

**PROSPECTUS SUPPLEMENT**  
(To Prospectus dated November 25, 2009)

**2,210,000 Shares of Common Stock**  
**Warrants to Purchase 552,500 Shares of Common Stock**



## **PSIVIDA CORP.**

We are offering 2,210,000 shares of our common stock and warrants to purchase 552,500 shares of our common stock in this offering (and the shares of common stock issuable from time to time upon exercise of these warrants). The common stock and warrants will be sold in units, with each unit consisting of one share of common stock and the equivalent of a warrant to purchase 0.25 of a share of common stock. Each purchaser will receive warrants to purchase a number of whole shares of our common stock equal to 25% of the number of shares of common stock purchased by such purchaser at an exercise price of \$5.00 per share. Each unit will be sold at a negotiated price of \$5.00 per unit. The shares of common stock and warrants will be issued separately but can only be purchased together in this offering.

Units will not be issued or certificated. Our common stock is traded on the NASDAQ Global Market under the symbol "PSDV." On January 14, 2011, the closing price of our common stock was \$5.00 per share.

**Investing in our securities involves a high degree of risk. Before buying any securities, you should read the discussion of material risks of investing in our common stock under the heading "Risk Factors" beginning on page S-4 of this prospectus supplement and the risk factors in the other documents incorporated by reference herein.**

**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 supplement or the accompanying prospectus. Any representation to the contrary is a criminal offense.**

We have retained Rodman & Renshaw, LLC to act as lead placement agent and Ladenburg Thalmann & Co. Inc. to act as co-placement agent in connection with the units offered by this prospectus supplement. We have agreed to pay the placement agents the placement agent fees set forth in the table below, which assumes that we sell all of the units we are offering. The placement agents are not purchasing or selling any of the units we are offering, and they are not required to arrange the purchase or sale of any specific number of units or dollar amount, but they have agreed to use their best efforts to arrange for the sale of the units offered by this prospectus supplement.

	<b>Per Unit</b>	<b>Total</b>
Offering price	\$5.00	\$11,050,000
Placement agent fees <sup>(1)</sup>	\$0.30	\$663,000
Proceeds, before expenses, to us	\$4.70	\$10,387,000

(1) In addition, we have agreed to reimburse the placement agents for certain of their expenses as described under "Plan of Distribution" on page S-19 of this prospectus supplement.

We estimate the expenses of this offering, excluding placement agent fees, will be approximately \$260,000. Because there is no minimum offering amount required as a condition to closing this offering, the actual offering amount, the placement agent fees and net proceeds to us, if any, in this offering may be substantially less than the maximum offering amounts set forth above.

Delivery of the shares is expected to be made on or about January 24, 2011, subject to the satisfaction of certain conditions.

This prospectus supplement supplements and includes the 2,150,00 shares of our common stock and warrants to purchase 537,500 of our common stock contained in our prospectus supplement dated January 18, 2011.

**Rodman & Renshaw, LLC**

**Ladenburg Thalmann & Co. Inc.**

The date of this prospectus supplement is January 19, 2011.

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**ABOUT THIS PROSPECTUS SUPPLEMENT**

This document consists of two parts. The first part is this prospectus supplement, which describes the specific terms of this offering. The second part, the accompanying prospectus, gives more general information, some of which may not apply to this offering. Generally, when we refer only to the “prospectus,” we are referring to both parts combined. This prospectus supplement may add to, update or change information in the accompanying prospectus and the documents incorporated by reference into this prospectus supplement or the accompanying prospectus.

If information in this prospectus supplement is inconsistent with the accompanying prospectus, you should rely on this prospectus supplement. This prospectus supplement, the accompanying prospectus and the documents incorporated into each by reference include important information about us, the shares being offered and other information you should know before investing in our common shares.

You should rely only on this prospectus supplement, the accompanying prospectus and the information incorporated or deemed to be incorporated by reference in this prospectus supplement and the accompanying prospectus. We have not authorized anyone to provide you with information that is in addition to or different from that contained or incorporated by reference in this prospectus supplement and the accompanying prospectus. If anyone provides you with different or inconsistent information, you should not rely on it. We are not offering to sell these securities in any jurisdiction where the offer or sale is not permitted. You should not assume that the information contained or incorporated by reference in this prospectus supplement or the accompanying prospectus is accurate as of any date other than as of the date of this prospectus supplement or the accompanying prospectus, as the case may be, or in the case of the documents incorporated by reference, the date of such documents regardless of the time of delivery of this prospectus supplement and the accompanying prospectus or any sale of our common shares. Our business, financial condition, liquidity, results of operations and prospects may have changed since those dates.

All references in this prospectus supplement or the accompanying prospectus to “pSivida,” the “Company,” “we,” “us,” or “our” mean pSivida Corp., unless we state otherwise or the context otherwise requires.

## SUMMARY

*This summary highlights selected information appearing elsewhere or incorporated by reference in this prospectus supplement and accompanying prospectus and may not contain all of the information that is important to you. This prospectus supplement and the accompanying prospectus include or incorporate by reference information about the shares we are offering as well as information regarding our business and detailed financial data. You should read this prospectus supplement and the accompanying prospectus in their entirety, including the information incorporated by reference.*

### The Company

#### Introduction

We develop tiny, sustained release, drug delivery products that are administered by implantation, injection or insertion. Once administered, a drug is released on a controlled and level basis for months or years. We have two core technology systems, Durasert™ and BioSilicon™. Utilizing three generations of our Durasert technology system, we have one product candidate for chronic eye disease for which an NDA has been filed with the U.S. Food and Drug Administration (“FDA”) and two of the only three products approved by the FDA for the long-term, sustained release delivery of drug to treat chronic eye disease.

Iluvien®, our product candidate under FDA review, is designed to provide sustained release treatment for Diabetic Macula Edema (“DME”). DME is a leading cause of vision loss for people under the age of 65 and has been estimated to affect over 1,000,000 people in the United States. Using the third-generation of our Durasert technology system, Iluvien is injected into the eye and delivers the corticosteroid fluocinolone acetonide (“FA”) over a period of up to 3 years. Iluvien is licensed to Alimera Sciences, Inc (“Alimera”). Under our collaboration agreement with Alimera, Iluvien is also being studied in investigator-sponsored pilot clinical trials designed to assess the safety and efficacy of Iluvien in both wet and dry Age-Related Macular Degeneration and Retinal Vein Occlusion.

Our two FDA-approved products utilize earlier generations of our Durasert technology system, second-generation Retisert® for the treatment of posterior uveitis, and first-generation Vitrasert® for the treatment of AIDS-related cytomegalovirus retinitis. We have licensed both of these products and the technologies underlying them to Bausch & Lomb Incorporated (“Bausch & Lomb”). Retisert provides sustained release treatment for approximately two and a half years, and Vitrasert provides sustained release treatment for six to nine months.

We have a collaboration with Pfizer, Inc. (“Pfizer”), our largest shareholder, for ophthalmic product development. Under our collaborative research and license agreement with Pfizer, we are engaged in joint ophthalmic research utilizing our sustained release drug delivery technologies.

BioSilicon, our other principal technology system, is a fully-erodible, nanostructured, porous silicon designed to provide sustained delivery of various therapeutics, including small drug molecules, proteins and peptides. Based on results of our preliminary studies, we are currently targeting BioSilicon as a key second prong of our drug delivery technology platform.

Durasert™ and BioSilicon™ are our trademarks. Retisert® and Vitrasert® are Bausch & Lomb’s trademarks. Iluvien® is Alimera’s trademark.

#### Recent Developments

Alimera has completed 36-month Phase III clinical trials for Iluvien for DME. Based on analysis of 24-month data released in December 2009, Alimera filed an NDA with the FDA in June 2010 and registration filings in various European countries in July 2010. On August 30, 2010, the FDA granted Priority Review status. In December 2010, the FDA issued a Complete Response Letter (“CRL”) which communicated the FDA’s decision that the NDA for Iluvien for DME could not be approved in its present form. In the CRL, the FDA asked for analyses of safety and efficacy data through month 36, including exploratory analyses in addition to those analyses previously submitted in the NDA, to further assess the relative benefits and risks of Iluvien. Alimera reported that it is preparing analyses of the data through month 36. Alimera further reported that it has requested a meeting with the FDA to clarify the path to regulatory approval. In the CRL, the FDA also requested additional information regarding controls and specifications concerning the manufacturing, packaging and sterilization of Iluvien, which Alimera reported it is in the process of compiling. Additionally, the FDA indicated in the CRL that it had observed deficiencies in current good manufacturing practices (“cGMP”) during facility inspections of two of Alimera’s third-party manufacturers, which were completed in August and September of 2010, and that all facilities and

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controls will need to comply with cGMP. Alimera has reported that its third-party manufacturers are in the process of resolving these deficiencies.

**Risk Factors**

Our business is subject to substantial risk. Please carefully consider the “Risk Factors” beginning on page S-4 of this prospectus supplement and other information included and incorporated by reference in this prospectus supplement, for a discussion of the factors you should consider carefully before deciding to purchase these securities. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. You should be able to bear a complete loss of your investment.

**Corporate Information**

Our principal executive offices are located at 400 Pleasant Street, Watertown, MA, and our phone number is (617) 926-5000.

**The Offering**

Securities we are offering	2,210,000 units. Each unit is comprised of one share of our common stock and the equivalent of a warrant to purchase 0.25 of a share of our common stock. Each purchaser will receive warrants to purchase a number of whole shares of our common stock equal to 25% of the number of shares of common stock purchased by such purchaser. The warrants will be exercisable for five years from the date of issuance at an exercise price of \$5.00 per share of common stock.
Price per unit	\$5.00
Common stock to be outstanding after this offering	20,741,392 shares
Use of proceeds	We intend to use the net proceeds from the sale of the securities covered by this prospectus for general corporate purposes, which may include working capital, research and development expenditures, preclinical and clinical trial expenditures, capital expenditures, commercial expenditures, acquisitions of new technologies or businesses, and investments. See "Use of Proceeds."
NASDAQ Global Market symbol	PSDV
Australian Securities Exchange symbol	PVA

The number of shares of common stock shown above to be outstanding after this offering is based on 18,531,392 shares outstanding as of January 14, 2011 and excludes:

- 2,854,730 shares of our common stock issuable on exercise of options outstanding as of that date, which had a weighted average exercise price of \$2.85 per share at that date;
- 10,281,143 shares of our common stock issuable upon exercise of warrants outstanding as of that date, which have a weighted average exercise price of \$8.10 per share at that date; and
- 552,500 shares issuable on exercise of the warrants offered hereby.

## RISK FACTORS

*Investing in our common stock and warrants involves a high degree of risk. In addition to the risks related to our business set forth in the accompanying prospectus and the other information included and incorporated by reference in this prospectus supplement and accompanying prospectus, you should carefully consider the risks described below before purchasing our common stock. If any of the following risks actually occurs, our business, results of operations and financial condition will likely suffer. As a result, the trading price of our common stock may decline, and you might lose part or all of your investment.*

### RISKS RELATED TO OUR COMPANY AND OUR BUSINESS

***We may be required to seek additional capital in order to fund our operations, and our ability to obtain additional capital is uncertain.***

Our cash, cash equivalents and marketable securities totaled approximately \$15.3 million at September 30, 2010. We believe we can fund our operations as currently conducted into at least calendar year 2012. Receipt of the net proceeds from this offering will extend that date. Whether we will require additional capital will be influenced by many factors, including, but not limited to:

- the timely development and regulatory approval and successful commercialization of Iluvien and receipt of milestone, royalty and other payments;
- the scope and extent of our internally funded operations and programs, any new product candidates and any new business opportunities;
- our ability to establish and maintain strategic arrangements for product candidates for research, development, clinical testing, manufacturing and marketing;
- the success of our products and product candidates, including the timing and costs of regulatory approvals and the commercial success of approved products;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing any patent claims; and
- changes in our operating plan, including the pursuit of any new business opportunities, which may affect our need for capital.

In particular, our future cash position depends significantly on approval of Iluvien by the FDA and foreign regulatory authorities and the initiation and success of marketing of Iluvien. Alimera has agreed to pay us \$25 million upon FDA approval of Iluvien for DME. In addition, we will be entitled to 20% of any future profits, as defined, on sales of Iluvien by Alimera, subject to an offset of 20% of defined pre-profitability commercialization costs incurred by Alimera. In the event Alimera sublicenses commercialization, we would receive 20% of royalties and 33% of non-royalty consideration received by Alimera, less certain permitted deductions. However, there is no assurance that the FDA or other regulatory authorities will approve Iluvien or that Iluvien will achieve market acceptance even if it is approved.

The downturn in the economy and the disruptions in the financial and credit markets have made it significantly more difficult and more expensive to obtain financing. If we determine that it is desirable or necessary to raise additional capital in the future, we do not know if it will be available when needed or on terms favorable to us or our stockholders. If available, additional equity financing may be dilutive to stockholders, debt financing may involve restrictive covenants or other unfavorable terms and potential dilutive equity, and funding through collaboration agreements may be on unfavorable terms, including requiring us to relinquish rights to certain of our technologies or products. If adequate financing is not available if and when needed, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs, postpone the pursuit of product candidates and new business opportunities, or otherwise reduce our cash requirements.

***We have a history of losses and may incur losses in the future.***

With the exception of the fiscal year ended June 30, 2010 ("fiscal 2010"), we have incurred operating losses since our inception in 2000. For fiscal 2010, we recorded net income of \$8.8 million, primarily due to the accelerated payment in full by Alimera of a \$15.0 million conditional note. For fiscal 2009 and fiscal 2008 we incurred net losses of \$2.5 million and \$75.7 million, respectively. We incurred a loss of \$3.1 million in the quarter ended September 30, 2010 and expect to incur losses in the fiscal year ending June 30, 2011 ("fiscal 2011") and for the foreseeable future if Iluvien is not approved and successfully commercialized. Even if Iluvien is approved and marketed, our profit share on sales of Iluvien, combined with

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any royalty income from our current products, and any other sources of revenue, may not be sufficient to result in profitability on an ongoing basis.

***Our results could be adversely affected as a result of the impact of impairment of our intangible assets, which could adversely affect the price of our securities.***

Impairment charges on our intangible assets could have a material effect on our results of operations, which could, in turn, adversely affect the price of our securities. We recorded significant amounts of intangible assets in connection with earlier acquisitions. We took a \$60.1 million impairment charge on goodwill as of June 30, 2008 (which reduced the carrying value of our goodwill to zero), and a \$45.3 million impairment charge on the recorded value of our Durasert intangible asset as of June 30, 2007. We still had \$23.8 million of intangible assets on our balance sheet as of September 30, 2010, of which approximately \$16.2 million related to our BioSilicon technology and approximately \$7.6 million related to our Durasert technology. We do not believe that there has been any change in circumstance that would require us to conduct an impairment analysis of our intangible assets at December 31, 2010 under U.S. generally accepted accounting principles, but we have not completed our financial statements for the quarter and six months then ended, and there can be no assurance that there will not be an impairment in the value of our intangible assets at that date. We will continue to conduct impairment analyses of our intangible assets as required, and may be required to take significant impairment charges in the future.

***Our results could be adversely affected by non-cash charges due to fluctuations in the fair values of certain of our outstanding warrants, which could adversely affect the price of our securities.***

In the fiscal years ended June 30, 2008 and 2007, we issued warrants denominated in Australian dollars (A\$). The fair values of these warrants have been recorded as derivative liabilities on our balance sheet. We are required to assess the fair value of these warrants at each balance sheet date, and changes in their fair values result in adjustments to our recorded derivative liabilities, and corresponding gains or losses in our statements of operations. The fair values of these warrants are sensitive to changes in our share price, among other factors, and are measured using the Black-Scholes valuation model. Fluctuations in the fair values of these warrants could be substantial and will continue to affect our operating results until the last-to-expire of these warrants in July 2012.

***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:

- the timing, receipt and amount of payments, if any, from current and potential future collaboration partners, including, without limitation, collaborative research, milestone and royalty payments, and the revenue recognition policies related thereto;
- changes in accounting estimates, policies or principles;
- the entry into, or termination of, collaboration agreements;
- the scope, duration and effectiveness of our collaboration arrangements;
- the quarterly income or expense amounts recorded from the revaluation of our derivative liabilities;
- the amount of research and development costs, including pre-clinical studies and clinical trials, that we fund internally;
- general and industry-specific adverse economic conditions that may affect, among other things, our and our collaborators' operations and financial results; and
- impairment write-downs of one or more of our intangible assets.

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 a decrease in our stock price.

***Our royalty income from Bausch & Lomb may continue to decline.***

The annual trend of the royalties from Bausch & Lomb for Retisert (including the historical amounts retained by Bausch & Lomb) and Vitrasert has declined and may continue to do so. There is no assurance that Bausch & Lomb will continue to market either or both of these products. We do not expect that our royalty payments from Bausch & Lomb will ever become a material source of revenue for us.

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

***We do not know if the FDA or other regulatory authorities will approve Iluvien for DME. If Alimera is unable to obtain regulatory approval for and successfully commercialize Iluvien, or experiences significant delays in doing so, our business will be materially harmed.***

Alimera will not be able to market Iluvien for DME in the U.S. unless and until it receives FDA approval. Our ability to generate significant revenues from this product depends on the ability of Alimera to obtain regulatory approval for and successfully commercialize Iluvien. Alimera has completed 36 month Phase III clinical trials for the use of Iluvien in the treatment of DME (collectively, the “FAME Study”) and has reported that it is in the process of analyzing the data through month 36. Based on Alimera’s analysis of the month 24 clinical readout of data from the FAME Study (“24 Month Data”), Alimera filed an NDA for approval of the low dose of Iluvien in the United States in June 2010, followed by registration filings in Austria, France, Germany, Italy, Portugal and Spain in July 2010. The FDA accepted Alimera’s submission and granted a Priority Review. The FDA issued a CRL to Alimera in December 2010, which communicated the FDA’s decision that the NDA for Iluvien for DME could not be approved in its present form.

In the CRL, the FDA asked for analyses of safety and efficacy of the clinical readout of data from the FAME Study through month 36 (“36 Month Data”), including certain exploratory analyses in addition to analyses previously submitted in the NDA, to further assess the relative benefits and risks of Iluvien. Alimera reported that it is preparing analyses of the 36 Month Data and that it has requested a meeting with the FDA with respect to the CRL. In the CRL, the FDA requested additional information regarding controls and specifications concerning the manufacturing, packaging and sterilization of Iluvien, which Alimera reports it is in the process of compiling. Additionally, the FDA indicated in the CRL that it had observed deficiencies in cGMP during facility inspections of two of Alimera’s third-party manufacturers, which were completed in August and September of 2010, and that all facilities and controls will need to comply with cGMP. Alimera reports that its third-party manufacturers are in the process of resolving these deficiencies.

In the NDA, Alimera included analyses of the 24 Month Data utilizing the full data set of all 956 patients randomized into Alimera’s FAME Study, with data imputation employed using “last observation carried forward” (“LOCF”) for data missing because of patients who discontinued the trial or were unavailable for follow-up (the “Full Analysis Set”) as well as other data sets including one that excludes from the Full Analysis Set three patients who were enrolled but never treated, excludes data collected for patients subsequent to their use of treatments prohibited by Alimera’s FAME Study protocol and imputes the last observation prior to the protocol violation forward to month 24 using the LOCF method (the “Modified ART Data Set”). Both Alimera and we believed that the FDA would consider the Full Analysis Set the most relevant population for determining the safety and efficacy of Iluvien based on the month 24 data. The primary efficacy endpoint at month 24 was met with statistical significance for both the low dose and the high dose of Iluvien in both trials using the Full Analysis Set. However, Alimera’s FAME Study protocol did not include the Full Analysis Set. The FAME Study protocol provides that the primary assessment of efficacy will be based on the Modified ART Data Set. Statistical significance was not achieved at month 24 for either the low dose or the high dose of Iluvien in one trial using the Modified ART Data Set. Although the CRL requested certain exploratory analyses with respect to the 36 Month Data, it did not specify what data set or sets Alimera should utilize to analyze the 36 Month Data. There is no assurance that the FDA will utilize the Full Analysis Set and not the Modified ART Data Set or another data set in determining whether Iluvien is safe and effective. We do not know whether any analyses of the 36 Month Data will demonstrate to the FDA that Iluvien is safe and efficacious.

In order to obtain approval to market Iluvien for DME in the U.S., Alimera will need to demonstrate to the FDA that Iluvien for DME is safe and efficacious and satisfy the FDA on each of the issues raised in the CRL. There is no assurance that the 36 Month Data or other responses provided by Alimera and its third-party manufacturers will be sufficient to satisfy the FDA. The FDA may not grant marketing approval or it may request additional information from Alimera, including requesting data from additional clinical trials, and ultimately may not grant marketing approval for Iluvien. In addition, Alimera will also require regulatory approvals to sell Iluvien for DME in other countries, and there is no assurance that it will receive those approvals.

If Alimera is not successful in obtaining regulatory approval for and commercializing Iluvien for DME, or is significantly delayed in doing so, our business will be materially harmed. Alimera’s ability to successfully obtain regulatory approval for and commercialize Iluvien will depend on, among other things, its ability to:

- receive marketing approval from the FDA and similar foreign regulatory authorities;
- maintain commercial manufacturing arrangements with third-party manufacturers;
- produce, or have its third-party manufacturers produce, sufficient quantities of Iluvien in a validated process to permit successful commercialization;



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- launch commercial sales of Iluvien; and
- secure acceptance of Iluvien in the medical community and with third-party payors.

Alimera reports that it expects to obtain a regulatory agency waiver from the requirement to perform carcinogenicity studies of Iluvien in animals. Alimera's month 18 readouts from its open-label Phase II human pharmacokinetic clinical trial (the "PK Study") indicated to Alimera that there is negligible systemic absorption of FA in patients being treated with Iluvien. However, Alimera may be unable to demonstrate negligible systemic absorption of FA in its PK Study beyond month 18, or may not obtain a regulatory agency waiver from the requirement to perform carcinogenicity studies of Iluvien in animals regardless. Alimera reports that if it is required to perform carcinogenicity studies of Iluvien in animals, the approval of Iluvien could be delayed by up to 36 months.

***Iluvien utilizes FA, a corticosteroid that has demonstrated undesirable side effects in the eye, and the success of Iluvien, therefore, will be dependent upon achieving an acceptable risk/benefit profile.***

Iluvien utilizes FA, a corticosteroid whose use in the eye has been associated with undesirable side effects such as increased incidence of intraocular pressure (IOP), which may increase the risk of glaucoma and cataract formation. Alimera has performed a full analysis of only the month 24 clinical data from its FAME Study, and the extent of Iluvien's long-term side-effect profile is not yet known. Upon review of Alimera's NDA for the low dose of Iluvien in the treatment of DME as well as the analysis of the 36 Month Data, the FDA may conclude that Alimera's FAME Study did not demonstrate that Iluvien has sufficient levels of efficacy to outweigh the risks associated with its side-effect profile. Conversely, the FDA may conclude that Iluvien's side-effect profile does not demonstrate an acceptable risk/benefit relationship in line with Iluvien's demonstrated efficacy. In the event of such conclusions, Alimera may not receive regulatory approval from the FDA or from similar regulatory agencies in other countries.

***Even if Alimera receives regulatory approval for Iluvien, the FDA and other regulatory agencies may impose limitations on the indicated uses for which Iluvien may be marketed, may subsequently withdraw approval for Iluvien or may take other actions against Iluvien that would be adverse to our business.***

Regulatory agencies generally approve products for particular indications. If any regulatory agency approves Iluvien for a limited indication, the size of the potential market for Iluvien will be reduced. For example, the potential market for Iluvien would be reduced if the FDA limited the indications of use to only those patients who had previously undergone cataract surgery or to those patients diagnosed with particularly severe DME as opposed to all those diagnosed with clinically significant DME.

Additionally, product approvals, once granted, may be withdrawn if problems occur after initial marketing. If and when Iluvien does receive regulatory approval or clearance, the marketing, distribution and manufacture of Iluvien will be subject to regulation by the FDA in the United States and by similar entities in other countries. Alimera will need to comply with facility registration and product listing requirements of the FDA and similar entities in other countries, and will need to adhere to the FDA's Quality System Regulations. Noncompliance with applicable FDA and similar entities' requirements could result in warning letters, fines, injunctions, civil penalties, recall or seizure of Iluvien, total or partial suspension of production, refusal of regulatory agencies to grant approvals, withdrawal of approvals by regulatory agencies or criminal prosecution. Alimera also will need to maintain compliance with federal, state and foreign laws regarding sales incentives, referrals and other programs.

***If we or our licensees are unable to 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 United States and in any other country 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. Generally, in order to obtain these approvals, pre-clinical studies and clinical trials must demonstrate that each of these product candidates is safe for human use and effective for its targeted disease or condition.

Our product candidates, other than Iluvien for DME, are in early stages of development. Product development involves a high degree of risk, and only a small proportion of research and development programs result in an approved product. If clinical trials that may be conducted by us or our licensees for any of our product candidates do not provide the necessary evidence of safety and effectiveness, those product candidates could not be manufactured and sold, and would not generate revenues. Clinical trials initiated by us or our licensees for product candidates may fail or be delayed by many factors, including the following:

- our (or our licensees') lack of sufficient funding to pursue trials rapidly or at all;

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- 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 reach agreement with a licensee to undertake the clinical trials;
- adverse side effects;
- failure of the trials to demonstrate a product's safety or efficacy;
- our (or our licensees') failure to meet FDA or other regulatory agency requirements for 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, or changes in our (or our licensees') relationship with, 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;
- 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; and
- governmental or regulatory delays, or changes in approval policies or regulations.

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.

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 marketing or commercialization partners, or our marketing or commercialization 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 includes 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, Bausch & Lomb and Intrinsiq Materials Cayman Limited. 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

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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;
- 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, limiting the areas of research and development that we can pursue;
- our licensees may develop and commercialize, either alone or with others, products that are similar to or competitive with our products;
- our licensees, consistent with other pharmaceutical and biotechnology companies that have historically acted similarly, may for a variety of reasons 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 financial 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, disagreements over rights or technologies or other proprietary interests may occur.

We have exclusively licensed certain of our controlled drug delivery technologies to Pfizer for certain ophthalmic applications. We have negotiated and continue to negotiate with Pfizer about potential amendments to the agreement, but we cannot predict whether or how that agreement will be amended. Pfizer may terminate the agreement 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 licensed the technology underlying Iluvien for DME and certain ophthalmic applications to Alimera. Alimera has the financial responsibility for the development of Iluvien 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 or to commercialize any or all of the licensed products under their respective agreements, change strategic focus, pursue alternative 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 if approved, Iluvien would be its first 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.

***If our competitors and potential competitors develop products that receive regulatory approval before our product candidates are approved or reach the market prior to our product candidates, are more effective or have fewer side effects than our products or product candidates or are more effectively marketed or cost less, our products or product candidates 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,

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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. 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 cure our targeted diseases or their underlying causes completely, which could reduce demand for our products and product candidates and could render them noncompetitive or obsolete. For example, sales of Vitrasert for the treatment of CMV retinitis, a disease that affects people with late-stage AIDS, declined significantly because of treatments that delay the onset of late-stage AIDS.

Many of our competitors and potential competitors have substantially greater financial, technological, research and development, marketing and personnel resources than us. 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; 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 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 uses of our products for certain disease indications. 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 December 31, 2010, we had 168 patents and 164 pending patent applications, including patents and pending applications covering our Durasert, BioSilicon and CODRUG technologies. 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

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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 Co-operation 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 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 some or all of our key personnel, our business could suffer.***

We are dependent upon the principal members of our management, administrative and scientific staff. In addition, we believe that our future success in developing our products and achieving a competitive position will depend to a large extent on whether we can attract and retain additional qualified management and scientific personnel. There is strong competition for such personnel within the industry in which we operate and we may not be able to continue to attract such personnel either to Massachusetts, where much of our research and development is conducted, or to Malvern in the U.K. As we have a small number of employees and our products are unique and highly specialized, the loss of the services of one or more of the 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.

#### ***The trend towards consolidation in the pharmaceutical and biotechnology industries may adversely affect us.***

There is an ongoing trend of consolidation in the pharmaceutical and biotechnology industries. This consolidation trend could result in the remaining companies having greater financial resources and technological capabilities, thus intensifying competition. This trend could also result in 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 fail to comply with environmental laws and regulations, our 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 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 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 for injury or contamination that results from our use or the use by third parties of these materials, and our liability may exceed our total assets. Compliance with environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development or production efforts or harm our operating results.

***If we encounter problems with product manufacturing, we could experience delays in product development and commercialization, which would adversely affect our future profitability.***

Our ability to conduct timely pre-clinical and clinical research and development programs, obtain regulatory approvals, develop and commercialize our product candidates will depend, in part, upon our and our collaborative partners' 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. 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 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 are a limited number of manufacturers that operate under cGMP regulations that are both capable of manufacturing our products and product candidates and are willing to do so. 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, 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 our own manufacturing facilities or to obtain or retain third-party manufacturing on acceptable terms, we may not be able to conduct certain future pre-clinical and clinical testing or to 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 current reliance on third-party manufacturers entails risks, including:

- the possibility that third parties may not comply with the FDA's cGMP regulations, other regulatory requirements, and those of similar foreign regulatory bodies, and may not employ adequate quality assurance practices;
- supply disruption, deterioration in product quality or breach of a manufacturing or license agreement by the third party because of factors beyond our control;
- the possible termination or non-renewal of a manufacturing or licensing agreement with a third party at a time that is costly or inconvenient to us; and
- our inability to identify or qualify an alternative manufacturer in a timely manner, even if contractually permitted to do so.

Alimera has contracted with third party manufacturers with respect to the manufacture of the components of Iluvien. Our business could be significantly harmed if these third parties are not able to manufacture Iluvien in compliance with cGMP or to satisfy demand for Iluvien and alternative sources are not available. In addition, the materials necessary to produce Iluvien or to formulate the active pharmaceutical ingredient may not be available on commercially reasonable terms, or at all, which could affect the development and commercialization of Iluvien.

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***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 we intend to license products for sale and/or sell products in most major world healthcare markets. A number of risks are inherent in our international strategy. In order for us to license and manufacture our products, we must obtain country and jurisdiction-specific regulatory approvals or clearances to comply with regulations regarding safety and quality. We may not be able to obtain or maintain regulatory approvals or clearances in such countries, and we may be required to incur significant costs in obtaining or maintaining foreign regulatory approvals or clearances. In addition, our operations and 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
- obtaining required governmental approvals.

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

Sales of our products depend 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.

Development and sales of our products and product candidates also heavily 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 (the "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 this new law could significantly reduce payments from Medicare and Medicaid for our products and product candidates over the next 10 years, resulting in potentially significant reductions of our revenues. 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 product candidates, and could adversely affect our business strategy, operations and financial results.

The U.S. Food and Drug Administration Amendment 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.

## 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 CHESSE Depository Interests (CDIs)) may be affected by developments directly affecting our business and by developments out of our control or unrelated to us. 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, operating 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 trial results and other product and technological developments and innovations;
- FDA and other governmental regulatory actions, receipt and timing of approvals of our (and our licensees') product candidates, and any denials and withdrawals 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 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 the royalties payable 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.

### *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 31, 2010, we had outstanding approximately 10.3 million warrants and 2.9 million options to acquire shares of our common stock, or approximately 41.5% of our shares on a fully diluted basis. Certain of the options are subject to performance conditions, and the exercise prices of substantially all of these warrants and a small portion of the stock options were substantially above the market price at that date. The issuance of shares of our common stock upon exercise of our outstanding warrants and stock options would 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. The warrant exercise prices may be adjusted under certain circumstances, including, among others, in the event we issue securities in a rights offering at a lower price than the exercise price.

### *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 10.0% of our outstanding shares as of December 31, 2010 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 have paid penalties pursuant to registration agreements with securities holders relating to resale registration statements, and any requirement to pay such penalties in the future may have a material adverse effect on our financial condition.*

We have registration rights agreements that require us to file and maintain the effectiveness of registration statements for the resale of our common stock, which provide for monetary penalties in the event of our failure to do so. During the year ended June 30, 2007, we paid registration delay penalties of approximately \$2.3 million in connection with our then



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outstanding Sandell convertible promissory note and Absolute subordinated convertible notes. Our failure or inability to maintain the effectiveness of any of our required registration statements or to adequately update information in the related prospectuses may subject us to additional penalties under our current registration rights agreements. Payment of additional penalties may have a material adverse effect on our financial condition and may require us to suspend, curtail or terminate our operations or delay, reduce the scope of or eliminate one or more of our research and development programs, any of which could have a material adverse effect on our business.

***We do not currently intend to pay dividends on our common stock, and any return to investors will 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.

#### NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus supplement, the accompanying prospectus, any free writing prospectus used in connection with this offering and the other documents we have filed with the SEC that are incorporated herein by reference contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. All statements other than statements of historical fact are statements that could be deemed forward-looking statements, including any projections of financing needs, revenue, expenses, earnings or losses from operations, 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 plans and timelines; any statements regarding safety and efficacy of product candidates; any statements of expectation or belief; and any statements of assumptions underlying any of the foregoing. All forward-looking statements attributable to us or to persons acting on our behalf are expressly qualified in their entirety by the cautionary statements and risk factors set forth in Risk factors and elsewhere in this prospectus supplement and set forth in our Form 10-K for the fiscal year ended June 30, 2010 and our Form 10-Q for the fiscal quarter ended September 30, 2010. In addition, forward-looking statements may contain the words “believe,” “anticipate,” “expect,” “estimate,” “intend,” “plan,” “project,” “will be,” “will continue,” “will result,” “seek,” “could,” “may,” “might,” or any variations of such words or other words with similar meanings.

Given these uncertainties, you should not place undue reliance on these forward-looking statements. You should read this prospectus supplement, the accompanying prospectus and the documents that we reference in this prospectus with the understanding that our actual future results may be materially different from what we expect. Except as required by law, we do not undertake any obligation to update or revise any forward-looking statements contained in this prospectus and any supplements to this prospectus, whether as a result of new information, future events or otherwise.

## USE OF PROCEEDS

We estimate that the net proceeds from the sale of the 2,210,000 units offered by this prospectus supplement, after deducting placement agent fees and expenses, will be approximately \$10.1 million, assuming that we sell the maximum number of units we are offering pursuant to this prospectus supplement. Because there is no minimum offering amount required as a condition to the closing of this offering, the actual number of units sold, placement agent fees and proceeds to us are not presently determinable and may be substantially less than the maximum amount set forth above.

We intend to use the net proceeds of this offering for general corporate purposes, which may include working capital, research and development expenditures, pre-clinical and clinical trial expenditures, capital expenditures, commercial expenditures, acquisitions of new technologies or businesses, and investments.

## DILUTION

If you invest in our common stock, you will experience dilution to the extent of the difference between the price per share you pay in this offering and the net tangible book value per share of our common stock immediately after this offering.

Our net tangible book value as of September 30, 2010 was approximately \$7.3 million, or \$0.39 per share of common stock. Net tangible book value per share is equal to our total tangible assets minus total liabilities, all divided by the number of shares of common stock outstanding as of September 30, 2010. After giving effect to the sale of 2,210,000 shares of common stock by us at a price of \$5.00 per share and after deducting our estimated placement agent fees and offering expenses payable by us, our as adjusted net tangible book value would have been approximately \$17.4 million or approximately \$0.84 per share of common stock, as of September 30, 2010. This represents an immediate increase in net tangible book value of approximately \$0.45 per share to existing stockholders and an immediate dilution of approximately \$4.16 per share to new investors. The following table illustrates this calculation on a per share basis:

Offering price for one share of common stock	\$5.00
Net tangible book value per share as of September 30, 2010	\$0.39
Increase per share attributable to the offering	\$0.45
As adjusted net tangible book value per share after this offering	\$0.84
Dilution per share to new investors	\$4.16

The number of shares of common stock shown above to be outstanding after this offering is based on 18,531,392 shares outstanding as of September 30, 2010 and excludes:

- 2,500,320 shares of our common stock issuable on exercise of options outstanding as of that date, which had a weighted average exercise price of \$2.76 per share at that date;
- 10,997,681 shares of our common stock issuable on exercise of warrants outstanding as of that date, which had a weighted average exercise price of \$8.15 per share at that date; and
- 552,500 shares of our common stock issuable on exercise of warrants offered hereby.

Certain of our options and warrants are denominated in Australian dollars. As a result, the weighted average exercise price of our options and warrants is affected by currency translation.

Because there is no minimum offering amount required as a condition to the closing of this offering, the dilution per share to new investors may be more than that indicated above in the event that the actual number of shares sold, if any, is less than the maximum number of shares of our common stock we are offering.

The above illustration of dilution per share to investors participating in this offering assumes no exercise of outstanding options to purchase our common stock or outstanding warrants to purchase shares of our common stock. The exercise of outstanding options and warrants having an exercise price less than the offering price will increase dilution to new investors.

## DESCRIPTION OF SECURITIES

### **Common Stock**

The description of our common stock is 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.

### **Warrants**

The material terms and provisions of the warrants being offered under this prospectus supplement are summarized below. This summary is subject to, and is qualified in its entirety by, the form of warrant, which will be provided to the investors in this offering and will be filed with the SEC as an exhibit to a report on Form 8-K.

The warrants will provide for an exercise price of \$5.00 per share. They will be immediately exercisable upon issuance and will expire five years from the date of their issuance. The exercise price of the warrants will be subject to adjustment in the case of stock splits, stock dividends, share consolidations and similar recapitalization transactions. Unless the original number of warrant shares for which a warrant may be exercised is more than 250,000, the holder will not have the right to exercise any portion of the warrant if the holder, together with its affiliates, would, subject to limited exceptions, beneficially own in excess of 4.99% of the number of our common shares outstanding immediately after the exercise. The holder may elect to change this beneficial ownership limitation from 4.99% to up to 9.99% of the number of our common shares outstanding immediately after the exercise upon not less than 61 days' prior written notice to us.

The holders of warrants must make payment in cash of the exercise price of the shares being acquired upon exercise of the warrants. If, however, we are unable to offer and sell the shares underlying these warrants due to the ineffectiveness of the registration statement of which this prospectus supplement is a part, then the warrants may be exercised on a "net" or "cashless" basis. No fractional common shares will be issued upon the exercise of the warrants.

If, at any time while the warrant is outstanding, we (i) consolidate or merge with or into another corporation, (ii) sell all or substantially all of our assets, or (iii) effect any reclassification of our common shares or any compulsory share exchange pursuant to which our common shares are converted into or exchanged for other securities, cash or property, each, a Fundamental Transaction, then each holder shall have the right thereafter to receive, upon exercise of the warrant, the same amount and kind of securities, cash or property as such holder would have been entitled to receive upon the occurrence of such Fundamental Transaction if it had been, immediately prior to such Fundamental Transaction, the holder of the number of warrant shares then issuable upon exercise of the warrant, or Alternate Consideration. Any successor to us, surviving entity or the corporation purchasing or otherwise acquiring such assets shall assume the obligation to deliver to the holder such Alternate Consideration as the holder may be entitled to purchase, and the other obligations under the warrant.

The warrants will not be listed on any national or foreign trading market.

We intend to enter into an agreement with Computershare Trust Company, N.A. to serve as Warrant Agent.

## PLAN OF DISTRIBUTION

Pursuant to placement agent agreements between us and each of Rodman & Renshaw, LLC and Ladenburg Thalmann & Co. Inc., we have engaged Rodman & Renshaw, LLC as lead placement agent and Ladenburg Thalmann & Co. Inc. as co-placement agent to solicit offers to purchase the units offered by this prospectus supplement. The placement agents are not purchasing or selling any of the units we are offering, and they are not required to arrange the purchase or sale of any specific number of units or dollar amount, but each placement agent has agreed to use its best efforts to arrange for the sale of the units offered by this prospectus supplement.

Each of the placement agents proposes to arrange for the sale of the units we are offering pursuant to this prospectus supplement to one or more investors through a securities purchase agreement directly between the purchasers and us. All of the shares will be sold at the same price and, we expect, at a single closing. We established the price following negotiations with prospective investors and with reference to the prevailing market price of our common stock, recent trends in such price and other factors. It is possible that not all of the units we are offering pursuant to this prospectus supplement will be sold at the closing, in which case our net proceeds would be reduced. We expect that the sale of the units will be completed on the date indicated on the cover page of this prospectus supplement.

In connection with this offering, each of the placement agents may distribute this prospectus supplement and the accompanying prospectus electronically.

We will pay the placement agents an aggregate placement agent fee equal to 6% of the gross proceeds of this offering. Subject to compliance with FINRA Rule 5110(f)(2)(D), we will also reimburse the placement agents for legal and other expenses incurred by them in connection with this offering in an aggregate amount equal to 0.8% of the aggregate offering proceeds but in no event more than \$35,000. The following table shows the per share and total placement agent fees we will pay to the placement agents in connection with the sale of the units, assuming the purchase of all of the units we are offering:

Per unit	\$ 0.30
Total	\$663,000

We estimate the total expenses of this offering which will be payable by us, excluding the placement agent fees, will be approximately \$260,000. After deducting certain fees due to the placement agents and our estimated offering expenses, we expect the net proceeds from this offering to be approximately \$10.1 million.

We have agreed to indemnify each of the placement agents against certain liabilities, including liabilities under the Securities Act of 1933, as amended, and liabilities arising from breaches and representations and warranties contained in each of the placement agent agreements. We have also agreed to contribute to payments each of the placement agents may be required to make in respect of such liabilities.

Each of the placement agent agreements is included as an exhibit to our Current Report on Form 8-K that we will file with the SEC in connection with this offering.

Each of the placement agents has informed us that it will not engage in over-allotment, stabilizing transactions or syndicate covering transactions in connection with this offering.

Each placement agent and its affiliates have provided and may in the future provide certain commercial banking, financial advisory or investment banking services for us for which it has received and may in the future receive fees but there are no current arrangements between us. Each of the placement agents and its affiliates may also from time to time in the future engage in transactions with us and perform services for us in the ordinary course of its business, but there are no current arrangements between us.

## LEGAL MATTERS

The validity of the issuance of the securities offered hereby will be passed upon for us by Ropes & Gray LLP, Boston, Massachusetts. Weinstein Smith LLP, New York, New York is acting as counsel for the placement agents in connection with certain legal matters related to this offering.

## WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and current reports, proxy statements and other information with the SEC. Our SEC filings are available to the public over the Internet at the SEC's website at <http://www.sec.gov>. The SEC's website contains reports, proxy and information statements and other information regarding issuers, such as us, that file electronically with the SEC. You may also read and copy any document we file with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You may also obtain copies of these documents at prescribed rates by writing to the SEC. Please call the SEC at 1-800-SEC-0330 for further information on the operation of its Public Reference Room.

## INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to "incorporate by reference" into this prospectus supplement the information we have filed with the SEC. The information we incorporate by reference into this prospectus supplement is an important part of this prospectus supplement. Any statement in a document we incorporate by reference into this prospectus supplement or the accompanying prospectus will be considered to be modified or superseded to the extent a statement contained in this prospectus supplement or any other subsequently filed document that is incorporated by reference into this prospectus supplement modifies or supersedes that statement. The modified or superseded statement will not be considered to be a part of this prospectus supplement or accompanying prospectus, as applicable, except as modified or superseded.

We incorporate by reference into this prospectus supplement the information contained in the documents listed below, which is considered to be a part of this prospectus supplement:

- our Annual Report on Form 10-K for the fiscal year ended June 30, 2010;
- our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2010;
- our Current Reports on Form 8-K filed with the SEC on December 13, 2010, December 21, 2010, December 28, 2010 and January 19, 2011;
- our Proxy Statement on Schedule 14A filed with the SEC on October 25, 2010; 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.

We also incorporate by reference all documents filed pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this prospectus supplement and prior to the termination of this offering; provided, however, that we are not incorporating any information furnished under Item 2.02 or Item 7.01 of any current report on Form 8-K we may subsequently file.

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Statements made in this prospectus supplement or the accompanying prospectus or in any document incorporated by reference in this prospectus supplement or the accompanying prospectus as to the contents of any contract or other document referred to herein or therein are not necessarily complete, and in each instance reference is made to the copy of such contract or other document filed as an exhibit to the documents incorporated by reference, each such statement being qualified in all material respects by such reference.

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

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

Copies of these filings are also available, without charge, through the "Investor Relations" section of our website ([www. psivida.com](http://www.pside.com)) as soon as reasonably practicable after they are filed electronically with the SEC. The information contained on our website is not a part of this prospectus.



# 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 \$41,997,500 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 November 23, 2009 was US\$4.17.

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

**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 November 25, 2009.**

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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.”

**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 US\$41,997,500. 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 17 of this prospectus.

## THE COMPANY

### Our Business

We develop tiny, sustained release, drug delivery products that are administered by implantation, injection or insertion. Once administered, the drug is released on a controlled and level basis for months or years. We have developed with partners two of the only three products approved by the U.S. Food and Drug Administration (FDA) for the long-term, sustained release delivery of drug to treat chronic back of the eye disease, and a third partnered product is currently in late-stage Phase III clinical trials with a New Drug Application (NDA) filing anticipated in early 2010.

Our Phase III partnered product, which utilizes the third-generation of our Duraser™ technology system, delivers fluocinolone acetonide (FA) for the treatment of diabetic macular edema (DME). DME is a leading cause of vision loss for people under the age of 65 and has been estimated to affect over 1,000,000 people in the United States. Currently there is no FDA-approved drug therapy for the treatment of DME, and the only FDA-approved method for treating DME is laser photocoagulation therapy, which can leave irreversible blind spots. This product candidate, formerly known as Medidur™ FA for DME, is licensed to Alimera Sciences, Inc. (Alimera), which is conducting fully-recruited Phase III clinical trials. Alimera expects that 24-month interim data from these clinical trials will be available in late 2009 and, assuming positive data, plans to file an NDA with the FDA in the second quarter of 2010. Alimera intends to commercialize the product under the name Iluvien®. Under our collaboration agreement with Alimera, investigator-sponsored pilot clinical trials are being conducted that are designed to assess the safety and efficacy of Iluvien in both wet and dry Age-Related Macular Degeneration (AMD) and retinal vein occlusion.

Our two FDA-approved sustained release products to treat chronic back of the eye diseases are our second-generation Retisert® for the treatment of posterior uveitis and our first-generation Vitrasert® for the treatment of AIDS-related cytomegalovirus (CMV) retinitis. We have licensed both of these products and the technologies underlying them to Bausch & Lomb Incorporated (Bausch & Lomb). Retisert provides sustained release for approximately two and a half years, and Vitrasert provides sustained release for six to nine months.

We also have a worldwide collaborative research and license agreement with Pfizer, Inc. (Pfizer) under which Pfizer may develop additional ophthalmic products based on certain of our technologies.

BioSilicon™, our other principal technology system, is a fully-erodible, nanostructured, porous silicon designed to provide sustained delivery of various therapeutics, including small drug molecules, proteins and peptides. Based on our pre-clinical data, we are currently targeting BioSilicon as a second key drug delivery technology.

Our lead BioSilicon product candidate, BrachySil™, delivers therapeutic phosphorus-32 (P32), a radioactive form of phosphorus used to treat cancer, directly to solid tumors. We completed an initial safety and efficacy clinical trial of BrachySil for the treatment of pancreatic cancer and in October 2009 completed a dose-ranging clinical trial for this developmental product.

Except as otherwise indicated, references in this prospectus to “pSivida”, “the Company”, “we”, “us”, “our”, or similar terms refer to pSivida Corp. and its subsidiaries and predecessor.

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**Trademarks**

Medidur™, Durasert™, BioSilicon™, BrachySil™ and CODRUG™ are our trademarks. Retisert® and Vitrasert® are Bausch & Lomb's trademarks. Iluvien® is Alimera's trademark.

**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 may be required to seek additional capital in order to fund our operations, and our ability to obtain additional capital is uncertain.***

Cash and cash equivalents totaled approximately \$6.0 million at September 30, 2009. We believe we can fund our operations as currently conducted through at least December 31, 2010. This expectation is based on certain key assumptions that include (i) Pfizer's continued payment of quarterly research and development funding; (ii) Alimera's continued funding of the development of Iluvien; and (iii) Alimera's continued payment of scheduled conditional note payments. Management has identified contingency plans in the event of a significant shortfall in payments, focused primarily on reduced spending for non-critical activities. Whether and when we will require, or desire to raise, additional capital will depend upon many other factors, including, but not limited to:

- the continuation of our collaborations with Pfizer and Alimera, including their continued funding of our programs and our receipt of applicable milestone, royalty, note and other payments;
- the timely development, regulatory approval and commercialization of Iluvien;
- the scope and extent of our internally funded existing operations and programs, any new product candidates and any new business opportunities;
- the amount and timing of sales of Retisert, which affect the timing of the resumption of Retisert royalty payments and the amounts of such royalty payments;
- our ability to establish and maintain strategic arrangements for BrachySil or any other product candidates for research, development, clinical testing, manufacturing and marketing;
- the success of our products and product candidates, including the timing and costs of regulatory approvals and the commercial success of approved products;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims;
- changes in our operating plan, including the pursuit of new business opportunities, which may affect our need for capital; and
- determination by our board of directors of the appropriate level of capital.

Absent adequate levels of funding from new collaboration agreements and/or financing transactions, management currently believes that our cash position beyond December 31, 2010 will be substantially dependent upon the timing of FDA approval and the initiation and success of marketing of Iluvien, and the resulting occurrence of certain milestone events under the terms of our collaboration agreement with Alimera. Alimera has agreed to pay us \$25.0 million upon FDA approval of Iluvien for DME and a 20% share in the future profits of Iluvien. In addition, the \$15.0 million note issued by Alimera becomes due and payable upon the occurrence of certain defined liquidity events (such as an initial public offering of Alimera) that result in aggregate proceeds to Alimera in excess of \$75 million. There is no assurance that the FDA will approve Iluvien or that Iluvien will achieve market acceptance even if it is approved by the FDA. There is similarly no assurance that a liquidity event resulting in aggregate proceeds to Alimera in excess of \$75 million will occur.

The downturn in the economy and the disruptions in the financial and credit markets have made it significantly more difficult and more expensive to obtain financing. If we determine that it is desirable or necessary to raise additional capital in the future, we do not know if it will be available when needed or on terms favorable to us or our stockholders. If available, additional equity financing may be dilutive to stockholders, debt financing may involve restrictive covenants or other unfavorable terms and potential dilutive equity, and funding through collaboration agreements may be on unfavorable terms, including requiring us to relinquish rights to certain of our technologies or products. If adequate financing is not available if and when needed, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs, postpone the pursuit of product candidates and new business opportunities, or otherwise reduce our cash requirements.

***We have a history of losses, we expect to continue to incur losses and we may never become profitable.***

We have incurred operating losses since our inception in 2000. For the years ended June 30, 2009, 2008 and 2007, we incurred net losses of \$2.5 million, \$75.7 million and \$81.2 million, respectively. As of September 30, 2009, we had an accumulated deficit of \$228.6 million. We expect to continue to incur net losses through at least the fiscal year ending June 30, 2010, and we may incur losses beyond that time if our Iluvien product candidate is not timely approved and successfully commercialized. Even if Iluvien is approved and marketed, our profit share on sales of Iluvien, combined with royalty income from our current products, and any other sources of revenue, may not be sufficient to result in profitability.

***We do not currently derive revenue from Retisert, and there is no assurance that Retisert will ever be a material source of revenue.***

In consideration of a June 2005 royalty advance of \$3.0 million, we agreed that Bausch & Lomb would retain \$6.25 million of future Retisert royalties that otherwise would be payable to us. As of September 30, 2009, an additional \$823,000 of future royalties otherwise payable to us from the sales of Retisert will be retained by Bausch & Lomb before we are entitled to receive any further royalty payments. At June 30, 2007, we decreased our assessment of the probable level of future sales of Retisert as a result of historical sales trends and Bausch & Lomb's decision to withdraw its European application for authorization to market Retisert, resulting in a \$45.3 million impairment charge on the recorded value that had been assigned to the Retisert patents. In addition, the amount of corticosteroid FA delivered by Retisert has been associated with increased incidence of cataract formation and increased intraocular pressure, which side effects we believe may have also negatively affected sales of Retisert. We currently do not expect to record royalty income on sales of Retisert by Bausch & Lomb until at least the fourth quarter of our fiscal year ending June 30, 2010. There is no assurance, however, if we will commence receiving full royalty amounts at that time or at any other time. We also cannot predict the amount of any future royalty payments that we will receive.

***Our results could be adversely affected as a result of the impact of impairment of our intangible assets, which could adversely affect the price of our securities.***

Impairment charges on our intangible assets could have a material effect on our results of operations, which could in turn adversely affect the price of our securities. We have recorded significant amounts of intangible assets in connection with acquisitions. We took a \$60.1 million impairment charge on goodwill as of June 30, 2008 (which reduced the carrying value of our goodwill to zero), and a \$45.3 million impairment charge on the recorded value of our Retisert intangible asset as of June 30, 2007. We still have \$27.3 million of intangible assets on our balance sheet as of September 30, 2009, of which approximately \$18.6 million relates to our BioSilicon technology and approximately \$8.7 million relates to Retisert. We will continue to conduct impairment analyses of our intangible assets as required, and may be required to take significant impairment charges in the future.

***Our results could be adversely affected by non-cash charges due to fluctuations in the fair values of certain of our outstanding warrants, which could adversely affect the price of our securities.***

In connection with certain capital raising transactions during the years ended June 30, 2008 and 2007, we issued detachable warrants denominated in A\$. The fair values of the warrants have been recorded as derivative liabilities on our balance sheet. We are required to assess the fair value of these warrants at each subsequent balance sheet date, and changes in their fair values will result in adjustments to our recorded derivative liabilities, and a corresponding gain or loss on our statement of operations. The fair values of these warrants are sensitive to changes in our share price, among other factors, and are measured using the Black-Scholes valuation model. Fluctuations in the fair values of these warrants could be substantial and could continue to affect our reported operating results until the last-to-expire of these warrants in July 2012.

***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:

- the timing, receipt and amount of payments, if any, from current and potential future collaboration partners and the revenue recognition policies related thereto;
- changes in accounting estimates, policies or principles;
- the entry into, or termination of, collaboration agreements;
- the scope, duration and effectiveness of our collaboration arrangements;

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- the quarterly income or expense amounts recorded from the revaluation of our derivative liabilities;
- the amount of research and development costs, including pre-clinical studies and clinical trials, that are funded internally;
- general and industry-specific adverse economic conditions that may affect, among other things, our and our collaborators' operations and financial results; and
- impairment write-downs of one or more of our intangible assets.

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 a decrease in our stock price.

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

***Certain of our current licensees may terminate their agreements with us at any time, and if they do, we may not be able to effectively develop and sell our products.***

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, at least temporarily, without development, marketing or sales resources, 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, disagreements over rights or technologies or other proprietary interests may occur.

We have exclusively licensed certain of our controlled drug delivery technologies to Pfizer for certain ophthalmic applications. Pfizer is currently funding early stage research and pre-clinical development of potential product candidates under our worldwide collaborative research and license agreement with it. Pfizer may terminate the agreement without penalty at any time and for any reason upon 90 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 licensed the technology underlying Iluvien and certain ophthalmic applications to Alimera. Alimera has the financial responsibility for the development of Iluvien 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 with or commercialize any or all of the licensed products, change strategic focus, pursue alternative technologies or develop competing products. Alimera was incorporated in June 2003 and may have limited resources. 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. 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 Retisert, Iluvien or other potential future product candidates licensed to such entities.

***If we or our licensees 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 United States and in any other country 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 first required. Generally, in order to obtain these approvals, pre-clinical studies and clinical trials must demonstrate that each of these product candidates is safe for human use and effective for its targeted disease or condition. Our product candidates are in various stages of pre-clinical and clinical testing. In particular, Iluvien is in fully-enrolled Phase III clinical trials being conducted by Alimera and BrachySil recently completed a Phase II dose ranging clinical trial. Product development involves a high degree of risk, and only a small number of research and development programs result in an approved product. If clinical trials for any of our product candidates do not provide the necessary evidence of safety and effectiveness, those product candidates cannot be manufactured and sold and will not generate revenue from sales. Clinical trials for our product candidates may fail or be delayed by many factors, including the following:

- 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 reach agreement with a licensee to undertake the clinical trials;
- adverse side effects;
- failure of the trials to demonstrate a product's safety or efficacy;
- our (or our licensees') failure to meet FDA or other regulatory agency requirements for 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, or changes in our relationship, or that of our licensees, with contract research organizations, third-party vendors and investigators responsible for pre-clinical testing and clinical trials;
- our inability to manufacture sufficient quantities of materials for use in clinical trials; and
- governmental or regulatory delays.

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. For example, Iluvien utilizes the corticosteroid FA as its active ingredient, which has been associated with certain undesirable side effects in Retisert. Alimera must demonstrate that Iluvien presents an acceptable risk/benefit profile in order to achieve FDA approval.

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. 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.

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.



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***We have a limited ability to develop and market products ourselves. If we are unable to find marketing or commercialization partners, or our marketing or commercialization 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 will 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 includes 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, Bausch & Lomb and Intrinsiq. The curtailment or termination of any of these arrangements could adversely affect our business, the ability to develop and commercialize our products 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 these decisions. 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;
- 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, limiting the areas of research and development that we can pursue;
- our licensees may develop and commercialize, either alone or with others, products that are similar to or competitive with our products;
- our licensees, consistent with other pharmaceutical and biotechnology companies that have historically acted similarly, may for a variety of reasons 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 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 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 technologies or future products independently in the absence of such agreements.

***If our competitors and potential competitors develop products that receive regulatory approval before our product candidates are approved or reach the market prior to our product candidates, are more effective or have fewer side effects than our products or product candidates or are more effectively marketed or cost less, our products or product candidates 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 the 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. 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 cure our targeted diseases or their underlying causes completely, which could reduce demand for our products and product candidates and could render them noncompetitive or obsolete. For example, sales of Vitraser for the treatment of CMV retinitis, a disease that affects people with late-stage AIDS, have declined significantly because of new treatments that delay the onset of late-stage AIDS.

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Many of our competitors and potential competitors have substantially greater financial, technological, research and development, marketing and personnel resources than us. 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; 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.

### ***Reimbursement of our products by government health administration authorities and other third-party payors could affect market acceptance.***

In both domestic and foreign markets, our ability to commercialize our products successfully depends, in part, upon the availability and extent of reimbursement from third-party payors, such as government health administration authorities, private health insurers and other organizations. Governments and other third-party payors attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for products. Third-party payors may challenge the price and cost-effectiveness of our products. If our products are not considered cost-effective, third-party payors may deny or limit reimbursement. Governments and other third-party payors may refuse to provide coverage for uses of approved products for disease indications for which they have not been granted regulatory approval. If government and third-party payors do not provide adequate coverage and reimbursement levels for uses of our products, the market acceptance of our products would be limited.

There have been a number of U.S. federal and state proposals during the last few years to subject the pricing of pharmaceuticals to government control and to make other changes to the health care system in the U.S. It is uncertain what legislative proposals will be adopted or what actions federal, state or private payors for health care goods and services may take in response to any health care reform proposals or legislation. Similar health care reforms may also be implemented outside of the U.S. We cannot predict the effect health care reforms may have on our business.

## **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 October 31, 2009, we had 156 patents and 195 pending patent applications, including patents and pending applications covering our Durasert, BioSilicon and CODRUG technologies. 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 Co-operation Treaty countries.

Prior art may reduce the scope or protection of, or invalidate, patents. Previously conducted research or published discoveries may prevent 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

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litigation would be likely to result in substantial costs to us and diversion of our efforts. 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 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 require 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 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 some or all of our key personnel, our business could suffer.***

We are dependent upon the principal members of our management, administrative and scientific staff. In addition, we believe that our future success in developing our products and achieving a competitive position will depend to a large extent on whether we can attract and retain additional qualified management and scientific personnel. There is strong competition for such personnel within the industry in which we operate and we may not be able to continue to attract such personnel either to Massachusetts, where much of our research and development is conducted, or to Malvern in the U.K. As we do not have large numbers of employees and our products are unique and highly specialized, the loss of the services of one or more of the 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 involves 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.

#### ***The trend towards consolidation in the pharmaceutical and biotechnology industries may adversely affect us.***

There is an ongoing trend of consolidation in the pharmaceutical and biotechnology industries. This consolidation trend could result in the remaining companies having greater financial resources and technological capabilities, thus intensifying competition. This trend could also result in 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 fail to comply with environmental laws and regulations, our 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 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 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 for injury or contamination that results from our use or the use by third parties of these materials, and our liability may exceed our total assets. Compliance with environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development or production efforts or harm our operating results.

***If we encounter problems with product manufacturing, we could experience delays in product development and commercialization, which would adversely affect our future profitability.***

Our ability to conduct timely pre-clinical and clinical research and development programs, obtain regulatory approvals, develop and commercialize our product candidates and fulfill our contract manufacturing obligations to others will depend, in part, upon our and our collaborative partners' ability to manufacture our products and product candidates, either directly or through third parties, in accordance with FDA and other regulatory requirements. The manufacture and packaging of our products and product candidates are regulated by the FDA and similar foreign regulatory entities and must be conducted in accordance with applicable current good manufacturing practices, or cGMP. There are a limited number of manufacturers that operate under these cGMP regulations which are both capable of manufacturing our products and product candidates and are willing to do so. 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, 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 our own manufacturing facilities or to obtain or retain third-party manufacturing on acceptable terms, we may not be able to conduct certain future pre-clinical and clinical testing or to supply commercial quantities of our products.

We manufacture clinical supplies of Iluvien and certain clinical supplies for Pfizer. BrachySil clinical supplies are manufactured by third parties under contract. We have licensed to Pfizer the exclusive rights to manufacture commercial quantities of ophthalmic products, if approved for marketing, covered by its worldwide collaborative research and license agreement with us. We have licensed to Bausch & Lomb the exclusive rights to manufacture commercial quantities of Vitrasert and Retisert. We have licensed to Alimera the rights to develop, manufacture and commercialize Medidur FA, which Alimera intends to commercialize under the name Iluvien, if approved for marketing, and have licensed to Alimera rights to other products covered by its collaboration agreement with us. Our current reliance on third-party manufacturers entails risks, including:

- the possibility that third parties may not comply with the FDA's cGMP regulations, other regulatory requirements, and those of similar foreign regulatory bodies, and may not employ adequate quality assurance practices;
- supply disruption, deterioration in product quality or breach of a manufacturing or license agreement by the third party because of factors beyond our control;
- the possible termination or non-renewal of a manufacturing or licensing agreement with a third party at a time that is costly or inconvenient to us; and
- our inability to identify or qualify an alternative manufacturer in a timely manner, even if contractually permitted to do so.

We believe that Alimera currently intends to rely on a single manufacturer of Iluvien and a single active pharmaceutical ingredient formulator. Our business could be significantly harmed if these third parties are not able to satisfy demand for Iluvien and alternative sources are not available. In addition, the materials necessary to produce Iluvien or formulate the active pharmaceutical ingredient may not be available on commercially reasonable terms, which could affect the development and commercialization of Iluvien.

***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 in the U.S. and the U.K. BrachySil is produced for us in Germany and the U.K., and BioSilicon is produced in-house and by third party contractors in the U.K. We have research and development facilities in the U.S. and the U.K., and we intend to license products for sale and/or sell products in most major world healthcare markets. A number of risks are inherent in our international strategy. In order for us to license and manufacture our products, we must obtain country and jurisdiction-specific regulatory approvals or clearances to comply with regulations regarding safety and quality. We may not be able to obtain or maintain regulatory approvals or clearances in such countries, and we may be required to incur significant costs in obtaining or maintaining foreign regulatory approvals or clearances. In addition, our operations and revenues may be subject to a number of risks associated with foreign commerce, including the following:

- staffing and managing foreign operations;

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- 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
- obtaining required governmental approvals.

### **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 CHESSE Depository Interests (CDIs)) may be affected by developments directly affecting our business and by developments out of our control or unrelated to us. 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, operating performance. The price of our stock (and CDIs) and their trading volumes may fluctuate based on a number of factors including, but not limited to:

- clinical trial results and other product and technological developments and innovations;
- FDA and other governmental regulatory actions, receipt and timing of approvals of our product candidates, and any denials and withdrawals 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 collaborative partners, including execution 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 the royalties payable 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. As of November 23, 2009, we had approximately 18.3 million shares of common stock outstanding. The average combined daily trading volume in the common stock (and CDIs) on the exchanges in which our common stock are listed was approximately 103,000 shares during the period August to October 2009. Holders of our common stock and CDIs may not be able to liquidate their positions at the desired time or price.

#### ***Exercise of our outstanding warrants and stock options could dilute our outstanding common stock, and our stock price may decline.***

The issuance of shares of our common stock upon exercise of our outstanding warrants and stock options could result in dilution to the interests of other holders of our outstanding common stock and could adversely affect our stock price. As of November 23, 2009, we had outstanding warrants and options to acquire 13,438,056 shares of our common stock, or approximately 42.3% of our shares on a fully diluted basis. The overhang of such warrants and options may also adversely affect our stock price. The warrant exercise prices may be adjusted under certain circumstances, including, among others, in the event we issue securities in a rights offering at a lower price than the exercise 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 10.2% of our outstanding shares as of October 31, 2009 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 have paid penalties pursuant to registration agreements with securities holders relating to resale registration statements, and any requirement to pay such penalties in the future may have a material adverse effect on our financial condition.***

We have registration rights agreements that require us to file and maintain the effectiveness of registration statements for the resale of our common stock, which provide for monetary penalties in the event of our failure to do so. During the year ended June 30, 2007, we paid registration delay penalties of approximately \$2.3 million in connection with our then outstanding Sandell convertible promissory note and Absolute subordinated convertible notes. Our failure or inability to maintain the effectiveness of any of our required registration statements or to adequately update information in the related prospectuses may subject us to additional penalties under our current registration rights agreements. Payment of additional penalties may have a material adverse effect on our financial condition and may require us to suspend, curtail or terminate our operations or delay, reduce the scope of or eliminate one or more of our research and development programs, any of which could have a material adverse effect on our business.

***We do not currently intend to pay dividends on our common stock, and any return to investors will 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 repayment of debt, capital expenditures, acquisitions, and working capital. Pending use, the net proceeds may also be temporarily invested in short-term securities.

Depending on market conditions and our financial needs, we may, from time to time, undertake additional financings. We cannot at this time estimate the amount and timing of such financings, if any.

## 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.

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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.

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.



## 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, which we refer to as “equity warrants.” Equity warrants may be issued independently or together with any other Securities and may be attached to or separate from those Securities. We will issue equity 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 equity warrants offered thereby, the warrant agreement relating to the equity warrants and the equity warrant certificates representing the equity warrants, including the following:

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

Unless we specify otherwise in a prospectus supplement, holders of equity 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 equity warrant, we may elect to adjust the number of equity warrants. No fractional shares of common stock or CDIs will be issued upon exercise of equity 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 equity 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 equity warrant was exercisable immediately prior to the particular triggering event.

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Each equity 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. Equity 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.

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 pSivida Corp. 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;

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- voting rights, if any, of the preferred stock;
- a discussion of any material and/or special U.S. federal income tax considerations applicable to the preferred stock;
- the relative ranking and preferences of the preferred stock as to dividend rights and rights upon liquidation, dissolution, or winding up of the affairs of pSivida Corp.; and
- any material limitations on issuance of any class or series of preferred stock ranking senior to or on a parity with the series of preferred stock as to dividend rights and rights upon liquidation, dissolution, or winding up of pSivida Corp.

### **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 financial statements incorporated in this Prospectus by reference from the Company's Annual Report on Form 10-K 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.

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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 (File No. 000-51122):

- Our annual report on Form 10-K for the fiscal year ended June 30, 2009 filed with the SEC on September 25, 2009;
- Our quarterly report on Form 10-Q for the quarter ended September 30, 2009 filed with the SEC on November 13, 2009;
- Our current report on Form 8-K filed with the SEC on November 25, 2009;
- Our definitive proxy statement on Schedule 14A filed with the SEC on October 13, 2009; 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 of Corporate Affairs and General Counsel  
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.psvida.com](http://www.psvida.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.