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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

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

For the fiscal year ended June 30, 2014

or

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

For the transition period from to

Commission File Number 000-51122

PSIVIDA CORP.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the common stock held by non-affiliates of the registrant, computed by reference to the closing price of the common stock on the NASDAQ Global Market on December 31, 2013, the last trading day of the registrant's most recently completed second fiscal quarter, was approximately $106,135,000.

There were 29,337,595 shares of the registrant's common stock, $0.001 par value, outstanding as of September 8, 2014.

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 11, 2014, are incorporated by reference into Part III of this Annual Report on Form 10-K.

PSIVIDA CORP.

Form 10-K
For the Fiscal Year Ended June 30, 2014

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PART I

Preliminary Note Regarding Forward-Looking Statements

This Form 10-K and our 2014 Annual Report contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (Exchange Act). Forward-looking statements are inherently subject to risks, uncertainties and potentially inaccurate assumptions. Such statements give our current expectations or forecasts of future events; they do not relate strictly to historical or current facts. All statements other than statements of historical fact could be deemed forward-looking statements, including, without limitation, any expectations of revenue, expenses, cash flows, earnings or losses from operations, capital or other financial items; any statements of the plans, strategies and objectives of management for future operations; any statements concerning product research, development and commercialization timelines; any statements of expectations or belief; and any statements of assumptions underlying any of the foregoing. We often, although not always, identify forward-looking statements by using words or phrases such as the following: “likely”, “expect”, “intend”, “anticipate”, “believe”, “estimate”, “plan”, “project”, “forecast” and “outlook”.

We cannot guarantee that the results and other expectations expressed, anticipated or implied in any forward-looking statement will be realized. The risks set forth under Item 1A of this Form 10-K describe major risks to our business, and you should read and interpret any forward-looking statements together with these risks. A variety of factors, including these risks, could cause our actual results and other expectations to differ materially from the anticipated results or other expectations expressed, anticipated or implied in our forward-looking statements. Should known or unknown risks materialize, or should our underlying assumptions prove inaccurate, actual results could differ materially from past results and those anticipated, estimated or projected in the forward-looking statements. You should bear this in mind as you consider any forward-looking statements.

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

ITEM 1. BUSINESS

Introduction

We develop tiny, sustained-release products designed to deliver drugs and biologics at a controlled and steady rate for weeks, months or years. Our strategy is to use our Durasert™ and Tethadur™ drug delivery technologies to independently develop products that deliver proven drugs and biologics, while continuing to leverage these technologies through collaboration and license agreements. We are focused on treatment of chronic diseases of the back of the eye and are also exploring applications outside ophthalmology. Our lead product candidate Medidur™ is in a pivotal Phase III clinical trial, our lead licensed product ILUVIEN® has been approved in the European Union (EU) and is pending approval with the U.S. Food and Drug Administration (FDA), and our pipeline includes potential product candidates at earlier stages of development. Our Durasert technology is the basis of three of the four sustained-release products for treatment of retinal diseases currently approved in the U.S. or EU.

Medidur is an injectable, sustained-release micro-insert designed to treat chronic, non-infectious uveitis affecting the posterior segment of the eye (posterior uveitis) over a period up to three years. Medidur uses the same Durasert micro-insert used in ILUVIEN (same polymers, same drug and same dose) and delivers a lower dose of the same drug as our FDA-approved Retisert® for posterior uveitis, which is licensed to Bausch & Lomb. Although we originally planned to seek FDA approval of Medidur based on two Phase III clinical trials, we now expect to seek approval based on safety and efficacy data from our single ongoing Phase III trial, with supplemental clinical data from a planned study of the safety and usability of our proprietary inserter, if ILUVIEN® is approved by the FDA later this year. We plan to have a confirmatory meeting with the FDA with

respect to our regulatory strategy. If the FDA does not approve this regulatory strategy, we may be required to complete a second Phase III trial for Medidur in order to submit for FDA approval, which would increase the development time and cost of Medidur. We are developing Medidur independently.

ILUVIEN, our lead licensed product, is an injectable, sustained-release micro-insert that provides treatment over a period of up to three years of vision impairment associated with diabetic macular edema (DME). 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 on a country-by-country basis. We are also entitled to a one-time $25.0 million milestone payment from Alimera if ILUVIEN is approved by the FDA.

ILUVIEN is commercially available in the United Kingdom (U.K.) and Germany for the treatment of chronic DME considered insufficiently responsive to available therapies, and Alimera expects to launch in France and Portugal in late 2014. ILUVIEN has marketing authorization in six other EU countries and is pending authorization in seven more EU countries.

Alimera is also seeking marketing approval of ILUVIEN for DME in the U.S. Alimera entered into labeling discussions with the FDA in December 2013 and refiled the New Drug Application (NDA) with the FDA in March 2014. The FDA set a Prescription Drug User Fee Act (PDUFA) goal date of September 26, 2014. The resubmission responded to issues raised in the FDA's October 2013 Complete Response Letter (CRL).

Alimera also entered into an exclusive agreement with a third party for distribution, regulatory and reimbursement matters of ILUVIEN for DME in Australia and New Zealand.

Our pre-clinical research is primarily focused on our Tethadur and Durasert technology platforms. We are seeking to develop products using Tethadur, part of our BioSilicon™ technology, to provide sustained delivery of peptides, proteins, antibodies and other large biologic molecules. We are also researching the use of our Durasert technology, in some instances in combination with our BioSilicon technology, to provide sustained delivery of therapeutic agents to treat wet and dry Age-Related Macular Degeneration (AMD), osteoarthritis and glaucoma, as well as to provide systemic delivery of biologics.

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. We receive royalties from these sales.

Durasert™, Medidur™, Tethadur™ and BioSilicon™ 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 reflects information publicly disclosed by Alimera.

Fiscal 2014, fiscal 2013 and fiscal 2012 mean the twelve months ended June 30, 2014, 2013 and 2012, respectively.

Strategy

Our strategy is to use our proprietary Durasert and Tethadur drug delivery technology platforms to independently develop new drug delivery products for already-approved drugs and biologics that will provide better treatment of 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 many already-approved drugs and biologics, resulting in improved therapeutic effectiveness and better patient compliance and

convenience, with reduced product development risk and cost for us. We believe our proven track record of three approved products, all providing sustained release of previously approved drugs, demonstrates the effectiveness of this strategy.

- **Develop Sustained Delivery of Off-Patent Drugs and Biologics.** Many drugs and biologics either are now or will soon be off-patent. It is estimated that over the next 7 years 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 less frequent dosing through sustained delivery and/or release at the treatment site through targeted delivery would materially improve the effectiveness or convenience of the original drugs or biologics. We are optimistic that our Tethadur technology can provide sustained delivery of large biologic molecules, which currently cannot be effectively delivered by other 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 investment 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 and biologics, that could materially benefit from sustained delivery, but would require expensive clinical trials or are in treatment areas outside of our technical expertise. We may also partner with companies where our drug delivery technologies could offer an improved product and effectively extend the patent protection on drugs coming off-patent.
- **Expand Beyond Ophthalmology.** While we continue to focus on our core ophthalmic competency, we are also 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 Opportunity for Delivery of Drugs and Biologics

We have developed and continue to develop products that address issues inherent in the delivery of drugs and biologics. The efficacy 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 in the location, and with an appropriate concentration, 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, infusion or 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 with an appropriate 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. To avoid issues of systemic delivery, drugs may be administered locally to the targeted site, typically by injection. However, maintaining a sufficient concentration at the targeted site over time typically requires timely and repeated administration of systemically and locally delivered drugs.

Biologics generally cannot be administered orally, but instead are administered by injection or infusion and require repeated injections or infusions to maintain appropriate levels over the course of treatment. Due to their size and complexity, it has been difficult to develop sustained-release formulations for biologics.

Patients often do not receive drugs or biologics on the schedule prescribed, or at all, because they do not self-administer them or do not go to medical professionals for administration as required. The risk of patient noncompliance increases due to various factors, such as treatment with multiple products, complex or painful dosing regimens, patient age, cognitive impairment or serious illness, and length and expense of treatment. Repeated administration by injection or infusion can result in serious infections and other complications.

Treating retinal diseases is a significant challenge for drug delivery. 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 causing 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. Significant ophthalmic biologics, such as Macugen® (pegaptanib sodium), Lucentis® (ranibizumab) and EYLEA® (afilbercept), are injected into the eye as frequently as every four weeks. In addition to the issues of inconvenience, cost and noncompliance, repeated intravitreal injections have medical risks, including intraocular infection, perforated sclera, vitreous hemorrhage and cataract formation.

Due to the drawbacks of traditional drug and biologic delivery, the development of methods to deliver drugs and biologics 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 sufficient duration of delivery, particularly in diseases that are chronic or require precise dosing. Moreover, skin patches and oral products still have issues of systemic delivery. There are currently very few approved sustained-delivery products for biologics.

Our Technology Systems and Products

Our two core technology platforms, Durasert and Tethadur, have attributes that can address the issues of sustained delivery for ophthalmic and other product candidates:

- *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

Our three approved products, as well as Medidur, use different generations of our Durasert technology platform to provide sustained, localized delivery of drugs to the back of the eye. In our Durasert products, a drug core is surrounded with one or more polymer layers, and the permeability of those layers and other aspects of the design of the product control the rate and duration of the drug release. By changing elements of the design, we can alter both the rate and duration of release to meet different therapeutic needs. Our later generation Durasert products and product candidates are injected at the target site, while early generations were surgically implanted.

The portfolio of our Durasert approved products and late-stage product candidates includes:

Product	Disease	Stage of Development	Partner
ILUVIEN	DME	EU-approved (10 countries) for chronic DME; U.S. – under FDA review (PDUFA date of September 26, 2014)	Alimera
Retisert	Posterior uveitis	FDA-approved; commercialized since 2005	Bausch & Lomb
Vitrasert	CMV Retinitis	FDA-approved; commercialized from 1996 through 2012 (patent expiration)	Bausch & Lomb
Medidur	Posterior Uveitis	Phase III	Developed by pSivida

Medidur for Posterior Uveitis

Medidur, our lead development product, is an injectable, sustained-release micro-insert designed to treat posterior uveitis over a period of up to three years. Posterior uveitis is an inflammatory disease of one of the linings in the posterior of the eye, which can cause sudden or gradual vision loss. The Medidur micro-insert delivers fluocinolone acetonide (FAc), a corticosteroid currently used in Retisert. Medidur uses the same micro-insert delivering the same drug at the same rate with the same polymers as the micro-insert used in ILUVIEN for DME. In contrast, Retisert delivers a higher dose of the same drug and must be surgically inserted into the eye. Medidur will also use a different inserter with a smaller needle than ILUVIEN. We are developing Medidur independently and have not licensed the rights to Medidur for posterior uveitis to Alimera or any other third party.

In June 2013, we initiated a pivotal Phase III clinical trial of Medidur for the treatment of posterior uveitis. This trial includes clinical sites in the U.S., Europe, Israel and India and is expected to enroll 120 patients. The primary end-point is recurrence of posterior uveitis at 12 months. We currently anticipate that enrollment will be completed in the first calendar quarter of 2015. The FDA has confirmed that we will be able to reference much of the data, including the clinical safety data, from Alimera's Phase III trials of ILUVIEN for DME, which we are permitted to do under our agreement with Alimera. If the results of our trial are positive, and if the FDA approves ILUVIEN, we believe we will be able to seek FDA approval on the basis of this one Phase III trial together with additional clinical data from a planned study of the use of our proprietary inserter. While we believe the FDA will permit us to pursue this regulatory strategy, we plan to have a confirmatory meeting with the FDA after the PDUFA date for ILUVIEN. If the FDA does not approve our regulatory strategy, we may be required to complete a second Phase III trial for Medidur in order to submit for FDA approval. We may conduct additional clinical studies to support regulatory filings outside the U.S.

Because Medidur delivers the same drug as our FDA-approved Retisert product for posterior uveitis, although at a lower dose, 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 and comparable to ILUVIEN for DME. As a result, although we cannot be certain, 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 of Medidur are consistent with this hypothesis. This three-year study is evaluating the safety and efficacy of Medidur in up to 12 patients with posterior uveitis. Interim results were measured on the twelve-month anniversary of the start of enrollment. Through this period, none of the eyes receiving Medidur experienced a recurrence of posterior uveitis, and inflammation was reduced in all of these eyes. In contrast, all control (untreated) eyes had either a recurrence of posterior uveitis or a worsening of inflammation. Furthermore, at the last follow-up visit reported in the interim results, best corrected visual acuity (on the Early Treatment Diabetic Retinopathy Study eye chart) improved by an average of more

than nine letters in treated eyes, while untreated eyes declined by an average of one letter. Interim data showed that Medidur was well tolerated, and the observed safety profile was consistent with the short-term safety profile reported in clinical studies of ILUVIEN in DME eyes. Only one eye receiving Medidur experienced an increase in intraocular pressure (IOP) above the normal range; this eye ultimately required a surgical procedure to control elevated IOP.

Medidur is easier to administer than Retisert because it is injected in an office visit, while Retisert is implanted in a surgical procedure.

In the U.S., posterior uveitis has been estimated to affect approximately 175,000 people and be responsible for approximately 30,000 cases of blindness, making it the third largest cause of blindness in the U.S.

ILUVIEN for DME

ILUVIEN is an injectable, sustained-release micro-insert delivering FAc over a period of up to 3 years for the treatment of DME. DME is a disease of diabetics where leaking capillaries result in swelling in the macula, the most sensitive part of the retina, and it is a leading cause of blindness in most developed countries in the working-age population.

ILUVIEN is licensed to Alimera. ILUVIEN is currently commercially available from Alimera in the U.K. and Germany for the treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies. Under our arrangement with Alimera, we are entitled to share in net profits (as defined) on sales of ILUVIEN by Alimera on a country-by-country basis. See “Strategic Collaborations—Alimera” below. Alimera 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 and commercialization of ILUVIEN is as follows:

European Union. Alimera commenced commercial sales of ILUVIEN in the U.K. and Germany in the second quarter of 2013 and has reported plans to launch in France and Portugal in late 2014. ILUVIEN has marketing authorization in six additional EU countries: Austria, Italy, Spain, Norway, Denmark and Sweden. These marketing authorizations followed a favorable determination of approvability for the treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies under the EU’s Decentralized Procedure (DCP) and, as of June 2014, under the EU’s Mutual Recognition Procedure (MRP). ILUVIEN is awaiting marketing authorization in the national phase under the MRP in seven countries: Belgium, Czech Republic, Finland, Ireland, Luxembourg, Netherlands and Poland. As part of this approval process, Alimera committed to conduct a five-year, post-authorization, open label registry study of ILUVIEN in 800 patients with the labeled indication.

In November 2013, the National Institute for Health and Care Excellence (NICE) in the U.K. recommended ILUVIEN as a treatment option for patients with chronic DME considered insufficiently responsive to available therapies who have previously undergone cataract surgery, subject to a simple patient access scheme (PAS). As a result, ILUVIEN became available to these patients under the U.K.’s National Health Service (NHS). Further, in February 2014, the Scottish Medicines Consortium accepted ILUVIEN for use within the NHS Scotland for treatment of patients with chronic DME considered insufficiently responsive to available therapies who have previously undergone cataract surgery and for certain retreatments, subject to a simple PAS.

In Germany, Alimera was able to launch ILUVIEN without price restrictions, but continues to work with Germany’s statutory health insurance funds to streamline reimbursement.

In France, the Transparency Commission (Commission de la Transparence or CT) of the French National Health Authority (Haute Autorité de Santé) issued a favorable opinion for the reimbursement and hospital listing

by the French National Health Insurance of ILUVIEN for the treatment of chronic DME considered insufficiently responsive to available therapies and despite optimized management of diabetes. In France, once Alimera agrees on a price with the French authorities, patients will be reimbursed for 100% of the cost of ILUVIEN under Affection de Longue Durée, a program for severe chronic disease, such as diabetes.

United States. Alimera resubmitted the NDA for ILUVIEN for DME to the FDA in March 2014, and the FDA set a PDUFA goal date of September 26, 2014.

The NDA was originally filed in June 2010 and resubmitted with revisions in May 2011 and April 2013 to address matters raised in the FDA's first two CRLs. The most recently resubmitted NDA responded to the October 2013 third CRL from the FDA, which stated that the NDA could not be approved in its then present form. The FDA identified clinical and statistical deficiencies and indicated that the benefits of ILUVIEN did not outweigh its risks. Further, the FDA indicated that results from a new clinical trial would need to be submitted, together with at least 12 months of follow-up data for all enrolled patients, to support certain indications previously discussed by Alimera with the FDA. In the third CRL, the FDA also referenced deficiencies in the methods and controls used for the drug product at the facility where ILUVIEN is manufactured.

In the third CRL, the FDA suggested that a meeting with the Dermatologic and Ophthalmic Drugs Advisory Committee, which was subsequently scheduled for January 2014, might be of assistance in addressing the deficiencies identified above and providing advice whether a patient population could be identified in which the benefits of the drug product might outweigh the risks. Alimera believes it clarified with the FDA that the purpose of the Advisory Committee meeting was to consider the benefits and risks of ILUVIEN based on existing data available from the completed FAME Study clinical trials. A meeting of Alimera and the FDA in preparation for the Advisory Committee meeting resulted in labeling discussions for ILUVIEN, and Alimera and the FDA agreed that the Advisory Committee meeting was no longer necessary.

Alimera's March 2014 resubmission of the NDA for ILUVIEN included responses to questions raised in the third CRL, addressed deficiencies noted in the methods and controls used for the drug product at the facility where ILUVIEN is manufactured and provided a safety update, which included commercial experience with ILUVIEN in the EU. In April 2014, Alimera was notified by the FDA that the resubmission of its NDA qualified as a complete class 2 response to the third CRL. Alimera does not plan to conduct any new clinical trials in connection with the FDA's review of this submission. FDA approval of ILUVIEN would entitle us to a one-time $25.0 million milestone payment from Alimera. In April 2014, Alimera entered into a $35.0 million term loan agreement with Hercules Technology Growth Capital (Hercules) under which Hercules will advance $25.0 million to fund the milestone payment obligation if the FDA approves ILUVIEN on or before October 31, 2014 and certain other conditions are satisfied.

Australia and New Zealand. In April 2014, Alimera entered into an exclusive agreement with Specialized Therapeutics Australia (STA) for the distribution of ILUVIEN in Australia and New Zealand. STA is responsible for regulatory and commercial matters, including marketing approval and reimbursement, in those countries. The agreement between Alimera and STA includes a milestone payment to Alimera upon achievement of a public reimbursement listing, and royalties based on net sales, which will increase if a sales target is met. We are entitled to 20% of any royalties and 33% of any other payments received by Alimera, including any milestone payment.

Other Diseases. Alimera is not currently studying the use of ILUVIEN to treat any ophthalmic diseases other than DME.

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, our first product, was 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 to and by Bausch & Lomb. During fiscal 2013, Bausch & Lomb discontinued sales of Vitrasert following patent expiration.

Tethadur Technology System

Our Tethadur technology system utilizes BioSilicon, a fully-erodible, nanostructured elemental silicon, designed to provide sustained delivery of large biologic molecules, including peptides, proteins and antibodies. The size of the pores and surface area of the BioSilicon is manufactured using nanotechnology to accommodate a specific protein, peptide or antibody molecule. A suspension of the specific biologic loaded into BioSilicon in solution is injected into the patient. Over a pre-determined period, the BioSilicon erodes and the biologic molecules are released from the pores on a sustained basis. We believe that by varying the pore size and surface area of Tethadur, the release rate of antibodies and other therapeutics loaded into Tethadur can be controlled, which could permit sustained delivery of antibodies and other therapeutics that currently must be delivered by frequent injections. The system is biocompatible and biodegradable. BioSilicon can also be designed to deliver smaller molecules.

Development Pipeline

Our pre-clinical research is focused on using our Tethadur and Durasert technology platforms, alone or in combination, to deliver therapeutic agents to treat wet and dry AMD, osteoarthritis and glaucoma, as well as to provide systemic delivery of biologics. A micro-insert delivering Latanoprost for the treatment of glaucoma and ocular hypertension is subject to an option by Pfizer.

Feasibility Study Agreements

We have entered into feasibility study agreements with various companies, some of which are funded, to evaluate our Durasert and Tethadur and other 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, as amended and restated in March 2008, 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 among 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.

Alimera has complete financial responsibility for the development of licensed products and regulatory submissions under the collaboration agreement.

Alimera has agreed to pay us a one-time $25.0 million milestone within 30 days following the first product to be approved by the FDA under the collaboration agreement. In addition, we are entitled to receive 20% of any net profits (as defined) on sales of each licensed product (including ILUVIEN) by Alimera, measured on a quarter-by-quarter and country-by-country basis. Alimera may recover 20% of previously incurred and unapplied net losses (as defined) for commercialization of each product in a country by offsetting up to 4% of the net profits earned in that country for that product each quarter, effectively reducing the Company's profit share to not less than 16% until those net losses are recouped. If Alimera sublicenses commercialization in any country, we are entitled to 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

Our June 2011 Amended and Restated Collaborative Research and License Agreement with Pfizer (the Restated Pfizer Agreement) provides Pfizer an exclusive option, under various circumstances, to license the development and commercialization of a sustained release bioerodible implant to deliver latanoprost by subconjunctival injection (the Latanprost Product) worldwide for human ophthalmic disease or conditions other than uveitis. Under the Restated Pfizer Agreement, at our discretion and expense, we can develop the Latanoprost Product through Phase II clinical trials. If we cease development, or if we commence and complete Phase II clinical trials, Pfizer may exercise its option at either juncture in exchange for payments of prescribed, but different levels of, license fee and potential future milestones plus royalties. If Pfizer does not exercise any such option, the Restated Pfizer Agreement will automatically be terminated.

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.

The Restated Pfizer Agreement replaces all of the rights and obligations under a 2007 Research and License Agreement, except for confidentiality and indemnification provisions. 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.

Pfizer owned approximately 6.3% of our outstanding stock as of August 31, 2014.

Bausch & Lomb

Under a 2003 amended license agreement, Bausch & Lomb has a worldwide exclusive license to make and sell our first-generation products (which, as defined in the agreement, includes Retisert) 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. This agreement also covered Vitrasert prior to patent expiration. Bausch & Lomb can terminate its agreement with us without penalty at any time upon 90 days' written notice.

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 (now named OncoSil™), a BioSilicon product candidate for the treatment of pancreatic and other types of cancer. We received an upfront fee of $100,000 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. The first annual license maintenance fee of $100,000 was paid in January 2014. 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 $9.6 million in fiscal 2014, $7.0 million in fiscal 2013 and $7.0 million in fiscal 2012. Of these amounts, $8.2 million in fiscal 2014, $5.4 million in fiscal 2013 and $4.2 million in fiscal 2012 were incurred for costs of research and development personnel, clinical and pre-clinical studies, contract services, testing and laboratory facilities. The remaining expense of $1.4 million in fiscal 2014, $1.6 million in fiscal 2013 and $2.8 million in fiscal 2012 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.

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 other countries. 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, 2014:

Technology	United States Patents	United States Applications	Foreign Patents	Foreign Applications	Patent Families
Durasert	11	8	87	40	12
Tethadur	7	6	9	22	6
Other BioSilicon	13	4	73	5	20
Other	9	6	22	30	16
Total	40	24	191	97	54

Employees

We had 24 employees as of August 31, 2014. 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.

Third Party Reimbursement and Pricing Controls

Sales of pharmaceutical products are significantly dependent on the availability and extent of reimbursement to consumers of the cost of the products from third-party payors, such as government health administration authorities and plans, private health insurers and other organizations, as well as the timing and complexity of obtaining those reimbursements. 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 the amount and/or process for reimbursement of ILUVIEN for chronic DME in various EU countries where it has received marketing authorization.

The passage of the Medicare Prescription Drug and Modernization Act of 2003 imposed requirements for the distribution and pricing of prescription drugs, which may affect the marketing of our products by us or our licensees. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, collectively referred to as the ACA, is expected to significantly change the way healthcare is financed by both governmental and private insurers. The ACA may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of new products, and the rebates, discounts, taxes and other costs resulting from the ACA may have a significant effect on our profitability in the future. In addition, potential reductions of the per capita rate of growth in Medicare spending under the ACA could potentially limit access to certain treatments or mandate price controls for our products.

In many foreign markets, including countries in the EU, pricing of pharmaceutical products is subject to governmental control. In the U.S., there have been, and there will likely continue to be, federal and state proposals to implement similar governmental pricing control.

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 we or our partners have. Competitors may reach the market earlier, may have obtained or could obtain patent protection that dominates or adversely affects our products and potential products, and may offer products with greater efficacy, lesser side effects and/or other competitive advantages. We believe that competition for treatments of back-of-the-eye diseases is based upon the effectiveness of the treatment, side effects, time to market, reimbursement and price, reliability, availability, patent position, and other factors.

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

- *DME.* Genentech USA Inc.'s products Lucentis (ranibizumab) and Regeneron Pharmaceutical's EYLEA (afibercept) are approved in the U.S. and the EU for the treatment of DME. Roche's lower-cost Avastin is approved to treat various cancers, but is used off-label for treatment of 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 maintains exclusive rights to EYLEA in the U.S., and Bayer HealthCare owns the exclusive marketing rights outside the U.S. Lucentis, EYLEA and Avastin are all injected into the back of the eye on a regular basis. Allergan, Inc.'s Ozurdex® (dexamethasone intraveal implant), a bioerodible, extended release intravitreal implant, has been approved for the treatment of DME in eyes that have had, or are scheduled for, cataract surgery. It has a duration of therapy of several months. Other companies, including Genentech, are working on the development of product candidates and extended delivery devices for the potential treatment of DME, including those that act by blocking VEGF and VEGF receptors, as well as use of small interfering ribonucleic acids (siRNAs) that modulate gene expression.

- *Posterior Uveitis.* Periocular steroid injections and systemic delivery of corticosteroids are used to treat posterior uveitis. Ozurdex is approved in the U.S. and EU for posterior uveitis. Many companies have ongoing trials of posterior uveitis treatments, including Abbvie's Humera® (adalimumab), Santen Pharmaceutical Co. Ltd.'s sirolimus drug DE-109, Novartis' AIN457 and XOMA Ltd.'s Gevokizumab™.
- *Dry AMD.* There are no FDA-approved treatments for any form of dry AMD. Many companies have products in development, including Acucela Inc.'s Emixustat Hydrochloride, a visual cycle modulator administered orally, Roche/Genentech's lampalizumab, an intravitreal injection therapy; GlaxoSmithKline's GSK933776, an intravenously administered anti-amyloid immunotherapy drug; MacuCLEAR's MC1101, an antihypertensive drug being developed as an eye drop; and several complement inhibitors.
- *Wet AMD.* There are a variety of therapies used for the treatment of wet AMD, principally Lucentis, EYLEA and Avastin. Lucentis and EYLEA are approved in the U.S. and EU to treat the disease, and Avastin is used off- label.
- *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.

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,								
	2014			2013			2012		
	U.S.	U. K.	Total	U.S.	U. K.	Total	U.S.	U. K.	Total
	(In thousands)								
Revenue:									
Collaborative research and development	$1,930	$225	$2,155	$ 510	$270	$ 780	$ 939	$1,141	$2,080
Royalty income	1,318	—	1,318	1,363	—	1,363	1,446	—	1,446
	$3,248	$225	$3,473	$1,873	$270	$2,143	$2,385	$1,141	$3,526

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 product for its intended use;
- submission to the FDA of an NDA to obtain marketing approval; and
- FDA review and approval of the NDA.

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

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

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators. Clinical trials are conducted in accordance with protocols that detail the objectives of the study, the parameters to be used to monitor safety and any efficacy criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND. Further, each clinical study must be conducted under the auspices of an independent Institutional Review Board (IRB). 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 or our collaborative partners may not 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 a product 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 and 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.

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.

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, including physicians, and third-party payors play a primary role in the recommendation and prescription of drug products that are granted marketing approval. Arrangements with healthcare providers, third-party payors and other healthcare customers are subject to broadly applicable fraud and abuse and other healthcare laws and regulations in the U.S. and in other countries and jurisdictions. Within the U.S., these laws generally apply to pharmaceutical companies once the companies have marketed products or marketed products reimbursable by federal healthcare programs such as Medicare and Medicaid. For the laws with such applicability, we could be subject to the laws if any of our product candidates in the future receive marketing approval and/or coverage under federal healthcare programs. Although the specific provisions of these laws vary, their scope is generally broad and there may not be regulations, guidance or court decisions that apply the laws to particular industry practices. Such U.S. federal 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 engaging in certain activities, including 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; and
- the federal transparency requirements under the Health Care Reform Law require manufacturers of drugs, devices and medical supplies to report to the federal government information related to certain payments and other transfers of value to physicians and teaching hospitals, as well as physician ownership and investment interests.

Within the U.S., analogous state 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 governmental as well as non-governmental third-party payors, including private insurers. Foreign laws may also seek to prevent fraud and abuse.

Laws and regulations have been enacted by various states to regulate the sales and marketing practices of pharmaceutical companies with marketed products. The laws and regulations generally limit financial interactions between manufacturers and health-care providers; 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; and/or require disclosure to the government and public of financial interactions. Many of these laws and regulations contain ambiguous requirements or require administrative guidance for implementation. Given the lack of clarity in laws and their implementation, any future reporting (if we obtain approval and/or reimbursement from federal healthcare programs for our product candidates) could be subject to the penalty provisions of the pertinent laws and regulations.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and its implementing regulations, also imposes obligations on certain health care providers, health plans, and health care clearinghouses (which are entities that processor facilitate the processing of nonstandard data elements of health information into standard data elements, or vice versa) and certain of their contractors with respect to safeguarding the privacy, security and transmission of individually identifiable health information. 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.

Foreign Laws. We and our collaborative partners are also subject to regulatory requirements governing human clinical trials and marketing approval for pharmaceutical products sold in foreign 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. Our principal executive office is located at 480 Pleasant Street, Suite B300, 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 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 may 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 is selling ILUVIEN for chronic DME in the U.K. and Germany, with plans to launch in France and Portugal in late 2014, and also has marketing authorization in 6 other EU countries, we do not know the timing and extent of any revenues we may receive from sales of ILUVIEN for chronic DME in the EU, if any. We do not know whether we will receive the one-time $25.0 million milestone payment to which we would be entitled if the FDA approves ILUVIEN, nor the timing or extent of revenues we might receive from sales in the U.S., if any. We receive royalties from Bausch & Lomb's sales of Retisert, but we do not expect those royalties to increase to a level sufficient to sustain our operations and they may decline. 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 and our or any other licensees' ability to achieve regulatory approval and sufficient revenues from commercialization of one or more other products.

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

With the exception of net income in fiscal year 2010 resulting from a non-recurring event, we have incurred operating losses each year since inception, and at June 30, 2014, we had a total accumulated deficit of $277.0 million. During the past three fiscal years, we financed our operations primarily from sales of equity, as well as operating cash flows from license fees, research and development funding and royalty income from our collaboration partners. We believe that our capital resources of $18.3 million at June 30, 2014, together with expected cash inflows under existing collaboration agreements, should enable us to fund our operations as currently planned through the third quarter of calendar year 2015. This does not include either the potential milestone or any net profits payments under the Alimera collaboration agreement. Our ability to fund our planned operations beyond that date, including completion of clinical development of Medidur, is expected to depend on the amount and timing of cash receipts under our Alimera collaboration agreement, as well as proceeds from any future collaboration or other agreements and/or financing transactions. If we receive the one-time $25.0 million milestone payment from Alimera that would be due if the FDA approves ILUVIEN, we believe our capital resources and other expected cash inflows will fund our operations as currently planned into calendar 2017.

Whether we will require, or desire, to raise additional capital will be influenced by many factors, including, but not limited to:

- whether and when we receive the one-time $25.0 million milestone from Alimera to which we would be entitled if the FDA approves ILUVIEN;
- whether, when and to what extent we receive other revenues from Alimera with respect to the commercialization of ILUVIEN;
- the timing and cost of development of Medidur for posterior uveitis;
- whether and to what extent we internally fund, when we initiate, and how we conduct other product development and programs, including Tethadur applications;
- whether and when we initiate Phase II clinical trials for the Latanoprost Product and whether and when Pfizer exercises its option;
- whether and when we enter into strategic arrangements for our product candidates 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 believe that extending our cash position beyond the third quarter of calendar year 2015 depends significantly on receipt of the one-time $25.0 million milestone to which we would be entitled on an FDA approval of ILUVIEN and the successful commercialization by Alimera of ILUVIEN for DME that would provide us with our share of net profits receipts. There is no assurance that ILUVIEN for DME will be approved by the FDA in the U.S. or that Alimera will be able to make the milestone payment if ILUVIEN is approved. In April 2014, Alimera entered into a term loan agreement with Hercules Technology Growth Capital (Hercules) under which Hercules agreed to advance $25.0 million to Alimera to fund the milestone payment obligation if the FDA approves ILUVIEN on or before October 31, 2014 and certain other conditions are satisfied. Alimera has reported that due to the limited revenue generated by ILUVIEN to date, it may not be able to maintain compliance with certain covenants under its loan agreement. There is no assurance that Alimera will have the funds to pay the milestone payment when due. Further, there is no assurance that ILUVIEN for chronic DME will achieve market acceptance in any country in the EU, or, if ILUVIEN is approved in the U.S., Australia or New Zealand, or that we will receive significant, if any, revenues from ILUVIEN.

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 or times we seek any additional financing may make it more difficult and more expensive to obtain. If available, additional equity financing may be dilutive to stockholders, debt financing may involve restrictive covenants or other unfavorable terms and potential dilutive equity, and funding through collaboration agreements may be on unfavorable terms, including requiring us to relinquish rights to certain of our technologies or products. If adequate financing is not available if and when needed, we may be required to delay, reduce the scope of or eliminate research or development programs, postpone or cancel the pursuit of product candidates, including pre-clinical and clinical trials and new business opportunities, reduce staff and operating costs or otherwise significantly curtail our operations to reduce our cash requirements and extend our capital.

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 $2.8 million of intangible assets on our balance sheet as of June 30, 2014, of which $1.9 million related to our Durasert technology and $912,000 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;
- 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 the payments to which we would be entitled upon such approval and from successful commercialization, which could materially impair our financial prospects.

Alimera has received three CRLs from the FDA with respect to its NDA for ILUVIEN for DME in which the FDA stated that it was unable to approve the NDA in each instance in its then current form. Although Alimera again refiled the NDA in March 2014 following labeling discussions with the FDA in December 2013 and the FDA has set a new PDUFA goal date of September 26, 2014, 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, or that Alimera will be able to obtain FDA 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 U.S. commercialization, which would be materially adverse to our business. Further, studies of ILUVIEN for the treatment of three other eye diseases have been discontinued and 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 included under Alimera's agreement with us.

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

Prices, coverage and reimbursement to consumers of the price of ILUVIEN in EU countries are generally regulated by third-party payors, such as government health administration authorities and plans, private health

insurers and other organizations. Consumers are also affected by the timing and complexity of those reimbursements. Prices are generally lower and coverage and access to drugs more limited than in the U.S., which has and is expected to continue to affect our potential revenues from the commercialization of ILUVIEN for chronic DME in the EU. There is no assurance as to what level of governmental pricing and reimbursement will be permitted in various EU countries. For example, in the U.K. and Scotland, NHS reimbursement is limited to the treatment of pseudophakic eyes. Similarly, there is no assurance that Alimera will achieve satisfactory agreements with statutory insurers in other countries to streamline reimbursement. We do not know what levels of pricing will be approved in other EU countries, or what restrictions will be placed on the use or reuse of ILUVIEN. Further, if ILUVIEN were approved in the U.S., we do not know what restrictions will be put on its use or what level of pricing will be reimbursed. Future sales of ILUVIEN may be adversely affected by pricing and reimbursement decisions, and such effects may be material.

Alimera's expansion of its commercial infrastructure in the EU is a significant undertaking that requires substantial financial and managerial resources, and Alimera may not be successful in its efforts, or it may encounter unexpected delays in connection with its continued expansion, which may negatively impact its efforts to market and sell ILUVIEN. Alimera also could fail to successfully manage its international operations, which could materially harm our business, operating results and financial condition.

Our financial results depend heavily on Alimera's ability to successfully commercialize ILUVIEN in the EU. ILUVIEN for chronic DME has marketing authorization in ten EU countries and is pending authorization in seven more EU countries. Alimera launched ILUVIEN in the United Kingdom and Germany in April and May of 2013, respectively, and currently plans to launch ILUVIEN in Portugal and France in late 2014, but has not announced commercialization plans for the other EU countries where it has or has sought marketing approval. A commercial launch of this size is a significant undertaking that requires substantial financial and managerial resources. Alimera may not be able to maintain and expand its commercial operation in a cost-effective manner or realize a positive return on its investments, which could negatively impact its ability to market and sell ILUVIEN. Factors that may inhibit Alimera's efforts to commercialize ILUVIEN include:

- Alimera's inability to expand its sales and marketing infrastructure, to grow its organization or to manage its growth, including integrating any personnel hired through Quintiles Commercial or similar organizations;
- Alimera's inability to recruit and retain adequate numbers of effective personnel;
- the inability of Alimera's sales personnel to obtain access to or persuade adequate numbers of ophthalmologists to prescribe ILUVIEN;
- the lack of complementary products to be offered by Alimera's sales personnel, which may put Alimera at a competitive disadvantage relative to companies with more extensive product lines;
- the inability of Alimera's market access personnel to obtain sufficient levels of pricing and reimbursement in each jurisdiction; or
- unforeseen costs and expenses associated with creating a commercial organization in the EU.

Additionally, Alimera may encounter unforeseen delays in expanding its commercial operations that delay the commercial launch in one or more EU countries in which ILUVIEN has received or been recommended for marketing authorization. These delays may increase the cost of and the resources required for successful commercialization of ILUVIEN in the EU. Alimera does not have experience in a commercial operation of this size in the EU or elsewhere. Alimera has limited international commercialization experience and international operations require significant management attention and financial resources. In addition, there are many risks inherent in international business activities, including, but not limited to:

- extended collection timelines for accounts receivable and greater working capital requirements;
- multiple legal systems and unexpected changes in legal requirements;

- tariffs, export restrictions, trade barriers and other regulatory or contractual limitations on Alimera's ability to sell or develop ILUVIEN in certain foreign markets;
- trade laws and business practices favoring local competition;
- potential tax issues, including restrictions on repatriating earnings, multiple and conflicting and complex tax laws and regulations;
- weaker intellectual property protection in some countries;
- political instability, including war and terrorism or the threat of war and terrorism; or
- adverse economic conditions, including the stability and solvency of business financial markets, financial institutions and sovereign nations.

In addition, compliance with foreign and U.S. laws and regulations that are applicable to Alimera's international operations is complex and may increase Alimera's cost of doing business in international jurisdictions, and Alimera's international operations could expose Alimera to fines and penalties if Alimera fails to comply with these laws and regulations. These laws and regulations include import and export requirements and anti-bribery laws. Any violations of these laws or regulations could subject Alimera to civil or criminal penalties, including substantial fines or prohibitions on Alimera's ability to offer ILUVIEN in one or more countries, which could materially and adversely harm our business and financial condition.

If Alimera does not develop an effective marketing strategy, or if it is not successful in recruiting and retaining personnel or in expanding its sales and marketing infrastructure and entering into additional collaboration arrangements with third parties, or if it encounters delays or other difficulties in commercializing ILUVIEN, it would adversely affect our business, operating results and financial condition.

We do not know if and when we will receive revenues from any commercialization of ILUVIEN for DME 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. Because we are entitled to a net profit participation on a country-by-country and quarter-by-quarter basis on sales of ILUVIEN where Alimera markets ILUVIEN directly and to a percentage of royalties and non-royalty consideration where 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. We cannot project what the demand will be for ILUVIEN for DME or when, or if, it will achieve net profits in countries where Alimera markets it.

Alimera has announced its intention to market ILUVIEN directly in certain EU countries and, if approved by the FDA, in the U.S. Although Alimera commercially launched ILUVIEN for chronic DME in the U.K. and Germany during the quarter ended June 2013, Alimera has reported that it has not achieved net profits in either country. Alimera has announced its intention to launch ILUVIEN in France and Portugal in late 2014 and to launch in the U.S. in early 2015 if the FDA approves ILUVIEN, but has not announced commercialization plans for the other EU countries where it has or has sought 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 the U.S. or that it will have sufficient capital to do so.

Alimera has signed a distribution agreement with STA for ILUVIEN in Australia and New Zealand. We do not know when or if STA will achieve a public reimbursement listing for ILUVIEN entitling Alimera to a milestone in which we would share, or when or if there will be net sales entitling Alimera to royalties in which we would share.

The micro-insert for ILUVIEN and Medidur delivers FAc, a corticosteroid that has adverse side effects in the eye, which may affect the approvability and success of this micro-insert for treatment of DME, posterior uveitis and other eye diseases.

The micro-insert for both ILUVIEN and Medidur delivers the non-proprietary corticosteroid FAc, which is associated with adverse side effects in the eye, such as cataract formation and elevated IOP, which may increase the risk of glaucoma and related surgery to manage those side effects. In the 2011 and 2013 CRLs, the FDA stated that the risks of adverse reactions shown for ILUVIEN in the FAME Study were significant and were not offset by the benefits demonstrated in those clinical trials. These side effects may affect the approvability of ILUVIEN for DME in certain jurisdictions. 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 ILUVIEN and Medidur are approved, these side effects may limit the population for which marketing authorization is granted or for which reimbursement is provided and/or adversely affect sales of the product. For example, NHS reimbursement for ILUVIEN for chronic DME in the U.K. and Scotland is limited to eyes that have undergone cataract surgery.

There is no assurance that we will be able to seek FDA approval of Medidur based on one Phase III trial together with a utilization study, and if we are required to conduct an additional Phase III trial, the time and expense required to obtain U.S. regulatory approval would increase.

If the results of our current Phase III trial are positive, and if the FDA approves ILUVIEN for DME, we plan to seek FDA approval on the basis of this single Phase III trial together with additional clinical data from a planned open label study on use of our proprietary inserter. However, we may need to complete two Phase III trials to obtain FDA approval, which would extend the time for filing an NDA and, accordingly, any regulatory approval of Medidur, and would also increase the cost of its development prior to approval.

There is no assurance that Medidur will be found to be safe and effective for the treatment of posterior uveitis

We are optimistic that Medidur will be as efficacious for posterior uveitis as Retisert is, but with a better side effect profile than Retisert, comparable to ILUVIEN. However, this is only a hypothesis, and there is no assurance that the ongoing Phase III program or investigator-sponsored study for Medidur will demonstrate these results. While early interim data from the investigator-sponsored study of Medidur are consistent with this hypothesis, that trial is not complete, involves only up to 12 patients and is not intended to be a clinical trial that can serve as the basis for approval of Medidur. Data from the Retisert and ILUVIEN trials and early data from this investigator-sponsored study may not accurately predict the results of our Medidur Phase III trial(s). There is no assurance that the clinical trial or trials for Medidur will provide the necessary evidence of safety and efficacy required for approval by the FDA and other regulatory authorities. Actions by the FDA and other regulatory authorities with respect to Retisert and ILUVIEN are not predictive of the FDA's action with respect to Medidur.

There is no assurance that Pfizer will exercise its option with respect to the Latanoprost Product, in which case we will not receive any further financial consideration under the Restated Pfizer Agreement.

Development of the Latanoprost Product through at least 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 upon our cessation of development of the Latanoprost Product at any time 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.

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.

Marketing and manufacture of pharmaceutical products is subject to stringent regulation by applicable governmental authorities. Generally, in order to obtain marketing approval, 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 a pivotal Phase III trial of Medidur for posterior uveitis is ongoing. All of our other product development is at earlier stages. 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 any feasibility study agreements we have, or enter into, 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 fund and undertake, or to find or reach agreement with licensees to fund and undertake, clinical trials;
- decisions by licensees not to exercise options for products or 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 clinical materials;
- failure to comply with current good laboratory practices (GLP), good clinical practices (GCP), cGMP or similar foreign regulatory requirements that affect the conduct of pre-clinical and clinical studies and the manufacturing of products;
- requests by regulatory authorities for additional data or clinical trials;
- governmental or regulatory agency assessments of pre-clinical or clinical testing that differ 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 or 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 requires 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 various companies. The curtailment or termination of these arrangements with Alimera or Bausch & Lomb could adversely affect our business, our ability to develop and commercialize our products, product candidates and proposed products and our ability to fund operations.

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

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

- we are required, and expect to be required, under our collaborative and licensing arrangements not to conduct specified types of research and development in the field that is the subject of the arrangement or not to sell products in such field, limiting the areas of research, development and commercialization that we can pursue;
- our licensees may 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, Alimera may abandon the development and commercialization of any licensed product, including ILUVIEN for DME, and Bausch & Lomb may terminate its license agreement with respect to Retisert without penalty at any time upon 90 days' written notice.

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 alternatives to our technologies or develop competing products. While Bausch & Lomb has significant experience in the ophthalmic field and substantial resources, there is no assurance whether, and to what extent, that experience and those resources will be devoted to Retisert. Alimera has limited experience and limited financial resources, and ILUVIEN for DME is Alimera's first and only commercial product. Actions, including breaches or termination of these agreements by our licensees, could delay, impair or stop the development or 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 our targeted diseases, competitors have alternate therapies that are already commercialized or are in various stages of development, ranging from discovery to advanced clinical trials. Any of these drugs, therapies, products, approaches or methods may receive government approval or gain market acceptance more rapidly than our products and product candidates, may offer therapeutic or cost advantages, or may 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 recommend our products and product candidates, limit the indications for which they are recommended, or do not provide adequate and timely coverage and reimbursement levels for our products, 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 may challenge the price and cost-effectiveness of our products, or refuse to provide coverage for our products. If our products and product candidates fail to achieve and maintain market acceptance, they may fail to generate significant revenues and our business may be significantly harmed.

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

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

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

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

Our success is dependent on whether we can obtain patents, defend our existing patents and operate without infringing on the proprietary rights of third parties. As of August 31, 2014, we had 229 patents and 115 pending patent applications, including patents and pending applications covering our Durasert, 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 likely result in substantial costs to us and diversion of our efforts, and could prevent or delay our discovery or development of product candidates. If our competitors claim technology also claimed by us, and if they prepare and file patent applications in the U.S. or other jurisdictions, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office or the appropriate foreign patent office to determine priority of invention, which could result in substantial cost to us and diversion of our efforts. Any such litigation or interference proceedings, regardless of the outcome, could be expensive and time consuming. Litigation could subject us to significant liabilities to third parties, requiring disputed rights to be licensed from third parties and/or requiring us to cease using certain technologies.

We also rely on trade secrets, know-how and technology that are not protected by patents to maintain our competitive position. We try to protect this information by entering into confidentiality agreements with parties that have access to it, such as our corporate partners, collaborators, employees, and consultants. Any of these parties could breach these agreements and disclose our confidential information, or our competitors may learn of the information in some other way. If any material trade secret, know-how or other technology not protected by a patent were to be disclosed to or independently developed by a competitor, our competitive position could be materially harmed.

RISKS RELATED TO OUR BUSINESS, INDUSTRY, STRATEGY AND OPERATIONS

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

We are dependent upon the principal members of our management and scientific staff. In addition, we believe that our future success in developing our products and achieving a competitive position may depend on whether we can attract and retain additional qualified management and scientific personnel. There is strong competition for management and scientific personnel within the industry in which we operate, and we may not be

able to attract and retain such personnel. As we have a small number of employees and we believe our products are unique and highly specialized, the loss of the services of one or more of the principal members of our 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 any of our competitors, we could lose existing or potential future licensees or collaboration partners as a result of such consolidation.

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

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

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

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

There are a limited number of manufacturers that operate under cGMP and other foreign regulations that are both capable of manufacturing our products and product candidates and are willing to do so. Alimera has contracted with individual third-party manufacturers for the manufacture for each of (i) the ILUVIEN implant; (ii) the ILUVIEN applicator; (iii) ILUVIEN's active pharmaceutical ingredient; and (iv) the quality release testing of ILUVIEN in the EU. If any of Alimera's third-party manufacturers breach their agreements or are unable or unwilling to perform for any reason, Alimera may not be able to locate alternative acceptable manufacturers, enter into favorable agreements with them or get them approved by the applicable regulatory authorities in a timely manner. Furthermore, all of these manufacturers rely on additional third parties for the manufacture of component parts. Any inability to acquire sufficient quantities of ILUVIEN implants, the ILUVIEN applicator or the active pharmaceutical ingredient in a timely manner from these third parties could delay commercial production of, and impact Alimera's ability to fulfil any demand for, ILUVIEN, which, in turn, would impact our ability to receive our contractual share of net profits from the sales of ILUVIEN on a country-by-country basis.

Failure by us, our collaborative partners, or our or their third-party manufacturers, to comply with applicable manufacturing requirements could result in sanctions being imposed on us or our collaborative partners, 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. In the 2013 CRL, the FDA cited deficiencies at the facility where ILUVIEN is manufactured. Although Alimera has responded to the FDA and reported that it does not believe those deficiencies will affect its European commercial supply, there is no assurance that the FDA will be satisfied.

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 to obtain country and jurisdiction-specific regulatory approvals and clearances. We or our licensees may not be able to comply with such regulations or 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.

U.S. federal and state governments continue to propose and pass legislation designed to reduce the cost of healthcare. The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (PPACA) represents one of the most significant health care reform measures in decades. The PPACA is intended to expand U.S. healthcare coverage primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program. Several provisions of the PPACA could significantly reduce payments from Medicare and Medicaid for any product candidates that obtain marketing approval in the future. Federal and state legislatures within the U.S. and foreign governments will likely continue to consider changes in existing health care legislation. We cannot predict the reform initiatives that may be adopted in the future or whether initiatives that have been adopted will be repealed or modified. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect the demand for any products for which we may obtain regulatory approval; our ability to set a price that we believe is fair for our products; our ability to obtain coverage and reimbursement approval for a product; our ability to generate revenues and achieve or maintain profitability; or the level of taxes that we are required to pay.

In addition, other legislative changes have been proposed and adopted since PPACA. The Budget Control Act (BCA) of 2011 includes provisions to reduce the federal deficit. The BCA, as amended, resulted in the imposition of 2% reductions in Medicare payments to providers beginning in 2013. More recent legislation extends reductions through 2024. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented, and/or any significant taxes or fees that may be imposed on us, as part of any broader deficit reduction effort or legislative replacement to the BCA, could have an adverse impact on our anticipated product revenues.

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 CHESS Depositary Interests (CDIs)) may be affected by developments directly affecting our business, as well as by developments out of our control or not specific to us. The price of our common stock dropped significantly when the FDA issued each of the 2011 CRL and the 2013 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 volumes 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, 2014, we had outstanding warrants and options to acquire approximately 5.4 million shares of our common stock, or approximately 15.5% 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.

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:

- 1,750 square feet of laboratory space, 1,000 square feet of clean room space and 10,900 square feet of office space in Watertown, Massachusetts under a lease agreement that expires in April 2019;
- 1,250 square feet of laboratory space and 1,665 square feet of office space in Malvern, United Kingdom under a lease agreement that expires in August 2016; 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.

PART II

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

Market Information, Holders and Dividends

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

	High	Low
Fiscal year ended June 30, 2014:		
First Quarter	$4.28	$3.10
Second Quarter	5.60	2.28
Third Quarter	5.45	3.85
Fourth Quarter	4.36	3.26
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

On September 8, 2014, the last reported sale price of our common stock on the NASDAQ Global Market was $4.77. As of that date, we had approximately 20 holders of record of our common stock and, according to our estimates, approximately 5,700 beneficial owners of our common stock. In addition, as of that date, there were approximately 2,140 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, 2014:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in Column a) (c)
Equity Compensation plans approved by security holders	3,791,001	$ 3.08	1,144,572
Equity Compensation plans not approved by security holders	—	—	—
Total	3,791,001	$ 3.08	1,144,572

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, 2014, the number of shares issuable under the 2008 Incentive Plan was increased by 750,000 shares.

Issuer Repurchases of Equity Securities

None.

ITEM 6. SELECTED FINANCIAL DATA

The selected historical financial data set forth below as of June 30, 2014, 2013, 2012, 2011 and 2010 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, 2014 and 2013 and for the years ended June 30, 2014, 2013 and 2012 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,				
	2014	2013	2012	2011	2010
	(In thousands except per share data)				
Consolidated Statements of Operations Data:					
Revenues:					
Collaborative research and development (1)	$ 2,155	$ 780	$ 2,080	$ 3,612	$22,570
Royalty income	1,318	1,363	1,446	1,353	483
Total revenues	3,473	2,143	3,526	4,965	23,053
Operating expenses:					
Research and development	9,573	7,005	7,039	6,864	6,994
General and administrative	7,468	7,169	6,868	8,104	6,968
Gain on sale of property and equipment	(78)	—	—	—	—
Impairment of intangible assets (2)	—	—	14,830	—	—
Total operating expenses	16,963	14,174	28,737	14,968	13,962
Operating (loss) income	(13,490)	(12,031)	(25,211)	(10,003)	9,091
Other income (expense):					
Change in fair value of derivatives	—	—	170	1,140	(339)
Interest income	6	16	38	30	27
Other expense, net	(1)	(2)	(1)	(13)	(3)
Total other income (expense)	5	14	207	1,157	(315)
(Loss) income before income taxes	(13,485)	(12,017)	(25,004)	(8,846)	8,776
Income tax benefit (expense)	130	117	169	218	(23)
Net (loss) income	$(13,355)	$(11,900)	$(24,835)	$ (8,628)	$ 8,753
Net (loss) income per share:					
Basic	$ (0.49)	$ (0.52)	$ (1.19)	$ (0.44)	$ 0.48
Diluted	$ (0.49)	$ (0.52)	$ (1.19)	$ (0.44)	$ 0.46
Weighted average common shares outstanding:					
Basic	27,444	23,044	20,791	19,489	18,405
Diluted	27,444	23,044	20,791	19,489	18,895

	As of June 30,				
	2014	2013	2012	2011	2010
	(In thousands)				
Consolidated Balance Sheet Data:					
Cash and cash equivalents	$ 15,334	$ 6,899	$ 4,625	$12,912	$15,514
Marketable securities	2,944	3,374	9,946	11,216	2,051
Total assets	22,671	16,249	20,597	47,113	43,014
Total deferred revenue—current and long-term	5,722	5,984	5,959	7,847	6,896
Total stockholders' equity	14,924	7,700	13,636	37,433	33,041

(1) Amounts recognized were inconsequential in fiscal 2014, and included $368,000 in fiscal 2013, $754,000 in fiscal 2012 and $3.3 million in fiscal 2011 from our Restated Pfizer Agreement; included $114,000 in fiscal 2014, $67,000 in fiscal 2013, $111,000 in fiscal 2012, $192,000 in fiscal 2011 and $22.3 million in fiscal 2010 from our collaboration agreement with Alimera; included $1.9 million in fiscal 2014 and $245,000 in fiscal 2013 in connection with feasibility study agreements; and included $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. Our strategy is to use our Durasert™ and Tethadur™ drug delivery technologies to independently develop products that deliver proven drugs and biologics, while continuing to leverage these technologies through collaboration and license agreements. We are focused on treatment of chronic diseases of the back of the eye and are also exploring applications outside ophthalmology. Our lead product candidate Medidur is in a pivotal Phase III clinical trial, our lead licensed product ILUVIEN® has been approved in the European Union (EU) and is pending approval with the U.S. Food and Drug Administration (FDA), and our pipeline includes potential product candidates at earlier stages of development. Our Durasert technology is the basis of three of the four sustained-release products for treatment of retinal diseases currently approved in the U.S. or EU.

Medidur™ is an injectable, sustained-release micro-insert designed to treat chronic, non-infectious uveitis affecting the posterior segment of the eye (posterior uveitis) over a period up to three years. Medidur uses the same Durasert micro-insert used in ILUVIEN (same polymers, same drug and same dose) and delivers a lower dose of the same drug as our FDA-approved Retisert® for posterior uveitis, which is licensed to Bausch & Lomb. Although we originally planned to seek FDA approval of Medidur based on two Phase III clinical trials, we now expect to seek approval based on safety and efficacy data from our single ongoing Phase III trial, with supplemental clinical data from a planned study of the safety and usability of our proprietary inserter, if ILUVIEN is approved by the FDA later this year. We plan to have a confirmatory meeting with the FDA with respect to this regulatory strategy. If the FDA does not approve this regulatory strategy, we may be required to complete a second Phase III trial for Medidur in order to submit for FDA approval, which would increase the development time and cost of Medidur.

ILUVIEN, our lead licensed product, is an injectable, sustained-release micro-insert that provides treatment over a period of up to three years of vision impairment associated with diabetic macular edema (DME). 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 on a country-by-country basis and a $25.0 million milestone payment from Alimera if ILUVIEN is approved by the FDA.

ILUVIEN is commercially available in the United Kingdom (U.K.) and Germany for the treatment of chronic DME considered insufficiently responsive to available therapies, and Alimera expects to launch in France and Portugal in late 2014. ILUVIEN has marketing authorization in six other EU countries and is pending authorization in seven more EU countries.

Alimera is also seeking marketing approval of ILUVIEN for DME in the U.S. Alimera entered into labeling discussions with the FDA in December 2013 and refiled the New Drug Application (NDA) with the FDA in March 2014. The FDA set a Prescription Drug User Fee Act (PDUFA) goal date of September 26, 2014. The resubmission responded to issues raised in the FDA's October 2013 Complete Response Letter (CRL).

Alimera also entered into an exclusive agreement with a third party for distribution, regulatory and reimbursement matters of ILUVIEN for DME in Australia and New Zealand.

Our pre-clinical research is primarily focused on our Tethadur and Durasert technology platforms. We are seeking to develop products using Tethadur, part of our BioSilicon™ technology, to provide sustained delivery of peptides, proteins, antibodies and other large biologic molecules. We are also researching the use of our Durasert technology, in some instances in combination with our BioSilicon technology, to provide sustained delivery of therapeutic agents to treat wet and dry Age-Related Macular Degeneration, osteoarthritis and glaucoma, as well as to provide systemic delivery of biologics.

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. We receive royalties from these sales.

Summary of Critical Accounting Policies and Estimates

The 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 method using management's best estimate of the standalone selling price of deliverables when vendor-specific objective evidence or third-party evidence of selling price is not available. Allocated consideration is recognized as revenue upon application of the appropriate revenue recognition principles 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, 2014, we reported $2.2 million of collaborative research and development revenue. Revenue is recognized when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable and collection is reasonably assured.

We 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 clinical trials (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 $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, fiscal 2013 and fiscal 2014 by 10%, or approximately $75,000, $37,000 and $1,000, 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.

Recognition of Expense in Outsourced Clinical Trial Agreements

We recognize research and development expense with respect to outsourced agreements for clinical trials to contract research organizations ("CROs") as the services are provided, based on our assessment of the services performed. We make our assessments of the services performed based on various factors, including evaluation by the third-party CROs and our own internal review of the work performed during the period, measurements of progress by us or by the third-party providers, data analysis with respect to work completed and our management's judgment. We have agreements with two CROs to conduct the Phase III clinical trial program for Medidur for posterior uveitis. Our financial obligations under the agreements are determined by the services that we request from time to time under the agreements. The actual amounts owed under the agreements and the timing of those obligations will depend on various factors, including the number of, and protocols for, the trials conducted, the number of patients and rate of patient enrollment and other factors relating to the clinical trials. We can change the protocol and/or services requested and thereby increase or decrease our obligations under the agreements from time to time. As of June 30, 2014, our CRO agreements provided for two Phase III clinical trials at an aggregate remaining cost of approximately $16.2 million. As we refine our clinical trial strategy for Medidur for posterior uveitis through continued dialogue with regulatory authorities, we expect to adjust the services under the CRO agreements accordingly. We can terminate the agreements at any time without penalty, and if terminated, we would be liable only for services through the termination date plus non-cancellable CRO obligations to third parties.

During fiscal 2014, we recognized approximately $4.1 million of research and development expense attributable to the initial Medidur Phase III clinical trial for posterior uveitis. Changes in our estimates or differences between the actual level of services performed and our estimates may result in changes to our research and development expenses in future periods.

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 Durasert 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 the 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 $790,000 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;
- 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 our 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, 2014 and 2013

	Year Ended June 30,		Change	
	2014	2013	Amounts	%
	(In thousands except percentages)			
Revenues:				
Collaborative research and development	$ 2,155	$ 780	$ 1,375	176%
Royalty income	1,318	1,363	(45)	(3)%
Total revenues	3,473	2,143	1,330	62%
Operating expenses:				
Research and development	9,573	7,005	2,568	37%
General and administrative	7,468	7,169	299	4%
Gain on sale of property and equipment	(78)	—	(78)	na
Total operating expenses	16,963	14,174	2,789	20%
Operating loss	(13,490)	(12,031)	(1,459)	(12)%
Other income (expense):				
Interest income	6	16	(10)	(63)%
Other expense, net	(1)	(2)	1	50%
Total other income	5	14	(9)	(64)%
Loss before income taxes	(13,485)	(12,017)	(1,468)	(12)%
Income tax benefit	130	117	13	11%
Net loss	$(13,355)	$(11,900)	$(1,455)	(12)%

Revenues

Collaborative research and development revenue increased to $2.2 million in fiscal 2014, a 176% increase from $780,000 in fiscal 2013, primarily due to recognition of $1.5 million of arrangement consideration upon resolution of a contingency associated with completion of a feasibility study agreement. Of the remaining deferred revenue balance of $5.7 million at June 30, 2014, $138,000 related to an ongoing feasibility study is expected to be recognized as revenue during fiscal 2015.

Royalty income, predominantly related to Retisert, decreased by $45,000, or 3%, to $1.3 million in fiscal 2014 compared to $1.4 million in fiscal 2013. We do not expect Retisert royalty income to increase significantly in the next fiscal year, and it may decline.

We are entitled to share in net profits, on a country-by-country basis, from sales by Alimera of ILUVIEN. Alimera launched ILUVIEN in the U.K. and Germany in the second quarter of calendar year 2013, and has reported plans to launch in France and Portugal in late calendar year 2014 and in the U.S. during the first quarter of calendar year 2015 if ILUVIEN is approved by the FDA. We do not know when and if we will receive net profit payments with respect to any country where Alimera sells ILUVIEN or payments with respect to countries where another entity sells ILUVIEN. We will be entitled to a milestone payment of $25.0 million from Alimera if the FDA approves ILUVIEN in the U.S. The PDUFA goal date for ILUVIEN is September 26, 2014.

Research and Development

Research and development totaled $9.6 million in fiscal 2014, an increase of $2.6 million, or 37%, compared to $7.0 million in fiscal 2013. A $3.3 million increase in CRO costs for the Medidur Phase III clinical trial was partially offset by a $665,000 decrease in personnel costs, including stock-based compensation. If we

are required to conduct an additional Phase III clinical trial for Medidur in order to submit for FDA approval, we expect our research and development expense could increase significantly in fiscal 2015.

General and Administrative

General and administrative increased by $300,000, or 4%, to $7.5 million for fiscal 2014 from $7.2 million for fiscal 2013, primarily attributable to increased stock-based compensation and professional fees.

Other Income

Other income totaled $5,000 in fiscal 2014 compared to $14,000 in fiscal 2013 due to lower average balances of marketable securities investments.

Income Tax Benefit

Income tax benefit, which consisted of foreign research and development tax credits, increased by $13,000, or 11%, to $130,000 in fiscal 2014 from $117,000 in fiscal 2013.

Years Ended June 30, 2013 and 2012

	Year Ended June 30,		Change	
	2013	2012	Amounts	%
	(In thousands except percentages)			
Revenues:				
Collaborative research and development	$ 780	$ 2,080	$ (1,300)	(63)%
Royalty income	1,363	1,446	(83)	(6)%
Total 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	$(11,900)	$(24,835)	$ 12,935	52%

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

development revenue was recognition of deferred revenue from collaboration agreements in fiscal 2013 compared to substantially all in the prior year.

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.

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 Phase III clinical trial 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.

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.

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 May 2014, the FASB issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers* (Topic 606) ("ASU 2014-09"), which requires an entity to recognize revenue in an amount that reflects the consideration to which the entity expects to be entitled in exchange for the transfer of promised goods or services to customers. The standard will replace most existing revenue recognition guidance in U.S. GAAP. ASU 2014-09 will become effective on July 1, 2017, and early application is not permitted. The standard permits the use of either the retrospective or cumulative effect transition method. We are evaluating the impact this standard will have on our financial statements.

Liquidity and Capital Resources

During fiscal 2011 through fiscal 2014, we financed our operations primarily from registered direct offerings of our equity securities in January 2011, August 2012, July 2013 and March 2014, as well as the issuance of shares pursuant to our at-the-market ("ATM") facility during fiscal 2014, and from operating cash inflows from license fees and research and development funding pursuant to collaboration arrangements. At June 30, 2014, our principal sources of liquidity consisted of cash, cash equivalents and marketable securities totaling $18.3 million. Our cash equivalents are invested in an institutional money market fund, and our marketable securities are invested in investment-grade corporate debt and commercial paper with maturities at June 30, 2014 ranging from 3 to 8.5 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, 2014, we had a total accumulated deficit of $277.0 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 $18.3 million at June 30, 2014, together with expected cash inflows under existing collaboration agreements, will enable us to fund our operations as currently planned through the third quarter of calendar year 2015. This estimate includes expected costs of clinical development of Medidur for posterior uveitis, but excludes any potential milestone or net profit receipts under our Alimera collaboration agreement. Our ability to fund our planned operations beyond then, including completion of clinical development of Medidur, is expected to depend on the amount and timing of cash receipts under our Alimera collaboration agreement, as well as proceeds from any future collaboration or other agreements and/or financing transactions. Our capital resources would be enhanced if Alimera successfully commercializes ILUVIEN for chronic DME in the EU and if ILUVIEN for DME is 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 ongoing clinical development of Medidur for posterior uveitis, as well as other research and development programs and operations. Whether we will require, or desire, to raise additional capital will be influenced by many factors, including, but not limited to:

- whether and when we receive the $25.0 million milestone payment from Alimera to which we would be entitled if the FDA approves ILUVIEN;
- whether, when and to what extent we receive other revenues from Alimera with respect to the commercialization of ILUVIEN;
- the timing and cost of development of Medidur for posterior uveitis;
- whether and to what extent we internally fund, when we initiate, and how we conduct product development and programs, including Tethadur applications;
- whether and when we initiate Phase II clinical trials for the Latanoprost Product and whether and when Pfizer exercises its option;
- whether and when we are able to enter into strategic arrangements for our product candidates 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.

Management currently believes that extending our cash position beyond the third quarter of calendar year 2015 depends significantly on possible cash flows from an FDA approval of ILUVIEN and the successful commercialization by Alimera of ILUVIEN for DME. However, there is no assurance that ILUVIEN for DME will be approved by the FDA, achieve market acceptance in any country in the EU, or, if approved, in the U.S., or that we will receive significant, if any, revenues from ILUVIEN for DME.

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. Although we may be able to sell common shares with an aggregate offering price of up to $10.7 million under our existing ATM facility as of June 30, 2014, we do not know whether and to what extent we will seek to sell shares pursuant to that program and, if we are able to do so, on what terms. The state of the economy and the financial and credit markets at the time or times we seek additional financing may make it more difficult and more expensive to obtain. If available, additional equity financing may be dilutive to stockholders, debt financing may involve restrictive covenants or other unfavorable terms and potential dilutive equity, and funding through collaboration agreements may be on unfavorable terms, including requiring us to relinquish rights to certain of our technologies or products. If adequate financing is not available if and when needed, we may be required to delay, reduce the scope of, or eliminate research or development programs, postpone or cancel the pursuit of product candidates, including pre-clinical and clinical trials and new business opportunities, reduce staff and operating costs or otherwise significantly curtail our operations to reduce our cash requirements and extend our capital.

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

	Year Ended June 30,		
	2014	2013	2012
	(In thousands)		
Net loss:	$(13,355)	$(11,900)	$(24,835)
Changes in operating assets and liabilities	389	692	(2,715)
Other adjustments to reconcile net loss to cash flows from operating activities	2,295	2,463	18,549
Cash flows used in operating activities	$(10,671)	$ (8,745)	$ (9,001)
Cash flows provided by investing activities	$ 66	$ 6,358	$ 606
Cash flows provided by financing activities	$ 19,044	$ 4,669	$ 114

Sources and uses of operating cash flows for the years ended June 30, 2014, 2013 and 2012 are summarized as follows:

	Year Ended June 30,		
	2014	2013	2012
	(In thousands)		
Operating cash inflows:			
License and collaboration agreements	$ 1,963	$ 854	$ 187
Royalty income	1,348	1,477	1,277
Foreign R&D tax credits	125	152	93
Investment interest received, net	45	215	372
	3,481	2,698	1,929
Operating cash outflows:			
Personnel costs	(5,340)	(4,539)	(4,906)
Professional fees	(2,869)	(2,729)	(3,330)
Clinical development and third-party R&D	(3,834)	(2,153)	(690)
All other operating cash outflows, net	(2,109)	(2,022)	(2,004)
	(14,152)	(11,443)	(10,930)
Cash flows used in operating activities	$(10,671)	$ (8,745)	$ (9,001)

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 Alimera represented 5.8% in fiscal 2014, 8.4% in fiscal 2013 and 57.2% in fiscal 2012, amounts attributable to Enigma represented 6.9% in fiscal 2014 and 11.7% in fiscal 2013 and amounts attributable to various feasibility study agreements represented 86.6% in fiscal 2014, 73.2% in fiscal 2013 and 26.7% in fiscal 2012.

Operating cash outflows increased by $2.7 million, or 23.7%, from fiscal 2013 to fiscal 2014, primarily as a result of: (a) an increase of $1.4 million for Medidur clinical development; (b) $1.1 million of incentive compensation, which included awards for fiscal 2013 and awards for fiscal 2012 that were conditioned on events occurring in fiscal 2013; and (c) an increase of $205,000 of consulting services, partially offset by a $300,000 net reduction of other personnel costs. Operating cash outflows increased by $513,000, or 4.7%, from fiscal 2012 to fiscal 2013, primarily as a result of $1.6 million of initial payments with respect to the Phase III trial of Medidur for posterior uveitis, partially offset by the absence in fiscal 2013 of approximately $600,000 of cash incentive compensation paid in fiscal 2012 based on fiscal 2011 awards and an approximate $600,000 decrease in professional fees.

Cash flows from investing activities were primarily attributable to maturities of marketable securities, net of purchases, of $386,000 for fiscal 2014 and $6.4 million for fiscal 2013 and to maturities and sales of marketable securities, net of purchases, of $1.0 million for fiscal 2012. Purchases of property and equipment totaled $248,000 in fiscal 2014, $68,000 in fiscal 2013 and $405,000 in fiscal 2012.

Cash flows from financing activities in fiscal 2014 were primarily attributable to an underwritten public offering in July 2013, a registered direct offering in March 2014 and sale of shares pursuant to an ATM facility consummated in December 2013, resulting in aggregate gross proceeds of $19.3 million, net of $1.2 million of share issue costs. Cash flows from financing activities in fiscal 2013 were attributable to $5.4 million of gross proceeds from an August 2012 registered direct offering of shares and warrants, net of approximately $700,000 of share issue costs. In addition, cash flows from financing activities included proceeds from the exercise of stock options totaling $987,000 in fiscal 2014 and $114,000 in fiscal 2012.

Off-Balance Sheet Arrangements

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

Tabular Disclosure of Contractual Obligations

The following table summarizes our minimum contractual obligations as of June 30, 2014:

	Payments Due by Period				
Contractual Obligations	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
			(In thousands)		
Operating Lease Obligations	$2,152	$ 475	$1,319	$ 358	$ —
Purchase Obligations	149	149	—	—	—
Total	$2,301	$ 624	$1,319	$ 358	$ —

Our operating lease obligations consist predominantly of office and lab space in Watertown, Massachusetts and Malvern, U.K. Our purchase obligations consist of non-cancellable purchase orders for supplies and services.

We have agreements with two CROs to conduct the Phase III clinical development program for Medidur for posterior uveitis. Our financial obligations under the agreements are determined by the services that we request from time to time under the agreements. The actual amounts owed under the agreements and the timing of those obligations will depend on various factors, including the number of, and protocols for, the trials conducted, the number of patients and rate of patient enrollment and other factors relating to the clinical trials. We can change the services requested and thereby increase or decrease our obligations under the agreements from time to time. As of June 30, 2014, our CRO agreements provided for two Phase III clinical trials at an aggregate remaining cost of approximately $16.2 million. As we refine our clinical trial strategy for Medidur for posterior uveitis through continued dialogue with regulatory authorities, we expect to adjust the services under the CRO agreements accordingly. We can terminate the agreements at any time without penalty.

We also have employment agreements with our three executive officers that would require us to make severance payments to them if we terminate their employment without cause or the executives resign for good cause.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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 weakening of the U.S. dollar in fiscal 2014 compared to fiscal 2013 resulted in a net increase in research and development expense of approximately $70,000. 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 2014 would have decreased or increased by $100,000, 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 weakening of the U.S.

dollar in relation to the Pound Sterling at June 30, 2014 compared to June 30, 2013 resulted in $124,000 of other comprehensive income due to the translation of £593,000 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, 2014 in relation to the Pound Sterling, our stockholders' equity at June 30, 2014 would have decreased or increased, respectively, by approximately $50,000.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by this item may be found on pages F-1 through F-25 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, 2014. 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, 2014, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

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

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

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

All internal control systems, no matter how well designed, have inherent limitations and may not prevent or detect misstatements. Projections of any evaluations of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of June 30, 2014. 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 (1992)*. Based on this assessment, our management concluded that, as of such date, our internal control over financial reporting was effective based on those criteria.

Deloitte & Touche LLP, the independent registered public accounting firm that audited our consolidated financial statements, has issued an attestation report on our internal control over financial reporting as of June 30, 2014, which is included below in this Item 9A of our Annual Report on Form 10-K.

(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**.**

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the internal control over financial reporting of pSivida Corp. and subsidiaries (the "Company") as of June 30, 2014, based on the criteria established in *Internal Control—Integrated Framework (1992)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit 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 effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed by, or under the supervision of, the company's principal executive and principal financial officers, or persons performing similar functions, and effected by the company's 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) 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 of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of June 30, 2014, based on the criteria established in *Internal Control—Integrated Framework (1992)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements as of and for the year ended June 30, 2014 of the Company and our report dated September 11, 2014 expressed an unqualified opinion on those financial statements.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
September 11, 2014

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, 53

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, 47

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, 64

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.

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 2014 Proxy Statement.

ITEM 11. EXECUTIVE COMPENSATION

The information required to be disclosed in Item 11 is hereby incorporated by reference to our 2014 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 2014 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 2014 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 2014 Proxy Statement.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENTS

(a)(1) Financial Statements

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

(a)(2) Financial Statement Schedules

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

(a)(3) Exhibits.

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-K	07/19/12	3.1
	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	Lease Agreement between pSivida Corp. and Farley White Aetna Mills, LLC dated November 1, 2013	10-Q	11/13/13	10.1
	Material Contracts—License and Collaboration Agreements			
10.11#	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
10.12#	Second Amendment to Amended and Restated License Agreement between pSivda US, Inc. and Bausch & Lomb dated August 1, 2009	10-K	09/25/09	10.13
10.13#	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

Exhibit No.	Exhibit Description	Incorporated by Reference to SEC Filing		
		Form	SEC Filing Date	Exhibit No.
10.14#	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	The following materials from pSivida Corp.'s Annual Report on Form 10-K for the year ended June 30, 2014, formatted in eXtensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets at June 30, 2014 and 2013; (ii) Consolidated Statements of Comprehensive Loss for the years ended June 30, 2014, 2013 and 2012; (iii) Consolidated Statements of Stockholders' Equity for the years ended June 30, 2014, 2013 and 2012; (iv) Consolidated Statements of Cash Flows for the years ended June 30, 2014, 2013 and 2012; 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.

(a) Filed herewith

SIGNATURES

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

PSIVIDA CORP.

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

Date: September 11, 2014

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

Name	Title	Date
/s/ DAVID J. MAZZO **David J. Mazzo**	Chairman of the Board of Directors	September 11, 2014
/s/ PAUL ASHTON **Paul Ashton**	President, Chief Executive Officer and Director (Principal Executive Officer)	September 11, 2014
/s/ LEONARD S. ROSS **Leonard S. Ross**	Vice President, Finance (Principal Financial and Accounting Officer)	September 11, 2014
/s/ DOUGLAS GODSHALL **Douglas Godshall**	Director	September 11, 2014
/s/ MICHAEL ROGERS **Michael Rogers**	Director	September 11, 2014
/s/ PETER SAVAS **Peter Savas**	Director	September 11, 2014
/s/ JAMES BARRY **James Barry**	Director	September 11, 2014

PSIVIDA CORP. AND SUBSIDIARIES

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Consolidated Financial Statements:

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, 2014 and 2013, 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, 2014. 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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes 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, 2014 and 2013, and the results of their operations and their cash flows for each of the three years in the period ended June 30, 2014, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of June 30, 2014, based on the criteria established in *Internal Control-Integrated Framework (1992)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated September 11, 2014 expressed an unqualified opinion on the Company's internal control over financial reporting.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
September 11, 2014

PSIVIDA CORP. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS
(In thousands except share amounts)

	June 30, 2014	June 30, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 15,334	$ 6,899
Marketable securities	2,944	3,374
Accounts and other receivables	517	597
Prepaid expenses and other current assets	547	1,594
Total current assets	19,342	12,464
Property and equipment, net	297	179
Intangible assets, net	2,765	3,430
Other assets	117	176
Restricted cash	150	—
Total assets	$ 22,671	$ 16,249
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 464	$ 671
Accrued expenses	1,524	1,894
Deferred revenue	138	738
Total current liabilities	2,126	3,303
Deferred revenue, less current portion	5,584	5,246
Deferred rent	37	—
Total liabilities	7,747	8,549
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, 29,298,558 and 23,297,011 shares issued and outstanding at June 30, 2014 and 2013, respectively	29	23
Additional paid-in capital	290,864	270,415
Accumulated deficit	(277,013)	(263,658)
Accumulated other comprehensive income	1,044	920
Total stockholders' equity	14,924	7,700
Total liabilities and stockholders' equity	$ 22,671	$ 16,249

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,		
	2014	2013	2012
Revenues:			
Collaborative research and development	$ 2,155	$ 780	$ 2,080
Royalty income	1,318	1,363	1,446
Total revenues	3,473	2,143	3,526
Operating expenses:			
Research and development	9,573	7,005	7,039
General and administrative	7,468	7,169	6,868
Gain on sale of property and equipment	(78)	—	—
Impairment of intangible assets	—	—	14,830
Total operating expenses	16,963	14,174	28,737
Operating loss	(13,490)	(12,031)	(25,211)
Other income (expense):			
Change in fair value of derivatives	—	—	170
Interest income, net	6	16	38
Other expense, net	(1)	(2)	(1)
Total other income	5	14	207
Loss before income taxes	(13,485)	(12,017)	(25,004)
Income tax benefit	130	117	169
Net loss	$(13,355)	$(11,900)	$(24,835)
Net loss per share:			
Basic and diluted	$ (0.49)	$ (0.52)	$ (1.19)
Weighted average common shares outstanding:			
Basic and diluted	27,444	23,044	20,791
Net loss	$(13,355)	$(11,900)	$(24,835)
Other comprehensive income (loss):			
Foreign currency translation adjustments	124	(29)	(492)
Net unrealized gain on marketable securities	—	7	5
Other comprehensive income (loss)	124	(22)	(487)
Comprehensive loss	$(13,231)	$(11,922)	$(25,322)

See notes to consolidated financial statements

PSIVIDA CORP. AND SUBSIDIARIES

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

	Common Stock				Accumulated	
	Number of Shares	Par Value Amount	Additional Paid-In Capital	Accumulated Deficit	Other Comprehensive Income	Total Stockholders' Equity
Balance at July 1, 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	23,297,011	23	270,415	(263,658)	920	7,700
Net loss	—	—	—	(13,355)	—	(13,355)
Other comprehensive income	—	—	—	—	124	124
Issuance of stock, net of issue costs	5,576,112	6	18,051	—	—	18,057
Exercise of stock options	425,435	—	987	—	—	987
Stock-based compensation	—	—	1,411	—	—	1,411
Balance at June 30, 2014	29,298,558	$ 29	$290,864	$(277,013)	$ 1,044	$ 14,924

See notes to consolidated financial statements

PSIVIDA CORP. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended June 30,		
	2014	2013	2012
Cash flows from operating activities:			
Net loss	$(13,355)	$(11,900)	$(24,835)
Adjustments to reconcile net loss to cash flows from operating activities:			
Impairment of intangible assets	—	—	14,830
Amortization of intangible assets	778	769	2,037
Depreciation of property and equipment	139	225	190
Change in fair value of derivatives	—	—	(170)
Amortization of bond premium on marketable securities	45	152	264
Stock-based compensation	1,411	1,317	1,411
Gain on sale of property and equipment	(78)	—	—
Deferred income tax benefit	—	—	(13)
Changes in operating assets and liabilities:			
Accounts and other receivables	103	364	(128)
Prepaid expenses and other current assets	1,110	(1,272)	(44)
Accounts payable	(213)	277	64
Accrued expenses	(381)	1,288	(712)
Deferred revenue	(267)	35	(1,895)
Deferred rent	37	—	—
Net cash used in operating activities	(10,671)	(8,745)	(9,001)
Cash flows from investing activities:			
Purchases of marketable securities	(2,964)	(7,758)	(15,392)
Maturities of marketable securities	3,350	14,184	15,299
Proceeds from sales of marketable securities	—	—	1,104
Purchases of property and equipment	(248)	(68)	(405)
Proceeds from sale of property and equipment	78	—	—
Change in restricted cash	(150)	—	—
Net cash provided by investing activities	66	6,358	606
Cash flows from financing activities:			
Proceeds from issuance of stock, net of issuance costs	18,057	4,669	—
Proceeds from exercise of stock options	987	—	114
Net cash provided by financing activities	19,044	4,669	114
Effect of foreign exchange rate changes on cash and cash equivalents	(4)	(8)	(6)
Net increase (decrease) in cash and cash equivalents	8,435	2,274	(8,287)
Cash and cash equivalents at beginning of year	6,899	4,625	12,912
Cash and cash equivalents at end of year	$ 15,334	$ 6,899	$ 4,625

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. The Company's strategy is to use its Durasert™ and Tethadur™ drug delivery technologies to independently develop products that deliver proven drugs and biologics, while continuing to leverage these technologies through collaboration and license agreements. The Company is focused on treatment of chronic diseases of the back of the eye and is also exploring applications outside ophthalmology. The Company's lead product candidate Medidur™ is in a pivotal Phase III clinical trial, its lead licensed product ILUVIEN® has been approved in the European Union ("EU") and is pending approval with the U.S. Food and Drug Administration ("FDA"), and the Company's pipeline includes potential product candidates at earlier stages of development. Using different generations of the Durasert technology, the Company developed three of the four sustained-release products for treatment of retinal diseases approved in the U.S. or EU.

Medidur™ is an injectable, sustained-release micro-insert designed to treat chronic, non-infectious uveitis affecting the posterior of the eye ("posterior uveitis") over a period of up to three years. 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, which is licensed to Bausch & Lomb. Although the Company originally planned to seek FDA approval of Medidur based on two Phase III clinical trials, the Company now expects to seek approval based on safety and efficacy data from its single ongoing Phase III trial, with supplemental clinical data on the safety and usability of its proprietary inserter, if ILUVIEN is approved by the FDA later this year. The Company plans to have a confirmatory meeting with the FDA with respect to the Company's regulatory strategy. If the FDA does not approve the Company's regulatory strategy, the Company may be required to complete a second Phase III trial for Medidur in order to submit for FDA approval, which would increase the development time and cost of Medidur. The Company is developing Medidur independently.

ILUVIEN®, the Company's lead licensed product, is an injectable, sustained-release micro-insert that provides treatment over a period of up to three years of vision impairment associated with diabetic macular edema ("DME"). ILUVIEN is licensed to and sold by Alimera Sciences, Inc. ("Alimera"), and the Company is entitled to 20% of the net profits (as defined) from Alimera's sales of ILUVIEN on a country-by-country basis. The Company is also entitled to a one-time $25.0 million milestone payment from Alimera if ILUVIEN is approved by the FDA.

ILUVIEN is commercially available in the United Kingdom ("U.K.") and Germany for the treatment of chronic DME considered insufficiently responsive to available therapies, and Alimera expects to launch in France and Portugal in late 2014. ILUVIEN has marketing authorization in six other EU countries and is pending authorization in seven more EU countries.

Alimera is also seeking marketing approval for ILUVIEN for DME in the U.S. Alimera entered into labeling discussions with the FDA in December 2013 and refiled its New Drug Application ("NDA") with the FDA in March 2014. The FDA set a new Prescription Drug User Fee Act goal date of September 26, 2014. The NDA resubmission responded to issues raised in the FDA's October 2013 Complete Response Letter ("CRL").

The Company's pre-clinical research is primarily focused on its Tethadur and Durasert technology platforms. The Company is seeking to develop products using Tethadur, part of its BioSilicon™ technology, to provide sustained delivery of peptides, proteins, antibodies and other large biologic molecules. The Company is also researching the use of its Durasert technology, in some instances in combination with its BioSilicon technology, to provide sustained delivery of therapeutic agents to treat wet and dry age-related macular degeneration ("AMD"), osteoarthritis and glaucoma, as well as to provide systemic delivery of biologics.

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 and royalty income from its collaboration partners. The Company believes that its cash, cash equivalents and marketable securities of $18.3 million at June 30, 2014, together with expected cash inflows under existing collaboration agreements, will enable the Company to maintain its current and planned operations through the third quarter of calendar year 2015. This estimate includes expected costs of clinical development of Medidur, but excludes any potential milestone or net profits receipts under the Alimera collaboration agreement. The Company's ability to fund its planned operations beyond then, including completion of clinical development of Medidur, is expected to depend on the amount and timing of cash receipts under the Alimera collaboration agreement, as well as proceeds from 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, 2014, 2013 and 2012 may be referred to herein as fiscal 2014, fiscal 2013 and fiscal 2012, 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, recognition of expense in outsourced clinical trial agreements, 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 the Company and each of its subsidiaries 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 $1,045,000 at June 30, 2014 and $921,000 at June 30, 2013. Foreign currency gains or losses arising from transactions denominated in foreign currencies, whether realized or unrealized, are recorded in other expense, 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.

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 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, 2014 and 2013, 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 date 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, 2014, all of the Company's interest-bearing cash equivalent balances, aggregating $14.3 million, were concentrated in one institutional money market fund that has investments consisting primarily of certificates of deposit, commercial paper, time deposits and treasury repurchase agreements. Generally, these deposits may be redeemed upon demand and, therefore, the Company believes they bear minimal risk. Marketable securities at June 30, 2014 and 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 revenues, which were inconsequential in fiscal 2014, accounted for $368,000, or 17%, of total revenues in fiscal 2013 and $754,000, or 21%, of total revenues in fiscal 2012. Bausch & Lomb accounted for $1.3 million, or 38% of total revenues in fiscal 2014, $1.4 million, or 64%, of total revenues in fiscal 2013 and $1.4 million, or 41%, of total revenues in fiscal 2012. A completed feasibility study agreement accounted for $1.7 million, or 49%, of total revenues in fiscal 2014.

Bausch & Lomb accounted for $302,000, or 58% of total accounts receivable at June 30, 2014 and $316,000, or 53% of total accounts receivable at June 30, 2013.

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.

Property and Equipment

Property and equipment are recorded at cost and depreciated over their estimated useful lives (generally three to five years) using the straight-line method. Leasehold improvements are amortized on a straight-line basis over the shorter of the remaining non-cancellable lease term or their estimated useful lives. Repair and maintenance costs are expensed as incurred. When assets are retired or sold, the assets and accumulated depreciation are removed from the respective accounts and any gain or loss is recognized.

Leases

The Company leases real estate and office equipment under operating leases. Its primary real estate lease contains rent holiday and rent escalation clauses. The Company recognizes the rent holiday and scheduled rent increases on a straight-line basis over the lease term, with the excess of rent expense over cash payments recorded as a deferred rent liability.

Impairment of Intangible Assets

The Company's finite life intangible assets include its acquired Durasert and BioSilicon (including Tethadur) 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 using management's best estimate of the standalone selling price of deliverables when vendor-specific objective evidence or third-party evidence of selling price is not available. Allocated consideration is recognized as revenue upon application of the appropriate revenue recognition principles to each unit. When the Company determines that an arrangement should be accounted for as a single unit of accounting, it must determine the period over which the performance obligations will be performed and revenue will be recognized.

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

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. Any such revenues are included as collaborative research and development revenues.

Reimbursement of Costs

The Company may provide research and development services and incur maintenance costs of licensed patents under collaboration arrangements to assist in advancing the development of licensed products. The Company acts primarily as a principal in these transactions, and, accordingly, reimbursement 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, third-party costs and services for clinical trials, clinical materials, pre-clinical programs, regulatory affairs, external consultants, and other operational costs related to the Company's research and development of its product candidates.

Stock-Based Compensation

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

Net Loss per Share

Basic net loss per share is computed by dividing net loss 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, 2014, 2013 and 2012, as they would be anti-dilutive:

	June 30,		
	2014	2013	2012
Options	3,791,001	3,554,549	3,165,855
Warrants	1,176,105	1,176,105	2,270,189
	4,967,106	4,730,654	5,436,044

Comprehensive Loss

Comprehensive loss is comprised of net loss, 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 uncertainty. The Company accounts for interest and penalties related to uncertain tax positions as part of its income tax benefit.

Recently Adopted and Recently Issued Accounting Pronouncements

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

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers* (Topic 606) ("ASU 2014-09"), which requires an entity to recognize revenue in an amount that reflects the consideration to which the entity expects to be entitled in exchange for the transfer of promised goods or services to customers. The standard will replace most existing revenue recognition guidance in U.S. GAAP. ASU 2014-09 will become effective on July 1, 2017, and early application is not permitted. The standard permits the use of either the retrospective or cumulative effect transition method. The Company is evaluating the impact this standard will have on its financial statements.

3. License and Collaboration Agreements

Alimera

Under the 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, and Alimera assumed all financial responsibility for the development of licensed products. The Company is entitled to receive a one-time $25.0 million milestone payment from Alimera within 30 days following an FDA approval of ILUVIEN. In addition, the Company is entitled to receive 20% of any net profits (as defined) on sales of each licensed product (including ILUVIEN) by Alimera, measured on a quarter-by-quarter and country-by-country basis. Alimera may recover 20% of previously incurred and unapplied net losses (as defined) for commercialization of each product in a country, but only by an offset of up to 4% of the net profits earned in that country each quarter, reducing the Company's net profit share to 16% in each country until those net losses are recouped. In the event that Alimera sublicenses commercialization in any country, the Company is entitled to 20% of royalties and 33% of non-royalty consideration received by Alimera, less certain permitted deductions.

The Company's performance obligations ended on December 31, 2009 and, accordingly, all amounts received thereafter under the Alimera Agreement are recognized as revenue upon receipt or at such earlier date, if applicable, on which any such amounts are both fixed and determinable and reasonably assured of collectability.

Revenue related to the Alimera Agreement totaled $114,000 for fiscal 2014, $67,000 for fiscal 2013 and $111,000 for fiscal 2012, and consisted of reimbursements for licensed patent 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 "Latanoprost Product"). Pfizer made an upfront payment of $2.3 million and the Company agreed to use commercially reasonable efforts to fund the development for at least one year, including assumption of an investigator-sponsored Phase I/II dose-escalation study that enrolled and followed six patients to treat ocular hypertension and glaucoma. The Company may, at its option, conduct Phase II clinical trials, which have not commenced, for the purpose of demonstrating Proof-of-Concept ("POC"). If the Company were to issue a final report demonstrating POC, Pfizer would have a 90-day exercise option for an exclusive, worldwide license to further develop and commercialize the Latanoprost Product in return for a $20.0 million payment to the Company and potential double-digit sales-based royalties and prescribed development, regulatory and sales performance milestone payments. If the Company elects to cease development of the Latanoprost Product prior to POC, Pfizer could exercise its option for the same worldwide license upon payment of a lesser option fee, with comparable reductions in any future milestones and royalties. If Pfizer does not exercise its option when available, the Restated Pfizer Agreement will automatically terminate, with any remaining deferred revenue balance recorded as revenue at that time, provided, however, that the Company would retain the right to develop and commercialize the Latanoprost Product.

The Company considered the Restated Pfizer Agreement a material modification and applied the guidance of ASU No. 2009-13, Revenue Recognition (Topic 605), *Multiple-Deliverable Revenue Arrangements*, to this arrangement. The Company concluded that Pfizer's exercise option is not a deliverable of the arrangement because it is a substantive option and not priced at a significant and incremental discount. Conducting the research and development program for the Latanoprost Product through completion of Phase II trials (the "R&D program") was deemed to be the Company's sole consequential deliverable and, accordingly, the arrangement was treated as a single unit of accounting. The performance period is the expected period over which the services are to be performed.

The arrangement consideration of the Restated Pfizer Agreement totaled $10.05 million, which consisted of $7.75 million of deferred revenue on the Company's balance sheet at the effective date plus the $2.3 million upfront payment. The excess of the arrangement consideration over the $6.7 million estimated selling price of the Company's deliverables, or $3.3 million, was recognized as collaborative research and development revenue in the period of the modification, with the remaining $6.7 million deferred and recognized as collaborative research and development revenue over the expected performance period using the lesser of straight-line amortization or the proportional performance method. As of June 30, 2014, the Company continues to evaluate the need for additional research prior to any commencement of Phase II clinical trials and, consequently, the Company cannot currently estimate the remaining performance period. As a result, the current portion of deferred revenue has been reduced to $0 at June 30, 2014 compared to $371,000 at June 30, 2013. Total deferred revenue was approximately $5.6 million at each of June 30, 2014 and 2013. Collaborative research and development revenue related to the Restated Pfizer Agreement was inconsequential in fiscal 2014, $368,000 in fiscal 2013 and $754,000 in fiscal 2012. Costs associated with conducting the R&D program are included in operating expenses as incurred.

Pfizer owned approximately 6.4% of the Company's outstanding shares at June 30, 2014.

Bausch & Lomb

Pursuant to a licensing and development agreement, as amended, Bausch & Lomb has a worldwide exclusive license to make and sell Retisert in return for royalties based on sales. Bausch & Lomb was also licensed to make and sell Vitrasert, an implant for sustained release of CMV retinitis, pursuant to this agreement, but discontinued sales of Vitrasert in the second quarter of fiscal 2013 following patent expiration.

Royalty income totaled approximately $1.3 million in fiscal 2014 and approximately $1.4 million in each of fiscal 2013 and 2012. Accounts receivable from Bausch & Lomb totaled $302,000 at June 30, 2014 and $316,000 at June 30, 2013.

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, the Company's BioSilicon product candidate for the treatment of pancreatic and other types of cancer. The Company received an upfront fee of $100,000 and is entitled to 8% sales-based royalties, 20% of sublicense consideration and milestone payments based on aggregate product sales. Enigma is obligated to pay an annual license maintenance fee of $100,000 by the end of each calendar year, the first of which was received in January 2014. For each calendar year commencing with 2014, the Company is entitled to receive reimbursement of any patent maintenance costs, sales-based royalties and sub-licensee sales-based royalties earned to the extent such amounts, in the aggregate, exceed the $100,000 annual license maintenance fee. 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 are recognized as revenue on the earlier of receipt or when collectability is reasonably assured. Revenue related to the Enigma agreement totaled $102,000 for fiscal 2014 and $100,000 for fiscal 2013. At June 30, 2014, no deferred revenue was recorded for this agreement.

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.

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.

Feasibility Study Agreements

The Company from time to time enters into funded agreements to evaluate the potential use of its technology systems for sustained release of third party drug candidates in the treatment of various diseases. Consideration received is generally recognized as revenue over the term of the feasibility study agreement. Revenue recognition for consideration, if any, related to a license option right is assessed based on the terms of any such future license agreement or is otherwise recognized at the completion of the feasibility study agreement. Revenues under feasibility study agreements totaled $1.9 million for fiscal 2014, $245,000 for fiscal 2013 and $75,000 for fiscal 2012.

4. Intangible Assets

The reconciliation of intangible assets for the years ended June 30, 2014 and 2013 was as follows (in thousands):

	June 30,	
	2014	2013
Patented technologies		
Gross carrying amount at beginning of year	$ 38,941	$ 39,556
Foreign currency translation adjustments	2,748	(615)
Gross carrying amount at end of year	41,689	38,941
Accumulated amortization at beginning of year	(35,511)	(35,330)
Amortization expense	(778)	(769)
Foreign currency translation adjustments	(2,635)	588
Accumulated amortization at end of year	(38,924)	(35,511)
Net book value at end of year	$ 2,765	$ 3,430

In a second CRL issued in November 2011 with respect to an earlier NDA submission for ILUVIEN, the FDA did not grant marketing approval for ILUVIEN for DME and, as a result, the Company did not receive a one-time $25.0 million milestone payment from Alimera and Alimera was unable to commence marketing 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 marketing 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
	$ 19,426	$ (14,830)	$ 4,596

The net book value of the Company's intangible assets at June 30, 2014 and 2013 is summarized as follows (in thousands):

	June 30,		Estimated Remaining Useful Life at June 30, 2014
	2014	2013	(Years)
Patented technologies			
Durasert	$1,853	$2,383	3.5
BioSilicon	912	1,047	3.5
	$2,765	$3,430	

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 $778,000 in fiscal 2014, $769,000 in fiscal 2013 and $2.0 million in fiscal 2012. The carrying value of intangible assets at June 30, 2014 of $2.8 million is expected to be amortized on a straight-line basis of approximately $790,000 per year.

5. Marketable Securities

The amortized cost, unrealized loss and fair value of the Company's available-for-sale marketable securities at June 30, 2014 and 2013 were as follows (in thousands):

	June 30, 2014		
	Amortized Cost	Unrealized Loss	Fair Value
Corporate bonds	$ 2,446	$ (1)	$2,445
Commercial paper	499	—	499
Total marketable securities	$ 2,945	$ (1)	$2,944

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

During fiscal 2014, $3.0 million of marketable securities were purchased and $3.4 million matured. At June 30, 2014, the marketable securities had maturities ranging between 3 and 8.5 months, with a weighted average maturity of 7.3 months.

6. Property and Equipment, Net

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

	June 30,	
	2014	2013
Property and equipment	$ 1,956	$ 1,908
Leasehold improvements	231	317
Gross property and equipment	2,187	2,225
Accumulated depreciation and amortization	(1,890)	(2,046)
	$ 297	$ 179

Depreciation expense was $139,000 for fiscal 2014, $225,000 for fiscal 2013 and $190,000 for fiscal 2012.

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).
- 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 A$ 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, 2014 and 2013 by valuation hierarchy (in thousands):

	June 30, 2014			
Description	Total Carrying Value	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets:				
Cash equivalents	$14,260	$ 14,260	$ —	$ —
Marketable securities:				
Corporate bonds	2,444	1,936	508	—
Commercial paper	500	—	500	—
	$17,204	$ 16,196	$ 1,008	$ —

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

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

There was no fair value measurement on a non-recurring basis at June 30, 2014 or at June 30, 2013.

8. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	June 30,	
	2014	2013
Personnel costs	$ 952	$1,252
Professional fees	249	288
Clinical	316	353
Other	7	1
	$1,524	$1,894

9. Stockholders' Equity

Sales of Common Stock and Warrants

In March 2014, the Company sold 1,700,000 shares of its common stock in a registered direct offering to a single institutional investor at a price of $4.11 per share for gross proceeds of $7.0 million. Placement agent fees and other share issue costs totaled $191,000.

In December 2013, the Company entered into an at-the-market ("ATM") program pursuant to which the Company may, at its option, offer and sell shares of its common stock from time to time for an aggregate offering price of up to $19.2 million. In connection with execution of the ATM program, the Company incurred transaction costs of $153,000. In addition, the Company pays the sales agent a commission of up to 3.0% of the gross proceeds from the sale of such shares. During fiscal 2014, the Company sold 381,562 common shares for net proceeds of $1.5 million, reflecting a weighted-average gross selling price of $3.98 per share. At June 30, 2014, an aggregate registered amount of approximately $10.7 million of common stock remains available for sale under the Company's existing shelf registration statement.

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 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.

Warrants to Purchase Common Shares

The following table provides a reconciliation of all US$ warrants for the years ended June 30, 2014 and 2013:

	Year Ended June 30,			
	2014		2013	
	Number of Warrants	Weighted Average Exercise Price	Number of Warrants	Weighted Average Exercise Price
Balance at beginning of year	1,176,105	$ 3.67	2,064,710	$ 6.17
Issued	—	—	623,605	2.50
Expired	—	—	(1,512,210)	6.60
Balance and exercisable at end of year	1,176,105	$ 3.67	1,176,105	$ 3.67

At June 30, 2014, the remaining lives of these outstanding warrants ranged from 1.6 to 3.1 years, representing a weighted-average term of 2.4 years.

The following table provides a reconciliation of all A$ warrants for the year ended June 30, 2013:

	Year Ended June 30, 2013	
	Number of Warrants	Weighted Average Exercise Price A$
Balance at beginning of year	205,479	7.68
Expired	(205,479)	7.68
Balance and exercisable at end of year	—	—

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.

10. Stock-Based Compensation

2008 Incentive Plan

The pSivida Corp. 2008 Incentive Plan (the "2008 Plan") provides for the issuance of stock options and other stock 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, 2014, a total of 5,591,255 shares of common stock were authorized for issuance under the 2008 Plan, of which 1,144,572 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 authorized for issuance under the 2008 Plan is 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, 2014.

Options to purchase a total of 778,500 shares were granted during fiscal 2014 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 613,500 shares were issued to employees with ratable annual vesting over 4 years and options to purchase 165,000 shares were issued to non-executive directors with 1-year cliff vesting. A total of 490,381 options vested during fiscal 2014. 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 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, 2014, 2013 and 2012 were as follows:

	2014	2013	2012
Option life (in years)	5.50 - 6.25	5.50 - 6.25	3.50 - 6.25
Stock volatility	94% - 96%	95% - 98%	88% - 97%
Risk-free interest rate	1.70% - 1.99%	0.81% - 0.98%	0.53% - 2.02%
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.

The following table summarizes information about stock options for the years ended June 30, 2014, 2013 and 2012 (in thousands except per share amounts):

	2014	2013	2012
Weighted-average grant date fair value, per share	$2.48	$1.29	$2.41
Total cash received from exercise of stock options	987	—	114
Total intrinsic value of stock options exercised	841	—	119

At June 30, 2014, there was approximately $1.1 million of unrecognized stock-based compensation expense related to unvested stock options, which is expected to be recognized as expense over a weighted average period of 1.7 years.

The following table provides a reconciliation of stock option activity under the 2008 Plan for fiscal 2014:

	Number of options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at July 1, 2013	3,554,549	$ 2.92		
Granted	778,500	3.51		
Exercised	(425,435)	2.32		
Forfeited	(116,613)	3.97		
Outstanding at June 30, 2014	3,791,001	$ 3.08	6.49	$ 5,120
Outstanding at June 30, 2014—vested or unvested and expected to vest	3,719,977	$ 3.07	6.46	$ 5,050
Exercisable at June 30, 2014	2,465,556	$ 2.88	5.49	$ 3,809

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,		
	2014	2013	2012
Compensation expense included in:			
Research and development	$ 516	$ 632	$ 597
General and administrative	895	685	814
	$1,411	$1,317	$1,411

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 a portion 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 $189,000 for fiscal 2014, $231,000 for fiscal 2013 and $181,000 for fiscal 2012 in connection with these retirement plans.

12. Income Taxes

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

	Year Ended June 30,		
	2014	2013	2012
U.S. operations:			
Current income tax provision	$ —	$ —	$ —
Deferred income tax benefit	—	—	(13)
	—	—	(13)
Non-U.S. operations:			
Current income tax benefit	(130)	(117)	(156)
Deferred income tax benefit	—	—	—
	(130)	(117)	(156)
Income tax benefit	$(130)	$(117)	$(169)

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

	Year Ended June 30,		
	2014	2013	2012
U.S. operations	$(11,712)	$(10,101)	$(11,215)
Non-U.S. operations	(1,773)	(1,916)	(13,789)
Loss before income taxes	$(13,485)	$(12,017)	$(25,004)

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,		
	2014	2013	2012
Income tax benefit at statutory rate	$(4,585)	$(4,086)	$(8,501)
State income taxes, net of federal benefit	(693)	(569)	(599)
Non-U.S. income tax rate differential	157	145	1,163
Research and development tax credits	(169)	(134)	(156)
Changes in valuation allowance	4,619	2,939	7,500
Expiration of state net operating loss carryforwards	161	706	—
Other, net	380	882	424
Income tax benefit	$ (130)	$ (117)	$ (169)

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

	June 30,	
	2014	2013
Deferred tax assets:		
Net operating loss carryforwards	$30,123	$26,068
Deferred revenue	2,194	2,196
Stock-based compensation	3,079	2,589
Provision for losses on note receivable	511	511
Other	652	843
Total deferred tax assets	36,559	32,207
Deferred tax liabilities:		
Intangible assets	910	1,177
Deferred tax assets, net	35,649	31,030
Valuation allowance	35,649	31,030
Total deferred tax liability	$ —	$ —

The valuation allowance generally reflects 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 $4.6 million during fiscal 2014 and $2.9 million during fiscal 2013.

The Company has tax net operating loss and tax credit carry forwards in its individual tax jurisdictions. At June 30, 2014, the Company had U.S. federal net operating loss carry forwards of approximately $65.4 million, which expire at various dates between calendar years 2023 and 2034. 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, 2014, the Company had state net operating loss carry forwards of approximately $24.5 million, which expire between 2031 and 2034. Additionally, at June 30, 2014 the Company had net operating loss carry forwards in the U.K. of £19.2 million (approximately $32.8 million), which are not subject to any expiration dates. During fiscal 2014, the Company recognized a current income tax benefit of $130,000 related to foreign research and development tax credits earned by its U.K. subsidiary. In addition, at June 30, 2014, the Company had U.S. federal and state research and development tax credit carry forwards of approximately $600,000, which expire at various dates between calendar years 2016 and 2033.

The Company's U.S. federal income tax returns for calendar years 2002 through 2013 remain subject to examination by the Internal Revenue Service. The Company's U.K. tax returns for fiscal years 2006 through 2013 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, 2014, 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, 2014 or 2013.

As of June 30, 2014 and 2013, the Company had no accrued penalties or interest related to uncertain tax positions.

13. Commitments and Contingencies

Operating Leases

On March 21, 2014, the Company commenced a lease for approximately 13,650 square feet of combined office and laboratory space in Watertown, Massachusetts to replace the Company's previous facilities lease that expired on April 5, 2014. The Company provided a cash-collateralized $150,000 irrevocable standby letter of credit as security for the Company's obligations under the lease. The initial lease term extends through April 2019, with a five-year renewal option at market rates. In addition to base rent, the Company is obligated to pay its proportionate share of building operating expenses and real estate taxes in excess of base year amounts. In addition, the Company leases approximately 2,200 square feet of laboratory and office space in Malvern, U.K. through August 2016.

At June 30, 2014, the Company's total future minimum lease payments under non-cancellable operating leases were as follows (in thousands):

Fiscal Year:	
2015	$ 475
2016	475
2017	425
2018	419
2019	358
	$2,152

Rent expense related to the Company's real estate and other operating leases charged to operations was approximately $485,000 for fiscal 2014, $454,000 for fiscal 2013 and $466,000 for fiscal 2012.

Litigation

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

14. Segment and Geographic Area Information

(a) Business Segment

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

(b) Geographic Area Information

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

	Revenues			Long-lived assets, net	
	2014	2013	2012	2014	2013
U.S.	$3,248	$1,873	$2,385	$ 248	$ 55
U.K.	225	270	1,141	49	124
Consolidated	$3,473	$2,143	$3,526	$ 297	$ 179

15. Quarterly Financial Data (unaudited)

The following table summarizes the quarterly results of operations for the years ended June 30, 2014 and 2013 (in thousands except per share amounts):

	Fiscal Year 2014				
	First Quarter Ended September 30, 2013	Second Quarter Ended December 31, 2013	Third Quarter Ended March 31, 2014 (1)	Fourth Quarter Ended June 30, 2014	Year Ended June 30, 2014
Total revenues	$ 597	$ 592	$ 1,992	$ 292	$ 3,473
Operating loss	(3,718)	(3,541)	(2,219)	(4,012)	(13,490)
Net loss	(3,687)	(3,514)	(2,187)	(3,967)	(13,355)
Net loss per share—basic and diluted	$ (0.14)	$ (0.13)	$ (0.08)	$ (0.14)	$ (0.49)
Weighted average common shares—basic and diluted	25,918	26,953	27,672	29,256	27,444

	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	(2,551)	(2,608)	(2,794)	(3,947)	(11,900)
Net loss per share—basic and diluted	$ (0.11)	$ (0.11)	$ (0.12)	$ (0.17)	$ (0.52)
Weighted average common shares—basic and diluted	22,294	23,297	23,297	23,297	23,044

(1) Results for the third quarter of fiscal 2014 included $1.5 million of revenue for recognition of arrangement consideration upon resolution of a contingency associated with completion of a feasibility study agreement (see Note 3).

Exhibit 21.1

List of Subsidiaries of pSivida Corp.

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

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-152146 and 333-163208 on Form S-8 and Registration Statement No. 333-185549 on Form S-3 of our reports dated September 11, 2014, relating to the consolidated financial statements of pSivida Corp., and the effectiveness of pSivida Corp.'s internal control over financial reporting, appearing in this Annual Report on Form 10-K of pSivida Corp. for the year ended June 30, 2014.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
September 11, 2014

Exhibit 31.1

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

CERTIFICATIONS

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

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

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

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

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

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

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

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

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

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

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

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

Date: September 11, 2014

/S/ PAUL ASHTON

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

Exhibit 31.2

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

CERTIFICATIONS

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

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

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

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

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

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

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

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

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

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

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

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

Date: September 11, 2014

/S/ LEONARD S. ROSS

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

Exhibit 32.1

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

In connection with the Annual Report of pSivida Corp. (the "Company") on Form 10-K for the year ended June 30, 2014, 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 11, 2014

/S/ PAUL ASHTON

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

Exhibit 32.2

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

In connection with the Annual Report of pSivida Corp. (the "Company") on Form 10-K for the year ended June 30, 2014, 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 11, 2014

/s/ Leonard S. Ross

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