ALIMERA SCIENCES INC
Form S-3/A
March 28, 2013
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As filed with the Securities and Exchange Commission on March 28, 2013

Registration No. 333-184996

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 2

to

FORM S-1 on 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

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:

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Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this Registration Statement, as determined by the selling stockholders.

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, check the following box. x

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b2 of the Exchange Act.

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

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 WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(A) OF THE SECURITIES ACT OF 1933 OR UNTIL THIS REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE COMMISSION, ACTING PURSUANT TO SAID SECTION 8(A), MAY DETERMINE.

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EXPLANATORY NOTE

This Amendment No. 2 to Form S-1 on Form S-3 is being filed to, among other things, convert the registration statement on Form S-1 (No. 333-184996) into a registration statement on Form S-3.

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The information in this preliminary prospectus is not complete and may be changed. The selling stockholders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED MARCH 28, 2013

Preliminary Prospectus

19,548,871 shares of Common Stock

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

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

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

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

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

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

Our common stock is listed on the NASDAQ Global Market under the symbol ALIM. The last reported sale price of our common stock on the NASDAQ Global Market on March 27, 2013 was $3.07.

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

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

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

The date of this prospectus is , 2013.

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PROSPECTUS

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ABOUT THIS PROSPECTUS

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

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

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

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

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

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

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

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

uncertainty of clinical trial results;

limited sales and marketing infrastructure; and

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

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

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

PROSPECTUS SUMMARY

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

Our Company

We are a biopharmaceutical company that specializes in the research, development and commercialization of prescription ophthalmic pharmaceuticals. We are presently focused on diseases affecting the back of the eye, or retina, because we believe these diseases are not well treated with current therapies and represent a significant market opportunity. Our most advanced product candidate is ILUVIEN®, which has received marketing authorization in Austria, the United Kingdom, Portugal, France, Germany and Spain, and has been recommended for marketing authorization in Italy, for the treatment of vision impairment associated with chronic diabetic macular edema (DME) considered insufficiently responsive to available therapies. DME is a disease of the retina that affects individuals with diabetes and can lead to severe vision loss and blindness. ILUVIEN is the first product approved for chronic DME. ILUVIEN has not been approved by the U.S. Food and Drug Administration (FDA).

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

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

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

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

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

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

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If ILUVIEN is not approved in additional jurisdictions or does not generate sufficient revenue, we may adjust our commercial plans so that we can continue to operate with our existing cash resources or seek to raise additional financing. We are a Delaware corporation incorporated on June 4, 2003. Our principal executive office is located at 6120 Windward Parkway, Suite 290, Alpharetta, Georgia 30005 and our telephone number is (678) 990-5740. Our website address is www.alimerasciences.com. The information contained in, or that can be accessed through, our website is not part of this prospectus and should not be considered incorporated by reference herein.

THE OFFERING

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

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

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

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

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

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

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

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

RISK FACTORS

Investing in our common stock involves risk. You should carefully consider the risks described below as well as those risk factors incorporated by reference herein, before making an investment decision. The risks and uncertainties described below are not the only risks and uncertainties we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. If any of the following risks actually occur, our business, results of operations and financial condition could suffer. In that event the trading price of our common stock could decline, and you may lose all or part of your investment. The risks discussed below and those incorporated by reference also include forward-looking statements and our actual results may differ substantially from those discussed in these forward-looking statements.

Risks Related to Our Dependence on ILUVIEN

We are heavily dependent on the commercial success of our lead product candidate, ILUVIEN, which only recently received marketing authorizations in Austria, the United Kingdom, Portugal, France, Germany and Spain, and on the regulatory approval of ILUVIEN for the treatment of DME in the U.S. and other countries, which may never occur.

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

We anticipate that in the near term our ability to generate revenues will depend solely on our ability to successfully commercialize ILUVIEN on our own in Germany, the United Kingdom and France, the first three countries in which we intend to make ILUVIEN available for sale. If we do not successfully commercialize ILUVIEN in these countries or other countries in the EU or receive regulatory approval in the U.S. for ILUVIEN

for the treatment of DME, our ability to generate revenue may be jeopardized and, consequently, our business may be seriously harmed. We may not succeed in our commercial efforts in the EU; we may not receive regulatory approval in the U.S. for ILUVIEN; and if we do receive regulatory approval in the U.S. for ILUVIEN, we may not be able to commercialize ILUVIEN successfully, all of which

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would have a material adverse effect on our business and prospects. In the near term, we may experience delays and unforeseen difficulties in the launch of ILUVIEN in one or more of the EU countries, including obtaining unfavorable pricing and/or reimbursement, which could negatively affect our stock price. We may continue to experience delays in obtaining regulatory approval in the U.S. for ILUVIEN, if it is approved at all, and our stock price may be negatively affected.

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

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

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

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

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

We anticipate that in the near term our ability to generate revenues will depend solely on our ability to successfully commercialize ILUVIEN on our own in Germany, the United Kingdom and France, the first three countries in which we intend to make ILUVIEN available for sale. We currently plan to launch ILUVIEN in 2013. A commercial launch of this size is a significant undertaking that requires substantial financial and managerial resources.

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

- our or Quintiles Commercial s inability to recruit and retain adequate numbers of effective personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of ophthalmologists to prescribe our products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- the inability of market access personnel to obtain sufficient levels of pricing and reimbursement in each jurisdiction; and

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

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

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

Additionally, we, Quintiles Commercial and/or other third-party collaborators may encounter unexpected or unforeseen delays in establishing our commercial operations that delay the commercial launch in one or more EU countries in which ILUVIEN has received or been recommended for marketing authorization. These delays may increase the cost of and the resources required for successful commercialization of ILUVIEN in the EU. We do not have experience in a commercial launch of this size in the EU or elsewhere.

ILUVIEN may not be commercially successful.

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

- cost of treatment;
- pricing and availability of alternative products;
- our ability to obtain third-party coverage or reimbursement for ILUVIEN;
- perceived efficacy relative to other available therapies;
- shifts in the medical community to new treatment paradigms or standards of care;
- relative convenience and ease of administration; and
- prevalence and severity of adverse side effects associated with treatment.

Because we have not yet initiated the commercialization of ILUVIEN, we have limited information with regard to the market acceptance of ILUVIEN in the EU or elsewhere. As a result, we may have to revise our estimates regarding the acceptance of ILUVIEN under our anticipated pricing structure, reevaluate and/or change the anticipated pricing for ILUVIEN.

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

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

- are more effective;

have fewer or less severe adverse side effects;

are better tolerated;

receive better reimbursement terms;

are more accepted by physicians;

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are more adaptable to various modes of dosing;

have better distribution channels;

are easier to administer; or

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

We expect that ILUVIEN may compete in the EU, and, if approved by the FDA, in the U.S., with other products that are being developed for the treatment of DME. There are no ophthalmic drug therapies other than Lucentis, a drug sponsored by Genentech, Inc., a wholly-owned member of the Roche Group, which has been approved by the FDA for the treatment of DME. Lucentis is also approved for the treatment of visual impairment due to DME in the EU. Lucentis is expected to provide competition for ILUVIEN. Retinal specialists are currently using laser photocoagulation and off-label therapies for the treatment of DME, and may continue to use these therapies in competition with ILUVIEN. Additional treatments for DME are in various stages of preclinical or clinical testing. Later stage products for the treatment of DME include Ozurdex, a drug sponsored by Allergan, Inc. and Eyelea, a drug sponsored by Regeneron Pharmaceuticals, Inc. and Bayer HealthCare. If approved, these treatments would also compete with ILUVIEN. Other laser, surgical or pharmaceutical treatments for DME may also compete against ILUVIEN. These competitive therapies may result in pricing pressure even if ILUVIEN is otherwise viewed as a preferable therapy.

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

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

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

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

multiple legal systems and unexpected changes in legal requirements;

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

trade laws and business practices favoring local competition;

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

weaker intellectual property protection in some countries;

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

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

In addition, compliance with foreign and U.S. laws and regulations that are applicable to our international operations is complex and may increase our cost of doing business in international jurisdictions, and our international operations could expose us to fines and penalties if we fail to comply with these regulations. These laws and regulations include import and export requirements, U.S. laws such as the Foreign

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Corrupt Practices Act, and local laws prohibiting corrupt payments to governmental officials. Although we have implemented policies and procedures designed to help ensure compliance with these laws, there can be no assurance that our employees, partners and other persons with whom we do business will not take actions in violation of our policies or these laws. Any violations of these laws could subject us to civil or criminal penalties, including substantial fines or prohibitions on our ability to offer our products in one or more countries, and could also materially and adversely harm our business and financial condition.

Risks Related to Our Business and Industry

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

We are not currently generating revenues and we cannot estimate with precision the extent of our future losses. ILUVIEN is our only product currently approved for commercial sale and it is only approved in limited markets in the EU. We may never generate revenue from selling products or achieve profitability. We expect to continue to incur substantial and increasing losses through the projected commercialization of ILUVIEN. We currently do not expect to generate revenue from the sale of ILUVIEN in the EU until 2013, at the earliest. ILUVIEN has not been approved for marketing in the U.S. and may never receive such approval. As a result of these factors, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it. As of December 31, 2012, we have accumulated a deficit of $231.1 million. Our ability to achieve revenue and profitability is dependent on our ability to complete the development of our product candidates, obtain necessary regulatory approvals, and have our products manufactured and successfully marketed and sold. We cannot assure you that we will be profitable even if we successfully commercialize our products. Failure to become and remain profitable may adversely affect the market price of our common stock and our ability to raise capital and continue operations.

As of December 31, 2012, we had approximately $49.6 million in cash and cash equivalents. If ILUVIEN does not generate sufficient revenue in the EU, we may adjust our commercial plans so that we can continue to operate with our existing cash resources or seek to raise additional financing.

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

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

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

- a drug candidate may not be safe or effective;
- regulatory agencies may interpret data from preclinical and clinical testing in different ways from those which we do;
- they may not approve of our manufacturing processes;
- they may conclude that the drug candidate does not meet quality standards for stability, quality, purity and potency; and

they may change their approval policies or adopt new regulations.

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

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

The use of corticosteroids in the eye has been associated with undesirable side effects, including increased incidence of cataract formation and elevated intraocular pressure (IOP), which may increase the risk of glaucoma. We have 36 months of clinical data from our FAME Study, but the extent of ILUVIEN s long-term side-effect profile beyond month 36 is not yet known. We have agreed with EU regulatory authorities to conduct a five-year post-authorization, open label registry study of the safety of ILUVIEN in 800 patients treated per the labeled indication. Although ILUVIEN has received marketing authorization in Austria, the United Kingdom, Portugal, France, Germany and Spain, and been recommended for marketing authorization in Italy, the FDA s current position is that our FAME Study did not demonstrate that ILUVIEN has sufficient levels of efficacy to outweigh the risks associated with its side-effect profile. In the event the FDA maintains this conclusion, ILUVIEN may not receive regulatory approval from the FDA. If other regulatory bodies adopt a conclusion similar to the FDA s we may not receive approval in any other jurisdiction. Additionally, data accumulated from the five-year post-authorization study, or other commercial experience, could result in the withdraw of ILUVIEN approval in one or more jurisdictions.

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

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

Our product candidates may never achieve market acceptance even if we obtain regulatory approvals.

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

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

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its potential advantages over other therapies;

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

the effectiveness of our marketing and distribution capabilities.

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

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

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

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

We do not have, nor currently intend to have, in-house manufacturing capability and will depend completely on a single third-party manufacturer for the manufacture of the ILUVIEN insert (Alliance Medical Products, Inc. (Alliance)), a single third-party manufacturer for the manufacture of the ILUVIEN applicator (Flextronics International, Ltd. or an affiliate of Flextronics International, Ltd. (Flextronics)), a single third-party manufacturer for the manufacture of ILUVIEN s active pharmaceutical ingredient (FARMABIOS SpA./Byron Chemical Company Inc. (FARMABIOS)) and a single third-party manufacturer for the quality release testing of ILUVIEN in the EU (Brecon Pharmaceuticals Limited (Brecon)). Although we have agreements for the manufacture of the ILUVIEN insert (with Alliance), the manufacture of the ILUVIEN applicator (with Flextronics) for the supply of ILUVIEN s active pharmaceutical ingredient (with FARMABIOS) and for the quality release testing of ILUVIEN in the EU (with Brecon), if any of the third-party manufacturers breach their agreements or are unable or unwilling to perform for any reason, we may not be able to locate alternative acceptable manufacturers, enter into favorable agreements with them or get them approved by the applicable regulatory authorities, such as the FDA in the U.S., in a timely manner. Further, all of our manufacturers rely on additional third-parties for the manufacture of component parts. Any inability to acquire sufficient quantities of ILUVIEN inserts, the ILUVIEN applicator or the active pharmaceutical ingredient in a timely manner from these third-parties could delay commercial production of, and impact our ability to fulfill demand for, ILUVIEN, if any.