex to treat adult patients with vision loss due to diabetic macular edema (DME) who are pseudophakic (have an artificial lens implant), or who are considered insufficiently responsive to, or unsuitable for non-corticosteroid therapy. Ozurdex is indicated for macular edema resulting from RVO and for uveitis in the U.S and the EU.

Retinal specialists are currently using laser photocoagulation and off-label therapies for the treatment of DME, and may continue to use these therapies in competition with ILUVIEN. Other laser, surgical or pharmaceutical treatments for DME may also compete against ILUVIEN. These competitive therapies may result in pricing pressure even if ILUVIEN is otherwise viewed as a preferable therapy.

In addition, there are many pharmaceutical companies, biotechnology companies, public and private universities, government agencies and research organizations actively engaged in research and development of products, some of which may target the same indications as ILUVIEN or any future products or product candidates. Our competitors include larger, more established, fully integrated pharmaceutical companies and biotechnology companies that have substantially greater capital resources, existing competitive products, larger research and development staffs and facilities, greater experience in drug development and in obtaining regulatory approvals and greater marketing capabilities than we do.

***Failure to successfully manage our international operations could harm our business, operating results and financial condition.***

We have limited international commercialization experience and international operations require significant management attention and financial resources. In addition, there are many risks inherent in international business activities including, but not limited to:

extended collection timelines for accounts receivable and greater working capital requirements;

multiple legal systems and unexpected changes in legal requirements;

tariffs, export restrictions, trade barriers and other regulatory or contractual limitations on our ability to sell or develop our products in certain foreign markets;

trade laws and business practices favoring local competition;

potential tax issues, including restrictions on repatriating earnings, multiple and conflicting and complex tax laws and regulations;

weaker intellectual property protection in some countries;

political instability, including war and terrorism or the threat of war and terrorism; and

adverse economic conditions, including the stability and solvency of business financial markets, financial institutions and sovereign nations.

In addition, compliance with foreign and U.S. laws and regulations that are applicable to our international operations is complex and may increase our cost of doing business in international jurisdictions, and our international operations could expose us to fines and penalties if we fail to comply with these regulations. These laws and regulations include import and export requirements, U.S. laws such as the Foreign Corrupt Practices Act, and local laws prohibiting corrupt payments to governmental officials. Although we have implemented policies and procedures designed to help ensure compliance with these laws, there can be no assurance that our employees, partners and other persons with whom we do business will not take actions in violation of our policies or these laws. Any violations of these laws could subject us to civil or criminal penalties, including substantial fines or prohibitions on our ability to offer our products in one or more countries, and could also materially and adversely harm our business and financial condition.

### **Risks Related to Our Business and Industry**

*We have incurred operating losses in each year since our inception and expect to continue to incur substantial and increasing losses for the foreseeable future.*

## **Table of Contents**

We launched ILUVIEN in the United Kingdom and Germany in April and May of 2013, respectively, and currently plan to launch ILUVIEN in Portugal and France in late 2014. We are not currently generating significant revenues and we cannot estimate with precision the extent of our future losses. ILUVIEN is our only product currently approved for commercial sale and it is only approved in limited markets in the EU. We may never achieve profitability. We expect to continue to incur substantial and increasing losses. ILUVIEN has not been approved for marketing in the U.S. and may never receive such approval. As a result of these factors, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it. As of June 30, 2014, we have accumulated a deficit of \$297.0 million. Our ability to achieve revenue and profitability is dependent on our ability to obtain necessary regulatory approvals, have our products manufactured, successfully marketed and sold and to complete the development of any future products or product candidates. We cannot assure you that we will be profitable even if we successfully commercialize our products. Failure to become and remain profitable may adversely affect the market price of our common stock and our ability to raise capital and continue operations.

As of June 30, 2014, we had approximately \$42.0 million in cash and cash equivalents. Due to the limited revenue generated by ILUVIEN to date, we may not be able to maintain compliance with covenants under our loan agreements. In an event of default, our lender may call our term loan or restrict the availability of our line of credit, and we will likely need to raise additional financing. If ILUVIEN does not generate sufficient revenue in the EU, we may adjust our commercial plans so that we can continue to operate with our existing cash resources or seek to raise additional financing.

### ***Our operating results may fluctuate significantly.***

Our operating results will continue to be subject to fluctuations. The revenues we generate, if any, and our operating results will be affected by numerous factors, including:

product sales;

cost of product sales;

marketing and other expenses;

manufacturing or supply issues;

regulatory developments affecting our products or those of our competitors;

variations in the level of expenses related to our products or future development programs;

the timing and amount of royalties or milestone payments;

our addition or termination of development programs;

our execution of collaborative, licensing or other arrangements, and the timing of payments we may make or receive under these arrangements;

any intellectual property infringement or other lawsuit in which we may become involved; and

the timing and recognition of stock-based compensation expense.

If our operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

***Prolonged economic uncertainties or downturns, as well as unstable market, credit and financial conditions, may exacerbate certain risks affecting our business and have serious adverse consequences on our business.***

The global economic downturn and market instability has made the business climate more volatile and more costly. These economic conditions, and uncertainty as to the general direction of the macroeconomic environment, are beyond our control. Sales of our products will be dependent, in large part, on reimbursement from government health administration authorities, private health insurers, distribution partners and other organizations in Germany, the United Kingdom, Portugal and France. As a result of negative trends in the general economy in the EU or other jurisdictions in which we may do business, these organizations may be unable to satisfy their reimbursement obligations or may delay payment. In addition, health authorities in some

---

**Table of Contents**

jurisdictions may reduce reimbursements, and private insurers may increase their scrutiny of claims. A reduction in the availability or extent of reimbursement could negatively affect our product sales and revenue.

In addition, we rely on third parties for several important aspects of our business. During challenging and uncertain economic times and in tight credit markets, there may be a disruption or delay in the performance of our third party contractors, suppliers or partners. If such third parties are unable to satisfy their commitments to us, our business and results of operations would be adversely affected. Moreover, two customers in Europe accounted for approximately 23% of our total consolidated revenues for the year ended December 31, 2013 and for approximately 6% of our total consolidated revenues for the six months ended June 30, 2014. The loss of or a substantial reduction in activity by one or more of these customers could have an adverse effect on our business, financial condition and results of operations.

***We face heavy government regulation, and regulatory approval of ILUVIEN and any future products or product candidates from the FDA and from similar entities in other countries is uncertain.***

The research, testing, manufacturing and marketing of drug products are subject to extensive regulation by U.S. federal, state and local government authorities, including the FDA and similar entities in other countries. To obtain regulatory approval of a product, we must demonstrate to the satisfaction of the regulatory agencies that, among other things, the product is safe and effective for its intended use. In addition, we must show that the manufacturing facilities used to produce the products are in compliance with current Good Manufacturing Practice (cGMP) regulations.

The process of obtaining regulatory approvals and clearances in the U.S. and other jurisdictions where ILUVIEN is not approved will require us to expend substantial time and capital. Despite the time and expense incurred, regulatory approval is never guaranteed. The number of preclinical and clinical tests that will be required for regulatory approval varies depending on the drug candidate, the disease or condition for which the drug candidate is in development, the jurisdiction in which we are seeking approval and the regulations applicable to that particular drug candidate. Regulatory agencies, including those in the U.S., Canada, the EU and other countries where drugs are regulated, can delay, limit or deny approval of a drug candidate for many reasons, including that:

a drug candidate may not be safe or effective;

regulatory agencies may interpret data from preclinical and clinical testing in different ways from those which we do;

they may not approve of our manufacturing processes;

they may conclude that the drug candidate does not meet quality standards for stability, quality, purity and potency; and

they may change their approval policies or adopt new regulations.

The FDA may make requests or suggestions regarding conduct of our clinical trials, resulting in an increased risk of difficulties or delays in obtaining regulatory approval in the U.S. For example, the FDA may not approve of certain of

our methods for analyzing our trial data, including how we evaluate the relationship between risk and benefit. Further, we may pursue approval of and market other future products or product candidates, outside the U.S. and specifically in additional countries in the EU and Canada. Regulatory agencies within these countries will require that we obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedures within these countries can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Additionally, the foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. For all of these reasons, we may not obtain additional foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or jurisdictions or by the FDA.

***ILUVIEN utilizes FAc, a corticosteroid that has demonstrated undesirable side effects in the eye; therefore, the success of ILUVIEN will be dependent upon the achievement of an appropriate relationship between the benefits of its efficacy and the risks of its side-effect profile.***

The use of corticosteroids in the eye has been associated with undesirable side effects, including increased incidence of cataract formation and elevated intraocular pressure (IOP), which may increase the risk of glaucoma. We have 36 months of

---

**Table of Contents**

clinical data from our FAME Study, but the extent of ILUVIEN's long-term side-effect profile beyond month 36 is not yet known. We have agreed with EU regulatory authorities to conduct a five-year post-authorization, open label registry study of the safety of ILUVIEN in 800 patients treated per the labeled indication. Although ILUVIEN has received marketing authorization in Austria, the United Kingdom, Portugal, France, Germany, Spain, Italy, Norway and Denmark, and been recommended for marketing authorization in eight additional EU countries, the FDA's current position is that our FAME Study did not demonstrate that ILUVIEN has sufficient levels of efficacy to outweigh the risks associated with its side-effect profile. In the event the FDA maintains this conclusion, ILUVIEN may not receive regulatory approval from the FDA. If other regulatory bodies adopt a conclusion similar to the FDA's we may not receive approval in any other jurisdiction. Additionally, data accumulated from the five-year post-authorization study, or other commercial experience, could result in the withdrawal of ILUVIEN approval in one or more jurisdictions. Further, we may not be able to complete the five-year post-authorization study, which could result in the withdrawal of ILUVIEN approval in one or more jurisdictions.

***Even if we do receive additional regulatory approvals for ILUVIEN, the FDA or other regulatory agencies may impose limitations on the indicated uses for which ILUVIEN may be marketed, subsequently withdraw approval or take other actions against us or ILUVIEN that would be adverse to our business.***

Regulatory agencies generally approve products for particular indications. If any such regulatory agency approves ILUVIEN for a limited indication, the size of our potential market for ILUVIEN will be reduced. For example, our potential market for ILUVIEN in the U.S. would be reduced if the FDA limited the indications of use to patients diagnosed with only clinically significant DME as opposed to DME, or restricted its use to patients exhibiting IOP below a certain level or having an artificial lens at the time of treatment. ILUVIEN has received marketing authorization in Austria, the United Kingdom, Portugal, France, Germany, Spain, Italy, Norway and Denmark and been recommended for marketing authorization in eight additional EU countries for the treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies which may limit the use of ILUVIEN to a segment of the DME population. Product approvals, once granted, may be withdrawn if problems occur after initial marketing. The marketing, distribution and manufacture of ILUVIEN in the EU, and if approved in the U.S. or elsewhere, will be subject to regulation. We will need to comply with facility registration and product listing requirements of the FDA and similar entities in other countries and adhere to the FDA's Quality System Regulations. Noncompliance with applicable FDA and similar entities' requirements can result in warning letters, fines, injunctions, civil penalties, recall or seizure of ILUVIEN, total or partial suspension of production, refusal of regulatory agencies to grant approvals, withdrawal of approvals by regulatory agencies or criminal prosecution. We would also need to maintain compliance with federal, state and foreign laws regarding sales incentives, referrals and other programs.

***Our ability to pursue the development and commercialization of ILUVIEN depends upon the continuation of our license from pSivida US, Inc.***

Our license rights to pSivida US, Inc.'s (pSivida) proprietary delivery device could revert to pSivida if we (i) fail twice to cure our breach of an obligation to make certain payments to pSivida following receipt of written notice thereof; (ii) fail to cure other breaches of material terms of our agreement with pSivida within 30 days after notice of such breaches or such longer period (up to 90 days) as may be reasonably necessary if the breach cannot be cured within such 30-day period; (iii) file for protection under the bankruptcy laws, make an assignment for the benefit of creditors, appoint or suffer appointment of a receiver or trustee over our property, file a petition under any bankruptcy or insolvency act or have any such petition filed against us and such proceeding remains undismissed or unstayed for a period of more than 60 days; or (iv) notify pSivida in writing of our decision to abandon our license with respect to a certain product using pSivida's proprietary delivery device. If our agreement with pSivida were terminated, we would lose our rights to develop and commercialize ILUVIEN, which would materially and adversely affect our business,



results of operations and future prospects.

***We rely on a single manufacturer for ILUVIEN, a single manufacturer for the ILUVIEN applicator and a single active pharmaceutical ingredient manufacturer for ILUVIEN s active pharmaceutical ingredient. Our business would be seriously harmed if any of these third-parties are not able to satisfy our demand and alternative sources are not available.***

We do not have, nor currently intend to have, in-house manufacturing capability and depend completely on a single third-party manufacturer for the manufacture of the ILUVIEN implant (Alliance Medical Products, Inc. (Alliance)), a single third-party manufacturer for the manufacture of the ILUVIEN applicator (Flextronics International, Ltd. or an affiliate of Flextronics International, Ltd. (Flextronics)), a single third-party manufacturer for the manufacture of ILUVIEN s active pharmaceutical ingredient (FARMABIOS SpA./Byron Chemical Company Inc. (FARMABIOS)) and a single third-party manufacturer for the

---

**Table of Contents**

quality release testing of ILUVIEN in the EU (Brecon Pharmaceuticals Limited (Brecon)). Although we have agreements for the manufacture of the ILUVIEN implant (with Alliance), the manufacture of the ILUVIEN applicator (with Flextronics), for the supply of ILUVIEN's active pharmaceutical ingredient (with FARMABIOS) and for the quality release testing of ILUVIEN in the EU (with Brecon), if any of the third-party manufacturers breach their agreements or are unable or unwilling to perform for any reason, we may not be able to locate alternative acceptable manufacturers, enter into favorable agreements with them or get them approved by the applicable regulatory authorities, such as the FDA in the U.S., in a timely manner. Further, all of our manufacturers rely on additional third-parties for the manufacture of component parts. Any inability to acquire sufficient quantities of ILUVIEN implants, the ILUVIEN applicator or the active pharmaceutical ingredient in a timely manner from these third-parties could delay commercial production of, and impact our ability to fulfill demand for, ILUVIEN, if any.

***Materials necessary to manufacture ILUVIEN may not be available on commercially reasonable terms, or at all, which may delay the development, regulatory approval and commercialization of ILUVIEN.***

We rely on our manufacturers to purchase materials from third-party suppliers necessary to produce ILUVIEN. Suppliers may not sell these materials to our manufacturers at the times we need them or on commercially reasonable terms. We do not have any control over the process or timing of the acquisition of these materials by our manufacturers. If our manufacturers are unable to obtain these materials, the commercial launch of ILUVIEN would be delayed or there would be a shortage in supply, which would materially affect our ability to generate revenues from the sale of ILUVIEN. Moreover, although we have entered into agreements for the commercial production of the ILUVIEN implant, the commercial production of the ILUVIEN applicator, and the supply of the active pharmaceutical ingredient in ILUVIEN, the suppliers may be unable or choose not to supply us in a timely manner or in the minimum guaranteed quantities. If we are unable to obtain these supplies, our ability to manufacture ILUVIEN for commercial sale would be delayed, significantly impacting our ability to generate revenue from the sale of ILUVIEN.

***The manufacture and packaging of pharmaceutical products such as ILUVIEN are subject to the requirements of the FDA and similar foreign regulatory entities. If we or our third-party manufacturers fail to satisfy these requirements, our product development and commercialization efforts may be materially harmed.***

The manufacture and packaging of pharmaceutical products such as ILUVIEN and any future product candidates are regulated by the FDA and similar foreign regulatory agencies and must be conducted in accordance with the FDA's cGMP and comparable requirements of foreign regulatory agencies. There are a limited number of manufacturers that operate under these cGMP regulations which are both capable of manufacturing ILUVIEN and willing to do so. Failure by us or our third-party manufacturers to comply with applicable regulations, requirements, or guidelines could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of ILUVIEN or any future products or product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. Failure of our manufacturers to maintain compliance could interrupt the production of ILUVIEN, resulting in delays and additional costs which could significantly and adversely affect our business. For example, during routine manufacturing inspection, we identified a quality issue related to one of our suppliers that affected certain batches of work in process, which resulted in a write-off of \$1.4 million during the year ended December 31, 2013. Any significant delays in the manufacture of ILUVIEN or the quality of the product could materially harm our business and prospects.

Changes in the manufacturing process or procedure, including a change in the location where the product is manufactured or a change of a third-party manufacturer, will require prior FDA review and/or approval of the manufacturing process and procedures in accordance with the FDA's cGMP regulations. There are comparable foreign

requirements as well. This review may be costly and time consuming and could delay or prevent the launch of a product. If we elect to manufacture products in our own facility or at the facility of another third-party, we would need to ensure that the new facility and the manufacturing process are in substantial compliance with cGMP and comparable foreign regulations. The new facility will also be subject to pre-approval inspection. In addition, we have to demonstrate that the product made at the new facility is equivalent to the product made at the former facility by physical and chemical methods, which are costly and time consuming. It is also possible that the FDA or a foreign regulatory agency may require clinical testing as a way to prove equivalency, which would result in additional costs and delay.

Furthermore, in order to obtain approval of ILUVIEN or any future products or product candidates by the FDA and foreign regulatory agencies, we need to complete testing on both the active pharmaceutical ingredient and on the finished product in the packaging that we propose for commercial sales. This includes testing of stability, identification of impurities and testing of

---

**Table of Contents**

other product specifications by validated test methods. In addition, we will be required to consistently produce in commercial quantities and of specified quality in a reproducible manner and document our ability to do so. This requirement is referred to as process validation. The FDA and similar foreign regulatory agencies may also implement new standards, or change their interpretation and enforcement of existing standards and requirements, for the manufacture, packaging, or testing of products at any time. For example, in the CRL we received in October 2013, the FDA referenced deficiencies in the methods and controls used for the drug product at the facility where ILUVIEN is manufactured. If we are unable to comply, ILUVIEN may not be approved, or we may be subject to regulatory or civil actions or penalties that could significantly and adversely affect our business.

***In order to expand our sales and marketing infrastructure, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.***

As of June 30, 2014, we had 30 employees, 24 of whom were located in the U.S. and six of whom were located in the United Kingdom or Germany. Recognizing that we would need resources beyond this core management team to commercialize ILUVIEN on our own in the EU, in November 2012 we entered into a master services agreement with Quintiles Commercial to provide additional personnel for our planned launch of ILUVIEN, and subsequent operations, in Germany, the United Kingdom and France. Under this agreement and its related project orders, Quintiles Commercial, as of June 30, 2014, employed six persons fully dedicated to Alimera. Quintiles Commercial also employed 24 persons partially dedicated to Alimera in Germany, the United Kingdom and France, as of June 30, 2014. While these individuals are employed by Quintiles Commercial, and are not employed directly by us, we will not be able to operate effectively unless we integrate them into our organization, which may be difficult. For example, we have determined that Quintiles Commercial is not as effective in filling certain positions in certain geographies as we believe that we can be in hiring directly. Therefore, in July 2014, the project orders with Quintiles Commercial in Germany, the United Kingdom and France were amended, effective July 1, 2014, to align the terms with the actual staffing in place, account for positions that have been hired directly into Alimera and provide for the early termination of the project orders associated with Germany as of December 31, 2014 and transition of the German positions to our payroll effective January 1, 2015 or earlier. As our development and commercialization plans and strategies evolve beyond our initial planned EU launches, we will need to further expand the size of our organization by recruiting additional managerial, operational, sales, marketing, financial and other personnel, who may be hired directly by us or through Quintiles Commercial or other similar organizations. This future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional personnel. Also, our management may have to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. Our future financial performance and our ability to commercialize ILUVIEN and our future products or product candidates and compete effectively will depend, in part, on our ability to effectively manage any such future growth and related costs. We may not be able to effectively manage a rapid pace of growth and timely implement improvements to our management infrastructure and control systems.

***ILUVIEN and any future products or product candidates may not be commercially viable if we fail to obtain an adequate level of reimbursement for these products from governments, private insurers, the Medicare program and other third-party payers. The market for our products may also be limited by the indications for which their use or frequency of administration may be reimbursed.***

The availability and levels of reimbursement by governmental and other third-party payers affect the market for products such as ILUVIEN and others that we may develop. These third-party payers continually attempt to contain or reduce the costs of health care by challenging the prices charged for medical products and services.

In many countries, the pricing of prescription pharmaceuticals is subject to governmental control. In the EU, each country has a different reviewing body that evaluates reimbursement dossiers submitted by marketing authorization holders of new drugs and then makes recommendations as to whether or not the drug should be reimbursed. In these countries, pricing negotiations with governmental authorities can take 12 months or longer after the receipt of regulatory approval, or delay regulatory approval. 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 products, including ILUVIEN, to other available therapies. Limitations on reimbursement could be imposed at the national, regional or local level or by fiscal intermediaries in each country. Our business could be materially adversely affected if such limitations were imposed. Our business also could be adversely affected if retinal specialists are not reimbursed for the cost of the procedure in which they administer ILUVIEN on a basis satisfactory to the administering retinal specialists.

---

**Table of Contents**

In the U.S., in the event that ILUVIEN is approved, we will need to obtain approvals for payment for ILUVIEN from private insurers, including managed care organizations, and from the Medicare program. In recent years, through legislative and regulatory actions, the federal government has made substantial changes to various payment systems under the Medicare program. Comprehensive reforms to the U.S. healthcare system were recently enacted, including changes to the methods for, and amounts of, Medicare reimbursement. These reforms could significantly reduce payments from Medicare and Medicaid over the next ten years. Reforms or other changes to these payment systems, including modifications to the conditions on qualification for payment, bundling of payments or the imposition of enrollment limitations on new providers, may change the availability, methods and rates of reimbursements from Medicare, private insurers and other third-party payers for ILUVIEN and our other potential products. Some of these changes and proposed changes could result in reduced reimbursement rates for ILUVIEN and our other potential products, which would adversely affect our business strategy, operations and financial results.

We expect that private insurers will consider the efficacy, cost effectiveness and safety of ILUVIEN in determining whether to approve reimbursement for ILUVIEN and at what level. Obtaining these approvals can be a time consuming and expensive process. Our business would be materially adversely affected if we do not receive approval for reimbursement of ILUVIEN from private insurers on a timely or satisfactory basis. Although drugs that are not self-administered are covered by Medicare, the Medicare program has taken the position that it can decide not to cover particular drugs if it determines that they are not reasonable and necessary for Medicare beneficiaries. Limitations on coverage could also be imposed at the local Medicare carrier level or by fiscal intermediaries. Our business could be materially adversely affected if the Medicare program, local Medicare carriers or fiscal intermediaries were to make such a determination and deny or limit the reimbursement of ILUVIEN. Our business also could be adversely affected if retinal specialists are not reimbursed by Medicare for the cost of the procedure in which they administer ILUVIEN on a basis satisfactory to the administering retinal specialists. If the local contractors that administer the Medicare program are slow to reimburse retinal specialists for ILUVIEN, the retinal specialists may pay us more slowly, which would adversely affect our working capital requirements.

Our business could also be adversely affected if governments, private insurers, the Medicare program or other reimbursing bodies or payers limit the indications for which ILUVIEN will be reimbursed to a smaller set than we believe it is effective in treating or establish a limitation on the frequency with which ILUVIEN may be administered that is less often than we believe would be effective.

We expect to experience pricing pressures in connection with the sale of ILUVIEN and any future products or product candidates due to the potential healthcare reforms discussed above, as well as the trend toward programs aimed at reducing health care costs, the increasing influence of health maintenance organizations and additional legislative proposals, and the economic health of companies. If reimbursement for our products is unavailable, limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

***We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.***

The development and commercialization of new drugs is highly competitive and the commercial success of ILUVIEN will depend on several factors, including, but not limited to, its efficacy and side effect profile, authorization for reimbursement by foreign regulatory bodies, private insurers and Medicare, acceptance of pricing, the development of our sales and marketing organization, an adequate payment to physicians for the insertion procedure and our ability to differentiate ILUVIEN from our competitors' products. We will face competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide with respect to ILUVIEN and to any future products or product candidates that we may develop or commercialize in the future. Our competitors may develop products or other novel technologies that are more effective, safer or less costly than any that we are

developing. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours. The active pharmaceutical ingredient in ILUVIEN is FAc, which is not protected by currently valid patents. As a result, our competitors could develop an alternative formulation or delivery mechanisms to treat diseases of the eye with FAc. We do not have the right to develop and sell pSivida's proprietary delivery device for indications for diseases outside of the eye or for the treatment of uveitis, which are retained by pSivida. Further, our agreement with pSivida permits pSivida to grant to any other party the right to use its intellectual property (i) to treat DME through an incision smaller than that required for a 25-gauge needle, unless using a corticosteroid delivered to the back of the eye, (ii) to deliver any compound outside the back of the eye unless it is to treat DME through an incision required for a 25-

**Table of Contents**

gauge or larger needle, or (iii) to deliver non-corticosteroids to the back of the eye, unless it is to treat DME through an incision required for a 25-gauge or larger needle.

Many of our competitors have substantially greater financial, technical and human resources than we have. Additional mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated by our competitors. Competition may increase further as a result of advances made in the commercial applicability of technologies and greater availability of capital for investment in these fields.

***Other than the master services agreement entered into with Quintiles Commercial in November 2012, we currently do not have any collaboration agreements with third-parties. We expect to depend on collaborations to develop and commercialize our products. If we are unable to identify or enter into an agreement with any material third-party collaborator, if our collaborations with any such third-party are not scientifically or commercially successful or if our agreement with any such third-party is terminated or allowed to expire, we could be adversely affected financially or our business reputation could be harmed.***

Our business strategy includes entering into collaborations with corporate and academic collaborators for the research, development and commercialization of ILUVIEN and any future products or product candidates. Other than the master services agreement entered into with Quintiles Commercial in November 2012, we currently do not have any collaboration agreements with third-parties. Areas in which we may potentially enter into third-party collaboration arrangements include joint sales and marketing arrangements for sales and marketing of ILUVIEN in certain EU countries and elsewhere outside of North America, and future product development arrangements. If we are unable to identify or enter into an agreement with any material third-party collaborator we could be adversely affected financially or our business reputation could be harmed. Any arrangements we do enter into may not be scientifically or commercially successful. The termination of any of these arrangements might adversely affect our ability to develop, commercialize and market our products.

The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Our collaborators will have significant discretion in determining the efforts and resources that they will apply to these collaborations. We expect that the risks which we face in connection with these future collaborations will include the following:

our collaboration agreements are expected to be for fixed terms and subject to termination under various circumstances, including, in many cases, on short notice without cause;

we expect to be required in our collaboration agreements not to conduct specified types of research and development in the field that is the subject of the collaboration. These agreements may have the effect of limiting the areas of research and development that we may pursue, either alone or in cooperation with third-parties;

our collaborators may develop and commercialize, either alone or with others, products and services that are similar to or competitive with our products which are the subject of their collaboration with us; and



our collaborators may change the focus of their development and commercialization efforts. In recent years there have been a significant number of mergers and consolidations in the pharmaceutical and biotechnology industries, some of which have resulted in the participant companies reevaluating and shifting the focus of their business following the completion of these transactions. The ability of our products to reach their potential could be limited if any of our future collaborators decreases or fails to increase spending relating to such products.

Collaborations with pharmaceutical companies and other third-parties often are terminated or allowed to expire by the other party. With respect to our future collaborations, any such termination or expiration could adversely affect us financially as well as harm our business reputation.

***If we lose key management personnel, or if we fail to recruit additional highly skilled personnel, it will impair our ability to identify, develop and commercialize ILUVIEN and any future products or product candidates.***

We are highly dependent upon the principal members of our management team, including C. Daniel Myers, our President and Chief Executive Officer, Richard Eiswirth, our Chief Operating Officer and Chief Financial Officer, Philip Ashman, Ph.D., our EU Senior Vice President and EU Managing Director, Dave Holland, our Senior Vice President of Sales and Marketing, Susan Caballa, our Senior Vice President of Regulatory Affairs and Kenneth Green, Ph.D., our Senior Vice President and Chief

**Table of Contents**

Scientific Officer. These executives have significant ophthalmic, regulatory industry, sales and marketing, operational, and/or corporate finance experience. The loss of any such executives or any other principal member of our management team would impair our ability to identify, develop and market ILUVIEN and any future products or product candidates.

In addition, our growth will require us to hire a significant number of qualified technical, commercial and administrative personnel. There is intense competition from other companies and research and academic institutions for qualified personnel in the areas of our activities. If we cannot continue to attract and retain, on acceptable terms, the qualified personnel necessary for the continued development of our business, we may not be able to sustain our operations or grow.

***Our products could be subject to restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements, or if we experience unanticipated problems with our products, when and if any of them are approved.***

Any product for which we have or obtain marketing approval, including ILUVIEN in the EU, along with the manufacturing processes, post-approval pharmacovigilance, advertising and promotional activities for such product, will be subject to continual requirements, review and periodic inspections by the FDA and other regulatory bodies. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Later discovery of previously unknown problems with our products, manufacturer or manufacturing processes, or failure to comply with regulatory requirements, may result in:

restrictions on such products or manufacturing processes;

withdrawal of the products from the market;

voluntary or mandatory recall;

fines;

suspension of regulatory approvals;

product seizure; and

injunctions or the imposition of civil or criminal penalties.

We may be slow to adapt, or we may never adapt, to changes in existing regulatory requirements or adoption of new regulatory requirements or policies.

***Failure to obtain regulatory approval in additional foreign jurisdictions would prevent us from marketing ILUVIEN in additional markets.***

ILUVIEN has received marketing authorization in Austria, the United Kingdom, Portugal, France, Germany, Spain, Italy, Norway and Denmark, and been recommended for marketing authorization in eight additional EU countries. We intend to continue to pursue market authorizations for ILUVIEN internationally in additional jurisdictions. In order to market our products in foreign jurisdictions, we will be required to obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and jurisdictions and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval or approval in the seventeen EU countries in which ILUVIEN has received or been recommended for marketing authorization. Additionally, the foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. For all of these reasons, we may not obtain additional foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or jurisdictions or by the FDA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize ILUVIEN in any additional market. The failure to obtain these approvals could harm our business materially.

***We face the risk of product liability claims and may not be able to obtain or maintain insurance.***

## Table of Contents

Our business exposes us to the risk of product liability claims, which is inherent in the manufacturing, testing and marketing of drugs and related products. If the use of one or more of our products harms people, we may be subject to costly and damaging product liability claims. We maintain product liability insurance covering our clinical trial activities and our product sales. The insurance provides worldwide coverage where allowed by law. As product revenue is generated in new countries, we intend to obtain compulsory coverage in those countries that require it. We may not be able to obtain or maintain adequate protection against potential liabilities. If we are unable to obtain insurance at acceptable cost or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may materially and adversely affect our business and financial position. These liabilities could prevent or interfere with our product development and commercialization efforts.

### *We may not be successful in our efforts to expand our portfolio of products.*

In the future, we may choose to commercialize a portfolio of new ophthalmic drugs in addition to ILUVIEN. We may seek to do so through our internal research programs and through licensing or otherwise acquiring the rights to potential new drugs and drug targets for the treatment of ophthalmic disease.

A significant portion of the research that we may choose to conduct may involve new and unproven technologies. Research programs to identify new disease targets and product candidates require substantial technical, financial and human resources whether or not we ultimately identify any candidates. Any future research programs may initially show promise in identifying potential products or product candidates, yet fail to yield products or product candidates for clinical development for a number of reasons, including:

the research methodology used may not be successful in identifying potential products or product candidates;  
or

potential products or product candidates may on further study be shown to have harmful side effects or other characteristics that indicate they are unlikely to be effective drugs.

We may be unable to license or acquire suitable products or product candidates or products from third-parties for a number of reasons. In particular, the licensing and acquisition of pharmaceutical products is a competitive area. Several more established companies are also pursuing strategies to license or acquire products in the ophthalmic field. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. Other factors that may prevent us from licensing or otherwise acquiring suitable products or product candidates include the following:

we may be unable to license or acquire the relevant technology on terms that would allow us to make an appropriate return from the product;

companies that perceive us to be their competitors may be unwilling to assign or license their product rights to us; or

we may be unable to identify suitable products or product candidates within our areas of expertise.

Additionally, it may take greater human and financial resources to develop suitable potential products or product candidates through internal research programs or by obtaining rights than we will possess, thereby limiting our ability to develop a diverse product portfolio.

If we are unable to develop suitable potential product candidates through internal research programs or by obtaining rights to novel therapeutics from third-parties, our business may suffer.

***We may acquire additional businesses or form strategic alliances in the future, and we may not realize the benefits of such acquisitions or alliances.***

We may acquire additional businesses or products, form strategic alliances or create joint ventures with third-parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may have difficulty in developing, manufacturing and marketing the products of a newly acquired company that enhances the performance of our combined businesses or product lines to realize value from

**Table of Contents**

expected synergies. We cannot assure that, following an acquisition, we will achieve the revenues or specific net income that justifies the acquisition.

***Any future products or product candidates may never achieve market acceptance even if we obtain regulatory approvals.***

Even if we receive regulatory approvals for the sale of any future products or product candidates, the commercial success of these products will depend, among other things, on their acceptance by retinal specialists, patients, third-party payers and other members of the medical community as a therapeutic and cost-effective alternative to competing products and treatments. The degree of market acceptance of any future products or product candidates will depend on a number of factors, including, among other things:

the demonstration of its safety and efficacy;

its cost-effectiveness;

its potential advantages over other therapies;

the reimbursement policies of government and third-party payers with respect to the product candidate; and

the effectiveness of our marketing and distribution capabilities.

If any future products or product candidates fail to gain market acceptance, we may be unable to earn sufficient revenue to continue our business. If any future product candidates are not accepted by retinal specialists, patients, third-party payers and other members of the medical community, it is unlikely that we will ever become profitable.

***Any failure or delay in completing clinical trials for any future product candidates could severely harm our business.***

Preclinical studies and clinical trials required to demonstrate the safety and efficacy of any future product candidates will be time consuming and expensive and together will take several years to complete. The completion of clinical trials for any product candidates may be delayed by many factors, including:

our inability to manufacture or obtain from third-parties materials sufficient for use in preclinical studies and clinical trials;

delays in patient enrollment and variability in the number and types of patients available for clinical trials;

difficulty in maintaining contact with patients after treatment, resulting in incomplete data;

poor effectiveness of product candidates during clinical trials;

unforeseen safety issues or side effects; and

governmental or regulatory delays and changes in regulatory requirements and guidelines.

If we fail to successfully complete any future clinical trials for any future product candidates, we may not receive the regulatory approvals needed to market those product candidates. Therefore, any failure or delay in commencing or completing such clinical trials would harm our business materially.

In addition, a clinical trial may be suspended or terminated by us, the FDA 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 resulting in the imposition of a clinical hold;

unforeseen safety issues or any determination that a trial presents unacceptable health risks; and

---

**Table of Contents**

lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our contract research organizations, and other third parties.

If we are required to conduct additional clinical trials or other studies with respect to any future product candidates beyond those that we initially contemplated, if we are unable to successfully complete our clinical trials or other studies or if the results of these trials or studies are not positive or are only modestly positive, we may be delayed in obtaining marketing approval for those future product candidates, we may not be able to obtain marketing approval or we may obtain approval for indications that are not as broad as intended. Our product development costs will also increase if we experience delays in testing or approvals. Significant clinical trial delays could allow our competitors to bring products to market before we do and impair our ability to commercialize our products or potential products. If any of this occurs, our business will be materially harmed.

***If our contract research organizations (CROs), third-party vendors and investigators do not successfully carry out their duties or if we lose our relationships with them, our development efforts with respect to any future product candidates could be delayed.***

We expect to be dependent on CROs, third-party vendors and investigators for preclinical testing and clinical trials related to our discovery and development efforts with respect to any future product candidates. These parties are not our employees and we cannot control the amount or timing of resources that they devote to our programs. If they fail to devote sufficient time and resources to our development programs with respect to our product candidates or if their performance is substandard, it will delay the development and commercialization of our product candidates. The parties with which we contract for execution of clinical trials play a significant role in the conduct of the trials and the subsequent collection and analysis of data. Their failure to meet their obligations could adversely affect clinical development of our product candidates. Moreover, these parties may also have relationships with other commercial entities, some of which may compete with us. If they assist our competitors, it could harm our competitive position.

If we lose our relationship with any one or more of these parties, we could experience a significant delay in identifying another comparable provider and contracting for its services. We may be unable to retain an alternative provider on reasonable terms, if at all. Even if we locate an alternative provider, this provider may need additional time to respond to our needs and may not provide the same type or level of service as the original provider. In addition, any provider that we retain will be subject to current Good Laboratory Practices (cGLP) and similar foreign standards, and we do not have control over compliance with these regulations by these providers. Consequently, if these practices and standards are not adhered to by these providers, the development and commercialization of ILUVIEN or any future product candidates could be delayed.

**Risks Related to Intellectual Property and Other Legal Matters**

***If we or our licensors are unable to obtain and maintain protection for the intellectual property incorporated into our products, the value of our technology and products will be adversely affected.***

Our success will depend in large part on our ability or the ability of our licensors to obtain and maintain protection in the U.S. and other countries for the intellectual property incorporated into our products. The patent situation in the field of biotechnology and pharmaceuticals generally is highly uncertain and involves complex legal and scientific questions. We or our licensors may not be able to obtain additional issued patents relating to our technology. Our success will depend in part on the ability of our licensors to obtain, maintain (including making periodic filings and payments) and enforce patent protection for their intellectual property, in particular, those patents to which we have secured exclusive rights. Under our license with pSivida, pSivida controls the filing, prosecution and maintenance of all patents. Our licensors may not successfully prosecute or continue to prosecute the patent applications to which we



are licensed. Even if patents are issued in respect of these patent applications, we or our licensors may fail to maintain these patents, may determine not to pursue litigation against entities that are infringing upon these patents, or may pursue such litigation less aggressively than we ordinarily would. Without protection for the intellectual property that we own or license, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects. Moreover, FAc is an off-patent active ingredient that is commercially available in several forms including the extended release ocular implant Retisert.

## **Table of Contents**

Even if issued, patents may be challenged, narrowed, invalidated, or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of term of patent protection that we may have for our products. In addition, our patents and our licensors' patents may not afford us protection against competitors with similar technology.

***Litigation or third-party claims of intellectual property infringement would require us to divert resources and may prevent or delay our development, regulatory approval or commercialization of our products.***

ILUVIEN or any future products or product candidates may infringe upon other parties' intellectual property rights that are protected by patents or patent applications. Third-parties may now or in the future own or control these patents and patent applications in the U.S. and abroad. These third-parties could bring claims against us or our collaborators that would cause us to incur substantial expenses or divert substantial employee resources from our business and, if successful, could cause us to pay substantial damages or prevent us from developing any future product candidates. Further, if a patent infringement suit were brought against us or our collaborators, we or they could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit.

Several issued and pending U.S. patents claiming methods and devices for the treatment of eye diseases, including through the use of steroids, implants and injections into the eye, purport to cover aspects of ILUVIEN. For example, one of our potential competitors holds issued and pending U.S. patents and a pending European patent application with claims covering injecting an ocular implant into a patient's eye similar to the ILUVIEN applicator. There is also an issued U.S. patent with claims covering implanting a steroidal anti-inflammatory agent to treat an inflammation-mediated condition of the eye. If these or any other patents were held by a court of competent jurisdiction to be valid and to cover aspects of ILUVIEN, then the owners of such patents would be able to block our ability to commercialize ILUVIEN unless and until we obtain a license under such patents (which license might require us to pay royalties or grant a cross-license to one or more patents that we own), until such patents expire or unless we are able to redesign our product to avoid any such valid patents.

As a result of patent infringement claims, or in order to avoid potential claims, we or our collaborators may choose to seek, or be required to seek, a license from the third-party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain a license, the rights may be nonexclusive, which would give our competitors access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations if, as a result of actual or threatened patent infringement claims, we or our collaborators are unable to enter into licenses on acceptable terms. This could harm our business significantly.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference proceedings declared by the U.S. Patent and Trademark Office and opposition proceedings in the European Patent Office, regarding intellectual property rights with respect to our products and technology. The cost to us of any litigation or other proceeding, regardless of its merit, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Intellectual property litigation and other proceedings may, regardless of their merit, also absorb significant management time and employee resources.

***If we fail to comply with our obligations in the agreements under which we license development or commercialization rights to products or technology from third-parties, we could lose license rights that are important to our business.***

Our licenses are material to our business, and we expect to enter into additional licenses in the future. We hold a license from pSivida to intellectual property relating to ILUVIEN. This license imposes various commercialization, milestone payment, profit sharing, insurance and other obligations on us. We also hold a license from Dainippon Sumitomo Pharma Co., Ltd. to patents relating to ILUVIEN. This license imposes a milestone payment and other obligations on us. If we fail to comply with these obligations, the licensor may have the right to terminate the applicable license, in which event we would not be able to market products, such as ILUVIEN, that may be covered by such license.

---

**Table of Contents**

***If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.***

In addition to patented technology, we rely upon unpatented proprietary technology, processes, trade secrets and know-how. Any involuntary disclosure or misappropriation by third-parties of our confidential or proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. We seek to protect confidential or proprietary information in part by confidentiality agreements with our employees, consultants and third-parties. While we require all of our employees, consultants, advisors and any third-parties who have access to our proprietary know-how, information and technology to enter into confidentiality agreements, we cannot be certain that this know-how, information and technology will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. These agreements may be terminated or breached, and we may not have adequate remedies for any such termination or breach. Furthermore, these agreements may not provide meaningful protection for our trade secrets and know-how in the event of unauthorized use or disclosure. To the extent that any of our staff were previously employed by other pharmaceutical or biotechnology companies, those employers may allege violations of trade secrets and other similar claims in relation to their drug development activities for us.

***If our efforts to protect the proprietary nature of the intellectual property related to our products are not adequate, we may not be able to compete effectively in our markets.***

The strength of our patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. In addition to the rights we have licensed from pSivida relating to ILUVIEN, we rely upon intellectual property we own, including patents, patent applications and trade secrets. Our patent applications may be challenged or fail to result in issued patents and our existing or future patents may be too narrow to prevent third-parties from developing or designing around these patents. As of June 30, 2014, the patent rights relating to ILUVIEN licensed to us from pSivida include five U.S. patents that expire between March 2019 and April 2020, two European patents expiring in April of 2021 and October of 2024, and counterpart filings to these patents in a number of other jurisdictions. No patent term extension will be available for any of these U.S. patents, European patent or any of our licensed U.S. or European pending patent applications. After these patents expire in April 2020 in the U.S. and October of 2024 in Europe, we will not be able to block others from marketing FAc in an implant similar to ILUVIEN. Moreover, it is possible that a third-party could successfully challenge the scope (i.e., whether a patent is infringed), validity and enforceability of our licensed patents prior to patent expiration and obtain approval to market a competitive product.

Further, the patent applications that we license or have filed may fail to result in issued patents. Some claims in pending patent applications filed or licensed by us have been rejected by patent examiners. These claims may need to be amended. Even after amendment, a patent may not be permitted to issue. Further, the existing or future patents to which we have rights based on our agreement with pSivida may be too narrow to prevent third-parties from developing or designing around these patents. Additionally, we may lose our rights to the patents and patent applications we license in the event of a breach or termination of the license agreement. Manufacturers may also seek to obtain approval to sell a generic version of ILUVIEN prior to the expiration of the relevant licensed patents. If the sufficiency of the breadth or strength of protection provided by the patents we license with respect to ILUVIEN or the patents we pursue related to ILUVIEN or any future product candidate is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize ILUVIEN and any future product candidates. Further, if we encounter delays in our clinical trials for any future product candidate, the period of time during which we could market such product candidates under patent protection would be reduced. We rely on trade secret protection and confidentiality agreements to protect certain proprietary know-how that is not patentable, for processes for which patents are difficult to enforce and for any other elements of our development processes with

respect to ILUVIEN that involve proprietary know-how, information and technology that is not covered by patent applications. While we require all of our employees, consultants, advisors and any third-parties who have access to our proprietary know-how, information and technology to enter into confidentiality agreements, we cannot be certain that this know-how, information and technology will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Further, the laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the U.S. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the U.S. and abroad. If we are unable to protect or defend the intellectual property related to our technologies, we will not be able to establish or maintain a competitive advantage in our market.

***Third-party claims of intellectual property infringement may prevent or delay our commercialization efforts with respect to ILUVIEN and our discovery, development or commercialization efforts with respect to any future product candidates.***

---

**Table of Contents**

Our commercial success depends in part on avoiding infringement of the patents and proprietary rights of third-parties. Third-parties may assert that we are employing their proprietary technology without authorization. In addition, at least several issued and pending U.S. patents claiming methods and devices for the treatment of eye diseases, including through the use of steroids, implants and injections into the eye, purport to cover aspects of ILUVIEN.

Although we are not currently aware of any litigation or other proceedings or third-party claims of intellectual property infringement related to ILUVIEN, the pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may in the future allege that our activities infringe their patents or that we are employing their proprietary technology without authorization. We may not have identified all the patents, patent applications or published literature that affect our business either by blocking our ability to commercialize our products or product candidates, by preventing the patentability of one or more aspects of our products or those of our licensors or by covering the same or similar technologies that may affect our ability to market our product. We cannot predict whether we would be able to obtain a license on commercially reasonable terms, if at all. Any inability to obtain such a license under the applicable patents on commercially reasonable terms, or at all, may have a material adverse effect on our ability to commercialize ILUVIEN or any future products or product candidates until such patents expire.

In addition, third-parties may obtain patents in the future and claim that use of ILUVIEN, our technologies or future products or product candidates infringes upon these patents. Furthermore, parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further commercialize ILUVIEN or develop and commercialize any future product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, obtain one or more licenses from third-parties or pay royalties, or we may be enjoined from further commercializing ILUVIEN or developing and commercializing any future product candidates or technologies. In addition, even in the absence of litigation, we may need to obtain licenses from third-parties to advance our research or allow commercialization of ILUVIEN or any future product candidate, and we have done so from time to time. We may fail to obtain future licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be unable to further commercialize ILUVIEN or develop and commercialize any future product candidates, which could harm our business significantly.

***We may become involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.***

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference proceedings brought by the U.S. Patent and Trademark Office may be necessary to determine the priority of inventions with respect to our patents and patent applications or those of our collaborators or licensors. An unfavorable outcome could require us to cease using the technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if a prevailing party does not offer us a license on terms that are acceptable to us. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distraction of our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our proprietary rights, particularly in countries where the laws may not protect those rights as

fully as in the U.S.

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 this type of litigation. In addition, there could 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 have a substantial adverse effect on the price of our common stock.

---

**Table of Contents**

***Product liability lawsuits could divert our resources, result in substantial liabilities and reduce the commercial potential of our products.***

The risk that we may be sued on product liability claims is inherent in the development of pharmaceutical products. We face an increased risk of product liability as we further commercialize ILUVIEN. We believe that we may be at a greater risk of product liability claims relative to other pharmaceutical companies because our products are inserted into the eye, and it is possible that we may be held liable for eye injuries of patients who receive our product. These lawsuits may divert our management from pursuing our business strategy and may be costly to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities and may be forced to limit or forego further commercialization of one or more of our products. Although we maintain product liability insurance covering our clinical trial activities and our product sales, our aggregate coverage limit under these insurance policies is limited to \$10.0 million in most jurisdictions, and while we believe this amount of insurance is sufficient to cover our product liability exposure, these limits may not be high enough to fully cover potential liabilities. The insurance provides worldwide coverage where allowed by law. As product revenue is generated in new countries, we intend to obtain compulsory coverage in those countries that require it. However, we may not be able to obtain or maintain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims, which could prevent or inhibit the commercial production and sale of our products.

***Legislative or regulatory reform of the health care system in the U.S. and foreign jurisdictions may adversely impact our business, operations or financial results.***

Our industry is highly regulated and changes in law may adversely impact our business, operations or financial results. In particular, in March 2010, the Patient Protection and Affordable Care Act, or PPACA, and a related reconciliation bill were signed into law. This legislation changes the current system of healthcare insurance and benefits intended to broaden coverage and control costs. The law also contains provisions that will affect companies in the pharmaceutical industry and other healthcare related industries by imposing additional costs and changes to business practices. Provisions affecting pharmaceutical companies include the following:

Mandatory rebates for drugs sold into the Medicaid program have been increased, and the rebate requirement has been extended to drugs used in risk-based Medicaid managed care plans.

The 340B Drug Pricing Program under the Public Health Services Act has been extended to require mandatory discounts for drug products sold to certain critical access hospitals, cancer hospitals and other covered entities.

Pharmaceutical companies are required to offer discounts on brand-name drugs to patients who fall within the Medicare Part D coverage gap, commonly referred to as the Donut Hole.

Pharmaceutical companies are required to pay an annual non-tax deductible fee to the federal government based on each company's market share of prior year total sales of branded products to certain federal healthcare programs, such as Medicare, Medicaid, Department of Veterans Affairs and Department of Defense. The aggregate industry-wide fee is expected to total \$28 billion through 2019, of which \$3.0 billion will be payable in 2014. Since we expect our branded pharmaceutical sales to constitute a small portion of



the total federal health program pharmaceutical market, we do not expect this annual assessment to have a material impact on our financial condition.

The law provides that biologic products may receive 12 years of market exclusivity, with a possible six-month extension for pediatric products. After this exclusivity ends, generic manufacturers will be permitted to enter the market, which is likely to reduce the pricing for such products and could affect the company's profitability. In addition, generic manufacturers will be permitted to challenge one or more of the patents for a branded drug after a product is marketed for four years.

The full effects of the U.S. healthcare reform legislation cannot be known until the new law is implemented through regulations or guidance issued by the Centers for Medicare & Medicaid Services and other federal and state healthcare agencies. The financial impact of the U.S. healthcare reform legislation over the next few years will depend on a number of factors including but not limited to the policies reflected in implementing regulations and guidance and changes in sales volumes for products affected by the new system of rebates, discounts and fees. If ILUVIEN is approved by the FDA, the legislation may also have a positive impact on our future net sales, if any, by increasing the aggregate number of persons with healthcare coverage in the U.S., but such increases are unlikely to be realized until approximately 2014, at the earliest.

**Table of Contents**

The Physician Payment Sunshine Act also imposes new reporting and disclosure requirements on device and drug manufacturers for any transfer of value made or distributed to prescribers and other healthcare providers. In addition, device and drug manufacturers will also be required to report and disclose any investment interests held by physicians and their immediate family members during the preceding calendar year. Failure to submit required information may result in significant civil monetary penalties.

In addition, in September 2007, the Food and Drug Administration Amendments Act of 2007 was enacted giving the FDA enhanced post-marketing authority including the authority to require post-marketing studies and clinical trials, labeling changes based on new safety information and compliance with risk evaluations and mitigation strategies approved by the FDA. The FDA's exercise of this authority could result in delays or increased costs during product development, clinical trials and regulatory review, increased costs to ensure compliance with post-approval regulatory requirements and potential restrictions on the sale and/or distribution of approved products.

Further, in some foreign countries, including the EU and Canada, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take 12 months or longer after the receipt of regulatory approval and product launch. 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 candidate to other available therapies. Our business could be materially harmed if reimbursement of our products is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels.

Moreover, we cannot predict what healthcare reform initiatives may be adopted in the future. Further federal and state legislative and regulatory developments are likely, and we expect ongoing initiatives in the U.S. to increase pressure on drug pricing. Such reforms could have an adverse effect on anticipated revenues from ILUVIEN or any future products or product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop drug candidates.

---

**Table of Contents**

***If we use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.***

Our research and development activities may involve the controlled use of potentially hazardous substances, including chemical and biological materials. In addition, our operations may produce hazardous waste products. Federal, state and local laws and regulations in both the U.S. and Canada govern the use, manufacture, storage, handling and disposal of hazardous materials. Although we believe that our procedures for use, handling, storing and disposing of these materials comply with legally prescribed standards, we may incur significant additional costs to comply with applicable laws in the future. Also, even if we are in compliance with applicable laws, we cannot completely eliminate the risk of contamination or injury resulting from hazardous materials and we may incur liability as a result of any such contamination or injury. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, operating results and financial condition.

***Our ability to use our net operating loss carry-forwards may be limited.***

At December 31, 2013, we had U.S. federal and state net operating loss (NOL) carry-forwards of approximately \$82.4 million and \$65.8 million, respectively, which expire at various dates beginning in 2020 through 2033. Section 382 of the Internal Revenue Code limits the annual utilization of NOL carry-forwards and tax credit carry-forwards following an ownership change in our company. NOL carry-forwards may be subject to annual limitations under Internal Revenue Code Section 382 (or comparable provisions of state law) in the event that certain changes in ownership of our company were to occur. In general, an ownership change occurs for purposes of Section 382 if there is a more than 50% change in ownership of a company over a 3-year testing period. The issuance of the Series A Convertible Preferred Stock in October 2012 constituted such a change in ownership. As a result of this change in ownership, we performed a formal analysis in connection with IRC Section 382 and determined that approximately \$13.7 million of our NOLs generated prior to the change in ownership could not be utilized in the future.

***We incur significant increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives.***

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, as well as rules subsequently implemented by the SEC and NASDAQ, has imposed various new requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Our management and other personnel are required to devote a substantial amount of time to these new compliance initiatives. Moreover, these rules and regulations have substantially increased our legal and financial compliance costs and have made some activities more time consuming and costly. These rules and regulations may make it more difficult and more expensive for us to maintain our existing director and officer liability insurance or to obtain similar coverage from an alternative provider.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, pursuant to Section 404 of the Sarbanes-Oxley Act (Section 404), we expect to be required as of December 31, 2014 and thereafter to perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting. Our testing, or the subsequent testing by our independent registered public accounting firm, if required, may reveal deficiencies in our internal controls over

financial reporting that are deemed to be material weaknesses. Our compliance with Section 404 would require us to continue to incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we may need to hire additional accounting and financial staff. Moreover, if we are not able to comply with the requirements of Section 404 in a timely manner or if we or our independent registered public accounting firm identifies deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities, which would require additional financial and management resources.

**Table of Contents**

**Risks Relating to Our Financial Results and Need for Financing**

***Fluctuations in our quarterly operating results and cash flows could adversely affect the price of our common stock.***

We expect our operating results and cash flows to be subject to quarterly fluctuations. The revenues we generate, if any, and our operating results will be affected by numerous factors, including, but not limited to:

the commercial success of ILUVIEN in the EU;

our ability to obtain regulatory approval of ILUVIEN in additional jurisdictions;

the emergence of products that compete with ILUVIEN;

variations in the level of expenses related to ILUVIEN;

the status of our preclinical and clinical development programs;

execution of collaborative, licensing or other arrangements, and the timing of payments received or made under those arrangements;

any intellectual property infringement lawsuits to which we may become a party; and

regulatory developments affecting our products or those of our competitors.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results and cash flows may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

***Exchange rate fluctuations could cause a decline in our financial condition and results of operations.***

As a result of our European operations, we are subject to increased risk because we incur a significant portion of our operating expenses and receive revenues in multiple currencies other than the U.S. dollar. For example, in Europe where we have operating costs in a foreign currency, we are subject to risk if the foreign currency in which our costs are paid appreciates against the currency in which we generate revenue because the appreciation effectively increases our cost in that country.

The financial condition and results of operations of some of our operating entities are reported in foreign currencies and then translated into U.S. dollars at the applicable exchange rate for inclusion in our consolidated financial statements. As a result, appreciation of the U.S. dollar against these foreign currencies generally will have a negative impact on our reported operating losses while depreciation of the U.S. dollar against these foreign currencies will generally have a positive effect on reported operating losses. We do not seek to mitigate this translation effect through the use of derivative financial instruments. To the extent we are unable to match revenues received in foreign currencies with costs paid in the same currency, exchange rate fluctuations in that currency could have a material adverse effect on our business and results of operations.

***We may need additional capital to support our growth, which may be difficult to obtain and restrict our operations and will result in additional dilution to our stockholders.***

Our business may require additional capital that we have not yet secured. At June 30, 2014, we had approximately \$42.0 million in cash and cash equivalents. We believe our cash and cash equivalents will be sufficient to fund our operations beyond the projected commercialization of ILUVIEN in Germany, the United Kingdom, Portugal and France and the expected generation of positive cash flow in late 2015, at the earliest. However, the actual amount of funds that we will need will be determined by many factors, some of which are beyond our control, and we may need funds sooner than currently anticipated. These factors include but are not limited to:

the amount of our future operating losses;

third party expenses relating to the commercialization of ILUVIEN;

**Table of Contents**

the level of success of the initial commercial launch of ILUVIEN in Germany, the United Kingdom, Portugal and France;

the status of our new drug application for ILUVIEN in the U.S.;

the \$25 million milestone payment owed to pSivida in the event that ILUVIEN is approved in the U.S.;

the timing of approvals, if any, of ILUVIEN in additional jurisdictions;

the need and cost of conducting additional clinical trials for ILUVIEN;

the amount of our research and development, marketing and general and administrative expenses;

the extent to which we enter into, maintain, and derive revenues from licensing agreements, including agreements to out-license ILUVIEN, research and other collaborations, joint ventures and other business arrangements;

the extent to which we acquire, and our success in integrating, technologies or companies; and

regulatory changes and technological developments in our markets.

General market conditions or the market price of our common stock may not support capital raising transactions such as an additional public or private offering of our common stock or other securities. In addition, our ability to raise additional capital may be dependent upon our stock being quoted on the NASDAQ Global Market or upon obtaining stockholder approval. There can be no assurance that we will be able to satisfy the criteria for continued listing on NASDAQ or that we will be able to obtain stockholder approval if it is necessary. If we are unable to obtain additional funds on a timely basis or on terms favorable to us, we may be required to cease or reduce further commercialization of ILUVIEN, to cease or reduce certain research and development projects, to sell some or all of our technology or assets or business units or to merge all or a portion of our business with another entity. In the event additional financing is needed or advisable, we may seek to fund our operations through the sale of equity securities, additional debt financing and strategic collaboration agreements. We cannot be sure that additional financing from any of these sources will be available when needed or that, if available, the additional financing will be obtained on terms favorable to us or our stockholders especially in light of the current difficult financial environment. If we raise additional funds by selling shares of our capital stock, the ownership interest of our current stockholders will be diluted. In addition, our Series A Convertible Preferred Stock is entitled to price-based anti-dilution protection in connection with certain financings, which has the potential to further dilute our other stockholders. If we attempt to raise additional funds through strategic collaboration agreements, we may not be successful in obtaining collaboration agreements, or in receiving milestone or royalty payments under those agreements, or the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to commercialize ILUVIEN or any future products or product candidates or operate our business. For example, under the secured credit facility, which Alimera Sciences Limited (Limited), our subsidiary, entered into in April 2014

(Credit Facility), we and certain of our subsidiaries are subject to a variety of affirmative and negative covenants, including required financial reporting, limitations on our cash balances, limitations on the disposition of assets, limitations on the incurrence of additional debt, and other requirements. Due to the limited revenue generated by ILUVIEN to date, we may not be able to maintain compliance with covenants under our loan agreements. In an event of default, our lender may call our term loan or restrict the availability of our line of credit, and we will likely need to raise additional financing. To secure the performance of our obligations under the Credit Facility, Limited pledged all of its assets to the lender. Our or Limited's failure to comply with the covenants under the Credit Facility could result in an event of default, the acceleration of our debt and the loss of our assets. We and certain of our subsidiaries are guarantors of the obligations of Limited to the lender under the Credit Facility (Guaranties). Pursuant to the Guaranties, we and these subsidiaries granted the lender a first priority security interest in substantially all of our respective assets. Any declaration of an event of default could significantly harm our business and prospects and could cause our stock price to decline. Insufficient funds may require us to delay, scale back, or eliminate some or all of our activities, and if we are unable to obtain additional funding, there may be substantial doubt about our ability to continue as a going concern.

### **Risks Related to the Offering and Ownership of Our Common Stock**

*Our stock price has been and may continue to be volatile, and the value of an investment in our common stock may decline.*

We completed our IPO in April 2010 at a price of \$11.00 per share. Subsequently, our common stock has traded as low as \$1.09 per share. The realization of any of the risks described in these risk factors or other unforeseen risks could have a dramatic and adverse effect on the market price of our common stock. The trading price of our common stock is likely to continue



**Table of Contents**

to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include:

our ability to successfully commercialize ILUVIEN in the EU, including our ability to build our own commercial infrastructure for the sale of ILUVIEN in Germany, the United Kingdom, Portugal and France;

the ability of ILUVIEN to be approved in any additional jurisdiction;

the ability of ILUVIEN or any future products or product candidates, if approved in additional jurisdictions, to achieve commercial success;

FDA or international regulatory actions, including failure to receive regulatory approval for ILUVIEN or any future products or product candidates;

quarterly variations in our results of operations or those of our competitors;

announcements by us or our competitors of acquisitions, regulatory approvals, clinical milestones, new products, significant contracts, commercial relationships or capital commitments;

third-party coverage and reimbursement policies;

additions or departures of key personnel;

commencement of, or our involvement in, litigation;

our ability to meet our repayment and other obligations under our loan agreements;

changes in governmental regulations or in the status of our regulatory approvals;

changes in earnings estimates or recommendations by securities analysts;

any major change in our board of directors or management;

results from our clinical trial programs;

our ability to develop and market new and enhanced products or product candidates on a timely basis;

general economic conditions and slow or negative growth of our markets; and

political instability, natural disasters, war and/or events of terrorism.

From time to time, we estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development goals or milestones. These milestones may include the commencement or completion of scientific studies and clinical trials, the submission of regulatory filings, the notification of the results of regulatory filings and the anticipated commercial launch of ILUVIEN or any future products or product candidates. Also, from time to time, we expect that we will publicly announce the anticipated timing of some of these milestones. All of these milestones are based on a variety of assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, our stock price may decline and the further commercialization of ILUVIEN or any future products or product candidates may be delayed.

In addition, the stock market has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of publicly traded companies. Broad market and industry factors may seriously affect the market price of companies' stock, including ours, regardless of actual operating performance. These fluctuations may be even more pronounced in the trading market for our stock. In addition, in the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been initiated against these companies. This litigation, if brought against us, could result in substantial costs and a diversion of our management's attention and resources.

***Certain of our stockholders have the ability to control the outcome of matters submitted for stockholder approval and may have interests that differ from those of our other stockholders.***

Our executive officers, key employees, directors and their affiliates and the investors that participated in our Series A Convertible Preferred Stock financing beneficially owned, in the aggregate, a majority of the outstanding voting power of our

## **Table of Contents**

common stock, assuming the exercise of the outstanding warrants to purchase shares of our Series A Convertible Preferred Stock. As a result, these stockholders, if acting together, may be able to exercise significant influence over all matters requiring stockholder approval, including the election of directors and the approval of significant corporate transactions, and this concentration of voting power may have the effect of delaying or impeding actions that could be beneficial to you, including actions that may be supported by our Board of Directors.

In addition, the terms of the Series A Convertible Preferred Stock provide that certain corporate actions require the prior consent of the holders of at least 70% of the then outstanding shares of Series A Convertible Preferred Stock.

***We currently do not intend to pay dividends on our common stock and, consequently, your only opportunity to achieve a return on your investment is if the price of our common stock appreciates.***

We do not anticipate that we will pay any cash dividends on shares of our common stock for the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our Board of Directors and will depend on results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law and other factors our Board of

Directors deems relevant. Further, for so long as at least 37.5% of the shares of Series A Convertible Preferred Stock originally issued to the investors at the closing of our Series A Convertible Preferred Stock financing in October 2012 are held by the initial investors or their affiliates, we may not, without first obtaining the approval of the holders of at least 70% of the then outstanding shares of Series A Convertible Preferred Stock, declare or pay any dividend or distribution on any shares of capital stock; provided, however, that this restriction shall not apply to (A) dividends payable to holders of common stock that consist solely of shares of common stock for which adjustment to the conversion price of the Series A Convertible Preferred Stock is made pursuant to the certificate of designation or (B) dividends or distributions issued pro rata to all holders of capital stock (on an as-converted basis) in connection with the implementation of a poison pill rights plan or similar plan by us. Accordingly, realization of a gain on your investment will depend on the appreciation of the price of our common stock, which may never occur.

***Significant sales of our common stock could depress or reduce the market price of our common stock, or cause our shares of common stock to trade below the prices at which they would otherwise trade, or impede our ability to raise future capital.***

A small number of institutional investors and private equity funds hold a significant number of shares of our common stock and all of our shares of Series A Convertible Preferred Stock and Series A Convertible Preferred Stock Warrants. Sales by these stockholders of a substantial number of shares, or the expectation of such sales, could cause a significant reduction in the market price of our common stock. Additionally, a small number of investors have rights, subject to certain conditions, to require us to file registration statements to permit the resale of their shares in the public market or to include their shares in registration statements that we may file for ourselves or other stockholders.

In addition to our outstanding common stock, as of June 30, 2014, there were a total of 7,599,768 shares of common stock that we have registered and that we are obligated to issue upon the exercise of currently outstanding options granted under our equity incentive plans. Upon the exercise of these options, in accordance with their respective terms, these shares may be resold freely, subject to restrictions imposed on our affiliates under the SEC's Rule 144. If significant sales of these shares occur in short periods of time, these sales could reduce the market price of our common stock. Any reduction in the trading price of our common stock could impede our ability to raise capital on attractive terms.

Actual or perceived significant sales of our common stock could depress or reduce the market price of our common stock, cause our shares of common stock to trade below the prices at which they would otherwise trade or impede our ability to raise future capital.

***Future sales and issuances of our equity securities or rights to purchase our equity securities, including pursuant to our equity incentive plans, would result in dilution of the percentage ownership of our stockholders and could cause our stock price to fall.***

To the extent we raise additional capital by issuing equity securities; our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one

---

**Table of Contents**

transaction, investors may be diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to existing stockholders. In addition, the Series A Convertible Preferred Stock is entitled to price-based anti-dilution protection in connection with certain financings, which has the potential to further dilute our other stockholders.

Pursuant to our 2010 Equity Incentive Plan, our Board of Directors is authorized to grant stock options to our employees, directors and consultants. The number of shares available for future grant under our 2010 Equity Incentive Plan increases each year by an amount equal to the lesser of 4% of all shares of our capital stock outstanding as of January 1st of each year, 2,000,000 shares, or such lesser number as determined by our Board of Directors. On January 1, 2014, an additional 1,264,440 shares became available for future issuance under our 2010 Equity Incentive Plan in accordance with the annual increase. In addition, we have reserved 494,422 shares of our common stock for issuance under our 2010 Employee Stock Purchase Plan. The number of shares eligible for purchase is replenished as of January 1st of each year in an amount equal to the shares purchased under the plan in the preceding year. As such, on January 1, 2014, an additional 26,123 shares became available for future issuance under our 2010 Employee Stock Purchase Plan.

***Our management will have broad discretion over the use of the proceeds we receive in this offering and might not apply the proceeds in ways that increase the value of your investment.***

Our management will have broad discretion to use the net proceeds from any offerings under this prospectus, and you will be relying on the judgment of our management regarding the application of these proceeds. They might not apply the net proceeds of this offering in ways that increase the value of your investment. Unless otherwise indicated in an accompanying prospectus supplement, we expect to use the net proceeds from this offering for general corporate purposes. We have not allocated these net proceeds for any specific purposes. Our management might not be able to yield a significant return, if any, on any investment of these net proceeds. You will not have the opportunity to influence our decisions on how to use the proceeds.

***The Series A Convertible Preferred Stock contains covenants that may limit our business flexibility.***

For so long as at least 37.5% of the shares of Series A Convertible Preferred Stock originally issued to the investors at the closing of our Series A Convertible Preferred Stock financing in October 2012 are held by the initial investors or their affiliates, we may not, without first obtaining the approval of the holders of at least 70% of the then outstanding shares of Series A Convertible Preferred Stock: (i) increase or decrease the authorized number of shares of Series A Convertible Preferred Stock; (ii) authorize, create, issue or obligate us to issue (by reclassification, merger or otherwise) any security (or any class or series thereof) or any indebtedness, in each case that has any rights, preferences or privileges senior to, or on a parity with, the Series A Convertible Preferred Stock, or any security convertible into or exercisable for any such security or indebtedness, subject to limited exceptions for certain debt transactions; (iii) amend our certificate of incorporation or the certificate of designation of the Series A Convertible Preferred Stock, in each case in a manner that adversely affects the rights, preference or privileges of the Series A Convertible Preferred Stock; (iv) redeem, purchase or otherwise acquire (or pay into or set aside for a sinking fund for such purpose) any shares of common stock or preferred stock; provided, however, that this restriction shall not apply to (A) the redemption of rights issued pursuant to any poison pill rights plan or similar plan adopted by us after the closing of the Series A Convertible Preferred Stock financing or (B) the repurchases of stock from former employees, officers, directors or consultants who performed services for us in connection with the cessation of such employment or service pursuant to the terms of existing agreements with such individuals; (v) declare or pay any dividend or distribution on any shares of capital stock; provided, however, that this restriction shall not apply to (A) dividends payable to holders of common stock that consist solely of shares of common stock for which adjustment to the conversion price of the Series A Convertible Preferred Stock is made pursuant to the certificate of designation or

(B) dividends or distributions issued pro rata to all holders of capital stock (on an as-converted basis) in connection with the implementation of a poison pill rights plan or similar plan by us; (vi) authorize or approve any increase to the number of aggregate shares of capital stock reserved for issuance pursuant to stock option, stock purchase plans or other equity incentive plans such that the total aggregate number of shares issued under such plans and reserved for issuance under such plans (on an as-converted basis) exceeds the number of shares issued and reserved for issuance under such plans (on an as-converted basis) on the date of the closing of the Series A Convertible Preferred Stock financing by more than 20% (as adjusted for stock splits, combinations, stock dividends, recapitalizations and the like), provided that any increases resulting solely from the annual increases resulting from the evergreen provisions of equity incentive plans in effect on the date of the closing of the Series A Convertible Preferred Stock financing shall not be subject to this restriction and shall not be included for purposes of determining whether such 20% increase has occurred; (vii) issue stock or other equity securities of any subsidiary (other than to us or another of our wholly-owned subsidiaries or declare or pay any dividend or other distribution of cash, shares or other assets or redemption or repurchase of shares of any subsidiary; or (viii) incur any secured indebtedness

**Table of Contents**

other than certain limited debt transactions. There is no guarantee that the holders of the Series A Convertible Preferred Stock would approve any such restricted action, even where such an action would be in the best interests of our stockholders. Any failure to obtain such approval could harm our business and result in a decrease in the value of our common stock.

***Anti-takeover provisions in our charter and bylaws and in Delaware law could prevent or delay acquisition bids for us that might be considered favorable and could entrench current management.***

We are a Delaware corporation and the anti-takeover provisions of the Delaware General Corporation Law may deter, delay or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change in control would be beneficial to our existing stockholders. In addition, our restated certificate of incorporation and bylaws may discourage, delay or prevent a change in our management or control over us that stockholders may consider favorable. Our restated certificate of incorporation and bylaws:

authorize the issuance of blank check preferred stock that could be issued by our Board of Directors to thwart a takeover attempt;

do not provide for cumulative voting in the election of directors, which would allow holders of less than a majority of our outstanding common stock to elect some directors;

establish a classified Board of Directors, as a result of which the successors to the directors whose terms have expired will be elected to serve from the time of election and qualification until the third annual meeting following their election;

require that directors only be removed from office for cause;

provide that vacancies on the Board of Directors, including newly created directorships, may be filled only by a majority vote of directors then in office;

contain certain protective provisions in favor of the holders of Series A Convertible Preferred Stock;

limit who may call special meetings of stockholders;

prohibit common stockholder action by written consent, requiring all actions of the holders of common stock to be taken at a meeting of the stockholders; and

establish advance notice requirements for nominating candidates for election to the Board of

Directors or for proposing matters that can be acted upon by stockholders at stockholder meetings.

***If securities or industry analysts do not publish research or reports or publish unfavorable research or reports about our business, our stock price and trading volume could decline.***

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. If one or more of the analysts who covers us downgrades our stock, our stock price would likely decline. If one or more of these analysts ceases to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline.



**Table of Contents**

**DESCRIPTION OF SECURITIES**

**PREFERRED STOCK**

**General**

We currently have authorized 10,000,000 shares of preferred stock, par value \$0.01, the rights and preferences of which may be established from time to time by our board of directors.

Under Delaware law and our restated certificate of incorporation, our board of directors is authorized, without stockholder approval, to issue shares of preferred stock from time to time in one or more series. Subject to limitations prescribed by Delaware law and our restated certificate of incorporation and by-laws, the board of directors can determine the number of shares constituting each series of preferred stock and the designation, preferences, voting powers, qualifications, and special or relative rights or privileges of that series. These may include provisions concerning voting, redemption, dividends, dissolution or the distribution of assets, conversion or exchange, and other subjects or matters as may be fixed by resolution of the board or an authorized committee of the board. The preferred stock offered by this prospectus will, when issued, be fully paid and nonassessable.

Our board of directors could authorize the issuance of shares of preferred stock with terms and conditions which could have the effect of discouraging a takeover or other transaction which holders of some, or a majority, of our common stock might believe to be in their best interests or in which holders of some, or a majority, of our common stock might receive a premium for their shares over the then market price of those shares.

If we offer a specific series of preferred stock under this prospectus, we will describe the terms of the preferred stock in the prospectus supplement for such offering and will file a copy of the certificate establishing the terms of the preferred stock with the SEC. To the extent required, this description will include:

the title and stated value;

the number of shares offered, the liquidation preference per share, and the purchase price;

the dividend rate(s), period(s), and/or payment date(s), or method(s) of calculation for such dividends;

whether dividends will be cumulative or non-cumulative and, if cumulative, the date from which dividends will accumulate;

the procedures for any auction and remarketing, if any;

the provisions for a sinking fund, if any;

any listing of the preferred stock on any securities exchange or market;

whether the preferred stock will be convertible into Alimera common stock, and, if applicable, the conversion price (or how it will be calculated) and conversion period;

whether the preferred stock will be exchangeable into debt securities, and, if applicable, the exchange price (or how it will be calculated) and exchange period;

voting rights, if any, of the preferred stock;

a discussion of any material and/or special U.S. federal income tax considerations applicable to the preferred stock;

the relative ranking and preferences of the preferred stock as to dividend rights and rights upon liquidation, dissolution, or winding up of the affairs of Alimera; and

any material limitations on issuance of any class or series of preferred stock ranking senior to or on a parity with the series of preferred stock as to dividend rights and rights upon liquidation, dissolution, or winding up of Alimera.

*Transfer Agent and Registrar.* The transfer agent and registrar for any series or class of preferred stock will be set forth in the applicable prospectus supplement.

### **Series A Convertible Preferred Stock**

Our board of directors is authorized to issue preferred stock in one or more series, to establish the number of shares to be included in each such series and to fix the designation, powers, preferences and rights of such shares and any qualifications,

**Table of Contents**

limitations or restrictions thereof. The issuance of preferred stock may have the effect of delaying, deferring or preventing a change in control of our company without further action by the stockholders and may adversely affect the voting and other

rights of the holders of common stock. The issuance of preferred stock with voting and conversion rights may adversely affect the voting power of the holders of common stock, including the loss of voting control to others. On October 2, 2012, we filed a certificate of designation which designated 1,300,000 shares of our preferred stock as Series A Convertible Preferred Stock.

*Conversion.* Each share of Series A Convertible Preferred Stock, including any shares of Series A Convertible Preferred Stock issued upon exercise of the warrants, is convertible into shares of Alimera's common stock at any time at the option of the holder at the rate (conversion rate) equal to \$40.00 (original purchase price) divided by a conversion price of \$2.66 (conversion price).

Each share of Series A Convertible Preferred Stock shall automatically be converted into shares of common stock at the conversion price upon the occurrence of the later to occur of both (i) we receive and publicly announce the approval by the United States Food and Drug Administration of our New Drug Application for ILUVIEN and (ii) the date on which we consummate an equity financing transaction pursuant to which we sell to one or more third party investors either (a) shares of common stock or (b) other equity securities that are convertible into shares of common stock and that have rights, preference or privileges, senior to or on a parity with, the Series A Convertible Preferred Stock, in each case having an as-converted per share of common stock price of not less than \$10.00 (adjusted for stock splits, combinations, stock dividends, recapitalizations and the like with respect to the Series A Convertible Preferred Stock) and that results in total gross proceeds to us of at least \$30,000,000. The Series A Convertible Preferred Stock is not convertible at our option.

All conversion prices and adjustments to the conversion price of the Series A Convertible Preferred Stock shall be appropriately adjusted in the event of stock splits, combinations, stock dividends, recapitalizations and the like with respect to the Series A Convertible Preferred Stock.

*Liquidation Preference.* In the event of a Liquidation Transaction, as defined below, holders of the Series A Convertible Preferred Stock will receive, before any proceeds are distributed to the holders of common stock or any other stock or equity security, a payment equal to the greater of (i) the original purchase price (as adjusted for stock dividends, splits, combinations and similar events with respect to the Series A Convertible Preferred Stock), plus any declared and unpaid dividends, per share of Series A Convertible Preferred Stock and (ii) the amount each holder of a share of Series A Convertible Preferred Stock would be entitled to receive all shares of Series A Convertible Preferred Stock been converted into shares of common stock at the then-effective conversion rate immediately prior to such Liquidation Transaction. Unless waived by the holders of at least 70% of the then outstanding shares of Series A Convertible Preferred Stock, voting together as a separate class, the following shall be deemed to constitute a Liquidation Transaction: (a) our acquisition by means of merger, consolidation, stock sale, tender offer, exchange offer or other form of corporate reorganization in which our outstanding shares are exchanged or sold, in one transaction or a series of related transactions, for cash, securities, property or other consideration issued, or caused to be issued, by the acquiring entity or its subsidiary, or any other person or group of affiliated persons and in which the holders of our capital stock hold less than a majority of the voting power of the surviving entity and (b) any sale, transfer, exclusive license or lease of all or substantially all of the properties or assets of us or our subsidiaries (each of such transactions in clause (a) and (b), together with our actual liquidation, dissolution or winding up, a Liquidation Transaction), provided that none of the following shall be deemed to constitute a Liquidation Transaction: (x) a transaction for which the sole purpose is to change the state of our incorporation, (y) a transaction for which the sole purpose is to create a holding company that will hold no assets other than our shares and that will have securities with

rights, preferences, privileges and restrictions substantially similar to ours and that are owned in substantially the same proportions by the persons who held such of our securities, in each case immediately prior to such transaction or (z) our entry into a license transaction for the purpose of developing and/or commercializing one or more of our products, so long as such license transaction would not be reasonably considered to be a sale or license of all or substantially all of our assets.

*Voting Rights.* Except as otherwise set forth in the certificate of designation, the Series A Convertible Preferred Stock will vote together with the common stock on an as converted basis based on a deemed conversion price of \$2.95 (adjusted for stock splits, combinations, stock dividends, recapitalizations and the like with respect to the Series A Convertible Preferred Stock).

In addition, for so long as at least 37.5% of the shares of Series A Convertible Preferred Stock issued to the selling stockholders at the closing of our Series A Convertible Preferred Stock financing are held by the initial selling stockholders or their affiliates, we may not without first obtaining approval of the holders of at least 70% of the then outstanding shares of Series A Convertible Preferred Stock, voting together as a separate class: (i) increase or decrease the authorized number of shares of Series A Convertible Preferred Stock; (ii) authorize, create, issue or obligate ourselves to issue (by reclassification, merger or

---

**Table of Contents**

otherwise) any security (or any class or series thereof) or any indebtedness, in each case that has any rights, preferences or privileges senior to, or on a parity with, the Series A Convertible Preferred Stock, or any security convertible into or exercisable for any such security or indebtedness (other than the issuance of (a) up to an aggregate of \$35,000,000 of

indebtedness pursuant to our Credit Facility, as the same may be amended, refinanced or resyndicated from time to time or (b) up to an aggregate of \$500,000 of indebtedness pursuant to operating, capital or equipment leases entered into in the ordinary course of business (such indebtedness being the Permitted Indebtedness)); (iii) amend our certificate of incorporation (including by filing any new certificate of designation or elimination) or the certificate of designation, in each case in a manner that adversely affects the rights, preference or privileges of the Series A Convertible Preferred Stock; (iv) redeem, purchase or otherwise acquire (or pay into or set aside for a sinking fund for such purpose) any shares of common stock or preferred stock; provided, however, that this restriction shall not apply to (a) the redemption of rights issued pursuant to any poison pill rights plan or similar plan we adopt after the closing of our Series A Convertible Preferred Stock financing or (b) the repurchases of stock from former employees, officers, directors or consultants who performed services for us in connection with the cessation of such employment or service pursuant to the terms of existing agreements with such individuals; (v) declare or pay any dividend or distribution on any shares of capital stock; provided, however, that this restriction shall not apply to (a) dividends payable to holders of common stock that consist solely of shares of common stock for which adjustment to the conversion price of the Series A Convertible Preferred Stock is made pursuant to the certificate of designation or (b) dividends or distributions issued pro rata to all holders of capital stock (on an as-converted basis) in connection with our the implementation of a poison pill rights plan or similar plan; (vi) authorize or approve any increase to the number of aggregate shares of capital stock reserved for issuance pursuant to our stock option, stock purchase plans or other equity incentive plans such that the total aggregate number of shares issued under such plans and reserved for issuance under such plans (on an as-converted basis) exceeds the number of shares issued and reserved for issuance under such plans (on an as-converted basis) on the date of the closing of the Series A Convertible Preferred Stock financing by more than 20% (adjusted for stock splits, combinations, stock dividends, recapitalizations and the like), provided that any increases resulting solely from the annual increases resulting from the evergreen provisions of our equity incentive plans in effect on the date of the closing of the offering shall not be subject to this restriction and shall not be included for purposes of determining whether such 20% increase has occurred; (vii) issue stock or other equity securities of any of our subsidiaries (other than to us or another wholly-owned subsidiary) or declare or pay any dividend or other distribution of cash, shares or other assets or redemption or repurchase of shares of any subsidiary; or (viii) incur any secured indebtedness other than any Permitted Indebtedness.

In connection with the Series A Convertible Preferred Stock financing, our board of directors approved an amendment to our bylaws, effective as of October 2, 2012, to provide that the holders of Series A Convertible Preferred Stock may take any exclusive action required or permitted to be taken by the stockholders holding Series A Convertible Preferred Stock pursuant to the certificate of designation by written consent at any time.

*Dividends.* The Series A Convertible Preferred Stock does not accrue dividends. The holders of Series A Convertible Preferred Stock will be entitled to receive dividends and other distributions on a pari passu basis with the holders of common stock on an as-converted basis.

*Redemption.* The Series A Convertible Preferred Stock is not redeemable.

The certificate of designation was filed as Exhibit 3.5 to our current report on Form 8-K dated July 18, 2012. The foregoing description of the certificate of designation and the Series A Convertible Preferred Stock does not purport to be complete and is qualified in its entirety by reference to such exhibit.

## COMMON STOCK

We currently have authorized 100,000,000 shares of common stock, par value \$0.01 per share. As of August 8, 2014, there were 40,424,241 shares of common stock outstanding held of record by 48 stockholders. Holders of our common stock have no preemptive rights and no right to convert their common stock into any other securities. There are no redemption or sinking fund provisions applicable to the common stock. All outstanding shares of our common stock are fully paid and nonassessable.

The following summary of the terms of our common stock is subject to and qualified in its entirety by reference to our restated certificate of incorporation and by-laws, copies of which are on file with the SEC as exhibits to previous SEC filings. Please refer to the section entitled *Where You Can Find More Information* for directions on obtaining these documents.

*Voting Rights.* The holders of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of stockholders, including, without limitation, the election of our board of directors. Our stockholders have no right to cumulate their votes in the election of directors.

**Table of Contents**

*Dividends.* Subject to preferences that may apply to shares of preferred stock outstanding at the time, the holders of our common stock are entitled to receive ratably those dividends declared from time to time by the board of directors.

*Rights Upon Liquidation.* Subject to preferences that may apply to shares of preferred stock outstanding at the time, in the event of liquidation, dissolution or winding up, holders of our common stock are entitled to share ratably in assets remaining after payment of liabilities.

*Anti-Takeover Effects of Our Restated Certificate of Incorporation, Bylaws and Delaware Law.* Some provisions of Delaware law and our restated certificate of incorporation and bylaws could make the following transactions more difficult: our acquisition by means of a tender offer; our acquisition by means of a proxy contest or otherwise; or removal of our incumbent officers and directors.

Section 203 of the Delaware General Corporation Law is applicable to takeovers of Delaware corporations. Subject to exceptions enumerated in Section 203, Section 203 provides that a corporation shall not engage in any business combination with any interested stockholder for a three-year period following the date that the stockholder becomes an interested stockholder unless:

prior to that date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;

upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, though some shares may be excluded from the calculation; and

on or subsequent to that date, the business combination is approved by the board of directors of the corporation and by the affirmative votes of holders of at least two-thirds of the outstanding voting stock that is not owned by the interested stockholder.

Except as specified in Section 203, an interested stockholder is generally defined to include any person who, together with any affiliates or associates of that person, beneficially owns, directly or indirectly, 15% or more of the outstanding voting stock of the corporation, or is an affiliate or associate of the corporation and was the owner of 15% or more of the outstanding voting stock of the corporation, any time within three years immediately prior to the relevant date. Under certain circumstances, Section 203 makes it more difficult for an interested stockholder to effect various business combinations with a corporation for a three-year period, although the stockholders may elect not to be governed by this section, by adopting an amendment to the certificate of incorporation or by-laws, effective 12 months after adoption. Our restated certificate of incorporation and by-laws do not opt out from the restrictions imposed under Section 203. We anticipate that the provisions of Section 203 may encourage companies interested in acquiring us to negotiate in advance with the board because the stockholder approval requirement would be avoided if a majority of the directors then in office excluding an interested stockholder approve either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder. These provisions may have the effect of deterring hostile takeovers or delaying changes in control, which could depress the market price of our common stock and deprive stockholders of opportunities to realize a premium on shares of common stock held by them.

In addition to our board of directors' ability to issue shares of preferred stock, our restated certificate of incorporation and by-laws contain provisions that may discourage, delay or prevent a change in our management or control over us that stockholders may consider favorable. Our restated certificate of incorporation and bylaws:

authorize the issuance of blank check preferred stock that could be issued by our board of directors to thwart a takeover attempt;

do not provide for cumulative voting in the election of directors, which would allow holders of less than a majority of the stock to elect some directors;

establish a classified board of directors, as a result of which the successors to the directors whose terms have expired will be elected to serve from the time of election and qualification until the third annual meeting following their election;

require that directors only be removed from office for cause;

provide that vacancies on the board of directors, including newly-created directorships, may be filled only by a majority vote of directors then in office;

limit who may call special meetings of stockholders;

prohibit stockholder action by written consent, requiring all actions to be taken at a meeting of the stockholders; and



## **Table of Contents**

establish advance notice requirements for nominating candidates for election to the board of directors or for proposing matters that can be acted upon by stockholders at stockholder meetings.

*Transfer Agent and Registrar.* The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company.

*Listing.* Our common stock is listed on The NASDAQ Global Market under the symbol ALIM.

## **DEBT SECURITIES**

We may issue, from time to time, debt securities in one or more series that will consist of either senior debt or subordinated debt under one or more trust indentures to be executed by us and a specified trustee. The terms of the debt securities will include those stated in the indenture and those made a part of the indenture (before any supplements) by reference to the Trust Indenture Act of 1939. The indentures will be qualified under the Trust Indenture Act. Debt securities, whether senior or subordinated, may be issued as convertible debt securities or exchangeable debt securities.

The following description sets forth certain anticipated general terms and provisions of the debt securities to which any prospectus supplement may relate. The particular terms of the debt securities offered by any prospectus supplement (which terms may be different than those stated below) and the extent, if any, to which such general provisions may apply to the debt securities so offered will be described in the prospectus supplement relating to such debt securities. Accordingly, for a description of the terms of a particular issue of debt securities, investors should review both the prospectus supplement relating thereto and the following description. Forms of the senior indenture (as discussed herein) and the subordinated indenture (as discussed herein) are included as exhibits to the registration statement of which this prospectus is a part.

### **General**

The debt securities will be our direct obligations and may be either senior debt securities or subordinated debt securities. The indebtedness represented by subordinated securities will be subordinated in right of payment to the prior payment in full of our senior debt (as defined in the applicable indenture). Senior securities and subordinated securities will be issued pursuant to separate indentures (respectively, a senior indenture and a subordinated indenture), in each case between us and a trustee.

Except as set forth in the applicable indenture and described in a prospectus supplement relating thereto, the debt securities may be issued without limit as to aggregate principal amount, in one or more series, secured or unsecured, in each case as established from time to time in or pursuant to authority granted by a resolution of our board of directors or as established in the applicable indenture. All debt securities of one series need not be issued at the time and, unless otherwise provided, a series may be reopened, without the consent of the holders of the debt securities of such series, for issuance of additional debt securities of such series. The applicable indenture may provide that we may issue debt securities in any currency or currency unit designated by us. Except for any limitations on consolidation, merger and sale of all or substantially all of our assets that may be contained in the applicable indenture, the terms of such indenture will not contain any covenants or other provisions designed to afford holders of any debt securities protection with respect to our operations, financial condition or transactions involving us.

The prospectus supplement relating to any series of debt securities being offered will contain the specific terms thereof, including, without limitation:

the title of such debt securities and whether such debt securities are senior securities or subordinated securities and the terms of any such subordination;

the aggregate principal amount of such debt securities and any limit on such aggregate principal amount;

the percentage of the principal amount at which such debt securities will be issued and, if other than the principal amount thereof, the portion of the principal amount thereof payable upon declaration of acceleration of the maturity thereof, or (if applicable) the portion of the principal amount of such debt securities which is convertible into common stock or preferred stock, or the method by which any such portion shall be determined;

the date or dates, or the method for determining the date or dates, on which the principal of such debt securities will be payable;

the rate or rates (which may be fixed or variable), or the method by which the rate or rates shall be determined, at which such debt securities will bear interest, if any;

the date or dates, or the method for determining such date or dates, from which any interest will accrue, the interest payment dates on which any such interest will be payable, the regular record dates for such interest payment dates, or

**Table of Contents**

the method by which any such date shall be determined, the person to whom such interest shall be payable, and the basis upon which interest shall be calculated if other than that of a 360-day year of twelve 30-day months;

the right, if any, to extend the interest payment periods and the duration of the extensions;

the place or places where the principal of (and premium, if any) and interest, if any, on such debt securities will be payable, such debt securities may be surrendered for conversion or registration of transfer or exchange and notices or demands to or upon us in respect of such debt securities and the applicable indenture may be served;

the period or periods within which, the price or prices at which and the terms and conditions upon which such debt securities may be redeemed, as a whole or in part, at our option, if we have such an option;

our obligation, if any, to redeem, repay or purchase such debt securities pursuant to any sinking fund or analogous provision or at the option of a holder thereof, and the period or periods within which, the price or prices at which and the terms and conditions upon which such debt securities will be redeemed, repaid or purchased, as a whole or in part, pursuant to such obligation;

if other than U.S. dollars, the currency or currencies in which such debt securities are denominated and payable, which may be a foreign currency or units of two or more foreign currencies or a composite currency or currencies, and the terms and conditions relating thereto;

whether the amount of payments of principal of (and premium, if any) or interest, if any, on such debt securities may be determined with reference to an index, formula or other method (which index, formula or method may, but need not be, based on a currency, currencies, currency unit or units or composite currencies) and the manner in which such amounts shall be determined;

any additions to, modifications of or deletions from the terms of such debt securities with respect to the events of default or covenants set forth in the indenture;

any provisions for collateral security for repayment of such debt securities;

whether such debt securities will be issued in certificated and/or book-entry form;

whether such debt securities will be in registered or bearer form and, if in registered form, the denominations thereof if other than \$1,000 and any integral multiple thereof and, if in bearer form, the denominations thereof and terms and conditions relating thereto;

whether issued in the form of one or more global securities and whether all or a portion of the principal amount of the debt securities is represented thereby;

if other than the entire principal amount of the debt securities when issued, the portion of the principal amount payable upon acceleration of maturity, and the terms and conditions of any acceleration;

if applicable, covenants affording holders of debt protection with respect to our operations, financial condition or transactions involving us;

the applicability, if any, of defeasance and covenant defeasance provisions of the applicable indenture;

the terms, if any, upon which such debt securities may be convertible into our common stock or preferred stock and the terms and conditions upon which such conversion will be effected, including, without limitation, the initial conversion price or rate and the conversion period;

if applicable, any limitations on the ownership or transferability of the common stock or preferred stock into which such debt securities are convertible;

whether and under what circumstances we will pay additional amounts as contemplated in the indenture on such debt securities in respect of any tax, assessment or governmental charge and, if so, whether we will have the option to redeem such debt securities in lieu of making such payment; and

any other material terms of such debt securities.

The debt securities may provide for less than the entire principal amount thereof to be payable upon declaration of acceleration of the maturity thereof. Special federal income tax, accounting and other considerations applicable to these original issue discount securities will be described in the applicable prospectus supplement. The applicable prospectus supplement will

## **Table of Contents**

set forth material U.S. federal income tax considerations for holders of any debt securities and the securities exchange or quotation system on which any debt securities are listed or quoted, if any.

The applicable indenture may contain provisions that would limit our ability to incur indebtedness or that would afford holders of debt securities protection in the event of a highly leveraged or similar transaction involving us or in the event of a change of control.

### **Senior Debt Securities**

Payment of the principal of premium, if any, and interest on senior debt securities will rank on parity with all of our other senior unsecured and unsubordinated debt.

### **Subordinated Debt Securities**

Payment of the principal of, premium, if any, and interest on subordinated debt securities will be subordinated and junior in right of payment to the prior payment in full of all of our senior debt. We will set forth in the applicable prospectus supplement relating to any subordinated debt securities the subordination terms of such securities as well as the aggregate amount of outstanding indebtedness, as of the most recent practicable date, that by its terms would be senior to the subordinated debt securities. We will also set forth in such prospectus supplement limitations, if any, on issuance of additional senior debt.

### **Merger, Consolidation or Sale**

The applicable indenture will provide that we may consolidate with, or sell, lease or convey all or substantially all of our assets to, or merge with or into, any other corporation, provided that:

either we shall be the continuing corporation, or the successor corporation (if other than the Company) formed by or resulting from any such consolidation or merger or which shall have received the transfer of such assets shall expressly assume payment of the principal of (and premium, if any), and interest on, all of the applicable debt securities and the due and punctual performance and observance of all of the covenants and conditions contained in the applicable indenture;

immediately after giving effect to such transaction and treating any indebtedness which becomes our obligation or an obligation of one of our subsidiaries as a result thereof as having been incurred by us or such subsidiary at the time of such transaction, no event of default under the applicable indenture, and no event which, after notice or the lapse of time, or both, would become such an event of default, shall have occurred and be continuing; and

an officer's certificate and legal opinion covering such conditions shall be delivered to the applicable trustee.

### **Covenants**

The applicable indenture will contain covenants requiring us to take certain actions and prohibiting us from taking certain actions. The covenants with respect to any series of debt securities will be described in the prospectus supplement relating thereto.

### **Events of Default, Notice and Waiver**

Each indenture will describe specific events of default with respect to any series of debt securities issued thereunder. Such events of default are likely to include (with grace and cure periods):

default in the payment of any installment of interest on any debt security of such series;

default in the payment of principal of (or premium, if any, on) any debt security of such series at its maturity or upon any redemption, by declaration or otherwise;

default in making any required sinking fund payment for any debt security of such series;

default in the performance or breach of any other covenant or warranty of the Company contained in the applicable indenture (other than a covenant added to the indenture solely for the benefit of a series of debt securities issued thereunder other than such series), continued for a specified period of days after written notice as provided in the applicable indenture;

**Table of Contents**

default in the payment of specified amounts of indebtedness of the Company or any mortgage, indenture or other instrument under which such indebtedness is issued or by which such indebtedness is secured, such default having occurred after the expiration of any applicable grace period and having resulted in the acceleration of the maturity of such indebtedness, but only if such indebtedness is not discharged or such acceleration is not rescinded or annulled;

certain events of bankruptcy, insolvency or reorganization, or court appointment of a receiver, liquidator or trustee of the Company or any of our significant subsidiaries or their property; and

any other event of default provided in the applicable resolution of our board of directors or the supplemental indenture under which we issue series of debt securities.

An event of default for a particular series of debt securities does not necessarily constitute an event of default for any other series of debt securities issued under the indenture. Unless otherwise indicated in the applicable prospectus supplement, if an event of default under any indenture with respect to debt securities of any series at the time outstanding occurs and is continuing, then the applicable trustee or the holders of not less than a majority of the principal amount of the outstanding debt securities of that series may declare the principal amount (or, if the debt securities of that series are original issue discount securities or indexed securities, such portion of the principal amounts may be specified in the terms thereof) of all the debt securities of that series to be due and payable immediately by written notice thereof to us (and to the applicable trustee if given by the holders). However, at any time after such a declaration of acceleration with respect to debt securities of such series (or of all debt securities then outstanding under any indenture, as the case may be) has been made, but before a judgment or decree for payment of the money due has been obtained by the applicable trustee, the holders of not less than a majority in principal amount of outstanding debt securities of such series (or of all debt securities then outstanding under the applicable indenture, as the case may be) may rescind and annul such declaration and its consequences if:

we shall have deposited with the applicable trustee all required payments of the principal of (and premium, if any) and interest on the debt securities of such series (or of all debt securities then outstanding under the applicable indenture, as the case may be), plus certain fees, expenses, disbursements and advances of the applicable trustee; and

all events of default, other than the non-payment of accelerated principal (or specified portion thereof), with respect to debt securities of such series (or of all debt securities then outstanding under the applicable indenture, as the case may be) have been cured or waived as provided in such indenture.

If an event of default relating to events of bankruptcy, insolvency or reorganization of the Company occurs and is continuing, then the principal amount of all of the debt securities outstanding, and any accrued interest, will automatically become due and payable immediately, without any declaration or other act by the trustee or any holder.

Each indenture also will provide that the holders of not less than a majority in principal amount of the outstanding debt securities of any series (or of all debt securities then outstanding under the applicable indenture, as the case may be) may waive any past default with respect to such series and its consequences, except a default:

in the payment of the principal of (or premium, if any) or interest on any debt security of such series; or

in respect of a covenant or provision contained in the applicable indenture that cannot be modified or amended without the consent of the holder of each outstanding debt security affected thereby.

Each trustee will be required to give notice to the holders of debt securities within 90 days of a default under the applicable indenture unless such default shall have been cured or waived; provided, however, that such trustee may withhold notice to the holders of any series of debt securities of any default with respect to such series (except a default in the payment of the principal of (or premium, if any) or interest on any debt security of such series or in the payment of any sinking fund installment in respect of any debt security of such series) if specified responsible officers of such trustee consider such withholding to be in the interest of such holders.

Each indenture will provide that no holders of debt securities of any series may institute any proceedings, judicial or otherwise, with respect to such indenture or for any remedy thereunder, except in the case of failure of the applicable trustee, for 60 days, to act after it has received a written request to institute proceedings in respect of an event of default from the holders of not less than 25% in principal amount of the outstanding debt securities of such series, as well as an offer of indemnity



## **Table of Contents**

reasonably satisfactory to it. This provision will not prevent, however, any holder of debt securities from instituting suit for the enforcement of payment of the principal of (and premium, if any) and interest on such debt securities at the respective due dates thereof.

Each indenture provides that in case an event of default shall occur and be known to any trustee and not be cured, the trustee must use the same degree of care as a prudent person would use in the conduct of his or her own affairs in the exercise of the trustee's power. Subject to provisions in each indenture relating to its duties in case of default, no trustee will be under any obligation to exercise any of its rights or powers under an indenture at the request or direction of any holders of any series of debt securities then outstanding under such indenture, unless such holders shall have offered to the trustee thereunder reasonable security or indemnity. The holders of not less than a majority in principal amount of the outstanding debt securities of any series (or of all debt securities then outstanding under an indenture, as the case may be) shall have the right to direct the time, method and place of conducting any proceeding for any remedy available to the applicable trustee, or of exercising any trust or power conferred upon such trustee. However, a trustee may refuse to follow any direction which is in conflict with any law or the applicable indenture, which may involve such trustee in personal liability or which may be unduly prejudicial to the holders of debt securities of such series not joining therein.

Within 120 days after the close of each fiscal year, we will be required to deliver to each trustee a certificate, signed by one of several specified officers, stating whether or not such officer has knowledge of any default under the applicable indenture and, if so, specifying each such default and the nature and status thereof.

## **Modification of the Indenture**

Each indenture provides that we and the trustee may enter into supplemental indentures without the consent of the holders of debt securities to:

secure any debt securities;

evidence the assumption by a successor corporation of our obligations;

add covenants for the protection of the holders of debt securities;

cure any ambiguity or correct any inconsistency in the indenture;

establish the forms or terms of debt securities of any series; and

evidence and provide for the acceptance of appointment by a successor trustee.

It is anticipated that modifications and amendments of an indenture may be made by us and the trustee, with the consent of the holders of not less than a majority in principal amount of each series of the outstanding debt securities issued under the indenture that are affected by the modification or amendment, provided that no such modification or amendment may, without the consent of each holder of such debt securities affected thereby:

change the stated maturity date of the principal of (or premium, if any) or any installment of interest, if any, on any such debt security;

reduce the principal amount of (or premium, if any) or the interest, if any, on any such debt security or the principal amount due upon acceleration of an original issue discount security;

change the time or place or currency of payment of principal of (or premium, if any) or interest, if any, on any such debt security;

impair the right to institute suit for the enforcement of any such payment on or with respect to any such debt security;

reduce any amount payable on redemption;

modify any of the subordination provisions or the definition of senior indebtedness applicable to any subordinated debt securities in a manner adverse to the holders of those securities;

reduce the above-stated percentage of holders of debt securities necessary to modify or amend the indenture;  
or

modify the foregoing requirements or reduce the percentage of outstanding debt securities necessary to waive compliance with certain provisions of the indenture or for waiver of certain defaults.

## **Table of Contents**

A record date may be set for any act of the holders with respect to consenting to any amendment. The holders of not less than a majority in principal amount of outstanding debt securities of each series affected thereby will have the right to waive our compliance with certain covenants in such indenture. Each indenture will contain provisions for convening meetings of the holders of debt securities of a series to take permitted action.

A prospectus supplement may set forth modifications or additions to these provisions with respect to a particular series of debt securities.

## **Conversion or Exchange Rights**

A prospectus supplement will describe the terms, if any, on which a series of debt securities may be convertible into or exchangeable for our common stock, preferred stock or other securities. These terms will also include provisions as to whether conversion or exchange is mandatory, at the option of the holder or at our option. Such provisions will also include the conversion or exchange price (or manner or calculation thereof), the conversion or exchange period, the events requiring an adjustment of the conversion or exchange price, and provisions affecting conversion or exchange in the event of the redemption of such series of debt securities.

## **Registered Global Securities**

We may issue the debt securities of a series in whole or in part in the form of one or more fully registered global securities that we will deposit with a depositary or with a nominee for a depositary identified in the applicable prospectus supplement and registered in the name of such depositary or nominee. In such case, we will issue one or more registered global securities denominated in an amount equal to the aggregate principal amount of all of the debt securities of the series to be issued and represented by such registered global security or securities.

Unless and until it is exchanged in whole or in part for debt securities in definitive registered form, a registered global security may not be transferred except as a whole:

by the depositary for such registered global security to its nominee;

by a nominee of the depositary to the depositary or another nominee of the depositary; or

by the depositary or its nominee to a successor of the depositary or a nominee of the successor.

The prospectus supplement relating to a series of debt securities will describe the specific terms of the depositary arrangement with respect to any portion of such series represented by a registered global security. We anticipate that the following provisions will apply to all depositary arrangements for debt securities:

ownership of beneficial interests in a registered global security will be limited to persons that have accounts with the depositary for the registered global security, those persons being referred to as participants, or persons that may hold interests through participants;

upon the issuance of a registered global security, the depository for the registered global security will credit, on its book-entry registration and transfer system, the participants' accounts with the respective principal amounts of the debt securities represented by the registered global security beneficially owned by the participants;

any dealers, underwriters, or agents participating in the distribution of the debt securities will designate the accounts to be credited; and

ownership of any beneficial interest in the registered global security will be shown on, and the transfer of any ownership interest will be effected only through, records maintained by the depository for the registered global security (with respect to interests of participants) and on the records of participants (with respect to interests of persons holding through participants).

The laws of some states may require that certain purchasers of securities take physical delivery of the securities in definitive form. These laws may limit the ability of those persons to own, transfer or pledge beneficial interests in registered global securities.

**Table of Contents**

So long as the depository for a registered global security, or its nominee, is the registered owner of the registered global security, the depository or the nominee, as the case may be, will be considered the sole owner or holder of the debt securities represented by the registered global security for all purposes under the indenture. Except as set forth below, owners of beneficial interests in a registered global security:

will not be entitled to have the debt securities represented by a registered global security registered in their names;

will not receive or be entitled to receive physical delivery of the debt securities in the definitive form; and

will not be considered the owners or holders of the debt securities under the indenture.

Accordingly, each person owning a beneficial interest in a registered global security must rely on the procedures of the depository for the registered global security and, if the person is not a participant, on the procedures of a participant through which the person owns its interest, to exercise any rights of a holder under the indenture.

We understand that under existing industry practices, if we request any action of holders or if an owner of a beneficial interest in a registered global security desires to give or take any action that a holder is entitled to give or take under the indenture, the depository for the registered global security would authorize the participants holding the relevant beneficial interests to give or take the action, and those participants would authorize beneficial owners owning through those participants to give or take the action or would otherwise act upon the instructions of beneficial owners holding through them.

We will make payments of principal and premium, if any, and interest, if any, on debt securities represented by a registered global security registered in the name of a depository or its nominee to the depository or its nominee, as the case may be, as the registered owners of the registered global security. None of the Company, the trustee or any other agent of the Company or the trustee will be responsible or liable for any aspect of the records relating to, or payments made on account of, beneficial ownership interests in the registered global security or for maintaining, supervising or reviewing any records relating to the beneficial ownership interests.

We expect that the depository for any debt securities represented by a registered global security, upon receipt of any payments of principal and premium, if any, and interest, if any, in respect of the registered global security, will immediately credit participants' accounts with payments in amounts proportionate to their respective beneficial interests in the registered global security as shown on the records of the depository. We also expect that standing customer instructions and customary practices will govern payments by participants to owners of beneficial interests in the registered global security held through the participants, as is now the case with the securities held for the accounts of customers in bearer form or registered in street name. We also expect that any of these payments will be the responsibility of the participants.

If the depository for any debt securities represented by a registered global security is at any time unwilling or unable to continue as depository or ceases to be a clearing agency registered under the Exchange Act, we will appoint an eligible successor depository. If we fail to appoint an eligible successor depository within 90 days, we will issue the debt securities in definitive form in exchange for the registered global security. In addition, we may at any time and in our sole discretion decide not to have any of the debt securities of a series represented by one or more registered global securities. In such event, we will issue debt securities of that series in a definitive form in exchange for all of

the registered global securities representing the debt securities. The trustee will register any debt securities issued in definitive form in exchange for a registered global security in such name or names as the depositary, based upon instructions from its participants, shall instruct the trustee.

We may also issue bearer debt securities of a series in the form of one or more global securities, referred to as bearer global securities. We will deposit these bearer global securities with a common depositary for Euroclear System and Clearstream Bank Luxembourg, Societe Anonyme, or with a nominee for the depositary identified in the prospectus supplement relating to that series. The prospectus supplement relating to a series of debt securities represented by a bearer global security will describe the specific terms and procedures, including the specific terms of the depositary arrangement and any specific procedures for the issuance of debt securities in definitive form in exchange for a bearer global security, with respect to the position of the series represented by a bearer global security.

#### **Discharge, Defeasance and Covenant Defeasance**

We can discharge or defease our obligations under the indenture as set forth below. Unless otherwise set forth in the applicable prospectus supplement, the subordination provisions applicable to any subordinated debt securities will be expressly subject to the discharge and defeasance provisions of the indenture.

## **Table of Contents**

We may discharge some of our obligations to holders of any series of debt securities that have not already been delivered to the trustee for cancellation and that have either become due and payable or are by their terms to become due and payable within one year (or are scheduled for redemption within one year). We may effect a discharge by irrevocably depositing with the trustee cash or U.S. government obligations, as trust funds, in an amount certified to be sufficient to pay when due, whether at maturity, upon redemption or otherwise, the principal of, premium, if any, and interest on the debt securities and any mandatory sinking fund payments.

Unless otherwise provided in the applicable prospectus supplement, we may also discharge any and all of our obligations to holders of any series of debt securities at any time ( defeasance ). We also may be released from the obligations imposed by any covenants of any outstanding series of debt securities and provisions of the indenture, and we may omit to comply with those covenants without creating an event of default ( covenant defeasance ). We may effect defeasance and covenant defeasance only if, among other things:

we irrevocably deposit with the trustee cash or U.S. government obligations, as trust funds, in an amount certified to be sufficient to pay at maturity (or upon redemption) the principal, premium, if any, and interest on all outstanding debt securities of the series; and

we deliver to the trustee an opinion of counsel from a nationally recognized law firm to the effect that the holders of the series of debt securities will not recognize income, gain or loss for U.S. federal income tax purposes as a result of the defeasance or covenant defeasance and that defeasance or covenant defeasance will not otherwise alter the holders' U.S. federal income tax treatment of principal, premium, if any, and interest payments on the series of debt securities, which opinion, in the case of legal defeasance, must be based on a ruling of the Internal Revenue Service issued, or a change in U.S. federal income tax law.

Although we may discharge or defease our obligations under the indenture as described in the two preceding paragraphs, we may not avoid, among other things, our duty to register the transfer or exchange of any series of debt securities, to replace any temporary, mutilated, destroyed, lost or stolen series of debt securities or to maintain an office or agency in respect of any series of debt securities.

## **Redemption of Securities**

Debt securities may also be subject to optional or mandatory redemption on terms and conditions described in the applicable prospectus supplement.

From and after notice has been given as provided in the applicable indenture, if funds for the redemption of any debt securities called for redemption shall have been made available on such redemption date, such debt securities will cease to bear interest on the date fixed for such redemption specified in such notice, and the only right of the holders of the debt securities will be to receive payment of the redemption price.

## **Notices**

Holders of our debt securities will receive notices by mail at their addresses as they appear in the security register.

## **Title**

We may treat the person in whose name a debt security is registered on the applicable record date as the owner of the debt security for all purposes, whether or not it is overdue.

### **Governing Law**

Unless otherwise set forth in the applicable prospectus supplement, New York law will govern the indentures and the debt securities, without regard to its conflicts of law principles.

### **Concerning the Trustee**

Each indenture provides that there may be more than one trustee under the indenture, each with respect to one or more series of debt securities. If there are different trustees for different series of debt securities, each trustee will be a trustee of a trust under the indenture separate and apart from the trust administered by any other trustee under the indenture. Except as otherwise indicated in this prospectus or any prospectus supplement, any action permitted to be taken by a trustee may be taken



**Table of Contents**

by such trustee only with respect to the one or more series of debt securities for which it is the trustee under the indenture. Any trustee under the indenture may resign or be removed with respect to one or more series of debt securities. All payments of principal of, premium, if any, and interest on, and all registration, transfer, exchange, authentication and delivery (including authentication and delivery on original issuance of the debt securities) of, the debt securities of a series will be effected by the trustee with respect to that series at an office designated by the trustee in New York, New York.

Each indenture contains limitations on the right of the trustee, should it become a creditor of the Company, to obtain payment of claims in some cases or to realize on certain property received in respect of any such claim as security or otherwise. The trustee may engage in other transactions. If it acquires any conflicting interest relating to any duties with respect to the debt securities, however, it must eliminate the conflict or resign as trustee.

**WARRANTS**

We may issue warrants for the purchase of debt securities, preferred stock, common stock, or any combination thereof. We may issue warrants independently or together with any other securities offered by any prospectus supplement and may be attached to or separate from the other offered securities. Each series of warrants will be issued under a separate warrant agreement to be entered into by us with a warrant agent. The warrant agent will act solely as our agent in connection with the warrants and will not assume any obligation or relationship of agency or trust for or with any holders or beneficial owners of warrants. Further terms of the warrants and the applicable warrant agreements will be set forth in the applicable prospectus supplement.

The applicable prospectus supplement relating to any particular issue of warrants will describe the terms of the warrants, including, as applicable, the following:

the title of the warrants;

the aggregate number of the warrants;

the price or prices at which the warrants will be issued;

the designation, terms and number of shares of preferred stock or common stock or principal amount of debt securities purchasable upon exercise of the warrants;

the designation and terms of the offered securities, if any, with which the warrants are issued and the number of the warrants issued with each offered security;

the date, if any, on and after which the warrants and the related debt securities, preferred stock or common stock will be separately transferable;

the price at which each share of preferred stock, common stock or underlying debt securities purchasable upon exercise of the warrants may be purchased or the manner of determining such price;

the date on which the right to exercise the warrants shall commence and the date on which that right shall expire;

the minimum or maximum amount of the warrants which may be exercised at any one time;

information with respect to book-entry procedures, if any;

a discussion of certain federal income tax considerations; and

any other material terms of the warrants, including terms, procedures and limitations relating to the exchange and exercise of the warrants.

We and the warrant agent may amend or supplement the warrant agreement for a series of warrants without the consent of the holders of the warrants issued thereunder to effect changes that are not inconsistent with the provisions of the warrants and that do not materially and adversely affect the interests of the holders of the warrants.

**Table of Contents**

**USE OF PROCEEDS**

We currently intend to use the net proceeds from the sale of our securities for general corporate purposes, which may include commercial launch activities, sales and marketing expenditures, funding of clinical trials, research and development, regulatory activities, acquisitions of companies, products, intellectual property or other technology, investments, capital expenditures, and for any other purposes that we may specify in any prospectus supplement. While we have no current plans for any specific acquisitions at this time, we believe opportunities may exist from time to time to expand our current business through strategic alliances or acquisitions of other companies, products or compounds. We have not yet determined the amount of net proceeds to be used specifically for any of the foregoing purposes. Accordingly, our management will have significant discretion and flexibility in applying the net proceeds from the sale of these securities. Pending any use, as described above, we intend to

invest the net proceeds in high-quality, short-term, interest-bearing securities. Our plans to use the estimated net proceeds from the sale of these securities may change, and if they do, we will update this information in a prospectus supplement.

**RATIO OF FIXED CHARGES AND PREFERENCE DIVIDENDS TO EARNINGS**

Our ratio of combined fixed charges and preference dividends to earnings for each of the five most recently completed fiscal years and any required interim periods will each be specified in a prospectus supplement or in a document that we file with the SEC and incorporate by reference pertaining to the issuance, if any, by us of preference securities in the future.

**DIVIDEND POLICY**

We have not declared or paid cash dividends on our common stock since our inception. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any cash dividends in the foreseeable future. Any future determination to declare cash dividends will be made at the discretion of our board of directors, subject to compliance with certain covenants under our credit facilities (including our currently outstanding Credit Facility), which restrict or limit our ability to declare of pay dividends, and will depend on our financial condition, results of operations, capital requirements, general business conditions and other factors that our board of directors may deem relevant. Consequently, stockholders will need to sell our securities to realize a return on their investment, if any.

**PLAN OF DISTRIBUTION**

We may sell the securities from time to time pursuant to underwritten public offerings, negotiated transactions, block trades or a combination of these methods. We may sell the securities to or through underwriters or dealers, through agents, or directly to one or more purchasers. We may distribute securities from time to time in one or more transactions:

at a fixed price or prices, which may be changed;

at market prices prevailing at the time of sale;

at prices related to such prevailing market prices; or

at negotiated prices.

We may also sell equity securities covered by this registration statement in an at the market offering as defined in Rule 415 under the Securities Act. Such offering may be made into an existing trading market for such securities in transactions at other than a fixed price, either:

on or through the facilities of The NASDAQ Global Market or any other securities exchange or quotation or trading service on which such securities may be listed, quoted or traded at the time of sale; and/or

to or through a market maker otherwise than on The NASDAQ Global Market or such other securities exchanges or quotation or trading services.

Such at-the-market offerings, if any, may be conducted by underwriters acting as principal or agent.

A prospectus supplement or supplements (and any related free writing prospectus that we may authorize to be provided to you) will describe the terms of the offering of the securities, including, to the extent applicable:

**Table of Contents**

the name or names of any underwriters, dealers or agents, if any;

the purchase price of the securities and the proceeds we will receive from the sale;

any over-allotment options under which underwriters may purchase additional securities from us;

any agency fees or underwriting discounts and other items constituting agents' or underwriters' compensation;

any public offering price;

any discounts or concessions allowed or reallocated or paid to dealers; and

any securities exchange or market on which the securities may be listed.

Only underwriters named in the prospectus supplement are underwriters of the securities offered by the prospectus supplement.

If underwriters are used in the sale, they will acquire the securities for their own account and may resell the securities from time to time in one or more transactions at a fixed public offering price or at varying prices determined at the time of sale. The obligations of the underwriters to purchase the securities will be subject to the conditions set forth in the applicable underwriting agreement. We may offer the securities to the public through underwriting syndicates represented by managing underwriters or by underwriters without a syndicate. Subject to certain conditions, the underwriters will be obligated to purchase all of the securities offered by the prospectus supplement. Any public offering price and any discounts or concessions allowed or reallocated or paid to dealers may change from time to time. We may use underwriters with whom we have a material relationship. We will describe in the prospectus supplement, naming the underwriter, the nature of any such relationship.

We may sell securities directly or through agents we designate from time to time. We will name any agent involved in the offering and sale of securities, and we will describe any commissions we will pay the agent in the prospectus supplement. Unless the prospectus supplement states otherwise, our agent will act on a best-efforts basis for the period of its appointment.

We may authorize agents or underwriters to solicit offers by certain types of institutional investors to purchase securities from us at the public offering price set forth in the prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. We will describe the conditions to these contracts and the commissions we must pay for solicitation of these contracts in the prospectus supplement.

We may provide agents and underwriters with indemnification against civil liabilities related to this offering, including liabilities under the Securities Act, or contribution with respect to payments that the agents or underwriters may make with respect to these liabilities. Agents and underwriters may engage in transactions with, or perform services for, us in the ordinary course of business.

All securities we offer, other than common stock, will be new issues of securities with no established trading market. Any underwriters may make a market in these securities, but will not be obligated to do so and may discontinue any market making at any time without notice. We cannot guarantee the liquidity of the trading markets for any securities.

Any underwriter may engage in overallotment, stabilizing transactions, short covering transactions and penalty bids. Overallotment involves sales in excess of the offering size, which create a short position. Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum. Short covering transactions involve purchases of the securities in the open market after the distribution is completed to cover short positions. Penalty bids permit the underwriters to reclaim a selling concession from a dealer when the securities originally sold by the dealer are purchased in a stabilizing or covering transaction to cover short positions. Those activities may cause the price of the securities to be higher than it would otherwise be. If commenced, the underwriters may discontinue any of the activities at any time. These transactions may be effected on any exchange or over-the-counter market or otherwise.

Any underwriters who are qualified market makers on The NASDAQ Global Market may engage in passive market making transactions in the securities on The NASDAQ Global Market in accordance with Rule 103 of Regulation M, during the business day prior to the pricing of the offering, before the commencement of offers or sales of the securities. Passive market makers must comply with applicable volume and price limitations and must be identified as passive market makers. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for such security; if all independent bids are lowered below the passive market maker's bid, however, the passive market maker's bid must then be lowered when certain purchase limits are exceeded. Passive market making may stabilize the market price of the securities at a level above that which might otherwise prevail in the open market and, if commenced, may be discontinued at any time.

**Table of Contents**

**LEGAL MATTERS**

The validity of the securities being offered hereby will be passed upon by Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP, Boston, Massachusetts.

**EXPERTS**

The financial statements incorporated by reference in this prospectus and elsewhere in the registration statement have been so incorporated by reference in reliance upon the report of Grant Thornton LLP, independent registered public accountants, upon the authority of said firm as experts in accounting and auditing.

**Table of Contents**

**18,000,000 Shares**

**Common Stock**

**Prospectus Supplement**

**Cowen and Company**

**Laidlaw & Company (UK) Ltd.**

**August 11, 2016**