ALIMERA SCIENCES INC
Form 424B3
May 08, 2013
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Filed Pursuant to Rule 424(b)(3)
Registration No. 333-184996

Prospectus

19,548,871 shares of Common Stock

This prospectus relates to the resale by certain of our stockholders, or selling stockholders, of up to 19,548,871 shares of our common stock in connection with the resale of up to:

- 12,658,228 shares of common stock issuable as of the date of this prospectus upon voluntary conversion by the selling stockholders of our Series A Convertible Preferred Stock, par value $0.01 per share (Series A Convertible Preferred Stock);
- 3,797,468 shares of common stock directly issuable upon exercise of certain warrants held by the selling stockholders (Warrants); and
- 3,093,175 shares of common stock that may become issuable to the selling stockholders upon the conversion of the outstanding shares of Series A Convertible Preferred Stock held by the selling stockholders and directly upon the exercise of the Warrants in the event that the conversion rate of the Series A Convertible Preferred Stock is adjusted because of the occurrence or non-occurrence of certain events, as discussed in the section of this prospectus entitled Description of Capital Stock Series A Convertible Preferred Stock.

The Series A Convertible Preferred Stock and the Warrants were issued to the selling stockholders on October 2, 2012 in connection with our private placement of units, each of which consisted of (i) one share of Series A Convertible Preferred Stock and (ii) one Warrant to purchase 0.30 shares of Series A Convertible Preferred Stock (or such number of shares of common stock then issuable upon conversion of such shares of Series A Convertible Preferred Stock). Although the Warrants may be exercised for shares of Series A Convertible Preferred Stock, the shares of common stock issuable upon conversion of such subsequently issued shares of Series A Convertible Preferred Stock are not being registered for resale hereunder.

We are registering these shares of common stock for resale by the selling stockholders named in this prospectus, or their transferees, pledgees, donees or successors. The selling stockholders may offer to sell the shares of common stock being offered in this prospectus at fixed prices, at prevailing market prices at the time of sale, at varying prices, at negotiated prices or in any other manner specified under the section of this prospectus entitled Plan of Distribution. We do not know when or in what amount the selling stockholders may offer the securities for sale. The selling stockholders may sell any, all or none of the securities offered in this prospectus.

Although we will pay substantially all of the expenses incident to the registration of the shares of common stock, we will not receive any proceeds from the sales by the selling stockholders. We will, however, to the extent the Warrants are exercised for cash, receive proceeds from such exercises; to the extent we receive such proceeds, they will be used for general corporate and working capital purposes.

The selling stockholders and any brokers executing sell orders on behalf of the selling stockholders may be deemed to be underwriters within the meaning of the Securities Act of 1933, as amended (Securities Act). Commissions received by a broker executing sell orders may be deemed to be underwriting commissions under the Securities Act.

Our common stock is listed on the NASDAQ Global Market under the symbol ALIM. The last reported sale price of our common stock on the NASDAQ Global Market on May 7, 2013 was $3.03.

Investing in our securities involves risks, including those described under Risk Factors beginning on page 4 of this prospectus.

We may amend or supplement this prospectus from time to time by filing amendments or supplements as required. You should read the entire prospectus and any amendment or supplements to this prospectus carefully before you make your investment decision.

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

The date of this prospectus is May 8, 2013.

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PROSPECTUS

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ABOUT THIS PROSPECTUS

In this prospectus, the Company, Alimera, we, us, and our and similar terms refer to Alimera Sciences, Inc. We have registered the trademar ILUVIEN®, which is used throughout this prospectus.

This prospectus is part of a registration statement on Form S-3 filed with the SEC under the Securities Act of 1933, as amended. This prospectus does not contain all of the information set forth in the registration statement. You should read the registration statement and this prospectus together with additional information described under the headings Where You Can Find More Information and Documents Incorporated by Reference. If there is any inconsistency between the information in this prospectus and the documents incorporated by referenced herein, you should rely on the information in this prospectus.

You should rely only on the information contained in or incorporated by reference into this prospectus. Neither we nor the selling stockholders have authorized any person to provide information different from that contained in this prospectus and the documents incorporated by reference herein. If anyone provides you with different or inconsistent information, you should not rely on it. You should assume that the information appearing in this prospectus is accurate as of the date on the cover page, regardless of time of delivery of the prospectus or any sale of securities. Our business, financial condition, results of operation and prospects may have changed since that date.

THIS PROSPECTUS IS NOT AN OFFER TO SELL ANY SECURITIES OTHER THAN THE SHARES OF COMMON STOCK FOR SALE BY THE SELLING STOCKHOLDERS. THIS PROSPECTUS IS NOT AN OFFER TO SELL SECURITIES IN ANY CIRCUMSTANCES IN WHICH SUCH AN OFFER IS UNLAWFUL. NEITHER WE NOR THE SELLING STOCKHOLDERS ARE MAKING AN OFFER TO SELL THESE SECURITIES IN ANY JURISDICTION WHERE THE OFFER OR SALE IS NOT PERMITTED.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

Various statements in this prospectus are 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 report 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 project, target, likely, potential, continue, will, would, should, could, or the negative of these terms and similar expressions or w 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:

- delay in or failure to obtain regulatory approval of our product candidates;
- uncertainty as to our ability to commercialize (alone or with others), and market acceptance of, ILUVIEN in the EU;
- our inability to successfully market and sell ILUVIEN following regulatory approval in additional markets;
- the extent of government regulations;
- uncertainty as to the pricing and reimbursement guidelines for our product candidates, including ILUVIEN in the various EU countries;
- uncertainty as to the relationship between the benefits of our product candidates and the risks of their side-effect profiles;

dependence on third-party manufacturers to manufacture our product candidates in sufficient quantities and quality;

uncertainty of clinical trial results;

limited sales and marketing infrastructure; and

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

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.

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We encourage you to read the discussion and analysis of our financial condition and our consolidated financial statements contained in this prospectus. We also encourage you to read the Risk Factors section 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, in the section entitled Risk Factors and in the other documents incorporated by reference herein, 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.

PROSPECTUS SUMMARY

This summary, which highlights information contained elsewhere in this prospectus, is not complete and may not contain all of the information that you should consider before investing in our common stock. You should read this entire prospectus and the financial statements and notes thereto, and other documents incorporated by reference herein.

Our Company

We are 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 treated with current therapies and represent a significant market opportunity. Our most advanced product candidate is ILUVIEN®, which has received marketing authorization in Austria, the United Kingdom, Portugal, France, Germany and Spain, and has been recommended for marketing authorization in Italy, 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. ILUVIEN has not been approved by the U.S. Food and Drug Administration (FDA).

We currently plan to launch ILUVIEN in Germany, the United Kingdom and France in 2013, and are pursuing pricing and reimbursement in those countries. In July 2012, we received a letter from Germany s Federal Joint Committee indicating that the automatic obligation to submit a dossier on ILUVIEN, per the Arzneimittelmarkt-Neuordnungsgesetz law, would not be necessary, and that a benefit assessment would not be required. Receipt of this letter allows us to launch ILUVIEN in Germany without price restriction. In January 2013, the United Kingdom s National Institute for Health and Clinical Excellence (NICE) published final guidance indicating that ILUVIEN is not cost effective for the treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies given the cost of £5500. We subsequently submitted a simple patient access scheme (PAS) for ILUVIEN to the Patient Access Schemes Liaison Unit (PASLU) which has been agreed to by the United Kingdom s Department of Health and is now under consideration by NICE for inclusion in its rapid review facility. Under this facility, the Appraisal Committee at NICE is expected to assess the impact of the ILUVIEN PAS on ILUVIEN s cost effectiveness and determine whether an update to the recently published final guidance is warranted. ILUVIEN is also being studied in two Phase 2 clinical trials for the treatment of the dry form of age-related macular degeneration (AMD) and retinal vein occlusion. A phase 2 trial studying ILUVIEN in the treatment of the wet form of AMD has been terminated based on an interim analysis, due to the determination that the endpoint of reducing the number of anti-VEGF injections may not be appropriate to assess the benefit of ILUVIEN in that disease.

We commenced operations in June 2003. Since our inception we have incurred significant losses. As of December 31, 2012, we have accumulated a deficit of $231.1 million. We expect to incur substantial losses through the projected commercialization of ILUVIEN as we:

- complete the clinical development and registration of ILUVIEN;
- prepare for the anticipated commercial launch of ILUVIEN in the EU in early 2013, at the earliest;
- continue to seek regulatory approval of ILUVIEN in the U.S. and other jurisdictions;
- evaluate the use of ILUVIEN for the treatment of other diseases; and

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

As of December 31, 2012, we had approximately $49.6 million in cash and cash equivalents.

We plan to proceed with the direct commercialization of ILUVIEN in Germany, the United Kingdom and France in 2013. We believe that we have sufficient funds available to fund our operations beyond the projected commercialization of ILUVIEN in these EU countries. We do not expect the generation of revenue until 2013, and therefore do not expect to have positive cash flow from operations until 2014, if at all.

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If ILUVIEN is not approved in additional jurisdictions or does not generate sufficient revenue, we may adjust our commercial plans so that we can continue to operate with our existing cash resources or seek to raise additional financing. We are a Delaware corporation incorporated on June 4, 2003. 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. The information contained in, or that can be accessed through, our website is not part of this prospectus and should not be considered incorporated by reference herein.

THE OFFERING

Common stock being offered by selling stockholders:	We are registering up to an aggregate of 19,548,871 shares of common stock issuable upon conversion of the outstanding shares of our Series A Convertible Preferred Stock, par value $0.01 per share (Series A Convertible Preferred Stock) [1] and directly issuable upon exercise of certain warrants held by the selling stockholders (Warrants). The following shares may be offered, from time to time, for resale by the selling stockholders under this prospectus: 12,658,228 shares of common stock issuable as of the date of this prospectus upon voluntary conversion by the selling stockholders of the Series A Convertible Preferred Stock; 3,797,468 shares of common stock directly issuable upon exercise of the Warrants by the selling stockholders (Warrants); and 3,093,175 shares of common stock that may become issuable to the selling stockholders upon the conversion of the outstanding shares of Series A Convertible Preferred Stock and directly upon the exercise of the Warrants in the event that the conversion rate of the Series A Convertible Preferred Stock is reduced to $2.66 because of the occurrence or non-occurrence of certain events, as discussed in the section of this prospectus entitled Description of Capital Stock Series A Convertible Preferred Stock. Although the Warrants may be exercised for shares of Series A Convertible Preferred Stock, the shares of common stock issuable upon conversion of such subsequently issued shares of Series A Convertible Preferred Stock are not being registered for resale hereunder.
Common stock being offered by us:	None.
Shares of common stock outstanding after this offering:	44,199,512[2] shares of common stock
Use of Proceeds	

	We will not receive any of the proceeds from the sale of shares of common stock by the selling stockholders. Any proceeds received by us from the exercise of Warrants by the selling stockholders will be used for working capital and general corporate purposes. See Use of Proceeds.
Risk Factors	An investment in our common stock involves various risks, and prospective investors should carefully consider the matters discussed under Risk Factors beginning on page 4 of this prospectus.
NASDAQ Global Market Symbol	ALIM

(1) Each share of Series A Convertible Preferred Stock is convertible into shares of common stock at any time at the option of the holder at the rate equal to $40.00 divided by the then current conversion price. The Series A Convertible Preferred Stock is not convertible at the

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option of the Company. The conversion price of the Series A Convertible Preferred Stock is subject to adjustment from $2.91 to $2.66 or $3.16 based on the occurrence or non-occurrence of certain events, in addition to certain customary price based anti-dilution adjustments, subject to a floor of $1.00. Any voluntary conversion of the Series A Convertible Preferred Stock into common stock at any time prior to the earlier of July 1, 2013 and the adjustment to either $2.66 or $3.16 (as so adjusted, the Final Guidance Price) shall be at a conversion price of $3.16 (as adjusted for any price-based anti-dilution). The dollar amounts set forth above are subject to adjustment for stock splits, combinations, stock dividends, recapitalizations and the like with respect to the Series A Convertible Preferred Stock. For a more detailed description of the conversion provisions of the Series A Convertible Preferred Stock, see the section of this prospectus entitled Description of Capital Stock Series A Convertible Preferred Stock.

(2) The number of shares of common stock outstanding after this offering is based on the number of shares outstanding as of March 1, 2013, including 12,658,228 shares of common stock issuable as of the date of this prospectus upon voluntary conversion by the selling stockholders of the Series A Convertible Preferred Stock, and excludes:

5,780,579 shares of common stock reserved for issuance upon the exercise of outstanding stock options at a weighted average exercise price per share of $2.63;

82,568 shares of common stock issuable upon the exercise of outstanding warrants (other than the Warrants) at a weighted average exercise price per share of $6.85; and

69,999 shares of common stock underlying outstanding warrants at an exercise price per share of $11.00 which are not exercisable.

RISK FACTORS

Investing in our common stock involves risk. You should carefully consider the risks described below as well as those risk factors incorporated by reference herein, before making an investment decision. The risks and uncertainties described below are not the only risks and uncertainties we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. If any of the following risks actually occur, our business, results of operations and financial condition could suffer. In that event the trading price of our common stock could decline, and you may lose all or part of your investment. The risks discussed below and those incorporated by reference 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 candidate, ILUVIEN, which only recently received marketing authorizations in Austria, the United Kingdom, Portugal, France, Germany and Spain, and on the regulatory approval of ILUVIEN for the treatment of DME in the U.S. and other countries, which may never occur.

We are a biopharmaceutical 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 for the treatment of DME in Europe and the U.S. In February 2012, ILUVIEN received a positive outcome from the Decentralized Procedure (DCP) in Europe with the issuance of a Final Assessment Report (FAR) from the United Kingdom Medicines Healthcare products Regulatory Agency (MHRA) indicating that that it is approvable for commercial use to treat vision impairment associated with chronic DME considered insufficiently responsive to available therapies in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain. Following the issuance of the FAR from the MHRA, ILUVIEN received marketing authorization from governing regulatory bodies in Austria, the United Kingdom, Portugal, France, Germany and Spain. ILUVIEN has not yet received marketing authorization in Italy, however, and we cannot be certain when, or if, it will receive such authorization. ILUVIEN has not been approved by the FDA in the U.S. and may never receive such approval. The timing of the commercial launch of ILUVIEN in the EU countries is dependent upon each specific EU country s pricing and reimbursement timelines, and we do not anticipate commercial sales of ILUVIEN until 2013, at the earliest. Because we do not currently have any 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 and France, the first three countries in which we intend to make ILUVIEN available for sale. 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

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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 as we prepare for the commercial launch of ILUVIEN in Germany, the United Kingdom and France, continue to pursue the approval of ILUVIEN in the U.S. 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 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.

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 establishing a 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 and France, the first three countries in which we intend to make ILUVIEN available for sale. We currently plan to launch ILUVIEN in 2013. 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 will require significant management attention and additional financial resources. We may not be able to establish a 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 will 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.

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If we or Quintiles Commercial are not successful in recruiting sales and marketing personnel or in building a sales and marketing infrastructure or if we do not successfully enter into additional collaboration arrangements with third-parties, we will have difficulty commercializing ILUVIEN and our other 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 establishing a 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 establish a 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 establishing our commercial operations that delay the commercial launch in one or more EU countries in which ILUVIEN 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 launch 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 have not yet 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;

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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 are being developed for the treatment of DME. There are no ophthalmic drug therapies other than Lucentis, a drug sponsored by Genentech, Inc., a wholly-owned member of the Roche Group, which has been approved by the FDA for the treatment of DME. Lucentis is also approved for the treatment of visual impairment due to DME in the EU. Lucentis is expected to provide competition for ILUVIEN. 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. Additional treatments for DME are in various stages of preclinical or clinical testing. Later stage products for the treatment of DME include Ozurdex, a drug sponsored by Allergan, Inc. and Eyelea, a drug sponsored by Regeneron Pharmaceuticals, Inc. and Bayer HealthCare. If approved, these treatments would also compete 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 our 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

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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.

We are not currently generating 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 generate revenue from selling products or achieve profitability. We expect to continue to incur substantial and increasing losses through the projected commercialization of ILUVIEN. We currently do not expect to generate revenue from the sale of ILUVIEN in the EU until 2013, at the earliest. 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 December 31, 2012, we have accumulated a deficit of $231.1 million. Our ability to achieve revenue and profitability is dependent on our ability to complete the development of our product candidates, obtain necessary regulatory approvals, and have our products manufactured and successfully marketed and sold. 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 December 31, 2012, we had approximately $49.6 million in cash and cash equivalents. 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.

We face heavy government regulation, and regulatory approval of ILUVIEN and our other 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.

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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 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 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 and Spain, and been recommended for marketing authorization in Italy, 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 withdraw 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 and Spain, and been recommended for marketing authorization in Italy 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 product candidates may never achieve market acceptance even if we obtain regulatory approvals.

Even if we receive regulatory approvals for the sale of our 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 of our product candidates will depend on a number of factors, including, among other things:

- the demonstration of its safety and efficacy;
- its cost-effectiveness;

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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 our product candidates fail to gain market acceptance, we may be unable to earn sufficient revenue to continue our business. If our 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.

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 will 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 will depend completely on a single third-party manufacturer for the manufacture of the ILUVIEN insert (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 quality release testing of ILUVIEN in the EU (Brecon Pharmaceuticals Limited (Brecon)). Although we have agreements for the manufacture of the ILUVIEN insert (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 inserts, 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 will 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 insert, 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.

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The manufacture and packaging of pharmaceutical product candidates 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 product candidates such as ILUVIEN and our 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 our 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. If our manufacturers fail to maintain compliance, the production of ILUVIEN could be interrupted, resulting in delays and additional costs. Any significant delays in the manufacture of ILUVIEN 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 our 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 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. With respect to ILUVIEN, although we have validated the manufacturing process at our anticipated commercial scale batch size, some of the steps in the manufacturing processes will need to be revalidated if we choose to begin to manufacture larger commercial scale batches, including in connection with our anticipated commercial launch in the EU. If the required testing or process validation is delayed or produces unfavorable results, we may not be able to increase the commercial scale batch, which may impact our ability to fulfill demand for the product. 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. If we are unable to comply, we may be subject to regulatory or civil actions or penalties that could significantly and adversely affect our business.

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

Preclinical studies and clinical trials required to demonstrate the safety and efficacy of our product candidates are time consuming and expensive and together take several years to complete. The completion of clinical trials for our 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.

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If we fail to successfully complete our clinical trials for any of our product candidates, we may not receive the regulatory approvals needed to market those product candidates. Therefore, any failure or delay in commencing or completing these 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
- 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 of our 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 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.

In order to establish 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 December 31, 2012, we had 23 employees, 21 of whom were located in the U.S. and two of whom were located in the United Kingdom, where our EU operations are based. In January 2013 and March 2013, we added two additional employees to the management team for our EU operations. 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 in November 2012 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 currently employs 16 persons fully dedicated to Alimera and expects this number to grow to 25 by December 2013. Quintiles Commercial also employs 20 persons partially dedicated to Alimera in Germany, the United Kingdom and France. 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. As our development and commercialization plans and strategies evolve beyond our initial planned launch, 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 other 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 our other potential products 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.

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In the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain, as well as many other foreign 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.

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 our future products 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 products 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. 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-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.

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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 additional 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 entering 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.

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

A key element of our strategy is to commercialize a portfolio of new ophthalmic drugs in addition to ILUVIEN. We are seeking 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.

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A significant portion of the research that we are conducting involves 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. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying potential product candidates; or
- potential 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 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 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 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 will 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 expected synergies. We cannot assure that, following an acquisition, we will achieve the revenues or specific net income that justifies the acquisition.

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

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 with a total aggregate liability limit of $10.0 million 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.

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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 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, Susan Caballa, our Senior Vice President of Regulatory Affairs, Kenneth Green, Ph.D., our Senior Vice President and Chief Scientific Officer and Dave Holland, our Senior Vice President of Sales and Marketing. 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 new products.

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.

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 ILUVIEN or any of our other product candidates could be delayed.

We are dependent on CROs, third-party vendors and investigators for preclinical testing and clinical trials related to our discovery and development efforts with respect to our product candidates and we will likely continue to depend on them to assist in our future discovery and development efforts. 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 our product candidates could be delayed.

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.

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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 our products abroad.

ILUVIEN has received marketing authorization in Austria, the United Kingdom, Portugal, France, Germany and Spain, and been recommended for marketing authorization in Italy. We intend to continue to pursue market authorizations for ILUVIEN and other product candidates 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 seven 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 our products in any additional market. The failure to obtain these approvals could harm our business materially.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval or limit their marketability.

Undesirable side effects caused by our product candidates could interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, and in turn prevent us from commercializing our product candidates and generating revenues from their sale. Possible side effects of ILUVIEN include, but are not limited to, extensive blurred vision, cataracts, eye irritation, eye pain, increased IOP, which may increase the risk of glaucoma, ocular discomfort, reduced visual acuity, visual disturbance, endophthalmitis, or long-standing vitreous floaters.

In addition, if following marketing approval in a jurisdiction, we or others later identify undesirable side effects caused by the product, we could face one or more of the following consequences:

- regulatory authorities may require the addition of labeling statements, such as a black box warning or a contraindication;
- regulatory authorities may withdraw their approval of the product;
- we may be required to change the way that the product is administered, conduct additional clinical trials or change the labeling of the product; and
- our reputation may suffer.

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

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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.

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 product candidates.

Our products or potential products 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 one or more 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.

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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.

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 our product candidates, we rely upon intellectual property we own relating to our products, including patents, patent applications and trade secrets. As of December 31, 2012, we owned one pending non-provisional U.S. utility patent application, one European patent application, one issued U.S. design patent and corresponding applications in a number of other jurisdictions, relating to our applicator for ILUVIEN. As of December 31, 2012, we also owned one allowed or issued U.S. utility patent relating to reduced incidence of intraocular pressure lowering surgery a year or more after treatment with ILUVIEN with corresponding applications in a number of other jurisdictions. In March 2013, we received notice that our pending non-provisional U.S. utility patent would issue. 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 December 31, 2012, the patent rights relating to ILUVIEN licensed to us from pSivida include three U.S. patents that expire between March 2019 and April 2020, one European patent expiring in April of 2021, 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 April of 2021 in Europe, we will not be able to block others from marketing FAc in an insert similar to ILUVIEN in the U.S. Our allowed or issued U.S. utility patent relating to reduced incidence of intraocular pressure lowering surgery will expire in the U.S. in July of 2031 and may provide protection for specific uses of FAc. 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 another product candidate is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize ILUVIEN and our other product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market ILUVIEN and our other 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 and our other product candidates 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 discovery, development and commercialization efforts with respect to ILUVIEN and our other product candidates.

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 product, 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 other products until such patents expire.

In addition, third-parties may obtain patents in the future and claim that use of our product candidates or technologies 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 develop and commercialize one or more of our 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 developing or commercializing our product candidates and 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 our product candidates, 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 develop and commercialize one or more of our 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.

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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 a risk of product liability exposure related to the testing of our product candidates in clinical trials and will face even greater risks upon any commercialization by us of our product candidates. 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 $10.0 million, 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 $2.8 billion will be payable in 2013. 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.

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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 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.

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, 2012, we had U.S. federal and state net operating loss (NOL) carry-forwards of approximately $142.5 million and $126.0 million, respectively, which expire at various dates beginning in 2020 through 2032. 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 on October 2, 2012 constituted such a change in ownership. We are currently performing a formal analysis of our NOLs in connection with IRC Section 382 as a result of this change to determine the extent of the limitation of our NOL carry-forwards.

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.

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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 may be required 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.

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 our product candidates, particularly ILUVIEN in the EU;
- our ability to obtain regulatory approval of ILUVIEN in additional jurisdictions;
- the emergence of products that compete with our product candidates;
- the status of our preclinical and clinical development programs;
- variations in the level of expenses related to our existing product candidates or 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 product candidates 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.

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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. Including the net proceeds from our Series A Convertible Preferred Stock financing, completed in the fourth quarter of 2012, based on our current plans, we believe our cash and cash equivalents will be sufficient to fund our operations beyond the projected commercialization of ILUVIEN in the United Kingdom, France and Germany and the expected generation of revenue in 2013, 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;
- the level of success of the initial commercial launch of ILUVIEN in the United Kingdom, France and Germany;
- 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 shareholder 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 shareholder 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 our product candidates or operate our business. For example, under the senior secured credit facility, which we entered into in October 2010 (Credit

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Facility), we 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. To secure the performance of our obligations under the Credit Facility, we pledged all of our assets, including our intellectual property to the lenders. Our 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. 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 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 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 and France;
- the ability of ILUVIEN to be approved in any additional jurisdiction;
- the ability of ILUVIEN or any of our product candidates, if approved in additional jurisdictions, to achieve commercial success;
- results from our clinical trial programs;
- FDA or international regulatory actions, including failure to receive regulatory approval for any of our product candidates;
- quarterly variations in our results of operations or those of our competitors;
- our ability to develop and market new and enhanced product candidates on a timely basis;
- 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 credit facility;

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;

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

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

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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 our 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 commercialization of our product and 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.

As of December 31, 2012, 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 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, including under this prospectus, 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.

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In addition to our outstanding common stock, as of December 31, 2012, there were a total of 5,493,079 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 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, 2013, an additional 1,261,651 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, 2013, an additional 15,984 shares became available for future issuance under our 2010 Employee Stock Purchase Plan.

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

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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 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 you might consider 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.

USE OF PROCEEDS

We will not receive any proceeds from the sale of shares of common stock by the selling stockholders. A portion of the shares of common stock covered by this prospectus are issuable directly upon exercise of the Warrants. The exercise price of a Warrant directly exercised for common stock equals the quotient of (i) $44.00 divided by (ii) the number of shares of common stock then issuable upon conversion of one share of Series A Convertible Preferred Stock. Upon any exercise of a Warrant for cash, the exercising selling stockholders

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would pay us the exercise price of the applicable Warrants. In the event all of the Warrants are exercised for cash, we would receive approximately $13,200,000. Under certain conditions set forth in the Warrants, the Warrants are exercisable on a cashless basis. If a Warrant is exercised on a cashless basis, we would not receive any cash payment from the selling stockholders upon exercise of such Warrant. Instead, the applicable selling stockholder would satisfy its obligation to pay the exercise price through a formula-based transfer of Warrant shares to us. There is no certainty that we will ever receive any proceeds from the exercise of the Warrants. We intend to use any proceeds from the exercise of Warrants for general corporate and working capital purposes.

The selling stockholders will pay any underwriting discounts and commissions and expenses incurred by the selling stockholders for brokerage, accounting, tax or legal services or any other expenses incurred by the selling stockholders in selling the common stock covered by this prospectus. We will bear all other costs, fees and expenses incurred in effecting the registration of the shares of common stock covered by this prospectus, including, without limitation, all registration and filing fees and expenses of our counsel and our accountants.

SELLING STOCKHOLDERS

This prospectus relates to the resale of common stock issuable to the selling stockholders upon conversion of the outstanding shares of Series A Convertible Preferred Stock and upon exercise of the Warrants directly for common stock. We are also registering an additional 3,093,175 shares of common stock that may become issuable to the selling stockholders upon the conversion of the outstanding shares of Series A Convertible Preferred Stock and directly upon the exercise of the Warrants in the event that the conversion price of the Series A Convertible Preferred Stock is reduced to $2.66 because of the occurrence or non-occurrence of certain events, as discussed in the section of this prospectus entitled Description of Capital Stock Series A Convertible Preferred Stock. Although the Warrants may be exercised for shares of Series A Convertible Preferred Stock, the shares of common stock issuable upon conversion of such subsequently issued shares of Series A Convertible Preferred Stock are not being registered for resale hereunder.

The following table, based upon information currently known by us, sets forth as of March 1, 2013: (i) the number of shares held of record or beneficially by the selling stockholders as of such date and assuming conversion of all outstanding Series A Convertible Preferred Stock held by the selling stockholders as of such date and common stock directly issuable upon exercise of the Warrants held by the selling stockholders as of such date, (ii) the number of shares that may be offered under this prospectus, and (iii) a footnote reference to any material relationship between us and the applicable selling stockholder. The table below includes the additional shares of common stock that may become issuable to the selling stockholders upon the conversion of all outstanding Series A Convertible Preferred Stock held by the selling stockholders as of such date and shares of common stock directly issuable upon exercise of the Warrants held by the selling stockholders as of such date in the event that the conversion price of the Series A Convertible Preferred Stock is reduced to $2.66 because of the occurrence or non-occurrence of certain events.

The percentages of common stock owned after the offering are based on 31,541,286 shares of common stock outstanding on March 1, 2013. Beneficial ownership is determined in accordance with Rule 13d-3(d) promulgated by the SEC under the Exchange Act. In computing the number of shares owned and the percentage ownership of a selling stockholder, shares of common stock that could be issued upon the conversion of outstanding Series A Convertible Preferred Stock or upon the exercise of the Warrants or other warrants, options or other rights held by that selling stockholder that are currently exercisable or exercisable within 60 days of March 1, 2013 are considered outstanding. However, such shares are not included in the shares outstanding as of March 1, 2013 when computing the percentage ownership of each other selling stockholder. Unless otherwise noted, each person or group identified possesses sole voting and investment power with respect to the shares, subject to community property laws where applicable. The inclusion of any securities in this table does not constitute an admission of beneficial ownership for the person named below.

Selling Stockholder	Beneficial Ownership Prior to this Offering (1),(2)	Shares that may be Offered and Sold Hereby (1),(3)	Beneficial Ownership After this Offering	% Holding After Completion of this Offering
Palo Alto Investors, LLC (4)	15,364,307	11,729,323	3,634,984	8.4%
Sofinnova Venture Partners VIII, L.P. (5)	4,887,218	4,887,218	0	*
Growth Equity Opportunities Fund III, LLC (6)	2,932,330	2,932,330	0	*
Total	23,183,855	19,548,871	3,634,984	7.1%

* Less than 1.0%

(1) The number of shares offered by the selling stockholders in the table above reflects the shares of common stock issuable upon conversion of Series A Convertible Preferred Stock and upon exercise of the Warrants in the event that the conversion price of the Series A Convertible Preferred Stock is reduced to $2.66 as a result of the occurrence or non-occurrence of certain events. In the event that the shares of Series A Convertible Preferred Stock were voluntarily converted and the Warrants were exercised in full for shares of common stock by the selling stockholders as of the date of this prospectus (based on the applicable conversion price of $3.16), the selling stockholders would beneficially own the following number of shares of common stock:

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Selling Stockholder	Beneficial Ownership Prior to this Offering
Palo Alto Investors, LLC	13,508,401
Sofinnova Venture Partners VIII, L.P.	4,113,924
Growth Equity Opportunities Fund III, LLC	2,468,354
Total	20,090,679

(2) Pursuant to the terms of the Series A Convertible Preferred Stock, the Series A Convertible Preferred Stock will vote together with common stock on an as converted basis based on a deemed conversion price of $2.95 (as adjusted for stock splits, combinations, stock dividends, recapitalizations and the like with respect to the Series A Convertible Preferred Stock). As such, as of the date hereof, assuming the selling stockholders exercised their Warrants in full directly for common stock, the selling stockholders would be entitled to vote the following number of shares of common stock at any meeting of our stockholders:

Selling Stockholder	Voting Power Prior to this Offering
Palo Alto Investors, LLC	14,211,255
Sofinnova Venture Partners VIII, L.P.	4,406,779
Growth Equity Opportunities Fund III, LLC	2,644,067
Total	21,262,101

(3) Assumes that (a) the selling stockholders dispose of all the shares of common stock covered by this prospectus and do not acquire or dispose of any additional shares of common stock and (b) that there is no price-based anti-dilution adjustment to the conversion rate of the Series A Convertible Preferred Stock. The selling stockholders are not representing, however, that any of the shares covered by this prospectus will be offered for sale, and the selling stockholders reserve the right to accept or reject, in whole or in part, any proposed sale of shares. We have entered into registration rights agreements with the selling stockholders pursuant to we are required to file a resale registration statement for the shares underlying the Series A Convertible Preferred Stock and Warrants to enable the resale of such shares by such selling stockholders on a delayed or continuous basis under Rule 415 of the Securities Act.

(4) Includes 1,170,492 shares held by Micro Cap Partners, L.P. (Micro Cap), 5,736,262 shares held by Palo Alto Healthcare Master Fund, L.P. (Healthcare Master) and 8,457,553 shares held by Palo Alto Healthcare Master Fund II, L.P. (Healthcare Master II and collectively with Micro Cap and Healthcare Master, PAI). Palo Alto Investors, Inc. (PAI Corp) is the manager of Palo Alto Investors, LLC (PAI LLC). William Leland Edwards is the controlling shareholder of PAI Corp. Dr. Anthony Joonkyoo Yun is the President of PAI LLC and PAI Corp. PAI LLC, PAI Corp, Mr. Edwards and Dr. Yun filed Schedule 13G jointly, but not as members of a group, and each of them expressly disclaims membership in a group. Each of PAI LLC, PAI Corp, Mr. Edwards and Dr. Yun disclaims beneficial ownership of the shares except to the extent of their respective pecuniary interest therein. In addition, Healthcare Master II should not be construed as a member of a group, and it disclaims that it is a beneficial owner. PAI LLC is a registered investment adviser and is the general partner and investment adviser of Healthcare Master II and other investment limited partnerships, and is the investment adviser to other investment funds. PAI LLC s clients have the right to receive or the power to direct the receipt of dividends from, or the proceeds from the sale of, the share No individual client, other than Healthcare Master II, separately holds more than five percent of the outstanding shares of the Company. PAI purchased units consisting of an aggregate of 600,000 shares of Series A Convertible Preferred Stock and Warrants to purchase an additional 180,000 shares of Series A Convertible Preferred Stock (or directly for such number of shares of common stock then issuable upon conversion of such shares of Series A Convertible Preferred Stock) from us on October 2, 2012 in our Series A Convertible Preferred Stock financing. In connection with such purchase, we entered into a Registration Rights Agreement with PAI and the other purchasers.

(5) The securities are owned directly by Sofinnova Venture Partners VIII, L.P. (SVP VIII). Sofinnova Management VIII, L.L.C. (SM VIII), the general partner of SVP VIII, and Garheng Kong, Michael Powell, and James I. Healy, the managing members of SM VIII, may be deemed to have shared voting and dispositive power over the shares owned by SVP VIII. Such persons and entities disclaim beneficial ownership over the shares owned by SVP VIII except to the extent of any pecuniary interest therein. SVP VIII purchased units consisting of an aggregate of 250,000 shares of Series A Convertible Preferred Stock and Warrants to purchase an additional 75,000 shares of Series A Convertible Preferred Stock (or directly for such number of shares of common stock then issuable upon conversion of such shares of Series A Convertible Preferred Stock) from us on October 2, 2012 in our Series A Convertible Preferred Stock financing. In connection with such purchase, we entered into a Registration Rights Agreement with SVP VIII and the other purchasers.

(6) The securities are owned directly by Growth Equity Opportunities Fund III, LLC (GEO). New Enterprise Associates 14, L.P. (NEA 14), which is the sole member of GEO; NEA Partners 14, L.P. (NEA Partners 14), which is the sole general partner of NEA 14; NEA 14 GP, LTD (NEA 14 GP), which is the sole general partner of NEA Partners 14; and Michael James Barrett, Peter J. Barris, Forest Baskett, Ryan

D. Drant, Anthony A. Florence, Jr., Patrick J. Kerins, Krishna S. Kolluri, David M. Mott, Scott D. Sandell, Peter W. Sonsini, Ravi Viswanathan and Harry R. Weller (collectively, the Directors). The Directors are the individual directors of NEA 14 GP. GEO, NEA 14, NEA Partners 14, NEA 14 GP and the Directors are sometimes referred to collectively herein as the NEA Reporting Persons. Each

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NEA Reporting Person disclaims beneficial ownership of such shares of common stock except for the shares, if any, such NEA Reporting Person holds of record. GEO purchased units consisting of an aggregate of 150,000 shares of Series A Convertible Preferred Stock and Warrants to purchase an additional 45,000 shares of Series A Convertible Preferred Stock (or directly for such number of shares of common stock then issuable upon conversion of such shares of Series A Convertible Preferred Stock) from us on October 2, 2012 in our Series A Convertible Preferred Stock financing. In connection with such purchase, we entered into a Registration Rights Agreement with GEO and the other purchasers.

OUR CORPORATE INFORMATION

We were incorporated in Delaware and commenced operations on June 4, 2003. 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. The information contained on, or that can be accessed through, our website is not part of this prospectus.

DESCRIPTION OF CAPITAL STOCK

The following summary of our capital stock and certain provisions of our restated certificate of incorporation and bylaws do not purport to be complete and is qualified in its entirety by the provisions of our restated certificate of incorporation and bylaws, copies of which have been filed as exhibits to the registration statement of which this prospectus is a part.

General

Our authorized capital stock consists of 100,000,000 shares of common stock, par value $0.01 per share, and 10,000,000 shares of preferred stock, par value $0.01 per share. 1,300,000 shares of preferred stock have been designated as Series A Convertible Preferred Stock.

Common Stock

As of March 1, 2013, there were 31,541,286 shares of common stock outstanding held of record by approximately 45 stockholders.

Holders of 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 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 bylaws, 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.

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. 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.

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.

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.

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, 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

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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 the Company 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 the then current conversion price (conversion price). The initial conversion price of $2.91 of the Series A Convertible Preferred Stock is subject to adjustment based on the occurrence or non-occurrence of certain events, in addition to certain customary price-based anti-dilution adjustments. The conversion price will be adjusted pursuant to the first to occur of the following occurrences (such adjusted conversion price being referred to herein as the Final Guidance Price): (i) the then-effective conversion price shall be automatically increased by $0.25 as of the date on which NICE issues final guidance (following the review of a PAS (as commonly used by NICE), if required) recommending ILUVIEN (a Positive Guidance), provided that such Positive Guidance is issued on or before June 30, 2013; (ii) the then-effective conversion price shall be automatically decreased by $0.25 (as adjusted for stock splits, combinations, stock dividends, recapitalizations and the like with respect to the Series A Convertible Preferred Stock) on July 1, 2013, if ILUVIEN has not received Positive Guidance on or before June 30, 2013; or (iii) the then-effective conversion price shall be automatically decreased by $0.25 as of the date, on or prior to June 30, 2013, on which: (a) NICE issues final unappealable guidance (following the review of a PAS) failing to recommend ILUVIEN (a Negative Guidance) or (b) the Company ceases to seek NICE approval of ILUVIEN. For the avoidance of doubt with respect to subsection (iii), the issuance of a FAD (as commonly used by NICE) by NICE prior to the review of a PAS is not final guidance for these purposes.

In the event (i) we are acquired or (ii) the automatic conversion of the Series A Convertible Preferred Stock into common stock pursuant to the terms of the Certificate of Designation occurs, in each case prior to the determination of the Final Guidance Price, then the conversion price shall be $2.91, subject to certain customary price-based anti-dilution adjustments. Any voluntary conversion by the holder of Series A Convertible Preferred Stock into common stock at any time prior to July 1, 2013 and the determination of the Final Guidance Price shall be at a conversion price of $3.16, subject to certain customary price based anti-dilution adjustments. The adjustments to the conversion price for purposes of the price based anti-dilution adjustments shall be determined by reference to an assumed conversion price which does not take into account adjustments made in connection with the Final Guidance Price (i.e., for purposes of the anti-dilution provisions, $2.91, shall be the initial assumed conversion price from which anti-dilution adjustments will be determined). The price-based anti-dilution adjustment for the Series A Convertible Preferred Stock is calculated on a weighted average basis and is restricted such that the this adjustment may not result in a conversion price less than $1.00.

Each share of Series A Convertible Preferred Stock shall automatically be converted into shares of common stock at the then-effective 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 or 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

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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 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 with Silicon Valley Bank and/or MidCap Financial, 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 is filed as Exhibit 3.5 to the registration statement of which this prospectus forms a part. 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.

Registration of the Underlying Common Stock

We and the selling stockholders entered into a Registration Rights Agreement (Registration Rights Agreement) dated October 2, 2012, whereby we are required to file this registration statement pursuant to the Securities Act to register the shares of common stock issuable upon conversion of the Series A Convertible Preferred Stock issued and sold in the Series A Convertible Preferred Stock financing (Conversion Shares), and the shares of common stock issuable upon exercise of the Warrants (Warrant Shares, and together with the Conversion Shares,

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Registrable Securities) for resale. The Registration Rights Agreement also contains provisions for demand registration rights, pursuant to which the selling stockholders may require us to register all or a portion of their Registrable Securities and offer them for resale in an underwritten offering, and piggyback registration rights pursuant to which the selling stockholders may include their Registrable Securities in any future registration statement we file, with certain exceptions as set forth in the Registration Rights Agreement. In addition, we agreed to use commercially reasonable efforts to keep the registration, and any qualification, exemption or compliance under state securities laws which the Company determines to obtain, continuously effective, and to keep the registration statement and any related prospectuses or prospectus supplement free of any material misstatements or omissions, until the date on which we shall have obtained a written opinion of legal counsel reasonably satisfactory to the selling stockholders and addressed to us and the selling stockholders to the effect that the Registrable Securities may be publicly offered for sale in the United States by the selling stockholders or any subsidiary of such selling stockholders without restriction as to manner of sale and amount of securities sold and without registration or other restriction under the Securities Act. The Registration Rights Agreement is filed as Exhibit 4.11 to the registration statement of which this prospectus forms a part. The foregoing description of the Registration Rights Agreement does not purport to be complete and is qualified in its entirety by reference to such exhibit.

Investor Representation on Our Board of Directors

For as long as Sofinnova Venture Partners VIII, L.P., together with its affiliates (Sofinnova), continues to hold at least 50% of the shares of Series A Convertible Preferred Stock originally issued to Sofinnova at the closing of our Series A Convertible Preferred Stock financing (or shares of common stock issued upon conversion thereof), the holders of Series A Convertible Preferred Stock, voting as single class, shall be entitled to elect, at any election of our Class II Directors, one individual to serve as a Class II Director (Series A Director), who shall be designated by Sofinnova. The initial Series A Director, Garheng Kong, was appointed as of the closing of our Series A Convertible Preferred Stock financing and is a current director of the Company.

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 bylaws, effective 12 months after adoption. Our restated certificate of incorporation and bylaws 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 common stock and deprive stockholders of opportunities to

realize a premium on shares of common stock held by them. Our Board of Directors waived the provisions of Section 203 with respect to the issuance of the Series A Convertible Preferred Stock and Warrants to selling stockholders in our Series A Convertible Preferred Stock financing.

In addition to our Board of Directors ability to issue shares of preferred stock, our restated certificate of incorporation and bylaws 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;

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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, other than action by the holders of the Series A Convertible Preferred Stock; 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.

Further, 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:

increase or decrease the authorized number of shares of Series A Convertible Preferred Stock; or

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.

Warrants

Warrants issued to selling stockholders in our Series A Convertible Preferred Stock financing. Each unit sold to the selling stockholders in the Series A Convertible Preferred Stock financing included a Warrant to purchase 0.30 shares of Series A Convertible Preferred Stock (or directly for such number of shares of common stock then issuable upon conversion of such shares of Series A Convertible Preferred Stock) at an exercise price equal to $44.00 per share (or, if the Warrant is directly exercised for common stock, the quotient of (i) $44.00 divided by (ii) the number of shares of common stock then issuable upon conversion of one share of Series A Convertible Preferred Stock). As of March 1, 2013, there were outstanding Warrants to purchase up to an aggregate of 300,000 shares of Series A Convertible Preferred Stock, which as of such date were voluntarily convertible into 3,797,468 shares of common stock. The Warrants may be exercised for cash or, if the fair market value of the underlying stock exceeds the exercise price, on a cashless net exercise basis. The Warrants are exercisable beginning on the original date of issuance and will expire on the earlier to occur of (i) immediately following the consummation of a sale of the Company (for cash or freely tradable securities), if the warrants are not exercised or exchanged at or prior to the consummation of such sale or (ii) October 2, 2017. The terms of the Warrants provide that they will automatically be exercised on a cashless basis prior to their expiration if the fair market value of the underlying stock exceeds the exercise price. At the election of the holder of a Warrant, the Warrant may be exercised for the number of shares of common stock then issuable upon conversion of the Series A Convertible Preferred Stock that would otherwise be issued upon such exercise at the then-effective conversion price. The exercise price and the number of shares issuable upon exercise of the Warrants are subject to appropriate adjustment in the event of recapitalization events, stock dividends, stock splits, stock combinations, reclassifications, reorganizations

or similar events affecting the Series A Convertible Preferred Stock, and also upon any distributions of assets, including cash, stock or other property to our stockholders. Prior to the exercise of any Warrants, holders of the Warrants will not have any of the rights of holders of the Series A Convertible Preferred Stock purchasable upon exercise, including the right to vote or to receive any payments of dividends on the stock purchasable upon exercise. Although the Warrants may be exercised for shares of Series A Convertible Preferred Stock, the shares of common stock issuable upon conversion of such subsequently issued shares of Series A Convertible Preferred Stock are not being registered for resale hereunder. The Warrants are filed as Exhibits 4.10.A, 4.10.B, 4.10.C, 4.10.D, 4.10.E to the registration statement of which this prospectus forms a part. The foregoing description of the Warrants does not purport to be complete and is qualified in its entirety by reference to such exhibits.

PLAN OF DISTRIBUTION

The selling stockholders, which as used herein includes donees, pledgees, transferees or other successors-in-interest selling shares of common stock or interests in shares of common stock received after the date of this prospectus from a selling stockholder as a gift, pledge, partnership distribution or other transfer, may, from time to time, sell, transfer or otherwise dispose of any or all of their shares of common stock or interests in shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale or at negotiated prices.

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If any of the selling stockholders are deemed an underwriter within the meaning of Section 2(11) of the Securities Act in connection with the resale of common stock under this prospectus, any commissions received by such selling stockholders and any profit on the resale of the shares of common stock (including the shares of common stock issuable upon the conversion to common stock of the outstanding shares of Series A Convertible Preferred Stock and upon exercise of the Warrants, as applicable) sold by such security holders while acting as principals will be deemed to be underwriting discounts or commissions. Because it will have been deemed to be an underwriter within the meaning of Section 2(11) of the Security Act, such selling stockholders will be subject to prospectus delivery requirements under the Securities Act.

The selling stockholders may use any one or more of the following methods when disposing of shares or interests therein:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent, but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- short sales;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

The selling stockholders may, from time to time, pledge or grant a security interest in some or all of the shares of the common stock issuable to them upon the exercise or conversion of the Series A Convertible Preferred Stock and the Warrants, as applicable, owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock issuable upon the exercise or conversion of the Series A Convertible Preferred Stock and the Warrants, as applicable, from time to time, under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus. The selling stockholders also may transfer the share of common stock issuable upon the exercise or conversion of the Series A Convertible Preferred Stock and the Warrants, as applicable, in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

In connection with the sale of common stock or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the common stock in the course of hedging the positions they assume. The selling stockholders may also sell shares of common stock short and deliver these securities, once issued, to close out their

short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities that require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The aggregate proceeds to the selling stockholders from the sale of the common stock offered by them will be the purchase price of the common stock less discounts or commissions, if any. Each of the selling stockholders reserves the right to accept and, together with their agents from time to time, to reject, in whole or in part, any propose purchase of common stock to be made directly or through agents. We will not receive any of the proceeds from this offering. Upon any exercise of the Warrants by payment of cash, however, we will receive the exercise price of the warrants.

The selling stockholders also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act, provided that they meet the criteria and conform to the requirements of that rule.

To the extent required, the shares of common stock to be sold, the names of the selling stockholders, the respective purchase prices and public offering prices, the names of any agents, dealer or underwriter, any applicable commissions or discounts with respect to a particular offer will be set forth in an accompanying prospectus supplement or, if appropriate, a post-effective amendment to the registration statement that includes this prospectus.

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In order to comply with the securities laws of some states, if applicable, the common stock may be sold in these jurisdictions only through registered or licensed brokers or dealer. In addition, in some states the common stock may not be sold unless it has been registered or qualified for sale or an exemption from registration or qualification requirements is available and is complied with.

We have advised the selling stockholders that the anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of shares in the market and to the activities of the selling stockholders and their affiliates. In addition, we will make copies of this prospectus (as it may be supplemented or amended from time to time) available to the selling stockholders for purposes of satisfying the prospectus delivery requirements of the Securities Act. The selling stockholders may indemnify any broker-dealer that participated in transactions involving the sale of the shares against certain liabilities, including liabilities arising under the Securities Act.

We have agreed to indemnify the selling stockholders against liabilities, including liabilities under the Securities Act and state securities laws, relating to the registration of the shares offered by this prospectus.

We have agreed to use commercially reasonable efforts to maintain the effectiveness of this registration statement until the earlier of (i) the five-year anniversary of the date of the Registration Rights Agreement or (ii) until all shares of common stock that may become issuable to the selling stockholders upon the exercise or conversion, as applicable, of the Series A Convertible Preferred Stock and Warrants are sold pursuant to this registration statement.

Blue Sky Restrictions on Resale

If a selling stockholder wants to sell shares of common stock under this prospectus in the United States, the selling stockholder will also need to comply with state securities laws, also known as Blue Sky laws, with regard to secondary sales. As a result, holders may not resell their shares of common stock in the United States without satisfying the applicable state securities law or qualifying for an exemption therefrom, including the exemptions provided under the U.S. National Securities Markets Improvement Act of 1996. The broker for a selling stockholder will be able to advise a selling stockholder as to which states common stock is exempt from registration with that state for secondary sales.

Any person who purchases shares of common stock from a selling stockholder under this prospectus who then wants to sell such shares will also have to comply with Blue Sky laws regarding secondary sales. These restrictions and potential costs could be significant burdens to our stockholders seeking to effect resales of common stock with in the United States.

SELLING RESTRICTIONS

Notice to Prospective Investors in the Dubai International Financial Centre

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority (DFSA). This prospectus is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The shares to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

Notice to Prospective Investors in the European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive, each underwriter has represented and agreed that with effect from and including the date on which the Prospectus Directive is implemented in that Member State it has not made and will not make an offer of securities to the public in that Member State, except that it may, with effect from and including such date, make an offer of securities to the public in that Member State:

(a) at any time 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;

(b) at any time to any legal entity which has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than 43,000,000 and (3) an annual net turnover of more than 50,000,000, as shown in its last annual or consolidated accounts; or

(c) at any time in any other circumstances which do not require the publication by us of a prospectus pursuant to Article 3 of the Prospectus Directive.

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For the purposes of the above, the expression an offer of securities to the public in relation to any securities in any 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 same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State, and the expression Prospectus Directive means Directive 2003/71/EC and includes any relevant implementing measure in that Member State.

Notice to Prospective Investors in France

Neither this prospectus nor any other offering material relating to the shares described in this prospectus has been submitted to the clearance procedures of the *Autorité des Marchés Financiers* or of the competent authority of another member state of the European Economic Area and notified to the *Autorité des Marchés Financiers*. The shares have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in France. Neither this prospectus nor any other offering material relating to the shares has been or will be:

- released, issued, distributed or caused to be released, issued or distributed to the public in France; or
- used in connection with any offer for subscription or sale of the shares to the public in France.

Such offers, sales and distributions will be made in France only:

- to qualified investors (*investisseurs qualifiés*) and/or to a restricted circle of investors (*cercle restreint d investisseurs*), in each case investing for their own account, all as defined in, and in accordance with articles L.411-2, D.411-1, D.411-2, D.734-1, D.744-1, D.754-1 and D.764-1 of the French Code *monétaire et financier*;
- to investment services providers authorized to engage in portfolio management on behalf of third parties; or
- in a transaction that, in accordance with article L.411-2-II-1°-or-2°-or 3° of the French Code *monétaire et financier* and article 211-2 of the General Regulations (*Règlement Général*) of the *Autorité des Marchés Financiers*, does not constitute a public offer (*appel public à l épargn e*).

The shares may be resold directly or indirectly, only in compliance with articles L.411-1, L.411-2, L.412-1 and L.621-8 through L.621-8-3 of the French Code *monétaire et financier*.

Notice to Prospective Investors in Germany

The common stock which are the object of this prospectus are neither registered for public distribution with the Federal Financial Supervisory Authority (Bundesanstalt für Finanzdienstleistungsaufsicht or BaFin) according to the German Investment Act nor listed on a German exchange. No sales prospectus pursuant to the German Securities Prospectus Act or German Sales Prospectus Act or German Investment Act has been filed with the BaFin. Consequently, the common stock must not be distributed within the Federal Republic of Germany by way of a public offer, public advertisement or in any similar manner and this prospectus and any other document relating to the common stock, as well as information or statements contained therein, may not be supplied to the public in the Federal Republic of Germany or used in connection with any offer for subscription of the common stock to the public in the Federal Republic of Germany or any other means of public marketing.

Notice to Prospective Investors in Hong Kong

The shares may not be offered or sold by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong), or (ii) to professional investors within the meaning of the Securities and Futures Ordinance (Cap.571, Laws of Hong Kong) and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a prospectus within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong), and no advertisement, invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case

whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to professional investors within the meaning of the Securities and Futures Ordinance (Cap.571 Laws of Hong Kong) and any rules made thereunder.

Notice to Prospective Investors in Israel

In the State of Israel, the shares of common stock offered hereby may not be offered to any person or entity other than the following:

(a) a fund for joint investments in trust (i.e., mutual fund), as such term is defined in the Law for Joint Investments in Trust, 5754-1994, or a management company of such a fund;

(b) a provident fund as defined in Section 47(a)(2) of the Income Tax Ordinance of the State of Israel, or a management company of such a fund;

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(c) an insurer, as defined in the Law for Oversight of Insurance Transactions, 5741-1981, (d) a banking entity or satellite entity, as such terms are defined in the Banking Law (Licensing), 5741-1981, other than a joint services company, acting for their own account or for the account of investors of the type listed in Section 15A(b) of the Securities Law 1968;

(d) a company that is licensed as a portfolio manager, as such term is defined in Section 8(b) of the Law for the Regulation of Investment Advisors and Portfolio Managers, 5755-1995, acting on its own account or for the account of investors of the type listed in Section 15A(b) of the Securities Law 1968;

(e) a company that is licensed as an investment advisor, as such term is defined in Section 7(c) of the Law for the Regulation of Investment Advisors and Portfolio Managers, 5755-1995, acting on its own account;

(f) a company that is a member of the Tel Aviv Stock Exchange, acting on its own account or for the account of investors of the type listed in Section 15A(b) of the Securities Law 1968;

(g) an underwriter fulfilling the conditions of Section 56(c) of the Securities Law, 5728-1968;

(h) a venture capital fund (defined as an entity primarily involved in investments in companies which, at the time of investment, (i) are primarily engaged in research and development or manufacture of new technological products or processes and (ii) involve above-average risk);

(i) an entity primarily engaged in capital markets activities in which all of the equity owners meet one or more of the above criteria; and

(j) an entity, other than an entity formed for the purpose of purchasing shares of common stock in this offering, in which the shareholders equity (including pursuant to foreign accounting rules, international accounting regulations and U.S. generally accepted accounting rules, as defined in the Securities Law Regulations (Preparation of Annual Financial Statements), 1993) is in excess of NIS 250 million.

Any offeree of the shares of common stock offered hereby in the State of Israel shall be required to submit written confirmation that it falls within the scope of one of the above criteria. This prospectus will not be distributed or directed to investors in the State of Israel who do not fall within one of the above criteria.

Notice to Prospective Investors in Japan

The securities have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (the Financial Instruments and Exchange Law) and each underwriter has agreed that it will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Law and any other applicable laws, regulations and ministerial guidelines of Japan.

Notice to Prospective Investors in Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (SFA), (ii) to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 by a relevant person which is: (a) a corporation (which is not an accredited investor) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or (b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary is an accredited investor, shares, debentures and units of shares and debentures of that corporation or the beneficiaries rights and interest in that trust shall not be transferable for six months after that corporation or that trust has acquired the shares under Section 275 except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA; (2) where no consideration is given for the transfer; or (3) by operation of law.

Notice to Prospective Investors in Spain

The proposed offer of common stock has not been registered with the *Comision Nacional del Mercado de Valores* (the CNMV). Accordingly, no communication nor any document or offer material may be distributed in Spain or targeted at Spanish resident investors, save in compliance and in accordance with the requirements of Law 24/1988, 28 July, as amended.

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Notice to Prospective Investors in Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (SIX) or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, the company, or the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA (FINMA), and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes (CISA). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of the shares.

Notice to Prospective Investors in the United Kingdom

This prospectus and any other material in relation to the shares described herein is only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors within the meaning of Article 2(1)(e) of the Prospective Directive (qualified investors) that also (i) 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, as amended, or the Order, (ii) who fall within Article 49(2)(a) to (d) of the Order or (iii) to whom it may otherwise lawfully be communicated (all such persons together being referred to as relevant persons). The shares are only available to, and any invitation, offer or agreement to purchase or otherwise acquire such shares will be engaged in only with, relevant persons. This prospectus and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other person in the United Kingdom. Any person in the United Kingdom that is not a relevant person should not act or rely on this prospectus or any of its contents.

LEGAL MATTERS

The validity of the shares of common stock offered by this prospectus will be passed upon for us by Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP.

EXPERTS

The financial statements of Alimera Sciences, Inc. as of December 31, 2011, incorporated by reference in this prospectus, have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report incorporated by reference herein, which report expresses an unqualified opinion on the financial statements and includes an explanatory paragraph regarding the company s ability to continue as a going concern. Such financial statements have been so incorporated by reference herein in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

The consolidated balance sheet as of December 31, 2012, and the related consolidated statements of operations, stockholders equity, and cash flows for the year ended December 31, 2012, 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 in giving said report.

CHANGE IN INDEPENDENT ACCOUNTANTS

On August 23, 2012, the audit committee of our Board of Directors dismissed Deloitte & Touche LLP as our independent registered public accounting firm, effective as of August 23, 2012. Deloitte & Touche LLP s report on our financial statements for the fiscal years ended December 31, 2011 and 2010 contained an explanatory paragraph regarding our ability to continue as a going concern. Other than such statement, no report of Deloitte & Touche LLP on our financial statements for either of the fiscal years ended December 31, 2011 and 2010 contained an adverse opinion or disclaimer of opinion, or was qualified or modified as to uncertainty, audit scope or accounting principles. During the fiscal years ended December 31, 2011 and 2010 and through August 23, 2012, there were no disagreement(s) with Deloitte & Touche LLP on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreement(s), if not resolved to the satisfaction of Deloitte & Touche LLP, would have caused Deloitte & Touche LLP to make reference to the subject matter of the disagreement in connection with its reports on our consolidated financial statements.

On August 23, 2012, the audit committee of our Board of Directors approved the engagement of Grant Thornton LLP as our independent registered public accounting firm, subject to Grant Thornton LLP s acceptance of such engagement. On August 27, 2012, we formally engaged Grant Thornton LLP as our independent registered public accounting firm.

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DISCLOSURE OF COMMISSION POSITION ON

INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

The Delaware General Corporation Law and our certificate of incorporation and bylaws provide for indemnification of our directors and officers for liabilities and expenses that they may incur in such capacities. In general, directors and officers are indemnified with respect to actions taken in good faith in a manner reasonably believed to be in, or not opposed to, the best interests of our company, and with respect to any criminal action or proceeding, actions that the indemnitee had no reasonable cause to believe were unlawful.

We have also entered into identification agreements with our directors and executive officers. These identification agreements generally require us to pay, on behalf of each director and officer party thereto, all amounts that he or she is or becomes legally obligated to pay because of any claim or claims made against him or her because of any act or omission which he or she commits or suffers while acting in his or her capacity as our director and/or officer and because of his or her being a director and/or officer. Under the Delaware General Corporation Law, absent an identification agreement or a provision in a corporation s bylaws or certificate of incorporation, indemnification of a director or officer is discretionary rather than mandatory (except in the case of a proceeding in which a director or officer is successful on the merits).

We currently maintain a directors and officers liability insurance policy.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, may be permitted to such directors, officers or controlling persons pursuant to the foregoing provisions, or otherwise, we have been informed that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and special reports, proxy statements and other information with the Securities and Exchange Commission (the SEC). You can inspect and copy these reports, proxy statements and other information at the SEC s Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the Public Reference Room. The SEC also maintains a web site that contains reports, proxy and information statements and other information regarding issuers, such as Alimera Sciences, Inc. (www.sec.gov). Our web site is located at www.alimerasciences.com (which is not intended to be an active hyperlink in this prospectus). The information contained on our website is not part of this prospectus.

DOCUMENTS INCORPORATED BY REFERENCE

The SEC allows us to incorporate by reference information into this document. This means that we can disclose important information to you by referring you to another document filed separately with the SEC. The information incorporated by reference is considered to be a part of this document, except for any information superseded by information that is included directly in this document or incorporated by reference subsequent to the date of this document.

This prospectus incorporates by reference the documents listed below:

- Our Annual Report on Form 10-K for the year ended December 31, 2012, filed with the SEC on March 28, 2013, including the Form 10K/A filed with the SEC on March 29, 2013;
- Our Current Reports on Form 8-K filed with the SEC on March 21, 2013, April 29, 2013, May 1, 2013, May 7, 2013 and May 8, 2013 (other than any portions thereof deemed furnished and not filed); and
- The description of common stock contained on Form 8-A, filed with the SEC on April 19, 2010, including any amendments or reports filed for the purpose of updating the description.

In addition, all documents filed by us with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act (other than those furnished pursuant to Item 2.02 or Item 7.01 on Form 8-K) after the date of the initial registration statement and prior to the termination of the offering, will be considered to be incorporated by reference into this prospectus and to be a part of this prospectus from the dates of the filing of such

documents.

You may request a copy of these filings, at no cost, by writing or calling us at the following:

Alimera Sciences, Inc.

6120 Windward Parkway, Suite 290

Alpharetta, Georgia 30005

Attn: Secretary of the Company

Copies of the documents incorporated by reference may also be found on our website at www.alimerasciences.com (information, other than these documents, contained on our website is not a part of this prospectus).

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19,548,871 Shares of Common Stock

ALIMERA SCIENCES, INC.

You should rely only on the information contained in this prospectus. No dealer, salesperson or other person is authorized to give information that is not contained in this prospectus. This prospectus is not an offer to sell nor is it seeking an offer to buy these securities in any jurisdiction where the offer or sale is not permitted. The information contained in this prospectus is correct only as of the date of this prospectus, regardless of the time of the delivery of this prospectus or the sale of these securities.