PSIVIDA CORP.

FORM 10-K
(Annual Report)

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended June 30, 2012

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number 000-51122

PSIVIDA CORP.

(Exact name of registrant as specified in Its charter)

Delaware	**26-2774444**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
400 Pleasant Street Watertown, MA	**02472**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 926-5000

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Name of each exchange on which registered**
Common Stock, $.001 par value per share	**The NASDAQ Stock Market LLC (NASDAQ Global Market)**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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

Large accelerated filer ☐ Accelerated filer ☐
Nonaccelerated filer ☒ Smaller reporting company ☐
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the common stock held by non-affiliates of the registrant, computed by reference to the closing price of the common stock on the NASDAQ Global Market on December 31, 2011, the last trading day of the registrant's most recently completed second fiscal quarter, was approximately $20,408,000.

There were 23,297,011 shares of the registrant's common stock, $0.001 par value, outstanding as of September 24, 2012.

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant's definitive proxy statement, to be filed in connection with the Annual Meeting of Stockholders to be held on December 14, 2012, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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PART I

Preliminary Note Regarding Forward-Looking Statements

This Form 10-K and our 2012 Annual Report contain 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 Item 1A of this Form 10-K 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, or otherwise.

ITEM 1. BUSINESS

Introduction

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

ILUVIEN. Our most recently approved product, ILUVIEN ®, is an injectable, sustained-release micro-insert delivering the corticosteroid fluocinolone acetonide (FAc) over a period of up to 3 years for the treatment of vision impairment associated with chronic diabetic macular edema (DME) considered insufficiently responsive to available therapies. ILUVIEN is being developed by our licensee Alimera Sciences, Inc. (Alimera).

ILUVIEN has received marketing authorization in the United Kingdom, Austria, France, Germany and Portugal, and marketing authorization is pending in Italy and Spain. The International Diabetes Federation has estimated that approximately 19.1 million people in these seven countries have diabetes, of which Alimera has estimated that approximately 1.1 million suffer from vision loss associated with DME. Alimera has announced its intention to proceed with the direct commercialization of ILUVIEN in Germany, the U.K. and France in 2013.

To date, Alimera has not received marketing approval for ILUVIEN in the U.S. Following receipt of a Complete Response Letter in November 2011 (2011 CRL) from the U.S. Food and Drug Administration (FDA), and based on a meeting with the FDA in June 2012, Alimera has reported that it intends to resubmit its New Drug Application (NDA) for ILUVIEN for DME in early 2013. Alimera further reported that it intends to include additional analysis of the benefits and risks of ILUVIEN based upon the clinical data from its two previously completed pivotal Phase III clinical trials (FAME™ Study) and to focus on the population of patients for which regulatory approval has been granted in the various EU countries.

Product Development . We are pursuing the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye (posterior uveitis) as another indication for the same injectable micro-insert used in ILUVIEN. We did not license this indication to Alimera. The FDA has cleared our Investigational New Drug application (IND), permitting us to move directly to two Phase III trials for this indication without the necessity of first conducting Phase I or Phase II trials. The FDA has agreed that the primary end point in these trials will be recurrence of uveitis within 12 months and that we can reference much of the data, including the clinical safety data, from the clinical trials for ILUVIEN for DME. We plan to enroll a total of approximately 300 patients in our clinical trials and to utilize an inserter with a different design and a smaller gauge needle than the planned commercial inserter for ILUVIEN for DME. Because this micro-insert delivers the same drug as our approved Retisert ® product for posterior uveitis, we expect these trials will show efficacy. Further, as the same micro-insert was used in the ILUVIEN trials, we expect to observe a side-effect profile in uveitis patients comparable to that seen in DME patients. As a result, we are optimistic that this micro-insert will be efficacious for posterior uveitis with a favorable risk/benefit profile and fewer side effects compared to Retisert. An investigator-sponsored Phase I/II study of the safety and efficacy of this micro-insert for the treatment of posterior uveitis is ongoing.

We are also developing a bioerodible, injectable micro-insert delivering latanoprost (the Latanoprost Product) to treat glaucoma and ocular hypertension. An investigator-sponsored Phase I/II dose-escalation study is ongoing to assess the safety and efficacy of this micro-insert in patients with elevated intraocular pressure (IOP). We have granted Pfizer, Inc. an exclusive option under various circumstances to license the worldwide development and commercialization of the Latanoprost Product for the treatment of human ophthalmic disease or conditions other than uveitis.

We are investigating the use of Durasert technology for the treatment of orthopedic diseases.

BioSilicon. The second key technology platform we are targeting is BioSilicon, which uses fully-erodible, nanostructured, porous material for sustained drug delivery. Our primary focus is on Tethadur™, an application of BioSilicon technology designed to provide sustained delivery of large biologic molecules, including proteins, antibodies and peptides. The sizes of the pores in the BioSilicon material are manufactured using nanotechnology to accommodate specific protein, peptide or antibody molecules that are then released on a sustained basis over time as the material bioerodes. Our BioSilicon technology can also be designed to deliver smaller molecules. We are investigating the use of BioSilicon in our Latanoprost Product and the use of Tethadur in other ophthalmic applications.

FDA-Approved Products. Our two FDA-approved products utilize two earlier generations of our Durasert technology system and are surgically implanted. Second-generation Retisert delivers FAc to provide sustained release treatment of posterior uveitis for approximately two and a half years, and first-generation Vitrasert ® delivers ganciclovir to provide sustained release treatment of AIDS-related cytomegalovirus (CMV) retinitis for six to nine months. We licensed both of these products to Bausch & Lomb.

Durasert™, Tethadur™, BioSilicon™ and CODRUG™ are our trademarks. Retisert ® and Vitrasert ® are Bausch & Lomb's trademarks. ILUVIEN ® and FAME™ are Alimera's trademarks. This Annual Report also contains trademarks, trade names and service marks of other companies, which are the property of their respective owners.

Market Overview

Drug Delivery Generally

The therapeutic value of a drug depends on its distribution throughout the body, reaction with the targeted site, reaction with other tissues and organs in the body and clearance from the body. In an ideal treatment, the appropriate amount of drug is delivered to the intended site at an adequate concentration and maintained there for a sufficient period of time without causing adverse effect to other tissues and organs. Accordingly, the manner in which a drug is delivered can be as important to the ultimate therapeutic value of the treatment as the intrinsic properties of the drug itself.

Drugs are typically administered systemically by oral dosing or by injection, and are subsequently dispersed throughout the body via the circulatory system. In many cases, systemic administration does not deliver drugs to the intended site at an adequate concentration for a sufficient period of time or fails to achieve the maximum potential therapeutic benefit.

Because systemically delivered drugs disperse throughout the body, they often must be administered at high dosage levels in order to achieve sufficient concentrations at the intended site. Some areas of the body, such as the eyes, joints, brain and nervous system, have natural barriers that impede the movement of drugs to those areas, requiring the administration of even higher systemic doses. These high dosage levels can cause harmful side effects when the drug interacts with other tissues and organs.

Timely and repeated administration of drugs is often necessary to maintain therapeutic drug levels over an extended period of time. However, patients often fail to take drugs as prescribed or fail to attend follow-up visits and, as a result, they do not receive the potential therapeutic benefit. The risk of patient noncompliance increases if multiple drugs are required, if the dosing regimen is complicated or if the patient is elderly or cognitively impaired.

Due to the drawbacks of traditional systemic drug delivery, the development of methods to deliver drugs to patients in a more precise, controlled fashion over sustained periods of time has become a multi-billion dollar industry. Such methods include oral and injectable controlled-release products and skin patches. These methods seek to improve the consistency of the dosage over time and extend the duration of delivery. However, most of these methods still cannot provide constant, controlled dosage or deliver drugs for a sufficiently long duration. This reduces their effectiveness for diseases that are chronic or require precise dosing. In addition, most of these methods still deliver drugs systemically and, as a result, can still cause adverse side effects throughout the body.

Ophthalmic Drug Delivery

Delivery of drugs to treat back-of-the-eye diseases is a significant issue in ophthalmology. Due to the effectiveness of the blood/eye barrier, it is difficult for systemically administered drugs to reach the eye in sufficient quantities to have a beneficial effect without adverse side effects to other parts of the body. There is a need for drug delivery inside the eye in a manner that is safe, effective and practical for long-term use. While there are currently many approaches to delivering medications to the eye, most do not achieve sufficient and consistent concentrations within the eye for the appropriate period of time.

Injecting drugs in solution directly into the back of the eye can achieve effective, but often transient, drug levels in the eye, requiring repeated injections. Examples include Macugen ® (pegaptanib sodium) and Lucentis ® (ranibizumab), which are injected into the eye as frequently as approximately every four to eight weeks. Apart from inconvenience and cost, repeated intravitreal injections carry risks, including intraocular infection, perforated sclera, vitreous hemorrhage and cataract formation.

Technologies and Products

Our primary technology systems are Durasert and BioSilicon.

Durasert Technology System

ILUVIEN, Retisert and Vitrasert, as well as our glaucoma and posterior uveitis product candidates, use different generations of our proprietary Durasert technology system, which delivers specific quantities of drugs directly to a target site in the body at controlled rates for predetermined periods of time ranging from weeks to years. The Durasert technology system is designed to provide the benefits of direct delivery of appropriate quantities of drug over an extended period, while addressing the drawbacks of systemic drug delivery, including adverse side effects characteristic of high dosing levels and reduced treatment benefits due to variations in drug levels at the target site. The Durasert technology system has three principal attributes designed to deliver these advantages:

- *Localized Delivery* . The Durasert technology system permits drug to be delivered directly at the target site. This administration allows the natural barriers of the body to isolate and assist in maintaining appropriate concentrations of the drug at the target site in an effort to achieve the maximum therapeutic effect of a drug while minimizing unwanted systemic effects.
- *Controlled Release Rate* . The Durasert technology system releases drugs at a constant, controlled rate. We believe that this feature allows our products and product candidates to deliver and maintain optimal drug concentrations at a target site and eliminate variability in dosing over time.
- *Extended Delivery* . The Durasert technology system delivers drugs for predetermined periods of time ranging from days to years. We believe that uninterrupted, sustained delivery offers the opportunity to develop products that reduce the need for repeated applications, eliminate the risk of patient noncompliance and provide more effective treatment.

The Durasert technology system consists of a drug core with one or more surrounding polymer layers. Drug release is controlled by the permeability of the polymer layers. By changing elements of the design, we can control both the rate and duration of release to meet different therapeutic needs. We believe that the Durasert technology system can be used to deliver a wide variety of different drugs.

The portfolio of our Durasert products and product candidates being developed by us alone or in partnership with others includes:

Product	Disease	Stage of Development	Licensee
Vitrasert	CMV Retinitis	FDA-approved; commercialized since 1996	Bausch & Lomb
Retisert	Posterior uveitis	FDA-approved; commercialized since 2005	Bausch & Lomb
ILUVIEN	Diabetic macular edema (DME)	EU-approved (5 countries); Expected resubmission of NDA in the U.S.	Alimera
ILUVIEN	Wet age-related macular degeneration (Wet AMD)	Investigator-sponsored pilot clinical trial	Alimera
ILUVIEN	Dry age-related macular degeneration (Dry AMD)	Investigator-sponsored pilot clinical trial	Alimera
ILUVIEN	Retinal vein occlusion (RVO)	Investigator-sponsored pilot clinical trial	Alimera
TBD	Glaucoma	Investigator-sponsored Phase I/II clinical trial	Option by Pfizer
TBD	Posterior Uveitis	IND cleared by FDA to conduct two Phase III trials	None

ILUVIEN

ILUVIEN, licensed to Alimera, has received marketing approval in five EU countries to treat chronic DME considered insufficiently responsive to available therapies, and Alimera has reported that it intends to focus resubmission of its NDA seeking marketing approval in the U.S. for this indication. DME causes swelling in the macula, the most sensitive part of the retina, and is a leading cause of blindness in most developed countries in the working-age population. The International Diabetes Federation estimated that approximately 19.0 million people have diabetes in the U.K., France, Germany, Austria, Portugal, Italy and Spain, and Alimera estimates that approximately 1.1 million of those people suffer from vision loss associated with DME. In addition, DME has been estimated to affect over 1.0 million people in the United States. ILUVIEN, which is inserted via a 25-gauge, transconjunctival delivery system to the back of the eye in an in-office procedure, is designed to deliver FAc on a sustained basis for up to 36 months. There is currently no sustained release drug treatment for DME in the U.S. or the EU. We are entitled to share in net profits, as defined, on sales of ILUVIEN for DME by Alimera on a country-by-country basis.

Under our agreement with Alimera, ILUVIEN is being studied in three Phase II clinical trials with respect to other chronic eye diseases. One trial is designed to assess the safety and efficacy of ILUVIEN in conjunction with Lucentis in patients with wet AMD to provide information on the potential of ILUVIEN to maintain the efficacy of Lucentis while reducing the overall number of Lucentis treatments. The second trial is designed to assess the safety and efficacy of ILUVIEN in patients with bilateral geographic atrophy secondary to dry AMD. The third trial is designed to assess the safety and efficacy of ILUVIEN in patients with macular edema secondary to RVO.

Development Program for ILUVIEN for the Treatment of DME

Alimera completed the 36-month FAME Study for ILUVIEN involving 956 patients in sites across the United States, Canada, Europe and India to assess the efficacy and safety of ILUVIEN in the treatment of DME. Combined enrollment of the FAME Study was completed in October 2007, the 24-month clinical readout was received in December 2009, and 36-month follow-up was completed in October 2010.

European Union. Alimera received marketing authorization for ILUVIEN in Austria, France, Germany, Portugal and the U.K. for the treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies. These approvals followed a favorable determination of approvability under the EU's Decentralized Procedure (DCP). Italy and Spain also participated in the DCP, and marketing authorization in these countries is pending. As part of the approval process in these countries, Alimera reported it has committed to conduct a five-year, post-authorization, open label registry study of ILUVIEN in patients with chronic DME.

Alimera has reported that in the first half of 2013 it intends to use the Mutual Recognition Procedure (MRP) to pursue marketing authorizations for ILUVIEN for DME in other EU countries, prioritizing its efforts based on the size of the available diabetic population and the anticipated ease or complexity of obtaining adequate pricing and reimbursement. Alimera indicated that its initial targets are likely to be the Netherlands, Belgium, Sweden, Denmark and Finland.

Alimera reported that it plans to launch ILUVIEN in Germany, the United Kingdom and France in 2013, and is pursuing pricing and reimbursement in those countries. In July 2012, Alimera reported that it received a letter from Germany's Federal Joint Committee indicating that the obligation to submit a dossier on ILUVIEN for DME, per the Arzneimittelmarkt-Neuordnungsgesetz law, would not be necessary, and that a benefit assessment would not be required, which allows Alimera to launch ILUVIEN for DME in Germany without price restriction. In August 2012, the U.K.'s National Institute for Health and Clinical Excellence (NICE) issued draft guidance that ILUVIEN is not recommended for the treatment of chronic DME based on the assessment of its Independent Appraisal Committee that Alimera's economic models underestimated the incremental cost-effectiveness ratio, and that the evidence submitted by Alimera did not accurately reflect current clinical practice.

In September 2012, Alimera reported that as part of its comments on the draft guidance, NICE has accepted for review additional data relating to the pseudophakic subgroup of patients with chronic DME (those patients who already had cataract surgery and received an artificial lens when they entered the FAME Study). Alimera reported that it determined that ILUVIEN was more cost-effective in this subgroup because patients with artificial lenses cannot develop another cataract in the treated eyes and therefore cannot experience a transient reduction in visual acuity as the result of cataract development nor incur the costs associated with cataract surgery. NICE has not yet issued final guidance to the U.K. National Health Service, and its draft recommendations may change. NICE has reported that final guidance is likely to be published in November 2012.

Alimera reported that it plans to launch ILUVIEN for DME on its own in Germany during the first quarter of 2013 and in the U.K. and France later in 2013. Alimera further reported that it has agreements for a $40.0 million equity financing, subject to certain closing conditions, including the approval of the holders of a majority of the outstanding shares of common stock of Alimera, to provide capital to launch ILUVIEN in the EU. Stockholders holding approximately 56% of Alimera's common stock as of July 17, 2012 were reported as having agreed to vote their shares in favor of the financing transaction.

United States. In June 2010, Alimera submitted an NDA for ILUVIEN in the U.S., largely based on analyses of clinical data through month 24 of the FAME Study. In December 2010, Alimera received a Complete Response Letter (2010 CRL) in which the FDA communicated its decision that the ILUVIEN NDA could not be approved in its current form. In the 2010 CRL, the FDA asked for analyses of safety and efficacy data through month 36 of the FAME Study, including exploratory analyses in addition to those previously submitted in the NDA, to further assess the relative benefits and risks of ILUVIEN. In May 2011, Alimera submitted its response to the 2010 CRL to the FDA, including additional safety and efficacy data through month 36 of the FAME Study. Additionally, Alimera reported analyses of data from the FAME Study for the subgroup of patients who had been diagnosed with DME for three or more years at entry of the FAME Study.

In November 2011, the FDA issued the 2011 CRL to communicate that the resubmitted NDA could not be approved in its current form, stating that the NDA did not provide sufficient data to support that ILUVIEN is safe and effective in the treatment of patients with DME. The FDA stated that the risks of adverse reactions shown for ILUVIEN in the FAME Study were significant and were not offset by the benefits demonstrated by ILUVIEN in these clinical trials. The FDA further indicated that Alimera would need to conduct two additional clinical trials to demonstrate that the product is safe and effective for the proposed indication. Alimera reported that in June 2012 it met with the FDA to gain a better understanding of the regulatory path for ILUVIEN in the U.S. and, based on that meeting, it plans to resubmit its NDA for ILUVIEN for DME in early 2013. Alimera reported that it intends to include additional analysis of the benefits and risks of ILUVIEN based upon clinical data from the FAME Study and to focus on the population of patients with chronic DME considered insufficiently responsive to available therapies, the same indication for which regulatory approval has been granted in various EU countries. The resubmission is expected to address the issues raised in the 2011 CRL and in Alimera's June 2012 meeting with the FDA. Alimera also reported that it expects to continue enrollment of patients in the physician utilization study, suspended after issuance of the 2011 CRL, that is evaluating the safety and utility of the commercial version of the inserter for ILUVIEN in a targeted 100 patient eyes. Results of this study will be required for any approval of ILUVIEN for DME in the U.S.

Retisert for Posterior Uveitis

Retisert is approved in the U.S. for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye, an autoimmune condition characterized by inflammation of the posterior of the eye that can cause sudden or gradual vision loss. Retisert is surgically implanted through a 3-4 mm incision and delivers sustained levels of FAc for approximately 30 months. Retisert was approved as an orphan drug in 2005, which provided for seven-year exclusive marketing rights. Retisert is licensed to Bausch & Lomb, which sells the product in the U.S and pays sales-based royalties to us.

Vitrasert for CMV Retinitis

Vitrasert is approved in the U.S. and the EU for the treatment of CMV retinitis, a blinding eye disease that occurs in individuals with advanced AIDS. Vitrasert, which is surgically implanted through a 5-6 mm incision, provides sustained treatment for six to eight months through the intravitreal delivery of the anti-viral drug ganciclovir. Studies have shown that Vitrasert is one of the most effective approved treatments for CMV retinitis. Vitrasert has been sold since 1996, first by Chiron Corporation and subsequently by Bausch & Lomb. Although CMV retinitis was relatively common in AIDS patients in the early 1990s, improvements in the treatment of AIDS/HIV have since significantly decreased the incidence of the disease in more developed countries. Accordingly, sales of Vitrasert, and associated royalty income to us, are not material.

Other Durasert Product Candidates

Posterior Uveitis Product Candidate

We are pursuing the use of the same micro-insert used in ILUVIEN for the treatment of posterior uveitis, the same indication for which Retisert is approved. We did not license Alimera the right to use our technology, including this micro-insert, for development of a product to treat uveitis. In the U.S., posterior uveitis affects approximately 175,000 people and is responsible for approximately 30,000 cases of blindness, making it the third largest cause of blindness.

The FDA has cleared our IND for this indication, permitting us to move directly to two Phase III trials, with a primary endpoint of recurrence of uveitis within 12 months, without the necessity to first conduct Phase I or Phase II trials. We currently plan to enroll a total of approximately 300 patients and to utilize an inserter with a different design and a smaller gauge needle than the commercial inserter to be used by Alimera for ILUVIEN for DME in the EU. The FDA will permit us to reference much of the data, including clinical safety data, from the ILUVIEN NDA for DME. Because this micro-insert delivers the same drug as our approved Retisert product for posterior uveitis, we expect these trials will show efficacy. Further, as the same micro-insert was used in the ILUVIEN trials, we expect to observe a comparable side-effect profile in posterior uveitis patients as was seen in DME patients. As a result, we are optimistic that this micro-insert will be efficacious for posterior uveitis with a favorable risk/benefit profile and fewer side effects compared to Retisert.

An investigator-sponsored Phase I/II dose-ranging study of the safety and efficacy of this micro-insert for the treatment of posterior uveitis is ongoing. To date, three out of a projected six patients have been enrolled in this study.

Glaucoma Latanoprost Product Candidate.

In connection with our June 2011 amended Pfizer collaboration, we are developing an injectable, bioerodible drug delivery micro-insert for the treatment of glaucoma and ocular hypertension. The Latanoprost Product is designed to provide long-term, sustained delivery of latanoprost, currently the most commonly prescribed agent for the reduction of IOP in patients with ocular hypertension and glaucoma worldwide. This product candidate is based on a fourth generation of our Durasert technology system. The micro-insert is designed to be injected under the conjunctiva into the sclera by an eye care professional in a minimally invasive, outpatient procedure. This product is subject to an option by Pfizer described below under “Strategic Collaborations—Pfizer”.

This Durasert implant is being evaluated in an investigator-sponsored Phase I/II dose-escalating study designed to assess the safety and efficacy of the implant in patients with elevated IOP. We are currently developing a prototype of this implant that contains BioSilicon to assist in the delivery of latanoprost. A pre-clinical study is ongoing to evaluate the new prototype design. If successful, we plan to advance the new prototype into a multi-center Phase II trial.

BioSilicon Technology System

Our BioSilicon technology system utilizes a fully-erodible, "honeycomb" structure of nano-porous, elemental silicon to provide sustained delivery of therapeutics. BioSilicon is biocompatible and biodegradable. Our primary focus is on Tethadur, an application of BioSilicon technology designed to provide sustained delivery of large biologic molecules, including peptides and proteins. In this application, the sizes of the pores in the BioSilicon material are manufactured using nanotechnology to accommodate specific protein, peptide or antibody molecules, which are then released on a sustained basis over time as the material bioerodes. Our BioSilicon technology can also be designed to deliver smaller molecules. Based on results of our preliminary studies, we are currently targeting the BioSilicon technology as a key second prong of our drug delivery technology platform.

Evaluation Agreements

We have evaluation agreements with various companies to evaluate our Durasert and BioSilicon technology systems for the treatment of various ophthalmic and other diseases. In addition, Hospital for Special Surgery is evaluating our Durasert technology for the treatment of orthopedic diseases.

Strategic Collaborations

We have entered into a number of collaboration/license agreements to develop and commercialize our product candidates and technologies. In all of our collaboration agreements, we retain the right to use and develop the underlying technologies outside of the scope of the exclusive licenses granted.

Alimera

In February 2005, we granted Alimera an exclusive worldwide license to manufacture, develop, market and sell ILUVIEN for the treatment and prevention of eye diseases in humans other than uveitis. We also granted Alimera a worldwide non-exclusive license to manufacture, develop, market and sell certain additional Durasert-based products (1) to deliver a corticosteroid and no other active ingredient by a direct delivery method to the back of the eye or (2) to treat DME by delivering a compound by a direct delivery method through an incision no smaller than that required for a 25-gauge or larger needle, in each case solely for the treatment and prevention of eye diseases in humans other than uveitis. The non-exclusive license is limited to those products that (i) are not an implant required to be surgically inserted through an incision of at least 2 mm in the scelera into the vitreous, are secured in the posterior of the eye, cannot be injected, and use a certain reservoir design, (ii) have a drug core within a polymer layer (with certain limitations regarding chemically bonded combinations of active agents), and (iii) are approved, or designed to be approved, to deliver a corticosteroid and no other active ingredient by a direct delivery method to the posterior portion of the eye, or to treat DME by delivering a compound by a direct delivery method through an incision required for a 25-gauge or larger needle. With the exception of licenses earlier granted to Bausch & Lomb, during the term of the collaboration agreement, we are not permitted to use, or grant a license to any third party to use, the licensed technologies to make or sell any products that are or would be (but for delivering a corticosteroid in combination with another active ingredient) subject to the non-exclusive license granted to Alimera.

Under the collaboration agreement, we and Alimera agreed to collaborate on the development of ILUVIEN for DME and to share the development expenses equally. In connection with a March 2008 amendment of the collaboration agreement, we received $12.0 million in cash and a $15.0 million conditional note (paid in full in April 2010), and Alimera cancelled $5.7 million of accrued development costs, penalties and accrued interest that we owed Alimera at that date. In addition, Alimera agreed to pay us a $25.0 million milestone payment upon the first product to be approved by the FDA under the collaboration agreement and assumed all financial responsibility for the development of licensed products (including reimbursement of approved development costs incurred by us in support of the ongoing clinical studies of ILUVIEN) and regulatory submissions. In exchange, we decreased our share in any net profits, as defined, on sales of ILUVIEN by Alimera on a country-by-country

basis from 50% to 20%, subject to an offset of 20% of net losses, as defined, previously incurred by Alimera on a country-by-country basis. If Alimera sublicenses commercialization, we are entitled to receive 20% of royalties and 33% of non-royalty consideration received by Alimera, less certain permitted deductions.

Either party may terminate the collaboration agreement for the other party's uncured material breach under various conditions and upon various bankruptcy events. We may terminate the collaboration agreement with respect to a particular product if Alimera notifies us that it is abandoning or has abandoned such product, in which case the agreement provides for specific, exclusive remedies.

Pfizer

In April 2007, we entered into an exclusive worldwide Collaborative Research and License Agreement (the Original Pfizer Agreement) with Pfizer for the use of certain of our technologies in ophthalmic applications that were not licensed to others. Under this agreement, we engaged in a joint research program, and Pfizer had an exclusive license to market any products developed under the agreement.

In June 2011, we entered into an Amended and Restated Collaborative Research and License Agreement (the Restated Pfizer Agreement) to focus solely on the development of a sustained release bioerodible implant designed to deliver latanoprost by subconjunctival injection. Under the Restated Pfizer Agreement, we granted Pfizer an exclusive option under various circumstances to a license to develop and commercialize worldwide the Latanoprost Product for human ophthalmic disease or conditions other than uveitis. We are eligible to receive future consideration of up to $166.5 million plus royalties, we regained all rights to our intellectual property in ophthalmic applications previously included in the Original Pfizer Agreement other than pursuant to the Restated Pfizer Agreement, and we have rights to develop and commercialize the Latanoprost Product if Pfizer does not exercise its option.

Under the Restated Pfizer Agreement, Pfizer paid us $2.3 million in cash as an upfront payment, and we agreed to use commercially reasonable efforts to develop the Latanoprost Product at our expense, and with technical assistance from Pfizer, for at least one year and thereafter, at our option, through completion of Phase II clinical trials, as defined. An investigator-sponsored Phase I/II dose-escalation study is ongoing to assess the safety and efficacy of this insert. Upon completion of Phase II clinical trials, Pfizer has the option to acquire, upon payment of $20 million, an exclusive, worldwide license to develop and commercialize the Latanoprost Product for ophthalmic disease in humans other than uveitis. If Pfizer exercises its option, it must use commercially reasonable efforts at its expense to develop and commercialize the Latanoprost Product, and we are eligible to receive development, regulatory and commercial milestone payments that could total up to $146.5 million and double-digit royalties based on net sales of the Latanoprost Product. If Pfizer does not exercise this option, we will have the right to develop and commercialize the Latanoprost Product on our own or with a partner, with rights to Pfizer intellectual property necessary to develop and commercialize the Latanoprost Product. If we elect to cease development of the Latanoprost Product prior to completion of Phase II clinical trials, Pfizer also has an option to acquire, upon payment of a lesser option fee, an exclusive, worldwide license to develop and commercialize the Latanoprost Product for ophthalmic disease in humans other than uveitis at its expense. In this case, Pfizer must also use commercially reasonable efforts to develop and commercialize the Latanoprost Product, and we are eligible to receive lesser development, regulatory and commercial milestone payments and a lower royalty on net sales of the Latanoprost Product. If Pfizer does not exercise this option, we will have the right to develop and commercialize the Latanoprost Product on our own or with a partner, with rights to Pfizer intellectual property necessary to develop and commercialize the Latanaprost Product, following a one-year cessation of development activities.

Either Pfizer or we may terminate the Restated Pfizer Agreement for various reasons, including in the event of a material breach of this agreement that is not cured within the applicable cure period or if the other party enters into bankruptcy or similar proceedings. Pfizer may terminate this agreement at its sole discretion on 60 days' notice. In the event Pfizer terminates in its discretion on 60 days' notice or we terminate for Pfizer's material breach, we have the right to develop and commercialize the Latanoprost Product.

The Restated Pfizer Agreement replaces all of the rights and obligations under the Original Pfizer Agreement, except for confidentiality and indemnification provisions.

Pfizer owns approximately 8.0% of pSivida's total shares outstanding as of August 31, 2012.

Bausch & Lomb

Retisert was developed and commercialized under a 2003 amended licensing agreement with Bausch & Lomb, and Vitrasert was developed and commercialized under a 1992 agreement with Chiron Vision, which was subsequently acquired by Bausch & Lomb.

Bausch & Lomb has a worldwide exclusive license to make and sell Vitrasert and our first-generation products (as defined in the agreement, including the Retisert device) in return for royalties based on sales. We agreed with Bausch & Lomb not to develop, license or commercialize a product designed to receive regulatory approval to treat uveitis, but only for so long as Bausch & Lomb is actively commercializing a product the net sales of which bear the base royalty payable to us that is not subject to any royalty reduction or offset and Bausch & Lomb has not developed or commercialized a uveitis product that does not bear such royalties. Bausch & Lomb can terminate its agreement with us without penalty at any time upon 90 days' written notice.

Intrinsiq

In January 2008, we granted an exclusive field-of-use license to Intrinsiq Materials Cayman Limited (Intrinsiq) for the development and commercialization of nutraceutical and food science applications of BioSilicon, under which we received aggregate license fee and minimum royalty payments of $1.7 million through June 2011. In February 2009, we entered into a 2-year supply agreement with Intrinsiq under which we leased certain equipment to Intrinsiq for their use in manufacturing BioSilicon material for total payments of $122,000. In July 2011, we purchased BioSilicon-related capital equipment and intellectual property assets of Intrinsiq for $223,000, and assumed four Intrinsiq employees. In connection with this asset purchase agreement, Intrinsiq terminated its field-of-use license agreement.

Research and Development

Our clinical and pre-clinical research programs primarily consist of ophthalmic applications of our technology systems. Our research and development expenses were $7.0 million in the year ended June 30, 2012 (fiscal 2012), $6.9 million in the year ended June 30, 2011 (fiscal 2011) and $7.0 million in the year ended June 30, 2010 (fiscal 2010). Of these amounts, $4.2 million in fiscal 2012, $3.2 million in fiscal 2011 and $3.4 million in fiscal 2010 were incurred for costs of research and development personnel, clinical and pre-clinical studies, contract services, testing and laboratory facilities. Fiscal 2011 costs were reduced by a one-time IRS grant award of $208,000. All such costs were charged to operations as incurred. The remaining expense of $2.8 million in fiscal 2012, $3.7 million in fiscal 2011 and $3.6 million in fiscal 2010 consisted of non-cash charges for amortization of intangible assets, depreciation of property, plant and equipment and stock-based compensation expense specifically allocated to research and development personnel. In addition, during fiscal 2012 we recorded a $14.8 million intangible asset impairment write-down, which is classified as a separate category of operating expenses in the accompanying consolidated statement of operations.

Intellectual Property

Our intellectual property rights are crucial to our business. We hold or are licensed patents relating to our core technology systems in the United States and international markets. The following table provides general

details relating to our owned and licensed patents (including both patents that have been issued and applications that have been accepted for issuance) and patent applications as of August 31, 2012:

Technology	United States Patents	United States Applications	Foreign Patents	Foreign Applications	Patent Families
Durasert	9	13	75	64	18
Tethadur	4	4	7	10	3
BioSilicon	12	9	61	26	24
CODRUG	3	5	18	3	9
Other	3	1	7	1	4
Total	31	32	168	104	58

Employees

We had 29 employees as of August 31, 2012. None of our employees is covered by a collective bargaining agreement.

Sales and Marketing

We have no marketing or sales staff. We depend on collaborative partners to market our products. Significant additional expenditures would be required for us to develop an independent sales and marketing organization.

Reimbursement

The successful commercialization of our current products depends, and of any future products will depend, in significant part on the extent to which reimbursement of the cost of the products and the related administration procedures will be available from government health administration authorities, private health insurers and other organizations. Medicaid and Medicare, most major health maintenance organizations and most health insurance carriers reimburse $4,240 for the cost of the Vitrasert implant, with associated surgical fees reimbursed separately. The Centers for Medicare and Medicaid Services designated Retisert as eligible for Medicare reimbursement at the rate of $19,345, with associated surgical fees reimbursed separately. Alimera reported that it is pursuing pricing and reimbursement discussions in certain EU countries for which marketing authorization of ILUVIEN has been received.

Competition

The market for products treating back-of-the-eye diseases is highly competitive and is characterized by extensive research efforts and rapid technological progress. We face substantial competition for our products and product candidates. Pharmaceutical, drug delivery and biotechnology companies, as well as research organizations, governmental entities, universities, hospitals, other nonprofit organizations and individual scientists, have developed and are seeking to develop drugs, therapies and novel delivery methods to treat our targeted diseases. Most of our competitors and potential competitors are larger, better established and more experienced and have substantially more resources than us or Alimera. Competitors may reach the market earlier than us or Alimera, may have obtained or could obtain patent protection that dominates or adversely affects our products and potential products, and may offer products with greater efficacy, lesser side effects and/or other competitive advantages. We believe that competition for treatments of back-of-the-eye diseases is based upon the effectiveness of the treatment, side effects, time to market, reimbursement and price, reliability, availability, patent position, and other factors.

Many companies have or are pursuing products to treat back-of-the-eye diseases, which are or would be competitive with our products and product candidates. Some of these include the following:

- *DME, AMD, RVO, etc.* Genentech Inc.'s products Lucentis ® (ranibizumab) and Avastin ® (bevacizumab) block isoforms of vascular endothelial growth factor (VEGF). Both products are injected directly into the vitreous on a recurring basis. Lucentis is currently approved in the U.S. and the EU for the treatment of DME, neovascular wet AMD and macular edema following RVO. The relatively low-cost Avastin is approved to treat various cancers, but is used off-label for treatment of wet AMD and diabetic retinopathy. Studies are ongoing on the use of Avastin in back-of-the-eye diseases. Novartis has the right to market and sell Lucentis outside of the U.S. Regeneron Pharmaceuticals, Inc.'s product EYLEA ® is approved in the U.S. and Australia for the treatment of wet AMD, marketing applications have been submitted in the EU and other countries and a Phase III clinical study for wet AMD has commenced in China. EYLEA, like Lucentis and Avastin, is injected directly into the vitreous on a regular basis. Phase III clinical trials of EYLEA for DME are underway. Regeneron maintains exclusive rights to EYLEA in the U.S., and Bayer HealthCare owns the exclusive marketing rights outside the United States. Other companies, including Genentech, are working on the development of product candidates and extended delivery devices for the potential treatment of DME, wet AMD and RVO, including those that act by blocking VEGF and VEGF receptors, as well as use of small interfering ribonucleic acids (siRNAs) that modulate gene expression. For example, in January 2012, Genentech submitted an IND for an extended delivery device to deliver Lucentis. Eyetech, Inc.'s product Macugen (pegaptanib sodium injection) is an anti-VEGF aptamer against VEGF 165. It has been approved in the U.S. for treatment of all subtypes of choroidal neovascularization in patients with AMD.
- *Posterior Uveitis.* Periocular steroid injections and systemic delivery of corticosteroids are used to treat posterior uveitis. Allergan, Inc.'s product Ozurdex ® (dexamethasone intraveal implant) is a bioerodible, extended release intravitreal implant that delivers the corticosteroid dexamethasone. Ozurdex is approved for posterior uveitis and macular edema following branch or central RVO, and has a duration of therapy of three to five months. In addition, Allergan's product Trivaris™ (triamcinolone acetonide injectable suspension) is approved for uveitis and other inflammatory conditions unresponsive to topical corticosteroids. Many companies have ongoing trials of posterior uveitis treatments, including Abbott Laboratories' Humera ® (adalimumab), Santen Pharmaceutical Co. Ltd's sirolimus drug DE-109, Novartis' AIN457, Lux Biosciences, Inc.'s Luveniq™ (oral voclosporin), XOMA Ltd.'s Gevokizumab™ and Genetech's Lucentis.
- *CMV Retinitis.* Systemic delivery of ganciclovir, a Roche Holdings AG product, and other drugs are used to treat CMV Retinitis.
- *Glaucoma and Elevated IOP.* Topical eye medications such as Allergan Inc.'s LUMIGAN ® (bimatoprost), Pfizer's Xalatan ® (latanoprost), and Merck & Co.'s ZIOPTAN ® (tafluprost) and Cosopt ® (dorzolamide/timolol) are daily eye drops used to treat glaucoma and elevated ocular pressure. QLT Inc. is developing a punctal plug latanoprost implant for sustained release of more than one month. This product recently completed a Phase II clinical trial.

Many other companies, including Glaxo SmithKline plc, Thrombogenics NV and Novagali Pharma S.A., are seeking to develop drug therapies or sustained delivery platforms for the treatment of ocular disease.

Revenues

We operate in one segment. The following table summarizes our revenues by type and by geographical location. Revenue is allocated geographically by the location of the subsidiary that earns the revenue. For more detailed information regarding our operations, see our Consolidated Financial Statements commencing on page F-1.

	Year Ended June 30,								
	2012			2011			2010		
	U.S.	U. K.	Total	U.S.	U. K.	Total	U.S.	U. K.	Total
	(In thousands)								
Revenue:									
Collaborative research and development	$ 939	$1,141	$2,080	$3,529	$ 83	$3,612	$22,449	$121	$22,570
Royalty income	1,446	—	1,446	1,353	—	1,353	483	—	483
	$2,385	$1,141	$3,526	$4,882	$ 83	$4,965	$22,932	$121	$23,053

Government Regulation

The FDA and comparable regulatory agencies in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of pharmaceutical and radiological products. These agencies regulate, among other things, the research, development, testing, manufacture, quality control, labeling, storage, record-keeping, approval, distribution, advertising and promotion of our drug delivery products. The process required by the FDA under the new drug provisions of the Federal Food, Drug, and Cosmetic Act before our products may be marketed in the United States generally involves the following:

- pre-clinical laboratory and animal tests;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- adequate and well-controlled studies to establish the safety and efficacy of the proposed pharmaceutical for its intended use;
- submission to the FDA of an NDA to obtain marketing approval; and
- FDA review and approval of the NDA.

The testing and approval process requires substantial time, effort and financial resources, and varies substantially based upon the type, complexity and novelty of the product. We cannot be certain that any approval will be granted on a timely basis, if at all.

Pre-clinical tests include laboratory evaluation of the product, its chemistry, formulation and stability, as well as animal studies to assess the potential safety and efficacy of the product. The results of the pre-clinical tests, together with manufacturing information, analytical data and protocols for proposed human clinical trials, are submitted to the FDA as part of an IND, which must become effective before the IND sponsor may begin human clinical trials. The IND automatically becomes effective 30 days after receipt by the FDA unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the proposed clinical trials as outlined in the IND, and imposes a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin. There is no certainty that pre-clinical trials will result in the submission of an IND, or that submission of an IND will result in FDA authorization to commence clinical trials.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators. Clinical trials are conducted in accordance with protocols that detail the objectives of the study, the parameters to be used to monitor safety and any efficacy criteria to be evaluated.

Each protocol must be submitted to the FDA as part of the IND. Further, each clinical study must be conducted under the auspices of an independent institutional review board (IRB) at the institution where the study will be conducted. The IRB will consider, among other things, ethical factors, safety of human subjects and possible liability of the institution. Some clinical trials, called “investigator-sponsored” clinical trials, are conducted by third-party investigators responsible for the regulatory obligations associated with sponsorship of a clinical trial. The results of these trials may be used as supporting data by a company in its application for FDA approval, provided that the company has contractual rights to use the results.

Human clinical trials are typically conducted in three sequential phases which may overlap:

- *Phase I* : The drug is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, distribution, metabolism and excretion.
- *Phase II* : Studies are conducted in a limited patient population to identify possible adverse effects and safety risks, to determine the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- *Phase III* : Phase III trials are undertaken to further evaluate clinical efficacy and to further test for safety in an expanded patient population, often at geographically dispersed clinical study sites.

In the case of products for life-threatening diseases such as cancer, or severe conditions such as blinding eye disease, or for products that require invasive delivery, initial human testing is often conducted in patients with the disease rather than in healthy volunteers. Since these patients already have the targeted disease or condition, these studies may provide initial evidence of efficacy traditionally obtained in Phase II trials, and so these trials are frequently referred to as Phase I/II or IIa trials.

We cannot be certain that we or our collaborative partners will successfully complete Phase I, Phase II or Phase III testing of our product candidates within any specific time period, if at all. Furthermore, we, our collaborative partners, the FDA, the IRB, foreign regulatory authorities or the sponsor, if any, may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

The Food and Drug Administration Amendments Act of 2007 (FDAAA) is designed to provide the public with more easily accessible information about the safety and efficacy of marketed drugs and the FDA with increased authority to ensure drug safety. The FDAAA requires that we register each controlled clinical trial, aside from a Phase I trial, on a website (www.ClinicalTrials.gov) administered by National Institutes of Health (NIH), including descriptive information (e.g., a summary in lay terms of the study design, type and desired outcome), recruitment information (e.g., target number of participants and whether healthy volunteers are accepted), location and contact information and administrative data (e.g., FDA identification numbers). Within one year of a trial’s completion, information about the trial, including characteristics of the patient sample, primary and secondary outcomes, trial results written in lay and technical terms and the full trial protocol must be submitted to the website, unless the drug has not yet been approved. In that case the information is posted shortly after product approval has been obtained. The FDA requires certification of compliance with all relevant FDAAA clinical trials reporting requirements during product development.

The results of product development, pre-clinical studies and clinical studies are submitted to the FDA as part of an NDA for approval of the marketing and commercial shipment of the product. The FDA may deny an NDA if the applicable regulatory criteria are not satisfied, or may require additional clinical data. Even if the additional data are submitted, the FDA ultimately may decide that the NDA does not satisfy the criteria for approval. As a condition of approval, the FDA may require a sponsor to conduct additional clinical trials to confirm that the drug is safe and effective for its intended uses.

Satisfaction of FDA requirements or similar requirements of foreign regulatory agencies typically takes several years or more, and varies substantially. Regulatory authorities may delay marketing of potential products for a considerable period of time or prevent it entirely, and may require costly procedures in order to obtain regulatory approval. The time and expense required to obtain FDA or foreign regulatory clearance or approval for regulated products can frequently exceed the time and expense of the research and development initially required to create the product. Success in pre-clinical or early stage clinical trials does not assure success in later stage clinical trials. Data from pre-clinical and clinical activities may not be conclusive, and may be susceptible to varying interpretations, which could delay or prevent regulatory approval. Even if a product receives regulatory approval, the approval may be subject to significant limitations based on data from pre-clinical and clinical activities. After initial FDA or foreign regulatory approval has been obtained, we or our collaborative partners could be required to conduct further studies to provide additional data on safety or efficacy or, should we desire, to gain approval for the use of a product as a treatment for additional clinical indications. The FDA or foreign regulatory authorities may also require surveillance programs to monitor approved products which have been commercialized and may require changes in labeling. Once issued, the FDA or foreign regulatory authorities may withdraw product approval for non-compliance with regulatory requirements or if safety or efficacy problems occur or are demonstrated in subsequent studies after the product reaches the market. Any product manufactured or distributed under FDA or foreign regulatory approval is subject to pervasive and continuing regulation. All manufacturers must comply with regulations related to requirements for record-keeping and reporting adverse experiences with the product, and the FDA may also require surveillance programs to monitor approved products that have been commercialized. The FDA has the power to require changes in product labeling or to prevent further marketing of a product based on the results of these post-marketing programs. For certain drugs that the FDA determines pose risks that outweigh the benefits, FDA approval may be subject to the manufacturers' continued adherence to a Risk Evaluation Mitigation Strategy (REMS). REMS, which are tailored to specifically address the risks of a given drug, may contain elements that restrict distribution of the drug to certain physicians, pharmacists and patients, or that require the use of communication tools such as letters to healthcare providers and patients detailing the risks associated with the drug. Foreign regulatory authorities also regulate post-approval activities.

Commercial drug manufacturers and their subcontractors are required to register with the FDA and state agencies. Drug manufacturers and their subcontractors are also subject to periodic unannounced inspections by the FDA and state agencies for compliance with good manufacturing practices, which impose procedural and documentation requirements upon us and our third-party manufacturers.

We are also subject to numerous other federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future. In addition, we cannot predict what adverse governmental regulations may arise from future U.S. or foreign governmental action.

We and our collaborative partners are also subject to foreign regulatory requirements governing human clinical trials and marketing approval for pharmaceutical products sold in their countries. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary widely by country. Whether or not FDA approval is obtained, we or our collaborative partners must obtain approval of a product by the comparable regulatory authorities of foreign countries before manufacturing or marketing the product in those countries. The approval process varies from country to country, and the time required for these approvals may differ substantially from that required for FDA approval. There is no assurance that clinical trials conducted in one country will be accepted by other countries, or that approval in one country will result in approval in any other country. For clinical trials conducted outside the U.S., the clinical stages generally are comparable to the phases of clinical development established by the FDA.

Even after initial FDA or other foreign regulatory approval has been obtained, we or our collaborative partners could be required to conduct further studies to provide additional data on safety or efficacy or, should

we desire, to gain approval for the use of a product as a treatment for additional clinical indications. In addition, use of a product during testing and after marketing approval has been obtained could reveal side effects which, if serious, could limit uses, or in the most serious cases, result in a market withdrawal of the product or expose us to product liability claims.

Corporate Information

pSivida Corp. was organized as a Delaware corporation in March 2008. Its predecessor, pSivida Limited, was formed in December 2000 as an Australian company incorporated in Western Australia. On June 19, 2008, we reincorporated from Western Australia to the United States (the Reincorporation). Except as otherwise indicated, references in this Annual Report to “pSivida”, “the Company”, “we”, “us”, “our” or similar terms refer to pSivida Limited, a West Australia corporation, and its subsidiaries prior to June 19, 2008, and refer to pSivida Corp., a Delaware corporation, and its subsidiaries from such date. All share amounts and all information relating to options and warrants in this Annual Report have been retroactively adjusted to reflect the Reincorporation share exchange ratio, unless otherwise stated. Our principal executive office is located at 400 Pleasant Street, Watertown, Massachusetts 02472 and our telephone number is (617) 926-5000.

Additional Information

Our website address is http://www.psivida.com. Information contained on, or connected to, our website is not incorporated by reference into this Annual Report on Form 10-K. Copies of our annual reports on Form 10-K, proxy statements, quarterly reports on Form 10-Q, current reports on Form 8-K and, if applicable, amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, are available free of charge through our website under “SEC Filings” as soon as reasonably practicable after we electronically file these materials with, or otherwise furnish them to, the Securities and Exchange Commission (SEC).

ITEM 1A. RISK FACTORS

RISKS RELATED TO OUR COMPANY AND OUR BUSINESS

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

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

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

We expect to continue to generate negative cash flows from operations unless and until ILUVIEN for DME achieves sufficient revenues from commercialization or one or more of our product candidates achieves regulatory approval and sufficient revenues from commercialization. During the past three fiscal years, we have financed our operations primarily from consideration received from our collaborative partners, including license fees, research and development funding and contingent note payments, and from the proceeds of offerings of our common stock and warrants. We currently have no committed funding from collaborative partners. We believe that our cash, cash equivalents and marketable securities of $14.6 million at June 30, 2012 together with the $4.7 million net proceeds of an August 2012 offering of common stock and warrants and expected royalty income from Bausch & Lomb should enable us to maintain our current and planned operations through calendar year 2013. Our capital resources would be enhanced if Alimera successfully commercializes ILUVIEN for DME in the EU and if ILUVIEN for DME were approved and successfully commercialized in the U.S., although even so, the amount and timing of our receipt of any revenues from such activities is uncertain. Accordingly, we expect to need additional resources to complete our planned Phase III trials for our posterior uveitis micro-insert and to fund our operations. Our need for additional capital resources will be influenced by the following factors, among others:

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

- timely and successful development, regulatory approval and commercialization of our products and product candidates;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing any patent claims; and
- changes in our operating plan, resulting in increases or decreases in our need for capital.

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

If the recorded value of our intangible assets under GAAP is further impaired, our financial results could be adversely affected, which could adversely affect the price of our securities.

We recorded significant amounts of intangible assets in connection with earlier acquisitions. We took impairment charges of $3.1 million with respect to the value of our Durasert intangible asset and $11.7 million with respect to the value of our BioSilicon intangible asset as of December 31, 2011. We have $4.2 million of intangible assets on our balance sheet as of June 30, 2012, of which $2.9 million relates to our Durasert technology and $1.3 million relates to our BioSilicon technology. We will continue to conduct impairment analyses of our intangible assets as required, and we would be required to take additional impairment charges in the future if any recoverability assessments of those assets reflect fair market values which are less than our recorded values, and such charges could be significant. The carrying values of our Durasert and BioSilicon technology systems could be impaired if there is a future triggering event, including, without limitation, adverse events with respect to the timing and status of clinical development, regulatory approval and success of commercialization of products using those technologies, and significant changes in our market capitalization. Further impairment charges on our intangible assets could have a material adverse effect on our results of operations, which could, in turn, adversely affect the price of our securities.

Our operating results may fluctuate significantly from period to period.

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

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

- general and industry-specific adverse economic conditions that may affect, among other things, our and our collaborators' operations and financial results; and
- changes in accounting estimates, policies or principles and intangible asset impairments.

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

Our royalty income from Bausch & Lomb may decline.

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

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

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

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

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

There is no assurance if and when, and to what extent, we will receive revenues from the commercialization of ILUVIEN for DME in the EU. To date, Alimera has received marketing authorization from Austria, France, Germany, Portugal and the U.K., but still must obtain separate national licenses in Italy and Spain, and there is no assurance that Alimera will receive those licenses, what the terms of the licenses will be and whether their issuances will be delayed beyond Alimera's expectations, which could delay Alimera's commercialization of

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our business strategy 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 and Bausch & Lomb. The curtailment or termination of any of these arrangements could adversely affect our business, our ability to develop and commercialize our products, product candidates and proposed products and our ability to fund operations.

The success of these and future collaborative and licensing arrangements will depend heavily on the experience, resources, efforts and activities of our licensees. Our licensees have, and are expected to have, significant discretion in making decisions related to the development of product candidates and the

commercialization of products under these collaboration agreements. Risks that we face in connection with our collaboration and licensing strategy include the following:

- our collaborative and licensing arrangements are, and are expected to be, subject to termination under various circumstances, including on short notice and without cause;
- we are required, and expect to be required, under our collaborative and licensing arrangements not to conduct specified types of research and development in the field that is the subject of the arrangement or not to sell products in such field, limiting the areas of research, development and commercialization that we can pursue;
- our licensees may be permitted to develop and commercialize, either alone or with others, products that are similar to or competitive with our products;
- our licensees may change the focus of their development and commercialization efforts or decrease or fail to increase spending related to our products or product candidates, thereby limiting the ability of these products to reach their potential;
- our licensees may lack the funding, personnel or experience to develop and commercialize our products successfully or may otherwise fail to do so; and
- our licensees may not perform their obligations, in whole or in part.

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

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

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

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

Any of Pfizer, Alimera or Bausch & Lomb may decide not to continue to develop, exercise options or commercialize products under their respective agreements, change strategic focus, or pursue alternative technologies instead of our technologies or develop competing products. While Pfizer and Bausch & Lomb have significant experience in the ophthalmic field and have substantial resources, there is no assurance whether, and to what extent, that experience and those resources will be devoted to our technologies. Alimera has limited

experience and limited financial resources, and ILUVIEN for DME is Alimera's first commercial product. Because we do not currently have sufficient funding or internal capabilities to develop and commercialize our products and product candidates, decisions, actions, breach or termination of these agreements by Pfizer, Bausch & Lomb or Alimera could delay or stop the development or commercialization of any of the products or product candidates licensed to such entities.

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

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

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

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

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

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

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

and, accordingly, they might challenge the price and cost-effectiveness of our products, or refuse to provide coverage for our products. If our products and product candidates fail to achieve and maintain market acceptance, they may fail to generate significant revenues and our business may be significantly harmed.

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

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

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

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

Our success is dependent on whether we can obtain patents, defend our existing patents and operate without infringing on the proprietary rights of third parties. As of August 31, 2012, we had 199 patents and 136 pending patent applications, including patents and pending applications covering our Durasert, Tethadur, 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, 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 key personnel, our business could suffer.

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

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

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

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

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

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

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

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

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

There are a limited number of manufacturers that operate under cGMP and other foreign regulations that are both capable of manufacturing our products and product candidates and are willing to do so. Alimera has contracted with third-party manufacturers with respect to the manufacture of components of ILUVIEN. 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 and our licensees' reliance on third-party manufacturers entails risks, including:

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

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

We currently maintain offices and research and development facilities in the U.S. and the U.K., and our goal is to develop products for sale by us and our licensees in most major world healthcare markets. Manufacturing of pharmaceutical products requires us or our licensees to comply with regulations regarding safety and quality and

to obtain country and jurisdiction-specific regulatory approvals and clearances. We or our licensees may not be able to comply with such regulations or to obtain or maintain needed regulatory approvals and clearances or may be required to incur significant costs in doing so. In addition, our operations and future revenues may be subject to a number of risks associated with foreign commerce, including the following:

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

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

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

The Food and Drug Administration Amendments Act of 2007 granted the FDA enhanced authority over products already approved for sale, including authority to require post-marketing studies and clinical trials, labeling changes based on new safety information and compliance with risk evaluations and mitigation strategies approved by the FDA. The FDA's exercise of this relatively new authority could result in delays and increased costs during product development, clinical trials and regulatory review and approval, increased costs following regulatory approval to assure compliance with new post-approval regulatory requirements, and potential restrictions on the sale or distribution of approved products following regulatory approval.

Changes in the regulatory approval policy during the development period, changes in or the enactment of additional regulations or statutes, or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application. For example, the July 9, 2012 reauthorization of the Prescription Drug User Fee Act (PDUFA) extended by two months the period in which the FDA is expected to review and approve certain NDAs. Although the FDA has recently stated that it expects to meet PDUFA's updated timing goals, it has in the past provided its managers discretion to miss them due to heightened agency workload or understaffing in the review divisions; accordingly, it remains unclear whether and to what extent the FDA will adhere to PDUFA timing goals in the future, which could delay approval and commercialization of our product candidates.

RISKS RELATED TO OUR COMMON STOCK

The price of our common stock may be volatile.

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

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

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

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

As of August 31, 2012, we had outstanding warrants and options to acquire approximately 4.6 million shares of our common stock, or approximately 16.6% of our shares on a fully diluted basis. The issuance of shares of our common stock upon exercise of these warrants and stock options could result in dilution to the interests of other holders of our common stock and could adversely affect our stock price. The overhang of outstanding warrants and options may adversely affect our stock price.

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

Pfizer owned approximately 8.0% of our outstanding shares as of August 31, 2012 and is a collaborative partner. As a result, Pfizer may be able to exert significant influence over our board of directors and how we operate our business. The concentration of ownership may also have the effect of delaying or preventing a change in control of our company.

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

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We do not own any real property. We lease the following:

- 3,940 square feet of laboratory space, 1,582 square feet of clean room space and 7,890 square feet of office space in Watertown, Massachusetts under a lease agreement that expires in April 2014;
- 1,665 square feet of office space and 1,250 square feet of laboratory space in Malvern, United Kingdom under a lease agreement that expires in August 2016, subject to our right to terminate in August 2014 upon six months advance written notice; and
- 526 square feet of laboratory space in Malvern, United Kingdom under a lease agreement that expires in June 2015, subject to a mutual termination right in June 2014 upon six months advance written notice.

ITEM 3. LEGAL PROCEEDINGS

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

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PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information, Holders and Dividends

Our common stock is traded on the NASDAQ Global Market under the trading symbol "PSDV". The following table sets forth the high and low prices per share of our common stock as reported on the NASDAQ Global Market for the periods indicated:

	High	Low
Fiscal year ended June 30, 2012:		
First Quarter	$5.23	$4.00
Second Quarter	4.81	1.02
Third Quarter	2.85	1.11
Fourth Quarter	2.80	1.47
Fiscal year ended June 30, 2011:		
First Quarter	$4.54	$3.16
Second Quarter	7.22	4.26
Third Quarter	5.15	3.75
Fourth Quarter	4.68	3.50

On September 21, 2012, the last reported sale price of our common stock on the NASDAQ Global Market was $1.62. As of that date, we had approximately 23 holders of record of our common stock and, according to our estimates, approximately 3,500 beneficial owners of our common stock. In addition, as of that date, there were approximately 2,370 registered owners of our CDIs.

We have never paid cash dividends, and we do not anticipate paying cash dividends in the foreseeable future.

Equity Compensation Plan Information

The following table provides information about the securities authorized for issuance under the Company's equity compensation plans as of June 30, 2012:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (*) (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in Column a) (c)
Equity Compensation plans approved by security holders	3,165,855	$ 3.19	807,653
Equity Compensation plans not approved by security holders	—	—	—
Total	3,165,855	$ 3.19	807,653

(*) Of the total outstanding options, 112,500 are denominated in A$ and were translated at the June 30, 2012 exchange rate of A$1.00 = US$1.0159.

On the first day of each fiscal year until July 1, 2017, the number of shares reserved for issuance under the Company's 2008 Incentive Plan will be increased by the least of (i) 750,000 shares; (ii) 4% of the then outstanding shares of common stock; and (iii) any such lesser number of shares as is determined by the Compensation Committee of the Board of Directors. On July 1, 2012, the number of shares issuable under the 2008 Incentive Plan was increased by 750,000 shares.

Recent Sales of Unregistered Securities; Uses of Proceeds from Registered Securities; Issuer Repurchases of Equity Securities

None.

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ITEM 6. SELECTED FINANCIAL DATA

The selected historical financial data set forth below as of June 30, 2012, 2011, 2010, 2009 and 2008 and for each of the years then ended have been derived from our audited consolidated financial statements, of which the financial statements as of June 30, 2012 and 2011 and for the years ended June 30, 2012, 2011 and 2010 are included elsewhere in this Annual Report on Form 10-K.

The information set forth below should be read in conjunction with Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations", and the audited consolidated financial statements, and the notes thereto, and other financial information included elsewhere herein. Our historical financial information may not be indicative of our future results of operations or financial position.

	Year Ended June 30,				
	2012 (1,2)	2011 (1)	2010 (1)	2009 (1)	2008 (1,3)
	(In thousands except per share data)				
Consolidated Statements of Operations Data:					
Revenues:					
Collaborative research and development	$ 2,080	$ 3,612	$22,570	$12,002	$ 3,328
Royalty income	1,446	1,353	483	160	148
Total revenues	3,526	4,965	23,053	12,162	3,476
Operating expenses:					
Research and development	7,039	6,864	6,994	8,007	14,426
General and administrative	6,868	8,104	6,968	8,791	13,951
Impairment of intangible assets	14,830	—	—	—	—
Impairment of goodwill	—	—	—	—	60,106
Total operating expenses	28,737	14,968	13,962	16,798	88,483
Operating (loss) income	(25,211)	(10,003)	9,091	(4,636)	(85,007)
Other income (expense):					
Change in fair value of derivatives	170	1,140	(339)	959	8,357
Interest income	38	30	27	162	648
Interest and finance costs	—	—	—	—	(507)
Other (expense) income, net	(1)	(13)	(3)	53	356
Total other income (expense)	207	1,157	(315)	1,174	8,854
(Loss) income before income taxes	(25,004)	(8,846)	8,776	(3,462)	(76,153)
Income tax benefit (expense)	169	218	(23)	951	483
Net (loss) income	$(24,835)	$ (8,628)	$ 8,753	$ (2,511)	$(75,670)
Net (loss) income per share:					
Basic	$ (1.19)	$ (0.44)	$ 0.48	$ (0.14)	$ (4.17)
Diluted	$ (1.19)	$ (0.44)	$ 0.46	$ (0.14)	$ (4.17)
Weighted average common shares outstanding:					
Basic	20,791	19,489	18,405	18,263	18,166
Diluted	20,791	19,489	18,895	18,263	18,166

	As of June 30,				
	2012	2011	2010	2009	2008
			(In thousands)		
Consolidated Balance Sheet Data:					
Cash and cash equivalents	$ 4,625	$12,912	$15,514	$ 6,899	$15,609
Marketable securities	9,946	11,216	2,051	—	—
Total assets	20,597	47,113	43,014	37,104	55,784
Total deferred revenue	5,959	7,847	6,896	10,534	18,590
Total stockholders' equity	13,636	37,433	33,041	23,541	30,078

(1) We recognized $754,000 in fiscal 2012 and $3.3 million in fiscal 2011 of collaborative research and development revenue under our Restated Pfizer Agreement. We recognized $111,000 in fiscal 2012, $192,000 in fiscal 2011, $22.3 million in fiscal 2010, $11.8 million in fiscal 2009 and $3.3 million in fiscal 2008 of collaborative research and development revenue under our collaboration agreement with Alimera. We recognized $1.1 million in fiscal 2012 of collaborative research and development revenue in connection with the termination of our field-of-use license agreement with Intrinsiq. See Note 3 to the accompanying audited consolidated financial statements for additional information.

(2) At December 31, 2011, we recorded a $14.8 million impairment charge related to our BioSilicon and Durasert intangible assets as discussed in Notes 4 and 6 to the accompanying audited consolidated financial statements.

(3) At June 30, 2008, in connection with our annual review of goodwill, we recorded a $60.1 million goodwill impairment charge.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of financial condition and results of operations should be read in conjunction with our audited consolidated financial statements and related notes beginning on page F-1 of this Annual Report on Form 10-K. This discussion contains forward-looking statements, based on current expectations and related to future events and our future financial performance, that involve risks and uncertainties. Our actual results may differ significantly from those anticipated or implied in these forward-looking statements as a result of many important factors, including, but not limited to, those set forth under Item 1A, "Risk Factors", and elsewhere in this report.

Overview

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

ILUVIEN. Our most recently approved product ILUVIEN ® is an injectable, sustained-release micro-insert delivering the corticosteroid fluocinolone acetonide (FAc) over a period of up to 3 years for the treatment of vision impairment associated with chronic diabetic macular edema (DME) considered insufficiently responsive to available therapies. ILUVIEN is being developed by our licensee Alimera Sciences, Inc. (Alimera).

ILUVIEN has received marketing authorization in the United Kingdom, Austria, France, Germany and Portugal, and marketing authorization is pending in Italy and Spain. The International Diabetes Federation has estimated that approximately 19.1 million people in these seven countries have diabetes, of which Alimera has estimated that approximately 1.1 million suffer from vision loss associated with DME. Alimera has announced its intention to proceed with the direct commercialization of ILUVIEN in Germany, the U.K. and France in 2013.

To date, Alimera has not received marketing approval for ILUVIEN in the U.S. Following receipt of a Complete Response Letter in November 2011 (2011 CRL) from the U.S. Food and Drug Administration (FDA), and based on a meeting with the FDA in June 2012, Alimera has reported that it intends to resubmit its New Drug Application (NDA) for ILUVIEN for DME in early 2013. Alimera further reported that it intends to include additional analysis of the benefits and risks of ILUVIEN based upon the clinical data from its two previously completed pivotal Phase III clinical trials (FAME™ Study) and to focus on the population of patients for which regulatory approval has been granted in the various EU countries.

Product Development . We are pursuing the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye (posterior uveitis) as another indication for the same injectable micro-insert used in ILUVIEN. We did not license this indication to Alimera. The FDA has cleared our Investigational New Drug application (IND), permitting us to move directly to two Phase III trials for this indication without the necessity of first conducting Phase I or Phase II trials. The FDA has agreed that the primary end point in these trials will be recurrence of uveitis within 12 months and that we can reference much of the data, including the clinical safety data, from the clinical trials for ILUVIEN for DME. We plan to enroll a total of approximately 300 patients in our clinical trials and to utilize an inserter with a different design and a smaller gauge needle than the planned commercial inserter for ILUVIEN for DME. Because this micro-insert delivers the same drug as our approved Retisert ® product for posterior uveitis, we expect these trials will show efficacy. Further, as the same micro-insert was used in the ILUVIEN trials, we expect to observe a side-effect profile in uveitis patients comparable to that seen in DME patients. As a result, we are optimistic that this micro-insert will be efficacious for posterior uveitis with a favorable risk/benefit profile and fewer side effects compared to Retisert. An investigator-sponsored Phase I/II study of the safety and efficacy of this micro-insert for the treatment of posterior uveitis is ongoing.

We are developing a bioerodible, injectable micro-insert delivering latanoprost (the Latanoprost Product) to treat glaucoma and ocular hypertension. An investigator-sponsored Phase I/II dose-escalation study has been initiated to assess the safety and efficacy of this micro-insert in patients with elevated intraocular pressure (IOP). We have granted to Pfizer, Inc. an exclusive option under various circumstances to license the worldwide development and commercialization of the Latanoprost Product for the treatment of human ophthalmic disease or conditions other than uveitis.

We are investigating the use of Durasert technology for the treatment of orthopedic diseases.

BioSilicon. The second key technology platform we are targeting is BioSilicon, which uses fully-erodible, nanostructured, porous material for sustained drug delivery. Our primary focus is on Tethadur™, an application of BioSilicon technology designed to provide sustained delivery of large biologic molecules, including proteins, antibodies and peptides. The sizes of the pores in the BioSilicon material are manufactured using nanotechnology to accommodate specific protein, peptide or antibody molecules that are then released on a sustained basis over time as the material bioerodes. Our BioSilicon technology can also be designed to deliver smaller molecules. We are investigating the use of BioSilicon in our Latanoprost Product and the use of Tethadur in other ophthalmic applications.

FDA Approved Products. Our two FDA-approved products utilize two earlier generations of our Durasert technology system and are surgically implanted. Second-generation Retisert delivers FAc to provide sustained release treatment of posterior uveitis for approximately two and a half years, and first-generation Vitrasert ® delivers ganciclovir to provide sustained release treatment of AIDS-related cytomegalovirus (CMV) retinitis for six to nine months. We licensed both of these products to Bausch & Lomb.

Summary of Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles, or U.S. GAAP. The preparation of these financial statements requires that we make certain estimates, judgments and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. We base our estimates on historical experience, anticipated results and trends and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily available from other sources. By their nature, these estimates, judgments and assumptions are subject to an inherent degree of uncertainty and management evaluates them on an ongoing basis for changes in facts and circumstances. Changes in estimates are recorded in the period in which they become known. Actual results may differ from our estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to the accompanying consolidated financial statements, we believe that the following accounting policies are critical to understanding the judgments and estimates used in the preparation of our financial statements. It is important that the discussion of our operating results that follows be read in conjunction with the critical accounting policies discussed below.

Revenue Recognition

Our business strategy includes entering into collaborative license and development agreements for the development and commercialization of product candidates utilizing our technology systems. The terms of these arrangements typically include multiple deliverables by us (for example, granting of license rights, providing research and development services and manufacturing of clinical materials, participating on joint research committee) in exchange for consideration to us of some combination of non-refundable license fees, funding of

research and development activities, payments based upon achievement of clinical development, regulatory and sales milestones and royalties in the form of a designated percentage of product sales or profits.

Revenue arrangements with multiple deliverables are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the customer and based on the selling price of the deliverables. When deliverables are separable, consideration received is allocated to the separate units of accounting based on the relative selling price of the elements and the appropriate revenue recognition principles are applied to each unit.

The assessment of multiple deliverable arrangements requires judgment in order to determine the appropriate units of accounting, the estimated selling price of each unit of accounting, and the points in time that, or periods over which, revenue should be recognized.

For the year ended June 30, 2012, we reported $2.1 million of collaborative research and development revenue. Revenue is recognized when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable and collection is reasonably assured.

We prospectively adopted the provisions of ASU No. 2009-13, Revenue Recognition (Topic 605): *Multiple-Deliverable Revenue Arrangements* ("ASU 2009-13") for new and materially modified arrangements originating on or after July 1, 2010. ASU 2009-13 requires a vendor to allocate revenue to each unit of accounting in arrangements involving multiple deliverables. It changes the level of evidence of standalone selling price required to separate deliverables by allowing a vendor to make its best estimate of the standalone selling price of deliverables when vendor-specific objective evidence or third-party evidence of selling price is not available.

As discussed further in Note 3 to our consolidated financial statements, adoption of this accounting pronouncement in fiscal 2011 resulted in the recognition of revenue in connection with our 2007 Collaborative Research and License Agreement with Pfizer that became subject to the new accounting pronouncement after a material modification to the agreement occurred. As a result of the adoption of ASU 2009-13, deferred revenues associated with this Pfizer agreement will be recognized as revenues earlier than would otherwise have occurred.

Our deliverables under the Restated Pfizer Agreement include conducting the research and development program for the Latanoprost Product through completion of Phase II (the "R&D program") and participation on a Joint Steering Committee (JSC). We concluded that the Pfizer exercise option for the worldwide exclusive license is not a deliverable of the arrangement, due to it being a substantive option and not being priced at a significant and incremental discount. We determined that the JSC does not have standalone value from the R&D program and therefore we combined these deliverables into a single unit of accounting.

The total arrangement consideration of the Restated Pfizer Agreement totaled $10.05 million, which consisted of the $7.75 million of deferred revenue on our balance sheet at the effective date plus the $2.3 million upfront payment. The difference between the total arrangement consideration and the estimated selling price of the combined deliverables, or $3.3 million, was recognized as collaborative research and development revenue in the quarter ended June 30, 2011, the period of the modification. To determine the estimated selling price of the combined deliverable, we applied an estimated margin to our cost projections for the combined deliverable. A change in the estimated margin or our cost projections would have directly impacted the amount of revenue recognized during fiscal 2011. An increase of 10% in our estimated selling price of the combined deliverables would have reduced revenue recognized in fiscal 2011 by $670,000 and would have increased the amount of deferred revenue recognized in fiscal 2012 by 10%, or $75,000.

Valuation of Intangible Assets

At December 31, 2011, we recorded a $14.8 million intangible asset impairment write-down of our Durasert and BioSilicon technology systems. Following the November 2011 public announcement of the 2011 CRL, there

was a significant decline in the Company's share price, resulting in a decrease of the Company's market capitalization from $82.0 million to $23.1 million at December 31, 2011. The combination of the 2011 CRL and the decline in the Company's share price were determined to be impairment indicators of the Company's finite-lived intangible assets. To assess the recoverability of the combined intangible assets (which had a carrying value of $19.4 million at December 31, 2011), we used a combination of market-based and income-based valuation methodologies. Using the market-based approach as the primary indicator of fair value, an enterprise value of $4.4 million (market capitalization less existing capital resources) was adjusted for an estimated control premium and for other working capital items to derive an implied fair value of the intangible assets of $4.6 million. Under the income-based approach, the forecasted cash flows expected for the intangible assets were discounted using after-tax cost of capital rates taking into account Company-specific risks. The resulting fair value under this approach supported the conclusions of the market-based approach. Based on these analyses, the fair value of the combined intangible assets was allocated to each intangible based on values determined under the income-based approach, resulting in an $11.7 million write-down of the BioSilicon intangible and a $3.1 million write-down of the Durasert intangible.

At June 30, 2012, we reported $4.2 million of intangible assets, net of accumulated amortization, which consisted of $2.9 million related to Durasert and $1.3 million related to BioSilicon. We amortize these intangible assets using the straight-line method over their estimated economic lives, which currently extend through calendar year 2017 and is expected to result in a charge to operations of approximately $770,000 per year. We believe that the carrying value of our intangible assets will be recouped primarily through expected net cash flows from our existing collaboration agreements described under License and Collaboration Agreements above or through other licensing or commercialization.

We will continue to review our intangible assets for impairment whenever events or changes in business circumstances indicate that the asset carrying value may not be fully recoverable or that the useful life of the asset is no longer appropriate. Factors that could trigger an impairment review include the following:

- Change relative to historical or projected future operating results,
- Modification or termination of our existing collaboration agreements,
- Factors affecting the development of products utilizing the intangible assets,
- Changes in the expected use of the intangible assets or the strategy for the overall business, and
- Industry or economic trends and developments.

If an impairment trigger is identified, we determine recoverability of an intangible asset by comparing projected undiscounted net cash flows to be generated by the asset to its carrying value. If the carrying value is not recoverable, an impairment charge is recorded equal to the excess of the asset's carrying value over its fair value, and the carrying value is adjusted. Estimated future undiscounted cash flows, which relate to existing contractual agreements as well as projected cash flows from future research and development collaboration agreements utilizing the underlying technology systems, require management's judgment regarding future events and probabilities. Actual results could vary from these estimates. Future adverse changes or other unforeseeable factors could result in an impairment charge with respect to some or all of the carrying value of our intangible assets. Such an impairment charge could materially impact future results of operations and financial position in the reporting period identified.

A significant change in the estimation of the projected undiscounted net cash flows for the products and product candidates utilizing the Durasert or BioSilicon technology systems, among other things, could result in the further impairment of the carrying value of the respective assets.

Results of Operations

Years Ended June 30, 2012 and 2011

	Year ended June 30,		Change	
	2012	2011	Amounts	%
	(In thousands except percentages)			
Revenues	$ 3,526	$ 4,965	$ (1,439)	(29)%
Operating expenses:				
Research and development	7,039	6,864	175	3%
General and administrative	6,868	8,104	(1,236)	(15)%
Impairment of intangible assets	14,830	—	14,830	na
Total operating expenses	28,737	14,968	13,769	92%
Operating loss	(25,211)	(10,003)	(15,208)	(152)%
Other income (expense):				
Change in fair value of derivatives	170	1,140	(970)	(85)%
Interest income	38	30	8	27%
Other expense, net	(1)	(13)	12	92%
Total other income	207	1,157	(950)	(82)%
Loss before income taxes	(25,004)	(8,846)	(16,158)	(183)%
Income tax benefit	169	218	(49)	(22)%
Net loss	$(24,835)	$ (8,628)	$(16,207)	(188)%

Revenues

We recognized total revenue of $3.5 million for fiscal 2012 as compared to $5.0 million for fiscal 2011. The decrease in revenue was primarily due to a $1.5 million decrease in collaborative research and development revenue, partially offset by a $93,000 increase in royalty income.

Collaborative research and development revenue for fiscal 2012 of $2.1 million consisted primarily of recognition of $754,000 related to the June 2011 Restated Pfizer Agreement and $1.1 million resulting from the termination of a field-of-use license. This compares to $3.6 million of collaborative research and development revenue for fiscal 2011, which was predominantly associated with the Restated Pfizer Agreement. At the effective date of the Restated Pfizer Agreement, we had $7.75 million of deferred revenue from the Original Pfizer Agreement on our balance sheet, and we received $2.3 million of upfront consideration. The $6.7 million balance of Pfizer deferred revenue at June 30, 2011, after initial revenue recognition of $3.3 million, is being recognized as revenue using the proportional performance method over the estimated period of our performance obligations (the Latanoprost Product research program) under the Restated Pfizer Agreement. Of the remaining Pfizer deferred revenue balance of $6.0 million at June 30, 2012, approximately $2.2 million is currently expected to be recognized as revenue during fiscal 2013.

Substantially all of our royalty income in fiscal 2012 and fiscal 2011 was from sales of Retisert. Our Retisert royalty income increased 9% to $1.4 million in fiscal 2012 compared to $1.2 million in fiscal 2011. Despite this increase, we do not expect that royalty income from Bausch & Lomb for Retisert (or for Vitrasert) will be a material source of revenues for us, and it may decline.

Research and Development

Research and development increased by $175,000, or 3%, to $7.0 million for fiscal 2012 from $6.9 million for fiscal 2011. This increase was primarily attributable to increased personnel costs and the absence in fiscal 2012 of a federal therapeutic discovery grant received in fiscal 2011, substantially offset by decreased amortization of

intangible assets in fiscal 2012 resulting from a $14.8 million intangible asset impairment write-down at December 31, 2011. We may significantly increase our research and development expense in fiscal 2013, primarily dependent upon whether and when we initiate internally funded pivotal clinical trials of our sustained-release micro-insert to treat patients with posterior uveitis or Phase II clinical trials for the Latanoprost Product.

General and Administrative

General and administrative costs decreased by $1.2 million, or 15%, to $6.9 million for fiscal 2012 from $8.1 million for fiscal 2011, primarily attributable to decreased stock-based compensation (including performance stock option forfeitures), professional fees and the absence in fiscal 2012 of cash incentive compensation, payment of which is subject to future conditions.

Change in Fair Value of Derivatives

Change in fair value of derivatives represented income of $170,000 for fiscal 2012 compared to income of $1.1 million for fiscal 2011. Warrants denominated in A$ were recorded as derivative liabilities, subject to revaluation at subsequent reporting dates. Fiscal 2011 income from the change in fair value of derivatives, determined using the Black-Scholes valuation model, was predominantly due to the expiration of approximately 3.7 million, or 95%, of the A$-denominated warrants during that year. The derivative liabilities balance was reduced to zero during fiscal 2012 in connection with the July 2012 expiration of our last remaining A$-denominated warrants, with the result that we will not recognize income or loss relating to the change in the fair value of derivatives from these warrants in the future.

Income Tax Benefit

Income tax benefit decreased by $49,000, or 22%, to $169,000 in fiscal 2012 from $218,000 in fiscal 2011, primarily attributable to the absence in fiscal 2012 of a net reduction of deferred tax liabilities and federal alternative minimum tax expense in fiscal 2011, partially offset by higher foreign research and development tax credits.

Years Ended June 30, 2011 and 2010

	Year ended June 30,		Change	
	2011	2010	Amounts	%
	(In thousands except percentages)			
Revenues	$ 4,965	$23,053	$(18,088)	(78)%
Operating expenses:				
Research and development	6,864	6,994	(130)	(2)%
General and administrative	8,104	6,968	1,136	16%
Total operating expenses	14,968	13,962	1,006	7%
Operating (loss) income	(10,003)	9,091	(19,094)	(210)%
Other income (expense):				
Change in fair value of derivatives	1,140	(339)	1,479	436%
Interest income	30	27	3	11%
Other expense, net	(13)	(3)	(10)	(333)%
Total other income (expense)	1,157	(315)	1,472	467%
(Loss) income before income taxes	(8,846)	8,776	(17,622)	(201)%
Income tax benefit (expense)	218	(23)	241	1,048%
Net (loss) income	$ (8,628)	$ 8,753	$(17,381)	(199)%

Revenues

We recognized total revenue of $5.0 million for fiscal 2011 as compared to $23.1 million for fiscal 2010. The decrease in revenue was primarily due to a $19.0 million decrease in collaborative research and development revenue, partially offset by an $870,000 increase in royalty income.

Collaborative research and development revenue for fiscal 2011of $3.6 million was predominantly related to the June 2011 Restated Pfizer Agreement discussed above. Collaborative research and development revenue for fiscal 2010 was predominantly attributable to $22.3 million recognized in connection with our amended collaboration agreement with Alimera. The Alimera revenue consisted of (i) the payment in full by Alimera of a $15.0 million conditional note plus interest in April 2010 and (ii) $7.1 million of revenue related to recognition of up-front license consideration, reimbursement of our development costs and receipt of conditional note interest payments through the December 31, 2009 end date of our performance obligations under the restated agreement.

For fiscal 2011, we earned $1.2 million of Retisert royalties. For fiscal 2010, we recognized $342,000 in Retisert royalty income and $1.2 million of Retisert royalties otherwise payable to us were retained by Bausch & Lomb as the result of a 2005 advance payment from Bausch & Lomb, thereby completing an advance royalty agreement. Retisert royalty income for fiscal 2011 represented a 19.3% decrease compared to the aggregate of fiscal 2010 royalty income and amounts retained by Bausch & Lomb.

Research and Development

Research and development decreased by $130,000, or 2%, to $6.9 million for fiscal 2011 from $7.0 million for fiscal 2010. This decrease was primarily attributable to a federal therapeutic discovery grant, partially offset by a small increase in research and development costs.

General and Administrative

General and administrative costs increased by $1.1 million, or 16%, to $8.1 million for fiscal 2011 from $7.0 million for fiscal 2010, primarily attributable to increased stock-based compensation and professional fees.

Change in Fair Value of Derivatives

Change in fair value of derivatives represented income of $1.1 million for fiscal 2011 compared to expense of $339,000 for fiscal 2010. The change in fair value of derivatives for fiscal 2011 was predominantly due to the expiration of approximately 95% of the A$-denominated warrants during the year. The corresponding net expense in fiscal 2010 was primarily due to a substantial increase in the market price of our shares in fiscal 2010 (resulting in a smaller spread between the market price and the US$-equivalent exercise prices of the warrants), partially offset by the decrease in the weighted average remaining life of the underlying warrants during the period.

Income Tax Benefit (Expense)

Income tax benefit of $218,000 in fiscal 2011 compares to $23,000 of income tax expense for fiscal 2010, primarily attributable to a net reduction of deferred tax liabilities.

Inflation and Seasonality

Our management believes inflation has not had a material impact on our operations or financial condition and that our operations are not currently subject to seasonal influences.

Recently Adopted and Recently Issued Accounting Pronouncements

New accounting pronouncements are issued periodically by the Financial Accounting Standards Board ("FASB") and are adopted by us as of the specified effective dates. Unless otherwise disclosed below, we believe that the impact of recently issued and adopted pronouncements will not have a material impact on our financial position, results of operations and cash flows or do not apply to our operations.

In June 2011, the FASB issued new guidance on the presentation of comprehensive income that will require a company to present components of net income (loss) and other comprehensive income in one continuous statement or in two separate, but consecutive statements. There are no changes to the components that are recognized in net income (loss) or other comprehensive income under current GAAP. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2011, with early adoption permitted. We are not adopting the standard early and it is applicable for our fiscal quarter beginning July 1, 2012. We have not yet determined which method we will elect to present comprehensive income under the new standard. Other than a change in presentation, the adoption of this guidance will not have a material impact on our consolidated financial statements.

Liquidity and Capital Resources

During the period of fiscal 2010 through fiscal 2012, we financed our operations primarily from license fees, research and development funding and contingent cash payments from our collaboration partners and a January 2011 registered direct offering of our equity securities. At June 30, 2012, our principal source of liquidity consisted of cash, cash equivalents and marketable securities totaling $14.6 million. In August 2012, we enhanced our cash resources through the sale, in a registered direct offering, of 2,494,419 shares of common stock and warrants to purchase 623,605 shares of common stock for net proceeds of $4.7 million. Our cash equivalents are invested in institutional money market funds, and our marketable securities are invested in investment-grade corporate debt, commercial paper and certificates of deposit with maturities at June 30, 2012 ranging from zero to nine months.

With the exception of fiscal 2010, we have incurred operating losses since inception and, at June 30, 2012, we had a total accumulated deficit of $251.8 million. We generally expect negative cash flows from operations on a quarterly basis at least until such time as we receive sufficient revenues from ILUVIEN for DME or one or more of our products or product candidates achieves regulatory approval and provides us sufficient revenues. We believe that our capital resources of $14.6 million at June 30, 2012, together with the $4.7 million net proceeds of our August 2012 share offering and expected royalty income from Bausch & Lomb should enable us to fund our operations as currently planned through the end of calendar year 2013. Whether we will require, or desire, to raise additional capital will be influenced by many factors, including, but not limited to:

- whether, when and to what extent we receive revenues from Alimera with respect to ILUVIEN for DME, including from commercialization in the EU or upon any approval or commercialization in the U.S.;
- whether and when we are able to enter into strategic arrangements for our product candidates and the nature of those arrangements;
- when and if we initiate, how we conduct, and whether and the extent to which we internally fund product development and programs, including clinical trials for the posterior uveitis micro-insert and the Latanoprost Product and ongoing research and development of BioSilicon technology applications;
- whether and when Pfizer exercises its option with respect to the Latanoprost Product;
- timely and successful development, regulatory approval and commercialization of our products and product candidates;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing any patent claims; and
- changes in our operating plan resulting in increases or decreases in our need for capital.

Absent adequate levels of funding from new collaboration agreements and/or financing transactions, management currently believes that our cash position beyond calendar year 2013 depends significantly on possible revenues from the successful commercialization by Alimera of ILUVIEN for DME in the EU and if ILUVIEN for DME were to be approved by the FDA and successfully commercialized in the U.S. However, there is no assurance that the FDA or other additional regulatory authorities will approve ILUVIEN for DME, that it will achieve market acceptance in any market or that we will receive significant, if any, revenues from ILUVIEN for DME. Exercise by Pfizer of its option for the Latanoprost Product would also enhance our cash position, although there is no assurance when the option will become exercisable or if Pfizer will exercise it.

We enhanced our capital resources in the first quarter of fiscal 2013, raising net proceeds of $4.7 million through a registered direct offering of common stock and warrants. 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. The state of the economy and the financial and credit markets at the time we seek additional financing may make it more difficult and more expensive to obtain. 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 research or development programs, postpone or cancel the pursuit of product candidates, including pre-clinical and clinical trials and new business opportunities, reduce staff and operating costs or otherwise significantly curtail our operations to reduce our cash requirements and extend our capital.

Our consolidated statements of historical cash flows are summarized as follows:

	Year Ended June 30,		
	2012	2011	2010
		(In thousands)	
Net (loss) income:	$(24,835)	$ (8,628)	$ 8,753
Changes in operating assets and liabilities	(2,715)	1,211	(4,015)
Other adjustments to reconcile net (loss) income to cash flows from operating activities	18,549	4,247	5,161
Cash flows (used in) provided by operating activities	$ (9,001)	$ (3,170)	$ 9,899
Cash flows provided by (used) in investing activities	$ 606	$ (9,498)	$(2,069)
Cash flows provided by financing activities	$ 114	$10,060	$ 802

Sources and uses of operating cash flows for the years ended June 30, 2012, 2011 and 2010 are summarized as follows:

	Year Ended June 30,		
	2012	2011	2010
	(In thousands)		
Operating cash inflows:			
License and collaboration agreements	$ 187	$ 4,665	$19,123
Royalty income	1,277	1,360	127
Foreign R&D tax credits	93	142	130
Federal R&D grants	—	208	—
Investment interest received (paid)	372	129	(22)
	1,929	6,504	19,358
Operating cash outflows:			
Legal and audit fees	(2,593)	(2,388)	(1,770)
All other operating cash outflows, net	(8,337)	(7,286)	(7,689)
	(10,930)	(9,674)	(9,459)
Cash flows (used in) provided by operating activities	$ (9,001)	$(3,170)	$ 9,899

Operating cash inflows for each year consisted primarily of payments received pursuant to license and collaboration agreements, predominantly with Alimera and Pfizer. As a percentage of total license and collaboration agreements, amounts attributable to Pfizer represented 92.2% in fiscal 2011 and 10.5% in fiscal 2010 and amounts attributable to Alimera represented 57.2% in fiscal 2012, 5.3% in fiscal 2011 and 86.9% in fiscal 2010.

Operating cash outflows increased by $1.3 million, or 13.0%, from fiscal 2011 to fiscal 2012, primarily as a result of increased personnel costs and professional fees, and increased by $215,000, or 2.3%, from fiscal 2010 to fiscal 2011, primarily as a result of increased professional fees.

Cash used in investing activities were primarily attributable to maturities and sales of marketable securities, net of purchases, of $1.0 million for fiscal 2012 and to purchases of marketable securities, net of maturities, totaling $9.4 million for fiscal 2011 and $2.1 million for fiscal 2010. Purchases of property and equipment totaled $405,000 in fiscal 2012, $133,000 in fiscal 2011 and $15,000 in fiscal 2010.

Net cash flows from financing activities were predominantly attributable to $11.0 million of gross proceeds from the January 2011 registered direct offering of 2,210,000 common shares and 552,500 warrants to purchase common shares at a price per unit of $5.00, net of $1.0 million of stock issuance costs. In addition, cash flows from financing activities included proceeds from the exercise of stock options and warrants totaling $114,000 in fiscal 2012, $17,000 in fiscal 2011 and $802,000 in fiscal 2010.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that would be material to investors.

Tabular Disclosure of Contractual Obligations

The following table summarizes our minimum contractual obligations as of June 30, 2012:

	Payments Due by Period				
Contractual Obligations	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
			(In thousands)		
Operating Lease Obligations	$ 830	$ 450	$ 380	$ —	$ —
Purchase Obligations	305	305	—	—	—
Total	$1,135	$ 755	$ 380	$ —	$ —

Our purchase obligations primarily consist of purchase orders for clinical trial and pre-clinical study costs, supplies and other operating needs.

We also have contractual obligations that are variable in nature and, as such, are not included in the above table. These include agreements with our three executive officers that would require us to make severance payments to them if we terminate their employment without cause or the executives resign for good cause.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We have exposure to changes in the valuation of derivative liabilities, foreign currency exchange rates and interest rates.

Derivative Liabilities

During fiscal 2011, approximately 3.7 million warrants denominated in A$ expired. The remaining 205,479 A$ warrants outstanding at June 30, 2012 had a US$-equivalent exercise price of $7.80 per share compared to the $2.31 NASDAQ closing price of our common shares at that date and an expiration date of July 19, 2012. At June 30, 2012, the balance of our derivative liabilities was $0 and was determined using the Black-Scholes valuation model. The change in fair value of derivatives resulted in income of $170,000 for fiscal 2012, income of $1.1 million for fiscal 2011 and expense of $339,000 for fiscal 2010.

Foreign Currency Exchange Rates

We conduct operations in two principal currencies, the U.S. dollar and the Pound Sterling (£). The U.S. dollar is the functional currency for our U.S. operations, and the Pound Sterling is the functional currency for our U.K. operations. Changes in the foreign exchange rate of the U.S. dollar and Pound Sterling impact the net operating expenses of our U.K. operations. The minimal strengthening of the U.S. dollar in fiscal 2012 compared to fiscal 2011 resulted in a net decrease in research and development expense of approximately $11,000. All cash and cash equivalents, and most other asset and liability balances, are denominated in each entity's functional currency and, accordingly, we do not consider our statement of operation exposure to realized and unrealized foreign currency gains and losses to be significant.

Changes in the foreign exchange rate of the U.S. dollar and Pound Sterling also impact total stockholders' equity. During fiscal 2012, the relative strengthening of the U.S. dollar in relation to the Pound Sterling resulted in a net decrease of $492,000 in stockholders' equity due to the translation of approximately £1.1 million of net assets of our U.K. operations, predominantly the BioSilicon technology intangible asset, into U.S. dollars. For every incremental 5% strengthening or weakening of the U.S. dollar at June 30, 2012 in relation to the Pound Sterling, our stockholders' equity at June 30, 2012 would have decreased or increased, respectively, by approximately $87,000.

Interest Rates

Cash and cash equivalent balances are subject to variable interest rates. We do not consider our exposure to interest rates to be significant.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by this item may be found on pages F-1 through F-27 of this Annual Report.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2012. The term “disclosure controls and procedures”, as defined in Rules 13a-15(e) and 15d-15 (e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act’), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their desired objectives, and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2012, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

(a) Management’s Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) or 15d-15(f) of the Exchange Act as a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the U.S., and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures are being made only in accordance with authorizations of management and our directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

All internal control systems, no matter how well designed, have inherent limitations and may not prevent or detect misstatements. Projections of any evaluations of effectiveness to future periods are subject to the risk that

controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of June 30, 2012. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in *Internal Control—Integrated Framework* . Based on this assessment, our management concluded that, as of such date, our internal control over financial reporting was effective based on those criteria.

This Annual Report does not include an attestation report of the Company's independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's independent registered public accounting firm pursuant to the rules of the Securities and Exchange Commission that permit the Company, as a non-accelerated filer, to provide only management's report in this Annual Report.

(b) Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the last quarter of the fiscal year covered by this Annual Report on Form 10-K that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

Executive Officers

Each of our officers holds office until the first meeting of the board of directors following the next annual meeting of stockholders and until such officer's respective successor is chosen and qualified, unless a shorter period shall have been specified by the terms of such officer's election or appointment. Our current officers are listed below.

Paul Ashton, 51

President and Chief Executive Officer

Dr. Ashton has served as our President and Chief Executive Officer since January 2009 and was previously our Managing Director from January 2007 and our Executive Director of Strategy from December 2005 to January 2007. From 1996 until acquired by us in December 2005, Dr. Ashton was the President and Chief Executive Officer of Control Delivery Systems, Inc. (CDS), a drug delivery company that he co-founded in 1991. Dr. Ashton was previously a joint faculty member in the Departments of Ophthalmology and Surgery at the University of Kentucky, served on the faculty of Tufts University and worked as a pharmaceutical scientist at Hoffman-LaRoche.

Lori Freedman, 45

Vice President of Corporate Affairs, General Counsel and Company Secretary

Ms. Freedman has served as our Vice President of Corporate Affairs, General Counsel and Secretary since May 2006, and held the same positions at CDS from 2001 to May 2006. Prior to that, Ms. Freedman served as

Vice President, Business Development, and Counsel of Macromedia, Inc., a provider of software for creating Internet content and business applications, from March 2001 through September 2001. Ms. Freedman has also served as Vice President, General Counsel, and Secretary of Allaire Corporation, a provider of Internet infrastructure for building business applications, from 1999 until Allaire's acquisition by Macromedia in 2001, as Corporate Counsel of Polaroid Corporation from May 1998 to December 1998 and with the law firm of McDermott, Will & Emery.

Leonard S. Ross, 62

Vice President, Finance and Principal Financial Officer

Mr. Ross has served as our Vice President, Finance since November 2009 and was previously our Corporate Controller from October 2006. Mr. Ross was designated as the Company's principal financial officer in March 2009. From 2001 through April 2006, Mr. Ross served as Corporate Controller for NMT Medical, Inc., a medical device company. From 1990 to 1999, Mr. Ross was employed by JetForm Corporation, a developer of workflow software solutions, where he served in various capacities, including Vice President, Finance and Vice President, International Operations.

Corporate Governance

We have adopted a written code of ethics that applies to all of our employees, officers and directors. The Code of Conduct is designed to ensure that our business is conducted with integrity, and to comply with SEC regulations and NASDAQ and Australian Securities Exchange (ASX) listing standards. The Code of Conduct covers adherence to laws and regulations as well as professional conduct, including employment policies, conflicts of interest and the protection of confidential information. The Code of Conduct is available on the "Corporate Governance" section of our website at www.psivida.com.

We intend to disclose any future amendments to, or waivers from, the Code of Conduct that affect the directors, senior financial officers or executive officers within four business days of the amendment or waiver by filing with the SEC a Current Report on Form 8-K.

Other Information

The other information required to be disclosed in Item 10 is hereby incorporated by reference to our 2012 Proxy Statement.

ITEM 11. EXECUTIVE COMPENSATION

The information required to be disclosed in Item 11 is hereby incorporated by reference to our 2012 Proxy Statement.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required to be disclosed in Item 12 is hereby incorporated by reference to our 2012 Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required to be disclosed in Item 13 is hereby incorporated by reference to our 2012 Proxy Statement.

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ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required to be disclosed in Item 14 is hereby incorporated by reference to our 2012 Proxy Statement.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENTS

(a)(1) Financial Statements

The financial statements filed as part of this report are listed on the Index to Consolidated Financial Statements on page F-1.

(a)(2) Financial Statement Schedules

Schedules have been omitted because of the absence of conditions under which they are required or because the required information is included in the consolidated financial statements or notes thereto.

(a)(3) Exhibits.

		Incorporated by Reference to SEC Filing		
Exhibit No.	Exhibit Description	Form	SEC Filing Date	Exhibit No.
	Articles of Incorporation and By-Laws			
3.1	Certificate of Incorporation of pSivida Corp.	8-K12G3	06/19/08	3.1
3.2	By-Laws of pSivida Corp.	8-K12G3	06/19/08	3.2
	Instruments Defining the Rights of Security Holders			
4.1	Form of Specimen Stock Certificate for Common Stock	8-K12G3	06/19/08	4.1
4.2 +	Form of Warrant to Purchase Common Shares, dated January 24, 2011	8-K	01/19/11	99.3
4.3 +	Form of Warrant to Purchase Common Shares, dated August 7, 2012	8-K	08/02/12	4.1
	Material Contracts—Management Contracts and Compensatory Plans (*)			
10.1	Employment Agreement, between pSivida Limited and Paul Ashton, dated January 1, 2006	20-F	12/08/06	4.35
10.2	Non-Competition Agreement, between pSivida Limited and Paul Ashton, dated October 3, 2005	20-F	01/18/06	4.35
10.3	Employment Agreement, between pSivida Limited and Lori Freedman, dated as of May 16, 2006	6-K	05/23/06	99.3
10.4	Employment Agreement, between pSivida Corp and Leonard S. Ross, dated December 17, 2010	8-K	12/21/10	10.1
10.5	Option Amendment Agreement, between pSivida Corp and Leonard S. Ross, dated December 17, 2010	8-K	12/21/10	10.2
10.6	Rules of the pSivida Corp. Employee Share Option Plan	8-K	06/20/08	10.40
10.7	2008 Equity Incentive Plan	8-K	08/01/12	10.1
10.8 +	Form of Stock Option Certificate for grants to executive officers under the pSivida Corp. 2008 Incentive Plan	8-K	09/10/08	10.1
10.9 +	Form of pSivida Corp. Nonstatutory Stock Options granted to Lori Freedman on September 4, 2008 and September 10, 2008	10-K	09/26/08	10.36

Exhibit No.	Exhibit Description	Incorporated by Reference to SEC Filing		
		Form	SEC Filing Date	Exhibit No.
	Material Contracts—Leases			
10.10	Commercial Sublease, between Exergen Corporation and Control Delivery Systems, Inc., dated as of April 6, 2005	20-F	01/18/06	4.19
10.11	Lease Renewal Agreement between pSivida Inc. and Exergen Corporation dated October 18, 2007	10-Q	02/11/08	10.1
	Material Contracts—License and Collaboration Agreements			
10.12 #	Amended and Restated License Agreement between Control Delivery Systems, Inc. and Bausch & Lomb Incorporated dated December 9, 2003, as amended on June 28, 2005	20-F	01/18/06	4.12
10.13 #	Second Amendment to Amended and Restated License Agreement between pSivda US, Inc. and Bausch & Lomb dated August 1, 2009	10-K	09/25/09	10.13
10.14 #	Amended and Restated Collaborative Research and License Agreement, dated as of June 14, 2011, by and among pSivida Corp, pSivida US, Inc., pSiMedica Limited and Pfizer, Inc.	10-K/A	12/27/11	10.13
10.15 #	Amended and Restated Collaboration Agreement by and between pSivida Inc. and Alimera Sciences, Inc. dated March 14, 2008	8-K	04/26/10	10.01
	Other Exhibits			
21.1 (a)	Subsidiaries of pSivida Corp.			
23.1 (a)	Consent of Independent Registered Public Accounting Firm, Deloitte & Touche LLP			
31.1 (a)	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act, as amended			
31.2 (a)	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act, as amended			
32.1 (a)	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002			
32.2 (a)	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002			
101 (b)	The following materials from pSivida Corp.'s Annual Report on Form 10-K for the year ended June 30, 2012, formatted in eXtensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets at June 30, 2012 and 2011; (ii) Consolidated Statements of Operations for the years ended June 30, 2012, 2011 and 2010; (iii) Consolidated Statements of Changes in Stockholders' Equity for the years ended June 30, 2012, 2011 and 2010; (iv) Consolidated Statements of Cash Flows for the years ended June 30, 2012, 2011 and 2010; and (v) Notes to Consolidated Financial Statements.			

Confidential treatment has been granted for portions of this exhibit

\+ The final versions of documents denoted as “form of” have been omitted pursuant to Rule 12b-31. Such final versions are substantially identical in all material respects to the filed versions of such documents, provided that the name of the investor, and the investor's and/or the Company's signatures are included in the final versions.

* Management contracts and compensatory plans and arrangements required to be filed as exhibits pursuant to Item 15(b) of this annual report.

(a) Filed herewith

(b) Pursuant to Rule 406T of Regulation S-T, the XBRL-related information in Exhibit 101 to this Annual Report on Form 10-K shall not be deemed “filed” or a part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, and is not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of those sections.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

PSIVIDA CORP.

By: /s/ Paul Ashton
Paul Ashton,
President and Chief Executive Officer

Date: September 27, 2012

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ David J. Mazzo **David J. Mazzo**	Chairman of the Board of Directors	September 27, 2012
/s/ Paul Ashton **Paul Ashton**	President, Chief Executive Officer and Director (Principal Executive Officer)	September 27, 2012
/s/ Leonard S. Ross **Leonard S. Ross**	Vice President, Finance (Principal Financial and Accounting Officer)	September 27, 2012
/s/ Douglas Godshall **Douglas Godshall**	Director	September 27, 2012
/s/ Paul A. Hopper **Paul Hopper**	Director	September 27, 2012
/s/ Michael Rogers **Michael Rogers**	Director	September 27, 2012
/s/ Peter Savas **Peter Savas**	Director	September 27, 2012

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of pSivida Corp.
Watertown, Massachusetts

We have audited the accompanying consolidated balance sheets of pSivida Corp. and subsidiaries (the "Company") as of June 30, 2012 and 2011, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended June 30, 2012. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of pSivida Corp. and subsidiaries as of June 30, 2012 and 2011, and the results of their operations and their cash flows for each of the three years in the period ended June 30, 2012, in conformity with accounting principles generally accepted in the United States of America.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
September 27, 2012

PSIVIDA CORP. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS
(In thousands except share amounts)

	June 30, 2012	June 30, 2011
Assets		
Current assets:		
Cash and cash equivalents	$ 4,625	$ 12,912
Marketable securities	9,946	11,216
Accounts and other receivables	967	843
Prepaid expenses and other current assets	421	395
Total current assets	15,959	25,366
Property and equipment, net	335	123
Intangible assets, net	4,226	21,564
Other assets	77	60
Total assets	$ 20,597	$ 47,113
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 394	$ 328
Accrued expenses	608	1,322
Deferred revenue	2,176	3,212
Derivative liabilities	—	170
Total current liabilities	3,178	5,032
Deferred revenue	3,783	4,635
Deferred tax liabilities	—	13
Total liabilities	6,961	9,680
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Preferred stock, $.001 par value, 5,000,000 shares authorized, no shares issued and outstanding	—	—
Common stock, $.001 par value, 60,000,000 shares authorized, 20,802,592 and 20,748,642 shares issued and outstanding at June 30, 2012 and 2011, respectively	21	21
Additional paid-in capital	264,431	262,906
Accumulated deficit	(251,758)	(226,923)
Accumulated other comprehensive income	942	1,429
Total stockholders' equity	13,636	37,433
Total liabilities and stockholders' equity	$ 20,597	$ 47,113

See notes to consolidated financial statements

PSIVIDA CORP. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands except per share data)

	Year Ended June 30,		
	2012	2011	2010
Revenues:			
Collaborative research and development	$ 2,080	$ 3,612	$22,570
Royalty income	1,446	1,353	483
Total revenues	3,526	4,965	23,053
Operating expenses:			
Research and development	7,039	6,864	6,994
General and administrative	6,868	8,104	6,968
Impairment of intangible assets	14,830	—	—
Total operating expenses	28,737	14,968	13,962
Operating (loss) income	(25,211)	(10,003)	9,091
Other income (expense):			
Change in fair value of derivatives	170	1,140	(339)
Interest income, net	38	30	27
Other expense, net	(1)	(13)	(3)
Total other income (expense)	207	1,157	(315)
(Loss) income before income taxes	(25,004)	(8,846)	8,776
Income tax benefit (expense)	169	218	(23)
Net (loss) income	$(24,835)	$ (8,628)	$ 8,753
Net (loss) income per share:			
Basic	$ (1.19)	$ (0.44)	$ 0.48
Diluted	$ (1.19)	$ (0.44)	$ 0.46
Weighted average common shares outstanding:			
Basic	20,791	19,489	18,405
Diluted	20,791	19,489	18,895

See notes to consolidated financial statements

PSIVIDA CORP. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands except share data)

	Common Stock					
	Number of Shares	Par Value Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
Balance at July 1, 2009	18,293,961	$ 18	$248,500	$ (227,048)	$ 2,071	$ 23,541
Comprehensive income:						
Net income	—	—	—	8,753	—	8,753
Foreign currency translation adjustments	—	—	—	—	(1,548)	(1,548)
Net unrealized loss on marketable securities	—	—	—	—	(2)	(2)
Total comprehensive income						$ 7,203
Exercise of warrants	100,000	—	484	—	—	484
Exercise of stock options	110,000	1	317	—	—	318
Issuance of fully vested shares	27,431	—	110	—	—	110
Stock-based compensation	—	—	1,385	—	—	1,385
Balance at June 30, 2010	18,531,392	19	250,796	(218,295)	521	33,041
Comprehensive loss:						
Net loss	—	—	—	(8,628)	—	(8,628)
Foreign currency translation adjustments	—	—	—	—	919	919
Net unrealized loss on marketable securities	—	—	—	—	(11)	(11)
Total comprehensive loss						$ (7,720)
Issuance of stock, net of issue costs	2,210,000	2	10,041	—	—	10,043
Exercise of stock options	7,250	—	17	—	—	17
Stock-based compensation	—	—	2,052	—	—	2,052
Balance at June 30, 2011	20,748,642	21	262,906	(226,923)	1,429	37,433
Comprehensive loss:						
Net loss	—	—	—	(24,835)	—	(24,835)
Foreign currency translation adjustments	—	—	—	—	(492)	(492)
Net unrealized gain on marketable securities	—	—	—	—	5	5
Total comprehensive loss						$ (25,322)
Exercise of stock options	53,950	—	114	—	—	114
Stock-based compensation	—	—	1,411	—	—	1,411
Balance at June 30, 2012	20,802,592	$ 21	$264,431	$ (251,758)	$ 942	$ 13,636

See notes to consolidated financial statements

PSIVIDA CORP. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended June 30,		
	2012	2011	2010
Cash flows from operating activities:			
Net (loss) income	$(24,835)	$ (8,628)	$ 8,753
Adjustments to reconcile net (loss) income to cash flows (used in) provided by operating activities:			
Impairment of intangible assets	14,830	—	—
Amortization of intangible assets	2,037	3,302	3,289
Depreciation of property and equipment	190	53	37
Change in fair value of derivatives	(170)	(1,140)	339
Amortization of bond premium on marketable securities	264	189	1
Stock-based compensation	1,411	2,052	1,495
Deferred income tax benefit	(13)	(209)	—
Changes in operating assets and liabilities:			
Accounts and other receivables	(128)	285	(290)
Prepaid expenses and other current assets	(44)	(36)	52
Accounts payable	64	(64)	110
Accrued expenses	(712)	146	(360)
Deferred revenue	(1,895)	880	(3,527)
Net cash (used in) provided by operating activities	(9,001)	(3,170)	9,899
Cash flows from investing activities:			
Purchases of marketable securities	(15,392)	(15,963)	(2,054)
Maturities of marketable securities	15,299	6,598	—
Proceeds from sales of marketable securities	1,104	—	—
Purchases of property and equipment	(405)	(133)	(15)
Net cash provided by (used in) investing activities	606	(9,498)	(2,069)
Cash flows from financing activities:			
Proceeds from issuance of stock, net of issuance costs	—	10,043	—
Proceeds from exercise of stock options and warrants	114	17	802
Net cash provided by financing activities	114	10,060	802
Effect of foreign exchange rate changes on cash and cash equivalents	(6)	6	(17)
Net (decrease) increase in cash and cash equivalents	(8,287)	(2,602)	8,615
Cash and cash equivalents at beginning of year	12,912	15,514	6,899
Cash and cash equivalents at end of year	$ 4,625	$ 12,912	$15,514
Supplemental disclosure of cash flow information:			
Cash paid for income taxes	$ —	$ 56	$ 266

See notes to consolidated financial statements

PSIVIDA CORP. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(tabular amounts in thousands except share, per share and percentage amounts)

1. Operations

pSivida Corp. (together with its subsidiaries, the "Company"), incorporated in Delaware, develops tiny, sustained release, drug delivery products that are administered by implantation, injection or insertion and designed to deliver drug at a controlled and steady rate for months or years. The Company is currently focused on the treatment of chronic eye diseases utilizing its core technology systems, Durasert™ and BioSilicon™. The Company's most recently approved product, ILUVIEN ®, is an injectable, sustained-release micro-insert delivering the corticosteroid fluocinolone acetonide ("FAc") for up to 3 years for the treatment of vision impairment associated with chronic diabetic macular edema ("DME") considered insufficiently responsive to available therapies. The Company has two sustained-release drug delivery products approved by the U.S. Food and Drug Administration ("FDA") to treat other back-of-the-eye diseases. The FDA recently cleared the Company's Investigational New Drug ("IND") application to study the same micro-insert used in ILUVIEN for the treatment of posterior uveitis and an investigator-sponsored trial is ongoing for an injectable bioerodible insert delivering latanoprost designed to treat glaucoma.

ILUVIEN, licensed to Alimera Sciences, Inc. ("Alimera"), has received marketing authorization in the United Kingdom ("U.K."), Austria, France, Germany and Portugal, and has been recommended for marketing authorization in Italy and Spain following completion of the Decentralized Procedure ("DCP") involving all seven of these countries in the European Union ("EU"). Subject to determination of pricing and reimbursement, Alimera has announced its intention to directly commercialize ILUVIEN in Germany, the U.K. and France in 2013. Following a meeting with the FDA in June 2012 in response to receipt of the FDA's November 2011 Complete Response Letter ("2011 CRL"), Alimera reported that it intends to resubmit its New Drug Application ("NDA") for ILUVIEN for DME to the FDA in early 2013. Alimera further reported that it intends to include additional analysis of the benefits and risks of ILUVIEN based upon the clinical data from its two previously completed pivotal Phase III clinical trials (the "FAME™ Study") and to focus on the same indication for which regulatory approval has been granted in the various EU countries.

In June 2011, the Company amended and restated its 2007 collaborative research and license agreement with Pfizer, Inc.("Pfizer") to focus solely on the development of an injectable bioerodible sustained-release Durasert implant to deliver latanoprost for the treatment of patients with ocular hypertension and glaucoma (the "Latanoprost Product"). The Company granted Pfizer an exclusive option, under various circumstances, to license the development and commercialization of the Latanoprost Product worldwide. The Company is currently developing a prototype of this implant that contains BioSilicon to assist in the delivery of latanoprost.

The Company's two FDA-approved products utilizing earlier generations of the Durasert technology system, second-generation Retisert ® for the treatment of posterior uveitis and first-generation Vitrasert ® for the treatment of AIDS-related cytomegalovirus ("CMV") retinitis, have been licensed to Bausch & Lomb Incorporated ("Bausch & Lomb").

BioSilicon, the Company's 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 its preliminary studies, the Company is currently targeting BioSilicon as a second key drug delivery technology.

The Company is subject to risks, including, but not limited to, the ability of Alimera to successfully complete pricing and reimbursement discussions and to successfully finance and execute the direct commercialization of ILUVIEN for DME in the applicable EU countries, from which the Company is entitled to a share of net profits, as defined; the ability of Alimera to achieve FDA approval of ILUVIEN for DME

following its planned NDA resubmission and if so, to successfully commercialize the product in the U.S.; the Company's ability, and that of its collaboration partners, to obtain adequate financing to fund its and their respective operations through collaborations, sales of securities or otherwise, to successfully advance research, pre-clinical and clinical development of, and obtain regulatory approvals for, product candidates utilizing the Company's technologies and to successfully commercialize them, to protect proprietary technologies, to comply with FDA and other governmental regulations and approval requirements and to execute on business strategies; competitive products and new disease treatments; and dependence on key personnel.

The Company has a history of operating losses and has financed its operations in recent years primarily from license fees, research and development funding and contingent cash payments from its collaboration partners, and from sales of equity securities. The Company's future operating results are expected to depend, among other things, upon the success of, consideration received from, and revenue recognition associated with, and costs of, product research, development and commercialization by the Company and its current and any potential future collaborative partners. The Company believes that its cash, cash equivalents and marketable securities of $14.6 million at June 30, 2012, together with $4.7 million of net proceeds from a registered direct offering of common shares and warrants consummated in August 2012 and expected royalty income, should enable the Company to maintain its current and planned operations through calendar year 2013. The Company's ability to fund its planned operations internally beyond then, including completion of planned Phase III trials of the posterior uveitis micro-insert, may be substantially dependent upon whether Alimera successfully commercializes ILUVIEN for DME in the EU and if and when ILUVIEN for DME is approved by the FDA and successfully commercialized in the U.S., although even so, the amount and timing of the Company's receipt of any revenues from such activities is uncertain.

2. Significant Accounting Policies

Basis of Presentation

The consolidated financial statements are presented in U.S. dollars in accordance with generally accepted accounting principles in the United States ("U.S. GAAP") and include the accounts of pSivida Corp. and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated. The Company's fiscal year ends on June 30 of each year. The years ended June 30, 2012, 2011 and 2010 may be referred to herein as fiscal 2012, fiscal 2011 and fiscal 2010, respectively. Throughout these financial statements, references to "US$" and "$" are to U.S. dollars and references to "A$" are to Australian dollars.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make certain estimates and assumptions that affect the reported amounts and disclosure of assets and liabilities at the date of the consolidated financial statements and the reported amounts and disclosure of revenues and expenses during the reporting periods. Significant management estimates and assumptions include, among others, those related to revenue recognition for multiple-deliverable arrangements, recoverability of intangible assets, realization of deferred tax assets and the valuation of stock option awards. Actual results could differ from these estimates.

Foreign Currency

The functional currency of each entity is the currency of the primary economic environment in which that entity operates - the U.S. dollar or the Pound Sterling.

Assets and liabilities of the Company's foreign subsidiary are translated at period-end exchange rates. Amounts included in the statements of operations are translated at the weighted average exchange rates for the period. Gains and losses from currency translation are included in accumulated other comprehensive income as a separate component of stockholders' equity in the consolidated balance sheets. The balance of accumulated other comprehensive income attributable to foreign currency translation was $950,000 at June 30, 2012 and

$1.4 million at June 30, 2011. Foreign currency gains or losses arising from transactions denominated in foreign currencies, whether realized or unrealized, are recorded in other income, net in the consolidated statements of operations and were not significant for all periods presented.

Cash Equivalents

Cash equivalents represent highly liquid investments with maturities of three months or less at the date of purchase, principally consisting of institutional money market funds.

Marketable Securities

Marketable securities consist of investments with an original or remaining maturity of greater than ninety days at the date of purchase. The Company has classified its marketable securities as available-for-sale and, accordingly, records these investments at fair value, with unrealized gains and temporary losses excluded from earnings and reported, net of tax, in accumulated other comprehensive income, which is a component of stockholders' equity. If it is determined that a decline of any investment is other-than-temporary, the investment would be written down to fair value. As of June 30, 2012 and 2011, there were no investments in a significant unrealized loss position. The fair value of marketable securities is determined based on quoted market prices at the balance sheet dates of the same or similar instruments. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts through to the earlier of sale or maturity. Such amortization and accretion amounts are included in interest income, net in the consolidated statements of operations. The cost of marketable securities sold is determined by the specific identification method.

Concentrations of Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash, cash equivalents and marketable securities. At June 30, 2012, substantially all of the Company's interest-bearing cash equivalent balances, aggregating approximately $4.3 million, were concentrated in one institutional money market fund that has investments consisting primarily of certificates of deposit, commercial paper, time deposits, U.S. government agency securities, treasury bills and treasury repurchase agreements. Generally, these deposits may be redeemed upon demand and, therefore, bear minimal risk. Marketable securities at June 30, 2012 consist of investment-grade corporate bonds, commercial paper and certificates of deposit. The Company's investment policy, approved by the Board of Directors, includes guidelines relative to diversification and maturities designed to preserve principal and liquidity.

Pfizer accounted for $754,000, or 21%, of total revenues in fiscal 2012 and $3.3 million, or 67%, of total revenues in fiscal 2011. Bausch & Lomb accounted for $1.4 million, or 41%, of total revenues in fiscal 2012 and $1.4 million, or 27%, of total revenues in fiscal 2011. Alimera accounted for approximately $22.3 million, or 97%, of total revenues in fiscal 2010.

Fair Value of Financial Instruments

The carrying amounts of cash equivalents, accounts receivable, accounts payable and accrued expenses approximate fair value because of their short-term maturity.

Accounts and Other Receivables

Receivables consist primarily of (i) quarterly royalties earned; (ii) accrued interest on marketable securities; and (iii) U.K. research and development tax credits.

Debt and Equity Instruments

Debt and equity instruments are classified as either liabilities or equity in accordance with the substance of the contractual arrangement. Warrants issued in connection with share issues that are denominated in a currency

(A$) other than the Company's functional currency (US$) are treated as derivative liabilities, reflecting the variable amount of functional currency to be received upon potential exercise. After initial recognition, subsequent changes in the fair value of the derivative liabilities are recorded in the consolidated statements of operations in each reporting period. Fair value is determined using a Black-Scholes valuation model.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation, which is computed using the straight-line method over the estimated useful lives of the assets (generally three years). Leasehold improvements are amortized on a straight-line basis over the shorter of the remaining non-cancellable lease term or the useful lives of the assets. Repairs and maintenance costs are expensed as incurred.

Leases

Leases are classified at their inception as either operating or capital leases based on the economic substance of the agreement. Lease payments made under operating leases are recognized as an expense on a straight-line basis over the lease term. Contingent rentals are recognized as an expense in the financial year in which they are incurred.

Impairment of Intangible Assets

The Company's finite life intangible assets include its acquired Durasert and BioSilicon patented technologies, which are being amortized on a straight-line basis over twelve years. The intangible asset lives were determined based upon the anticipated period that the Company will derive future cash flows from the intangible assets, considering the effects of legal, regulatory, contractual, competitive and other economic factors. The Company continually monitors whether events or circumstances have occurred that indicate that the remaining estimated useful life of its intangible assets may warrant revision. The Company assesses potential impairments to its intangible assets when there is evidence that events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An impairment loss is recognized when the future undiscounted net cash flows expected to result from the use of an asset is less than its carrying value. If an asset is considered to be impaired, the impairment charge to be recognized is measured by the amount by which the carrying value of the asset exceeds its estimated fair value. During the quarter ended December 31, 2011, the Company recorded a $14.8 million intangible asset impairment charge related to its Durasert and BioSilicon technologies (see Note 4).

Revenue Recognition

Collaborative Research and Development and Multiple-Deliverable Arrangements

The Company enters into collaborative arrangements with strategic partners for the development and commercialization of product candidates utilizing the Company's technologies. The terms of these agreements have typically included multiple deliverables by the Company (for example, license rights, research and development services and manufacturing of clinical materials) in exchange for consideration to the Company of some combination of non-refundable license fees, research and development funding, payments based upon achievement of clinical development or other milestones and royalties in the form of a designated percentage of product sales or profits.

Revenue is recognized when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable and collection is reasonably assured. Multiple-deliverable arrangements, such as license and development agreements, are analyzed to determine whether the deliverables can be separated or whether they must be accounted for as a single unit of accounting. When deliverables are separable, consideration received is allocated to the separate units of accounting based on the relative selling price method and the appropriate revenue recognition principles are applied to each unit. When the Company determines that

an arrangement should be accounted for as a single unit of accounting, it must determine the period over which the performance obligations will be performed and revenue will be recognized.

The Company estimates its performance period used for revenue recognition based on the specific terms of each agreement, and adjusts the performance periods, if appropriate, based on the applicable facts and circumstances. Significant management judgment may be required to determine the level of effort required under an arrangement and the period over which the Company is expected to complete its performance obligations under the arrangement. If the Company cannot reasonably estimate when its performance obligations either are completed or become inconsequential, then revenue recognition is deferred until the Company can reasonably make such estimates. Revenue is then recognized over the remaining estimated period of performance using the cumulative catch-up method.

The Company prospectively adopted the provisions of Accounting Standards Update No. 2009-13, Revenue Recognition (Topic 605); *Multiple-Deliverable Revenue Arrangements* ("ASU 2009-13") for new and materially modified arrangements originating on or after July 1, 2010. ASU 2009-13 provides updated guidance on how the deliverables in an arrangement should be separated, and how consideration should be allocated, and it changes the level of evidence of standalone selling price required to separate deliverables by allowing a vendor to make its best estimate of the standalone selling price of deliverables when vendor-specific objective evidence or third-party evidence of selling price is not available.

In June 2011, the Company materially modified its 2007 Collaborative Research and License Agreement with Pfizer, and the Company applied the provisions of ASU 2009-13 to this arrangement. The accounting for all the Company's other existing arrangements will continue under the prior accounting standards unless an arrangement is materially modified. The adoption of ASU 2009-13 had a material impact on the Company's financial results, increasing collaborative research and development revenues by $3.3 million for the year ended June 30, 2011, compared to what would have been recognized had the Company continued to apply prior revenue recognition guidance.

Royalties

Royalty income is recognized upon the sale of the related products, provided that the royalty amounts are fixed and determinable, collection of the related receivable is reasonably assured and the Company has no remaining performance obligations under the arrangement. Such revenues are included as royalty income.

If royalties are received when the Company has remaining performance obligations, the royalty payments would be attributed to the services being provided under the arrangement and therefore revenue would be recognized as such performance obligations are performed. Such revenues are included as collaborative research and development revenues.

Reimbursement of Costs

The Company may provide research and development services under collaboration arrangements to assist in advancing the development of licensed products. The Company acts primarily as a principal in these transactions, and, accordingly, amounts received are classified as a component of revenue to be recognized consistent with the revenue recognition policy summarized above. The Company records the expenses incurred and reimbursed on a gross basis.

Deferred Revenue

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying consolidated balance sheets. Amounts not expected to be recognized within one year following the balance sheet date are classified as non-current deferred revenue.

Research and Development

Research and development costs are charged to operations as incurred. These costs include all direct costs, including cash compensation, stock-based compensation and benefits for research and development personnel, amortization of intangible assets, supplies and materials, direct external costs including costs of clinical trials, clinical materials, pre-clinical programs, regulatory affairs, external consultants, and other operational costs related to the Company's research and development of its product candidates.

Stock-Based Compensation

The Company may award stock options and other equity-based instruments to its employees, directors and consultants pursuant to stockholder-approved plans. Compensation cost related to such awards is based on the fair value of the instrument on the grant date and is recognized, net of estimated forfeitures, on a graded vesting basis over the requisite service period for each separately vesting tranche of the awards. The Company estimates the fair value of stock option awards using the Black-Scholes option valuation model.

Net (Loss) Income per Share

Basic net (loss) income per share is computed by dividing net (loss) income by the weighted average number of common shares outstanding during the period. For periods in which the Company reports net income, diluted net income per share is determined by adding to the weighted average number of common shares outstanding the average number of dilutive common equivalent shares using the treasury stock method, unless the effect is anti-dilutive.

The calculation of shares used to compute basic and diluted net (loss) income per share is as follows:

	Year Ended June 30,		
	2012	2011	2010
Number of common shares—basic	20,791,202	19,489,154	18,404,823
Effect of dilutive securities:			
Stock options	—	—	489,783
Number of common shares—diluted	20,791,202	19,489,154	18,894,606

The following potentially dilutive securities outstanding, prior to the application of the treasury stock method, have been excluded from the computation of diluted weighted-average shares outstanding for the years ended June 30, 2012, 2011 and 2010, as they would be anti-dilutive:

	June 30,		
	2012	2011	2010
Options	3,165,855	2,740,895	907,219
Warrants	2,270,189	7,820,227	10,997,681
	5,436,044	10,561,122	11,904,900

Comprehensive (Loss) Income

Comprehensive (loss) income is comprised of net (loss) income, foreign currency translation adjustments and unrealized gains and losses on available-for-sale marketable securities.

Income Tax

The Company accounts for income taxes under the asset and liability method. Deferred income tax assets and liabilities are computed for the expected future impact of differences between the financial reporting and income tax bases of assets and liabilities and for the expected future benefit to be derived from tax credits and

loss carry forwards. Such deferred income tax computations are measured based on enacted tax laws and rates applicable to the years in which these temporary differences are expected to be recovered or settled. A valuation allowance is provided against net deferred tax assets if, based on the available evidence, it is more likely than not that some or all of the net deferred tax assets will not be realized.

The Company determines whether it is more likely than not that a tax position will be sustained upon examination. If it is not more likely than not that a position will be sustained, none of the benefit attributable to the position is recognized. The tax benefit to be recognized for any tax position that meets the more likely than not recognition threshold is calculated as the largest amount that is more than 50% likely of being realized upon resolution of the contingency. The Company accounts for interest and penalties related to uncertain tax positions as part of its income tax (expense) benefit.

Recently Adopted and Recently Issued Accounting Pronouncements

New accounting pronouncements are issued periodically by the Financial Accounting Standards Board ("FASB") and are adopted by the Company as of the specified effective dates. Unless otherwise disclosed below, the Company believes that the impact of recently issued and adopted pronouncements will not have a material impact on the Company's financial position, results of operations and cash flows or do not apply to the Company's operations.

In June 2011, the FASB issued new guidance on the presentation of comprehensive income that will require a company to present components of net income (loss) and other comprehensive income in one continuous statement or in two separate, but consecutive statements. There are no changes to the components that are recognized in net income (loss) or other comprehensive income under current GAAP. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2011, with early adoption permitted. The Company will adopt this standard in fiscal quarter beginning July 1, 2012. The Company has not yet determined which method it will elect to present comprehensive income under the new standard. Other than a change in presentation, the adoption of this guidance will not have a material impact on the Company's consolidated financial statements.

3. License and Collaboration Agreements

Alimera

Under a collaboration agreement with Alimera, as amended in March 2008, (the "Alimera Agreement"), the Company licensed to Alimera the rights to develop, market and sell certain product candidates, including ILUVIEN.

In connection with the March 2008 amendment, the Company received $12.0 million in cash and a $15.0 million conditional, interest-bearing note, Alimera cancelled $5.7 million of accrued development cost liabilities then owed by the Company, Alimera agreed that it would pay a $25.0 million milestone payment upon FDA approval of ILUVIEN for DME and would assume all financial responsibility for the development of licensed products under the Alimera Agreement, which had previously been shared equally. In exchange, the Company decreased its share in any future net profits, as defined, on sales of ILUVIEN by Alimera from 50% to 20%, measured quarterly on a country-by-country basis, subject to an offset of 20% of pre-profitability net losses, as defined, previously incurred by Alimera on a country-by-country basis. In the event that Alimera sublicenses commercialization, the Company is entitled to 20% of royalties and 33% of non-royalty consideration received by Alimera, less certain permitted deductions.

The Company considered the Alimera Agreement to be a revenue arrangement with multiple deliverables and, having determined that its deliverables did not have stand-alone value, concluded that the deliverables represented a single unit of accounting. The terms of the collaboration agreement specifically defined the end period of the Company's performance obligations as December 31, 2009 and, accordingly, the total initial

consideration of $18.3 million was deferred and recognized as revenue on a straight-line basis over the 21.5 month performance period ended December 31, 2009. Additional cash consideration received from Alimera during the performance period, which consisted of conditional note interest payments and development cost reimbursements, was recognized as revenue during the performance period using the cumulative catch-up method. As a conditional payment obligation, the $15.0 million Alimera note was not recorded as an asset but instead treated by the Company as contingent future revenue consideration. Amounts received from Alimera subsequent to December 31, 2009, including payment in full of the conditional note in April 2010, have been, and any future milestone and profit share payments will be, recognized as revenue upon receipt or at such earlier date, if applicable, on which any such amount is both fixed and determinable and reasonably assured of collectability.

Revenue related to the Alimera Agreement totaled $111,000 for fiscal 2012, $192,000 for fiscal 2011 and $22.3 million for fiscal 2010. These revenues represented substantially all of the Company's collaborative research and development revenue for fiscal 2010.

Pfizer

In April 2007, the Company entered into a worldwide Collaborative Research and License Agreement (the "Original Pfizer Agreement") with Pfizer for the use of certain of its technologies in ophthalmic applications that were not licensed to others. Commencing in calendar 2008, Pfizer paid the Company a minimum of $500,000 quarterly in consideration of the Company's costs in performing the research program.

In June 2011, the Company and Pfizer entered into an Amended and Restated Collaborative Research and License agreement (the "Restated Pfizer Agreement") to focus solely on the development of a sustained-release bioerodible micro-insert designed to deliver latanoprost for human ophthalmic disease or conditions other than uveitis (the "Latanoprost Product"). The Original Pfizer Agreement was effectively terminated, including the cessation of Pfizer's $500,000 quarterly funding of the research program. Upon execution of the Restated Pfizer Agreement, Pfizer made an upfront payment of $2.3 million and the Company agreed to use commercially reasonable efforts to fund development of the Latanoprost Product, with technical assistance from Pfizer, for at least one year and, thereafter, at the Company's option, through completion of Phase II clinical trials, designated as Proof-of-Concept ("POC"). An investigator-sponsored Phase I/II dose-escalation study is ongoing to assess the safety and efficacy of this insert for patients with ocular hypertension and glaucoma. Within 90 days following receipt of the Company's final report demonstrating POC, Pfizer may exercise its option for an exclusive, worldwide license to develop and commercialize the Latanoprost Product in return for a $20.0 million payment, double-digit sales-based royalties and additional development, regulatory and sales performance milestone payments of up to $146.5 million. If the Company elects to cease development of the Latanoprost Product after one year, but prior to completion of Phase II clinical trials, Pfizer would still have the right to exercise an option for an exclusive worldwide license to develop and commercialize the Latanoprost Product upon payment of a lesser option fee, with comparable reductions in future sales-based royalties and other designated milestones. If Pfizer does not exercise its option, the Restated Pfizer Agreement will automatically terminate provided, however, that the Company will retain the right to develop and commercialize the Latanoprost Product on its own or with a partner.

Based upon the significant changes to the terms of the Original Pfizer Agreement, which included (i) changes in the consideration payable by Pfizer; (ii) changes in the deliverables; and (iii) changes in the research program, which now is solely related to the Latanoprost Product, the Company considered the June 2011 Restated Pfizer Agreement a material modification and applied the guidance of ASU 2009-13 to this arrangement.

The Company's deliverables under the Restated Pfizer Agreement include conducting the research and development program for the Latanoprost Product through completion of Phase II (the "R&D program") and participation on a Joint Steering Committee ("JSC"). Having determined that the JSC does not have standalone value from the R&D program, the Company combined these deliverables into a single unit of accounting. The

performance period is the expected period over which the services of the combined unit are performed, which the Company currently expects will extend through approximately December 2014.

The Company concluded that the Pfizer exercise option for the worldwide exclusive license is not a deliverable of the arrangement, because it is a substantive option and is not priced at a significant and incremental discount.

The total arrangement consideration of the Restated Pfizer Agreement totaled $10.05 million, which consisted of the $7.75 million of deferred revenue on the Company's balance sheet at the effective date plus the $2.3 million upfront payment. The difference between the total arrangement consideration and the estimated selling price of the combined deliverables, or $3.3 million, was recognized as collaborative research and development revenue in the quarter ended June 30, 2011, the period of the modification. To determine the estimated selling price of the combined deliverable, the Company applied an estimated margin to its cost projections for the combined deliverable. The estimated selling price of $6.7 million is being recognized as collaborative research and development revenue over the expected performance period of 3.5 years using the proportional performance method. The Company recorded collaborative research and development revenue related to the Restated Pfizer Agreement of $754,000 in fiscal 2012 and $3.3 million in fiscal 2011. Costs associated with conducting the R&D program are reflected in operating expenses in the period in which they are incurred.

Intrinsiq

In January 2008, the Company and Intrinsiq Materials Cayman Limited ("Intrinsiq") entered into an agreement pursuant to which Intrinsiq acquired an exclusive field-of-use license to develop and commercialize nutraceutical and food science applications of BioSilicon, and certain related assets, for $1.2 million. Provided the license agreement remained in effect, Intrinsiq was obligated to pay the Company aggregate minimum royalties of $3.55 million through April 2014, of which the first $450,000 was paid in July 2009.

The Company determined the performance period of the license arrangement to be 17 years, coinciding with the last to expire of the patents licensed to Intrinsiq, and recognized collaborative research and development revenue using the cumulative catch-up method.

In July 2011, the Company consummated an asset purchase agreement, under which it acquired BioSilicon-related capital equipment assets of Intrinsiq for $223,000, and employed four former Intrinsiq employees. The fair value of the tangible assets acquired approximated the total acquisition consideration. Coincident with the transaction, Intrinsiq terminated the agreements underlying its original 2008 license. The license termination resulted in the recognition of collaborative research and development revenue of $1.1 million in the quarter ended September 30, 2011, representing the total Intrinsiq deferred revenue balance at June 30, 2011, which had been classified as a current liability. The Company recognized collaborative research and development revenue under the license agreement of $83,000 in fiscal 2011 and $121,000 in fiscal 2010.

Bausch & Lomb

The Company's Retisert and Vitrasert products have been commercialized under a licensing and development agreement with Bausch & Lomb. Pursuant to the agreement as amended, Bausch & Lomb has a worldwide exclusive license to make and sell Vitrasert and the Company's first-generation products (as defined in the agreement, including Retisert) in return for royalties based on sales.

Royalty income totaled $1.4 million in fiscal 2012, $1.4 million in fiscal 2011 and $483,000 in fiscal 2010. An additional $1.2 million of Retisert royalty income otherwise payable in fiscal 2010 was retained by Bausch &

Lomb pursuant to the completion of a 2005 royalty advance agreement. Accounts receivable from Bausch & Lomb totaled $442,000 at June 30, 2012 and $290,000 at June 30, 2011.

4. Intangible Assets

The reconciliation of intangible assets for the years ended June 30, 2012 and 2011 is as follows:

	June 30, 2012	June 30, 2011
Patented technologies		
Gross carrying amount at beginning of year	$ 55,422	$ 53,275
Asset impairment write-down	(14,830)	—
Foreign currency translation adjustments	(1,036)	2,147
Gross carrying amount at end of year	39,556	55,422
Accumulated amortization at beginning of year	(33,858)	(29,398)
Amortization expense	(2,037)	(3,302)
Foreign currency translation adjustments	565	(1,158)
Accumulated amortization at end of year	(35,330)	(33,858)
Net book value at end of year	$ 4,226	$ 21,564

In the 2011 CRL, the FDA did not grant marketing approval for ILUVIEN for DME and, as a result, the Company did not receive a $25.0 million milestone payment from Alimera and Alimera was unable to market ILUVIEN for DME in the U.S. Following the public announcement of the 2011 CRL, there was a significant decline in the Company's share price, resulting in a decrease of the Company's market capitalization from $82.0 million to $23.1 million at December 31, 2011. The combination of the 2011 CRL and the decline in the Company's share price were determined to be impairment indicators of the Company's finite-lived intangible assets.

As of December 31, 2011, the forecasted probability-weighted undiscounted cash flows for the intangible assets were not expected to be sufficient to recover the aggregate carrying value of $19.4 million, which consisted of $6.3 million for the Durasert technology and $13.1 million for the BioSilicon technology. To assess the recoverability of the combined intangible assets, management used a combination of market-based and income-based valuation methodologies. Using the market-based approach as the primary indicator of fair value, an enterprise value of $4.4 million (market capitalization less existing capital resources) was adjusted for an estimated control premium and for other working capital items to derive an implied fair value of the intangible assets of $4.6 million. Under the income-based approach, the forecasted cash flows expected for the intangible assets were discounted using after-tax cost of capital rates taking into account Company-specific risks. The resulting fair value under this approach supported the fair value determined under the market-based approach. Based on the above analyses, the fair value of the combined intangible assets was allocated to each intangible based on the values determined under the income-based approach, as follows:

	Pre-impairment Carrying Value at December 31, 2011	Impairment Charge	Post-impairment Carrying Value at December 31, 2011
Durasert	$ 6,318	$ (3,141)	$ 3,177
BioSilicon	13,108	(11,689)	1,419
	$ 19,426	$ (14,830)	$ 4,596

The net book value of the Company's intangible assets at June 30, 2012 and 2011 is summarized as follows:

	June 30, 2012	June 30, 2011	Estimated Remaining Useful Life at June 30, 2012 (Years)
Patented technologies			
Durasert	$2,912	$ 6,845	5.5
BioSilicon	1,314	14,719	5.5
	$4,226	$21,564	

The Company amortizes its intangible assets with finite lives on a straight-line basis over their respective estimated useful lives. Amortization expense for intangible assets totaled $2.0 million in fiscal 2012 and $3.3 million in each of fiscal 2011 and fiscal 2010. The carrying value of intangible assets at June 30, 2012 of $4.2 million is expected to be amortized on a straight-line basis over the remaining estimated life of 5.5 years, or approximately $770,000 per year.

5. Marketable Securities

The amortized cost, unrealized (loss) gain and fair value of the Company's available-for-sale marketable securities at June 30, 2012 and 2011 were as follows:

	June 30, 2012		
	Amortized Cost	Unrealized (Loss)	Fair Value
Corporate bonds	$ 5,958	$ (8)	$5,950
Commercial paper	3,046	—	3,046
Certificates of deposit	950	—	950
Total marketable securities	$ 9,954	$ (8)	$9,946

	June 30, 2011		
	Amortized Cost	Unrealized (Loss) Gain	Fair Value
Corporate bonds	$ 7,326	$ (14)	$ 7,312
U.S. Government obligations	1,204	1	1,205
Commercial Paper	2,699	—	2,699
Total marketable securities	$ 11,229	$ (13)	$11,216

During fiscal 2012, $15.4 million of marketable securities were purchased and $16.4 million matured or were sold (called by the issuers) prior to scheduled maturity. At June 30, 2012, the marketable securities had maturities ranging between zero and nine months, with a weighted average maturity of 4.1 months.

6. Property and Equipment, Net

	June 30, 2012	June 30, 2011
Property and equipment	$ 1,937	$ 3,755
Leasehold improvements	321	194
Gross property and equipment	2,258	3,949
Accumulated depreciation and amortization	(1,923)	(3,826)
	$ 335	$ 123

Depreciation expense was $190,000 for fiscal 2012, $53,000 for fiscal 2011 and $37,000 for fiscal 2010.

7. Fair Value Measurements

The Company accounts for certain assets and liabilities at fair value. The hierarchy below lists three levels of fair value based on the extent to which inputs used in measuring fair value are observable in the market. The Company categorizes each of its fair value measurements in one of these three levels based on the lowest level input that is significant to the fair value measurement in its entirety. These levels are:

- Level 1—Inputs are quoted prices in active markets that are accessible at the measurement date for identical assets and liabilities.
- Level 2—Inputs are directly or indirectly observable in the marketplace, such as quoted prices for similar assets or liabilities in active markets or quoted prices for identical assets or liabilities with insufficient volume or infrequent transaction (less active markets).
- Level 3—Inputs are unobservable estimates that are supported by little or no market activity and require the Company to develop its own assumptions about how market participants would price the assets or liabilities.

The Company's cash equivalents and marketable securities are classified within Level 1 or Level 2 on the basis of valuations using quoted market prices or alternative pricing sources and models utilizing market observable inputs, respectively. Certain of the Company's corporate debt securities were valued based on quoted prices for the specific securities in an active market and were therefore classified as Level 1. The remaining marketable securities have been valued on the basis of valuations provided by third-party pricing services, as derived from such services' pricing models. Inputs to the models may include, but are not limited to, reported trades, executable bid and ask prices, broker/dealer quotations, prices or yields of securities with similar characteristics, benchmark curves or information pertaining to the issuer, as well as industry and economic events. The pricing services may use a matrix approach, which considers information regarding securities with similar characteristics to determine the valuation for a security, and have been classified as Level 2. The Company's derivative liabilities are classified as Level 3 and valued using the Black-Scholes model.

The following table summarizes the Company's assets and liabilities carried at fair value measured on a recurring basis at June 30, 2012 and 2011 by valuation hierarchy:

	June 30, 2012			
Description	Total Carrying Value	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets:				
Cash equivalents	$ 4,292	$ 4,042	$ 250	$ —
Marketable securities:				
Corporate bonds	5,950	3,684	2,266	—
Commercial paper	3,046	—	3,046	—
Certificates of Deposit	950	—	950	—
	$ 14,238	$ 7,726	$ 6,512	$ —
Liabilities:				
Derivative liabilities	$ —	$ —	$ —	$ —

Description	June 30, 2011 Total Carrying Value	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets:				
Cash equivalents	$ 8,678	$ 8,678	$ —	$ —
Marketable securities:				
Corporate bonds	7,312	5,792	1,520	—
U.S. Government obligations	1,205	—	1,205	—
Commercial paper	2,699	—	2,699	—
	$ 19,894	$ 14,470	$ 5,424	$ —
Liabilities:				
Derivative liabilities	$ 170	$ —	$ —	$ 170

The Company's derivative liabilities were classified as Level 3 and valued using the Black-Scholes model. At June 30, 2012 and 2011, the fair values were derived by applying the following assumptions:

	June 30, 2012	June 30, 2011
Expected term (in years)	0.05	1.05
Stock volatility	90%	95%
Risk-free interest rate	0.03%	0.19%
Expected dividends	0%	0%

The reconciliation of the Company's liabilities measured at fair value on a recurring basis using unobservable inputs (Level 3) is as follows:

	June 30, 2012	June 30, 2011
Balance at beginning of year	$170	$1,310
Change in fair value of derivatives—other income	170	1,140
Balance at end of year	$—	$ 170

At December 31, 2011, the Company recorded a $14.8 million intangible asset impairment charge related to its Durasert and BioSilicon technologies (see Note 4). These fair value measurements were determined using a combination of market-based and income-based valuation methodologies, which incorporate unobservable inputs, thereby classifying the fair value as a Level 3 measurement within the fair value hierarchy. The primary input used in the market-based approach was a 15% control premium that the Company estimated would be used by a market participant in valuing these assets. The primary inputs used in the income-based approach included after-tax weighted average cost of capital rates ranging from 10% to 20% that the Company estimated would be used by a market participant.

The following table summarizes the Company's assets carried at fair value measured on a nonrecurring basis at December 31, 2011 and the losses recorded for the six month period then ended:

	December 31, 2011 Total Carrying Value	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total Losses
	(In thousands)				
Finite-lived intangible assets	$ 4,596	$ —	$ —	$ 4,596	$14,830

There was no fair value measurement on a non-recurring basis at March 31, 2012 or at June 30, 2012.

8. Accrued Expenses

	June 30, 2012	June 30, 2011
Personnel costs	$149	$ 711
Professional fees	262	434
Clinical	181	140
Other	16	37
	$608	$1,322

9. Stockholders' Equity

Sales of Common Stock and Warrants

In August 2012, the Company completed a registered direct offering of 2,494,419 shares of its common stock and warrants to purchase 623,605 shares of its common stock to institutional investors for gross proceeds of $5.4 million. The shares and warrants were sold in units, each unit consisting of one share together with 0.25 of one warrant, at a negotiated price of $2.15 per unit. Each whole warrant has an exercise price of $2.50 per share and a five-year term, provided, however, that the warrants are not exercisable for a period of six months from date of issuance. Placement agent fees and other share issue costs approximated $700,000.

In January 2011, the Company completed a registered direct offering of 2,210,000 shares of its common stock and warrants to purchase 552,500 shares of its common stock to institutional investors for gross proceeds of $11.05 million. The shares and warrants were sold in units, each unit consisting of one share together with 0.25 of one warrant, at a negotiated price of $5.00 per unit. Each whole warrant has an exercise price of $5.00 per share and a five-year term. Placement agent fees and other share issue costs totaled $1.0 million.

Warrants to Purchase Common Shares

The following table provides a reconciliation of all US$ warrants for the years ended June 30, 2012 and 2011:

	Year Ended June 30, 2012		2011	
	Number of Warrants	Weighted Average Exercise Price	Number of Warrants	Weighted Average Exercise Price
Balance at beginning of year	7,614,748	$ 7.35	7,062,248	$ 7.53
Issued	—	—	552,500	5.00
Expired	(5,550,038)	7.79	—	—
Balance and exercisable at end of year	2,064,710	$ 6.17	7,614,748	$ 7.35

At June 30, 2012, the remaining lives of these outstanding warrants ranged from one week to 3.6 years, representing a weighted average term of 1.0 year.

The following table provides a reconciliation of all A$ warrants for the years ended June 30, 2012 and 2011:

	Year Ended June 30,			
	2012		2011	
	Number of Warrants	Weighted Average Exercise Price A$	Number of Warrants	Weighted Average Exercise Price A$
Balance at beginning of year	205,479	7.68	3,935,433	9.54
Expired	—	—	(3,729,954)	9.65
Balance and exercisable at end of year	205,479	7.68	205,479	7.68

The weighted average exercise price of these warrants translated to US$ was $7.80 at June 30, 2012 and $8.14 at June 30, 2011. These outstanding warrants expired on July 19, 2012.

Because the potential exercise of the A$-denominated warrants would result in a variable amount of proceeds in the Company's functional currency, the fair value of the warrants was recorded as a derivative liability, subject to revaluation of the liability on a recurring basis through the statement of operations. As of June 30, 2012, the Company had no liability recorded.

10. Stock-Based Compensation

2008 Incentive Plan

The pSivida Corp. 2008 Incentive Plan (the "2008 Plan") permits the issuance of stock-based awards to directors, executives, employees and consultants. Awards may include stock options, stock appreciation rights, restricted and unrestricted stock, deferred stock, performance awards, convertible securities and cash grants. At June 30, 2012, the number of shares reserved for issuance under the 2008 Plan was 4,091,255, of which 807,653 shares were available for grant under the 2008 Plan. The 2008 Plan includes an "evergreen provision" that allows for an annual increase in the number of shares of common stock available for issuance under the 2008 Plan. On the first day of each fiscal year until July 1, 2017, the number of shares reserved for issuance under the 2008 Plan will be increased by the least of (i) 750,000 shares; (ii) 4% of the then outstanding shares of common stock; and (iii) any such lesser amount of shares of common stock as is determined by the Compensation Committee of the Board of Directors. The number of shares reserved for issuance increased by 750,000 shares on July 1, 2012.

Options to purchase a total of 768,350 shares were granted during fiscal 2012 at exercise prices equal to the closing market price of the Company's common stock on the NASDAQ Global Market ("NASDAQ") on the respective option grant dates. Of this total, options to purchase 533,350 shares were issued to employees with ratable annual vesting over 4 years, options to purchase 135,000 shares were issued to non-employee directors with 1-year cliff vesting and options to purchase 100,000 shares were issued subject to both performance and service condition vesting. All options have a 10-year life.

The Company measures the fair value of options on their grant date using the Black-Scholes option-pricing model. Based upon limited option exercise history, the Company has generally used the "simplified" method outlined in SEC Staff Accounting Bulletin No. 107 to estimate the expected life of stock option grants. Management believes that the historical volatility of the Company's stock price on NASDAQ, for which there has been trading history for approximately 7.5 years, best represents the expected volatility over the estimated life of the option. The risk-free interest rate is based upon published U.S. Treasury yield curve rates at the date of grant corresponding to the expected life of the stock option. An assumed dividend yield of zero reflects the fact that the Company has never paid cash dividends and has no intentions to pay dividends in the foreseeable future.

The key assumptions used to apply the option pricing model for options granted under the 2008 Plan during the years ended June 30, 2012, 2011 and 2010 were as follows:

	2012	2011	2010
Option life (in years)	3.50 - 6.25	3.50 - 6.25	5.50 - 6.25
Stock volatility	88% - 97%	95%	95%
Risk-free interest rate	0.53% - 2.02%	1.13% - 2.35%	2.36% - 2.62%
Expected dividends	0.0%	0.0%	0.0%

The Company recognizes compensation expense for only the portion of options that are expected to vest. Based on historical trends, the Company applies estimated forfeiture rates to determine the numbers of awards that are expected to vest. Additional expense is recorded if the actual forfeiture rate for each tranche of option grants is lower than estimated, and a recovery of prior expense is recorded if the actual forfeiture rate is higher than estimated. The Company assesses the forfeiture rate at the end of each reporting period. The Company begins to record stock-based compensation expense for performance-based options at the time it becomes probable that the respective performance conditions will be achieved. The Company will continue to recognize the grant date fair value of performance-based options through the vesting date of the respective awards so long as it remains probable that the related performance conditions will be satisfied. In fiscal 2012, the Company recorded a reversal of $121,000 of expense for performance-based option awards forfeited during fiscal 2012.

The following table summarizes information about stock options for the years ended June 30, 2012, 2011 and 2010:

	2012	2011	2010
Weighted-average grant date fair value, per share	$2.41	$3.24	$3.10
Total cash received from exercise of stock options (in thousands)	114	17	318
Total intrinsic value of stock options exercised (in thousands)	119	12	78

At June 30, 2012, there was approximately $1.2 million of unrecognized stock-based compensation expense related to unvested stock options, which is expected to be recognized as expense over a weighted average period of 1.8 years.

The following table provides a reconciliation of stock option activity under the 2008 Plan for fiscal 2012:

	Number of options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at July 1, 2011	2,605,895	$ 2.63		
Granted	768,350	4.93		
Exercised	(53,950)	2.12		
Forfeited	(266,940)	4.05		
Outstanding at June 30, 2012	3,053,355	$ 3.10	7.44	$ 915
Outstanding at June 30, 2012—vested or unvested and expected to vest	2,977,909	$ 3.08	7.42	$ 910
Exercisable at June 30, 2012	1,668,034	$ 2.40	6.84	$ 781

Employee Share Option Plan

The Company's Employee Share Option Plan (the "Plan") provided for the issuance of non-qualified stock options to eligible employees and directors. As of June 30, 2008, no further options could be granted under the Plan. Options outstanding under the Plan, denominated in A$, had vesting periods ranging from immediate vesting to 3-year graded vesting and a contractual life of five years.

The following table provides a reconciliation of stock option activity under the Plan for fiscal 2012:

	Number of options	Weighted Average Exercise Price A$	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value A$
Outstanding at July 1, 2011	135,000	6.75		
Cancelled	(22,500)	13.00		
Outstanding and exercisable at June 30, 2012	112,500	5.50	0.25	—

At June 30, 2012 the weighted average exercise price of outstanding and exercisable options translated into US$ was $5.59.

Stock-Based Compensation Expense

The Company's statements of operations included total compensation expense from stock-based payment awards as follows:

	Year ended June 30,		
	2012	2011	2010
Compensation expense from:			
Stock options	$1,411	$2,052	$1,385
Issuance of fully vested shares	—	—	110
	$1,411	$2,052	$1,495
Compensation expense included in:			
Research and development	$ 597	$ 400	$ 306
General and administrative	814	1,652	1,189
	$1,411	$2,052	$1,495

11. Retirement Plans

The Company operates a defined contribution plan intended to qualify under Section 401(k) of the U.S. Internal Revenue Code. Participating U.S. employees may contribute up to 15% of their pre-tax compensation, as defined, subject to statutory maximums. The Company matches employee contributions up to 5% of eligible compensation, subject to a stated calendar year Internal Revenue Service maximum.

The Company operates a defined contribution pension plan for U.K. employees pursuant to which the Company makes contributions on behalf of employees plus a matching percentage of elective employee contributions.

The Company contributed a total of $181,000 for fiscal 2012, $160,000 for fiscal 2011 and $153,000 for fiscal 2010 in connection with these retirement plans.

12. Income Taxes

The components of income tax (benefit) expense are as follows:

	Year Ended June 30,		
	2012	2011	2010
U.S. operations:			
Current income tax provision	$ —	$ 96	$ 156
Deferred income tax benefit	(13)	(209)	—
	(13)	(113)	156
Non-U.S. operations:			
Current income tax benefit	(156)	(105)	(133)
Deferred income tax benefit	—	—	—
	(156)	(105)	(133)
Income tax (benefit) provision	$(169)	$(218)	$ 23

The components of (loss) income before income taxes are as follows:

	Year Ended June 30,		
	2012	2011	2010
U.S. operations	$(11,215)	$(5,519)	$12,353
Non-U.S. operations	(13,789)	(3,327)	(3,577)
(Loss) income before income taxes	$(25,004)	$(8,846)	$ 8,776

The difference between Company's expected income tax (benefit) expense, as computed by applying the statutory U.S. federal tax rate of 34% to (loss) income before income taxes, and actual tax is reconciled in the following table:

	Year Ended June 30,		
	2012	2011	2010
Income tax (benefit) provision at statutory rate	$(8,501)	$(3,008)	$ 2,984
State income taxes, net of federal benefit	(599)	(350)	953
Non-U.S. income tax rate differential	1,163	228	180
Research and development tax credits	(156)	(106)	(132)
Changes in valuation allowance	7,500	3,045	(4,219)
Other, net	424	(27)	257
Income tax (benefit) provision	$ (169)	$ (218)	$ 23

The components of deferred income taxes are as follows:

	June 30, 2012	June 30, 2011
Deferred tax assets:		
Net operating loss carryforwards	$24,021	$23,799
Deferred revenue	2,341	555
Stock-based compensation	2,119	1,608
Provision for losses on note receivable	511	511
Other	572	620
Total deferred tax assets	29,564	27,093
Deferred tax liabilities:		
Intangible assets	1,472	6,516
Deferred tax assets, net	28,092	20,577
Valuation allowance	28,092	20,590
Net deferred tax liability	$ —	$ 13

The valuation allowances generally reflect limitations on the Company's ability to use the tax attributes and reduce the value of such attributes to the more-likely-than-not realizable amount. The valuation allowance increased by $7.5 million during fiscal 2012 and $3.0 million during fiscal 2011.

The Company has tax loss carry forwards in its individual tax jurisdictions. At June 30, 2012, the Company had U.S. federal net operating loss carry forwards of approximately $46.6 million which expire at various dates between calendar years 2023 and 2032. The utilization of certain of these loss carry forwards may be limited by Section 382 of the Internal Revenue Code as a result of historical or future changes in the Company's ownership. At June 30, 2012, the Company had state net operating loss carry forwards of approximately $22.1 million, of which $13.4 million expires in 2012, $3.1 million expires in 2013 and $5.6 million expires in 2031 and 2032. Additionally, at June 30, 2012 the Company had loss carry forwards in the U.K. of £18.0 million (approximately $28.1 million). During fiscal 2012, the Company recognized a current income tax benefit of $156,000 related to foreign research and development tax credits earned by its U.K. subsidiary.

The Company's U.S. federal income tax returns for calendar years 2002 through 2011 remain subject to examination by the Internal Revenue Service. The Company's U.K. tax returns for fiscal 2006 to 2011 remain subject to examination. The Australian tax returns for the former parent company for fiscal 2004 through 2008 remain subject to examination.

Through June 30, 2012, the Company had no unrecognized tax benefits in its consolidated statements of operations and no unrecognized tax benefits in its consolidated balance sheets as of June 30, 2012 or 2011.

As of June 30, 2012 and 2011, the Company had no accrued penalties or interest related to uncertain tax positions.

13. Commitments and Contingencies

Operating Leases

The Company leases its office and research laboratory space in Watertown, Massachusetts through April 6, 2014. In addition to base rent, the lease agreement requires the Company to pay for utilities, taxes, insurance, maintenance and other operating expenses. The Company leases laboratory and office space in Malvern, U.K. through August 2016, subject to a 6-month advance notice of cancellation at September 2014. The Company also leases certain office equipment under operating lease agreements that expire through calendar year 2016.

At June 30, 2012, the Company's total future minimum lease payments under non-cancellable operating leases were as follows:

Fiscal Year:	
2013	$450
2014	360
2015	18
Thereafter	2
	$830

Rent expense related to operating leases charged to operations was approximately $466,000 for fiscal 2012, $449,000 for fiscal 2011 and $449,000 for fiscal 2010.

Litigation

The Company is subject to various routine legal proceedings and claims incidental to its business, which management believes will not have a material effect on the Company's financial position, results of operations or cash flows.

14. Segment and Geographic Area Information

(a) Business Segment

The Company operates in only one business segment, being the biotechnology sector. Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker in making decisions regarding resource allocation and assessing performance. The chief operating decision maker made such decisions and assessed performance at the company level, as one segment.

(b) Geographic Area Information

The following table summarizes the Company's revenues and long-lived assets by geographic area:

	Revenues			Long-lived assets	
	2012	2011	2010	2012	2011
United States	$2,385	$4,882	$22,932	$ 57	$ 62
United Kingdom	1,141	83	121	278	61
Consolidated	$3,526	$4,965	$23,053	$ 335	$ 123

15. Related Party Transactions

As of June 30, 2012, Pfizer owned approximately 9.0% of the Company's outstanding shares. The Company received research and development program payments from Pfizer under the Original Pfizer Agreement of $2.0 million during fiscal 2011 and $2.0 million during fiscal 2010. In addition, in connection with consummation of the Restated Pfizer Agreement in June 2011, the Company received an upfront license fee of $2.3 million.

16. Quarterly Financial Data (unaudited)

The following table summarizes the quarterly results of operations for the years ended June 30, 2012 and 2011:

	Fiscal Year 2012				
	First Quarter Ended September 30, 2011 (1)	Second Quarter Ended December 31, 2011 (2)	Third Quarter Ended March 31, 2012	Fourth Quarter Ended June 30, 2012	Year Ended June 30, 2012 (1, 2)
Total revenues	$ 1,659	$ 630	$ 538	$ 699	$ 3,526
Operating loss	(2,531)	(17,643)	(2,727)	(2,310)	(25,211)
Net loss	(2,427)	(17,460)	(2,686)	(2,262)	(24,835)
Net loss per share:					
Basic and diluted	$ (0.12)	$ (0.84)	$ (0.13)	$ (0.11)	$ (1.19)
Weighted average common shares:					
Basic and diluted	20,757	20,803	20,803	20,803	20,791

	Fiscal Year 2011				
	First Quarter Ended September 30, 2010	Second Quarter Ended December 31, 2010	Third Quarter Ended March 31, 2011	Fourth Quarter Ended June 30, 2011 (3)	Year Ended June 30, 2011 (3)
Total revenues	$ 476	$ 414	$ 360	$ 3,715	$ 4,965
Operating loss	(3,435)	(3,121)	(3,139)	(308)	(10,003)
Net loss	(3,108)	(2,695)	(2,685)	(140)	(8,628)
Net loss per share:					
Basic and diluted	$ (0.17)	$ (0.15)	$ (0.13)	$ (0.01)	$ (0.44)
Weighted average common shares:					
Basic and diluted	18,531	18,531	20,177	20,745	19,489

(1) Results for the first quarter of fiscal 2012 included $1.1 million of revenue related to the termination of a field-of-use license by Intrinsiq (see Note 3)

(2) Results for the second quarter of fiscal 2012 included a $14.8 million impairment write-down of finite-lived intangible assets (see Note 4).

(3) Results for the fourth quarter of fiscal 2011 included $3.3 million of revenue related to a material modification of the Pfizer collaborative research and license agreement in June 2011 (see Note 3).

Exhibit 21.1

List of Subsidiaries of pSivida Corp.

Subsidiary Name	Jurisdiction of Incorporation
pSivida US, Inc.	Delaware
pSiMedica Limited	United Kingdom
pSivida Securities Corporation	Massachusetts

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-152146 and 333-163208 on Form S-8 and Registration Statement No. 333-163347 on Form S-3 of our report dated September 27, 2012, relating to the financial statements of pSivida Corp., appearing in this Annual Report on Form 10-K of pSivida Corp. for the year ended June 30, 2012.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
September 27, 2012

Exhibit 31.1

Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.

CERTIFICATIONS

I, **Paul Ashton** , certify that:

1. I have reviewed this Annual Report on Form 10-K of **PSIVIDA CORP.** ;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: September 27, 2012

/s/ P AUL A SHTON
Name: Paul Ashton
Title: President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.

CERTIFICATIONS

I, **Leonard S. Ross** , certify that:

1. I have reviewed this Annual Report on Form 10-K of **PSIVIDA CORP.** ;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: September 27, 2012

/s/ L EONARD S. R OSS

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

Exhibit 32.1

Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

In connection with the Annual Report of pSivida Corp. (the "Company") on Form 10-K for the year ended June 30, 2012, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Paul Ashton, President and Chief Executive Officer of the Company, certify that to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: September 27, 2012

/s/ PAUL ASHTON

Name: **Paul Ashton**
Title: **President and Chief Executive Officer**
(Principal Executive Officer)

Exhibit 32.2

Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

In connection with the Annual Report of pSivida Corp. (the "Company") on Form 10-K for the year ended June 30, 2012, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Leonard S. Ross, Vice President, Finance of the Company, certify that to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: September 27, 2012

/s/ Leonard S. Ross

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