ALIMERA SCIENCES INC
Form S-3
May 27, 2011

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As filed with the Securities and Exchange Commission on May 27, 2011
Registration No. 333-

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Form S-3
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933
Alimera Sciences, Inc.
(Exact name of Registrant as specified in its charter)

Delaware	**20-0028718**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification Number)*

6120 Windward Parkway,
Suite 290
Alpharetta, GA 30005
(678) 990-5740
(Address, including zip code, and telephone number, including area code, of Registrant s principal executive offices)

C. Daniel Myers
President and Chief Executive Officer
6120 Windward Parkway
Suite 290
Alpharetta, GA 30005
(678) 990-5740
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Gregg A. Griner, Esq.
Gunderson Dettmer Stough
Villeneuve Franklin & Hachigian, LLP
850 Winter Street
Waltham, MA 02451
Telephone: (781) 890-8800
Telecopy: (781) 622-1622

Approximate date of commencement of proposed sale to the public: From time to time after this Registration Statement becomes effective.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. o

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended (the Securities Act) other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. þ

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

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

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. o

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or classes of additional securities pursuant to Rule 413(b) under the Securities Act, check the following box. o

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

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

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered(1)(2)	Proposed Maximum Offering Price per Share(1)(2)	Proposed Maximum Aggregate Offering Price(1)(3)	Amount of Registration Fee
Preferred Stock, par value $0.01 per share				
Common Stock, par value $0.01 per share				
Debt Securities				
Warrants				
Total			$75,000,000	$8,707.50(4)

(1) Such indeterminate amount or number of debt securities, shares of preferred stock, shares of common stock, and warrants to purchase any combination of the foregoing securities, as may from time to time be issued at indeterminate prices, with an aggregate initial offering price not to exceed $75,000,000. If any debt securities are issued at an original issue discount, then the issue price, and not the principal amount of such debt securities shall be used for purposes of calculating the aggregate initial offering price of all securities issued. Securities registered hereunder may be sold separately, together or as units with other securities registered hereunder. The securities also include such indeterminate number of shares of preferred stock, shares of common stock or principal amounts of debt securities as may be issued upon conversion or exchange for debt securities that provide for conversion or exchange, upon exercise of warrants to purchase preferred stock, common stock or debt securities, upon conversion of shares of preferred stock or pursuant to the anti-dilution provisions of any such securities.

(2) With respect to the primary offering, such information is not required to be included pursuant to General Instruction II.D of Form S-3 under the Securities Act of 1933, as amended, or the Securities Act.

(3) The proposed maximum aggregate price has been estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act.

(4) Calculated pursuant to Rule 457(o) under the Securities Act.

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

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THE INFORMATION IN THIS PROSPECTUS IS NOT COMPLETE AND MAY BE CHANGED. THESE SECURITIES MAY NOT BE SOLD UNTIL THE REGISTRATION STATEMENT FILED WITH THE SECURITIES AND EXCHANGE COMMISSION IS EFFECTIVE. THIS PROSPECTUS IS NOT AN OFFER TO SELL THESE SECURITIES AND IS NOT AN OFFER TO BUY THESE SECURITIES IN ANY STATE WHERE THE OFFER OR SALE IS NOT PERMITTED.

SUBJECT TO COMPLETION, DATED MAY 27, 2011

PROSPECTUS

$75,000,000

Preferred Stock
Common Stock
Debt Securities
Warrants

From time to time, we may offer and sell shares of preferred stock, common stock, debt securities or warrants to purchase preferred stock, common stock or any combination of these securities, either separately or in units, in one or more offerings in amounts, at prices and on terms that we will determine at the time of the offering. The debt securities and warrants may be convertible into or exercisable or exchangeable for preferred stock, common stock or debt securities and the preferred stock may be convertible into or exchangeable for common stock. The aggregate initial offering price of all securities sold by us under this prospectus will not exceed $75,000,000.

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

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

Our common stock is listed on The NASDAQ Global Market under the symbol ALIM . The last reported sale price of our common stock on May 25, 2011 was $8.10 per share.

INVESTING IN OUR SECURITIES INVOLVES A HIGH DEGREE OF RISKS. SEE RISK FACTORS ON PAGE 6 OF THIS PROSPECTUS AND IN THE OTHER DOCUMENTS INCORPORATED BY REFERENCE IN THIS PROSPECTUS AND THE APPLICABLE PROSPECTUS SUPPLEMENT TO READ ABOUT FACTORS YOU SHOULD CONSIDER BEFORE BUYING OUR SECURITIES.

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

The date of this prospectus is May 27, 2011.

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

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

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or the SEC, using a shelf registration process. Using this process, we may, from time to time, sell any combination of the securities described in this prospectus in one or more offering transactions up to a total dollar amount of $75,000,000. This prospectus provides you with a general description of the securities we may offer. Each time we sell any securities under this prospectus, we will provide a prospectus supplement that will contain more specific information about the specific terms of that particular offering. Each such prospectus supplement may also add, update or change information contained in this prospectus or in documents we have incorporated by reference into this prospectus. To the extent that any statements that we make in a prospectus supplement are inconsistent with statements made in this prospectus, the statements made in this prospectus will be deemed modified or superseded by those made in the prospectus supplement. This prospectus, together with the applicable prospectus supplements and the documents incorporated by reference into this prospectus, includes all material information relating to the offering of the securities described in this prospectus. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sales of securities. To obtain additional information that may be important to you, you should read the exhibits filed by us with the registration statement of which this prospectus is a part or our other filings with the SEC. You should read this prospectus, any applicable prospectus supplement and the additional information described below under Where You Can Find More Information before making any investment decision with respect to the securities offered hereby.

WHERE YOU CAN FIND MORE INFORMATION

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

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

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

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to incorporate by reference into this prospectus the information we file with it, which means that we can disclose important information to you by referring you to those documents. The information we incorporate by reference is an important part of this prospectus, and later information that we file with the SEC will automatically update and supersede some of this information. We incorporate by

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reference the documents listed below and any future filings we make with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended (the Exchange Act) (other than Current Reports on Form 8-K containing only information furnished under Item 2.02 or Item 7.01 of Form 8-K, unless otherwise indicated therein), including filings made after the date of the initial registration statement, until we sell all of the shares covered by this prospectus or the sale of shares by us pursuant to this prospectus is terminated. The documents we incorporate by reference are:

our Annual Report on Form 10-K for the year ended December 31, 2010;

our Quarterly Report on Form 10-Q for the quarter ended March 31, 2011;

our Proxy Statement on Schedule 14A filed with the SEC on April 29, 2011;

our Current Reports on Form 8-K filed on April 18, 2011 and May 17, 2011 in each case only to the extent filed and not furnished; and

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

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

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

Corporate Secretary
Alimera Sciences, Inc.
6120 Windward Parkway, Suite 290
Alpharetta, GA 30005
(678) 990-5740

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

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, any applicable prospectus supplement and the documents incorporated by reference contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this prospectus, any applicable prospectus supplement and the documents incorporated by reference regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. These statements are subject to risks and uncertainties and are based on information currently available to our management. Words such as, but not limited to, anticipate, believe, estimate, expect, intend, may, plan, contemplates, predict, project, targets continue, will, would, should, could, or the negative of these terms and similar expressions or words, identify forward-looking statements. The events and circumstances reflected in the Company s forward-looking statements may not occur and actual results could differ materially from those projected in the Company s 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 the Company s product candidates;
- uncertainty as to the Company s ability to commercialize, and market acceptance of, the Company s product candidates;
- the extent of government regulations;
- uncertainty as to the relationship between the benefits of the Company s product candidates and the risks of their side-effect profiles;
- dependence on third-party manufacturers to manufacture the Company s product candidates in sufficient quantities and quality;
- uncertainty of clinical trial results;
- limited sales and marketing infrastructure;
- inability of our outside sales force to successfully sell and market ILUVIEN® in the U.S. following regulatory approval; and
- the Company s ability to operate its business in compliance with the covenants and restrictions that it is subject to under its 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 publicly revise any forward-looking statements, whether as a result of new information, future events or otherwise.

We encourage you to read the discussion and analysis of our financial condition and our consolidated financial statements contained in or incorporated by reference in this prospectus, and any prospectus supplement. We also encourage you to read the statements under Risk Factors, and other sections of this prospectus, which contains a more

complete discussion of the risks and uncertainties associated with our business. In addition to the risks described above and in the section entitled Risk Factors of this prospectus, other unknown or unpredictable factors also could affect our results. There can be no assurance that the actual results or developments anticipated by us will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, us. Therefore, no assurance can be given that the outcomes stated in such forward-looking statements and estimates will be achieved.

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THE COMPANY

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

Our most advanced product candidate is ILUVIEN®, which we are developing for the treatment of diabetic macular edema (DME). DME is a disease of the retina that affects individuals with diabetes and can lead to severe vision loss and blindness. In September 2010, we completed two Phase 3 pivotal clinical trials (collectively, our FAME™ Study) for ILUVIEN involving 956 patients in sites across the U.S., Canada, Europe and India to assess the efficacy and safety of ILUVIEN in the treatment of DME. Based on our analysis of the month 24 clinical readout from our FAME Study in December 2009, we filed a New Drug Application (NDA) in June 2010 for the low dose of ILUVIEN in the U.S. with the U.S. Food and Drug Administration (FDA), followed by registration filings in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain in July 2010. In December 2010, we received a Complete Response Letter (CRL) from the FDA regarding our NDA. The FDA issued the CRL to communicate its decision that the NDA for ILUVIEN could not be approved in its then current form. No new clinical studies were requested by the FDA in the CRL. However, the FDA asked us for analyses of the safety and efficacy data through the end of the FAME Study to further assess the relative benefits and risks of ILUVIEN and the FDA sought additional information regarding controls and specifications concerning the manufacturing, packaging and sterilization of ILUVIEN. We resubmitted our NDA to the FDA on May 12, 2011 to address the questions raised in the CRL and provide the FDA with additional analyses and data. Our resubmission to the FDA is considered a Class 2 resubmission, which will provide for a review period of up to an additional six months for our NDA. Based on our discussions with the FDA, we anticipate that the FDA will call an advisory committee during this review. If our NDA for ILUVIEN is approved by the FDA, we plan to commercialize ILUVIEN in the U.S. by marketing and selling it to retinal specialists as early as late 2011.

Additionally, we plan to submit the additional safety and efficacy data through the final readout at the end of the FAME Study to regulatory authorities in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain in the second quarter of 2011. If ILUVIEN is approved by the European regulatory authorities, we plan to commercialize ILUVIEN, directly or through a partnership, in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain.

According to the Centers for Disease Control and Prevention (CDC), the number of Americans diagnosed with diabetes had increased from approximately 8.1 million people in 1994 to approximately 18.8 million people in 2010. Per the International Diabetes Federation Atlas, the estimated prevalence of people diagnosed with diabetes for 2010 has increased to 285 million people worldwide and that this number is expected to reach 438 million people by 2030. All patients with diabetes are at risk of developing some form of diabetic retinopathy, an ophthalmic condition of diabetes that presents with symptoms that include the swelling and leakage of blood vessels within the retina or the abnormal growth of new blood vessels on the surface of the retina. As reported by the American Diabetes Association, in the U.S. diabetic retinopathy causes approximately 12,000 to 24,000 new cases of blindness each year, making diabetes the leading cause of new cases of blindness in adults aged 20 to 74. When the blood vessel leakage of diabetic retinopathy causes swelling in the macula, the part of the eye responsible for central vision, the condition is called DME. The Wisconsin Epidemiologic Study of Diabetic Retinopathy found that over a ten-year period approximately 19% of diabetics studied were diagnosed with DME. Based on this study and the current U.S. diabetic population, we estimate the incidence of DME in the U.S. to be approximately 340,000 cases annually. As the population of diabetics increases, we expect the annual incidence of diagnosed DME to increase.

There are no ophthalmic drug therapies currently approved by the FDA for the treatment of DME. The current standard of care for the treatment of DME is laser photocoagulation. Laser photocoagulation is a retinal procedure in which a laser is used to cauterize leaky blood vessels or to apply a pattern of burns to reduce edema. This procedure has undesirable side effects including partial loss of peripheral and night vision. As a result of these side effects and a desire for improved visual outcomes, retinal specialists have

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supplemented laser photocoagulation with alternate off-label therapies for the treatment of DME, including injections of corticosteroids and anti-vascular endothelial growth factor (anti-VEGF) agents. Both corticosteroids and anti-VEGFs have shown improved visual acuity in DME patients in non-pivotal clinical trials but are limited by a need for multiple injections to maintain a therapeutic effect. Corticosteroids have historically been associated with significant increases in intraocular pressure (IOP), which may increase the risk of glaucoma, and the acceleration of cataract formation.

ILUVIEN is inserted in the back of the patient s eye to a placement site that takes advantage of the eye s natural fluid dynamics to deliver the non-proprietary corticosteroid fluocinolone acetonide (FAc). ILUVIEN is inserted with a device that employs a 25-gauge needle which allows for a self-sealing wound. In the U.S., this procedure is non-surgical and is performed in the retinal specialist s office. ILUVIEN is an intravitreal insert designed to provide a therapeutic effect for up to 36 months by delivering sustained sub-microgram levels of FAc. ILUVIEN has demonstrated efficacy in the treatment of DME in our FAME Study. Additionally, by providing lower exposure to corticosteroids and focusing the delivery to the back of the eye, we believe that the adverse events associated with the use of ILUVIEN are within the acceptable limits of a drug for the treatment of DME.

ILUVIEN is also being studied in three Phase 2 clinical trials for the treatment of the dry form of age-related macular degeneration (AMD), the wet form of AMD and retinal vein occlusion (RVO). In addition to our activities related to the development and commercialization of ILUVIEN, we are also conducting testing on two classes of nicotinamide adenine dinucleotide phosphate (NADPH) oxidase inhibitors for which we have acquired exclusive, worldwide licenses from Emory University. Our initial focus is on the use of NADPH oxidase inhibitors in the treatment of dry AMD. We plan to evaluate the use of NADPH oxidase inhibitors in the treatment of other diseases of the eye, including wet AMD and diabetic retinopathy. We will pursue the development, license and acquisition of rights to compounds and technologies with the potential to treat diseases of the eye that we believe are not well treated by current therapies.

Our commercialization strategy is to establish ILUVIEN as a leading therapy for the treatment of DME and subsequently for any other indications for which ILUVIEN proves safe and effective. We are led by an executive team with extensive development and commercialization expertise with ophthalmic products including the launch and management of Visudyne, a drug product sponsored by Novartis and the first pharmacological treatment indicated for patients with wet AMD. We intend to capitalize on our management s experience and expertise in marketing eye-care products, by marketing and selling ILUVIEN to the approximately 1,600 retinal specialists practicing in the approximately 900 retina centers across the U.S. and Canada. If ILUVIEN is approved by the European regulatory authorities, we plan to commercialize ILUVIEN, directly or through a partnership, in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain. Our commercialization strategy is subject to and dependent upon regulatory approval of ILUVIEN for the treatment of DME.

OUR CORPORATE INFORMATION

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

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

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RISK FACTORS

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

Risks Related to Our Business and Industry

We are heavily dependent on the success of our lead product candidate, ILUVIEN, which is still under development. If we are unable to commercialize ILUVIEN, or experience significant delays in doing so, our business will be materially harmed.

We are a biopharmaceutical company with no products approved for commercial sale. We have incurred, and will continue to incur, significant costs relating to the regulatory approval and commercialization of ILUVIEN, our only product candidate in development. We anticipate that in the near term our ability to generate revenues will depend solely on the successful development and commercialization of ILUVIEN. We have not yet obtained regulatory approval to market this product candidate in any jurisdiction and we may never be able to obtain approval or, if approvals are obtained, to commercialize this product candidate successfully.

Based on our analysis of the month 24 clinical readout from our Phase 3 pivotal clinical trials for the use of ILUVIEN in the treatment of diabetic macular edema, or DME (collectively, our FAME Study), in June 2010 we filed a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for the low dose of ILUVIEN in the U.S., followed by registration filings in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain in July 2010. The European Marketing Authorization Application (MAA) was submitted through the Decentralized Procedure with the United Kingdom Medicines and Health products Regulatory Agency (MHRA) as the Reference Member State. In December 2010, we received a Complete Response Letter (CRL) from the FDA regarding our NDA. The FDA issued the CRL to communicate its decision that the NDA could not be approved in its then current form. No new clinical studies were requested by the FDA in the CRL. However, the FDA asked us for analyses of the safety and efficacy data through the end of the FAME Study to further assess the relative benefits and risks of ILUVIEN and the FDA sought additional information regarding controls and specifications concerning the manufacturing, packaging and sterilization of ILUVIEN. We resubmitted our NDA to the FDA on May 12, 2011 to address the questions raised in the CRL and provide the FDA with additional analyses and data. Our resubmission to the FDA is considered a Class 2 resubmission, which provides for a review period of up to an additional six months for our NDA. However, the FDA may request additional information from us, and, ultimately, may not grant marketing approval for ILUVIEN. In addition, although we believe the final clinical readout from our FAME Study demonstrates that ILUVIEN is safe and effective in the treatment of DME, clinical data often is susceptible to varying interpretations and many companies that have believed that their products performed satisfactorily in clinical trials have nonetheless failed to obtain FDA approval for their products. Furthermore, even if we receive FDA approval, we might not be

successful in commercializing ILUVIEN. If we are not successful in commercializing ILUVIEN, or are significantly delayed in doing so, our business will be

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materially harmed and we may need to curtail or cease operations. Our ability to successfully commercialize ILUVIEN will depend, among other things, on our ability to:

- produce batches of ILUVIEN in quantities sufficiently large to permit successful commercialization;
- receive marketing approvals from the FDA and similar foreign regulatory authorities;
- establish commercial manufacturing arrangements with third-party manufacturers;
- launch commercial sales of ILUVIEN; and
- secure acceptance of ILUVIEN in the medical community and with third-party payers.

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 have a limited operating history. We are not currently generating revenues and we cannot estimate with precision the extent of our future losses. We do not currently have any products that have been approved for commercial sale and 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, particularly as we increase our research, clinical development, administrative and sales and marketing activities. Assuming FDA approval of our NDA in 2011, we currently do not expect to generate revenue from the sale of ILUVIEN until late 2011 at the earliest, if at all. As a result, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it. As of March 31, 2011, we have accumulated a net deficit of $193.5 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 marketed. 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.

We face heavy government regulation, and 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 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 and the regulations applicable to that particular drug candidate. Regulatory agencies, including those in the U.S., Canada, the European Union 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 process;

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 risk/benefit relationship. Further, we intend to market ILUVIEN, and may market other product candidates, outside the U.S. and specifically in the European Union 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 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 submitted an NDA in the U.S. for the low dose of ILUVIEN in June 2010 with 24 months of clinical data from our FAME Study, followed in July 2010 by registration filings in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain. Consistent with recommendations regarding the appropriate population for primary analysis as described in the FDA-adopted International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Guidance E9, Statistical Principles for Clinical Trials, we believe that the FDA considers the most relevant population for determining safety and efficacy to be the full data set of all 956 patients randomized into our FAME Study, with data imputation employed using last observation carried forward, for data missing because of patients who discontinued the trial or are unavailable for follow-up (the Full Analysis Set). The primary efficacy endpoint was met with statistical significance for both the low dose and the high dose of ILUVIEN in both trials using the Full Analysis Set and we submitted an analysis based on this data set for the low dose to the FDA. However, our FAME Study protocol did not include the Full Analysis Set and provides that the primary assessment of efficacy will be based on another data set that excludes from the Full Analysis Set three patients who were enrolled but never treated as well as data collected for patients subsequent to their use of treatments prohibited by our FAME Study protocol (the Modified ART Data Set). Statistical significance was not achieved for either the low dose or the high dose in one trial using the Modified ART Data Set. In December 2010, we received a CRL from the FDA. The FDA issued the CRL to communicate its decision that the NDA for ILUVIEN could not be approved in its present form. No new clinical studies were requested by the FDA, and our use of the Full Analysis Set was not questioned in the CRL. However, the FDA asked us for analyses of the safety and efficacy data through the end of the FAME Study to further assess the relative benefits and risks of ILUVIEN. We resubmitted our NDA to the FDA on May 12, 2011 to address the questions raised in the CRL and provide the FDA with additional analyses and data. Our resubmission to the FDA is considered a Class 2 submission, which provides for a review period of up to an additional six months for our NDA. There is no assurance that the FDA will utilize the Full Analysis Set and not the Modified ART Data Set or another data set in determining whether ILUVIEN is safe and effective, any of which could result in the FDA not granting marketing approval for ILUVIEN.

In July 2010, we submitted in Europe a MAA using the Decentralized Procedure with the U.K. MHRA as the Reference Member State (RMS). Applications were submitted concurrently to the Concerned Member States (CMS) listed as follows: Germany, Spain, Italy, France, Portugal and Austria.

We received the initial assessment reports from the RMS and the CMS in December 2010. The issues raised were similar to the issues raised by the FDA. We plan to submit the additional safety and efficacy data through the final readout at the end of the FAME Study to regulatory authorities in the United Kingdom, Austria, France, Germany, Italy, Portugal and Spain in the second quarter of 2011.

Regulatory agencies require carcinogenicity studies in animals to identify tumorigenic potential in animals to assess the relevant risk in humans. Based on month 18 readouts from our open-label Phase 2 human pharmacokinetic clinical trial (PK Study), which indicate that there is negligible systemic absorption of fluocinolone acetonide (FAc) in patients being treated with ILUVIEN, we submitted a carcinogenicity waiver in our submissions to the FDA and European health authorities. Although the FDA did not specifically state in

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the CRL that the waiver has been granted, the CRL did not include any requirement to conduct a carcinogenicity study. In the Preliminary Assessment Report issued by the UK MHRA, the MHRA stated that the lack of single-dose, carcinogenicity and reproductive and developmental toxicity studies with ILUVIEN is acceptable. If we are required to perform carcinogenicity studies in animals, the approval of ILUVIEN could be delayed by up to 36 months.

In the CRL the FDA notified us that the methods used in and the facilities and controls used for, the manufacturing, processing, packing, or holding of the drug product at two of our manufacturers did not comply with cGMPs during recent inspections. One of the manufacturers received confirmation from the FDA in March 2011 that their facility is acceptable and the second manufacturer is in discussions with the FDA to resolve its deficiencies. Failure for our manufactures to comply with cGMP may have an adverse effect on our business.

Any delay or failure by us to obtain regulatory approvals for our product candidates could diminish competitive advantages that we may attain and would adversely affect the marketing of our products. We have not yet received regulatory approval to market any of our product candidates in any jurisdiction.

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 received the final month 36 clinical readout from our FAME Study, but the extent of ILUVIEN s long-term side effect profile beyond month 36 is not yet known. Upon review of our NDA for the low dose of ILUVIEN in the treatment of DME, the FDA may conclude that our FAME Study did not demonstrate that ILUVIEN has sufficient levels of efficacy to outweigh the risks associated with its side-effect profile. Conversely, the FDA may conclude that ILUVIEN s side-effect profile does not demonstrate an acceptable risk/benefit relationship in line with ILUVIEN s demonstrated efficacy. In the event of such conclusions, we may not receive regulatory approval from the FDA or from similar regulatory agencies in other countries.

Even if we do receive regulatory approval 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 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 the use to patients exhibiting IOP below a certain level or having an artificial lens at the time of treatment. Product approvals, once granted, may be withdrawn if problems occur after initial marketing. If and when ILUVIEN does receive regulatory approval or clearance, the marketing, distribution and manufacture of ILUVIEN will be subject to regulation in the U.S. by the FDA and by similar entities in other countries. 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

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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;

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 s) 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 were not in breach of our license agreement with pSivida as of May 27, 2011.

We will rely on a single manufacturer for ILUVIEN, a single manufacturer for the ILUVIEN inserter and a single active pharmaceutical ingredient formulator for ILUVIEN s active pharmaceutical ingredient. Our business would be seriously harmed if 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 inserter (Flextronics International, Ltd. or an affiliate of Flextronics International, Ltd. (Flextronics)) and a single third-party manufacturer for the manufacture of ILUVIEN s active pharmaceutical ingredient (FARMABIOS SpA./Byron Chemical Company Inc. (FARMABIOS)). Although we have finalized a long-term agreement for the manufacture of the ILUVIEN insert (with Alliance), we have not yet finalized long-term agreements for the manufacture of the ILUVIEN inserter (with Flextronics) or for the manufacture of ILUVIEN s active pharmaceutical ingredient (with FARMABIOS), and if any of the third-party manufacturers are unable or unwilling to perform for any reason, we may not be able to locate alternative acceptable manufacturers or formulators, enter into favorable agreements with them or get them approved

by the FDA 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 inserter 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.

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

We will rely on our manufacturers to purchase materials from third-party suppliers necessary to produce ILUVIEN and our other product candidates for our clinical trials and, if approved, for commercial distribution. 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. Moreover, we currently have not finalized all agreements for the commercial production of these materials. If our manufacturers are unable to obtain these materials for our clinical trials, product testing and potential regulatory approval of ILUVIEN and our other product candidates could be delayed, significantly affecting our ability to develop ILUVIEN and our other product candidates. If we or our manufacturers are unable to purchase these materials after regulatory approval has been obtained for ILUVIEN and our other product candidates, the commercial launch of ILUVIEN and our other product candidates 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 and our other product candidates. Moreover, although we have finalized an agreement for the commercial production of the ILUVIEN insert, we currently have not yet finalized any agreements for the commercial production of the active pharmaceutical ingredient in ILUVIEN or the ILUVIEN inserter. Even if we were able to secure such agreements, the suppliers may be unable or choose not to provide us the ingredients in a timely manner or in the minimum guaranteed quantities. If we are unable to obtain and then supply these ingredients to our contract manufacturer for our clinical trials, potential regulatory approval of our product candidates would be delayed, significantly impacting our ability to develop our product candidates, which would materially affect our ability to generate revenue from the sale of our product candidates.

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

The manufacture and packaging of pharmaceutical products such as ILUVIEN and our future product candidates are regulated by the FDA and similar foreign regulatory entities and must be conducted in accordance with the FDA s cGMP and comparable requirements of foreign regulatory entities. 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 products, 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. In December 2010, we received a CRL from the FDA. The FDA issued the CRL to communicate its decision that the NDA for ILUVIEN could not be approved in its then current form. Additionally, the FDA also indicated that it had observed deficiencies in current good manufacturing practices (cGMP) during its facility inspections of two of our third-party manufacturers, which were completed in August and September of 2010, and that all facilities and controls would need to comply with cGMP. The two third-party manufacturers have received confirmation from the FDA that their facilities are acceptable. If the FDA were to identify additional deficiencies at any of our third-party manufacturers, the FDA may not grant market approval for ILUVIEN. Additionally, 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. This review may be costly and time consuming and could delay or prevent

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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 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 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 products, including ILUVIEN, 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 ILUVIEN 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 pilot scale batches, some of the steps in the manufacturing processes will need to be revalidated when we begin to manufacture commercial scale batches. If the required testing or process validation is delayed or produces unfavorable results, we may have to launch the product using smaller pilot scale batches, which may impact our ability to fulfill demand for the product.

The FDA and similar foreign regulatory bodies 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.

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 that product candidate. 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;

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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, or CROs, 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 that product candidate, we may not be able to obtain marketing approval or we may obtain approval for indications that is 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.

We may not be successful in executing our sales and marketing strategy for the commercialization of ILUVIEN. We currently have a limited sales and marketing organization and, as part of our sales strategy, we expect to initially depend in large part on a third party contract sales force for the sale of ILUVIEN. If we are unable to successfully execute such strategy, we may not be able to generate significant revenue.

At present, we have no internal sales force and only a limited number of sales and marketing personnel. We began hiring additional sales and marketing personnel in the third quarter of 2010 to establish our own sales and marketing capabilities in the U.S. in time for our previously anticipated commercial launch of ILUVIEN. We have hired three field directors but have determined not to add the personnel and incur the costs of hiring and training an internal sales force at this time. In the fourth quarter of 2010, we entered into a relationship with OnCall LLC, a contract sales force company that will utilize its employees to act as our sales representatives if we receive approval of the ILUVIEN NDA from the FDA.

Pursuant to our agreement with OnCall, following FDA approval, ILUVIEN will be promoted primarily to retinal specialists in the U.S. by OnCall s sales representatives. We will rely in large part on this outside sales force for the sales of ILUVIEN in the U.S. Although we expect to be involved in the hiring, training and management of these sales representatives, they will be employees of OnCall and subject to its ultimate control.

If we determine to establish a direct sales force in the future to sell ILUVIEN or another product candidate following marketing approval, we may not be able to establish such a direct sales force in a cost-effective manner or realize a positive return on this investment. In addition, we will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, and retain sales and marketing personnel. Factors that may inhibit our efforts to commercialize our products without strategic partners or licensees include:

our inability to recruit and retain adequate numbers of effective sales and marketing personnel;

the inability of sales personnel to obtain access to or persuade adequate numbers of retinal specialists 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; and

unforeseen costs and expenses associated with creating an independent sales and marketing organization.

We have not yet entered into any agreements related to the marketing of ILUVIEN or any of our other product candidates in international markets and we may not be able to enter into any arrangements with respect to international collaborations on favorable terms or at all. In addition, these arrangements could result in lower levels of income to us than if we marketed our product candidates entirely on our own. If we are unable to enter into appropriate marketing arrangements for our product candidates in international markets,

we may not be able to develop an effective international sales force to successfully commercialize ILUVIEN and our other product candidates in international markets. If we fail to enter into marketing arrangements for our products or are unable to develop an effective international sales force, our ability to generate revenue outside of North America would be limited.

If we are unable to successfully implement our commercialization plans and drive adoption by patients and retinal specialists of ILUVIEN through our sales, marketing and commercialization efforts and the efforts of OnCall, then we will not be able to generate significant revenue, which will have a material adverse effect on our business, results of operations, financial condition and prospects.

In order to commercialize ILUVIEN, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of May 27, 2011, we had 27 employees. As our development and commercialization plans and strategies develop, we will need to expand the size of our employee base for managerial, operational, sales, marketing, financial and other resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. 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 future growth. 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 private insurers, the Medicare program and other third-party payers which could be affected by the recently enacted U.S. healthcare reform. The market for our products may also be limited by the indications for which their use may be reimbursed or the frequency at which they may be administered.

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

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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 private insurers, including managed care organizations, 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.

In some foreign countries, particularly Canada and the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In Canada, each province has a publicly funded drug plan with each having its own formulary citing specific criteria for reimbursement and prior authorization. Each provincial government except Québec considers the clinical and cost-effectiveness recommendations of the Common Drug Review performed by the Canadian Agency for Drugs and Technologies in Health. Québec has a separate drug review process that is performed by its Medication Council. In the European Union, each country has a different reviewing body that evaluates reimbursement dossiers submitted by manufacturers 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 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 products, including ILUVIEN, to other available therapies. 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 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.

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, reimbursement acceptance by private insurers and Medicare, acceptance of pricing, the development of our sales and marketing organization, an adequate payment to physicians for the insertion procedure (based on a cost assigned by the American Medical Association to the procedure, also known as a CPT code) 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 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 FA, 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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There are no ophthalmic drug therapies approved by the FDA for the treatment of DME. Lucentis, a drug sponsored by Genentech, Inc., a wholly-owned member of the Roche Group is approved for the treatment of visual impairment due to DME in the European Union and in later stage trials in the U.S. 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 the VEGF Trap, 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 if we receive marketing approval for ILUVIEN, even if ILUVIEN is otherwise viewed as a preferable therapy.

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.

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. We currently do not have any collaboration agreements with third-parties. Areas in which we anticipate entering into third-party collaboration arrangements include joint sales and marketing arrangements for sales and marketing of ILUVIEN 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 future arrangements might adversely affect our ability to develop, commercialize and market our products.

The success of our future 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

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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.

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. A number of 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.

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.

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We face the risk of product liability claims and may not be able to obtain 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 have primary product liability insurance that covers our clinical trials for a $5.0 million general aggregate limit and excess product liability insurance that covers our clinical trials for an additional $5.0 million general aggregate limit. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for any of the products that we may develop. 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.

In addition, our business is exposed to the risk of product liability claims related to our sale and distribution of our over-the-counter dry eye product prior to its acquisition by Bausch & Lomb Incorporated in July 2007. Our primary product liability insurance and excess product liability insurance policies cover product liability claims related to the product. To the extent this insurance is insufficient to cover any product related claims we may be exposed to significant liabilities, which may materially and adversely affect our business and financial condition.

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, Susan Caballa, our Senior Vice President of Regulatory Affairs, Kenneth Green, Ph.D., our Senior Vice President and Chief Scientific Officer, Richard Eiswirth, our Chief Operating Officer and Chief Financial 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

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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 is approved.

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

- restrictions on such products or manufacturing processes;
- withdrawal of the products from the market;
- voluntary or mandatory recall;
- fines;
- suspension of regulatory approvals;
- product seizure; and
- injunctions or the imposition of civil or criminal penalties.

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

Failure to obtain regulatory approval in foreign jurisdictions would prevent us from marketing our products abroad.

We intend to market our products internationally. 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. In July 2010, we submitted a MAA for ILUVIEN to the U.K. MHRA and to regulatory authorities in Austria, France, Germany, Italy, Portugal and Spain. 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. 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 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 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

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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 any of our product candidates receives marketing approval and 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.

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 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.

We may not have rights under some patents or patent applications that may be infringed by our products or potential products. 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

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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 with claims covering devices for injecting an ocular implant into a patient s eye similar to the ILUVIEN inserter. There is also an issued U.S. patent with claims covering implanting a steroidal anti-inflammatory agent to treat an inflammation-mediated condition of the eye. If these or any other patents were held by a court of competent jurisdiction to be valid and to cover aspects of ILUVIEN, then the owners of such patents would be able to block our ability to commercialize ILUVIEN unless and until we obtain a license under such patents (which license might require us to pay royalties or grant a cross-license to one or more patents that we own), until such patents expire or unless we are able to redesign our product to avoid any such valid patents.

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

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

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

Our licenses are important to our business, and we expect to enter into additional licenses in the future. We hold a license from pSivida under 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. under 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.

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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 March 31, 2011, we owned one pending non-provisional U.S. utility patent application, one issued U.S. design patent and one patent Cooperation Treaty Application, relating to our inserter system for ILUVIEN. 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 March 31, 2011, the patent rights relating to ILUVIEN licensed to us from pSivida include three U.S. patents that expire between March 2019 and April 2020 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 or any of our licensed U.S. pending patent applications. After these patents expire in April 2020, we will not be able to block others from marketing FAc in an insert similar to ILUVIEN in the U.S. 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

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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.

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 primary product liability insurance and excess product liability insurance that cover our clinical trials, 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. In addition, 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 new legislation changes the current system of healthcare insurance and benefits intended to broaden coverage and control costs. The new 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 aggregated industry-wide fee is expected to total $28 billion through 2019, of which $2.5 billion will be

payable in 2011. 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.

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The new 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. The new 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.

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 European Union and Canada, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take six to 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 involve the controlled use of potentially hazardous substances, including chemical and biological materials. In addition, our operations 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.

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

At March 31, 2011, we had U.S. federal and state net operating loss (NOL) carry-forwards of approximately $102.3 million and $85.5 million, respectively, which expire at various dates beginning in 2020 through 2030. 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. We have not yet completed a formal evaluation of the impact of our initial public offering in April 2010 (IPO) on our NOL carry-forwards and whether certain changes in ownership have occurred that would limit our ability to utilize a portion of our NOL carry-forwards. If it is determined that significant ownership changes have occurred since we generated these NOL carry-forwards, we may be subject to annual limitations on the use of these NOL carry-forwards under Internal Revenue Code Section 382 (or comparable provisions of state law).

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, as well as rules subsequently implemented by the SEC and Nasdaq, have imposed various new requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Our management and other personnel are required to devote a substantial amount of time to these new compliance initiatives. Moreover, these rules and regulations have substantially increased our legal and financial compliance costs and have made some activities more time consuming and costly. These rules and regulations may make it more difficult and more expensive for us to maintain our existing director and officer liability insurance or to obtain similar coverage from an alternative provider.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, pursuant to Section 404 of the Sarbanes-Oxley Act (Section 404), we may be required to perform system and process evaluation and testing of our internal controls over financial reporting to allow management and our independent registered public accounting firm to report, commencing in our annual report on Form 10-K for the year ending December 31, 2011, on the effectiveness of our internal controls over financial reporting. Our testing, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. Our compliance with Section 404 would require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will 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;

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;

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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.

We may need additional financing in the event that we do not receive regulatory approval for ILUVIEN or the approval is delayed or, if approved, the future sales of ILUVIEN do not generate sufficient revenues to fund our operations. This financing may be difficult to obtain and may restrict our operations.

Prior to our IPO, we funded our operations through the private placement of common stock, preferred stock and convertible debt, as well as by the sale of certain assets of the non-prescription business in which we were previously engaged. In October 2010, we obtained a $32.5 million senior secured credit facility (Credit Facility), consisting of a $12.5 million term loan and a $20.0 million working capital line of credit, to help fund our working capital requirements. Pursuant to the original terms of the term loan, the Company was entitled to borrow up to $12.5 million, of which $6.25 million was advanced to the Company on October 14, 2010. The Company was entitled to receive a second advance of $6.25 million under the term loan if the FDA approved the Company s NDA for ILUVIEN prior to or on July 31, 2011. The Credit Facility was amended in May 2011 to, among other things, increase the amount of the second advance under the term loan to $11.0 million and extend the date by which the FDA must approve the NDA in order for the Company to receive the second advance to December 31, 2011. In addition, the maturity date of each of the term loan and the working capital line of credit has been extended from October 31, 2013 to April 30, 2014. As of March 31, 2011, we had approximately $49.5 million in cash and cash equivalents and $0.5 million in investments which, together with the Credit Facility, we believe is sufficient to fund our operations through the projected commercialization of ILUVIEN and the expected generation of revenue in late 2011. The commercialization of ILUVIEN, as well as the availability of the second advance under the term loan, are dependent upon approval by the FDA, however, and we cannot be sure that ILUVIEN will be approved by the FDA in 2011, if at all, or that, if approved, future sales of ILUVIEN will generate enough revenue to fund our operations beyond its commercialization. Due to the uncertainty around FDA approval, we also cannot be sure that we will not need additional funds for the commercialization of ILUVIEN.

In the event additional financing is needed or advisable, we may seek to fund our operations through the sale of equity securities, strategic collaboration agreements and additional debt financing. 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 issuing equity securities, substantial dilution to existing stockholders would likely result and the terms of any new equity securities may have a preference over our common stock. If we attempt to raise additional funds through strategic collaboration agreements and additional debt financing, 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 Credit 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, other than our intellectual property (provided that if we fail to meet certain financial conditions, a curable lien will be imposed on our intellectual property as well), to the

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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.

Risks Related to the Offering and Ownership of Our Common Stock

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

We completed our IPO of shares of our common stock in April 2010 at a price of $11.00 per share. Subsequently, our common stock has traded as low as $6.30 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:

- the timing and final outcome of FDA review of our NDA for ILUVIEN;
- results from our clinical trial programs;
- FDA or international regulatory actions, including failure to receive regulatory approval for any of our product candidates;
- failure of any of our product candidates, if approved, to achieve commercial success;
- 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 or management;
- general economic conditions and slow or negative growth of our markets; and
- political instability, natural disasters, war and/or events of terrorism.

From time to time, we estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development goals or milestones. These milestones may include the commencement or completion of scientific studies and clinical trials and the submission of regulatory filings. 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.

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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 instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management s attention and resources.

Certain of our existing 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 April 13, 2011, our executive officers and directors and their affiliates beneficially owned, in the aggregate, approximately 65.8% of our outstanding common 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.

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. Accordingly, realization of a gain on your investment will depend on the appreciation of the price of our common stock, which may never occur.

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

A small number of institutional investors and private equity funds hold a significant number of shares of our common stock. 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 early investors in our company have rights, subject to certain conditions, to require us to file registration statements to permit the resale of their shares in the public market or to include their shares in registration statements that we may file for ourselves or other stockholders.

In addition to our outstanding common stock, as of March 31, 2011, there were a total of 2,664,455 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 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, 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.

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.

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, 2011, an additional 1,250,238 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 increases 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, 2011, an additional 8,246 shares became available for future issuance under our 2010 Employee Stock Purchase Plan.

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

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

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;

Limit who may call special meetings of stockholders;

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

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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.

DESCRIPTION OF SECURITIES

PREFERRED STOCK

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

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

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

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

the title and stated value;

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

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

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

the procedures for any auction and remarketing, if any;

the provisions for a sinking fund, if any;

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

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

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

voting rights, if any, of the preferred stock;

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

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

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

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

COMMON STOCK

We currently have authorized 100,000,000 shares of common stock, par value $0.01 per share. As of April 13, 2011, there were 31,333,483 shares of common stock outstanding held of record by 65 stockholders. Holders of our common stock have no preemptive rights and no right to convert their common stock into any other securities. There are no redemption or sinking fund provisions applicable to the common stock. All outstanding shares of our common stock are fully paid and nonassessable.

The following summary of the terms of our common stock is subject to and qualified in its entirety by reference to our restated certificate of incorporation and 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.

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

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

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

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

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

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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 our common stock and deprive stockholders of opportunities to realize a premium on shares of common stock held by them.

In addition to our board of directors ability to issue shares of preferred stock, our restated certificate of incorporation and 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;

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

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

require that directors only be removed from office for cause;

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

limit who may call special meetings of stockholders;

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

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

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

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

DEBT SECURITIES

We may issue, from time to time, debt securities in one or more series that will consist of either senior debt or subordinated debt under one or more trust indentures to be executed by us and a specified trustee. The terms of the debt securities will include those stated in the indenture and those made a part of the indenture

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(before any supplements) by reference to the Trust Indenture Act of 1939. The indentures will be qualified under the Trust Indenture Act. Debt securities, whether senior or subordinated, may be issued as convertible debt securities or exchangeable debt securities.

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

General

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

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

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

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

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

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

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

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

the date or dates, or the method for determining such date or dates, from which any interest will accrue, the interest payment dates on which any such interest will be payable, the regular record dates for such interest payment dates, or the method by which any such date shall be determined, the person to whom

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such interest shall be payable, and the basis upon which interest shall be calculated if other than that of a 360-day year of twelve 30-day months;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

any other material terms of such debt securities.

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The debt securities may provide for less than the entire principal amount thereof to be payable upon declaration of acceleration of the maturity thereof. Special federal income tax, accounting and other considerations applicable to these original issue discount securities will be described in the applicable prospectus supplement. The applicable prospectus supplement will set forth material U.S. federal income tax considerations for holders of any debt securities and the securities exchange or quotation system on which any debt securities are listed or quoted, if any.

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

Senior Debt Securities

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

Subordinated Debt Securities

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

Merger, Consolidation or Sale

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

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

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

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

Covenants

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

Events of Default, Notice and Waiver

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

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

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

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

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

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

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

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

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

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

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

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

Each indenture also will provide that the holders of not less than a majority in principal amount of the outstanding debt securities of any series (or of all debt securities then outstanding under the applicable indenture, as the case may

be) may waive any past default with respect to such series and its consequences, except a default:

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

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

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

Each indenture will provide that no holders of debt securities of any series may institute any proceedings, judicial or otherwise, with respect to such indenture or for any remedy thereunder, except in the case of failure of the applicable trustee, for 60 days, to act after it has received a written request to institute proceedings in respect of an event of default from the holders of not less than 25% in principal amount of the outstanding debt securities of such series, as well as an offer of indemnity reasonably satisfactory to it. This provision will not prevent, however, any holder of debt securities from instituting suit for the enforcement of payment of the principal of (and premium, if any) and interest on such debt securities at the respective due dates thereof.

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

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

Modification of the Indenture

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

- secure any debt securities;
- evidence the assumption by a successor corporation of our obligations;
- add covenants for the protection of the holders of debt securities;
- cure any ambiguity or correct any inconsistency in the indenture;
- establish the forms or terms of debt securities of any series; and
- evidence and provide for the acceptance of appointment by a successor trustee.

It is anticipated that modifications and amendments of an indenture may be made by us and the trustee, with the consent of the holders of not less than a majority in principal amount of each series of the outstanding debt securities issued under the indenture that are affected by the modification or amendment, provided that no

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such modification or amendment may, without the consent of each holder of such debt securities affected thereby:

- change the stated maturity date of the principal of (or premium, if any) or any installment of interest, if any, on any such debt security;
- reduce the principal amount of (or premium, if any) or the interest, if any, on any such debt security or the principal amount due upon acceleration of an original issue discount security;
- change the time or place or currency of payment of principal of (or premium, if any) or interest, if any, on any such debt security;
- impair the right to institute suit for the enforcement of any such payment on or with respect to any such debt security;
- reduce any amount payable on redemption;
- modify any of the subordination provisions or the definition of senior indebtedness applicable to any subordinated debt securities in a manner adverse to the holders of those securities;
- reduce the above-stated percentage of holders of debt securities necessary to modify or amend the indenture; or
- modify the foregoing requirements or reduce the percentage of outstanding debt securities necessary to waive compliance with certain provisions of the indenture or for waiver of certain defaults.

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

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

Conversion or Exchange Rights

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

Registered Global Securities

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

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

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

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

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

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

- ownership of beneficial interests in a registered global security will be limited to persons that have accounts with the depositary for the registered global security, those persons being referred to as participants, or persons that may hold interests through participants;
- upon the issuance of a registered global security, the depositary for the registered global security will credit, on its book-entry registration and transfer system, the participants accounts with the respective principal amounts of the debt securities represented by the registered global security beneficially owned by the participants;
- any dealers, underwriters, or agents participating in the distribution of the debt securities will designate the accounts to be credited; and
- ownership of any beneficial interest in the registered global security will be shown on, and the transfer of any ownership interest will be effected only through, records maintained by the depositary for the registered global security (with respect to interests of participants) and on the records of participants (with respect to interests of persons holding through participants).

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

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

- will not be entitled to have the debt securities represented by a registered global security registered in their names;
- will not receive or be entitled to receive physical delivery of the debt securities in the definitive form; and
- will not be considered the owners or holders of the debt securities under the indenture.

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

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

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

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

If the depositary for any debt securities represented by a registered global security is at any time unwilling or unable to continue as depositary or ceases to be a clearing agency registered under the Exchange Act, we will appoint an eligible successor depositary. If we fail to appoint an eligible successor depositary within 90 days, we will issue the debt securities in definitive form in exchange for the registered global security. In addition, we may at any time and in our sole discretion decide not to have any of the debt securities of a series represented by one or more registered global securities. In such event, we will issue debt securities of that series in a definitive form in exchange for all of the registered global securities representing the debt securities. The trustee will register any debt securities issued in definitive form in exchange for a registered global security in such name or names as the depositary, based upon instructions from its participants, shall instruct the trustee.

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

Discharge, Defeasance and Covenant Defeasance

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

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

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

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

we deliver to the trustee an opinion of counsel from a nationally recognized law firm to the effect that the holders of the series of debt securities will not recognize income, gain or loss for U.S. federal income tax purposes as a result of the defeasance or covenant defeasance and that defeasance or

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covenant defeasance will not otherwise alter the holders U.S. federal income tax treatment of principal, premium, if any, and interest payments on the series of debt securities, which opinion, in the case of legal defeasance, must be based on a ruling of the Internal Revenue Service issued, or a change in U.S. federal income tax law.

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

Redemption of Securities

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

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

Notices

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

Title

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

Governing Law

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

Concerning the Trustee

Each indenture provides that there may be more than one trustee under the indenture, each with respect to one or more series of debt securities. If there are different trustees for different series of debt securities, each trustee will be a trustee of a trust under the indenture separate and apart from the trust administered by any other trustee under the indenture. Except as otherwise indicated in this prospectus or any prospectus supplement, any action permitted to be taken by a trustee may be taken by such trustee only with respect to the one or more series of debt securities for which it is the trustee under the indenture. Any trustee under the indenture may resign or be removed with respect to one or more series of debt securities. All payments of principal of, premium, if any, and interest on, and all registration, transfer, exchange, authentication and delivery (including authentication and delivery on original issuance of the debt securities) of, the debt securities of a series will be effected by the trustee with respect to that series at an office designated by the trustee in New York, New York.

Each indenture contains limitations on the right of the trustee, should it become a creditor of the Company, to obtain payment of claims in some cases or to realize on certain property received in respect of any such claim as security or

otherwise. The trustee may engage in other transactions. If it acquires any conflicting interest relating to any duties with respect to the debt securities, however, it must eliminate the conflict or resign as trustee.

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WARRANTS

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

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

- the title of the warrants;
- the aggregate number of the warrants;
- the price or prices at which the warrants will be issued;
- the designation, terms and number of shares of preferred stock or common stock or principal amount of debt securities purchasable upon exercise of the warrants;
- the designation and terms of the offered securities, if any, with which the warrants are issued and the number of the warrants issued with each offered security;
- the date, if any, on and after which the warrants and the related debt securities, preferred stock or common stock will be separately transferable;
- the price at which each share of preferred stock, common stock or underlying debt securities purchasable upon exercise of the warrants may be purchased or the manner of determining such price;
- the date on which the right to exercise the warrants shall commence and the date on which that right shall expire;
- the minimum or maximum amount of the warrants which may be exercised at any one time;
- information with respect to book-entry procedures, if any;
- a discussion of certain federal income tax considerations; and
- any other material terms of the warrants, including terms, procedures and limitations relating to the exchange and exercise of the warrants.

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

USE OF PROCEEDS

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

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securities. Our plans to use the estimated net proceeds from the sale of these securities may change, and if they do, we will update this information in a prospectus supplement.

RATIO OF FIXED CHARGES AND PREFERENCE DIVIDENDS TO EARNINGS

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

DIVIDEND POLICY

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

PLAN OF DISTRIBUTION

We may sell the securities covered by this prospectus in any of three ways (or in any combination):

to or through underwriters or dealers;

directly to a limited number of purchasers or to a single purchaser; or

through agents.

Each time we offer and sell securities, we will provide a prospectus supplement that will set forth the terms of the offering of the securities covered by this prospectus, including:

the name or names of any underwriters, dealers or agents and the amounts of securities underwritten or purchased by each of them;

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

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

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

the initial public offering price of the securities;

any discounts, commissions or concessions allowed or reallowed or paid to dealers; and

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

Any public offering price and any discounts or concessions allowed or reallowed or paid to dealers may be changed from time to time.

Underwriters or dealers may offer and sell the securities from time to time in one or more transactions, including negotiated transactions, at a fixed public offering price or at varying prices determined at the time of sale. If underwriters or dealers are used in the sale of any securities, the securities will be acquired by such underwriters or dealers for their own account and may be resold from time to time in one or more transactions described above. We may offer the securities to the public through underwriting syndicates represented by

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managing underwriters, or directly by underwriters or dealers. Subject to certain conditions, the underwriters or dealers will be obligated to purchase all the securities of the series offered by the prospectus supplement. We will describe the nature of any such relationship in the prospectus supplement, naming the underwriter or dealer.

We may use underwriters with whom we have a material relationship. We may sell the securities through agents from time to time. The prospectus supplement will name any agent involved in the offer or sale of the securities and any commissions we pay to them. Unless the prospectus supplement states otherwise, any agent will be acting on a best efforts basis for the period of its appointment.

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

LEGAL MATTERS

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

EXPERTS

The financial statements, incorporated in this Prospectus by reference from the Company s Annual Report on Form 10-K for the year ended December 31, 2010 have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report, which is incorporated herein by reference, which report expresses an unqualified opinion of 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 in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

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PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. *Other Expenses of Issuance and Distribution*

The following table sets forth an itemization of all estimated expenses in connection with the issuance and distribution of the securities being registered.

	Amount to be Paid by Registrant
SEC Registration Fee	$ 8,708
Legal Fees and Expenses	*
Accounting Fees and Expenses	*
Printing and Engraving Fees	*
Blue Sky Fees and Expenses	*
Transfer Agent and Registrar Fees	*
Miscellaneous Expenses	*
Total	*

* The amount of securities and number of offerings are indeterminable and the expenses cannot be estimated at this time.

Item 15. *Indemnification of Directors and Officers*

The Delaware General Corporation Law and the registrant s certificate of incorporation and bylaws provide for indemnification of the registrant s 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 the registrant, and with respect to any criminal action or proceeding, actions that the indemnitee had no reasonable cause to believe were unlawful.

The registrant has also entered into identification agreements with its directors and executive officers. These identification agreements generally require that the registrant 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 the registrant s 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).

The registrant currently maintains a directors and officers liability insurance policy.

Item 16. *Exhibits*

The exhibits to this registration statement are listed in the Exhibit Index to this registration statement, which Exhibit Index is hereby incorporated by reference.

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Item 17. ***Undertakings.***

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a further post-effective amendment to the registration statement:

(i) To include any prospectus required by section 10(a)(3) of the Securities Act;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

Provided, however, that:

(A) Paragraphs (a)(1)(i) and (a)(1)(ii) of this section do not apply if the registration statement is on Form S-8, and the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the SEC by the registrant pursuant to section 13 or section 15(d) of the Exchange Act that are incorporated by reference in the registration statement; and

(B) Paragraphs (a)(1)(i), (a)(1)(ii) and (a)(1)(iii) of this section do not apply if the registration statement is on Form S-3 or Form F-3 and the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the SEC by the registrant pursuant to section 13 or section 15(d) of the Exchange Act that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(C) Provided, further, however, that paragraphs (a)(1)(i) and (a)(1)(ii) do not apply if the registration statement is for an offering of asset-backed securities on Form S-1 or Form S-3, and the information required to be included in a post-effective amendment is provided pursuant to Item 1100(c) of Regulation AB.

(2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act to any purchaser:

(i) If the registrant is relying on Rule 430B:

(A) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

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(B) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date; or

(ii) If the registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(5) That, for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of the securities:

The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

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(b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the registrant s annual report pursuant to Section 13(a) or 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan s annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offering therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(c) The undersigned registrant hereby undertakes that:

(i) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of the registration statement in reliance upon Rule 430A and contained in the form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of the registration statement as of the time it was declared effective.

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SIGNATURES

Pursuant to the requirements of the Securities Act, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Alpharetta, Georgia on May 27, 2011.

ALIMERA SCIENCES, INC.

By: /s/ C. Daniel Myers

C. Daniel Myers
Chief Executive Officer

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints C. Daniel Myers. and Richard S. Eiswirth, and each of them singly, his true and lawful attorney-in-fact and agent, with full power to act separately and full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement and all additional registration statements pursuant to Rule 462(b) of the Securities Act of 1933, as amended, and to file the same, with all exhibits thereto, and all other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act in person, hereby ratifying and confirming all that said attorney-in-fact and agent or his substitute may lawfully do or cause to be done by virtue hereof.

This Power of Attorney shall not revoke any powers of attorney previously executed by the undersigned. This Power of Attorney shall not be revoked by any subsequent power of attorney that the undersigned may execute, unless such subsequent power of attorney specifically provides that it revokes this Power of Attorney by referring to the date of the undersigned s execution of this Power of Attorney. For the avoidance of doubt, whenever two or more powers of attorney granting the powers specified herein are valid, the agents appointed on each shall act separately unless otherwise specified.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ C. Daniel Myers C. Daniel Myers	President, Chief Executive Officer and Director *(Principal Executive Officer)*	May 27, 2011
/s/ Richard S. Eiswirth, Jr. Richard S. Eiswirth, Jr.	Chief Operating Officer and Chief Financial Officer *(Principal Financial Officer and Principal Accounting Officer)*	May 27, 2011
/s/ Philip R. Tracy Philip R. Tracy	Director and Chairman of the Board	May 27, 2011

/s/ Glen Bradley	Director	May 27, 2011

Glen Bradley, Ph.D.

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Signature	Title	Date
/s/ Mark J. Brooks	Director	May 27, 2011
Mark J. Brooks		
/s/ Brian K Halak, Ph.D.	Director	May 27, 2011
Brian K. Halak, Ph.D.		
/s/ Calvin W. Roberts, M.D.	Director	May 27, 2011
Calvin W. Roberts, M.D.		
/s/ Peter J. Pizzo, III	Director	May 27, 2011
Peter J. Pizzo, III		
/s/ Bryce Youngren	Director	May 27, 2011
Bryce Youngren		

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EXHIBIT INDEX

Exhibit

1.1*	Form of Underwriting Agreement
3.2	Restated Certificate of Incorporation of Registrant, as amended on various dates (filed as Exhibit 3.2 to Amendment No. 4 to the Registrant s Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on April 6, 2010, and incorporated herein by reference)
3.4	Amended and Restated Bylaws of the Registrant (filed as Exhibit 3.4 to Amendment No. 4 to the Registrant s Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on April 6, 2010, and incorporated herein by reference)
4.2	Form of Registrant s Common Stock Certificate (filed as Exhibit 4.2 to Amendment No. 4 to the Registrant s Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on April 6, 2010, and incorporated herein by reference)
4.3	Second Amended and Restated Investor Rights Agreement, dated March 17, 2008, by and among the Registrant, certain stockholders and the investors listed on the signature pages thereto (filed as Exhibit 4.3 to Amendment No. 1 to the Registrant s Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on December 23, 2009, and incorporated herein by reference)
4.5	Omnibus Amendment, dated August 25, 2009, by and among the Registrant, certain stockholders and the investors listed on the signature pages thereto (filed as Exhibit 4.5 to Amendment No. 1 to the Registrant s Registration Statement on Form S-1 (SEC File No. 333-162782), as filed on December 23, 2009, and incorporated herein by reference)
4.6	Form of Senior Indenture
4.7*	Certificate of Designation of Preferred Stock
4.8*	Form of Warrant
4.9	Form of Subordinated Indenture
5.1	Opinion of Gunderson Dettmer Stough Villeneuve Franklin & Hachigian LLP
12.1*	Computation of Ratios of Earnings to Fixed Charges and Preference Dividends
23.1	Consent of Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP (included in Exhibit 5.1)
23.2	Consent of Deloitte & Touche, LLP
24.1	Power of Attorney (included on the signature page of this registration statement)
25.1*	Statement of Eligibility under the Trust Indenture Act of 1930, as amended, of the Trustee, as Trustee under the Indenture

* To be filed, if necessary, subsequent to the effectiveness of this registration statement by an amendment to this registration statement or by a report filed under the Securities Exchange Act of 1934, as amended, and incorporated herein by reference.