

**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, 2013

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
(State or other jurisdiction of
incorporation or organization)

400 Pleasant Street
Watertown, MA
(Address of principal executive offices)

26-2774444
(I.R.S. Employer
Identification No.)

02472
(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
Common Stock, \$.001 par value per share

Name of each
exchange
on which registered
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, 2012, the last trading day of the registrant's most recently completed second fiscal quarter, was approximately \$27,506,000.

There were 26,791,561 shares of the registrant's common stock, \$0.001 par value, outstanding as of September 23, 2013.

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 18, 2013, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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For the Fiscal Year Ended June 30, 2013
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PART I

Preliminary Note Regarding Forward-Looking Statements

This Form 10-K and our 2013 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.psvivida.com, or otherwise.

ITEM 1. BUSINESS

Introduction

We develop tiny, sustained-release products designed to deliver drugs and biologics at a controlled and steady rate for weeks, months or years. Utilizing our core technology platforms, Durasert™ and BioSilicon™, we are focused on treatment of chronic diseases of the back of the eye and are also exploring applications outside ophthalmology. We have developed three of the four sustained-release products for treatment of retinal diseases currently approved in the U.S. or European Union (EU), and our lead product candidate began a Phase III clinical trial in June 2013. Our strategy includes developing products independently while continuing to leverage our technology platforms through collaboration and license agreements.

ILUVIEN®, our most recently approved product, is an injectable, sustained-release micro-insert that provides treatment of vision impairment associated with chronic diabetic macular edema (DME) considered insufficiently responsive to available therapies over a period of up to three years. *ILUVIEN* is licensed to and sold by Alimera Sciences, Inc. (Alimera), and we are entitled to a share of the net profits, as defined, from Alimera’s sales of *ILUVIEN* for DME. Alimera commenced the commercial launch of *ILUVIEN* for DME in the U.K. and Germany in the second quarter of 2013 and expects to launch in France in the first quarter of 2014. The International Diabetes Federation has estimated that approximately 19.0 million people have diabetes in the seven EU countries where *ILUVIEN* has received or been recommended for marketing authorization, of which Alimera has estimated that approximately 1.1 million people suffer from vision loss associated with DME. Alimera is also seeking marketing approval for *ILUVIEN* for DME in the U.S. In the second quarter of 2013, Alimera received a new Prescription Drug User Fee Act (PDUFA) goal date of October 17, 2013 after

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resubmitting its New Drug Application (NDA) for ILUVIEN for DME. The resubmission responded to a second Complete Response Letter (CRL) received from the U.S. Food and Drug Administration (FDA) in November 2011.

*Medidur*TM, our lead development product, commenced the first of our two planned Phase III clinical trials for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye (posterior uveitis) in June 2013. Medidur uses the same Durasert micro-insert used in ILUVIEN and delivers a lower dose of the same drug as our FDA-approved Retisert[®] for posterior uveitis, which is licensed to Bausch & Lomb. We are developing Medidur independently.

We are also developing a bioerodible, injectable micro-insert delivering latanoprost (the Latanoprost Product) to treat glaucoma and ocular hypertension. Under an amended collaboration agreement, Pfizer Inc. has an option, under certain circumstances, to license the development and commercialization of the Latanoprost Product worldwide.

We are engaged in pre-clinical research with respect to both our BioSilicon and Durasert technology platforms. The primary focus of our BioSilicon technology research is the sustained delivery of peptides, proteins, antibodies and other large biologic molecules using our TethadurTM technology in both ophthalmic and non-ophthalmic applications. Our research program also includes the use of Durasert technology in orthopedic applications and for systemic delivery of therapeutic agents.

Our FDA-approved *Retisert* provides sustained release treatment of posterior uveitis for approximately two and a half years and is licensed to and sold by Bausch & Lomb.

DurasertTM, MedidurTM, TethadurTM and BioSiliconTM 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.

Information with respect to ILUVIEN and its regulatory and marketing status reflects information reported by Alimera.

Fiscal 2013, fiscal 2012 and fiscal 2011 mean the years ended June 30, 2013, 2012 and 2011, respectively.

Strategy

Our strategy is to use our proprietary Durasert and BioSilicon drug delivery technology platforms to independently develop new drug delivery products for already-approved drugs and biologics to better treat diseases in the ophthalmic area and beyond, while continuing to leverage our technology platforms through collaborations and licenses with leading pharmaceutical and biopharmaceutical companies, institutions and others. We believe our technologies can provide sustained, targeted delivery of several already-approved drugs and biologics, resulting in improved effectiveness, better patient compliance and convenience, with reduced risk and cost of product development for us. We believe our proven track record of three approved products demonstrates the effectiveness of this strategy.

- *Develop Sustained Delivery of Off-Patent Drugs and Biologics.* Many drugs and biologics either are or are soon to be off-patent. It is estimated over the next 8 years that patent coverage will end on products with world-wide sales aggregating over \$50 billion annually. We plan to use our technology platforms to develop products using off-patent and generic drugs and biologics with a significant market opportunity where either less frequent dosing through sustained delivery and/or release at the treatment site through targeted delivery would provide a material improvement to the effectiveness or convenience of the original product. We are optimistic that our BioSilicon technology can provide sustained delivery of large biologic molecules, which currently cannot be effectively delivered by other

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sustained delivery technologies. By focusing on delivery of already-approved drugs and biologics, particularly those requiring shorter clinical trials, we believe we can minimize the risks and financial investments required for product approval.

- *Continue Partnering with Leading Biopharmaceutical and Pharmaceutical Companies.* We intend to continue to partner with leading biopharmaceutical and pharmaceutical companies, institutions and others, where patent protection, development and regulatory costs, expertise or other factors make it desirable for us to have a partner. For example, many drugs and biologics that might be more effectively delivered by our platform technologies, whether as a result of less frequent dosing, targeted delivery or otherwise, have extended patent protection, which could make collaborations with the patent holders attractive. We might also partner the development of products, including off-patent drugs or biologics that could materially benefit from sustained delivery, but would require expensive clinical trials or are in treatment areas outside of our technical expertise. Our drug delivery technologies could also permit companies to extend the patent protection on drugs coming off-patent while offering an improved product.
- *Expand Beyond Ophthalmology.* While we are continuing to focus on our core ophthalmic competency, we are studying treatment of diseases in other areas where we believe our technology platforms could provide a significant advantage. For example, we are studying the potential use of our technologies in orthopedics as well as in systemic release of therapeutic agents.

Market Overview

Delivery of Drugs and Biologics Generally

The therapeutic value of a therapeutic agent (small drug molecule or biologic) depends on its distribution to, and reaction with, the targeted tissue and other tissues in the body, duration of treatment, and clearance from the body. In an ideal treatment, the appropriate amount of drug or biologic is delivered to the intended tissue at an adequate concentration and maintained for a sufficient period of time without causing adverse effects to other tissues. Accordingly, the manner in which a drug or biologic is delivered can be an important element of the ultimate therapeutic value of the treatment.

Drugs are frequently administered systemically by oral dosing or by injection and subsequently dispersed throughout the body via the circulatory system. In the case of many drugs, systemic administration does not deliver them to the intended site at an adequate concentration for a sufficient period of time or delivers them in a concentration that disperses too quickly, thereby not achieving the maximum potential therapeutic benefit. Because systemically delivered drugs disperse throughout the body, they often are administered at higher dosage levels to achieve sufficient concentrations at the intended sites. 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 higher doses of systemically delivered drugs. These dosage levels can cause harmful side effects when the drugs interact with other tissues. In some cases, drugs may be administered locally to the targeted site, typically by injection. While this may avoid the issues of systemic delivery, problems of sufficient concentrations over time at the targeted site remain. Timely and repeated administration of systemically and locally delivered drugs is often necessary to maintain therapeutic drug levels over an extended period of time.

The administration of biologics is typically more difficult than small drug molecules. Biologics generally cannot be administered orally, but instead are administered by injection or infusion. Due to the size and complexity of biologics, sustained release formulations are difficult to prepare and many biologics require repeated injections or infusions to maintain appropriate levels over the course of treatment.

Patients often do not get drugs or biologics on the schedule prescribed, or at all, because they do not self-administer the products correctly or do not go to medical professionals as required for administration. The risk of patient noncompliance increases due to various factors, such as requirements to receive multiple products, complex or painful dosing regimens, patient age, cognitive impairment or serious illness or length of treatment.

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Repeated administration by injection or infusion can result in serious infections and other complications. Further, repeated administration by medical professionals is often expensive.

Due to the drawbacks of traditional drug and biologic delivery, the development of methods to deliver them to patients in a more precise, controlled fashion over sustained periods of time is a medical goal. Methods for sustained drug delivery include oral and injectable controlled-release products and skin patches that seek to improve the consistency of the dosage over time and extend the duration of delivery. However, most of these methods cannot provide constant, controlled dosage or deliver drugs for a sufficiently long duration for many indications, particularly diseases that are chronic or require precise dosing. There are currently very few approved sustained delivery products for biologics.

Ophthalmic Drug Delivery

Treating retinal diseases is a significant challenge. Due to the effectiveness of the blood/eye barrier, it is difficult for systemically administered drugs to reach the retina in sufficient quantities to have a beneficial effect without adverse side effects to other parts of the body. Injecting drugs or biologics in solution directly into the back of the eye can achieve effective, but often transient, dosage levels in the eye, requiring repeated injections. Examples include Macugen® (pegaptanib sodium), Lucentis® (ranibizumab) and EYLEA® (afilbercept), 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.

Technology Systems and Products

Our two core technology platforms, Durasert and BioSilicon, have the following attributes:

- *Extended Delivery.* Our technology platforms can deliver therapeutics 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, thereby reducing the risks of patient noncompliance and adverse effects from repeated administrations.
- *Controlled Release Rate.* Our technology platforms can release therapeutics at a sustained, controlled rate. We believe that this feature allows us to develop products that deliver optimal concentrations of therapeutics and eliminate excessive variability in dosing over time.
- *Localized Delivery.* Our technology platforms can deliver therapeutics directly at a target site. This administration can allow the natural barriers of the body to isolate and assist in maintaining appropriate concentrations at the target site in an effort to achieve the maximum therapeutic effect while minimizing unwanted systemic effects.

Durasert Technology System

The Durasert technology platform uses a drug core with one or more surrounding polymer layers to provide sustained delivery of drugs. Drug release is controlled by the permeability of the polymer layers. By changing elements of the design, we can alter both the rate and duration of release to meet different therapeutic needs. Our three approved products, as well as our two current product candidates in clinical trials, use different generations of this technology system.

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

<u>Product</u>	<u>Disease</u>	<u>Stage of Development</u>	<u>Licensee</u>
Retisert	Posterior uveitis	FDA-approved; commercialized since 2005	Bausch & Lomb
ILUVIEN	Chronic DME	EU-approved (6 countries); NDA PDUFA date (October 17, 2013)	Alimera
Medidur	Posterior Uveitis	Phase III	None
ILUVIEN	Dry age-related macular degeneration (Dry AMD)	Phase II	Alimera
ILUVIEN	Retinal vein occlusion (RVO)	Phase II	Alimera
TBD	Glaucoma	Investigator-sponsored Phase I/II clinical trial	Option by Pfizer

ILUVIEN for Chronic DME

ILUVIEN is an injectable, sustained-release micro-insert delivering fluocinolone acetonide (FAc) over a period of up to 3 years for the treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies.

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 has estimated that approximately 19.0 million people have diabetes in the six EU countries where ILUVIEN has been approved, and Alimera estimates that approximately 1.1 million of those people suffer from vision loss associated with DME. There is currently no approved sustained release drug treatment for DME in the U.S. or (other than ILUVIEN) in the EU.

ILUVIEN is licensed to Alimera, which commenced the commercial launch of ILUVIEN for DME in the United Kingdom and Germany in the second quarter of 2013 and expects to launch in France in the first quarter of 2014. Alimera is also seeking marketing approval in the U.S. We are entitled to share in net profits, as defined, on sales of ILUVIEN for DME by Alimera on a country-by-country basis. See “Strategic Collaborations—Alimera” below. Alimera has completed two 36-month Phase III clinical trials (the FAME® Study), which involved 956 patients in sites in the U.S., 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. The status of marketing approvals in the EU and the U.S. for ILUVIEN for DME and its commercial launch are as follows:

European Union. Alimera has received marketing authorization for ILUVIEN for DME in the U.K., Germany, France, Austria, Portugal and Spain. These approvals followed a favorable determination of approvability under the EU’s Decentralized Procedure (DCP). Marketing authorization is pending in Italy, which participated in the DCP. As part of this approval process, Alimera has committed to conduct a five-year, post-authorization, open label registry study of ILUVIEN in patients with chronic DME.

In the second quarter of 2013, Alimera commercially launched ILUVIEN in Germany and the U.K. and expects to launch in France in the first quarter of 2014. Alimera does not currently plan to expand the commercialization of ILUVIEN for DME in the EU beyond those three countries until it achieves positive cash flows and sustainability in those countries. Alimera continues to pursue pricing and reimbursement in the EU countries and marketing authorization in Italy.

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In Germany, the Federal Joint Committee indicated 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 allowed Alimera to launch ILUVIEN for DME in Germany without price restriction. Alimera is in the process of securing agreements for reimbursement with German statutory insurance funds so that German patients will not be required to submit individual funding requests for reimbursement.

In the U.K., ILUVIEN for DME is currently only available for private pay and privately insured patients as a result of final guidance from the U.K.'s National Institute for Health and Care Excellence (NICE). In April 2013, Alimera submitted a Patient Access Scheme (PAS) to NICE to assess the likely impact of the PAS and to determine whether an update to NICE's previously issued final guidance was warranted. In June 2013, the NICE Appraisal Committee published draft guidance recommending ILUVIEN for the treatment of pseudophakic patients (those who have undergone prior cataract surgery) with chronic DME considered insufficiently responsive to available therapies. If NICE amends its guidance to adopt this recommendation, ILUVIEN will also become available to pseudophakic patients in the U.K, which typically constitute a large subgroup of chronic DME patients, with the anticipation that it would be funded in England and Wales through the National Health Service.

In France, the Transparency Commission (Commission de la Transparence or CT) of the French National Health Authority (Haute Autorite de Sante) has issued a favorable opinion for the reimbursement and hospital listing by the French National Health Insurance of ILUVIEN for chronic DME considered insufficiently responsive to available therapies and despite optimized management of diabetes. In France, patients will be reimbursed for 100% of the cost of ILUVIEN under Affection de Longue Duree, a program for severe chronic disease, such as diabetes. Alimera has reported that it will move forward with the next step in the process, which is to determine the price and any reimbursement conditions for ILUVIEN in France.

United States. Alimera received a new PDUFA goal date of October 17, 2013 following its second resubmission of the NDA for ILUVIEN for DME in March 2013. Using clinical data available from the previously completed FAME Study, this resubmission focused on the safety aspects of ILUVIEN and provided additional analyses as well as information to support that ILUVIEN is safe and effective in the treatment of the subgroup population of patients with chronic DME considered insufficiently responsive to available therapies, the same subgroup for which marketing authorization for ILUVIEN has been granted in six countries in the EU. Additionally, data was submitted from a completed physician utilization study for the ILUVIEN applicator and from a special reading center assessment of photographs of the fundus, or the interior surface of the eye, that were collected during the FAME study. If approved, Alimera intends to commercialize ILUVIEN directly to retina centers across the US.

Alimera has previously received two CRLs concluding that the NDA could not be approved in its then current form. Alimera originally submitted the NDA for ILUVIEN in June 2010, largely based on analyses of clinical data through month 24 of the Phase III trials. In December 2010, Alimera received its first CRL, in which the FDA asked for analyses of safety and efficacy data through month 36 of the Phase III trials. In May 2011, Alimera resubmitted the NDA in response to the 2010 CRL, including additional safety and efficacy data through month 36 and analyses of data for the subgroup of chronic DME patients.

In a second CRL received in November 2011, the FDA concluded that the resubmitted 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 Phase III trials were significant and were not offset by the benefits demonstrated by ILUVIEN in those 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. In June 2012, Alimera met with the FDA to gain a better understanding of the regulatory path for ILUVIEN in the U.S. Alimera's March 2013 resubmission responded to this CRL using data from the FAME Study.

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Other Diseases. Under our agreement with Alimera, ILUVIEN is also being studied in two Phase II clinical trials for the treatment of the dry form of age-related macular degeneration (AMD) and retinal vein occlusion (RVO). A Phase II trial studying ILUVIEN in the treatment of the wet form of AMD has been terminated based on an interim analysis, due to the determination that the endpoint of reducing the number of anti-VEGF injections may not be appropriate to assess the benefit of ILUVIEN in that disease.

Medidur for Posterior Uveitis

Medidur is our lead development product for the treatment of posterior uveitis, an autoimmune condition characterized by inflammation of the posterior of the eye that can cause sudden or gradual vision loss. This product uses the same micro-insert used in ILUVIEN for DME, but is administered with a different inserter than the commercial inserter for ILUVIEN for DME. Medidur delivers FAc, the same drug as our FDA-approved Retisert for posterior uveitis, but at a lower dose, and is expected to treat posterior uveitis on a sustained basis over a period of up to 3 years.

In June 2013, we initiated the first of two planned Phase III clinical trials of Medidur for the treatment of posterior uveitis. These trials are expected to include clinical sites in the U.S., Europe and Asia. The trials will have a primary end-point of recurrence of posterior uveitis at 12 months and are expected to enroll approximately 300 patients in total. If the results of the trials are positive, we plan to use the data to submit an NDA to the FDA. The FDA has permitted us to move directly to Phase III clinical trials and confirmed that we will be able to reference much of the data, including the clinical safety data, from Alimera's FAME Study of ILUVIEN for DME. We are developing Medidur independently and have not licensed the rights to Medidur for posterior uveitis to Alimera or any other third party.

Because Medidur delivers FAc, the same drug as our FDA-approved Retisert product for posterior uveitis, although at a slower rate, we are optimistic that Medidur will show efficacy comparable to Retisert. Further, as Medidur uses the same micro-insert as ILUVIEN, we expect to observe a side-effect profile in posterior uveitis patients that is superior to that observed for Retisert for posterior uveitis and comparable to ILUVIEN for DME. As a result, we are optimistic that Medidur will be efficacious for posterior uveitis with a more favorable risk/benefit profile and fewer side effects than Retisert. Early interim data from an investigator-sponsored study is consistent with this hypothesis. Medidur is also easier to administer than Retisert because it is injected in an office visit, whereas Retisert is implanted in a surgical procedure.

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 in the U.S.

Retisert for Posterior Uveitis

Retisert is approved in the U.S. for the treatment of posterior uveitis. 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 was our first product, 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 delivery of the anti-viral drug ganciclovir for six to eight months. Vitrasert was originally licensed to and sold by Chiron Corporation and subsequently by Bausch & Lomb. During fiscal 2013, Bausch & Lomb discontinued sales of Vitrasert following patent expiration.

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Glaucoma Latanoprost Product Candidate

In connection with our 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 intraocular pressure (IOP) in patients with ocular hypertension and glaucoma worldwide. This product candidate is based on a fourth generation of our Durasert technology system, and is also anticipated to utilize our BioSilicon technology. 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”.

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 our BioSilicon technology designed to provide sustained delivery of large biologic molecules, including peptides, proteins and antibodies. 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. Our BioSilicon technology can also be designed to deliver smaller molecules.

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.

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 a February 2005 collaboration agreement, we granted Alimera an exclusive worldwide license to manufacture, develop, market and sell ILUVIEN for the treatment and prevention of human eye diseases 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 solely for the treatment and prevention of eye diseases in humans other than uveitis or (2) to treat DME in humans by delivering a compound by a direct delivery method through an incision no smaller than that required for a 25-gauge or larger needle. The non-exclusive license is limited to those products that amongst other things (i) have a drug core within a polymer layer (with certain limitations regarding chemically bonded combinations of active agents), and (ii) are approved, or designed to be approved, to deliver a corticosteroid and no other active ingredient by a direct delivery to the posterior portion of the eye, or to treat DME by delivering a compound by a direct delivery through an incision required for a 25-gauge or larger needle. 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 subject to the non-exclusive license granted to Alimera. Following a March 2008 amendment, Alimera assumed financial responsibility for the development of licensed products and regulatory submissions, which had previously been shared.

Alimera has 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 20% of any net profits, as defined, on sales of ILUVIEN by Alimera on a country-by-country basis, subject to an offset of 20% of net losses, as defined, incurred by Alimera

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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 license the development and commercialization of the Latanoprost Product worldwide for human ophthalmic disease or conditions other than uveitis. If Pfizer were to exercise such option, we would be eligible to receive future consideration of up to \$166.5 million plus royalties. In addition, 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. 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 Latanoprost 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 so terminates, or if we terminate for Pfizer's material breach, we have the right to develop and commercialize the Latanoprost Product.

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

Pfizer owned approximately 7.0% of our outstanding stock as of August 31, 2013.

Bausch & Lomb

Under a 2003 amended licensing agreement, Bausch & Lomb has a worldwide exclusive license to make and sell our first-generation products (which, as defined in the agreement, includes Retisert) as well as Vitrasert 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 used in manufacturing BioSilicon material for total payments of \$122,000. In July 2011, Intrinsiq terminated its field-of-use license agreement, we purchased the BioSilicon-related capital equipment and intellectual property assets of Intrinsiq for \$223,000 and assumed four Intrinsiq employees.

Enigma Therapeutics

Under a December 2012 license agreement, amended and restated in March 2013, Enigma Therapeutics Limited (Enigma) acquired an exclusive, worldwide, royalty-bearing license for the development of BrachySil, a BioSilicon product candidate for the treatment of pancreatic and other types of cancer. We received an upfront fee of \$100,000, included in collaborative research and development revenue in fiscal 2013, and are entitled to an 8% sales-based royalty, 20% of sublicense consideration and milestones based on aggregate product sales. Enigma is obligated to pay an annual license maintenance fee of \$100,000, creditable during each ensuing twelve month period against reimbursable patent maintenance costs and sales-based royalties. Enigma has the right to terminate its license upon 60 days prior written notice.

Research and Development

Our clinical and pre-clinical research programs primarily consist of ophthalmic applications of our technology systems. Our research and development expenses totaled \$7.0 million in fiscal 2013, \$7.0 million in fiscal 2012 and \$6.9 million in fiscal 2011. Of these amounts, \$5.4 million in fiscal 2013, \$4.2 million in fiscal 2012 and \$3.2 million in fiscal 2011 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 \$1.6 million in fiscal 2013, \$2.8 million in fiscal 2012 and \$3.7 million in fiscal 2011 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 consolidated statements of comprehensive loss.

[Table of Contents](#)**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, 2013:

<u>Technology</u>	<u>United States Patents</u>	<u>United States Applications</u>	<u>Foreign Patents</u>	<u>Foreign Applications</u>	<u>Patent Families</u>
Durasert	8	9	77	52	19
Tethadur	6	6	9	23	6
Other BioSilicon	13	4	70	4	21
Other	6	8	23	5	14
Total	33	27	179	84	60

Employees

We had 25 employees as of August 31, 2013. None of our employees is covered by a collective bargaining agreement.

Sales and Marketing

We have no marketing or sales staff. We currently 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 extent to which reimbursement of the cost of the products and the related administration procedures is and will be available from government health administration authorities, private health insurers and other organizations, and the timing of those reimbursements, is important to the successful commercialization of those products. 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 has been engaged in regulatory proceedings and negotiations with respect to pricing and reimbursement of ILUVIEN for DME in various EU countries where it has or expects to receive marketing authorizations.

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 our partners. Competitors may reach the market earlier than us or our partners, 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.

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Many companies have or are pursuing products to treat back-of-the-eye diseases that 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. Genentech is a wholly-owned member of the Roche Group. Novartis has the right to market and sell Lucentis outside of the U.S. Regeneron Pharmaceuticals, Inc.'s product EYLEA (aflibercept) is approved in the U.S., EU and Australia for the treatment of neovascular wet AMD, marketing applications have been submitted in other countries and a Phase III clinical study for wet AMD is ongoing 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, and Regeneron has announced that it plans to file for approval in DME by the end of 2013. Regeneron maintains exclusive rights to EYLEA in the U.S., and Bayer HealthCare owns the exclusive marketing rights outside the U.S. Allergan, Inc. has announced that it has submitted marketing applications in the U.S. and Europe for Ozurdex® (dexamethasone intravitreal implant), its approved product for posterior uveitis and RVO, in DME patients. 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 is a bioerodible, extended release intravitreal implant that delivers the corticosteroid dexamethasone. Ozurdex is approved in the U.S. and EU 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, XOMA Ltd.'s Gevokizumab™ and Genentech's Lucentis.
- *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.

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

[Table of Contents](#)**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,								
	2013			2012			2011		
	U.S.	U. K.	Total	U.S.	U. K.	Total	U.S.	U. K.	Total
	(In thousands)								
Revenue:									
Collaborative research and development	\$ 510	\$270	\$ 780	\$ 939	\$1,141	\$2,080	\$3,529	\$ 83	\$3,612
Royalty income	1,363	—	1,363	1,446	—	1,446	1,353	—	1,353
	<u>\$1,873</u>	<u>\$270</u>	<u>\$2,143</u>	<u>\$2,385</u>	<u>\$1,141</u>	<u>\$3,526</u>	<u>\$4,882</u>	<u>\$ 83</u>	<u>\$4,965</u>

Government Regulation

Federal Food, Drug, and Cosmetic Act and Comparable Foreign Laws. The FDA and comparable regulatory agencies in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of pharmaceutical products. These agencies regulate, among other things, the research, development, testing, manufacture, quality control, labeling, storage, record-keeping, approval, distribution, advertising and promotion of drug 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 Investigational New Drug (IND) application, 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.

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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:* These 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.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a Risk Evaluation Mitigation Strategy (REMS) program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, product recalls, or complete withdrawal of the product from the market;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

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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. 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. 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. 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 REMS program. 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.

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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 (cGMP), which impose procedural and documentation requirements upon us and our third-party manufacturers.

Healthcare Law and Regulation. Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of drug products that are granted marketing approval. Arrangements with third-party payors and customers are subject to broadly applicable fraud and abuse and other healthcare laws and regulations in the U.S. and other countries and jurisdictions. Such restrictions under applicable U.S. federal and state healthcare laws and regulations include the following:

- the federal healthcare Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;
- the federal False Claims Act imposes civil penalties, and provides for civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of, or payment for, healthcare benefits, items or services; and
- the federal transparency requirements under the Health Care Reform Law will require manufacturers of drugs, devices, drugs and medical supplies to report to the Department of Health and Human Services information related to payments and other transfers of value to physicians and teaching hospitals and physician ownership and investment interests.

Analogous state and foreign laws and regulations, such as anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Other Laws. 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.

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Foreign Laws. 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.

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).

Information with respect to ILUVIEN for DME has been derived from public disclosures by Alimera.

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 net income in fiscal 2010 resulting from a non-recurring event, we have incurred operating losses since our inception in 2000. We do not currently have any assured sources of revenues. Although Alimera launched ILUVIEN commercially in the U.K. and Germany in the second quarter of 2013 and announced its intention to launch in France in the first quarter of 2014, we do not know the timing and extent of any revenues we may receive from ILUVIEN for DME. Unless 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, and Alimera will not be able to sell, nor will we earn any revenues from sales of, ILUVIEN for DME in the U.S. We will not receive any funding under our Restated Pfizer Agreement unless Pfizer exercises its option with respect to the Latanoprost Product, which becomes exercisable only if we complete Phase II clinical trials, which have not yet 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 Retisert royalty income from Bausch & Lomb is not expected to increase to a level sufficient to sustain our operations and may decline. Further, we expect to significantly increase our research and development expense as a result of our independent development of Medidur for posterior uveitis. Our ability to achieve profitability is expected to depend, among other things, upon Alimera's ability to achieve FDA approval of and to successfully commercialize ILUVIEN for DME and our or any other licensees' ability to achieve regulatory approval and sufficient revenues from commercialization of one or more products.

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 the proceeds of offerings of our common stock and warrants and consideration received from our collaborative partners, including license fees and research and development funding. We currently have no committed funding from collaborative partners. We believe that our cash, cash equivalents and marketable securities of \$10.3 million at June 30, 2013 together with the \$9.9 million of net proceeds from our July 2013 underwritten public offering of common stock, expected Retisert royalty income and other expected cash inflows under existing collaboration and technology evaluation agreements, will enable us to fund our current and planned operations through calendar year 2014. This includes expected costs through that date of Phase III clinical trials of Medidur for posterior uveitis, but does not include any potential milestone or net profits receipts under the Alimera collaboration agreement. 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 any such receipts is uncertain. Accordingly, we expect to need additional resources to fund our planned Phase III trials of Medidur for posterior uveitis and other research and development and 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.;
- the timing and cost of development of Medidur for posterior uveitis;
- whether and when we initiate and complete Phase II clinical trials for the Latanoprost Product and Pfizer exercises its option;
- whether and the extent to which we internally fund, when we initiate, and how we conduct product development and programs, including with respect to our BioSilicon and Tethadur technology;

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- whether and when we are able to enter into strategic arrangements for products and the nature of those arrangements;
- 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 sales of equity or debt securities or new collaborative or licensing agreements and/or possible other agreements and transactions. Many factors relating to our company, such as the status of FDA approval of 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 materially adversely affected.

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 had \$3.4 million of intangible assets on our balance sheet as of June 30, 2013, of which \$2.4 million related to our Durasert technology and \$1.0 million related 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 that 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 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.

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;

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- 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 decreases in our stock price.

Our royalty income from Bausch & Lomb may decline.

We do not expect that our Retisert royalty income from Bausch & Lomb will grow materially, if at all, and it may decline. There is no assurance that Bausch & Lomb will continue to market Retisert, which received marketing approval in 2005. Bausch & Lomb no longer markets Vitrasert.

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

If the FDA does not approve 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 and the 2011 CRL in response to its first resubmission of the NDA. In both the 2010 and 2011 CRLs, the FDA stated that it was unable to approve the then current NDA. Although Alimera resubmitted the NDA a second time and received a new PDUFA goal date of October 17, 2013, there is no assurance that Alimera's resubmission will demonstrate to the FDA that the benefits of ILUVIEN for DME outweigh its risks, that additional clinical trials will not be required, that the subgroup of patients with chronic DME considered insufficiently responsive to available therapies 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.

Sales of ILUVIEN for DME in the EU may be materially adversely affected by pricing and reimbursement decisions of regulatory bodies, insurers and others.

Prices, coverage and reimbursement in EU countries are regulated, with prices generally lower and access to drugs more limited than in the U.S., which could continue to affect the amount of revenues from the commercialization of ILUVIEN for DME in the EU. Alimera has been engaged in regulatory proceedings and negotiations with respect to pricing and reimbursement. 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. For example, there is no assurance that the patient population in the U.K. will expand beyond privately insured and private pay patients or what the level of permitted reimbursement will be. There can be no assurance that NICE will accept the recommendation of the Appraisal Committee and amend its final guidance to provide ILUVIEN for the treatment of pseudophakic patients or that such patients will be reimbursed by the National Health Service. Similarly, there is no assurance that Alimera will achieve satisfactory agreements with statutory insurers in Germany to avoid individual reimbursement submissions. Alimera has reported its belief that sales of ILUVIEN for DME in Germany and the U.K. have been adversely affected, and future sales in

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those and other EU countries may be adversely affected, by pricing and reimbursement decisions, and such affects may be material.

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. Although Alimera commercially launched ILUVIEN in the U.K. and Germany during the quarter ended June 2013, there were limited sales in that quarter. Alimera has announced its intention to launch in France in the first quarter of 2014, but has not announced commercialization plans for the other EU countries where it has marketing approval. 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 a net profit participation on sales of ILUVIEN wherever Alimera markets ILUVIEN directly and a percentage of royalties and non-royalty consideration wherever 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 such additional approvals. Further, we cannot project what the demand will be for ILUVIEN for DME in the EU countries where ILUVIEN is marketed.

Both ILUVIEN and Medidur 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 Medidur for posterior uveitis 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. These side effects may affect the approvability of ILUVIEN for DME and the other eye conditions for which it is being studied. Although FDA-approved Retisert and our product candidate Medidur both deliver FAc to treat posterior uveitis, there is no assurance that Medidur will be safe and efficacious for the treatment of posterior uveitis in light of its expected side effects from FAc. Even if these product candidates are approved, these side effects may adversely affect their successful marketing.

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 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; that if exercised, Pfizer will commence Phase III clinical trials; or that the Latanoprost Product will achieve successful Phase III trial results, regulatory approvals or commercial success. As a result, there is no assurance that we will receive any further licensing, milestone or royalty payments under the Restated Pfizer Agreement.

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

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

ILUVIEN for DME has completed pivotal clinical trials, which were conducted pursuant to our Alimera collaboration agreement, and Medidur for posterior uveitis has commenced the first of two pivotal Phase III clinical trials. All of our other product development is at earlier stages. An investigator-sponsored Phase I/II study of the Latanoprost Product is ongoing, but we have not commenced Phase II clinical trials, and BioSilicon and Tethadur product candidates are all in the pre-clinical stage. 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 laboratory practices (GLP), good clinical practices (GCP) or good manufacturing practices or similar foreign regulatory requirements that affect the conduct of pre-clinical and clinical studies and the manufacturing of products;

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- 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.

Our strategy includes independently developing products, but 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 or fund sufficient capabilities necessary to develop products and achieve market penetration ourselves.

Our business strategy also includes entering into collaborative and licensing arrangements for the development and commercialization of our product candidates, where appropriate, and we currently have collaboration and/or licensing arrangements with Alimera, Pfizer, Bausch & Lomb and Enigma. 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

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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 seek to independently manufacture, market and sell products or are unable to enter into future license agreements with marketing and sales partners where we deem appropriate, we would experience increased capital requirements to develop the ability to manufacture, market and sell future products. There can be no assurance that we will be able to manufacture, market or sell our products or future products independently.

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.

For example, 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, Bausch & Lomb may terminate its license agreement with respect to Retisert without penalty at any time upon 90 days' written notice and Alimera may abandon the development and commercialization of any licensed product, including ILUVIEN for DME, at any time.

Any of our licensees 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. Actions, including breaches or termination of these agreements by our licensees, could delay, impair or stop the development or

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commercialization of any of the products or product candidates licensed to them or require significant additional capital investment by us, which we may not have the resources to fund.

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.

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 than we do.

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.

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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, 2013, we had 212 patents and 111 pending patent applications, including patents and pending applications covering our Durasert, BioSilicon (including Tethadur) and other 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

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

RISKS RELATED TO OUR BUSINESS, INDUSTRY, STRATEGY AND OPERATIONS

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

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

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

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

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

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

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

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

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

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

There 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 licensees. Our licensees have 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

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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.

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

- clinical trials and their results and other product and technological developments and innovations;
- FDA and other domestic and international governmental regulatory actions, receipt and timing of approvals of our product candidates, and any denials and withdrawal of approvals;
- competitive factors, including the commercialization of new products in our markets by our competitors;
- advancements with respect to treatment of the diseases targeted by our product candidates;
- developments relating to and actions by our 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;
- actions with respect to pricing, reimbursement and coverage, and changes in reimbursement policies or other practices relating to our products 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 (ASX) for our stock and CDIs 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, 2013, we had outstanding warrants and options to acquire approximately 5.1 million shares of our common stock, or approximately 16.1% of our shares on a fully diluted basis. The issuance of shares of our common stock upon exercise of these warrants and stock options could result in dilution to the interests of other holders of our common stock and could adversely affect our stock price. The overhang of outstanding warrants and options may adversely affect our stock price.

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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 our right at any time to terminate 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:

	<u>High</u>	<u>Low</u>
Fiscal year ended June 30, 2013:		
First Quarter	\$3.50	\$1.45
Second Quarter	1.69	1.17
Third Quarter	2.58	1.18
Fourth Quarter	4.03	2.09
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

On September 23, 2013, the last reported sale price of our common stock on the NASDAQ Global Market was \$4.03. As of that date, we had approximately 26 holders of record of our common stock and, according to our estimates, approximately 3,750 beneficial owners of our common stock. In addition, as of that date, there were approximately 2,250 beneficial 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, 2013:

<u>Plan category</u>	<u>Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)</u>	<u>Weighted-average exercise price of outstanding options, warrants and rights (b)</u>	<u>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in Column a) (c)</u>
Equity Compensation plans approved by security holders	3,554,549	\$ 2.92	1,056,459
Equity Compensation plans not approved by security holders	—	—	—
Total	<u>3,554,549</u>	<u>\$ 2.92</u>	<u>1,056,459</u>

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, 2013, the number of shares issuable under the 2008 Incentive Plan was increased by 750,000 shares.

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Issuer Repurchases of Equity Securities

None.

ITEM 6. SELECTED FINANCIAL DATA

The selected historical financial data set forth below as of June 30, 2013, 2012, 2011, 2010 and 2009 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, 2013 and 2012 and for the years ended June 30, 2013, 2012 and 2011 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,				
	2013	2012	2011	2010	2009
	(In thousands except per share data)				
Consolidated Statements of Operations Data:					
Revenues:					
Collaborative research and development (1)	\$ 780	\$ 2,080	\$ 3,612	\$22,570	\$12,002
Royalty income	1,363	1,446	1,353	483	160
Total revenues	<u>2,143</u>	<u>3,526</u>	<u>4,965</u>	<u>23,053</u>	<u>12,162</u>
Operating expenses:					
Research and development	7,005	7,039	6,864	6,994	8,007
General and administrative	7,169	6,868	8,104	6,968	8,791
Impairment of intangible assets (2)	—	14,830	—	—	—
Total operating expenses	<u>14,174</u>	<u>28,737</u>	<u>14,968</u>	<u>13,962</u>	<u>16,798</u>
Operating (loss) income	<u>(12,031)</u>	<u>(25,211)</u>	<u>(10,003)</u>	<u>9,091</u>	<u>(4,636)</u>
Other income (expense):					
Change in fair value of derivatives	—	170	1,140	(339)	959
Interest income	16	38	30	27	162
Other (expense) income, net	(2)	(1)	(13)	(3)	53
Total other income (expense)	<u>14</u>	<u>207</u>	<u>1,157</u>	<u>(315)</u>	<u>1,174</u>
(Loss) income before income taxes	<u>(12,017)</u>	<u>(25,004)</u>	<u>(8,846)</u>	<u>8,776</u>	<u>(3,462)</u>
Income tax benefit (expense)	117	169	218	(23)	951
Net (loss) income	<u><u>\$ (11,900)</u></u>	<u><u>\$ (24,835)</u></u>	<u><u>\$ (8,628)</u></u>	<u><u>\$ 8,753</u></u>	<u><u>\$ (2,511)</u></u>
Net (loss) income per share:					
Basic	<u><u>\$ (0.52)</u></u>	<u><u>\$ (1.19)</u></u>	<u><u>\$ (0.44)</u></u>	<u><u>\$ 0.48</u></u>	<u><u>\$ (0.14)</u></u>
Diluted	<u><u>\$ (0.52)</u></u>	<u><u>\$ (1.19)</u></u>	<u><u>\$ (0.44)</u></u>	<u><u>\$ 0.46</u></u>	<u><u>\$ (0.14)</u></u>
Weighted average common shares outstanding:					
Basic	<u>23,044</u>	<u>20,791</u>	<u>19,489</u>	<u>18,405</u>	<u>18,263</u>
Diluted	<u>23,044</u>	<u>20,791</u>	<u>19,489</u>	<u>18,895</u>	<u>18,263</u>

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	As of June 30,				
	2013	2012	2011	2010	2009
	(In thousands)				
Consolidated Balance Sheet Data:					
Cash and cash equivalents	\$ 6,899	\$ 4,625	\$12,912	\$15,514	\$ 6,899
Marketable securities	3,374	9,946	11,216	2,051	—
Total assets	16,249	20,597	47,113	43,014	37,104
Total deferred revenue—current and long-term	5,984	5,959	7,847	6,896	10,534
Total stockholders' equity	7,700	13,636	37,433	33,041	23,541

- (1) Amounts recognized include \$368,000 in fiscal 2013, \$754,000 in fiscal 2012 and \$3.3 million in fiscal 2011 from our Restated Pfizer Agreement; \$67,000 in fiscal 2013, \$111,000 in fiscal 2012, \$192,000 in fiscal 2011, \$22.3 million in fiscal 2010 and \$11.8 million in fiscal 2009 from our collaboration agreement with Alimera; and \$1.1 million in fiscal 2012 in connection with the termination of our field-of-use license agreement with Intrinsiq. See Note 3 to the accompanying 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 7 to the accompanying consolidated financial statements.

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 products designed to deliver drugs and biologics at a controlled and steady rate for weeks, months or years. Utilizing our core technology platforms, Durasert™ and BioSilicon™, we are focused on treatment of chronic diseases of the back of the eye and are also exploring applications outside ophthalmology. We have developed three of the four sustained-release products for treatment of retinal diseases currently approved in the U.S. or European Union (EU), and our lead product candidate began a Phase III clinical trial in June 2013. Our strategy includes developing products independently while continuing to leverage our technology platforms through collaboration and license agreements.

ILUVIEN®, our most recently approved product, is an injectable, sustained-release micro-insert that provides treatment of vision impairment associated with chronic diabetic macular edema (DME) considered insufficiently responsive to available therapies over a period of up to three years. *ILUVIEN* is licensed to and sold by Alimera Sciences, Inc. (Alimera), and we are entitled to a share of the net profits, as defined, from Alimera's sales of *ILUVIEN* for DME. Alimera commenced the commercial launch of *ILUVIEN* for DME in the U.K. and Germany in the second quarter of 2013 and expects to launch in France in the first quarter of 2014. The International Diabetes Federation has estimated that approximately 19.0 million people have diabetes in the seven EU countries where *ILUVIEN* has received or been recommended for marketing authorization, of which Alimera has estimated that approximately 1.1 million people suffer from vision loss associated with DME. Alimera is also seeking marketing approval for *ILUVIEN* for DME in the U.S. In the second quarter of 2013, Alimera received a new Prescription Drug User Fee Act (PDUFA) goal date of October 17, 2013 after resubmitting its New Drug Application (NDA) for *ILUVIEN* for DME. The resubmission responded to a second Complete Response Letter (CRL) received from the U.S. Food and Drug Administration (FDA) in November 2011.

Medidur™, our lead development product, commenced the first of our two planned Phase III clinical trials for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye (posterior uveitis) in June 2013. *Medidur* uses the same Durasert micro-insert used in *ILUVIEN* and delivers a lower dose of the same drug as our FDA-approved Retisert® for posterior uveitis, which is licensed to Bausch & Lomb. We are developing *Medidur* independently.

We are also developing a bioerodible, injectable micro-insert delivering latanoprost (the Latanoprost Product) to treat glaucoma and ocular hypertension. Under an amended collaboration agreement, Pfizer has an option, under certain circumstances, to license the development and commercialization of the Latanoprost Product worldwide.

We are engaged in pre-clinical research with respect to both our BioSilicon and Durasert technology platforms. The primary focus of our BioSilicon technology research is the sustained delivery of peptides, proteins, antibodies and other large biologic molecules using our Tethadur™ technology in both ophthalmic and non-ophthalmic applications. Our research program also includes the use of Durasert technology in orthopedic applications and for systemic delivery of therapeutic agents.

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Our FDA-approved *Retisert* provides sustained release treatment of posterior uveitis for approximately two and a half years and is licensed to and sold by 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 committees) 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, 2013, we reported \$780,000 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.

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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.

We concluded that our deliverables under the Restated Pfizer Agreement are 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 treat these as a single deliverable, having concluded that the JSC does not have standalone value separate from the R&D program. 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.

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. The remaining balance is being recognized as revenue using the proportional performance method over the estimated period of our performance obligations under the R&D program.

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 each of fiscal 2012 and fiscal 2013 by 10%, or \$75,000 and \$37,000, respectively. Application of the proportional performance method in any fiscal period would result in an increase or decrease in revenue recognized to the extent that the aggregate projected costs to conduct the R&D program decreases or increases, respectively, compared to the previous period.

Valuation of Intangible Assets

At December 31, 2011, we recorded a \$11.7 million impairment of our BioSilicon intangible and a \$3.1 million impairment of our Duraserit intangible. The combination of the 2011 CRL and the subsequent significant decline in the Company's market capitalization were determined to be impairment indicators of the Company's finite-lived intangible assets. To assess the recoverability of these assets (which had a carrying value of \$19.4 million at December 31, 2011), we used both market-based and income-based valuation methodologies, and allocated the resulting fair value of the combined intangible assets to the individual assets based on values determined under the income-based approach.

We amortize our 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 \$760,000 per year. We believe that the carrying value of our intangible assets will be recouped primarily through expected net cash flows from our existing or future collaboration agreements or through our own product development and commercialization.

We will continue to review our intangible assets for impairment whenever events or changes in business circumstances indicate that the asset carrying values may not be fully recoverable or that the useful lives of assets are 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,

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- 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, 2013 and 2012

	Year ended June 30,		Change	
	2013	2012	Amounts	%
	(In thousands except percentages)			
Revenues	\$ 2,143	\$ 3,526	\$ (1,383)	(39)%
Operating expenses:				
Research and development	7,005	7,039	(34)	(0)%
General and administrative	7,169	6,868	301	4%
Impairment of intangible assets	—	14,830	(14,830)	(100)%
Total operating expenses	14,174	28,737	(14,563)	(51)%
Operating loss	(12,031)	(25,211)	13,180	52%
Other income (expense):				
Change in fair value of derivatives	—	170	(170)	(100)%
Interest income	16	38	(22)	(58)%
Other expense, net	(2)	(1)	(1)	(100)%
Total other income	14	207	(193)	(93)%
Loss before income taxes	(12,017)	(25,004)	12,987	52%
Income tax benefit	117	169	(52)	(31)%
Net loss	<u>\$(11,900)</u>	<u>\$(24,835)</u>	<u>\$ 12,935</u>	<u>52%</u>

Revenues

We recognized total revenue of \$2.1 million for fiscal 2013 as compared to \$3.5 million for fiscal 2012.

Collaborative research and development revenue declined to \$780,000 in fiscal 2013, a 63% decrease from \$2.1 million in fiscal 2012, primarily due to non-recurring revenue of \$1.1 million in fiscal 2012, which was recognized upon the termination of a field-of-use license. Approximately half of our collaborative research and

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development revenue was recognition of deferred revenue from collaboration agreements in fiscal 2013 compared to substantially all in the prior year. \$738,000 of the remaining deferred revenue balance of \$6.0 million at June 30, 2013 is expected to be recognized as revenue during fiscal 2014.

Our Retisert royalty income in fiscal 2013 increased to \$1.4 million, a 3.6% increase over the prior year. Substantially all of the royalty income in both years was derived from sales of Retisert by Bausch & Lomb. During fiscal 2013, Bausch & Lomb discontinued sales of Vitrasert. We do not expect Retisert royalty income to increase significantly in the future, and it may decline.

Research and Development

Research and development totaled \$7.0 million in each of fiscal 2013 and fiscal 2012. Periodic amortization of intangible assets decreased by \$1.3 million in fiscal 2013 compared to fiscal 2012, which resulted from a \$14.8 million intangible asset impairment write-down at December 31, 2011. This decrease was substantially offset in fiscal 2013 by approximately \$700,000 of initial costs incurred for the first of two planned pivotal Phase III clinical trials of Medidur for posterior uveitis, which commenced in the quarter ended June 30, 2013, and an approximate \$600,000 increase in personnel costs, which consisted primarily of additional headcount and cash incentive compensation accruals. We expect to significantly increase our research and development expense in fiscal 2014 in connection with patient enrollment for the Phase III clinical trial of Medidur.

General and Administrative

General and administrative costs increased by \$301,000, or 4%, to \$7.2 million for fiscal 2013 from \$6.9 million for fiscal 2012, primarily attributable to \$630,000 of cash incentive compensation accruals, which compared to zero in the prior year. This was partially offset by an approximate \$430,000 decrease in professional fees.

Other Income

Other income decreased by \$193,000, or 93%, to \$14,000 for fiscal 2013 from \$207,000 for fiscal 2012. Other income for fiscal 2012 consisted primarily of the change in fair value of derivatives of \$170,000. This income, which reduced the derivative liability balance to zero, was determined using the Black-Scholes valuation model, and resulted from the July 2012 expiration of the remaining warrants denominated in Australian dollars (A\$), which were recorded as derivative liabilities at issuance and revalued at subsequent period reporting dates. Interest income, net, decreased by \$23,000 from fiscal 2012 to fiscal 2013 as a result of lower levels of marketable securities investments and further decreases in yields for investment grade corporate bonds and commercial paper of short maturities.

Income Tax Benefit

Income tax benefit, which consisted of foreign research and development tax credits, decreased by \$52,000, or 31%, to \$117,000 in fiscal 2013 from \$169,000 in fiscal 2012, primarily attributable to the impact of third party funding of certain qualified research and development costs.

[Table of Contents](#)**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	<u>\$(24,835)</u>	<u>\$ (8,628)</u>	<u>\$(16,207)</u>	<u>(188)%</u>

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.

We restated the Pfizer Agreement in fiscal 2011, for which we received \$2.3 million in upfront consideration, resulting in an aggregate \$10.0 million balance of deferred revenue associated with that agreement. In fiscal 2011, we recognized \$3.3 million of deferred revenue from that agreement, and the remainder is being recognized as revenue using the proportional performance method over the estimated period of our performance obligations under the Latanoprost Product research program.

Collaborative research and development revenue for fiscal 2012 of \$2.1 million consisted primarily of deferred revenue recognition of \$754,000 related to the 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.

Substantially all of our royalty income in fiscal 2012 and fiscal 2011 was from sales of Retisert. Our total royalty income increased by \$92,000, or 6.8%, in fiscal 2012 compared to fiscal 2011, and approximated \$1.4 million in each year. Our remaining royalty income was from Vitrasert sales.

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.

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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 was 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 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.

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 ASU 2011-5 *Comprehensive Income (Topic 220) – Presentation of Comprehensive Income*, which provides new guidance on the presentation of comprehensive income. This guidance requires 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. The Company adopted this standard for the quarter ended September 30, 2012 and has presented the required information in one continuous statement of operations and comprehensive loss on a comparative basis. Other than a change in presentation, the adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

Liquidity and Capital Resources

During fiscal 2011 through fiscal 2013, we financed our operations primarily from registered direct offerings of our equity securities in January 2011 and August 2012, as well as operating cash flows from license fees and research and development funding from collaborations. At June 30, 2013, our principal source of liquidity consisted of cash, cash equivalents and marketable securities totaling \$10.3 million. In July 2013, we

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enhanced our cash resources through the sale, in an underwritten public offering, of 3,494,550 shares of common stock for net proceeds of \$9.9 million. Our cash equivalents are invested in institutional money market funds, and our marketable securities are invested in investment-grade corporate debt and commercial paper with maturities at June 30, 2013 ranging from one to seven months.

With the exception of net income in fiscal 2010 resulting from a non-recurring event, we have incurred operating losses since inception and, at June 30, 2013, we had a total accumulated deficit of \$263.7 million. We do not currently have any assured sources of revenue and we generally expect negative cash flows from operations on a quarterly basis unless and until such time as we receive sufficient revenues from ILUVIEN for DME or one or more of our other product candidates achieve regulatory approval and provide us sufficient revenues. We believe that our capital resources of \$10.3 million at June 30, 2013, together with the \$9.9 million of net proceeds from our July 2013 share offering, expected Retisert royalty income and other expected cash inflows under existing collaboration and evaluation agreements will enable us to fund our operations as currently planned through calendar year 2014. This includes expected costs through that date of Phase III clinical trials of Medidur for posterior uveitis, but does not include any potential milestone or net profit receipts under the Alimera collaboration agreement. 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 any such receipts is uncertain. Accordingly, we expect to need additional resources to fund our planned Phase III trials for Medidur for posterior uveitis, as well as other research and development and operations. 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.;
- the timing and cost of development of Medidur for posterior uveitis;
- whether and when we initiate Phase II clinical trials for the Latanoprost Product and Pfizer exercises its option;
- whether and the extent to which we internally fund, when we initiate, and how we conduct product development and programs, including with respect to BioSilicon and Tethadur applications;
- whether and when we are able to enter into strategic arrangements for products and the nature of those arrangements;
- 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 existing and potential future collaboration or other agreements and/or financing transactions, management currently believes that our cash position beyond calendar year 2014 depends significantly on possible revenues from the successful commercialization by Alimera of ILUVIEN for DME in the EU and, if approved by the FDA, 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.

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

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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,		
	2013	2012	2011
	(In thousands)		
Net loss:	\$(11,900)	\$(24,835)	\$ (8,628)
Changes in operating assets and liabilities	692	(2,715)	1,211
Other adjustments to reconcile net loss to cash flows from operating activities	2,463	18,549	4,247
Cash flows used in operating activities	<u>\$ (8,745)</u>	<u>\$ (9,001)</u>	<u>\$ (3,170)</u>
Cash flows provided by (used in) investing activities	<u>\$ 6,358</u>	<u>\$ 606</u>	<u>\$ (9,498)</u>
Cash flows provided by financing activities	<u>\$ 4,669</u>	<u>\$ 114</u>	<u>\$10,060</u>

Sources and uses of operating cash flows for the years ended June 30, 2013, 2012 and 2011 are summarized as follows:

	Year Ended June 30,		
	2013	2012	2011
	(In thousands)		
Operating cash inflows:			
License and collaboration agreements	\$ 854	\$ 187	\$ 4,665
Royalty income	1,477	1,277	1,360
Foreign R&D tax credits	152	93	142
Federal R&D grants	—	—	208
Investment interest received, net	215	372	129
	<u>2,698</u>	<u>1,929</u>	<u>6,504</u>
Operating cash outflows:			
Personnel costs	(4,539)	(4,906)	(3,926)
Professional fees	(2,729)	(3,330)	(3,061)
Clinical development and third-party R&D	(2,153)	(690)	(848)
All other operating cash outflows, net	(2,022)	(2,004)	(1,839)
	<u>(11,443)</u>	<u>(10,930)</u>	<u>(9,674)</u>
Cash flows used in operating activities	<u>\$ (8,745)</u>	<u>\$ (9,001)</u>	<u>\$ (3,170)</u>

Operating cash inflows for each year consisted primarily of payments received pursuant to license and collaboration agreements. As a percentage of total license and collaboration cash inflows, amounts attributable to Pfizer represented 92.2% in fiscal 2011, amounts attributable to Alimera represented 8.4% in fiscal 2013, 57.2% in fiscal 2012 and 5.3% in fiscal 2011, amounts attributable to Enigma represented 11.7% in fiscal 2013 and amounts attributable to various technology evaluation agreements represented 73.2% in fiscal 2013 and 26.7% in fiscal 2012.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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 Pound Sterling to the U.S. dollar impact the net operating expenses of our U.K. operations. The minimal strengthening of the U.S. dollar in fiscal 2013 compared to fiscal 2012 resulted in a net decrease in research and development expense of approximately \$22,000. For every incremental 5% strengthening or weakening of the weighted average exchange rate of the U.S. dollar in relation to the Pound Sterling, our research and development expense in fiscal 2013 would have decreased or increased by \$109,000, respectively. 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 comprehensive loss exposure to realized and unrealized foreign currency gains and losses to be significant.

Changes in the foreign exchange rate of the Pound Sterling to the U.S. dollar also impacted total stockholders' equity. As reported in the statement of comprehensive loss, the relative strengthening of the U.S. dollar in relation to the Pound Sterling at June 30, 2013 compared to June 30, 2012 resulted in a net increase of \$29,000 in other comprehensive loss due to the translation of £731,000 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, 2013 in relation to the Pound Sterling, our stockholders' equity at June 30, 2013 would have decreased or increased, respectively, by approximately \$56,000.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by this item may be found on pages F-1 through F-26 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, 2013. 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, 2013, 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.

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(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, 2013. 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 SEC that permit the Company, as a smaller reporting company, 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, 52

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, 46

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, 63

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 Conduct that applies to all of our employees, officers and directors. This Code of Conduct is designed to ensure that our business is conducted with integrity and in compliance with SEC regulations and NASDAQ and 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.

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We intend to disclose any future amendments to, or waivers from, the Code of Conduct that affect our directors or senior financial and 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 2013 Proxy Statement.

ITEM 11. EXECUTIVE COMPENSATION

The information required to be disclosed in Item 11 is hereby incorporated by reference to our 2013 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 2013 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 2013 Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required to be disclosed in Item 14 is hereby incorporated by reference to our 2013 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.

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(a)(3) Exhibits.

Exhibit No.	Exhibit Description	Incorporated by Reference to SEC Filing		
		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
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 pSivida US, Inc. and Bausch & Lomb dated August 1, 2009	10-K	09/25/09	10.13

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Exhibit No.	Exhibit Description	Incorporated by Reference to SEC Filing		
		Form	SEC Filing Date	Exhibit No.
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, 2013, formatted in eXtensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets at June 30, 2013 and 2012; (ii) Consolidated Statements of Comprehensive Loss for the years ended June 30, 2013, 2012 and 2011; (iii) Consolidated Statements of Stockholders' Equity for the years ended June 30, 2013, 2012 and 2011; (iv) Consolidated Statements of Cash Flows for the years ended June 30, 2013, 2012 and 2011; 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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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, 2013 and 2012, and the related consolidated statements of comprehensive loss, stockholders’ equity, and cash flows for each of the three years in the period ended June 30, 2013. 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, 2013 and 2012, and the results of their operations and their cash flows for each of the three years in the period ended June 30, 2013, in conformity with accounting principles generally accepted in the United States of America.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
September 27, 2013

PSIVIDA CORP. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(In thousands except share amounts)

	June 30,	
	2013	2012
Assets		
Current assets:		
Cash and cash equivalents	\$ 6,899	\$ 4,625
Marketable securities	3,374	9,946
Accounts and other receivables	597	967
Prepaid expenses and other current assets	1,594	421
Total current assets	12,464	15,959
Property and equipment, net	179	335
Intangible assets, net	3,430	4,226
Other assets	176	77
Total assets	\$ 16,249	\$ 20,597
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 671	\$ 394
Accrued expenses	1,894	608
Deferred revenue	738	2,176
Total current liabilities	3,303	3,178
Deferred revenue	5,246	3,783
Total liabilities	8,549	6,961
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, 23,297,011 and 20,802,592 shares issued and outstanding at June 30, 2013 and 2012, respectively	23	21
Additional paid-in capital	270,415	264,431
Accumulated deficit	(263,658)	(251,758)
Accumulated other comprehensive income	920	942
Total stockholders' equity	7,700	13,636
Total liabilities and stockholders' equity	\$ 16,249	\$ 20,597

See notes to consolidated financial statements

PSIVIDA CORP. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands except per share data)

	Year Ended June 30,		
	2013	2012	2011
Revenues:			
Collaborative research and development	\$ 780	\$ 2,080	\$ 3,612
Royalty income	<u>1,363</u>	<u>1,446</u>	<u>1,353</u>
Total revenues	<u>2,143</u>	<u>3,526</u>	<u>4,965</u>
Operating expenses:			
Research and development	7,005	7,039	6,864
General and administrative	7,169	6,868	8,104
Impairment of intangible assets	<u>—</u>	<u>14,830</u>	<u>—</u>
Total operating expenses	<u>14,174</u>	<u>28,737</u>	<u>14,968</u>
Operating loss	<u>(12,031)</u>	<u>(25,211)</u>	<u>(10,003)</u>
Other income (expense):			
Change in fair value of derivatives	—	170	1,140
Interest income, net	16	38	30
Other expense, net	<u>(2)</u>	<u>(1)</u>	<u>(13)</u>
Total other income	<u>14</u>	<u>207</u>	<u>1,157</u>
Loss before income taxes	<u>(12,017)</u>	<u>(25,004)</u>	<u>(8,846)</u>
Income tax benefit	<u>117</u>	<u>169</u>	<u>218</u>
Net loss	<u><u>\$(11,900)</u></u>	<u><u>\$(24,835)</u></u>	<u><u>\$ (8,628)</u></u>
Net loss per share:			
Basic and diluted	<u><u>\$ (0.52)</u></u>	<u><u>\$ (1.19)</u></u>	<u><u>\$ (0.44)</u></u>
Weighted average common shares outstanding:			
Basic and diluted	<u>23,044</u>	<u>20,791</u>	<u>19,489</u>
Net loss	<u><u>\$(11,900)</u></u>	<u><u>\$(24,835)</u></u>	<u><u>\$ (8,628)</u></u>
Other comprehensive (loss) income:			
Foreign currency translation adjustments	(29)	(492)	919
Net unrealized gain (loss) on marketable securities	<u>7</u>	<u>5</u>	<u>(11)</u>
Other comprehensive (loss) income	<u>(22)</u>	<u>(487)</u>	<u>908</u>
Comprehensive loss	<u><u>\$(11,922)</u></u>	<u><u>\$(25,322)</u></u>	<u><u>\$ (7,720)</u></u>

See notes to consolidated financial statements

PSIVIDA CORP. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands except share data)

	<u>Common Stock</u>		<u>Additional Paid-In Capital</u>	<u>Accumulated Deficit</u>	<u>Accumulated Other Comprehensive Income</u>	<u>Total Stockholders' Equity</u>
	<u>Number of Shares</u>	<u>Par Value Amount</u>				
Balance at July 1, 2010	18,531,392	\$ 19	\$250,796	\$(218,295)	\$ 521	\$ 33,041
Net loss	—	—	—	(8,628)	—	(8,628)
Other comprehensive income	—	—	—	—	908	908
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
Net loss	—	—	—	(24,835)	—	(24,835)
Other comprehensive loss	—	—	—	—	(487)	(487)
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
Net loss	—	—	—	(11,900)	—	(11,900)
Other comprehensive loss	—	—	—	—	(22)	(22)
Issuance of stock, net of issue costs	2,494,419	2	4,667	—	—	4,669
Stock-based compensation	—	—	1,317	—	—	1,317
Balance at June 30, 2013	<u>23,297,011</u>	<u>\$ 23</u>	<u>\$270,415</u>	<u>\$(263,658)</u>	<u>\$ 920</u>	<u>\$ 7,700</u>

See notes to consolidated financial statements

PSIVIDA CORP. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended June 30,		
	2013	2012	2011
Cash flows from operating activities:			
Net loss	\$(11,900)	\$(24,835)	\$ (8,628)
Adjustments to reconcile net loss to cash flows from operating activities:			
Impairment of intangible assets	—	14,830	—
Amortization of intangible assets	769	2,037	3,302
Depreciation of property and equipment	225	190	53
Change in fair value of derivatives	—	(170)	(1,140)
Amortization of bond premium on marketable securities	152	264	189
Stock-based compensation	1,317	1,411	2,052
Deferred income tax benefit	—	(13)	(209)
Changes in operating assets and liabilities:			
Accounts and other receivables	364	(128)	285
Prepaid expenses and other current assets	(1,272)	(44)	(36)
Accounts payable	277	64	(64)
Accrued expenses	1,288	(712)	146
Deferred revenue	35	(1,895)	880
Net cash used in operating activities	<u>(8,745)</u>	<u>(9,001)</u>	<u>(3,170)</u>
Cash flows from investing activities:			
Purchases of marketable securities	(7,758)	(15,392)	(15,963)
Maturities of marketable securities	14,184	15,299	6,598
Proceeds from sales of marketable securities	—	1,104	—
Purchases of property and equipment	(68)	(405)	(133)
Net cash provided by (used in) investing activities	<u>6,358</u>	<u>606</u>	<u>(9,498)</u>
Cash flows from financing activities:			
Proceeds from issuance of stock, net of issuance costs	4,669	—	10,043
Proceeds from exercise of stock options	—	114	17
Net cash provided by financing activities	<u>4,669</u>	<u>114</u>	<u>10,060</u>
Effect of foreign exchange rate changes on cash and cash equivalents	(8)	(6)	6
Net increase (decrease) in cash and cash equivalents	<u>2,274</u>	<u>(8,287)</u>	<u>(2,602)</u>
Cash and cash equivalents at beginning of year	<u>4,625</u>	<u>12,912</u>	<u>15,514</u>
Cash and cash equivalents at end of year	<u>\$ 6,899</u>	<u>\$ 4,625</u>	<u>\$ 12,912</u>
Supplemental disclosure of cash flow information:			
Cash paid for income taxes	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 56</u>

See notes to consolidated financial statements

PSIVIDA CORP. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Operations

pSivida Corp. (together with its subsidiaries, the “Company”), incorporated in Delaware, develops tiny, sustained-release products designed to deliver drugs and biologics at a controlled and steady rate for weeks, months or years. Using its core technology platforms, Durasert™ and BioSilicon™, the Company is focused on treatment of chronic diseases of the back of the eye and is also exploring applications outside ophthalmology. The Company has developed three of the four sustained-release products for treatment of retinal diseases currently approved in the U.S. or European Union (“EU”), and its lead product candidate began a Phase III clinical trial in the fiscal 2013 fourth quarter. The Company’s strategy includes developing products independently while continuing to leverage its technology platforms through collaboration and license agreements.

ILUVIEN®, the Company’s most recently approved product, is an injectable, sustained-release micro-insert that provides treatment of vision impairment associated with chronic diabetic macular edema (“DME”) considered insufficiently responsive to available therapies over a period of up to three years. ILUVIEN is licensed to and sold by Alimera Sciences, Inc. (“Alimera”), and the Company is entitled to a share of the net profits, as defined, from Alimera’s sales of ILUVIEN for DME. Alimera commenced the commercial launch of ILUVIEN for DME in the United Kingdom and Germany in the second quarter of 2013 and expects to launch in France in the first quarter of 2014. Alimera is also seeking marketing approval for ILUVIEN for DME in the U.S. In the second quarter of 2013, Alimera received a new Prescription Drug User Fee Act (“PDUFA”) goal date of October 17, 2013 after resubmitting its New Drug Application (“NDA”) for ILUVIEN for DME. The resubmission responded to a second Complete Response Letter (“CRL”) received from the U.S. Food and Drug Administration (“FDA”) in November 2011.

Medidur™, the Company’s lead development product, commenced the first of two planned pivotal Phase III clinical trials for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye (“posterior uveitis”) in June 2013. Medidur uses the same Durasert micro-insert used in ILUVIEN and delivers a lower dose of the same drug as the Company’s FDA-approved Retisert® for posterior uveitis. The Company is developing Medidur independently.

The Company is also developing a bioerodible, injectable micro-insert delivering latanoprost (the “Latanoprost Product”) to treat glaucoma and ocular hypertension. Under an amended collaboration agreement, Pfizer has an option, under certain circumstances, to license the development and commercialization of the Latanoprost Product worldwide.

The Company is engaged in pre-clinical research with respect to both its BioSilicon and Durasert technology platforms. The primary focus of the BioSilicon technology research is the sustained delivery, using Tethadur™, of peptides, proteins, antibodies and other large biologic molecules in both ophthalmic and non-ophthalmic applications. The Company’s research program also includes the use of Durasert technology in orthopedic applications and for systemic delivery of therapeutic agents.

The Company’s FDA-approved product *Retisert*® provides sustained release treatment of posterior uveitis for approximately two and a half years and is licensed to and sold by Bausch & Lomb.

The Company has a history of operating losses and has financed its operations primarily from the proceeds of sales of its equity securities and the receipt of license fees, research and development funding, royalties and contingent cash payments from its collaboration partners. The Company believes that its cash, cash equivalents and marketable securities of \$10.3 million at June 30, 2013, together with \$9.9 million of net proceeds received from an underwritten public offering of common shares in July 2013 and expected Retisert royalty income and

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other expected cash inflows under existing collaboration agreements, will enable the Company to maintain its current and planned operations through calendar year 2014. This includes expected costs through that date of Phase III clinical trials of the posterior uveitis micro-insert, but excludes any potential milestone or net profit receipts under the Alimera collaboration agreement. The Company's financial resources could be significantly improved if ILUVIEN for DME is approved by the FDA, which would entitle the Company to a \$25.0 million milestone payment, or if Alimera successfully commercializes ILUVIEN for DME in the EU or, if approved, in the U.S. The Company's ability to fund its planned operations beyond 2014, including completion of planned Phase III trials of the posterior uveitis micro-insert, is expected to depend on the amount and timing of cash receipts under existing collaboration agreements, as well as any future collaboration or other agreements and/or financing transactions.

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, 2013, 2012 and 2011 may be referred to herein as fiscal 2013, fiscal 2012 and fiscal 2011, 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 comprehensive loss and cash flows 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 \$921,000 at June 30, 2013 and \$950,000 at June 30, 2012. 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 comprehensive loss 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.

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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. Accordingly, the Company 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 the Company determines that a decline of any investment is other-than-temporary, the investment is written down to fair value. As of June 30, 2013 and 2012, 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 comprehensive loss. 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, 2013, all of the Company's interest-bearing cash equivalent balances, aggregating \$6.3 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, 2013 consist of investment-grade corporate bonds and commercial paper. 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 \$368,000, or 17%, of total revenues in fiscal 2013, \$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 64%, of total revenues in fiscal 2013, \$1.4 million, or 41%, of total revenues in fiscal 2012 and \$1.4 million, or 27%, of total revenues in fiscal 2011.

Bausch & Lomb accounted for \$316,000, or 53%, of total accounts receivable at June 30, 2013 and \$442,000, or 46%, of total accounts receivable at June 30, 2012.

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) U.K. research and development tax credits; and (iii) accrued interest on marketable securities.

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 were denominated in a currency (A\$) other than the Company's functional currency (US\$), the last of which expired in July 2012, were 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 were recorded in the consolidated statements of comprehensive loss in each reporting period. Fair value was determined using a Black-Scholes valuation model.

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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.

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 are less than its carrying value. If the Company considers an asset 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

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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 or 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.

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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 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, 2013, 2012 and 2011, as they would be anti-dilutive:

	June 30,		
	2013	2012	2011
Options	3,554,549	3,165,855	2,740,895
Warrants	1,176,105	2,270,189	7,820,227
	<u>4,730,654</u>	<u>5,436,044</u>	<u>10,561,122</u>

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

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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 ASU 2011-5 *Comprehensive Income (Topic 220) – Presentation of Comprehensive Income*, which provides new guidance on the presentation of comprehensive income. This guidance requires 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. The Company adopted this guidance for the quarter ended September 30, 2012 and has presented the required information in one continuous statement of operations and comprehensive loss on a comparative basis. Other than a change in presentation, the adoption of this guidance did 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. Alimera agreed to pay a \$25.0 million milestone payment upon FDA approval of ILUVIEN for DME and assumed all financial responsibility for the development of licensed products under the Alimera Agreement. In addition, the Company is entitled to a 20% share of any future net profits, as defined, on sales of ILUVIEN by Alimera, measured quarterly on a country-by-country basis, subject to an offset of 20% of 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 terms of the Alimera Agreement defined the end period of the Company's performance obligations as December 31, 2009. Accordingly, amounts received thereafter are 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 \$67,000 for fiscal 2013, \$111,000 for fiscal 2012 and \$192,000 for fiscal 2011 and consisted of reimbursements for licensed patent and development costs.

Pfizer

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 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 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

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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, 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. 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 using the proportional performance method. During fiscal 2013, the Company increased its estimate of the cumulative performance period from 4 to 6 years to provide for additional research under the agreement prior to commencement of Phase II clinical trials. As a result, the current portion of deferred revenue has been reduced to \$371,000 at June 30, 2013 compared to \$2.2 million at June 30, 2012. Total deferred revenue was \$5.6 million at June 30, 2013 and \$6.0 million at June 30, 2012. The Company recorded collaborative research and development revenue related to the Restated Pfizer Agreement of \$368,000 in fiscal 2013, \$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.

If any subsequent payments are received from Pfizer, including exercise option, milestone and sales-based royalty consideration, which would occur after completion of the Company's performance period under the Restated Pfizer Agreement, such payments would be recognized as revenue when all the revenue criteria are met.

Pfizer owned approximately 8.0% of the Company's outstanding shares at June 30, 2013.

Bausch & Lomb

Pursuant to a licensing and development agreement, as amended, Bausch & Lomb has a worldwide exclusive license to make and sell the Company's Retisert and Vitrasert products in return for royalties based on sales. Bausch & Lomb discontinued sales of Vitrasert in the second quarter of fiscal 2013.

Royalty income totaled approximately \$1.4 million in each of the three years in the period ended June 30, 2013. Accounts receivable from Bausch & Lomb totaled \$316,000 at June 30, 2013 and \$442,000 at June 30, 2012.

Enigma Therapeutics

The Company entered into an exclusive, worldwide royalty-bearing license agreement in December 2012, amended and restated in March 2013, with Enigma Therapeutics Limited ("Enigma") for the development of BrachySil, a BioSilicon product candidate for the treatment of pancreatic and other types of cancer. The Company received an upfront fee of \$100,000, included in collaborative research and development revenue, and

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is entitled to an 8% sales-based royalty, 20% of sublicense consideration and milestones based on aggregate product sales. Enigma is obligated to pay an annual license maintenance fee of \$100,000, creditable during the ensuing twelve months against reimbursable patent maintenance costs and sales-based royalties. The Company has no consequential performance obligations under the Enigma license agreement and, accordingly, any amounts to which the Company is entitled under the agreement will be recognized as revenue when the revenue recognition criteria are met. There was no balance of deferred revenue with respect to this agreement at June 30, 2013.

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, Intrinsiq terminated the license agreement, and the Company acquired the 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. 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. The Company recognized collaborative research and development revenue under the license agreement of \$83,000 in fiscal 2011.

4. Intangible Assets

The reconciliation of intangible assets for the years ended June 30, 2013 and 2012 was as follows (in thousands):

	June 30,	
	2013	2012
Patented technologies		
Gross carrying amount at beginning of year	\$ 39,556	\$ 55,422
Asset impairment write-down	—	(14,830)
Foreign currency translation adjustments	(615)	(1,036)
Gross carrying amount at end of year	<u>38,941</u>	<u>39,556</u>
Accumulated amortization at beginning of year	(35,330)	(33,858)
Amortization expense	(769)	(2,037)
Foreign currency translation adjustments	588	565
Accumulated amortization at end of year	<u>(35,511)</u>	<u>(35,330)</u>
Net book value at end of year	<u>\$ 3,430</u>	<u>\$ 4,226</u>

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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 market capitalization from \$82.0 million immediately prior to the announcement to \$23.1 million at December 31, 2011. The Company determined that the combination of the 2011 CRL and the decline in the Company's market capitalization were 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 (in thousands):

	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
	<u>\$ 19,426</u>	<u>\$ (14,830)</u>	<u>\$ 4,596</u>

The net book value of the Company's intangible assets at June 30, 2013 and 2012 is summarized as follows (in thousands):

	June 30,		Estimated Remaining Useful Life at June 30, 2013 (Years)
	2013	2012	
Patented technologies			
Durasert	\$2,383	\$2,912	4.5
BioSilicon	1,047	1,314	4.5
	<u>\$3,430</u>	<u>\$4,226</u>	

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 \$769,000 in fiscal 2013, \$2.0 million in fiscal 2012 and \$3.3 million in fiscal 2011. The carrying value of intangible assets at June 30, 2013 of \$3.4 million is expected to be amortized on a straight-line basis of approximately \$760,000 per year.

[Table of Contents](#)**5. Marketable Securities**

The amortized cost, unrealized loss and fair value of the Company's available-for-sale marketable securities at June 30, 2013 and 2012 were as follows (in thousands):

	June 30, 2013		
	Amortized Cost	Unrealized Loss	Fair Value
Corporate bonds	\$ 2,376	\$ (1)	\$2,375
Commercial paper	999	—	999
Total marketable securities	<u>\$ 3,375</u>	<u>\$ (1)</u>	<u>\$3,374</u>

	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	<u>\$ 9,954</u>	<u>\$ (8)</u>	<u>\$9,946</u>

During fiscal 2013, \$7.8 million of marketable securities were purchased and \$14.2 million matured. At June 30, 2013, the marketable securities had maturities ranging between one and seven months, with a weighted average maturity of 3.65 months.

6. Property and Equipment, Net

Property and equipment consisted of the following (in thousands):

	June 30,	
	2013	2012
Property and equipment	\$ 1,908	\$ 1,937
Leasehold improvements	317	321
Gross property and equipment	2,225	2,258
Accumulated depreciation and amortization	(2,046)	(1,923)
	<u>\$ 179</u>	<u>\$ 335</u>

Depreciation expense was \$225,000 for fiscal 2013, \$190,000 for fiscal 2012 and \$53,000 for fiscal 2011.

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 (unadjusted) 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).

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- 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 AS warrants, which expired during fiscal 2013, were derivative liabilities, classified as Level 3 and valued using the Black-Scholes model.

The following table summarizes the Company's assets carried at fair value measured on a recurring basis at June 30, 2013 and 2012 by valuation hierarchy (in thousands):

Description	June 30, 2013			
	Total Carrying Value	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets:				
Cash equivalents	\$ 6,330	\$ 6,330	\$ —	\$ —
Marketable securities:				
Corporate bonds	2,375	1,619	756	—
Commercial paper	999	—	999	—
	<u>\$ 9,704</u>	<u>\$ 7,949</u>	<u>\$ 1,755</u>	<u>\$ —</u>
Description	June 30, 2012			
	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	—
	<u>\$ 14,238</u>	<u>\$ 7,726</u>	<u>\$ 6,512</u>	<u>\$ —</u>

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

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

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

	June 30,	
	2013	2012
Balance at beginning of year	\$—	\$170
Change in fair value of derivatives—other income	—	170
Balance at end of year	<u>\$—</u>	<u>\$—</u>

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 non-recurring basis at December 31, 2011 and the losses recorded for the six month period then ended (in thousands):

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

There was no fair value measurement on a non-recurring basis at June 30, 2013 or at June 30, 2012.

8. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	June 30,	
	2013	2012
Personnel costs	\$1,252	\$149
Professional fees	288	262
Clinical	353	181
Other	1	16
	<u>\$1,894</u>	<u>\$608</u>

9. Stockholders' Equity

Sales of Common Stock and Warrants

In July 2013, the Company sold 3,494,550 shares of its common stock in an underwritten public offering at a price of \$3.10 per share for gross proceeds of \$10.8 million. Underwriter commissions and other share issue costs approximated \$890,000.

In August 2012, the Company sold 2,494,419 shares of its common stock and warrants to purchase 623,605 shares of its common stock in a registered direct offering 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

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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, and became exercisable in February 2013. Placement agent fees and other share issue costs approximated \$700,000.

In January 2011, the Company sold 2,210,000 shares of its common stock and warrants to purchase 552,500 shares of its common stock in a registered direct offering 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, 2013 and 2012:

	Year Ended June 30,			
	2013		2012	
	Number of Warrants	Weighted Average Exercise Price	Number of Warrants	Weighted Average Exercise Price
Balance at beginning of year	2,064,710	\$ 6.17	7,614,748	\$ 7.35
Issued	623,605	2.50	—	—
Expired	(1,512,210)	6.60	(5,550,038)	7.79
Balance and exercisable at end of year	<u>1,176,105</u>	<u>\$ 3.67</u>	<u>2,064,710</u>	<u>\$ 6.17</u>

At June 30, 2013, the remaining lives of these outstanding warrants ranged from 2.6 to 4.1 years, representing a weighted-average term of 3.4 years.

The following table provides a reconciliation of all A\$ warrants for the years ended June 30, 2013 and 2012:

	Year Ended June 30,			
	2013		2012	
	Number of Warrants	Weighted Average Exercise Price AS	Number of Warrants	Weighted Average Exercise Price AS
Balance at beginning of year	205,479	7.68	205,479	7.68
Expired	(205,479)	7.68	—	—
Balance and exercisable at end of year	<u>—</u>	<u>—</u>	<u>205,479</u>	<u>7.68</u>

The weighted-average exercise price of these warrants translated to US\$ was \$7.80 at June 30, 2012. These A\$ warrants expired on July 19, 2012.

Because the potential exercise of the A\$-denominated warrants would have resulted 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 comprehensive loss. As of June 30, 2012, the Company had no liability recorded.

[Table of Contents](#)**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, 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, 2013, the number of shares reserved for issuance under the 2008 Plan was 4,841,255, of which 1,056,459 shares were available for new awards. 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, 2013.

Options to purchase a total of 616,760 shares were granted during fiscal 2013 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 411,760 shares were issued to employees with ratable annual vesting over 4 years, options to purchase 60,000 shares were issued to a non-executive director with ratable annual vesting over 3 years and options to purchase 145,000 shares were issued to non-executive directors with 1-year cliff 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 8.5 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, 2013, 2012 and 2011 were as follows:

	2013	2012	2011
Option life (in years)	5.50 - 6.25	3.50 - 6.25	3.50 - 6.25
Stock volatility	95% - 98%	88% - 97%	95%
Risk-free interest rate	0.81% - 0.98%	0.53% - 2.02%	1.13% - 2.35%
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 continues 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 reversed \$121,000 of expense for performance-based options that were forfeited in that year.

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The following table summarizes information about stock options for the years ended June 30, 2013, 2012 and 2011 (in thousands except per share amounts):

	2013	2012	2011
Weighted-average grant date fair value, per share	\$1.29	\$2.41	\$3.24
Total cash received from exercise of stock options	—	114	17
Total intrinsic value of stock options exercised	—	119	12

At June 30, 2013, there was approximately \$748,000 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 1.65 years.

The following table provides a reconciliation of stock option activity under the 2008 Plan for fiscal 2013:

	Number of options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at July 1, 2012	3,053,355	\$ 3.10		
Granted	616,760	2.14		
Forfeited	(115,566)	3.31		
Outstanding at June 30, 2013	<u>3,554,549</u>	<u>\$ 2.92</u>	<u>6.67</u>	<u>\$ 4,081</u>
Outstanding at June 30, 2013—vested or unvested and expected to vest	<u>3,498,054</u>	<u>\$ 2.92</u>	<u>6.64</u>	<u>\$ 4,036</u>
Exercisable at June 30, 2013	<u>2,400,610</u>	<u>\$ 2.74</u>	<u>5.88</u>	<u>\$ 3,051</u>

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 2013:

	Number of options	Weighted Average Exercise Price A\$	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value A\$
Outstanding at July 1, 2012	112,500	5.50		
Expired	(112,500)	5.50		
Outstanding and exercisable at June 30, 2013	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>

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

[Table of Contents](#)**Stock-Based Compensation Expense**

The Company's statements of comprehensive loss included total compensation expense from stock-based payment awards as follows (in thousands):

	Year Ended June 30,		
	2013	2012	2011
Compensation expense included in:			
Research and development	\$ 632	\$ 597	\$ 400
General and administrative	685	814	1,652
	<u>\$1,317</u>	<u>\$1,411</u>	<u>\$2,052</u>

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 \$231,000 for fiscal 2013, \$181,000 for fiscal 2012 and \$160,000 for fiscal 2011 in connection with these retirement plans.

12. Income Taxes

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

	Year Ended June 30,		
	2013	2012	2011
U.S. operations:			
Current income tax provision	\$ —	\$ —	\$ 96
Deferred income tax benefit	—	(13)	(209)
	<u>—</u>	<u>(13)</u>	<u>(113)</u>
Non-U.S. operations:			
Current income tax benefit	(117)	(156)	(105)
Deferred income tax benefit	—	—	—
	<u>(117)</u>	<u>(156)</u>	<u>(105)</u>
Income tax benefit	<u>\$ (117)</u>	<u>\$ (169)</u>	<u>\$ (218)</u>

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

	Year Ended June 30,		
	2013	2012	2011
U.S. operations	<u>\$(10,101)</u>	<u>\$(11,215)</u>	<u>\$(5,519)</u>
Non-U.S. operations	<u>(1,916)</u>	<u>(13,789)</u>	<u>(3,327)</u>
Loss before income taxes	<u>\$ (12,017)</u>	<u>\$ (25,004)</u>	<u>\$ (8,846)</u>

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

	Year Ended June 30,		
	2013	2012	2011
Income tax benefit at statutory rate	\$ (4,086)	\$ (8,501)	\$ (3,008)
State income taxes, net of federal benefit	(569)	(599)	(350)
Non-U.S. income tax rate differential	145	1,163	228
Research and development tax credits	(134)	(156)	(106)
Changes in valuation allowance	2,939	7,500	3,045
Expiration of state net operating loss carryforwards	706	—	—
Other, net	882	424	(27)
Income tax benefit	<u>\$ (117)</u>	<u>\$ (169)</u>	<u>\$ (218)</u>

The components of deferred income taxes are as follows (in thousands):

	June 30,	
	2013	2012
Deferred tax assets:		
Net operating loss carryforwards	\$26,068	\$24,021
Deferred revenue	2,196	2,341
Stock-based compensation	2,589	2,119
Provision for losses on note receivable	511	511
Other	843	572
Total deferred tax assets	<u>32,207</u>	<u>29,564</u>
Deferred tax liabilities:		
Intangible assets	1,177	1,472
Deferred tax assets, net	31,030	28,092
Valuation allowance	31,030	28,092
Total deferred tax liability	<u>\$ —</u>	<u>\$ —</u>

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 \$2.9 million during fiscal 2013 and \$7.5 million during fiscal 2012.

The Company has tax net operating loss and tax credit carry forwards in its individual tax jurisdictions. At June 30, 2013, the Company had U.S. federal net operating loss carry forwards of approximately \$54.7 million which expire at various dates between calendar years 2023 and 2033. The utilization of certain of these loss and tax credit carry forwards may be limited by Sections 382 and 383 of the Internal Revenue Code as a result of historical or future changes in the Company's ownership. At June 30, 2013, the Company had state net operating loss carry forwards of approximately \$17.0 million, of which \$3.1 million expires in 2013 and \$13.9 million expires between 2031 and 2033. Additionally, at June 30, 2013 the Company had net operating loss carry forwards in the U.K. of £18.7 million (approximately \$28.5 million). During fiscal 2013, the Company recognized a current income tax benefit of \$117,000 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 2012 remain subject to examination by the Internal Revenue Service. The Company's U.K. tax returns for fiscal years 2006 through

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2012 remain subject to examination. The Australian tax returns for the former parent company for fiscal years 2004 through 2008 remain subject to examination.

Through June 30, 2013, the Company had no unrecognized tax benefits in its consolidated statements of comprehensive loss and no unrecognized tax benefits in its consolidated balance sheets as of June 30, 2013 or 2012.

As of June 30, 2013 and 2012, the Company had no accrued penalties or interest related to uncertain tax positions.

13. Commitments and Contingencies

Operating Leases

The Company has leased 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, 2013, the Company's total future minimum lease payments under non-cancellable operating leases were as follows (in thousands):

<u>Fiscal Year:</u>	
2014	\$363
2015	75
2016	18
	<u>\$456</u>

Rent expense related to its real estate and other operating leases charged to operations was approximately \$454,000 for fiscal 2013, \$466,000 for fiscal 2012 and \$449,000 for fiscal 2011.

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.

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(b) Geographic Area Information

The following table summarizes the Company's revenues and long-lived assets, net, by geographic area (in thousands):

	Revenues			Long-lived assets, net	
	2013	2012	2011	2013	2012
U.S.	\$1,873	\$2,385	\$4,882	\$ 55	\$ 57
U.K.	270	1,141	83	124	278
Consolidated	<u>\$2,143</u>	<u>\$3,526</u>	<u>\$4,965</u>	<u>\$ 179</u>	<u>\$ 335</u>

15. Quarterly Financial Data (unaudited)

The following table summarizes the quarterly results of operations for the years ended June 30, 2013 and 2012 (in thousands except per share amounts):

	Fiscal Year 2013				
	First Quarter Ended September 30, 2012	Second Quarter Ended December 31, 2012	Third Quarter Ended March 31, 2013	Fourth Quarter Ended June 30, 2013	Year Ended June 30, 2013
Total revenues	\$ 553	\$ 585	\$ 513	\$ 492	\$ 2,143
Operating loss	(2,590)	(2,648)	(2,812)	(3,981)	(12,031)
Net loss	<u>(2,551)</u>	<u>(2,608)</u>	<u>(2,794)</u>	<u>(3,947)</u>	<u>(11,900)</u>
Net loss per share—basic and diluted	\$ (0.11)	\$ (0.11)	\$ (0.12)	\$ (0.17)	\$ (0.52)
Weighted average common shares—basic and diluted	<u>22,294</u>	<u>23,297</u>	<u>23,297</u>	<u>23,297</u>	<u>23,044</u>
	Fiscal Year 2012				
	First Quarter Ended September 30, 2011	Second Quarter Ended December 31, 2011	Third Quarter Ended March 31, 2012	Fourth Quarter Ended June 30, 2012	Year Ended June 30, 2012
	(1)	(2)			(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	<u>(2,427)</u>	<u>(17,460)</u>	<u>(2,686)</u>	<u>(2,262)</u>	<u>(24,835)</u>
Net loss per share—basic and diluted	\$ (0.12)	\$ (0.84)	\$ (0.13)	\$ (0.11)	\$ (1.19)
Weighted average common shares—basic and diluted	<u>20,757</u>	<u>20,803</u>	<u>20,803</u>	<u>20,803</u>	<u>20,791</u>

- (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 Intrinsic (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).

List of Subsidiaries of pSivida Corp.

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

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. 333-185549 on Form S-3 of our report dated September 27, 2013, relating to the consolidated financial statements of pSivida Corp., appearing in this Annual Report on Form 10-K of pSivida Corp. for the year ended June 30, 2013.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
September 27, 2013

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, 2013

/s/ **PAUL ASHTON**

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

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, 2013

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

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, 2013, 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, 2013

/s/ **PAUL ASHTON**

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

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, 2013, 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, 2013

/s/ **Leonard S. Ross**

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

