

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

**FORM S-3  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933**

**pSivida Corp.**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

26-2774444  
(I.R.S. Employer  
Identification Number)

pSivida Corp.  
400 Pleasant Street  
Watertown, MA 02472  
(617) 926-5000

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Lori H. Freedman, Esq.  
Vice President of Corporate Affairs and General Counsel  
pSivida Corp.  
400 Pleasant Street  
Watertown, MA 02472  
(617) 926-5000

(Name, address, including zip code, and telephone number, including area code, of agent for service)

*Copies to:*  
Mary E. Weber, Esq.  
Ropes & Gray LLP  
Prudential Tower  
800 Boylston Street  
Boston, Massachusetts 02199  
(617) 951-7000

**Approximate date of commencement of proposed sale to the public:** From time to time after the effective date of this registration statement.

If any of the securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box:

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, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box:

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 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.

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 additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

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.

Large accelerated filer

Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company)

Smaller reporting company

**CALCULATION OF REGISTRATION FEE**

Title of Each Class of Securities to be Registered (1)	Amount to be Registered (1)	Proposed Maximum Offering Price Per Share	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee (1)
Common stock	(2)	(2)	(2)	
Preferred stock (3)	(2)	(2)	(2)	
Warrants (4)	(2)	(2)	(2)	
Units	(2)	(2)	(2)	
<b>Total</b>	\$30,000,000 (1)		\$30,000,000 (5)	\$603 (5)

(1) This registration statement registers an indeterminate amount of securities having an aggregate initial offering price of \$30,000,000. Of the securities registered hereunder \$4,415,600 are newly registered. Pursuant to Rule 415(a)(6), \$25,584,400 of the securities registered hereunder are unsold securities initially registered on Registration Statement 333-141091, filed on March 6, 2007, as amended by a Post-Effective Amendment filed on July 3, 2008 (the "Initial Registration Statement") and subsequently registered in Registration Statement 333-163347 (the "Subsequent Registration Statement"). Pursuant to Rule 415(a)(6), the offering of Common Stock, Preferred Stock, Warrants and Units by the registrant covered by the Subsequent Registration Statement will be deemed terminated as of the date of effectiveness of this registration statement other than the offering thereunder of 1,176,105 shares of Common Stock issuable on exercise of outstanding warrants registered thereon. The Subsequent Registration Statement shall remain effective only as to the offering of such 1,176,105 shares of Common Stock following the effectiveness of this registration statement.

(2) Omitted pursuant to General Instruction II.D of Form S-3 under the Securities Act of 1933, as amended.

(3) Also covered is such an indeterminate amount of common stock (i) as may be issuable or deliverable upon conversion of shares of preferred stock and (ii) as may be required for delivery upon conversion of shares of preferred stock as a result of anti-dilution provisions.

(4) Also covered is such an indeterminate amount of common stock and preferred stock (i) as may be issuable or deliverable upon exercise of warrants and (ii) as may be required for delivery upon exercise of any warrants as a result of anti-dilution provisions.

(5) The registrant paid \$1,004 as a registration fee in connection with the unsold securities previously registered on the Initial Registration Statement and the Subsequent Registration Statement that are registered on this registration statement. Pursuant to Rule 415(a)(6), such registration fee will continue to be applied to such unsold securities. Of the securities registered hereunder, \$4,415,600 are newly registered. The registration fee regarding these newly registered securities has been calculated pursuant to Rule 457(o).

**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 the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

**The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.**

**Preliminary Prospectus, subject to completion, dated December 19, 2012.**

# PSIVIDA CORP.



## Common Stock, Warrants, Preferred Stock and Units

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pSivida Corp. may offer from time to time, in one or more series or issuances and at prices and on terms that will be determined at the time of offering, up to \$30,000,000 in gross proceeds to pSivida Corp. of:

- Common Stock
- Warrants
- Preferred Stock
- Units

We will provide specific terms of the common stock, warrants, preferred stock and units (which we refer to collectively as the “Securities”) in supplements to this prospectus at the time when we offer them. You should read this prospectus and applicable supplement carefully before you invest in any of these securities.

Our common stock is quoted on the NASDAQ Global Market under the symbol “PSDV”. The last reported sale price of our common stock on the NASDAQ Global Market on December 18, 2012 was \$1.45.

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**Investing in our common stock involves risks. See “[Risk Factors](#)” beginning on page 3.**

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**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.**

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The date of this prospectus is \_\_\_\_\_, 2012.

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You should read this prospectus, including all documents incorporated herein by reference, together with additional information described under “Where You Can Find Additional Information.”

You may obtain the information incorporated herein by reference without charge by following the instructions under “Where You Can Find Additional Information” or “Incorporation of Certain Information by Reference.”

**You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with information that is different. This prospectus is not an offer to sell, nor is it seeking an offer to buy, these securities in any jurisdiction where the offer or sale of these securities is not permitted. You should assume that the information contained in this prospectus is accurate only as of the date on the front of this prospectus.**

## ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission utilizing a “shelf” registration process. Under this shelf registration process, we may sell any combination of the securities described in this prospectus in one or more offerings resulting in gross proceeds to us of up to \$30,000,000. This prospectus provides you with a general description of the securities we may offer. Each time we sell securities, we will provide a prospectus supplement that will contain specific information about the terms of that offering. The prospectus supplement may also add, update or change information contained in this prospectus. To the extent that any statement that we make in a prospectus supplement is inconsistent with statements made in this prospectus, you should assume that the statements made in the prospectus supplement modify or supersede those made in this prospectus. You should read both this prospectus and any prospectus supplement together with additional information described under the heading “Where You Can Find Additional Information” on page 23 of this prospectus.

## THE COMPANY

### Our Business

We develop tiny, sustained-release, drug delivery products designed to deliver drugs at a controlled and steady rate for months or years. We are focused on treatment of chronic diseases of the back of the eye utilizing our core technology platforms, Durasert™ and BioSilicon™. We currently have three approved products and two principal product candidates under development, which represent successive generations of our Durasert technology.

Our most recently approved product is an injectable, sustained-release micro-insert for the treatment of vision impairment associated with chronic diabetic macular edema (DME) considered insufficiently responsive to available therapies. The product, to be marketed under the name ILUVIEN®, is being developed by our licensee, Alimera Sciences, Inc. (Alimera). ILUVIEN for DME has received marketing authorization in the U.K., Austria, France, Germany and Portugal and has been approved for marketing authorization in Italy and Spain. Alimera has announced its plans to launch the direct commercialization of ILUVIEN for DME in Germany, the United Kingdom and France in 2013 and the pursuit of pricing and reimbursement in those countries.

Alimera has also indicated its intention to resubmit its application for ILUVIEN for DME to the U.S. Food and Drug Administration (FDA) following receipt of a second Complete Response Letter in November 2011 (2011 CRL). Based on a June 2012 meeting with the FDA, Alimera reported that it plans to respond to the issues raised by the FDA in the 2011 CRL, including additional analysis of the benefits and risks of ILUVIEN based on clinical data from its two previously completed pivotal Phase III clinical trials (FAME™ Study), and to focus on the population of patients with chronic DME considered insufficiently responsive to available therapies, the same indication for which regulatory approval was granted in various EU countries.

We plan to study the same micro-insert used in ILUVIEN for the treatment of uveitis affecting the posterior segment of the eye (posterior uveitis). The FDA has cleared our Investigational New Drug application (IND), permitting us to move directly to two Phase III trials for this indication without the necessity of Phase I or Phase II trials. The FDA has agreed that the primary end point in these trials, which are expected to involve a total of approximately 300 patients, will be recurrence of uveitis within 12 months and that we can reference much of the data, including the clinical safety data, from the clinical trials for ILUVIEN for DME. We did not license Alimera the rights to use this micro-insert for the treatment of uveitis.

We are also developing a bioerodible, injectable micro-insert delivering latanoprost (Latanoprost Product) to treat glaucoma and ocular hypertension. An investigator-sponsored Phase I/II dose-escalation study is ongoing to assess the safety and efficacy of this micro-insert in patients with elevated intraocular pressure. Pfizer Inc. (Pfizer) has an option, under certain circumstances, to license the development and commercialization of the Latanoprost Product worldwide.

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Our two FDA-approved products, Retisert® for the treatment of posterior uveitis and Vitrasert® for the treatment of AIDS-related cytomegalovirus retinitis, are surgically implanted. They are both licensed to Bausch & Lomb Incorporated (Bausch & Lomb).

BioSilicon, the second key technology platform we are targeting for sustained drug delivery, utilizes fully-erodible, nanostructured, porous material. Our primary focus is on Tethadur™, which utilizes BioSilicon to deliver large biologic molecules, including peptides and proteins, on a sustained basis. The sizes of the pores in the BioSilicon material are manufactured using nanotechnology to accommodate specific protein, peptide or antibody molecules. These molecules are then released and the material erodes slowly over time. Our BioSilicon technology can also be designed to deliver smaller molecules.

### **Trademarks**

Durasert™, BioSilicon™ and Tethadur™ are our trademarks. ILUVIEN® and FAME™ are Alimera's trademarks. Retisert® and Vitrasert® are Bausch & Lomb's trademarks.

### **Corporate Information**

Our principal executive office (and mailing address) is located at 400 Pleasant Street, Watertown, MA 02472, and our telephone number is (617) 926-5000.

## RISK FACTORS

*In considering whether to invest in our common stock, you should carefully read and consider the risks described below, together with all of the information we have included in this prospectus.*

***We have a history of losses and expect to continue to incur losses for the foreseeable future.***

With the exception of the year ended June 30, 2010 (fiscal 2010), we have incurred operating losses since our inception in 2000, and our fiscal 2010 net income resulted from a one-time event. We do not currently have any assured sources of revenues. We do not know the timing and extent of any revenues we may receive from ILUVIEN for DME. Although ILUVIEN has been approved in five EU countries for the treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies, we do not know when Alimera will receive marketing authorization in two remaining EU countries or will complete pricing and reimbursement discussions, whether those pricing and reimbursement discussions will be satisfactory, whether Alimera will be successful in directly commercializing ILUVIEN for DME in the EU, and if and when, and to what extent, we will earn revenues from the commercialization of ILUVIEN for DME in the EU. We do not know if or when Alimera will receive FDA approval of ILUVIEN for DME. Unless and until Alimera receives such approval, we will not be entitled to receive the \$25.0 million milestone payment that would be due on such an approval, nor will we earn any revenues from sales of ILUVIEN for DME by Alimera in the U.S. We will receive funding under our Restated Pfizer Agreement only if Pfizer exercises its option with respect to the Latanoprost Product, which becomes exercisable only if we complete Phase II clinical trials, which have yet not been initiated, or if we cease development of the Latanoprost Product prior to completion of those trials. There is no assurance that Pfizer will exercise its option. Our royalty income from Bausch & Lomb is not expected to increase to a level sufficient to sustain our operations and may decline. Our ability to achieve profitability will depend upon the generation of revenues to us from Alimera's commercialization of ILUVIEN for DME and our or any other licensees' ability to achieve regulatory approval and sufficient revenues from commercialization of one or more of our product candidates.

***We expect to need additional capital resources to fund our operations, and our ability to obtain them is uncertain.***

We expect to continue to generate negative cash flows from operations unless and until we receive sufficient revenues from the commercialization of ILUVIEN for DME or one or more of our product candidates achieves regulatory approval and provides sufficient revenues from commercialization. During the past three fiscal years, we have financed our operations primarily from consideration received from our collaborative partners, including license fees, research and development funding and contingent note payments, and from the proceeds of offerings of our common stock and warrants. We currently have no committed funding from collaborative partners. We believe that our cash, cash equivalents and marketable securities of \$17.6 million at September 30, 2012 and expected royalty income from Bausch & Lomb should enable us to maintain our current and planned operations through calendar year 2013. Our capital resources would be enhanced if Alimera successfully commercializes ILUVIEN for DME in the EU or if ILUVIEN for DME were approved and successfully commercialized in the U.S., although even so, the amount and timing of our receipt of any revenues from such activities is uncertain. Accordingly, we expect to need additional resources to complete our planned Phase III trials for our posterior uveitis micro-insert and to fund our operations. Our need for additional capital resources will be influenced by the following factors, among others:

- whether, when and to what extent we receive revenues from Alimera with respect to ILUVIEN for DME, including from commercialization in the EU or upon any approval or commercialization in the U.S.;
- whether and when we enter into strategic arrangements for any of our product candidates and the nature of those arrangements;
- when and if we initiate, how we conduct, and whether and the extent to which we internally fund product development and programs, including clinical trials for the posterior uveitis micro-insert and the Latanoprost Product, and ongoing research and development of BioSilicon technology applications;

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- whether and when Pfizer exercises its option with respect to the Latanoprost Product;
- timely and successful development, regulatory approval and commercialization of our products and product candidates;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing any patent claims; and
- changes in our operating plan resulting in increases or decreases in our need for capital.

We may seek additional capital resources through possible new collaborative or licensing agreements and/or possible other agreements and transactions (which may include sales of securities or assets). Many factors relating to our company, such as the 2011 CRL and the status of FDA approval with respect to ILUVIEN for DME, the status of commercialization of ILUVIEN for DME in the EU, and the status of development of our product candidates, as well as the state of the economy and the financial and credit markets, may make our ability to secure additional capital resources more difficult to obtain or result in less favorable terms. If available, funding through collaboration, licensing or other agreements may be on unfavorable terms, including requiring us to relinquish rights to certain of our technologies or products; any additional equity financing may be dilutive to stockholders; and any debt financing may involve restrictive covenants or other unfavorable terms and potential dilutive equity. If adequate financing is not available if and when needed, we may be required to delay, reduce the scope of or eliminate research or development programs, postpone or cancel the pursuit of product candidates, including pre-clinical and clinical trials and new business opportunities, reduce staff and operating costs or otherwise significantly curtail our operations to reduce our cash requirements and extend our capital.

***If the recorded values of our intangible assets under Accounting Principles Generally Accepted in the U.S. (GAAP) is further impaired, our financial results could be adversely affected, which could adversely affect the price of our securities.***

We recorded significant amounts of intangible assets in connection with earlier acquisitions. We took impairment charges of \$3.1 million with respect to the value of our Durasert intangible asset and \$11.7 million with respect to the value of our BioSilicon intangible asset as of December 31, 2011. We have \$4.1 million of net intangible assets on our balance sheet as of September 30, 2012, of which \$2.8 million relates to our Durasert technology and \$1.3 million relates to our BioSilicon technology. We will continue to conduct impairment analyses of our intangible assets as required, and we would be required to take additional impairment charges in the future if any recoverability assessments of those assets reflect fair market values which are less than our recorded values, and such charges could be significant. The carrying values of our Durasert and BioSilicon technology systems could be impaired if there is a future triggering event, including, without limitation, adverse events with respect to the timing and status of clinical development, regulatory approval and success of commercialization of products using those technologies. Further impairment charges on our intangible assets could have a material adverse effect on our results of operations, which could, in turn, adversely affect the price of our securities.

***Our operating results may fluctuate significantly from period to period.***

Our operating results have fluctuated significantly from period to period in the past and may continue to do so in the future due to many factors, including:

- timing, receipt, amount and revenue recognition of payments, if any, from collaboration partners, including, without limitation, collaborative research and development, milestone, royalty, net profit and other payments;
- execution, amendment and termination of collaboration agreements;
- scope, duration and success of collaboration agreements;

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- amount of internally funded research and development costs, including pre-clinical studies and clinical trials;
- general and industry-specific adverse economic conditions that may affect, among other things, our and our collaborators' operations and financial results; and
- changes in accounting estimates, policies or principles and intangible asset impairments.

Due to fluctuations in our operating results, quarterly comparisons of our financial results may not necessarily be meaningful, and investors should not rely upon such results as an indication of future performance. In addition, investors may react adversely if our reported operating results are less favorable than in a prior period or are less favorable than those anticipated by investors in the financial community, which may result in further decreases in our stock price.

### ***Our royalty income from Bausch & Lomb may decline.***

Our royalties from Bausch & Lomb for Retisert and Vitrasert may decline. There is no assurance that Bausch & Lomb will continue to market either or both of these products. We do not expect that our royalty income from Bausch & Lomb for these products will ever become a material source of revenue for us.

## **RISKS RELATED TO THE DEVELOPMENT AND COMMERCIALIZATION OF OUR PRODUCTS AND PRODUCT CANDIDATES**

***Without FDA approval for ILUVIEN for DME, Alimera will be unable to commercialize the product in the U.S., and we will not receive payments to which we would be entitled upon such approval or from successful commercialization, which could materially impair our financial prospects.***

Alimera received a Complete Response Letter received in December 2010 (2010 CRL) from the FDA with respect to its New Drug Application (NDA) for ILUVIEN for DME, which included 24-month data from the FAME Study, and received the 2011 CRL in response to a resubmitted NDA, which responded to the 2010 CRL and included 36-month data. In the 2011 CRL, the FDA stated that it was unable to approve the NDA because it did not provide sufficient data to support that ILUVIEN is safe and effective in the treatment of patients with DME, that the risks of adverse reactions shown for ILUVIEN in the FAME Study were significant and were not offset by the benefits demonstrated by ILUVIEN in these clinical trials and that Alimera will need to conduct two additional clinical trials to demonstrate that the product is safe and effective for the proposed indication. Based on a recent meeting with the FDA, Alimera has reported its plans to resubmit its NDA for ILUVIEN for DME to the FDA in early 2013 using data from the FAME Study and to focus on the population of patients with chronic DME considered insufficiently responsive to available therapies, the same indication for which regulatory approval has been granted in various EU countries. There is no assurance that Alimera will resubmit the NDA on such schedule or at all or that Alimera will be able to demonstrate to the FDA that the benefits of ILUVIEN for DME outweigh the risks using data from the FAME Study, that additional clinical trials will not be required, that the population of chronic DME patients will be acceptable to the FDA or that Alimera will be able to obtain regulatory approval for ILUVIEN for DME in the U.S. Accordingly, ILUVIEN for DME may never be approved and marketed in the U.S., in which case we would not receive the milestone payment to which we would be entitled on FDA approval or any revenues from commercialization, which would be materially adverse to our business. Further, we do not know whether Alimera will continue to seek to develop, or receive approval from the FDA or other regulatory agencies for, ILUVIEN for the treatment of other eye conditions currently being studied under Alimera's agreement with us.

***We do not know if and when we will receive revenues from any commercialization of ILUVIEN for DME in the EU and the extent of those revenues.***

There is no assurance if and when, and to what extent, we will receive revenues from the commercialization of ILUVIEN for DME in the EU. To date, Alimera has received marketing authorization from Austria, France, Germany, Portugal and the U.K., but still must obtain separate national licenses in Italy and Spain, and there is



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no assurance that Alimera will receive those licenses, what the terms of the licenses will be and whether their issuances will be delayed beyond Alimera's expectations, which could delay Alimera's commercialization of ILUVIEN for DME in Italy and Spain. There is no assurance as to what level of governmental pricing and reimbursement in the various countries will be permitted, particularly in light of the ongoing budget crises faced by a number of countries in the EU. Prices of drugs in the EU are regulated and are generally lower than those in the United States, which could affect the amount of any revenues from the commercialization of ILUVIEN for DME in the EU. Alimera announced its intention to proceed with the direct commercialization of ILUVIEN for DME in Germany, the U.K. and France in 2013 and also obtained \$40 million in equity financing to provide additional capital to proceed with the direct commercialization of ILUVIEN in those countries. Alimera has no prior experience in commercializing products. There is no assurance that Alimera will be able to build and manage a successful commercial operation in the EU or that it will have sufficient capital to do so. Further, because we are entitled to net profit participation on sales of ILUVIEN if Alimera markets ILUVIEN directly and a percentage of royalties and non-royalty consideration if Alimera sublicenses the marketing of ILUVIEN, the amount and timing of any revenues we receive will be affected by the manner in which Alimera determines to market ILUVIEN in other countries. Although Alimera has reported that it intends to seek marketing approval of ILUVIEN for DME in additional EU countries, there is no assurance that Alimera will apply for or obtain any additional approvals. Further, we cannot project what the demand will be for ILUVIEN for DME if marketed in the EU.

***Both ILUVIEN and our micro-insert for posterior uveitis deliver FAc, a corticosteroid that has demonstrated undesirable side effects in the eye, which may affect the approvability and success of these micro-inserts for DME, posterior uveitis and other eye diseases.***

Both ILUVIEN and our micro-insert for posterior uveitis of the same design deliver the non-proprietary corticosteroid fluocinolone acetonide (FAc), which is associated with undesirable side effects in the eye, such as cataract formation and elevated intraocular pressure, which may increase the risk of glaucoma and related surgery to manage those side effects. In the 2011 CRL, the FDA stated that the risks of adverse reactions shown for ILUVIEN for DME in the FAME Study were significant and were not offset by the benefits demonstrated by ILUVIEN for DME in those clinical trials. To date, Austria, France, Germany, Portugal and the U.K. have granted marketing authorization to ILUVIEN for the treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies, but there is no assurance that ILUVIEN for DME will receive marketing authorization from the Italian and Spanish or any other regulators. These side effects may affect the approvability of ILUVIEN for the other eye conditions for which it is being studied, and even if approved, these side effects may adversely affect the successful marketing of ILUVIEN. Although our approved Retisert product for posterior uveitis and our product candidate for the same condition both deliver FAc, there is no assurance that our micro-insert of the same design as ILUVIEN for the treatment of posterior uveitis will be able to demonstrate that it is safe and efficacious for the treatment of posterior uveitis in light of its expected side effects from FAc.

***There is no assurance that Pfizer will exercise its option with respect to the Latanoprost Product or that we will receive any further financial consideration under the Restated Pfizer Agreement.***

In June 2011, we amended our Collaborative Research and License Agreement with Pfizer (the Restated Pfizer Agreement) to focus solely on the development of the Latanoprost Product. Development of this product through Phase II clinical trials is at our expense. Pfizer has an option for an exclusive, worldwide license to develop and commercialize the Latanoprost Product upon our completion of Phase II clinical trials or if we cease development of the Latanoprost Product prior to completion of those trials. There is no assurance that we will commence or complete the Phase II clinical trials for the Latanoprost Product, that if completed, the trials will be successful, that Pfizer will, in any event, exercise its option or that if exercised, that Pfizer will commence Phase III clinical trials or that the Latanoprost Product will achieve successful Phase III trial results, regulatory approvals or commercial success. As a result, there is no assurance that we will receive any further licensing, milestone or royalty payments under the Restated Pfizer Agreement.

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***If we or our licensees are unable to or do not complete clinical trials for our product candidates or do not receive the necessary regulatory approvals, we or our licensees will be unable to commercialize our product candidates.***

Our current and future activities are and will be subject to stringent regulation by governmental authorities both in the U.S. and other countries in which our products are marketed. Before we or our licensees can manufacture, market and sell any of our product candidates, approval from the FDA and/or foreign regulatory authorities is required to market in the applicable jurisdictions. Generally, in order to obtain these approvals, pre-clinical studies and clinical trials must demonstrate that a product candidate is safe for human use and effective for its targeted disease or condition.

None of our product candidates (other than ILUVIEN for DME in the U.S.) has completed or is in pivotal clinical trials. An investigator-sponsored Phase I/II study of the Latanoprost Product is ongoing, but we have not commenced Phase II clinical trials; the FDA has cleared our IND to treat posterior uveitis with our injectable sustained-release micro-insert and we are now permitted to move directly to two Phase III trials to treat patients with posterior uveitis, but we have not commenced pivotal trials; and we have no ongoing clinical studies with respect to BioSilicon product candidates. Product development at all stages involves a high degree of risk, and only a small proportion of research and development programs result in product candidates that advance to pivotal clinical trials or to approved products. There is no assurance that evaluation agreements we have with third parties will result in any product candidates or licenses, or that we or our licensees will commence or continue clinical trials for any of our product candidates. If clinical trials conducted by or for us or our licensees for any of our product candidates do not provide the necessary evidence of safety and efficacy, those product candidates cannot be manufactured and sold, and will not generate revenues. Initial or subsequent clinical trials may not be initiated by or for us or our licensees for product candidates or may be delayed or fail due to many factors, including the following:

- decisions by parties evaluating our technologies not to pursue development of products with us;
- our (or our licensees') lack of sufficient funding to pursue trials rapidly or at all;
- our (or our licensees') inability to attract clinical investigators for trials;
- our (or our licensees') inability to recruit patients in sufficient numbers or at the expected rate;
- our inability to find or reach agreement with licensees to undertake clinical trials;
- decisions by licensees not to exercise options for products and not to pursue products licensed to them;
- adverse side effects;
- failure of trials to demonstrate a product candidate's safety and efficacy;
- our (or our licensees') failure to meet FDA or other regulatory agency requirements for clinical trial design or inadequate clinical trial design;
- our (or our licensees') inability to follow patients adequately after treatment;
- changes in the design or manufacture of a product;
- failures by, changes in our (or our licensees') relationship with, or other issues at contract research organizations, third-party vendors and investigators responsible for pre-clinical testing and clinical trials;
- our (or our licensees') inability to manufacture sufficient quantities of materials for use in clinical trials;
- stability issues with materials;
- failure to comply with current good manufacturing practices (cGMP) or similar foreign regulatory requirements or other manufacturing issues;
- requests by regulatory authorities for additional data or clinical trials;

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- governmental or regulatory agency assessments of pre-clinical or clinical testing that differs from our (or our licensees') interpretations or conclusions that product candidates meet quality standards for stability, quality, purity and potency;
- governmental or regulatory delays, or changes in approval policies or regulations; and
- developments, clinical trial results and other factors with respect to competitive products and treatments.

Results from pre-clinical testing and early clinical trials often do not accurately predict results of later clinical trials. Data obtained from pre-clinical and clinical activities are susceptible to varying interpretations, which may delay, limit or prevent regulatory approval. Data from pre-clinical studies, early clinical trials and interim periods in multi-year trials are preliminary and may change, and final data from pivotal trials for such products may differ significantly. Adverse side effects may develop that delay, limit or prevent the regulatory approval of products, or cause such regulatory approvals to be limited or even rescinded. Additional trials necessary for approval may not be undertaken or may ultimately fail to establish the safety and efficacy of our product candidates.

The FDA or other relevant regulatory agencies may not approve our product candidates for manufacture and sale, and any approval by the FDA does not ensure approval by other regulatory agencies or vice versa (which could require us to comply with numerous and varying regulatory requirements, possibly including additional clinical testing). Any product approvals we or our licensees achieve could also be withdrawn for failure to comply with regulatory standards or due to unforeseen problems after the products' marketing approval. In either case, marketing efforts with respect to the affected product would have to cease. In addition, the FDA or other regulatory agencies may impose limitations on the indicated uses for which a product may be marketed, which may reduce the size of or otherwise limit the potential market for the product.

In addition to testing, regulatory agencies impose various requirements on manufacturers and sellers of products under their jurisdiction, such as packaging, labeling, manufacturing practices, record keeping and reporting. Regulatory agencies may also require post-marketing testing and surveillance programs to monitor a product's effects. Furthermore, changes in existing regulations or the adoption of new regulations could prevent us from obtaining, or affect the timing of, future regulatory approvals.

***We have a limited ability to develop and market products ourselves. If we are unable to find development or marketing partners, or our development or marketing partners do not successfully develop or market our products, we may be unable to effectively develop and market products on our own.***

We have limited product development capability and no marketing or sales staff. Developing products and achieving market acceptance for them can require extensive and substantial efforts by experienced personnel as well as expenditure of significant funds. We may not be able to establish sufficient capabilities necessary to develop products and achieve market penetration ourselves.

Our business strategy has included entering into collaborative and licensing arrangements for the development and commercialization of our product candidates, and we currently have collaboration and licensing arrangements with Alimera, Pfizer and Bausch & Lomb. The curtailment or termination of any of these arrangements could adversely affect our business, our ability to develop and commercialize our products, product candidates and proposed products and our ability to fund operations.

The success of these and future collaborative and licensing arrangements will depend heavily on the experience, resources, efforts and activities of our licensees. Our licensees have, and are expected to have, significant discretion in making decisions related to the development of product candidates and the commercialization of products under these collaboration agreements. Risks that we face in connection with our collaboration and licensing strategy include the following:

- our collaborative and licensing arrangements are, and are expected to be, subject to termination under various circumstances, including on short notice and without cause;

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- we are required, and expect to be required, under our collaborative and licensing arrangements not to conduct specified types of research and development in the field that is the subject of the arrangement or not to sell products in such field, limiting the areas of research, development and commercialization that we can pursue;
- our licensees may be permitted to develop and commercialize, either alone or with others, products that are similar to or competitive with our products;
- our licensees may change the focus of their development and commercialization efforts or decrease or fail to increase spending related to our products or product candidates, thereby limiting the ability of these products to reach their potential;
- our licensees may lack the funding, personnel or experience to develop and commercialize our products successfully or may otherwise fail to do so; and
- our licensees may not perform their obligations, in whole or in part.

To the extent that we choose not to, or we are unable to, enter into future license agreements with marketing and sales partners and, alternatively, seek to market and sell products ourselves, we would experience increased capital requirements to develop the ability to manufacture, market and sell future products. We may not be able to manufacture, market or sell our products or future products independently in the absence of such agreements.

***Our current licensees may terminate their agreements with us at any time, and if they do, we will lose the benefits of those agreements and may not be able to develop and sell products currently licensed to them.***

Our licensees have rights of termination under our agreements with them. Exercise of termination rights by one or more of our licensees may leave us without the financial benefits and development, marketing or sales resources provided under the terminated agreement, which may have an adverse effect on our business, financial condition and results of operations. Additionally, our interests may not continue to coincide with those of our partners, and our partners may develop, independently or with third parties, products or technologies that could compete with our products. Further, we may disagree with our partners over the rights and obligations under those agreements, including ownership of technologies or other proprietary interests, noncompetition, payments or other issues, which could result in breach of the agreements including related damages or injunctive relief or termination.

Pfizer may terminate the Restated Pfizer Agreement with respect to the Latanoprost Product without penalty at any time and for any reason upon 60 days' written notice. We have exclusively licensed our technology underlying Vitrasert and Retisert to Bausch & Lomb, which can terminate its agreement with us without penalty at any time upon 90 days' written notice. We have exclusively licensed the technology underlying ILUVIEN for DME and certain ophthalmic applications to Alimera. Alimera has financial responsibility for the development of ILUVIEN for DME and any other licensed products developed under our collaboration agreement, along with sole responsibility for the commercialization of such licensed products. Alimera may abandon the development and commercialization of any licensed product at any time.

Any of Pfizer, Alimera or Bausch & Lomb may decide not to continue to develop, exercise options or commercialize products under their respective agreements, change strategic focus, or pursue alternative technologies instead of our technologies or develop competing products. While Pfizer and Bausch & Lomb have significant experience in the ophthalmic field and have substantial resources, there is no assurance whether, and to what extent, that experience and those resources will be devoted to our technologies. Alimera has limited experience and more limited financial resources, and ILUVIEN for DME is Alimera's first commercial product. Because we do not currently have sufficient funding or internal capabilities to develop and commercialize our products and product candidates, decisions, actions, breach or termination of these agreements by Pfizer, Bausch & Lomb or Alimera could delay or stop the development or commercialization of any of the products or product candidates licensed to such entities.

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***If products of our competitors receive regulatory approval or reach the market earlier, are more effective, have fewer side effects, are more effectively marketed or cost less, our products or product candidates may not be approved, may not achieve the sales we anticipate and could be rendered obsolete.***

We believe that pharmaceutical, drug delivery and biotechnology companies, research organizations, governmental entities, universities, hospitals, other nonprofit organizations and individual scientists are seeking to develop drugs, therapies, products, approaches or methods to treat our targeted diseases or their underlying causes. For many of our targeted diseases, competitors have alternate therapies that are already commercialized or are in various stages of development ranging from discovery to advanced clinical trials. For example, Lucentis<sup>®</sup> has been approved in the U.S. and EU to treat DME, and Bayer HealthCare and Regeneron have instituted Phase III studies of EYLEA<sup>®</sup>, already approved in the U.S. and Australia to treat wet-related macular degeneration, to treat DME. Any of these drugs, therapies, products, approaches or methods may receive government approval or gain market acceptance more rapidly than our products and product candidates, may offer therapeutic or cost advantages, or may more effectively treat our targeted diseases or their underlying causes, which could result in our product candidates not being approved, reduce demand for our products and product candidates or render them noncompetitive or obsolete. For example, sales of Vitrasert for the treatment of cytomegalovirus retinitis, a disease that affects people with late-stage AIDS, declined significantly with advances in the treatment of AIDS.

Many of our competitors and potential competitors have substantially greater financial, technological, research and development, marketing and personnel resources than we do. Our competitors may succeed in developing alternate technologies and products that, in comparison to the products we have and are seeking to develop:

- are more effective and easier to use;
- are more economical;
- have fewer side effects;
- offer other benefits; or
- may otherwise render our products less competitive or obsolete.

Many of these competitors have greater experience in developing products, conducting clinical trials, obtaining regulatory approvals or clearances and manufacturing and marketing products.

***Our products and product candidates may not achieve and maintain market acceptance and may never generate significant revenues.***

In both domestic and foreign markets, the commercial success of our products and product candidates will require not only obtaining regulatory approvals but also obtaining market acceptance by retinal specialists and other doctors, patients, government health administration authorities and other third-party payors. Whether and to what extent our products and product candidates achieve and maintain market acceptance will depend on a number of factors, including demonstrated safety and efficacy, cost-effectiveness, potential advantages over other therapies, our and our collaborative partners' marketing and distribution efforts and the reimbursement policies of government and other third-party payors. In particular, if government and other third-party payors do not provide adequate coverage and reimbursement levels for or recommend our products and product candidates, the market acceptance of our products and product candidates will be limited. Both government and other third-party payors attempt to contain healthcare costs by limiting coverage and the level of reimbursement for products and, accordingly, they might challenge the price and cost-effectiveness of our products, or refuse to provide coverage for our products. If our products and product candidates fail to achieve and maintain market acceptance, they may fail to generate significant revenues and our business may be significantly harmed.

***Guidelines, recommendations and studies published by various organizations could reduce the use of our products and product candidates.***

Government agencies, professional societies, practice management groups, private health and science foundations and organizations focused on various diseases may publish guidelines, recommendations or studies related to our products and product candidates or our competitors' products. Any such guidelines, recommendations or studies that reflect negatively on our products or product candidates could result in decreased use, sales of, and revenues from one or more of our products and product candidates. Furthermore, our success depends in part on our and our partners' ability to educate healthcare providers and patients about our products and product candidates, and these education efforts could be rendered ineffective by, among other things, third-parties' guidelines, recommendations or studies.

**RISKS RELATED TO OUR INTELLECTUAL PROPERTY**

***We rely heavily upon patents and trade secrets to protect our proprietary technologies. If we fail to protect our intellectual property or infringe on others' technologies, our ability to develop and market our products and product candidates may be compromised.***

Our success is dependent on whether we can obtain patents, defend our existing patents and operate without infringing on the proprietary rights of third parties. As of November 30, 2012, we had 197 patents and 124 pending patent applications, including patents and pending applications. Intellectual property protection of our technologies is uncertain. We expect to seek to patent and protect our proprietary technologies. However, there is no assurance that any additional patents will be issued to us as a result of our pending or future patent applications or that any of our patents will withstand challenges by others. In addition, we may not have sufficient funds to patent and protect our proprietary technologies to the extent that we would desire, or at all. If we were determined to be infringing any third party patent, we could be required to pay damages, alter our products or processes, obtain licenses, pay royalties or cease certain operations. We may not be able to obtain any required licenses on commercially favorable terms, if at all. In addition, many foreign country laws may treat the protection of proprietary rights differently from, and may not protect our proprietary rights to the same extent as, laws in the United States and Patent Cooperation Treaty countries.

Prior art may reduce the scope or protection of, or invalidate, our patents. Previously conducted research or published discoveries may prevent our patents from being granted, invalidate issued patents or narrow the scope of any protection obtained. Reduction in scope of protection or invalidation of our licensed or owned patents, or our inability to obtain patents, may enable other companies to develop products that compete with our products and product candidates on the basis of the same or similar technology. As a result, our patents and those of our licensors may not provide any or sufficient protection against competitors. While we have not been, and are not currently involved in, any litigation over intellectual property, such litigation may be necessary to enforce any patents issued or licensed to us or to determine the scope and validity of third party proprietary rights. We may also be sued by one or more third parties alleging that we infringe their intellectual property rights. Any intellectual property litigation would be likely to result in substantial costs to us and diversion of our efforts, and could prevent or delay our discovery or development of product candidates. If our competitors claim technology also claimed by us, and if they prepare and file patent applications in the U.S. or other jurisdictions, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office or the appropriate foreign patent office to determine priority of invention, which could result in substantial cost to us and diversion of our efforts. Any such litigation or interference proceedings, regardless of the outcome, could be expensive and time consuming. Litigation could subject us to significant liabilities to third parties, requiring disputed rights to be licensed from third parties and/or requiring us to cease using certain technologies.

We also rely on trade secrets, know-how and technology that are not protected by patents to maintain our competitive position. We try to protect this information by entering into confidentiality agreements with parties that have access to it, such as our corporate partners, collaborators, employees, and consultants. Any of these

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parties could breach these agreements and disclose our confidential information, or our competitors may learn of the information in some other way. If any material trade secret, know-how or other technology not protected by a patent were to be disclosed to or independently developed by a competitor, our competitive position could be materially harmed.

### **RISKS RELATED TO OUR BUSINESS, INDUSTRY, STRATEGY AND OPERATIONS**

#### ***If we fail to retain key personnel, our business could suffer.***

We are dependent upon the principal members of our management and scientific staff. In addition, we believe that our future success in developing our products and achieving a competitive position may depend on whether we can attract and retain additional qualified management and scientific personnel. There is strong competition for management and scientific personnel within the industry in which we operate and we may not be able to attract and retain such personnel. As we have a small number of employees and we believe our products are unique and highly specialized, the loss of the services of one or more of the principal members of our senior management or scientific staff, or the inability to attract and retain additional personnel and develop expertise as needed, could have a material adverse effect on our results of operations and financial condition.

#### ***If we are subject to product liability suits, we may not have sufficient insurance to cover damages.***

The testing, manufacturing, and marketing and sale of the products utilizing our technologies involve risks that product liability claims may be asserted against us and/or our licensees. Our current clinical trial and product liability insurance may not be adequate to cover damages resulting from product liability claims. Regardless of their merit or eventual outcome, product liability claims could require us to spend significant time, money and other resources to defend such claims, could result in decreased demand for our products and product candidates or result in reputational harm, and could result in the payment of a significant damage award. Our product liability insurance coverage is subject to deductibles and coverage limitations and may not be adequate in scope to protect us in the event of a successful product liability claim. Further, we may not be able to acquire sufficient clinical trial or product liability insurance in the future on reasonable commercial terms, if at all.

#### ***Consolidation in the pharmaceutical and biotechnology industries may adversely affect us.***

There has been consolidation in the pharmaceutical and biotechnology industries. Consolidation could result in the remaining companies having greater financial resources and technological capabilities, thus intensifying competition, and fewer potential collaboration partners or licensees for our product candidates. In addition, if a consolidating company is already doing business with our competitors, we could lose existing or potential future licensees or collaboration partners as a result of such consolidation.

#### ***If we or our licensees fail to comply with environmental laws and regulations, our or their ability to manufacture and commercialize products may be adversely affected.***

Medical and biopharmaceutical research and development involves the controlled use of hazardous materials, such as radioactive compounds and chemical solvents. We and our licensees are subject to federal, state and local laws and regulations in the U.S. and abroad governing the use, manufacture, storage, handling and disposal of such materials and waste products. We and they could be subject to both criminal liability and civil damages in the event of an improper or unauthorized release of, or exposure of individuals to, hazardous materials. In addition, claimants may sue us or them for resulting injury or contamination, and the liability may exceed our or their ability to pay. Compliance with environmental laws and regulations is expensive, and current or future environmental regulations may impair the research, development or production efforts of our company or our licensees and harm our operating results.

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***If we or our licensees encounter problems with product manufacturing, there could be delays in product development or commercialization, which would adversely affect our future profitability.***

Our ability and that of our licensees to conduct timely pre-clinical and clinical research and development programs, obtain regulatory approvals, and develop and commercialize our product candidates will depend, in part, upon our and our licensees' ability to manufacture our products and product candidates, either directly or through third parties, in accordance with FDA and other regulatory requirements. The manufacture, packaging and testing of our products and product candidates are regulated by the FDA and similar foreign regulatory entities and must be conducted in accordance with applicable cGMP and comparable foreign requirements. Any change in a manufacturing process or procedure used for one of our products or product candidates, including a change in the location at which a product or product candidate is being manufactured or in the third-party manufacturer being used, may require the FDA's and similar foreign regulatory entities' prior review and/or approval in accordance with applicable cGMP or other regulations. Additionally, the FDA and similar foreign regulatory entities may implement new standards, or change their interpretation and enforcement of existing standards, for the manufacture, packaging and testing of products at any time.

There may be a limited number of manufacturers that operate under cGMP or comparable foreign regulations that are both capable of manufacturing our products and product candidates and are willing to do so. Alimera has contracted with third-party manufacturers with respect to the manufacture of components of ILUVIEN for DME. Failure by us, our collaborative partners, or our or their third-party manufacturers, to comply with applicable manufacturing requirements could result in sanctions being imposed on us or them, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product, operating restrictions and criminal prosecutions. In addition, we or our collaborative partners may not be able to manufacture our product candidates successfully or have a third party manufacture them in a cost-effective manner. If we or our collaborative partners are unable to develop manufacturing facilities or to obtain or retain third-party manufacturing on acceptable terms, we or they may not be able to conduct future pre-clinical and clinical testing or supply commercial quantities of our products.

We manufacture supplies in connection with pre-clinical or clinical studies conducted by us or our collaboration partners. Under our collaboration agreements with Alimera, Pfizer and Bausch & Lomb, we have provided our licensees the exclusive rights to manufacture commercial quantities of products, once approved for marketing. Our and our licensees' reliance on third-party manufacturers entails risks, including:

- failure of third parties to comply with cGMP and other applicable U.S. and foreign regulations and to employ adequate quality assurance practices;
- inability to obtain the materials necessary to produce a product or to formulate the active pharmaceutical ingredient on commercially reasonable terms, if at all;
- supply disruption, deterioration in product quality or breach of a manufacturing or license agreement by the third party because of factors beyond our or our licensees' control;
- termination or non-renewal of a manufacturing or licensing agreement with a third party at a time that is costly or difficult; and
- inability to identify or qualify an alternative manufacturer in a timely manner, even if contractually permitted to do so.

***Problems associated with international business operations could affect our ability to manufacture and sell our products. If we encounter such problems, our costs could increase and our development of products could be delayed.***

We currently maintain offices and research and development facilities in the U.S. and the U.K., and our goal is to develop products for sale by us or our licensees in most major world healthcare markets. Manufacturing of pharmaceutical products requires us or our licensees to comply with regulations regarding safety and quality and to obtain country and jurisdiction-specific regulatory approvals and clearances. We or our licensees may not be



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able to comply with such regulations or to obtain or maintain needed regulatory approvals and clearances or may be required to incur significant costs in doing so. In addition, our operations and future revenues may be subject to a number of risks associated with foreign commerce, including the following:

- staffing and managing foreign operations;
- political and economic instability;
- foreign currency exchange fluctuations;
- foreign tax laws, tariffs and freight rates and charges;
- timing and availability of export licenses;
- inadequate protection of intellectual property rights in some countries; and
- receipt and maintenance of required government approvals.

### ***Credit and financial market conditions may exacerbate certain risks affecting our business.***

Sales of products are dependent on the availability and extent of reimbursement from government and other third-party payors. Difficult credit and financial market conditions may increase the risk that government and other third-party payors will reduce the availability or extent of reimbursement for our products, and the risk that third-party payors will delay or default on reimbursement obligations.

Sales of our products depend on, and development and sales of our product candidates may depend on, collaborative partners and third-party suppliers. Difficult credit and financial market conditions may increase the risk that there are delays, disruptions or defaults in the performance of these third parties' obligations to us.

### ***Legislative or regulatory changes may adversely affect our business, operations and financial results.***

Our industry is highly regulated and new laws, regulations and judicial decisions, and new interpretations of existing laws, regulations and judicial decisions, may adversely affect our business, operations and financial results.

The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (PPACA) is intended to expand U.S. healthcare coverage primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program. Several provisions of the PPACA could significantly reduce payments from Medicare and Medicaid for our products and any product candidates which obtain approval over the next 10 years. The PPACA's effects cannot be fully known until its provisions are implemented, and the Centers for Medicare & Medicaid Services, and other federal and state agencies, issue applicable regulations or guidance. Proposed U.S. state healthcare reforms, and any foreign healthcare reforms, also could alter the availability, methods and rates of reimbursements from the government and other third-party payors for our products and any product candidates which obtain approval, and could adversely affect our business strategy, operations and financial results.

The Food and Drug Administration Amendments Act of 2007 granted the FDA enhanced authority over products already approved for sale, including 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 relatively new authority could result in delays and increased costs during product development, clinical trials and regulatory review and approval, increased costs following regulatory approval to assure compliance with new post-approval regulatory requirements, and potential restrictions on the sale or distribution of approved products following regulatory approval.

Changes in the regulatory approval policy during the development period, changes in or the enactment of additional regulations or statutes, or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application. For example, the July 9, 2012 reauthorization of the Prescription Drug User Fee Act (PDUFA) extended by two months the period in which the FDA is expected to

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review and approve certain NDAs. Although the FDA has recently stated that it expects to meet PDUFA's updated timing goals, it has in the past provided its managers discretion to miss them due to heightened agency workload or understaffing in the review divisions; accordingly, it remains unclear whether and to what extent the FDA will adhere to PDUFA timing goals in the future, which could delay approval and commercialization of our product candidates.

### **RISKS RELATED TO OUR COMMON STOCK**

#### ***The price of our common stock may be volatile.***

The price of our common stock (including common stock represented by CHESD Depository Interests (CDIs)) may be affected by developments directly affecting our business as well as by developments out of our control or not specific to us. The price of our common stock dropped significantly when the FDA issued its 2011 CRL with respect to ILUVIEN for DME. The biotechnology sector, in particular, and the stock market generally, are vulnerable to abrupt changes in investor sentiment. Prices of securities and trading volume of companies in the biotechnology industry, including ours, can swing dramatically in ways unrelated to, or that bear a disproportionate relationship to, our performance. The price of our common stock (and CDIs) and their trading volumes may fluctuate based on a number of factors including, but not limited to:

- clinical trials and their results and other product and technological developments and innovations;
- FDA and other domestic and international governmental regulatory actions, receipt and timing of approvals of our product candidates, and any denials and withdrawal of approvals;
- competitive factors, including the commercialization of new products in our markets by our competitors;
- advancements with respect to treatment of the diseases targeted by our product candidates;
- developments relating to and actions by collaborative partners, including execution, amendment and termination of agreements, achievement of milestones and receipt of payments;
- the success of our collaborative partners in marketing any approved products and the amount and timing of payments to us;
- availability and cost of capital and our financial and operating results;
- changes in reimbursement policies or other practices relating to our product candidates or the pharmaceutical industry generally;
- meeting, exceeding or failing to meet analysts' or investors' expectations, and changes in evaluations and recommendations by securities analysts;
- economic, industry and market conditions, changes or trends; and
- other factors unrelated to us or the biotechnology industry.

In addition, low trading volume in our common stock or our CDIs may increase their price volatility. Holders of our common stock and CDIs may not be able to liquidate their positions at the desired time or price. Finally, we will need to continue to meet the listing requirements of the NASDAQ Global Market, including the minimum stock price, and the Australian Securities Exchange for our stock and CHESD Depository Interests to continue to be traded on those exchanges, respectively.

#### ***If the holders of our outstanding warrants and stock options exercise their warrants and options, ownership of our common stock holders may be diluted, and our stock price may decline.***

As of December 15, 2012, we had outstanding warrants and options to acquire approximately 4.8 million shares of our common stock, or approximately 17.2% of our shares on a fully diluted basis. The issuance of shares of our common stock upon exercise of these warrants and stock options could result in dilution to the interests of other holders of our common stock and could adversely affect our stock price. The overhang of outstanding warrants and options may adversely affect our stock price.

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***Pfizer owns a significant percentage of our common stock and is a collaborative partner and therefore may be able to influence our business in ways that are not beneficial to you.***

Pfizer owned approximately 8.0% of our outstanding shares as of November 30, 2012 and is a collaborative partner. As a result, Pfizer may be able to exert significant influence over our board of directors and how we operate our business. The concentration of ownership may also have the effect of delaying or preventing a change in control of our company.

***We do not currently intend to pay dividends on our common stock, and any return to investors is expected to come, if at all, only from potential increases in the price of our common stock.***

At the present time, we intend to use available funds to finance our operations. Accordingly, while payment of dividends rests within the discretion of our board of directors, no cash dividends on our common shares have been declared or paid by us and we have no intention of paying any such dividends in the foreseeable future.

## FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements, within the meaning of Section 27A of the Securities Act of 1933, as amended (Securities Act) and Section 21E of the Securities Exchange Act of 1934, as amended (Exchange Act). Forward-looking statements are inherently subject to risks, uncertainties and potentially inaccurate assumptions. Such statements give our current expectations or forecasts of future events; they do not relate strictly to historical or current facts. All statements other than statements of historical fact could be deemed forward-looking statements, including, without limitation, any expectations of revenue, expenses, cash flows, earnings or losses from operations, capital or other financial items; any statements of the plans, strategies and objectives of management for future operations; any statements concerning product research, development and commercialization timelines; any statements of expectations or belief; and any statements of assumptions underlying any of the foregoing. We often, although not always, identify forward-looking statements by using words or phrases such as the following: “likely”, “expect”, “intend”, “anticipate”, “believe”, “estimate”, “plan”, “project”, “forecast” and “outlook”.

We cannot guarantee that the results and other expectations expressed, anticipated or implied in any forward-looking statement will be realized. The risks set forth under “Risk Factors” herein describe major risks to our business, and you should read and interpret any forward-looking statements together with these risks. A variety of factors, including these risks, could cause our actual results and other expectations to differ materially from the anticipated results or other expectations expressed, anticipated or implied in our forward-looking statements. Should known or unknown risks materialize, or should our underlying assumptions prove inaccurate, actual results could differ materially from past results and those anticipated, estimated or projected in the forward-looking statements. You should bear this in mind as you consider any forward-looking statements.

Our forward-looking statements speak only as of the dates on which they are made. We do not undertake any obligation to update any forward-looking statement, whether to reflect new information, future events or otherwise. You are advised, however, to consult any further disclosures we may make in our future reports to the SEC, on our website, [www.psivida.com](http://www.psivida.com), or otherwise.

## USE OF PROCEEDS

Unless we identify other uses of proceeds in a prospectus supplement, we intend to use the net proceeds from the sale of the Securities for our general corporate purposes, which may include funding our clinical trials, capital expenditures, acquisitions, and working capital. Pending use, the net proceeds may also be temporarily invested in short-term securities. Additional information on the use of net proceeds from the sale of securities covered by this prospectus may be set forth in the prospectus supplement relating to the specific offering.

## PLAN OF DISTRIBUTION

We may sell the Securities in any one or more of the following ways from time to time:

- to or through underwriters;
- to or through dealers;
- through agents; or
- directly to purchasers, including our affiliates.

The prospectus supplement with respect to any offering of our Securities will set forth the terms of the offering, including:

- the name or names and addresses of any underwriters, dealers or agents;
- the purchase price of the Securities and the proceeds to us from the sale;
- any underwriting discounts and commissions or agency fees and other items constituting underwriters' or agents' compensation; and
- any delayed delivery arrangements.

The distribution of the Securities may be effected from time to time in one or more transactions at a fixed price or prices, which may be changed, at market prices prevailing at the time of sale, at prices related to the prevailing market prices or at negotiated prices.

If the Securities are sold by means of an underwritten offering, we will execute an underwriting agreement with an underwriter or underwriters, and the names of the specific managing underwriter or underwriters, as well as any other underwriters, and the terms of the transaction, including commissions, discounts and any other compensation of the underwriters and dealers, if any, will be set forth in the prospectus supplement which will be used by the underwriters to sell the Securities. If underwriters are utilized in the sale of the Securities, the Securities will be acquired by the underwriters for their own account and may be resold from time to time in one or more transactions, including negotiated transactions, at fixed public offering prices or at varying prices determined by the underwriters at the time of sale.

Our Securities may be offered to the public either through underwriting syndicates represented by managing underwriters or directly by the managing underwriters. If any underwriter or underwriters are utilized in the sale of the Securities, unless otherwise indicated in the prospectus supplement, the underwriting agreement will provide that the obligations of the underwriters are subject to conditions precedent and that the underwriters with respect to a sale of Securities will be obligated to purchase all of those Securities if they purchase any of those Securities.

We may grant to the underwriters options to purchase additional Securities to cover over-allotments, if any, at the public offering price with additional underwriting discounts or commissions. If we grant any over-allotment option, the terms of any over-allotment option will be set forth in the prospectus supplement relating to those Securities.

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If a dealer is utilized in the sales of Securities in respect of which this prospectus is delivered, we will sell those Securities to the dealer as principal. The dealer may then resell those Securities to the public at varying prices to be determined by the dealer at the time of resale. Any reselling dealer may be deemed to be an underwriter, as the term is defined in the Securities Act, of the Securities so offered and sold. The name of the dealer and the terms of the transaction will be set forth in the related prospectus supplement.

Offers to purchase Securities may be solicited by agents designated by us from time to time. Any agent involved in the offer or sale of the Securities in respect of which this prospectus is delivered will be named, and any commissions payable by us to the agent will be set forth, in the applicable prospectus supplement. Unless otherwise indicated in the prospectus supplement, any agent will be acting on a reasonable best efforts basis for the period of its appointment. Any agent may be deemed to be an underwriter, as that term is defined in the Securities Act, of the Securities so offered and sold.

Offers to purchase Securities may be solicited directly by us and the sale of those Securities may be made by us directly to institutional investors or others, who may be deemed to be underwriters within the meaning of the Securities Act with respect to any resale of those Securities. The terms of any sales of this type will be described in the related prospectus supplement.

Underwriters, dealers, agents and remarketing firms may be entitled under relevant agreements entered into with us to indemnification by us against certain civil liabilities, including liabilities under the Securities Act, that may arise from any untrue statement or alleged untrue statement of a material fact or any omission or alleged omission to state a material fact in this prospectus, any supplement or amendment hereto, or in the registration statement of which this prospectus forms a part, or to contribution with respect to payments which the agents, underwriters or dealers may be required to make.

If so indicated in the prospectus supplement, we will authorize underwriters or other persons acting as our agents to solicit offers by institutions to purchase Securities from us pursuant to contracts providing for payments and delivery on a future date. Institutions with which contracts of this type may be made include commercial and savings banks, insurance companies, pension funds, investment companies, educational and charitable institutions and others, but in all cases those institutions must be approved by us. The obligations of any purchaser under any contract of this type will be subject to the condition that the purchase of the Securities shall not at the time of delivery be prohibited under the laws of the jurisdiction to which the purchaser is subject. The underwriters and other persons acting as our agents will not have any responsibility in respect of the validity or performance of those contracts.

Disclosure in the prospectus supplement of our use of delayed delivery contracts will include the commission that underwriters and agents soliciting purchases of the Securities under delayed contracts will be entitled to receive in addition to the date when we will demand payment and delivery of the Securities under the delayed delivery contracts. These delayed delivery contracts will be subject only to the conditions that we describe in the prospectus supplement.

In connection with the offering of Securities, persons participating in the offering, such as any underwriters, may purchase and sell Securities in the open market. These transactions may include over-allotment and stabilizing transactions and purchases to cover syndicate short positions created in connection with the offering. Stabilizing transactions consist of bids or purchases for the purpose of preventing or retarding a decline in the market price of the Securities, and syndicate short positions involve the sale by underwriters of a greater number of Securities than they are required to purchase from any issuer in the offering. Underwriters also may impose a penalty bid, whereby selling concessions allowed to syndicate members or other broker-dealers in respect of the Securities sold in the offering for their account may be reclaimed by the syndicate if the Securities are repurchased by the syndicate in stabilizing or covering transactions. These activities may stabilize, maintain or otherwise affect the market price of the Securities, which may be higher than the price that might prevail in the open market, and these activities, if commenced, may be discontinued at any time.

**CERTAIN FINANCIAL DATA**

The following table sets forth our historical selected financial information. In June 2011, the Financial Accounting Standards Board issued ASU 2011-5 *Comprehensive Income (Topic 220) – Presentation of Comprehensive Income*, which provides new guidance on the presentation of comprehensive income in financial statements. This guidance revises the manner in which entities present comprehensive income in their financial statements. We adopted this standard for the quarter ended September 30, 2012, and presented net loss and comprehensive loss in a single, continuous statement of operations and comprehensive loss as contained in our quarterly report on Form 10-Q for the period ended September 30, 2012 (filed with the SEC on November 9, 2012). We will continue to use this presentation prospectively in our annual financial statements. The following selected financial information reflects the retrospective application of this guidance for each of the fiscal years ended June 30, 2012, 2011 and 2010. The retrospective application did not have a material impact on our financial condition or results of operations.

**PSIVIDA CORP. AND SUBSIDIARIES**  
**STATEMENTS OF COMPREHENSIVE (LOSS) INCOME**  
(Unaudited, in thousands)

	Year Ended June 30,		
	2012	2011	2010
Net (loss) income	\$(24,835)	\$(8,628)	\$ 8,753
Other comprehensive (loss) income:			
Foreign currency translation adjustments	(492)	919	(1,548)
Net unrealized gain (loss) on marketable securities	5	(11)	(2)
Other comprehensive (loss) income	(487)	908	(1,550)
Comprehensive loss (income)	<u>\$(25,322)</u>	<u>\$(7,720)</u>	<u>\$ 7,203</u>

**DESCRIPTION OF SECURITIES****Common Stock**

For a full description of our common stock, please refer to the documents identified in the section “Incorporation of Certain Information by Reference.”

**Warrants**

We may issue warrants to purchase our common stock or CDIs, each of which represents one share of our common stock. Warrants may be issued independently or together with any other Securities and may be attached to or separate from those Securities. We will issue warrants under warrant agreements to be entered into either between us and the warrant holders directly or between us and a bank or trust company, as warrant agent.

A prospectus supplement will describe the terms of warrants offered thereby, the warrant agreement relating to the warrants and the warrant certificates representing the warrants, including the following:

- the title of the warrants;
- the price or prices at which the warrants will be issued;
- if applicable, the number of warrants issued with common stock or CDIs;
- any date on and after which the warrants and such common stock or CDIs will be separately transferable;

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- the date on which the right to exercise the warrants will commence, and the date on which those rights will expire;
- the maximum or minimum number of warrants that may be exercised at any time;
- information with respect to any book-entry procedures for the registration and transfer of warrants;
- a discussion of any material federal income tax considerations applicable to holding, transferring or exercising warrants; and
- any other terms of the warrants, including terms, procedures and limitations relating to the exercise of the warrants.

Unless we specify otherwise in a prospectus supplement, holders of warrants will not be entitled, by virtue of being such holders, to vote, consent, receive dividends, receive notice as shareholders with respect to any meeting of our shareholders, or to exercise any rights whatsoever as shareholders.

As described in a prospectus supplement, the exercise price payable and the number of shares of common stock or CDIs purchasable upon the exercise of each equity warrant will be adjusted in certain events, including the issuance of a stock dividend to holders of common stock or a stock split, reverse stock split, combination, subdivision or reclassification of common stock. Instead of adjusting the number of shares of common stock or CDIs purchasable upon exercise of each warrant, we may elect to adjust the number of warrants. No fractional shares of common stock or CDIs will be issued upon exercise of warrants, but we will pay the cash value of any fractional shares of common stock or CDIs otherwise issuable. Unless we specify otherwise in a prospectus supplement, in case of any consolidation, merger, or sale or conveyance of our property as an entirety or substantially as an entirety, the holder of each outstanding warrant shall have the right to the kind and amount of shares of stock and other securities and property (including cash) receivable by a holder of the number of shares of common stock or CDIs into which the warrant was exercisable immediately prior to the particular triggering event.

Each warrant will entitle the holder to purchase the principal amount or number of securities at the exercise price as shall in each case be set forth in, or be determinable as set forth in, the applicable prospectus supplement. Warrants may be exercised at any time up to the close of business on the expiration date set forth in the prospectus supplement relating to the warrants offered thereby. After the close of business on the expiration date, unexercised warrants will become void.

We will describe the procedures for exercising warrants in a prospectus supplement. Upon receipt of payment and the warrant certificate properly completed and duly executed at the corporate trust office of the warrant agent or any other office indicated in the applicable prospectus supplement, we will, as soon as practicable, forward the securities purchasable upon that exercise. If less than all of the warrants represented by a particular warrant certificate are exercised, a new warrant certificate will be issued for the remaining warrants.

### **Preferred Stock**

We currently have authorized 5,000,000 shares of preferred stock, par value \$0.001 per share, of which no shares have been designated.

Under Delaware law and our charter, 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 charter, the board of directors may 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.



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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 our common stock, and, if applicable, the conversion price (or how it will be calculated) and conversion period;
- whether the preferred stock will be exchangeable into debt securities, and, if applicable, the exchange price (or how it will be calculated) and exchange period;
- voting rights, if any, of the preferred stock;
- a discussion of any material and/or special U.S. federal income tax considerations applicable to the preferred stock;
- the relative ranking and preferences of the preferred stock as to dividend rights and rights upon liquidation, dissolution, or winding up of our the affairs; 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 our liquidation, dissolution, or winding up.

## **Units**

As specified in the applicable prospectus supplement, we may issue units consisting of one or more warrants, preferred stock, common stock or any combination of such securities. The applicable prospectus supplement will describe:

- the terms of the units and of the warrants, preferred stock and common stock comprising the units, including whether and under what circumstances the securities comprising the units may be traded separately;
- a description of the terms of any unit agreement governing the units; and
- a description of the provisions for the payment, settlement, transfer or exchange of the units.

## LEGAL MATTERS

The validity of the issuance of the common stock underlying the warrants and offered hereby will be passed upon by Ropes & Gray LLP, Boston, Massachusetts.

Some partners of Ropes & Gray LLP are members in RGIP LLC, which owns 14,592 shares of our common stock.

## EXPERTS

The consolidated financial statements incorporated in this Prospectus by reference from the Company's Annual Report on Form 10-K for the year ended June 30, 2012 have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report, which is incorporated herein by reference. 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.

## WHERE YOU CAN FIND ADDITIONAL INFORMATION

As required by the Securities Act, we have filed with the SEC a registration statement on Form S-3, of which this prospectus is a part, with respect to the securities offered hereby. This prospectus does not contain all of the information included in the registration statement. Statements in this prospectus concerning the provisions of any document are not necessarily complete. You should refer to the copies of the documents filed as exhibits to the registration statement or otherwise filed by us with the SEC for a more complete understanding of the matter involved. Each statement concerning these documents is qualified in its entirety by such reference.

We are subject to the information reporting requirements of the Exchange Act, and we comply with those requirements by filing annual, quarterly and current reports, proxy statements and other information with the SEC. Those reports or other information may be inspected without charge at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Information on the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330. Our SEC filings and submissions also are available to the public on the SEC's website at [www.sec.gov](http://www.sec.gov).

## INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

This prospectus is part of a registration statement on Form S-3 filed by us with the SEC. This prospectus does not contain all of the information set forth in the registration statement, certain parts of which are omitted in accordance with the rules and regulations of the SEC. For further information about us and the common stock offered by this prospectus, we refer you to the registration statement and its exhibits and schedules which may be obtained as described above.

The SEC allows us to "incorporate by reference" the information contained in documents that we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus, and information in documents that we file later with the SEC will automatically update and supersede information in this prospectus. We incorporate by reference the documents listed below into this prospectus, and any future filings made by us with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Exchange Act until this offering is completed, including all filings made after the date of the registration statement of which this prospectus forms a part and prior to its effectiveness. We hereby incorporate by reference the documents listed below:

- Our annual report on Form 10-K for the fiscal year ended June 30, 2012 filed with the SEC on September 27, 2012;
- Our quarterly report on Form 10-Q for the quarter ended September 30, 2012 filed with the SEC on November 9, 2012;

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- Our current reports on Form 8-K filed with the SEC on July 18, 2012, July 19, 2012, August 1, 2012, August 2, 2012 and December 18, 2012;
- Our definitive proxy statement on Schedule 14A filed with the SEC on October 25, 2012; and
- The description of our common stock contained in our current report on Form 8-K filed under Rule 12g-3 of the Exchange Act on June 19, 2008, including any amendments or reports filed for the purpose of updating such description.

This prospectus may contain information that updates, modifies or is contrary to information in one or more of the documents incorporated by reference in this prospectus. Reports we file with the SEC after the date of this prospectus may also contain information that updates, modifies or is contrary to information in this prospectus or in documents incorporated by reference in this prospectus. Investors should review these reports as they may disclose a change in our business, prospects, financial condition or other affairs after the date of this prospectus.

Upon your written or oral request, we will provide at no cost to you a copy of any and all of the information that is incorporated by reference in this prospectus.

Requests for such documents should be directed to:

Lori Freedman, Esq.  
Vice President, Corporate Affairs, General Counsel and Secretary  
pSivida Corp.  
400 Pleasant Street  
Watertown, MA 02472  
Telephone: (617) 926-5000

You may also access the documents incorporated by reference in this prospectus through our website [www.psivida.com](http://www.psivida.com). Except for the specific incorporated documents listed above, no information available on or through our website shall be deemed to be incorporated in this prospectus or the registration statement of which it forms a part.

**PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****ITEM 14. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION.**

The following table sets forth the various expenses in connection with the sale and distribution of the securities being registered. All amounts shown are estimates, except the SEC registration fee, and reflect expenses incurred through the date of this registration statement. The registrant has agreed to pay these costs and expenses. The registrant may incur additional, and currently unknown, expenses in connection with the offering in the future.

Securities and Exchange Commission registration fee	\$ 603 (1)
Printing and engraving expenses (including Edgarization)	500 (2)
Legal fees and expenses	20,000 (2)
Accounting fees and expenses	15,000 (2)
Transfer Agent and Registrar fees	5,000 (2)
Miscellaneous	1,000 (2)
Total	<u>\$42,103 (2)</u>

- (1) This amount applies only to the newly registered securities on this Registration Statement. The registrant previously paid a filing fee with respect to \$25,584,400 of the securities being registered on this Registration Statement in connection with Registration Statement Nos. 333-141091 and No. 333-163347.
- (2) Estimated.

**ITEM 15. INDEMNIFICATION OF DIRECTORS AND OFFICERS**

Section 145 of the Delaware General Corporation Law permits, in general, a Delaware corporation to indemnify any person who was or is a party to any proceeding (other than an action by, or in the right of, the corporation) by reason of the fact that he or she is or was a director or officer of the corporation, or served another business enterprise at the request of the corporation, against liability incurred in connection with such proceeding, including the expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with such proceeding, if such person acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the best interests of the corporation and, in criminal actions or proceedings, additionally had no reasonable cause to believe that his or her conduct was unlawful. A Delaware corporation's power to indemnify applies to actions brought by or in the right of the corporation as well, but only to the extent of expenses (including attorneys' fees) actually and reasonably incurred by the person in connection with the defense or settlement of the action or suit, provided that no indemnification shall be provided in such actions in the event of any adjudication of negligence or misconduct in the performance of such person's duties to the corporation, unless a court believes that in light of all the circumstances indemnification should apply. Section 145 of the Delaware General Corporation Law also permits, in general, a Delaware corporation to purchase and maintain insurance on behalf of any person who is or was a director or officer of the corporation, or served another entity at the request of the corporation, against liability incurred by such person in such capacity, whether or not the corporation would have the power to indemnify such person against such liability.

We have entered into indemnification agreements with each of our directors and our executive officers and have obtained insurance covering our directors and officers against losses and insuring us against certain of our obligations to indemnify our directors and officers.

Our Certificate of Incorporation, as amended, provides that we shall indemnify each of our directors and officers, to the maximum extent permitted from time to time by law, against all expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by reason of the fact that he or she is a director or officer.

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This right of indemnification conferred in our Certificate of Incorporation, as amended, is not exclusive of any other right.

In addition, our Certificate of Incorporation, as amended, provides that our directors shall not be liable to the company or its stockholders for monetary damages for breach of fiduciary duty as a director, except to the extent that the exculpation from liability is not permitted under the Delaware General Corporation Law.

These indemnification provisions may be sufficiently broad to permit indemnification of our directors and officers for liabilities (including reimbursement of expenses incurred) arising under the Securities Act.

### **ITEM 16. EXHIBITS**

<u>Exhibit No.</u>	<u>Exhibit Title</u>
5.1(a)	Legal Opinion of Ropes & Gray LLP
23.1	Consent of Ropes & Gray LLP (contained in the opinion filed as Exhibit 5.1 to this Registration Statement)
23.2(a)	Consent of Independent Registered Public Accounting Firm, Deloitte & Touche LLP, dated December 19, 2012
24.1	Power of Attorney (included on the signature page of this Registration Statement)

(a) Filed herewith.

### **ITEM 17. UNDERTAKINGS**

(a) The undersigned registrant hereby undertakes:

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

(i) To include any prospectus required in Section 10(a)(3) of the Securities Act of 1933;

(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 Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 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 Commission by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement; and

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- (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 Commission by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 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 of 1933, 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 of 1933 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
      - (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 of 1933 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.

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- (6) 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.
- (b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) 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) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the provisions described under Item 8 above, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, 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 the City of Watertown, Commonwealth of Massachusetts on the 19th day of December, 2012.

**PSIVIDA CORP.**

By: /s/ Paul Ashton  
Name: Paul Ashton  
Title: President and Chief Executive Officer  
(Principal Executive Officer)

By: /s/ Leonard S. Ross  
Name: Leonard S. Ross  
Title: Vice President, Finance (Principal  
Financial and Accounting Officer)

Each of the undersigned hereby constitutes and appoints each of Paul Ashton, Lori Freedman and Leonard S. Ross, in each case acting singly, as his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, in his name, place and stead, in any and all capacities, to sign any and all amendments, including post-effective amendments, and supplements to this registration statement or any related registration statement that is to be effective upon filing pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that each said attorney-in-fact or agent, or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities indicated as of December 19, 2012.

<u>Name</u>	<u>Title</u>
<u>/s/ Paul Ashton</u> Name: Paul Ashton	President, Chief Executive Officer and Director (Principal Executive Officer)
<u>/s/ David J. Mazzo</u> Name: David J. Mazzo	Chairman of the Board of Directors and Director
<u>/s/ Douglas Godshall</u> Name: Douglas Godshall	Director
<u>/s/ Paul A. Hopper</u> Name: Paul A. Hopper	Director
<u>/s/ Michael W. Rogers</u> Name: Michael W. Rogers	Director
<u>/s/ Peter G. Savas</u> Name: Peter G. Savas	Director
<u>/s/ Leonard S. Ross</u> Name: Leonard S. Ross	Vice President, Finance (Principal Financial and Accounting Officer)



December 19, 2012

pSivida Corp.  
400 Pleasant Street  
Watertown, MA 02472

Re: pSivida Corp.'s Registration Statement on Form S-3

Ladies and Gentlemen:

This opinion is furnished to you in connection with the Registration Statement on Form S-3 (the "Registration Statement"), including the prospectus that is part of the Registration Statement (the "Prospectus"), filed by pSivida Corp., a Delaware corporation (the "Company"), with the Securities and Exchange Commission (the "Commission") on or about December 19, 2012 under the Securities Act of 1933, as amended (the "Securities Act"). The Registration Statement registers up to an aggregate amount of \$30,000,000 of (a) shares of the Company's common stock, \$0.001 par value per share (the "Shelf Common Stock"), (b) shares of the Company's preferred stock, \$0.001 par value per share (the "Shelf Preferred Stock"), (c) warrants to purchase shares of the Shelf Common Stock or CHESSE Depository Interests (the "Shelf Warrants") and/or (d) units consisting of one or more of the Shelf Common Stock, the Shelf Preferred Stock or the Shelf Warrants, or any combination of such securities (the "Units" and collectively with the Shelf Common Stock, the Shelf Preferred Stock and the Shelf Warrants, the "Shelf Securities").

The Shelf Securities are being registered for proposed issuance and sale from time to time pursuant to Rule 415 under the Securities Act, and the Prospectus provides that it will be supplemented in the future by one or more prospectus supplements (each, a "Prospectus Supplement"). The Prospectus, as supplemented by the various Prospectus Supplements, will provide for the issuance and sale by the Company from time to time of the Shelf Securities.

We have acted as counsel to the Company in connection with the Registration Statement. For purposes of this opinion, we have examined such certificates, documents and records and have made such investigation of fact and such examination of law as we have deemed appropriate in order to enable us to render the opinions set forth herein. In conducting such investigation, we have relied, without independent verification, upon certificates of officers of the Company, public officials and other appropriate persons.

The opinions expressed below are limited to the Delaware General Corporation Law.

Based upon the foregoing and subject to the assumptions, qualifications and limitations set forth below, we are of the opinion that:

1. When the issuance and sale of the shares of Shelf Common Stock have been duly authorized by all necessary corporate action of the Company; when such shares have been issued and delivered against payment of the purchase price therefor (in an amount at least equal to the par value) thereof in accordance with the applicable purchase, underwriting or similar agreement,

and as contemplated by the Registration Statement, the Prospectus and the related Prospectus Supplement; and if issued as a component of a Unit or upon the conversion, exchange or exercise of shares of Shelf Preferred Stock or Shelf Warrants, when such shares have been duly issued and delivered as contemplated by the terms of the applicable instrument, certificate of designation or Shelf Warrant, the shares of Shelf Common Stock will be validly issued, fully paid and nonassessable.

2. When the issuance and sale of the shares of Shelf Preferred Stock have been duly authorized by all necessary corporate action of the Company; when an appropriate certificate or certificates of designation relating to one or more series of the Shelf Preferred Stock to be sold under the Registration Statement has or have been duly authorized and adopted and filed with the Secretary of State of Delaware; when such shares have been issued and delivered against payment of the purchase price therefor (in an amount at least equal to the par value thereof) in accordance with the applicable purchase, underwriting or similar agreement and as contemplated by the Registration Statement, the Prospectus and the related Prospectus Supplement; and if issued as a component of a Unit, when such shares have been duly issued and delivered as contemplated by the terms of the applicable instrument, the shares of Shelf Preferred Stock will be validly issued, fully paid and nonassessable.

3. When the terms of the Shelf Warrants and of their issuance and sale have been duly authorized by all necessary corporate action of the Company; when the Shelf Warrants have been duly executed and delivered in accordance with the applicable warrant agreement and against payment of the purchase price therefor in accordance with the applicable purchase, underwriting or similar agreement and as contemplated by the Registration Statement, the Prospectus and the related Prospectus Supplement; and if issued as a component of a Unit, when such Shelf Warrants have been duly executed and issued and delivered as contemplated by the terms of the applicable instrument, the Shelf Warrants will constitute valid and binding obligations of the Company enforceable against the Company in accordance with their terms.

4. When the terms of the Units and of their issuance and sale have been duly authorized by all necessary corporate action of the Company, and when the Units have been duly executed (if applicable) and issued and sold in accordance with the applicable purchase, underwriting or similar agreement and as contemplated by the Registration Statement, the Prospectus and the related Prospectus Supplement, the Units will constitute valid and binding obligations of the Company enforceable against the Company in accordance with their terms.

In rendering the opinions set forth above, we have assumed that (i) the Registration Statement will have become effective under the Securities Act, a Prospectus Supplement will have been prepared and filed with the Commission describing the Shelf Securities offered thereby and such Shelf Securities will have been issued and sold in accordance with the terms of such Prospectus Supplement; (ii) a definitive purchase, underwriting or similar agreement with respect to such Shelf Securities (if applicable) will have been duly authorized, executed and delivered by the Company and the other parties thereto; (iii) the Shelf Securities will be duly authorized by all necessary corporate action by the Company and any other agreement pursuant to which such

Shelf Securities may be issued will be duly authorized, executed and delivered by the Company and the other parties thereto; (iv) the Company is and will remain duly organized, validly existing and in good standing under the laws of its jurisdiction of incorporation; (v) the Company will have reserved a sufficient number of shares of its duly authorized, but unissued, Common Stock and preferred stock, par value \$0.001 per share, as is necessary to provide for the issuance of the shares of Shelf Common Stock and Shelf Preferred Stock pursuant to the Registration Statement; and (vi) all the foregoing actions to be taken by the Company are taken so as not to violate any applicable law and so as to comply with any requirement or restriction imposed by any court or governmental or regulatory body having jurisdiction over the Company or any of its property.

The opinions set forth above are subject to the following exceptions, limitations and qualifications: (i) bankruptcy, insolvency, reorganization, fraudulent conveyance, moratorium or other similar laws now or hereafter in effect or affecting the rights and remedies of creditors; (ii) general principles of equity, including without limitation, concepts of materiality, reasonableness, good faith and fair dealing and the possible unavailability of specific performance or injunctive relief, regardless of whether enforcement is considered in a proceeding in equity or at law, and the discretion of the court before which any proceeding therefore may be brought; (iii) the unenforceability under certain circumstances under law or court decisions of provision providing for the indemnification of, or contribution to, a party with respect to a liability where such indemnification or contribution is contrary to public policy. Our opinions expressed herein are also subject to the qualification that no term or provision shall be included in any Shelf Warrant or any other agreement or instrument pursuant to which any of the Shelf Securities are to be issued that would affect the validity of such opinions.

We hereby consent to your filing this opinion as an exhibit to the Registration Statement and to the use of our name therein and in the Prospectuses under the caption "Legal Matters." In giving such consent we do not thereby admit that we are included in the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations of the Commission thereunder.

It is understood that this opinion is to be used only while the Registration Statement is in effect.

Very truly yours,  
/s/ Ropes & Gray LLP  
Ropes & Gray, LLP

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in this Registration Statement on Form S-3 of our report dated September 27, 2012, relating to the consolidated financial statements of pSivida Corp. appearing in the Annual Report on Form 10-K of pSivida Corp. for the year ended June 30, 2012, and to the reference to us under the heading "Experts" in the Prospectus, which is part of this Registration Statement.

/s/ Deloitte & Touche LLP

Boston, Massachusetts

December 19, 2012