

PSIVIDA CORP.

FORM 10-K (Annual Report)

Filed 09/10/15 for the Period Ending 06/30/15

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| Address | 480 PLEASANT STREET SUITE B300 WATERTOWN, MA 02472 |
| Telephone | 617-926-5000 |
| CIK | 0001314102 |
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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, 2015

or

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

For the transition period from

to

Commission File Number 000-51122

PSIVIDA CORP.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

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

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

02472
(Zip Code)

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

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

Title of each class
Common Stock, \$.001 par value per share

Name of each exchange
on which registered
**The NASDAQ Stock Market LLC
(NASDAQ Global Market)**

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

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

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

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

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

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

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

Large accelerated filer

Nonaccelerated filer

Accelerated 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, 2014, the last trading day of the registrant's most recently completed second fiscal quarter, was approximately \$118,606,000.

There were 29,417,365 shares of the registrant's common stock, \$0.001 par value, outstanding as of September 4, 2015.

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 3, 2015, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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Form 10-K
For the Fiscal Year Ended June 30, 2015
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PART I

Preliminary Note Regarding Forward-Looking Statements

This Form 10-K and our 2015 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, liquidity or other financial items; any statements of the plans, strategies and objectives of management for future operations; any statements concerning product and technology research, development, trials, trial results, regulatory requirements and approvals, reimbursement and commercialization; any other statements of expectations, estimations or beliefs; 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 are a leader in the development of sustained-release drug-delivery products for treating eye diseases. Our products deliver drugs at a controlled and steady rate for months or years. We have developed three of only four sustained-release products approved by the U.S. Food and Drug Administration (FDA) for treatment of back-of-the-eye diseases. The most recent is ILUVIEN[®] for diabetic macular edema (DME), sold by our licensee in the U.S. and three European Union (EU) countries. Our lead development product, Medidur[™] for posterior uveitis, is in pivotal phase III clinical trials. Our pre-clinical development program is focused primarily on developing products for chronic ophthalmic diseases utilizing our core technology platforms.

ILUVIEN is an injectable, sustained-release micro-insert that provides treatment of DME for three years from a single administration. ILUVIEN is licensed to Alimera Sciences, Inc. (Alimera), and we are entitled to a share of the net profits (as defined in our agreement with Alimera) from Alimera’s sales of ILUVIEN. ILUVIEN was launched in late February 2015 in the U.S., where it is indicated for the treatment of DME in patients previously treated with a course of corticosteroids without a clinically significant rise in intraocular pressure. ILUVIEN has been commercially available in the United Kingdom (U.K.) and Germany since June 2013 and in Portugal since January 2015. ILUVIEN has marketing approvals in these and 14 other EU countries for the treatment of chronic DME considered insufficiently responsive to available therapies. Alimera sublicensed distribution, regulatory and reimbursement matters for ILUVIEN for DME in Australia and New Zealand in April 2014, in Canada in July 2015 and in Italy in August 2015.

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Medidur, our lead development product, is an injectable, micro-insert designed to treat chronic non-infectious uveitis affecting the posterior segment of the eye (posterior uveitis) for three years from a single administration. Medidur, which is the same micro-insert as ILUVIEN, is in Phase III clinical trials, with the filing of a new drug application (NDA) anticipated in the first half of 2017. We are developing Medidur independently.

Our FDA-approved Retisert® provides sustained release treatment of posterior uveitis for approximately two and a half years. It is licensed to Bausch & Lomb, and we receive royalties from its sales.

Our pre-clinical development program is focused on developing products using our core platform technologies, Durasert™ and Tethadur™, to deliver drugs or biologics to treat wet and dry age-related macular degeneration (AMD), glaucoma, osteoarthritis and other diseases.

Durasert™, Medidur™, Tethadur™ and BioSilicon™ are our trademarks. Retisert® and Vitrasert® are Bausch & Lomb's trademarks. ILUVIEN® is Alimera's trademark. 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, including regulatory and marketing information, and Alimera's plans and intentions, reflects information publicly disclosed by Alimera.

Fiscal 2015, fiscal 2014 and fiscal 2013 mean the twelve months ended June 30, 2015, 2014 and 2013, 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 ophthalmic and other diseases, 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 therapeutic agents, 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 potential of this strategy.

- **Develop Sustained Delivery of Off-Patent Drugs and Biologics.** Many drugs and biologics 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 that deliver 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. 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 and/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 may also seek to partner the development of products 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 seek to partner with companies with drugs coming off patent where our drug delivery technologies could offer an improved product and effectively extend the patent protection.

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- **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 osteoarthritis, as well as in systemic release of therapeutic agents.

Market Opportunity for Delivery of Drugs and Biologics

We develop products to 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 is maintained in the location with an appropriate concentration for a sufficient period of time to provide effective treatment without causing adverse effects to other tissues. Accordingly, the delivery of a drug or biologic can be an important element of its ultimate therapeutic value.

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 duration or the appropriate concentration disperses too quickly or unevenly, thereby failing to achieve 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. This is particularly true for the eyes, joints, brain and nervous system, which have natural barriers that impede the movement of drugs to those areas. These higher dosage levels can cause harmful side effects to the tissues beyond the intended site. To avoid these issues, 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. The delivery methods themselves can have risks. Repeated administration by injection or infusion can result in serious infections and other complications.

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 molecular size and complexity, it has been difficult to develop sustained-release formulations for biologics.

Drugs or biologics are often not administered on the optimal schedule or at all, because patients do not self-administer them as prescribed or do not get medical professional administration as required. The risk of patient noncompliance increases when treatment involves multiple products or complex or painful dosing regimens, as patients age or if they suffer cognitive impairment or serious illness, or when the treatment is lengthy or expensive.

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. Ophthalmic biologics, such as Macugen[®] (pegaptanib sodium), Lucentis[®] (ranibizumab) and EYLEA[®] (afilbercept), require injection 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 and vitreous hemorrhage.

Due to the drawbacks of traditional delivery, the development of methods to deliver drugs and biologics to patients in a more precise, controlled fashion over sustained periods of time has been 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

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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 designed to address the issues of sustained delivery for ophthalmic and other product candidates:

- *Extended Delivery* . Our Durasert technology platform 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 are designed to release therapeutics at a sustained, controlled rate. We believe that this feature allows us to develop products that deliver optimal concentrations of therapeutics over time and eliminate excessive variability in dosing during treatment.
- *Localized Delivery* . Our technology platforms can deliver therapeutics directly to 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 our lead development product 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 ILUVIEN and Medidur products are injected at the target site in an office visit, while early generation Retisert and Vitrasert are surgically implanted.

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

| <u>Product</u> | <u>Disease</u> | <u>Stage of Development</u> | <u>Partner</u> |
|----------------|-------------------|--|-------------------------|
| ILUVIEN | DME | FDA-approved; commercialized since 2015; EU-approved (17 countries) for chronic DME; commercialized since 2013 | 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 clinical trials | Independent development |

Approved Product : *ILUVIEN for DME*

ILUVIEN is an injectable, sustained-release micro-insert delivering the off-patent corticosteroid fluocinolone acetonide (FAc) for treatment of DME. Injected in an office visit, ILUVIEN delivers 36 months of continuous, low-dose corticosteroid therapy with a single injection. ILUVIEN is approved in the U.S. for the treatment of DME in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure (IOP). In the 17 EU countries where ILUVIEN has been approved, it is indicated for the treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies. DME is a disease suffered by diabetics where leaking capillaries cause swelling in the macula, the most sensitive part of the retina. DME is a leading cause of blindness in most developed countries in the working-age population.

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ILUVIEN is licensed to Alimera, which launched ILUVIEN in the U.K. and Germany in the second quarter of 2013 and in Portugal and the U.S. in the first quarter of 2015. ILUVIEN has marketing authorizations in 14 additional EU countries. We are entitled to a 20% share in net profits on sales of ILUVIEN by Alimera on a quarter-by-quarter, country-by-country basis. See “Strategic Collaborations—Alimera” below.

Alimera has engaged in regulatory proceedings and negotiations with respect to the amount and/or process for reimbursement of ILUVIEN in various EU countries. In October 2013, the U.K.’s National Institute for Health and Care Excellence (NICE) issued a positive Final Appraisal Determination recommending ILUVIEN funding, utilizing a simple patient access scheme (PAS), for the treatment of pseudophakic eyes (eyes with an artificial lens) in chronic DME patients considered insufficiently responsive to available therapies. In February 2014, the Scottish Medicines Consortium, after completing its assessment and review of a similar simple PAS, announced its acceptance of ILUVIEN for restricted use within the National Health Service (NHS) Scotland. In July 2014, Alimera reached agreement with INFARMED, the marketing authorization body of the Portuguese Ministry of Health, for the pricing and reimbursement of ILUVIEN for the public sector in Portugal.

Approved Product: Retisert for Posterior Uveitis

Retisert is approved in the U.S. for the treatment of posterior uveitis. Retisert is surgically implanted in the eye and delivers sustained levels of FAc for approximately 30 months. Retisert is licensed to Bausch & Lomb, which sells the product in the U.S. and pays sales-based royalties to us. Retisert is eligible for Medicare reimbursement.

Approved Product: 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, provides sustained delivery of the anti-viral drug ganciclovir for six to eight months. Vitrasert was licensed to Bausch & Lomb, which discontinued sales in fiscal 2013 following patent expiration.

Development Product : Medidur for Posterior Uveitis

Medidur, our lead development product, is an injectable, sustained-release micro-insert designed to treat posterior uveitis for three years. Medidur uses the same micro-insert as ILUVIEN for DME (same drug, same release rate, same polymer, same design), but we have redesigned the inserter to utilize a smaller gauge needle typically used for intra-ocular injections. Like ILUVIEN, Medidur also delivers a lower dose of FA, the same drug delivered by Retisert for posterior uveitis. However, Medidur is easier to administer than Retisert because it is injected in an office visit, while Retisert is implanted in a surgical procedure. We are developing Medidur independently and have not licensed the rights to Medidur for posterior uveitis to Alimera or any other third party.

Posterior uveitis is a chronic, non-infectious inflammatory disease affecting the posterior segment of the eye, often involving the retina, which is a leading cause of blindness in the developed countries. It afflicts people of all ages, producing swelling and destroying eye tissues, which can lead to severe vision loss and blindness. In the U.S., posterior uveitis is estimated to affect approximately 175,000 people, resulting in approximately 30,000 cases of blindness and making it the third leading cause of blindness in the U.S. Patients with posterior uveitis are typically treated with systemic steroids, but frequently develop serious side effects over time that can limit effective dosing. Patients then often progress to steroid-sparing therapy with systemic immune suppressants or biologics, which themselves can have severe side effects including an increased risk of cancer.

Medidur Phase III Trials . We are currently conducting two Phase III trials to assess the safety and efficacy of Medidur for the treatment of posterior uveitis. These are randomized, sham-controlled, double-masked trials.

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The primary endpoint of both trials is recurrence of posterior uveitis, with patients in both trials followed for three years. The first Phase III Medidur trial is fully enrolled with 129 patients in 16 centers in the U.S. and 17 centers outside the U.S. The primary endpoint of this trial is recurrence of uveitis at 12 months and the last patient is scheduled to have their 12-month follow-up visit in March 2016, with top-line data expected in the second quarter of 2016. The second trial will enroll up to 150 patients in approximately 15 centers in India with a primary endpoint for the NDA filing of recurrence of disease at 6 months. We plan to seek FDA approval of Medidur based on 12-month data from the first Phase III trial, six-month data from the second Phase III trial and data from a short-duration utilization study of our redesigned proprietary inserter, together with data referenced from the Phase III trials of ILUVIEN for DME. Pending favorable results in our ongoing clinical trials and concurrence from the FDA regarding filing with the data package described, we expect to file an NDA in the first half of 2017.

In our ongoing assessment of masked safety data from our first Phase III trial, we compared elevated IOP (over 21 mm Hg) at three months of follow-up in study eyes (2/3's of which received Medidur) to fellow non-study eyes (none of which received Medidur). At that time, for all 129 enrolled patients, only 5% more study eyes experienced elevated IOP than the fellow non-study eyes. Initial IOP elevation is an indication of the likelihood of subsequent clinically significant IOP increases. We believe that the minimal difference observed in elevated IOP in our assessment suggests favorable results for a key safety measure of the trials, the number of eyes that develop clinically significant increases in IOP after receiving Medidur relative to control eyes.

Investigator-Sponsored Study of Medidur . In July 2015, Dr. Glenn J. Jaffe, Robert Machemer Professor of Ophthalmology at Duke University School of Medicine in Durham, NC (who is also a principal investigator in our first Phase III trial), reported positive top-line results from his investigator-sponsored study of Medidur, reporting a statistically significant reduction in recurrence of uveitis and a statistically significant improvement in visual acuity in eyes treated with Medidur. In the three-year, ongoing study, patients with recurrent non-infectious intermediate, posterior or pan uveitis were randomized to receive either a low dose or a high-dose of Medidur (our Phase III trials are studying only the low dose and only in patients with posterior uveitis). One eye received Medidur (which for subjects with disease in both eyes, was the eye with the worse disease) and fellow diseased eyes were treated with standard of care, which included steroid eye drops. At the most recent follow-up visit reported, 11 of the 13 participants had been followed for between 12 and 24 months. Dr. Jaffe reported that through the last follow-up visit reported, none of the eyes treated with Medidur had any recurrence of uveitis, while fellow eyes treated with standard of care averaged 2.33 recurrences. The difference between treatment with Medidur and standard of care was statistically significant ($p=0.014$). Eyes treated with Medidur experienced a significant improvement in visual acuity, gaining an average of 17 letters from baseline at 12 months on the Snellen eye chart ($p=0.014$ at 12 months). At the last follow-up visit reported, the average gain from baseline in Medidur-treated eyes was over 20 letters, while eyes treated with standard of care declined an average of 10 letters. The most common adverse event in study eyes was elevated IOP. Through the last follow-up visit reported, three study eyes developed elevated IOP and were treated with eye drops, with filtering procedures subsequently performed in two of these eyes. However, those two eyes still gained an average of over 25 letters from baseline at the last observation. Because the study remains masked as to the dosage, results cannot yet be separated for the low and high doses of Medidur.

Based on the ongoing IOP assessment from our first Phase III trial and the top-line results from the investigator-sponsored study, we are optimistic that the Phase III trials for Medidur will show it to be as efficacious as Retisert was shown to be in treating posterior uveitis, but with IOP safety results that could be even better than those shown in the ILUVIEN and Retisert Phase III trials.

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

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specific protein, peptide or antibody molecule. A suspension of the specific biologic loaded into BioSilicon in solution is injected into the subject. The BioSilicon erodes over a predetermined duration, 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 to deliver therapeutic agents to treat wet and dry AMD, glaucoma and osteoarthritis, as well as to provide systemic delivery of biologics.

We expect that an IND will shortly be filed in the U.S. to commence an investigator-sponsored study of an implant utilizing our Durasert technology to treat pain associated with severe osteoarthritis of the knee. We have been collaborating with Hospital for Special Surgery, a leading specialty hospital for orthopedics and rheumatology, on the development of this product. It will be surgically implanted in the knee to provide approximately six months of sustained delivery of a corticosteroid directly to the joint. The product is designed to offer long-term pain relief and to delay or eliminate the need for knee replacement surgery.

Feasibility Study Agreements

We have entered into numerous feasibility study agreements (some of which are funded) to evaluate our Durasert and Tethadur (including 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.

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In October 2014 Alimera paid us a one-time \$25.0 million milestone upon FDA approval of ILUVIEN as provided in our collaboration agreement. We are entitled to receive 20% of any net profits (as defined) on sales by Alimera of each licensed product (including ILUVIEN), 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 pSivida'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.

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 (i) 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 (ii) 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.

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 Latanoprost 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, 2015.

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

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(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. Annual license maintenance fees of \$100,000 were paid in January 2014 and January 2015. 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 \$12.1 million in fiscal 2015, \$9.6 million in fiscal 2014 and \$7.0 million in fiscal 2013. Of these amounts, \$10.6 million in fiscal 2015, \$8.2 million in fiscal 2014, and \$5.4 million in fiscal 2013 were incurred for costs of research and development personnel, clinical and pre-clinical studies, contract services, testing and laboratory facilities. The remaining expense of \$1.5 million in fiscal 2015, \$1.4 million in fiscal 2014 and \$1.6 million in fiscal 2013 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.

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, 2015:

| <u>Technology</u> | <u>United States Patents</u> | <u>United States Applications</u> | <u>Foreign Patents</u> | <u>Foreign Applications</u> | <u>Patent Families</u> |
|-------------------|------------------------------|-----------------------------------|------------------------|-----------------------------|------------------------|
| Durasert | 12 | 10 | 90 | 34 | 14 |
| Tethadur | 9 | 7 | 9 | 26 | 7 |
| Other BioSilicon | 16 | 4 | 72 | 10 | 20 |
| Other | 7 | 4 | 23 | 21 | 13 |
| Total | 44 | 25 | 194 | 91 | 54 |

Employees

We had 26 employees as of August 31, 2015. 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 on the timing and complexity of obtaining those reimbursements.

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

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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 results of operations 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, 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 products and potential products include the following:

- *DME.* Genentech USA Inc.'s 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 intravitreal 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[™].

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Revenues

We operate in one business 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, | | | | | | | | |
|--|---------------------|--------------|-----------------|----------------|--------------|----------------|----------------|--------------|----------------|
| | 2015 | | | 2014 | | | 2013 | | |
| | U.S. | U. K. | Total | U.S. | U. K. | Total | U.S. | U. K. | Total |
| Revenues: | (In thousands) | | | | | | | | |
| Collaborative research and development | \$25,311 | \$100 | \$25,411 | \$1,930 | \$225 | \$2,155 | \$ 510 | \$270 | \$ 780 |
| Royalty income | 1,154 | — | 1,154 | 1,318 | — | 1,318 | 1,363 | — | 1,363 |
| | <u>\$26,465</u> | <u>\$100</u> | <u>\$26,565</u> | <u>\$3,248</u> | <u>\$225</u> | <u>\$3,473</u> | <u>\$1,873</u> | <u>\$270</u> | <u>\$2,143</u> |

Government Regulation

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

- pre-clinical laboratory and animal tests;
- submission to the FDA of an Investigational New Drug (IND) application, which must become effective before human clinical trials may begin;
- adequate and well-controlled studies to establish the safety and efficacy of the proposed pharmaceutical 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.

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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) or Ethics Committee (EC). The IRB/EC 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 IRBs/ECs, 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

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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

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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 current 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

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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.

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ITEM 1A. RISK FACTORS

RISKS RELATED TO OUR COMPANY AND OUR BUSINESS

We do not know if or when we will achieve profitable operations from product sales, royalties and net profits participations and we may need additional capital to fund our operations, which may not be available on favorable terms or at all.

We have a history of operating losses, and at June 30, 2015, we had a total accumulated deficit of \$270.7 million. During the past three fiscal years, we financed our operations from license fees, milestone payments, research and development funding and royalty income from our collaboration partners and sales of equity securities. We do not have any assured sources of revenue, and we expect negative cash flows from operations in subsequent quarters until we receive sufficient revenues from commercialization of ILUVIEN or one or more of our other product candidates achieve regulatory approval and provide us sufficient revenues. We believe that our capital resources of \$28.5 million at June 30, 2015 should enable us to fund our operations as currently planned (including our Medidur clinical trials) into early calendar year 2017. This estimate excludes any potential net profits receipts from sales of ILUVIEN. We expect that our ability to fund our planned operations beyond then will depend on the amount and timing of those payments, as well as proceeds from any future collaboration or other agreements and/or financing transactions.

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

- whether, when and to what extent we receive revenues with respect to the commercialization of ILUVIEN;
- the timing and cost of development, approval and marketing of Medidur for posterior uveitis;
- whether and to what extent we internally fund, whether and when we initiate, and how we conduct other product development programs;
- the amount of Retisert royalties and other payments we receive under collaboration agreements;
- 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;
- changes in our operating plan, resulting in increases or decreases in our need for capital; and
- our views on the availability, timing and desirability of raising capital.

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. We have an at-the-market (ATM) facility, but 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 any additional financing may make it more difficult or 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.

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

At June 30, 2015, we had \$1.9 million of intangible assets relating to our Durasert and BioSilicon (including Tethadur) technologies on our balance sheet following impairment charges of \$14.8 million as of December 31, 2011. We conduct impairment analyses of our intangible assets as required under GAAP and could take additional impairment charges in the future if the recorded values for our intangible assets were to exceed our assessment of the recoverability of the fair market value of those assets. Adverse events relating to these technologies, including the clinical development, regulatory approval and success of commercialization of products using them, and significant changes in our market capitalization could result in impairment charges. Further impairment charges on our intangible assets could have a material adverse effect on our results of operations in the quarter of the impairment.

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:

- developments with respect to our products and product candidates, including pre-clinical and clinical trial results, regulatory developments and marketing and sales results;
- timing, receipt and amount of revenues, including receipt and recognition of collaborative research and development, milestone, royalty, net profits participation and other payments;
- announcement, execution, amendment and termination of collaboration agreements;
- scope, duration and success of collaboration agreements;
- costs of internally funded research and development, 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.

There is no assurance our Retisert royalty income will continue at current levels or at all.

Retisert royalty income, which totaled between \$1.3 million and \$1.4 million in each of the fiscal 2012, fiscal 2013 and fiscal 2014, declined to \$1.2 million in fiscal 2015. We do not expect Retisert royalty income to grow materially, if at all, and it may continue to decline. There is no assurance that Bausch & Lomb will continue to market Retisert, which received marketing approval in 2005, and accordingly that we will continue to receive royalties from the sale of Retisert. Bausch & Lomb no longer markets Vitrasert.

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

There is no assurance that Alimera will successfully commercialize ILUVIEN for DME or that we will receive any significant revenues from its commercialization. If Alimera does not successfully commercialize ILUVIEN for DME, it would adversely affect our future results of operations and financial position.

Our future financial results depend heavily on Alimera's ability to successfully commercialize ILUVIEN for DME. We do not know if, when, or to what extent we will receive future revenues from the commercialization of

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ILUVIEN for DME. 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, among other things, by the manner in which Alimera markets ILUVIEN, the amounts and timing of sales of ILUVIEN, commercialization costs incurred by Alimera's direct marketing efforts, and the terms of sublicense agreements.

The commercialization of ILUVIEN is a significant undertaking by Alimera, and ILUVIEN for DME is its first and only product. While Alimera believes that it has sufficient funds available to fund its operations for the continued commercialization of ILUVIEN in the U.S., Germany, Portugal and the United Kingdom, Alimera has reported that its negative cash flows from operations and accumulated deficit raise substantial doubt about its ability to continue as a going concern. Alimera may seek to raise additional financing to fund its working capital needs for the commercialization of ILUVIEN. We do not know whether Alimera will be successful in generating adequate cash flows, obtaining adequate capital or achieving additional marketing approvals for, obtaining adequate pricing and reimbursement for, successfully commercializing and achieving market acceptance of, and generating revenues to pSivida from, ILUVIEN for DME. Commercialization by Alimera in the U.S., Germany, Portugal and the U.K, including the transitioning from an outside provider of sales and marketing services in the U.K. and Germany and the provision of extended payment terms in the U.S., has required a significant expansion of Alimera's commercial infrastructure and significant financial investments. Delays in the commercial launch in other EU countries where ILUVIEN has received marketing authorization could result in withdrawal of marketing or regulatory authorization for ILUVIEN in one or more of those jurisdictions. Alimera's efforts to commercialize ILUVIEN successfully will be affected, among other things, by:

- Alimera's ability to generate positive cash flows from operations and to raise adequate capital when and as needed;
- Alimera's ability to recruit, manage and retain personnel, expand its sales, marketing and other infrastructure, and manage its growth;
- Alimera's ability to effectively market ILUVIEN, including accessing and persuading adequate numbers of ophthalmologists to prescribe ILUVIEN;
- the lack of other 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;
- Alimera's ability to obtain regulatory approvals and appropriate labeling to market ILUVIEN in other jurisdictions, and to timely expand its marketing into countries where it has previously obtained and may in the future obtain approvals;
- Alimera's ability to obtain desirable pricing, insurance coverage and reimbursement for ILUVIEN;
- potential delays in the commercial launch in one or more countries;
- manufacturing or supply issues;
- risks related to operating in international jurisdictions; and
- Alimera's ability to generate adequate financial resources.

If Alimera is not successful in commercializing ILUVIEN for DME and generating payments to us, it would adversely affect our business, operating results and financial condition.

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 ILUVIEN for DME, like other drugs, are generally regulated by third-party payors, such as government health administration authorities and plans, private health

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insurers and other organizations and affect ILUVIEN's sales. The timing and complexity of those reimbursements also affect sales. Prices in the EU are generally lower and coverage and access to drugs more limited than in the U.S. For example, in the U.K. and Scotland, National Health Service coverage is limited to the treatment of the eyes of chronic DME patients unresponsive to existing therapies that have undergone cataract surgery, subject to simple patient access schemes. Alimera may not achieve satisfactory agreements with statutory or other insurers. We do not know what levels of pricing will be approved or reimbursed for ILUVIEN, or what restrictions will be placed on its use or reuse in countries where ILUVIEN is not currently sold. In the U.S., Alimera has offered extended customer payment terms. Future sales of ILUVIEN and, accordingly, our net profits share, may be adversely affected by pricing and reimbursement decisions, and such effects may be material.

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

The micro-insert for both ILUVIEN and Medidur delivers the non-proprietary corticosteroid FAc, which is associated with cataract formation and elevated IOP and may increase the risk of glaucoma and related surgery to manage those side effects. Although Retisert, which also delivers FAc to treat posterior uveitis, and ILUVIEN for DME have both been approved by the FDA, there is no assurance that Medidur will be determined to be safe for the treatment of posterior uveitis in light of its expected side effects from FAc. These side effects may limit the population for which marketing authorization is granted or for which reimbursement is provided in one or more jurisdictions and/or adversely affect sales of Medidur, if approved, and/or ILUVIEN.

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

While we are optimistic that the Phase III trials for Medidur will show it to be as efficacious as Retisert was shown to be in treating posterior uveitis, but with IOP safety results that could be even better than those shown in the ILUVIEN and Retisert Phase III trials, this is only a hypothesis, and there is no assurance that the ongoing Medidur Phase III clinical trials will demonstrate these results. Data from our ongoing IOP assessment from the Medidur Phase III trials and top-line results from the Medidur investigator-sponsored study may not accurately predict the results of our Medidur Phase III program. There is no assurance that the Phase III program for Medidur will provide the necessary evidence of safety and efficacy required to file an NDA or for approval by the FDA and other regulatory authorities if an NDA is filed. Approvals of Retisert and ILUVIEN by the FDA and other regulatory authorities are not predictive of actions they may take with respect to Medidur.

There is no assurance that we will be able to file an NDA for Medidur as early as the first half of 2017, or that, if filed, the FDA will accept the NDA for review.

Filing an NDA for Medidur will require positive results from our two Phase III trials. Based on our most recent meeting with the FDA, we plan to seek approval of Medidur based on 12-month data from our first Phase III trial, six-month data from our second Phase III trial and data from a short-duration utilization study of our redesigned proprietary inserter, together with data referenced from the Phase III trials of ILUVIEN for DME. We will be filing an amendment with the Indian regulatory authority requesting to change the primary endpoint in the protocol of our second Phase III trial in India from twelve to six months consistent with the primary endpoint for filing the NDA in the U.S., although there is no assurance they will accept the amendment. Further, although enrollment is complete in our first Phase III trial, we do not expect enrollment to be completed in our second Phase III trial until the end of the second quarter of 2016. Many factors could affect the timing of filing any NDA for Medidur, including completion of enrollment in the second trial in the time frame we anticipate, utilizing the data on which we currently plan to base the NDA, analyzing the data in the time frame we anticipate, requirements from regulators that would affect our timing, and the actual results from the trials. As a result, there is no assurance that an NDA for Medidur will be filed on the basis of the data we currently plan to use or that it will be filed in the first half of 2017, if at all.

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Even if we file an NDA for Medidur, there is no assurance that the FDA will accept the NDA for review. While we believe the FDA will accept the filing of an NDA for Medidur based on the data we currently plan to utilize, the FDA has significant discretion in determining whether to accept an NDA for review and there is no assurance that the FDA will find the design of our clinical trials or the data we include in an NDA to be sufficient to accept the NDA for review. Any delay in the filing of an NDA for Medidur or the FDA's refusal to accept the NDA for review could materially and adversely affect our business and the price of our common stock.

We are currently conducting, and may in the future conduct, clinical trials for product candidates at sites outside the United States, and the FDA may not accept data from trials conducted in such locations.

We are currently conducting a Phase III trial of Medidur in India, and may in the future choose to conduct one or more of our clinical trials outside the United States.

In general, the FDA accepts data from clinical trials conducted outside the United States; however, acceptance of this data is subject to, among other things, the clinical trials being conducted and performed by qualified investigators in accordance with Good Clinical Practice principles. The trial population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. In addition, while these clinical trials are subject to applicable local laws, FDA acceptance of the data will depend on its determination that the trials also complied with all applicable U.S. laws and regulations. If the FDA does not accept the data from any trial that we conduct outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and delay or permanently halt our development of the applicable product candidates.

There is no assurance that Pfizer will exercise its option with respect to the Latanoprost Product if we initiate and complete Phase II trials or cease development, in which case we will not receive any further financial consideration under the Restated Pfizer Agreement.

Pfizer has an option for an exclusive, worldwide license to develop and commercialize the Latanoprost Product upon our completion of Phase II clinical trials, which are at our option and expense, 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.

We do not know if we will be able to deliver proteins (including antibodies) and peptides with our Tethadur technology or that we will be able to develop product candidates or approved products using this technology.

Although we are optimistic that our Tethadur technology platform can provide sustained delivery of proteins (including antibodies) and peptides, and our data from an in vitro study has shown that the long-term sustained release of antibodies such as Avastin is achievable using Tethadur, our research is at an early stage and we face challenges. Development of any product candidates is expected to require significant additional research. There is no assurance that our subsequent research will be successful or that we will be able to develop product candidates or approved products using Tethadur to deliver proteins and peptides.

Product development is very uncertain. If we do not develop product candidates to enter clinical trials, if we or any licensees do not initiate or complete clinical trials for our product candidates or if our product candidates do not receive the necessary regulatory approvals, neither we nor any licensees will be able to commercialize those product candidates and generate revenues for us.

Other than Medidur for posterior uveitis, for which pivotal Phase III trials are ongoing, all of our product development is at earlier stages. Product development at all stages involves a high degree of risk, and only a

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small proportion of research and development programs result in product candidates that advance to pivotal clinical trials or result in approved products. There is no assurance that any feasibility study agreements we have, or enter into, with third parties, or our own research and development programs and collaborations will result in any new product candidates, or that we or any licensees will commence clinical trials for any new product candidates or continue clinical trials once commenced. If clinical trials conducted by or for us or any licensees for any product candidates do not provide the necessary evidence of safety and efficacy, those product candidates will not receive the necessary regulatory approvals, cannot be sold, and will not generate revenues for us. Initial or subsequent clinical trials may not be initiated by or for us or any licensees for product candidates or may be delayed, terminated or fail due to many factors, including the following:

- decisions not to pursue development of product candidates due to pre-clinical or clinical trial results;
- lack of sufficient funding;
- inability to attract clinical investigators for trials;
- inability to recruit patients in sufficient numbers or at the expected rate;
- 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;
- failure to meet FDA or other regulatory agency requirements for clinical trial design, or inadequate clinical trial design;
- 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 (CROs), third-party vendors and investigators responsible for pre-clinical testing and clinical trials;
- 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;
- 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, early clinical trials, investigator-sponsored studies and other data and indications often do not accurately predict final pivotal clinical trial results. 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, other 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. There is no assurance, for example, that the Durasert product candidate to treat pain associated with severe knee osteoarthritis will advance to Phase III trials or will be safe or effective.

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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 product's 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. The imposition by the FDA or other regulatory organizations of any such limitations on the indicated uses for which any of our products may be marketed would reduce the size of, or otherwise limit, the potential market for the product subject to such limitations.

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 do not currently have sales and marketing capacity. There is no assurance that we will have the financial resources to develop the capacity to, or be able to, successfully market and sell products if we seek to do so.

Our strategy includes independently developing and commercializing products. We do not know when or if we will seek to directly commercialize any products ourselves. We currently have no marketing and sales staff and no experience in commercializing products. Direct commercialization would require us to develop sales and marketing capability and to make a significant financial investment. If we decide to independently and directly commercialize a product, there is no assurance we will be able to hire and manage a successful sales and marketing capability or have the financial resources necessary to fund independent commercialization of any products.

The success of our current and possible future collaborative and licensing arrangements depends and will depend heavily on the experience, resources, efforts and activities of our licensees, and if they are not successful in developing and marketing our products, it will adversely affect our revenues, if any, from those products.

Our business strategy includes continuing to leverage our technology platforms by entering into collaborative and licensing arrangements for the development and commercialization of our product candidates, where appropriate. The success of current and future collaborative and licensing arrangements do and will depend heavily on the experience, resources, skill, efforts and activities of our licensees. Our licensees have had, 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;

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- 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.

We currently have collaboration and licensing arrangements with various companies, most significantly Alimera and Bausch & Lomb. 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, and we do not expect revenues from Retisert to increase materially and they may decline further. Although we believe potential revenues from ILUVIEN for DME are important to our future results of operations and financial condition, Alimera has limited experience and limited financial resources, and ILUVIEN for DME is Alimera's first and only commercial product. Alimera has reported that its negative cash flows from operations and accumulated deficit raise substantial doubt about its ability to continue as a going concern. Further, due to the limited revenue generated by Alimera to date, Alimera may not be able to maintain compliance with covenants under its loan agreement and, in the event of a default, we do not know whether Alimera will be able to obtain amendments or waivers of those covenants. We do not know if Alimera will be able to raise additional financing if and when required.

If our current and future licensees are not successful in developing and marketing our products, it will adversely affect our revenues, if any, from those products.

Our current licensees may terminate their agreements with us at any time or fail to fulfill their obligations under those agreements, and, if they do, we will lose the benefits of those agreements.

Our licensees have rights of termination under our agreements with them and could terminate those agreements without cause on short notice. Further, our licensees may fail to fulfill their obligations under their agreements, or we may disagree with them over the rights and obligations under those agreements, which could result in breach of the agreements and/or termination. Exercise of termination rights by one or more of our licensees or by us may leave us without the financial benefits and development, marketing or sales resources provided under the terminated agreement. It could be necessary for us to replace, or seek to provide ourselves, the services provided by the licensee, and there is no assurance we would be successful in doing so. It could delay, impair or stop the development or commercialization of 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 any of our licensees do not perform their obligations under our agreements or if any of those agreements are terminated, it could have an adverse effect on our business, financial condition and results of operations.

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

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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 potential use of 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 that affect our or our competitors' products and product candidates. Any such guidelines, recommendations or studies that reflect negatively on our products or product candidates, either directly or relative to our competitive products, could result in current or potential 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, 2015, we had 238 patents and 116 pending

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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 U.S. 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 costs 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 have entered into many agreements that limit our or the third parties' rights with respect to our intellectual property, including rights to use, options on rights to use, or prohibitions on rights to use (including noncompetition obligations) our or jointly developed intellectual property. Those rights could adversely affect our rights to develop and commercialize products utilizing our intellectual property.

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 and marketing our products will depend on whether we can attract and retain additional qualified management and scientific personnel as well as a sales and marketing staff. There is strong competition for qualified 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

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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, 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

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with individual third-party manufacturers for the manufacture of ILUVIEN and its components. If any of Alimera's third-party manufacturers breach their agreements or are unable or unwilling to perform for any reason or fail to comply with cGMP and comparable foreign requirements, 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. Delays in the commercial production of ILUVIEN could delay or impair Alimera's marketing of ILUVIEN, which, in turn, could adversely affect Alimera's generation of net profits for us.

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. We manufacture supplies in connection with pre-clinical or clinical studies conducted by us and 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 or our licensees' ability to manufacture and sell our products. If we encounter such problems, our or their costs could increase and 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 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;

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- 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 healthcare 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 healthcare 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 or our licensees may obtain regulatory approval; our or our licensees' ability to set a price that we or they believe is fair for our products; our or our licensees' ability to obtain coverage and reimbursement approval for a product; our or our licensees' 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.

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RISKS RELATED TO OUR COMMON STOCK

The price of our common stock may be volatile.

The price of our common stock (including common stock represented by CHESSE Depository Interests (CDIs)) may be affected by developments directly affecting our business, as well as by developments out of our control or not specific to us. The biotechnology sector, in particular, and the stock market generally are vulnerable to abrupt changes in investor sentiment. Prices of securities and trading 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, 2015, we had outstanding warrants and options to acquire approximately 6.1 million shares of our common stock, or approximately 17.1% of our shares on a fully diluted basis. The issuance of shares of our common stock upon exercise of these warrants and stock options could result in dilution to the interests of other holders of our common stock and could adversely affect our stock price.

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.

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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 sublease agreement that expires in December 2015, with a six renewal option subject to advance termination by either party.

ITEM 3. LEGAL PROCEEDINGS

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

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PART II

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

Market Information, Holders and Dividends

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

| | <u>High</u> | <u>Low</u> |
|----------------------------------|-------------|------------|
| Fiscal year ended June 30, 2015: | | |
| First Quarter | \$4.94 | \$3.90 |
| Second Quarter | 4.61 | 3.45 |
| Third Quarter | 4.64 | 3.77 |
| Fourth Quarter | 4.44 | 3.67 |
| 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 |

On August 31, 2015, the last reported sale price of our common stock on the NASDAQ Global Market was \$3.75. As of that date, we had approximately 20 holders of record of our common stock and, according to our estimates, approximately 4,960 beneficial owners of our common stock. In addition, as of that date, there were approximately 2,010 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, 2015:

| <u>Plan category</u> | <u>Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)</u> | <u>Weighted-average exercise price of outstanding options, warrants and rights (b)</u> | <u>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in Column a) (c)</u> |
|--|--|--|--|
| Equity Compensation plans approved by security holders | 4,447,975 | \$ 3.36 | 1,123,791 |
| Equity Compensation plans not approved by security holders | — | — | — |
| Total | <u>4,447,975</u> | <u>\$ 3.36</u> | <u>1,123,791</u> |

On the first day of each fiscal year until July 1, 2017, the number of shares reserved for issuance under the Company's 2008 Incentive Plan will be increased by the least of (i) 750,000 shares; (ii) 4% of the then outstanding shares of common stock; and (iii) any such lesser number of shares as is determined by the Compensation Committee of the Board of Directors. On July 1, 2015, the number of shares issuable under the 2008 Incentive Plan was increased by 750,000 shares.

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Issuer Repurchases of Equity Securities

None.

ITEM 6. SELECTED FINANCIAL DATA

The selected historical financial data set forth below as of June 30, 2015, 2014, 2013, 2012 and 2011 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, 2015 and 2014 and for the years ended June 30, 2015, 2014 and 2013 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, | | | | |
|--|--------------------------------------|-------------------|-------------------|-------------------|-------------------|
| | 2015 | 2014 | 2013 | 2012 | 2011 |
| | (In thousands except per share data) | | | | |
| Consolidated Statements of Operations Data: | | | | | |
| Revenues: | | | | | |
| Collaborative research and development (1) | \$25,411 | \$ 2,155 | \$ 780 | \$ 2,080 | \$ 3,612 |
| Royalty income | 1,154 | 1,318 | 1,363 | 1,446 | 1,353 |
| Total revenues | <u>26,565</u> | <u>3,473</u> | <u>2,143</u> | <u>3,526</u> | <u>4,965</u> |
| Operating expenses: | | | | | |
| Research and development | 12,088 | 9,573 | 7,005 | 7,039 | 6,864 |
| General and administrative | 8,056 | 7,468 | 7,169 | 6,868 | 8,104 |
| Gain on sale of property and equipment | — | (78) | — | — | — |
| Impairment of intangible assets (2) | — | — | — | 14,830 | — |
| Total operating expenses | <u>20,144</u> | <u>16,963</u> | <u>14,174</u> | <u>28,737</u> | <u>14,968</u> |
| Operating income (loss) | <u>6,421</u> | <u>(13,490)</u> | <u>(12,031)</u> | <u>(25,211)</u> | <u>(10,003)</u> |
| Other income: | | | | | |
| Change in fair value of derivatives | — | — | — | 170 | 1,140 |
| Interest income | 19 | 6 | 16 | 38 | 30 |
| Other income (expense), net | 3 | (1) | (2) | (1) | (13) |
| Total other income | <u>22</u> | <u>5</u> | <u>14</u> | <u>207</u> | <u>1,157</u> |
| Income (loss) before income taxes | 6,443 | (13,485) | (12,017) | (25,004) | (8,846) |
| Income tax (expense) benefit | (96) | 130 | 117 | 169 | 218 |
| Net income (loss) | <u>\$ 6,347</u> | <u>\$(13,355)</u> | <u>\$(11,900)</u> | <u>\$(24,835)</u> | <u>\$ (8,628)</u> |
| Net income (loss) per share: | | | | | |
| Basic | <u>\$ 0.22</u> | <u>\$ (0.49)</u> | <u>\$ (0.52)</u> | <u>\$ (1.19)</u> | <u>\$ (0.44)</u> |
| Diluted | <u>\$ 0.21</u> | <u>\$ (0.49)</u> | <u>\$ (0.52)</u> | <u>\$ (1.19)</u> | <u>\$ (0.44)</u> |
| Weighted average common shares outstanding: | | | | | |
| Basic | <u>29,378</u> | <u>27,444</u> | <u>23,044</u> | <u>20,791</u> | <u>19,489</u> |
| Diluted | <u>30,584</u> | <u>27,444</u> | <u>23,044</u> | <u>20,791</u> | <u>19,489</u> |

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| | As of June 30, | | | | |
|--|----------------|----------|----------|----------|----------|
| | 2015 | 2014 | 2013 | 2012 | 2011 |
| | (In thousands) | | | | |
| Consolidated Balance Sheet Data: | | | | | |
| Cash and cash equivalents | \$19,121 | \$15,334 | \$ 6,899 | \$ 4,625 | \$12,912 |
| Marketable securities | 9,414 | 2,944 | 3,374 | 9,946 | 11,216 |
| Total assets | 32,367 | 22,671 | 16,249 | 20,597 | 47,113 |
| Total deferred revenue—current and long-term | 5,629 | 5,722 | 5,984 | 5,959 | 7,847 |
| Total stockholders' equity | 23,368 | 14,924 | 7,700 | 13,636 | 37,433 |

- (1) Includes the following: from our collaboration agreement with Alimera: \$25.1 million in fiscal 2015, \$114,000 in fiscal 2014, \$67,000 in fiscal 2013, \$111,000 in fiscal 2012 and \$192,000 in fiscal 2011; from our Restated Pfizer Agreement: \$368,000 in fiscal 2013, \$754,000 in fiscal 2012 and \$3.3 million in fiscal 2011; from feasibility study agreements: \$144,000 in fiscal 2015, \$1.9 million in fiscal 2014 and \$245,000 in fiscal 2013; and from field-of-use license termination: \$1.1 million in fiscal 2012. 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.

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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 are a leader in the development of sustained-release drug-delivery products for treating eye diseases. Our products deliver drugs at a controlled and steady rate for months or years. We have developed three of only four sustained-release products approved by the U.S. Food and Drug Administration (FDA) for treatment of back-of-the-eye diseases. The most recent is ILUVIEN[®] for diabetic macular edema (DME), sold by our licensee in the U.S. and three European Union (EU) countries. Our lead development product, Medidur[™] for posterior uveitis, is in pivotal phase III clinical trials. Our pre-clinical development program is primarily focused on developing products for chronic ophthalmic diseases utilizing our core technology platforms.

ILUVIEN is an injectable, sustained-release micro-insert that provides treatment of DME for three years from a single administration. ILUVIEN is licensed to Alimera Sciences, Inc. (Alimera), and we are entitled to a share of the net profits (as defined in our agreement with Alimera) from Alimera’s sales of ILUVIEN. ILUVIEN was launched in late February 2015 in the U.S., where it is indicated for the treatment of DME in patients previously treated with a course of corticosteroids without a clinically significant rise in intraocular pressure. ILUVIEN has been commercially available in the United Kingdom (U.K.) and Germany since June 2013 and in Portugal since January 2015. ILUVIEN has marketing approvals in these and 14 other EU countries for the treatment of chronic DME considered insufficiently responsive to available therapies. Alimera has sublicensed distribution, regulatory and reimbursement matters for ILUVIEN for DME in Australia and New Zealand in April 2014, in Canada in July 2015 and in Italy in August 2015.

Medidur, our lead development product, is an injectable, micro-insert designed to treat chronic non-infectious uveitis affecting the posterior segment of the eye (posterior uveitis) for three years from a single administration. Medidur, which is the same micro-insert as ILUVIEN, is in Phase III clinical trials, with the filing of a new drug application (NDA) anticipated in the first half of 2017. We are developing Medidur independently.

Our FDA-approved Retisert[®] provides sustained release treatment of posterior uveitis for approximately two and a half years. It is licensed to Bausch & Lomb, and we receive royalties from its sales.

Our pre-clinical development program is focused on developing products using our core platform technologies, Durasert[™] and Tethadur[™], to deliver drugs or biologics to treat wet and dry age-related macular degeneration (AMD), glaucoma, osteoarthritis and other diseases.

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

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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 (such as granting of license rights, providing research and development services, manufacturing of clinical materials and participating on joint research committees) in exchange for consideration to us of some combination of one or more of non-refundable license fees, funding of research and development activities, payments based upon achievement of clinical development, regulatory and sales milestones, royalties in the form of a designated percentage of product sales or participation in 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 collaborative partner 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, 2015, we reported \$25.4 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.

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. 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.

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Recognition of Expense in Outsourced Clinical Trial Agreements

We recognize research and development expense with respect to outsourced agreements for clinical trials with 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 CROs, 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 changes to the protocols and/or services requested, the number of patients to be enrolled and the rate of patient enrollment, achievement of pre-defined direct cost milestone events and other factors relating to the clinical trials. As of June 30, 2015, our CRO agreements provided for two Phase III clinical trials and a utilization study of our proprietary inserter at an aggregate remaining cost of approximately \$16.4 million. 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 2015, we recognized approximately \$6.1 million of research and development expense attributable to our Medidur Phase III clinical trial program. 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.

Results of Operations

Years Ended June 30, 2015 and 2014

| | Year Ended June 30, | | Change | |
|--|-----------------------------------|-------------------|-----------------|-------------|
| | 2015 | 2014 | Amounts | % |
| | (In thousands except percentages) | | | |
| Revenues: | | | | |
| Collaborative research and development | \$25,411 | \$ 2,155 | \$23,256 | 1079% |
| Royalty income | 1,154 | 1,318 | (164) | (12)% |
| Total revenues | <u>26,565</u> | <u>3,473</u> | <u>23,092</u> | <u>665%</u> |
| Operating expenses: | | | | |
| Research and development | 12,088 | 9,573 | 2,515 | 26% |
| General and administrative | 8,056 | 7,468 | 588 | 8% |
| Gain on sale of property and equipment | — | (78) | 78 | (100)% |
| Total operating expenses | <u>20,144</u> | <u>16,963</u> | <u>3,181</u> | <u>19%</u> |
| Operating income (loss) | <u>6,421</u> | <u>(13,490)</u> | <u>19,911</u> | <u>148%</u> |
| Other income (expense): | | | | |
| Interest income | 19 | 6 | 13 | 217% |
| Other income (expense), net | 3 | (1) | 4 | 400% |
| Total other income | <u>22</u> | <u>5</u> | <u>17</u> | <u>340%</u> |
| Income (loss) before income taxes | 6,443 | (13,485) | 19,928 | 148% |
| Income tax (expense) benefit | (96) | 130 | (226) | (174)% |
| Net income (loss) | <u>\$ 6,347</u> | <u>\$(13,355)</u> | <u>\$19,702</u> | <u>148%</u> |

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Revenues

Collaborative research and development revenue totaled \$25.4 million in fiscal 2015 compared to \$2.2 million in fiscal 2014. This increase was primarily attributable to recognition of the one-time \$25.0 million FDA approval milestone earned for ILUVIEN, partially offset by a \$1.8 million reduction in revenues from funded technology evaluation agreements.

Retisert royalty income decreased by \$164,000, or 12%, to \$1.2 million in fiscal 2015 compared to \$1.3 million in fiscal 2014. We do not expect Retisert royalty income to increase significantly in the next fiscal year, and it may decline further.

We are entitled to share in net profits, on a country-by-country basis, from sales of ILUVIEN by Alimera. Alimera initiated commercial sales of ILUVIEN in the U.K. and Germany in the fourth quarter of fiscal 2013 and in the U.S. and Portugal in the third quarter of fiscal 2015. We received \$43,000 of ILUVIEN net profits during fiscal 2015 and none in fiscal 2014. We do not know when and if we will receive future net profit payments with respect to any country where Alimera sells ILUVIEN or payments with respect to countries where Alimera sublicenses the sale of ILUVIEN.

Research and Development

Research and development totaled \$12.1 million in fiscal 2015, an increase of \$2.5 million, or 26%, compared to \$9.6 million in fiscal 2014. This increase was primarily attributable to a \$2.0 million increase in CRO costs for the Medidur Phase III clinical development program and \$240,000 of personnel related costs, including stock-based compensation. We currently expect costs of our ongoing Medidur clinical development program to increase by approximately \$600,000, or 10%, during fiscal 2016 over fiscal 2015.

General and Administrative

General and administrative increased by \$588,000, or 8%, to \$8.1 million for fiscal 2015 from \$7.5 million for fiscal 2014, primarily attributable to a \$530,000 increase in professional fees and a \$390,000 increase in stock-based compensation.

Other Income

Other income totaled \$22,000 in fiscal 2015 compared to \$5,000 in fiscal 2014, primarily due to interest income on higher average balances of marketable securities investments.

Income Tax (Expense) Benefit

Income tax expense of \$96,000 in fiscal 2015 compared to an income tax benefit of \$130,000 in fiscal 2014. During fiscal 2015, we paid \$263,000 of federal alternative minimum taxes based upon U.S. taxable income for calendar year 2014, which was primarily attributable to the \$25.0 million ILUVIEN FDA-approval milestone. Refundable foreign research and development tax credits totaled \$167,000 in fiscal 2015 compared to \$130,000 in fiscal 2014.

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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 | <u>3,473</u> | <u>2,143</u> | <u>1,330</u> | <u>62%</u> |
| 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 | <u>16,963</u> | <u>14,174</u> | <u>2,789</u> | <u>20%</u> |
| Operating loss | <u>(13,490)</u> | <u>(12,031)</u> | <u>(1,459)</u> | <u>(12)%</u> |
| Other income (expense): | | | | |
| Interest income | 6 | 16 | (10) | (63)% |
| Other expense, net | (1) | (2) | 1 | 50% |
| Total other income | <u>5</u> | <u>14</u> | <u>(9)</u> | <u>(64)%</u> |
| Loss before income taxes | <u>(13,485)</u> | <u>(12,017)</u> | <u>(1,468)</u> | <u>(12)%</u> |
| Income tax benefit | 130 | 117 | 13 | 11% |
| Net loss | <u><u>\$(13,355)</u></u> | <u><u>\$(11,900)</u></u> | <u><u>\$(1,455)</u></u> | <u><u>(12)%</u></u> |

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.

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.

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 first Medidur Phase III clinical trial was partially offset by a \$665,000 decrease in personnel costs, including stock-based compensation.

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.

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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.

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. In August 2015, the FASB issued ASU 2015-14, which officially deferred the effective date of ASU 2014-09 by one year, while also permitting early adoption. As a result, ASU 2014-09 will become effective on July 1, 2018, with early adoption permitted on July 1, 2017. 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.

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements—Going Concern*. ASU 2014-15 provides guidance around management’s responsibility to evaluate whether there is substantial doubt about an entity’s ability to continue as a going concern and to provide related footnote disclosures. For each reporting period, management will be required to evaluate whether there are conditions or events that raise substantial doubt about a company’s ability to continue as a going concern within one year from the date the financial statements are issued. The new standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016. Early adoption is permitted. We are evaluating the potential impact of adopting this standard on our financial statements.

Liquidity and Capital Resources

During fiscal 2012 through fiscal 2015, we financed our operations primarily from the receipt of license fees, milestone payments, research and develop funding and royalty income from our collaboration partners, and from proceeds of sales of our equity securities. At June 30, 2015, our principal sources of liquidity consisted of cash, cash equivalents and marketable securities totaling \$28.5 million. Our cash equivalents are invested in an institutional money market fund, and our marketable securities are invested in investment-grade corporate debt with maturities at June 30, 2015 ranging from 0.5 to 8.5 months.

With the exception of net income in fiscal 2015 resulting from the \$25.0 million ILUVIEN FDA approval milestone, we have generally incurred operating losses since inception and, at June 30, 2015, we had a total accumulated deficit of \$270.7 million. We do not currently have any assured sources of future 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 \$28.5 million at June 30, 2015, together with expected cash inflows under existing collaboration agreements, will enable us to fund our operations as currently planned into early calendar year 2017. This estimate excludes any potential net

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profits 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 from ILUVIEN net profits participation, as well as proceeds from any future collaboration or other agreements and/or financing transactions. There is no assurance that we will receive significant, if any, revenues from future sales of ILUVIEN or cash from any other sources. Accordingly, we expect to need additional resources to fund our planned operations. Whether we will require, or desire, to raise additional capital will be influenced by many factors, including, but not limited to:

- whether, when and to what extent we receive revenues with respect to commercialization of ILUVIEN;
- the timing and cost of development, approval and marketing of Medidur for posterior uveitis;
- whether and to what extent we internally fund, whether and when we initiate, and how we conduct other product development programs;
- the amount of Retisert royalties and other payments we receive under collaboration agreements;
- 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;
- changes in our operating plan, resulting in increases or decreases in our need for capital; and
- our views on the availability, timing and desirability of raising capital.

Management currently believes that extending our cash position beyond early calendar year 2017 from operations depends significantly on possible cash flows from the successful commercialization of ILUVIEN for DME by Alimera. However, there is no assurance that ILUVIEN for DME will achieve market acceptance in the U.S. or the EU 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 under our existing ATM facility, we do not know whether and to what extent we will seek to do so 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 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.

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

| | Year Ended June 30, | | |
|--|---------------------|-------------------|-------------------|
| | 2015 | 2014 | 2013 |
| | (In thousands) | | |
| Net income (loss): | \$ 6,347 | \$(13,355) | \$(11,900) |
| Changes in operating assets and liabilities | 1,009 | 389 | 692 |
| Other adjustments to reconcile net income (loss) to cash flows from operating activities | 2,941 | 2,295 | 2,463 |
| Cash flows provided by (used in) operating activities | <u>\$10,297</u> | <u>\$(10,671)</u> | <u>\$ (8,745)</u> |
| Cash flows (used in) provided by investing activities | <u>\$(6,733)</u> | <u>\$ 66</u> | <u>\$ 6,358</u> |
| Cash flows provided by financing activities | <u>\$ 235</u> | <u>\$ 19,044</u> | <u>\$ 4,669</u> |

Sources and uses of operating cash flows for the years ended June 30, 2015, 2014 and 2013 are summarized as follows:

| | Year Ended June 30, | | |
|---|---------------------|-------------------|-------------------|
| | 2015 | 2014 | 2013 |
| | (In thousands) | | |
| Operating cash inflows: | | | |
| License and collaboration agreements | \$ 25,317 | \$ 1,963 | \$ 854 |
| Royalty income | 1,086 | 1,348 | 1,477 |
| Foreign R&D tax credits | 120 | 125 | 152 |
| Investment interest received, net | 97 | 45 | 215 |
| | <u>26,620</u> | <u>3,481</u> | <u>2,698</u> |
| Operating cash outflows: | | | |
| Personnel costs | (5,086) | (5,340) | (4,539) |
| Professional fees | (3,234) | (2,869) | (2,729) |
| Clinical development and third-party R&D | (5,783) | (3,834) | (2,153) |
| All other operating cash outflows, net | (2,220) | (2,109) | (2,022) |
| | <u>(16,323)</u> | <u>(14,152)</u> | <u>(11,443)</u> |
| Cash flows provided by (used in) operating activities | <u>\$ 10,297</u> | <u>\$(10,671)</u> | <u>\$ (8,745)</u> |

Operating cash inflows for each year consisted primarily of payments received pursuant to license and collaboration agreements. As a percentage of total license and collaboration cash inflows, amounts attributable to Alimera represented 99.3% in fiscal 2015, 5.8% in fiscal 2014 and 8.4% in fiscal 2013, amounts attributable to Enigma represented 0.4% in fiscal 2015, 6.9% in fiscal 2014 and 11.7% in fiscal 2013 and amounts attributable to various feasibility study agreements represented 0.2% in fiscal 2015, 86.6% in fiscal 2014 and 73.2% in fiscal 2013.

Operating cash outflows increased by \$2.2 million, or 15.3%, from fiscal 2014 to fiscal 2015, primarily as a result of increases of (a) \$2.1 million in Medidur clinical development; (b) \$263,000 of federal alternative minimum taxes attributable to calendar year 2014 U.S. taxable income; and (c) a \$370,000 increase in professional fees, partially offset by decreases of \$255,000 in incentive compensation awards and \$230,000 in facility costs. 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 professional fees, partially offset by a \$300,000 reduction of other personnel costs.

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Cash flows from investing activities were primarily attributable to purchases of marketable securities, net of maturities, of \$6.6 million for fiscal 2015 and maturities of marketable securities, net of purchases, of \$386,000 for fiscal 2014 and \$6.4 million for fiscal 2013. Purchases of property and equipment totaled \$161,000 in fiscal 2015, \$248,000 in fiscal 2014 and \$68,000 in fiscal 2013.

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 \$235,000 in fiscal 2015 and \$987,000 in fiscal 2014.

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, 2015:

| <u>Contractual Obligations</u> | <u>Payments Due by Period</u> | | | | <u>More than 5 years</u> |
|--------------------------------|-------------------------------|-----------------------------|-------------------------------------|------------------|------------------------------|
| | <u>Total</u> | <u>Less than 1 year</u> | <u>1-3 years (In thousands)</u> | <u>3-5 years</u> | |
| Operating Lease Obligations | \$1,760 | \$ 482 | \$ 919 | \$ 359 | \$ — |
| Purchase Obligations | 210 | 210 | — | — | — |
| Total | \$1,970 | \$ 692 | \$ 919 | \$ 359 | \$ — |

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 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 patients and rate of patient enrollment, any protocol amendments 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, 2015, our CRO agreements provided for two Phase III clinical trials and a utilization study of the newly designed proprietary inserter at an aggregate remaining cost of approximately \$16.4 million. 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. These payments are contingent upon the occurrence of various future events, and the amounts payable under these provisions depend upon the level of compensation at the time of termination of employment, are therefore not calculable at this time, and, as a result, we have not included any such amounts in the table above.

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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 strengthening of the U.S. dollar relative to the Pound Sterling in fiscal 2015 compared to fiscal 2014 resulted in a net decrease in research and development expense of approximately \$62,000. 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 2015 would have decreased or increased by \$89,000, 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 income (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 income (loss), the relative strengthening of the U.S. dollar in relation to the Pound Sterling at June 30, 2015 compared to June 30, 2014 resulted in \$95,000 of other comprehensive loss due to the translation of £503,000 of net assets of our U.K. operations, predominantly the BioSilicon (including Tethadur) technology intangible asset, into U.S. dollars. For every incremental 5% strengthening or weakening of the U.S. dollar at June 30, 2015 in relation to the Pound Sterling, our stockholders' equity at June 30, 2015 would have decreased or increased, respectively, by approximately \$40,000.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by this item may be found on pages F-1 through F-24 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, 2015. 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, 2015, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

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

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

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

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

Our management assessed the effectiveness of our internal control over financial reporting as of June 30, 2015. 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 (2013)*. 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, 2015, 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 .

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the internal control over financial reporting of pSivida Corp. and subsidiaries (the “Company”) as of June 30, 2015, based on the criteria established in *Internal Control—Integrated Framework (2013)* 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, 2015, based on the criteria established in *Internal Control—Integrated Framework (2013)* 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, 2015 of the Company and our report dated September 10, 2015 expressed an unqualified opinion on those financial statements.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
September 10, 2015

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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, 54

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 to January 2009 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, 48

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 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, 65

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

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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 2015 Proxy Statement.

ITEM 11. EXECUTIVE COMPENSATION

The information required to be disclosed in Item 11 is hereby incorporated by reference to our 2015 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 2015 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 2015 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 2015 Proxy Statement.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENTS

(a)(1) Financial Statements

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

(a)(2) Financial Statement Schedules

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

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(a)(3) Exhibits.

| Exhibit No. | Exhibit Description | Incorporated by Reference to SEC Filing | | |
|--|--|---|-----------------|-------------|
| | | Form | SEC Filing Date | Exhibit No. |
| <i>Articles of Incorporation and By-Laws</i> | | | | |
| 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 |
| <i>Instruments Defining the Rights of Security Holders</i> | | | | |
| 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 |
| <i>Material Contracts—Management Contracts and Compensatory Plans</i> | | | | |
| 10.1(a) | Employment Agreement, between pSivida Corp. and Paul Ashton, dated October 31, 2008 | | | |
| 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(a) | 2008 Equity Incentive Plan, as amended on November 19, 2009 | | | |
| 10.7+ | Form of Stock Option Certificate for grants to executive officers under the pSivida Corp. 2008 Incentive Plan | 8-K | 09/10/08 | 10.1 |
| 10.8+ | 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 |
| <i>Material Contracts—Leases</i> | | | | |
| 10.9 | Lease Agreement between pSivida Corp. and Farley White Aetna Mills, LLC dated November 1, 2013 | 10-Q | 11/13/13 | 10.1 |
| <i>Material Contracts—License and Collaboration Agreements</i> | | | | |
| 10.10# | 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 |
| 10.11# | Second Amendment to Amended and Restated License Agreement between pSivida US, Inc. and Bausch & Lomb dated August 1, 2009 | 10-K | 09/25/09 | 10.13 |

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| Exhibit No. | Exhibit Description | Incorporated by Reference to SEC Filing | | |
|-----------------------|---|---|-----------------|-------------|
| | | Form | SEC Filing Date | Exhibit No. |
| 10.12# | Amended and Restated Collaborative Research and License Agreement, dated as of June 14, 2011, by and among pSivida Corp, pSivida US, Inc., pSiMedica Limited and Pfizer, Inc. | 10-K/A | 12/27/11 | 10.13 |
| 10.13# | 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, 2015, formatted in eXtensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets at June 30, 2015 and 2014; (ii) Consolidated Statements of Comprehensive Income (Loss) for the years ended June 30, 2015, 2014 and 2013; (iii) Consolidated Statements of Stockholders' Equity for the years ended June 30, 2015, 2014 and 2013; (iv) Consolidated Statements of Cash Flows for the years ended June 30, 2015, 2014 and 2013; 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

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of pSivida Corp. and subsidiaries (the “Company”) as of June 30, 2015 and 2014, and the related consolidated statements of comprehensive income (loss), stockholders’ equity, and cash flows for each of the three years in the period ended June 30, 2015. 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, 2015 and 2014, and the results of their operations and their cash flows for each of the three years in the period ended June 30, 2015, 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, 2015, based on the criteria established in *Internal Control-Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated September 10, 2015 expressed an unqualified opinion on the Company’s internal control over financial reporting.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
September 10, 2015

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

| | June 30, | |
|---|------------------|------------------|
| | 2015 | 2014 |
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 19,121 | \$ 15,334 |
| Marketable securities | 9,414 | 2,944 |
| Accounts and other receivables | 622 | 517 |
| Prepaid expenses and other current assets | 681 | 547 |
| Total current assets | 29,838 | 19,342 |
| Property and equipment, net | 338 | 297 |
| Intangible assets, net | 1,925 | 2,765 |
| Other assets | 116 | 117 |
| Restricted cash | 150 | 150 |
| Total assets | <u>\$ 32,367</u> | <u>\$ 22,671</u> |
| Liabilities and stockholders' equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 744 | \$ 464 |
| Accrued expenses | 2,571 | 1,524 |
| Deferred revenue | 33 | 138 |
| Total current liabilities | 3,348 | 2,126 |
| Deferred revenue, less current portion | 5,596 | 5,584 |
| Deferred rent | 55 | 37 |
| Total liabilities | <u>8,999</u> | <u>7,747</u> |
| 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, 29,412,365 and 29,298,558 shares issued and outstanding at June 30, 2015 and 2014, respectively | 29 | 29 |
| Additional paid-in capital | 293,060 | 290,864 |
| Accumulated deficit | (270,666) | (277,013) |
| Accumulated other comprehensive income | 945 | 1,044 |
| Total stockholders' equity | 23,368 | 14,924 |
| Total liabilities and stockholders' equity | <u>\$ 32,367</u> | <u>\$ 22,671</u> |

See notes to consolidated financial statements

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

| | Year Ended June 30, | | |
|---|---------------------|--------------------|--------------------|
| | 2015 | 2014 | 2013 |
| Revenues: | | | |
| Collaborative research and development | \$25,411 | \$ 2,155 | \$ 780 |
| Royalty income | 1,154 | 1,318 | 1,363 |
| Total revenues | <u>26,565</u> | <u>3,473</u> | <u>2,143</u> |
| Operating expenses: | | | |
| Research and development | 12,088 | 9,573 | 7,005 |
| General and administrative | 8,056 | 7,468 | 7,169 |
| Gain on sale of property and equipment | — | (78) | — |
| Total operating expenses | <u>20,144</u> | <u>16,963</u> | <u>14,174</u> |
| Operating income (loss) | <u>6,421</u> | <u>(13,490)</u> | <u>(12,031)</u> |
| Other income (expense): | | | |
| Interest income, net | 19 | 6 | 16 |
| Other income (expense), net | 3 | (1) | (2) |
| Total other income | <u>22</u> | <u>5</u> | <u>14</u> |
| Income (loss) before income taxes | 6,443 | (13,485) | (12,017) |
| Income tax (expense) benefit | (96) | 130 | 117 |
| Net income (loss) | <u>\$ 6,347</u> | <u>\$ (13,355)</u> | <u>\$ (11,900)</u> |
| Net income (loss) per share: | | | |
| Basic | <u>\$ 0.22</u> | <u>\$ (0.49)</u> | <u>\$ (0.52)</u> |
| Diluted | <u>\$ 0.21</u> | <u>\$ (0.49)</u> | <u>\$ (0.52)</u> |
| Weighted average common shares outstanding: | | | |
| Basic | <u>29,378</u> | <u>27,444</u> | <u>23,044</u> |
| Diluted | <u>30,584</u> | <u>27,444</u> | <u>23,044</u> |
| Net income (loss) | <u>\$ 6,347</u> | <u>\$ (13,355)</u> | <u>\$ (11,900)</u> |
| Other comprehensive (loss) income: | | | |
| Foreign currency translation adjustments | (95) | 124 | (29) |
| Net unrealized (loss) gain on marketable securities | (4) | — | 7 |
| Other comprehensive (loss) income | <u>(99)</u> | <u>124</u> | <u>(22)</u> |
| Comprehensive income (loss) | <u>\$ 6,248</u> | <u>\$ (13,231)</u> | <u>\$ (11,922)</u> |

See notes to consolidated financial statements

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

| | Common Stock | | Additional Paid-In Capital | Accumulated Deficit | Accumulated Other Comprehensive Income | Total Stockholders' Equity |
|---------------------------------------|---------------------|---------------------|----------------------------------|------------------------|---|----------------------------------|
| | Number of Shares | Par Value Amount | | | | |
| Balance at July 1, 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 |
| Net income | — | — | — | 6,347 | — | 6,347 |
| Other comprehensive loss | — | — | — | — | (99) | (99) |
| Exercise of stock options | 113,807 | — | 235 | — | — | 235 |
| Stock-based compensation | — | — | 1,961 | — | — | 1,961 |
| Balance at June 30, 2015 | <u>29,412,365</u> | <u>\$ 29</u> | <u>\$293,060</u> | <u>\$ (270,666)</u> | <u>\$ 945</u> | <u>\$ 23,368</u> |

See notes to consolidated financial statements

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

| | Year Ended June 30, | | |
|---|---------------------|------------------|-----------------|
| | 2015 | 2014 | 2013 |
| Cash flows from operating activities: | | | |
| Net income (loss) | \$ 6,347 | \$(13,355) | \$(11,900) |
| Adjustments to reconcile net income (loss) to cash flows from operating activities: | | | |
| Amortization of intangible assets | 770 | 778 | 769 |
| Depreciation of property and equipment | 112 | 139 | 225 |
| Amortization of bond premium on marketable securities | 98 | 45 | 152 |
| Stock-based compensation | 1,961 | 1,411 | 1,317 |
| Gain on sale of property and equipment | — | (78) | — |
| Changes in operating assets and liabilities: | | | |
| Accounts and other receivables | (124) | 103 | 364 |
| Prepaid expenses and other current assets | (136) | 1,110 | (1,272) |
| Accounts payable | 292 | (213) | 277 |
| Accrued expenses | 1,053 | (381) | 1,288 |
| Deferred revenue | (94) | (267) | 35 |
| Deferred rent | 18 | 37 | — |
| Net cash provided by (used in) operating activities | <u>10,297</u> | <u>(10,671)</u> | <u>(8,745)</u> |
| Cash flows from investing activities: | | | |
| Purchases of marketable securities | (10,222) | (2,964) | (7,758) |
| Maturities of marketable securities | 3,650 | 3,350 | 14,184 |
| Purchases of property and equipment | (161) | (248) | (68) |
| Proceeds from sale of property and equipment | — | 78 | — |
| Change in restricted cash | — | (150) | — |
| Net cash (used in) provided by investing activities | <u>(6,733)</u> | <u>66</u> | <u>6,358</u> |
| Cash flows from financing activities: | | | |
| Proceeds from issuance of stock, net of issuance costs | — | 18,057 | 4,669 |
| Proceeds from exercise of stock options | 235 | 987 | — |
| Net cash provided by financing activities | <u>235</u> | <u>19,044</u> | <u>4,669</u> |
| Effect of foreign exchange rate changes on cash and cash equivalents | (12) | (4) | (8) |
| Net increase in cash and cash equivalents | <u>3,787</u> | <u>8,435</u> | <u>2,274</u> |
| Cash and cash equivalents at beginning of year | <u>15,334</u> | <u>6,899</u> | <u>4,625</u> |
| Cash and cash equivalents at end of year | <u>\$ 19,121</u> | <u>\$ 15,334</u> | <u>\$ 6,899</u> |
| Supplemental disclosure of cash flow information: | | | |
| Cash paid for income taxes | <u>\$ 263</u> | <u>\$ —</u> | <u>\$ —</u> |

See notes to consolidated financial statements

PSIVIDA CORP. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Operations

pSivida Corp. (together with its subsidiaries, the “Company”), incorporated in Delaware, develops sustained-release drug-delivery products for treating eye diseases. Its products deliver drugs at a controlled and steady rate for months or years. The Company has developed three of only four sustained-release products approved by the U.S. Food and Drug Administration (“FDA”) for treatment of back-of-the-eye diseases. The most recent is ILUVIEN[®] for diabetic macular edema (“DME”), sold by the Company’s licensee in the U.S. and three European Union (“EU”) countries. The Company’s lead product candidate, Medidur[™] for posterior uveitis, is in pivotal Phase III clinical trials. The Company’s pre-clinical development program is focused primarily on developing products for chronic ophthalmic diseases utilizing its core technology platforms.

ILUVIEN is an injectable, sustained-release micro-insert that provides treatment of DME for three years from a single administration. ILUVIEN is licensed to Alimera Sciences, Inc. (“Alimera”), and the Company is entitled to a share of the net profits (as defined) from Alimera’s sales of ILUVIEN. ILUVIEN was launched in late February 2015 in the U.S., where it is indicated for the treatment of DME in patients previously treated with a course of corticosteroids without a clinically significant rise in intraocular pressure. ILUVIEN has been commercially available in the United Kingdom (“U.K.”) and Germany since June 2013 and in Portugal since January 2015. ILUVIEN has marketing approvals in these and 14 other EU countries for the treatment of chronic DME considered insufficiently responsive to available therapies. Distribution, regulatory and reimbursement matters for ILUVIEN for DME in Australia and New Zealand, Canada and Italy have been sublicensed.

Medidur, the Company’s lead development product, is an injectable, micro-insert designed to treat chronic, non-infectious uveitis affecting the posterior of the eye (“posterior uveitis”) for three years from a single administration. Medidur, which is the same micro-insert as ILUVIEN, is in Phase III clinical trials, with the filing of a new drug application (“NDA”) anticipated in the first half of 2017. The Company is developing Medidur independently.

The Company’s FDA-approved Retisert[®] provides sustained release treatment of posterior uveitis for approximately two and a half years. It is licensed to Bausch & Lomb, and the Company receives royalties from its sales.

The Company’s pre-clinical development program is focused on developing products using its core platform technologies, Durasert[™] and Tethadur[™], to deliver drugs and biologics to treat wet and dry age-related macular degeneration (“AMD”), glaucoma, osteoarthritis and other diseases.

The Company has a history of operating losses and has financed its operations primarily from the receipt of license fees, milestone payments, research and development funding and royalty income from its collaboration partners, and from proceeds of sales of its equity securities. The Company believes that its cash, cash equivalents and marketable securities of \$28.5 million at June 30, 2015, together with expected cash inflows under existing collaboration agreements, will enable the Company to maintain its current and planned operations into early calendar year 2017. This estimate excludes any potential net profits receipts from sales of ILUVIEN 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 from ILUVIEN net profits participation, as well as proceeds from any future collaboration or other agreements and/or financing transactions.

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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, 2015, 2014 and 2013 may be referred to herein as fiscal 2015, fiscal 2014 and fiscal 2013, respectively.

Certain prior period amounts have been reclassified to conform to the current presentation. Specifically, the significant components of the rate reconciliation have been reclassified to present permanent items and the significant components of the gross deferred tax assets have been reclassified to present tax credits (see Note 12).

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 income (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 \$950,000 at June 30, 2015 and \$1,045,000 at June 30, 2014. Foreign currency gains or losses arising from transactions denominated in foreign currencies, whether realized or unrealized, are recorded in other income (expense), net in the consolidated statements of comprehensive income (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 three months 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, 2015 and 2014, 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

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amortization and accretion amounts are included in interest income, net in the consolidated statements of comprehensive income (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, 2015, all of the Company's interest-bearing cash equivalent balances, aggregating \$15.8 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, 2015 and 2014 consisted 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.

Alimera Sciences accounted for \$25.1 million, or 95% of total revenues in fiscal 2015 and inconsequential revenues in each of fiscal 2014 and fiscal 2013. Bausch & Lomb accounted for \$1.2 million, or 5% of total revenues in fiscal 2015, \$1.3 million, or 38% of total revenues in fiscal 2014, and \$1.4 million, or 64%, of total revenues in fiscal 2013. A completed feasibility study agreement accounted for \$1.7 million, or 49%, of total revenues in fiscal 2014. Pfizer revenues, which were inconsequential in fiscal 2015 and fiscal 2014, accounted for \$368,000, or 17%, of total revenues in fiscal 2013.

Bausch & Lomb accounted for \$371,000, or 60% of total accounts receivable at June 30, 2015 and \$302,000, or 58% of total accounts receivable at June 30, 2014.

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.

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 derecognized 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.

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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.

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

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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 may also award stock options that are subject to objectively measurable performance and service criteria. Compensation expense for performance-based option awards begins at such time as 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.

The Company estimates the fair value of stock option awards using the Black-Scholes option valuation model.

Net Income (Loss) per Share

Basic net income (loss) per share is computed by dividing net income (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.

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The following table reconciles the number of shares used to compute basic and diluted net income (loss) per share:

| | Year Ended June 30, | | |
|---------------------------------|---------------------|-------------------|-------------------|
| | 2015 | 2014 | 2013 |
| Number of common shares—basic | 29,378,250 | 27,443,592 | 23,044,152 |
| Effect of dilutive securities: | | | |
| Stock options | 956,441 | — | — |
| Warrants | 249,449 | — | — |
| Number of common shares—diluted | <u>30,584,140</u> | <u>27,443,592</u> | <u>23,044,152</u> |

Potential common stock equivalents excluded from the calculation of diluted earnings per share because the effect would have been anti-dilutive were as follows:

| | Year Ended June 30, | | |
|----------------------|---------------------|------------------|------------------|
| | 2015 | 2014 | 2013 |
| Options outstanding | 2,010,793 | 3,791,001 | 3,554,549 |
| Warrants outstanding | 552,500 | 1,176,105 | 1,176,105 |
| | <u>2,563,293</u> | <u>4,967,106</u> | <u>4,730,654</u> |

Comprehensive Income (Loss)

Comprehensive income (loss) is comprised of net income (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.

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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. In August 2015, the FASB issued ASU 2015-14, which officially deferred the effective date of ASU 2014-09 by one year, while also permitting early adoption. As a result, ASU 2014-09 will become effective on July 1, 2018, with early adoption permitted on July 1, 2017. 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.

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements—Going Concern*. ASU 2014-15 provides guidance around management’s responsibility to evaluate whether there is substantial doubt about an entity’s ability to continue as a going concern and to provide related footnote disclosures. For each reporting period, management will be required to evaluate whether there are conditions or events that raise substantial doubt about a company’s ability to continue as a going concern within one year from the date the financial statements are issued. The new standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016. Early adoption is permitted. The Company is evaluating the potential impact of adopting this standard 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. 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 is also entitled to reimbursement of certain patent maintenance costs with respect to the patents licensed to Alimera.

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.

In September 2014, the Company earned a \$25.0 million milestone from Alimera as a result of the FDA approval of ILUVIEN, which amount was received in October 2014. Revenue under the Alimera Agreement totaled \$25.1 million for fiscal 2015, \$114,000 for fiscal 2014 and \$67,000 for fiscal 2013.

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 to date have not been undertaken, for the purpose of demonstrating Proof-of-Concept (“POC”). If the Company were to issue

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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, 2015, the Company continues to evaluate whether to undertake Phase II clinical trials and, consequently, the Company cannot currently estimate the remaining performance period and has therefore not recognized any additional revenue. As a result, the current portion of deferred revenue was \$0 at each of June 30, 2015 and 2014. Total deferred revenue was approximately \$5.6 million at each of June 30, 2015 and 2014. Collaborative research and development revenue related to the Restated Pfizer Agreement was inconsequential in each of fiscal 2015 and fiscal 2014, and totaled \$368,000 in fiscal 2013. Costs associated with conducting the R&D program are included in operating expenses as incurred.

Pfizer owned approximately 6.3% of the Company's outstanding shares at June 30, 2015.

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 \$1.2 million in fiscal 2015, \$1.3 million in fiscal 2014 and \$1.4 million in fiscal 2013. Accounts receivable from Bausch & Lomb totaled \$371,000 at June 30, 2015 and \$302,000 at June 30, 2014.

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

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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, but only 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 \$100,000 in fiscal 2015, \$102,000 in fiscal 2014 and \$100,000 in fiscal 2013. At June 30, 2015, no deferred revenue was recorded for this agreement.

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 \$144,000 in fiscal 2015, \$1.9 million in fiscal 2014 and \$245,000 in fiscal 2013.

4. Intangible Assets

The reconciliation of intangible assets for the years ended June 30, 2015 and 2014 was as follows (in thousands):

| | June 30, | |
|---|-----------------|-----------------|
| | 2015 | 2014 |
| Patented technologies | | |
| Gross carrying amount at beginning of year | \$ 41,689 | \$ 38,941 |
| Foreign currency translation adjustments | (1,979) | 2,748 |
| Gross carrying amount at end of year | 39,710 | 41,689 |
| Accumulated amortization at beginning of year | (38,924) | (35,511) |
| Amortization expense | (770) | (778) |
| Foreign currency translation adjustments | 1,909 | (2,635) |
| Accumulated amortization at end of year | (37,785) | (38,924) |
| Net book value at end of year | <u>\$ 1,925</u> | <u>\$ 2,765</u> |

The net book value of the Company's intangible assets at June 30, 2015 and 2014 is summarized as follows (in thousands):

| | June 30, | | Estimated Remaining Useful Life at June 30, 2015 (Years) |
|------------------------------|----------------|----------------|--|
| | 2015 | 2014 | |
| Patented technologies | | | |
| Durasert | \$1,324 | \$1,853 | 2.5 |
| BioSilicon | 601 | 912 | 2.5 |
| | <u>\$1,925</u> | <u>\$2,765</u> | |

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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 \$770,000 in fiscal 2015, \$778,000 in fiscal 2014 and \$769,000 in fiscal 2013. The carrying value of intangible assets at June 30, 2015 of \$1.9 million is expected to be amortized on a straight-line basis of approximately \$770,000 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, 2015 and 2014 were as follows (in thousands):

| | June 30, 2015 | | |
|-----------------------------|-----------------|---------------|----------------|
| | Amortized | Unrealized | Fair Value |
| | Cost | Loss | |
| Corporate bonds | <u>\$ 9,419</u> | <u>\$ (5)</u> | <u>\$9,414</u> |
| | | | |
| | June 30, 2014 | | |
| | Amortized | Unrealized | Fair Value |
| | Cost | Loss | |
| Corporate bonds | \$ 2,446 | \$ (1) | \$2,445 |
| Commercial paper | 499 | — | 499 |
| Total marketable securities | <u>\$ 2,945</u> | <u>\$ (1)</u> | <u>\$2,944</u> |

During fiscal 2015, \$10.2 million of marketable securities were purchased and \$3.7 million matured. At June 30, 2015, the marketable securities had maturities ranging between 15 days and 8.5 months, with a weighted average maturity of 5.1 months.

6. Property and Equipment, Net

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

| | June 30, | |
|---|---------------|---------------|
| | 2015 | 2014 |
| Property and equipment | \$ 1,927 | \$ 1,956 |
| Leasehold improvements | 217 | 231 |
| Gross property and equipment | 2,144 | 2,187 |
| Accumulated depreciation and amortization | (1,806) | (1,890) |
| | <u>\$ 338</u> | <u>\$ 297</u> |

Depreciation expense was \$112,000 for fiscal 2015, \$139,000 for fiscal 2014 and \$225,000 for fiscal 2013.

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 transactions (less active markets).

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- Level 3—Inputs are unobservable estimates that are supported by little or no market activity and require the Company to develop its own assumptions about how market participants would price the assets or liabilities.

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

The following table summarizes the Company's assets carried at fair value measured on a recurring basis at June 30, 2015 and 2014 by valuation hierarchy (in thousands):

| Description | June 30, 2015 | | | |
|------------------------|------------------|-----------------------------|--------------------------------|----------------------------------|
| | Total Carrying | Quoted prices in | Significant other | Significant |
| | Value | active markets (Level 1) | observable inputs (Level 2) | unobservable inputs (Level 3) |
| Assets: | | | | |
| Cash equivalents | \$ 15,835 | \$ 15,835 | \$ — | \$ — |
| Marketable securities: | | | | |
| Corporate bonds | 9,414 | 7,413 | 2,001 | — |
| | <u>\$ 25,249</u> | <u>\$ 23,248</u> | <u>\$ 2,001</u> | <u>\$ —</u> |
| Description | June 30, 2014 | | | |
| | Total Carrying | Quoted prices in | Significant other | Significant |
| | Value | active markets (Level 1) | observable inputs (Level 2) | unobservable inputs (Level 3) |
| Assets: | | | | |
| Cash equivalents | \$ 14,260 | \$ 14,260 | \$ — | \$ — |
| Marketable securities: | | | | |
| Corporate bonds | 2,444 | 1,936 | 508 | — |
| Commercial paper | 500 | — | 500 | — |
| | <u>\$ 17,204</u> | <u>\$ 16,196</u> | <u>\$ 1,008</u> | <u>\$ —</u> |

8. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

| | June 30, | |
|----------------------|----------------|----------------|
| | 2015 | 2014 |
| Personnel costs | \$ 735 | \$ 952 |
| Professional fees | 384 | 249 |
| Clinical trial costs | 1,424 | 316 |
| Other | 28 | 7 |
| | <u>\$2,571</u> | <u>\$1,524</u> |

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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 2015, the Company did not sell any shares under this program. 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, 2015, 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.

In connection with a January 2011 equity offering, the Company issued warrants to purchase 552,500 shares of its common stock with an exercise price of \$5.00 per share and a five-year term.

Warrants to Purchase Common Shares

A total of 1,176,105 warrants were outstanding at June 30, 2015 and 2014 with a weighted average exercise price of \$3.67. At June 30, 2015, the remaining lives of these outstanding warrants ranged from 7 months to 2.1 years, representing a weighted-average term of 1.4 years.

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, 2015, a total of 6,341,255 shares of common stock were authorized for issuance under the 2008 Plan, of which 1,123,791 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, 2015.

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Options to purchase a total of 831,200 shares were granted during fiscal 2015 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 701,200 shares were issued to employees with ratable annual vesting over 4 years, options to purchase 90,000 shares were issued to non-executive directors with 1-year cliff vesting and options to purchase 40,000 shares were issued to a newly appointed non-executive director with ratable annual vesting over 3 years. A total of 542,434 options vested during fiscal 2015. 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. 110 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, 2015, 2014 and 2013 were as follows:

| | 2015 | 2014 | 2013 |
|-------------------------|---------------|---------------|---------------|
| Option life (in years) | 5.50 - 6.25 | 5.50 - 6.25 | 5.50 - 6.25 |
| Stock volatility | 79% - 93% | 94% - 96% | 95% - 98% |
| Risk-free interest rate | 1.70% - 2.00% | 1.70% - 1.99% | 0.81% - 0.98% |
| 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 following table summarizes information about stock options for the years ended June 30, 2015, 2014 and 2013 (in thousands except per share amounts):

| | 2015 | 2014 | 2013 |
|--|--------|--------|--------|
| Weighted-average grant date fair value per share | \$3.33 | \$2.48 | \$1.29 |
| Total cash received from exercise of stock options | 235 | 987 | — |
| Total intrinsic value of stock options exercised | 257 | 841 | — |

At June 30, 2015, there was approximately \$1.7 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 1.9 years.

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The following table provides a reconciliation of stock option activity under the 2008 Plan for fiscal 2015:

| | Number of options | Weighted Average Exercise Price | Weighted Average Remaining Contractual Life (in years) | Aggregate Intrinsic Value (in thousands) |
|--|----------------------|--|---|---|
| Outstanding at July 1, 2014 | 3,791,001 | \$ 3.08 | | |
| Granted | 831,200 | 4.48 | | |
| Exercised | (113,807) | 2.07 | | |
| Forfeited | (60,419) | 4.00 | | |
| Outstanding at June 30, 2015 | <u>4,447,975</u> | <u>\$ 3.36</u> | <u>6.23</u> | <u>\$ 3,165</u> |
| Outstanding at June 30, 2015—vested or unvested and expected to vest | <u>4,365,104</u> | <u>\$ 3.35</u> | <u>6.19</u> | <u>\$ 3,141</u> |
| Exercisable at June 30, 2015 | <u>2,894,183</u> | <u>\$ 3.03</u> | <u>5.09</u> | <u>\$ 2,767</u> |

Stock-Based Compensation Expense

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

| | Year Ended June 30, | | |
|-----------------------------------|---------------------|----------------|----------------|
| | 2015 | 2014 | 2013 |
| Compensation expense included in: | | | |
| Research and development | \$ 676 | \$ 516 | \$ 632 |
| General and administrative | 1,285 | 895 | 685 |
| | <u>\$1,961</u> | <u>\$1,411</u> | <u>\$1,317</u> |

11. Retirement Plans

The Company operates a defined contribution plan intended to qualify under Section 401(k) of the U.S. Internal Revenue Code. Participating U.S. employees may contribute 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 \$187,000 for fiscal 2015, \$189,000 for fiscal 2014 and \$231,000 for fiscal 2013 in connection with these retirement plans.

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12. Income Taxes

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

| | Year Ended June 30, | | |
|------------------------------|---------------------|----------------|----------------|
| | 2015 | 2014 | 2013 |
| U.S. operations: | | | |
| Current income tax expense | \$ 263 | \$ — | \$ — |
| Deferred income tax benefit | — | — | — |
| | <u>263</u> | <u>—</u> | <u>—</u> |
| Non-U.S. operations: | | | |
| Current income tax benefit | (167) | (130) | (117) |
| Deferred income tax benefit | — | — | — |
| | <u>(167)</u> | <u>(130)</u> | <u>(117)</u> |
| Income tax expense (benefit) | <u>\$ 96</u> | <u>\$(130)</u> | <u>\$(117)</u> |

The significant components of domestic income tax expense for the fiscal year ended June 30, 2015 included a provision for current income tax expense of \$2.8 million, less a tax benefit of operating loss carry forwards of \$2.5 million, resulting in a net domestic income tax expense of \$263,000, which represented federal alternative minimum tax based on taxable income for the tax year ended December 31, 2014. During the fiscal years ended June 30, 2015, 2014 and 2013, the Company also recognized a current income tax benefit of \$167,000, \$130,000 and \$117,000, respectively, related to foreign research and development tax credits earned by its U.K. subsidiary.

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

| | Year Ended June 30, | | |
|-----------------------------------|---------------------|-------------------|-------------------|
| | 2015 | 2014 | 2013 |
| U.S. operations | \$ 8,120 | \$(11,712) | \$(10,101) |
| Non-U.S. operations | (1,677) | (1,773) | (1,916) |
| Income (loss) before income taxes | <u>\$ 6,443</u> | <u>\$(13,485)</u> | <u>\$(12,017)</u> |

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

| | Year Ended June 30, | | |
|--|---------------------|----------------|----------------|
| | 2015 | 2014 | 2013 |
| Income tax expense (benefit) at statutory rate | \$ 2,191 | \$(4,585) | \$(4,086) |
| State income taxes, net of federal benefit | 435 | (693) | (569) |
| Non-U.S. income tax rate differential | 137 | 157 | 145 |
| Research and development tax credits | (313) | (169) | (134) |
| Capital loss expiration | 511 | — | — |
| Permanent items | 236 | 221 | 201 |
| Changes in valuation allowance | (3,572) | 4,619 | 2,939 |
| Expiration of state net operating loss carryforwards | — | 161 | 706 |
| Other, net | 471 | 159 | 681 |
| Income tax expense (benefit) | <u>\$ 96</u> | <u>\$(130)</u> | <u>\$(117)</u> |

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The significant components of the prior period rate reconciliations have been reclassified to conform to the current presentation. Specifically, \$221,000 and \$201,000 for the years ended June 30, 2014 and 2013, respectively, have been reclassified from Other, net to Permanent items.

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

| | June 30, | |
|---------------------------------------|---------------|---------------|
| | 2015 | 2014 |
| Deferred tax assets: | | |
| Net operating loss carryforwards | \$25,736 | \$30,123 |
| Deferred revenue | 2,194 | 2,194 |
| Stock-based compensation | 3,431 | 3,079 |
| Tax credits | 1,246 | 564 |
| Provision for loss on note receivable | — | 511 |
| Other | 110 | 88 |
| Total deferred tax assets | <u>32,717</u> | <u>36,559</u> |
| Deferred tax liabilities: | | |
| Intangible assets | 640 | 910 |
| Deferred tax assets, net | <u>32,077</u> | <u>35,649</u> |
| Valuation allowance | <u>32,077</u> | <u>35,649</u> |
| Total deferred tax liability | <u>\$ —</u> | <u>\$ —</u> |

The significant components of the prior period gross deferred tax assets have been reclassified to conform to the current presentation. Specifically, \$564,000 as of June 30, 2014 has been reclassified from Other to Tax credits.

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. Management assessed the available positive and negative evidence to estimate if sufficient taxable income will be generated to use the existing net deferred tax assets. Based on a weighting of the objectively verifiable negative evidence in the form of cumulative operating losses over the three year period ended June 30, 2015, management believes that it is not more-likely-than-not that the deferred tax assets will be realized and, accordingly, a full valuation allowance has been established. The valuation allowance decreased \$3.6 million during the fiscal year ended June 30, 2015, which is attributed to the consumption of \$2.5 million in tax benefits from domestic net operating loss carry forwards and a decrease of \$1.1 million attributed to re-measurement of the remaining net deferred tax assets which continue to bear a full valuation allowance. The valuation allowance increased \$4.6 million and \$2.9 million during the fiscal years ended June 30, 2014 and 2013, respectively, with such increases being attributed to the re-measurement of the net deferred tax assets at the respective year-end dates.

The Company has tax net operating loss and tax credit carry forwards in its individual tax jurisdictions. At June 30, 2015, the Company had U.S. federal net operating loss carry forwards of approximately \$55.1 million, which expire at various dates between calendar years 2023 and 2035. 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, 2015, the Company had state net operating loss carry forwards of approximately \$14.2 million, which expire between 2033 and 2035, as well as U.S. federal and state research and development tax credit carry forwards of approximately \$742,000, which expire at various dates between calendar years 2016 and 2035. In addition, at June 30, 2015 the Company had net operating loss carry forwards in the U.K. of £19.8 million (approximately \$31.1 million), which are not subject to any expiration dates.

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The Company's U.S. federal income tax returns for calendar years 2003 through 2014 remain subject to examination by the Internal Revenue Service. The Company's U.K. tax returns for fiscal years 2006 through 2014 remain subject to examination. The Australian tax returns for the Company's predecessor for fiscal years 2004 through 2008 remain subject to examination.

Through June 30, 2015, the Company had no unrecognized tax benefits in its consolidated statements of comprehensive income (loss) and no unrecognized tax benefits in its consolidated balance sheets as of June 30, 2015 or 2014.

As of June 30, 2015 and 2014, 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, 2015, the Company's total future minimum lease payments under non-cancellable operating leases were as follows (in thousands):

| <u>Fiscal Year:</u> | |
|---------------------|----------------|
| 2016 | \$ 482 |
| 2017 | 482 |
| 2018 | 437 |
| 2019 | 359 |
| 2020 | — |
| | <u>\$1,760</u> |

Rent expense related to the Company's real estate and other operating leases charged to operations was approximately \$494,000 for fiscal 2015, \$485,000 for fiscal 2014 and \$454,000 for fiscal 2013.

Litigation

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

14. Segment and Geographic Area Information

(a) Business Segment

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

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(b) Geographic Area Information

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

| | Revenues | | | Long-lived assets, net | |
|--------------|-----------------|----------------|----------------|------------------------|---------------|
| | 2015 | 2014 | 2013 | 2015 | 2014 |
| U.S. | \$26,465 | \$3,248 | \$1,873 | \$ 273 | \$ 248 |
| U.K. | 100 | 225 | 270 | 65 | 49 |
| Consolidated | <u>\$26,565</u> | <u>\$3,473</u> | <u>\$2,143</u> | <u>\$ 338</u> | <u>\$ 297</u> |

15. Quarterly Financial Data (unaudited)

The following table summarizes the quarterly results of operations for the years ended June 30, 2015 and 2014 (in thousands except per share amounts):

| | Fiscal Year 2015 | | | | |
|--|-----------------------------------|--|------------------------------------|------------------------------------|--------------------------|
| | First Quarter Ended September 30, | Second Quarter Ended December 31, 2014 | Third Quarter Ended March 31, 2015 | Fourth Quarter Ended June 30, 2015 | Year Ended June 30, 2015 |
| | 2014 (1) | | | | |
| Total revenues | \$ 25,307 | \$ 521 | \$ 328 | \$ 409 | \$ 26,565 |
| Operating income (loss) | 20,789 | (4,116) | (5,052) | (5,200) | 6,421 |
| Net income (loss) | 20,566 | (4,075) | (4,998) | (5,146) | 6,347 |
| Net income (loss) per share: | | | | | |
| Basic | \$ 0.70 | \$ (0.14) | \$ (0.17) | \$ (0.17) | \$ 0.22 |
| Diluted | \$ 0.67 | \$ (0.14) | \$ (0.17) | \$ (0.17) | \$ 0.21 |
| Weighted average common shares: | | | | | |
| Basic | 29,323 | 29,367 | 29,412 | 29,412 | 29,378 |
| Diluted | 30,765 | 29,367 | 29,412 | 29,412 | 30,584 |
| | | | | | |
| | Fiscal Year 2014 | | | | |
| | First Quarter Ended September 30, | Second Quarter Ended December 31, 2013 | Third Quarter Ended March 31, 2014 | Fourth Quarter Ended June 30, 2014 | Year Ended June 30, 2014 |
| | 2013 | | (2) | | |
| 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 |

(1) Results for the first quarter of fiscal 2015 included \$25.0 million of revenue as a result of the FDA approval of ILUVIEN under the Company's collaboration agreement with Alimera (see Note 3).

(2) 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).

PSIVIDA C ORP.

October 31, 2008

Dr. Paul Ashton
76 Page Road
Newton, MA 02460

Dear Dr. Ashton:

On behalf of the Board of Directors of pSivida Corp., a Delaware corporation (the “**Company**”), I am pleased to offer you, Paul Ashton (referred to herein as “**you**” or “**Executive**”) the following employment agreement pursuant to this letter (the “**Agreement**”):

1. **Employment:** The Company agrees to employ you, and you agree to serve in the Company’s employ, on and subject to the terms and conditions hereinafter set forth.

2. **Duties and Responsibilities:** You will hold the title of and will serve as (i) Managing Director an executive officer position with ultimate executive authority in the management team reporting directly to the Board of Directors of the Company, You agree to work full-time at your positions with the Company and to devote your entire working time, skill, attention and best efforts to the discharge of your duties and responsibilities and to promoting the best interests of the Company. Participation in charitable and professional organizations is allowed so long as such activities do not interfere with your duties and responsibilities or compete with the business and activities of the Company, as further set forth in that certain Non-Competition Agreement, dated October 3, 2005, between you and the Company (the “**Non-Competition Agreement**”).

3. **Term:** The term of your employment will be from the date hereof until such time as your employment is terminated by mutual consent of the parties or in accordance with, and subject to the obligations set forth in, Section 8.

4. **Compensation:** You shall receive compensation commensurate with that received by the other Executive Directors of the Company, including without limitation the following initial terms:

(a) *Base Salary* : Your base salary as of the date hereof will be Three Hundred Thousand Dollars (\$300,000) per year (the “**Base Salary**”), payable in accordance with the policies and procedures of the Company or the Subsidiary, as the case may be, as in effect from time to time. The Company will review your Base Salary on an annual basis and may elect to increase (but not decrease) it pursuant to such review.

(b) *Bonus*: In addition to your base salary, you will be eligible to receive an annual cash bonus in an amount to be determined by the Company’s Board of Directors (the “**Bonus**”).

(c) *Stock Options*: You will be eligible to participate in the Company's Employee Share Option Plan in accordance with the terms and guidelines thereof. The issuance of options and shares thereunder shall be subject to the approval of the Board of Directors or shareholders of the Company. Notwithstanding the foregoing, the Company agrees that you will receive grants of stock options commensurate with those received by other Executive Directors of the Company. In addition, as soon as practicable after the execution of this Agreement, you will be granted stock options to purchase 500,000 of the Company's ordinary shares at an exercise price of 0.92 Australian dollars per share. Except as provided in Section 8(c), these options shall vest in accordance with the vesting schedule described below, subject to the Company achieving certain milestones that the parties shall determine by mutual agreement, and once vested shall be exercisable (unless earlier terminated) until December 31, 2010.

| <u>Number of Ordinary Shares</u> | <u>Vesting Schedule</u> |
|----------------------------------|-------------------------|
| 250,000 | December 31, 2006 |
| 250,000 | December 31, 2007 |

The initial terms set forth above shall be subject to review and adjustment on an annual basis to ensure that your overall compensation package is commensurate with the compensation package, including base salary, bonus and stock options grants, of other Executive Directors of the Company.

5. **Expenses**: You shall be reimbursed for reasonable business-related expenses in accordance with applicable policies and procedures of the Company or the Subsidiary, as the case may be, as in effect from time to time.

6. **Vacation, Fringe Benefits and Indemnification**: You will be entitled to four (4) weeks' paid vacation per calendar year and fringe benefits in accordance with the policies of the Subsidiary, which benefits shall include (i) participation in any employee pension benefit plan within the meaning of Section 3(2) of the Employee Retirement Income Security Act of 1974, as amended ("**ERISA**"), including the 401(k) savings plan adopted or maintained by the Subsidiary, made generally available to executives of the Subsidiary and (ii) participation in any health insurance, disability insurance, group life insurance or any other employee welfare benefit plan within the meaning of Section 3(1) of ERISA made generally available to executives of the Subsidiary. The Company and the Subsidiary will provide you with indemnification to the fullest extent permitted under the applicable Certificate of Incorporation, By-Laws, Constitution or other governing documents of the Company or the Subsidiary, as the case may be.

7. **Taxes**: All payments made to you pursuant to this Agreement or otherwise in connection with your employment shall be subject to the usual withholding practices of the Company or the Subsidiary, as the case may be, and will be made in compliance with existing federal and state requirements regarding the withholding of taxes.

8. **Termination and Severance Benefits**: Either you or the Company may at any time terminate your employment with the Company and the Subsidiary after giving two weeks' notice to the other party, provided that the parties discharge their respective obligations as set forth in this Section 8 and elsewhere in this Agreement.

(a) *Termination Upon Death or Disability*: If you cease to be an employee of the Company and the Subsidiary as a result of death or Disability, the Company will have no further obligation or liability to you hereunder other than for (i) Base Salary earned and unpaid at the date of termination, (ii) Bonus earned (*i.e.* all targets or other requirements necessary to receive the Bonus have been met) but unpaid at the date of termination, if any, and (iii) compensation for accrued vacation, if any (the “**Accrued Obligations**”). However, nothing in this Agreement shall adversely affect your rights or those of your family or beneficiaries under any applicable plans, policies or arrangements of the Company or the Subsidiary.

(b) *Termination by the Company for Cause or by You Without Good Cause*: If the Company terminates your employment for Cause (as defined in Section 8(d)) or if you terminate your employment other than for Good Cause (as defined in Section 8(d)), the Company and the Subsidiary shall have no further obligation or liability to you hereunder other than for payment of the Accrued Obligations.

(c) *Termination by the Company Without Cause or by You for Good Cause*: If the Company terminates your employment other than for Cause, or you terminate your employment for Good Cause, then, in addition to payment of the Accrued Obligations, you shall receive the following:

(i) The Company will pay you, within thirty (30) days following the later of (a) the termination of employment, or (b) the date you deliver to the Company a release of claims in accordance with Section 8(e), a lump-sum cash amount equal to the sum of (x) an amount equal to one year’s then-current Base Salary plus (y) a pro rata portion (based on the number of weeks worked in the year of termination) of the Maximum Bonus (as defined in Section 8(d)) that would otherwise be payable to you in the year that the termination occurs, if any (the “**Severance Payment**”). The parties acknowledge and agree that the obligation to pay the Severance Payment is solely that of the Company and that none of the directors or officers of the Company or the Subsidiary shall have any personal liability with respect thereto. You understand that payments to be made to you pursuant to Section 3(c) of the Non-Competition Agreement shall be offset against (and consequently reduced by) any payments made to you hereunder, on a dollar-for-dollar basis.

(ii) The Company will continue, for a period of twelve (12) months after termination, to provide you with medical benefits under (as the case may be) the Company’s or the Subsidiary’s group medical plan, life insurance arrangements and disability arrangements equivalent to those provided to executive-level employees. To the extent that the Company is unable to provide such benefits to you under its existing plans and arrangements, the Company will pay you cash amounts equal to the cost the Company or the Subsidiary would have incurred to provide those benefits.

(iii) Notwithstanding the terms of any awards of stock options or restricted stock, all options to purchase Company stock held by you will automatically and immediately vest and become exercisable upon such termination and remain exercisable for a

period of six (6) months thereafter (except that incentive stock options shall be exercisable for only three (3) months thereafter), and all restricted stock held by you pursuant to the restricted stock plans or arrangements of the Company shall automatically and immediately vest and no longer be subject to forfeiture.

(iv) Notwithstanding any other provision of this Agreement, should any benefit payment that is described in this subsection (c) be subject to Section 409A of the Internal Revenue Code of 1986 as amended, the Company is authorized to make payments in a manner that complies with the requirements of Section 409A. However, in the event that one or more provisions of Section 409A is violated, the Company shall not be responsible for the payment of any tax liability, penalties or interest that are imposed upon you as a result of said violation, nor shall the Company be under any obligation to make you whole or otherwise compensate you for such additional liability.

(d) *Definitions:* The following terms shall have the meanings set forth below:

“Cause” shall mean, in respect of the termination of your employment by the Company, (a) willful malfeasance, gross misconduct or gross negligence in your performance of the duties of your position that has a material adverse effect on the Company or the Subsidiary, (b) the material breach by you of this Agreement or of Sections 3(a), 4, 5 or 6 of the Non-Competition Agreement, (c) fraud or dishonesty by you with respect to the Company, the Subsidiary or your employment, (d) your conviction of any crime that involves deception, fraud or moral turpitude or any felony (including, in each case, entry of a guilty or nolo contendere plea and excluding traffic violations or similar minor offenses), or (e) your repeated or prolonged absence from work other than for illness, Disability or authorized vacation. The Company may treat a termination of your employment as termination for Cause only after (i) giving you written notice of the intention to terminate for Cause, including a description of the conduct that the Company believes constitutes the basis for a Cause termination, and of your right to a hearing by the Company’s Board of Directors, (ii) in the event of a termination under clause (a), (b) or (e) above, providing you with a 30-day period in which to cure the conduct giving rise to the Company’s notice of a Cause termination, unless, with respect to clause (a) and (b) above, (I) in the Company’s reasonable judgment, protective action inconsistent with such cure period (e.g., immediate termination) is necessary to avoid harm to the Company of the Subsidiary or (II) the Company reasonably determines that your conduct is egregious, in which event, the Company may shorten the cure period or terminate your employment immediately (subject to the requirements set forth in clauses (iii) and (iv) below), (iii) at least 30 days after giving the notice, conducting a hearing by the Board at which you may be represented by counsel, and (iv) giving you written notice of the results of the hearing and the factual basis for the Board’s determination of Cause, which shall require a vote of a majority of the members of the Board then in office other than yourself. Except in connection with your opportunity, if any, to cure the conduct giving rise to the Company’s notice of termination for Cause as set forth in clause (ii) above, nothing in the foregoing sentence shall prevent the Company from terminating your employment pending any determination of Cause as set forth in the foregoing sentence, any such determination shall be retroactive to the date of termination, and the Company shall not be obligated to compensate you hereunder for the period from such termination until such time, if any, as the Company’s Board of Directors determines that such termination was not for Cause. Notwithstanding the foregoing, Cause shall not include an act or failure to act based on authority

given pursuant to a resolution duly adopted by the Company's Board of Directors or based on the advice of the Company's General Counsel or willful failure due to incapacity resulting from Disability or any actual or anticipated failure after you provide written notice of a termination for Good Cause.

"Disability" shall mean physical or mental incapacity of a nature which prevents you, in the professional judgment of your physician or, at the Company's election, a board-certified physician mutually agreed upon by the Company and you, from performing the essential functions of your position with the Company or the Subsidiary with or without a reasonable accommodation for a period of ninety (90) consecutive days or one hundred eighty (180) days during any consecutive 12-month period.

"Good Cause" shall mean, in respect of the termination of your employment by you, (i) failure by the Company to maintain you in the position of Managing Director (ii) a material diminution of your duties and responsibilities in such position or a material diminution of your authority with respect to such position, as described in Section 2 hereof, excluding for this purpose an isolated, insubstantial and inadvertent action not taken in bad faith and which is remedied by the Company promptly after receipt of written notice thereof given by you, (iii) a breach by the Company of any material term of this Agreement or the Non-Competition Agreement, or (iv) relocation of your principal place of work to a location more than thirty (30) miles from your address as set forth in Section 10 below without your prior consent. You may treat a resignation from employment as termination for Good Cause only after (a) giving the Company written notice of the intention to terminate for Good Cause, (b) providing the Company at least 30 days after receipt of such notice to cure the conduct or action giving rise to Good Cause, unless, with respect to clause (i) and (ii), you reasonably determine that the Company's conduct is egregious and has resulted in significant, irreparable harm to you, in which event, you may shorten the cure period or terminate your employment immediately, and (c) if applicable, the Company has failed to cure the action or conduct giving rise to Good Cause during the 30 day cure period. Notwithstanding anything herein to the contrary, a change in your title from Managing Director to Chief Executive Officer shall not constitute Good Cause.

"Maximum Bonus" shall mean your bonus for the year in which termination occurs, calculated on the assumption that all targets and formulas for determining such bonus have been met. If no such targets or formulas have been established, then the Maximum Bonus shall be the total bonus you were eligible to receive during the preceding fiscal year, calculated on the assumption that all targets and formulas for determining such bonus have been met. The Maximum Bonus (A) payable upon termination shall be reduced by any bonus payments relating to services performed in the year in which termination occurs that (1) have already been paid to you as of the date of termination, (2) are payable to you as an Accrued Obligation hereunder, or (3) could have been earned during the year in which termination occurs but that were not so earned because of the failure to achieve targets or formulas which are no longer able to be achieved, and (B) shall not include any bonus paid or payable in the year in which termination occurs to the extent such payment represents payment for services rendered in a prior year. By way of illustration and not limitation, if you are paid a bonus on February 18, 2008 relating to your performance during all or part of the 2007 calendar year and you are later terminated without Cause on August 31, 2008, the Maximum Bonus payment due upon

termination will not be reduced by the bonus payment received on February 15, 2008, nor shall the amount of the February 15, 2008 bonus be included as part of the Maximum Bonus, because such payment relates to service rendered in the year preceding the year in which termination occurs. If you are paid a bonus on July 15, 2008 relating to your performance during the first and/or second quarter of the 2008 calendar year and are later terminated without Cause on August 31, 2008, the Maximum Bonus payment due upon termination will be reduced by the bonus payment received on July 15, 2008 because such payment relates to services rendered in the year in which termination occurs, and if you do not receive a bonus for the first and/or second quarter of the 2008 calendar year because quarterly performance objectives had not been achieved, the amount of such bonus that could have been earned shall not be included in determining the Maximum Bonus.

(e) *Release* : Notwithstanding anything to the contrary contained in this Agreement, in order for you to be eligible for any severance benefits under this Section 8, you must execute and deliver to the Company (and not revoke within seven (7) days of executing) the release of claims in the attached as Exhibit A hereto.

9. Non-Disparagement: You will not at any time during or after the term of your employment hereunder make any statement to any person, including, without limitation, employees, customers, suppliers or competitors of the Company or the Subsidiary, that is derogatory or negative about the Company or the Subsidiary or their respective affiliates or any statement regarding the future plans of the Company. This Section 9 will not apply to any statements made by you (i) in support of any claim or defense asserted by you in any mediation, arbitration or litigation process or proceeding between you and the Company or the Subsidiary and (ii) made only within the specific forum (i.e. arbitral tribunal, courtroom) in which such mediation, arbitration or litigation is taking place.

10. Notices: Any notices required or permitted to be sent under this Agreement shall be effective when delivered by hand or mailed by registered or certified mail, return receipt requested, and addressed as follows:

If to the Company:

pSivida Corp.
400 Pleasant Street
Watertown, MA 02472
Attn: General Counsel, pSivida Corp.

With a copy to:

Ropes & Gray One International Place Boston, MA 02110-2624 Attn: Mary Weber

If to Executive:

Paul Ashton
76 Page Road
Newton, MA 12460

Either party may change its address for receiving notices by giving notice to the other party.

11. **Waiver:** The failure of either party to enforce any of the provisions of this Agreement shall not be deemed a waiver thereof. No provision of this Agreement shall be deemed to have been waived or modified unless such waiver or modification shall be in writing and signed by both parties hereto.

12. **Arbitration:** All controversies and disputes between or among any of the parties hereto arising out of or in connection with the interpretation, performance or enforcement of this Agreement, whether based on federal, state or foreign law and whether grounded in common law or statutory law, shall be settled exclusively by arbitration conducted as provided herein, and otherwise in accordance with the National Employment Rules of the American Arbitration Association.

(a) *Procedure* : The arbitration shall be administered by the American Arbitration Association, as follows:

(i) the arbitration shall be conducted in Boston, Massachusetts by a panel of three (3) arbitrators, jointly selected by the parties, except that if the parties are unable to agree on all three arbitrators within fifteen (15) days after demand for arbitration has been made (or such later time as the parties may agree), the arbitration shall be conducted by three (3) arbitrators as are selected in accordance with the applicable rules of the American Arbitration Association;

(ii) final decision shall be by a majority of the arbitrators, which arbitrators shall prepare and deliver a written reasoned award. Judgment upon the award rendered by the arbitrators may be entered in any court having jurisdiction thereof; and

(iii) all costs and fees relating to the arbitration shall be borne by the losing party, except that if the arbitrators determine that any party has prevailed in part and lost in part, the costs and fees relating to the arbitration shall be allocated between the parties as equitably determined by the arbitrators.

(b) *Refusal to Arbitrate* : The failure or refusal of any party to submit to arbitration shall be deemed a breach of this Agreement. If a party seeks and secures judicial intervention requiring enforcement of this Section 12, such party shall be entitled to recover from the other party in such judicial proceeding all costs and expenses, including reasonable attorneys' fees, that it was thereby required to incur.

(c) *Sole Procedure*: The procedures specified in this Section 12 shall be the sole and exclusive procedures for the resolution of disputes between the parties arising out of or relating to this Agreement; provided, however, that a party, without prejudice to the above procedures, may seek a preliminary injunction or other equitable relief if in its judgment such

action is necessary to avoid irreparable damage or to preserve the status quo. Despite such action the parties will continue to participate in good faith in the procedures specified in this Section 12.

13. No Duty to Mitigate; No Offset: Benefits payable under this Agreement as a result of termination of your employment will be considered severance pay in consideration of your past service and your continued service or obligations from and after the date of execution of this Agreement, and your entitlement thereto will neither be governed by any duty to mitigate your damages by seeking further employment or offset by any compensation you may receive from other employment following the date of your termination of employment. Notwithstanding the foregoing, you agree that the Company may cease its payment for, or provision of, one or more of the continued benefits under Section 8(c)(ii) during the twelve month period following the date of your termination from employment to the extent that you obtain comparable benefit coverage with another employer. This provision shall be applied in an *ad seriatim* basis so that the Company may only cease payment of those comparable benefits that you obtain with another employer. You agree to notify the Company as soon as practicable in the event that you obtain comparable coverage or benefits during the period noted above and you acknowledge that the Company's obligation to continue payment for, or provision of, benefits shall cease from and after the date you obtain comparable coverage.

14. Successors: This agreement shall inure to and be binding upon the Company's successors and assigns. The Company shall require any successor to all or substantially all of the business or assets of the Company by sale, merger or consolidation (where the Company is not the surviving corporation), lease or otherwise, to expressly assume this Agreement. This Agreement is not otherwise assignable by the Company or you.

15. Rights of Survivors: If you die after becoming entitled to benefits under this Agreement following termination of employment but before all such benefits have been provided, (a) all unpaid cash amounts will be paid to your designated beneficiary or, if no such beneficiary has been designated, to your estate, (b) all applicable insurance coverage will be provided to your family as though you had continued to live, to the extent permitted under the plans, and (c) any stock options that become exercisable under Section 8 will be exercisable by the beneficiary or, if none, the estate.

16. Entire Agreement; Termination: This Agreement together with the Non-Competition Agreement shall constitute the entire agreement of the parties pertaining to this subject matter and shall supersede all prior agreements, representations and understandings of the parties with respect to such subject matter. Any and all employment, severance, compensation, or other agreements and arrangements between the Executive and the Company or the Subsidiary, whether dating from before or after the Company's acquisition of the Subsidiary (including, without limitation, the Severance Agreement, dated February 20, 2004, between the executive and the Subsidiary, as amended, and the Amended and Restated Change of Control Agreement, dated August 17, 2004, between the Executive and the Subsidiary) are hereby terminated and of no further force and effect, and no parties shall have any further rights, obligations or liabilities thereunder; provided, however, that the Retention Agreement, dated September 29, 2005, between the Executive, the Subsidiary and the Company shall remain in full force and effect. The parties hereto acknowledge and agree that this Agreement satisfies the Company's obligations under Section 2(b) of the Non-Competition Agreement.

17. **Partial Invalidity.** If any provision in this Agreement is held by a court of competent jurisdiction to be invalid, void or unenforceable, the remaining s nevertheless shall continue in full force and effect without being impaired or invalidated in any manner.

18. **Counterparts:** This Agreement may be executed in several counterparts, each of which shall be deemed to be an original but all of which together shall constitute one and the same instrument.

19. **Governing Law.** This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts. The parties agree that any action to enforce the terms of this Agreement shall be commenced in, and subject to the exclusive jurisdiction of, Suffolk County, Boston, Massachusetts.

[Signature Page to Immediately Follow]

IN WITNESS WHEREOF , the parties hereto have duly executed this Agreement the day and year first above written.

PSIVIDA, Corp.

By: /s/ David Mazzo

Name: David J. Mazzo, Ph.D.

Title: Chairman of the Board of Directors

EXECUTIVE

By: /s/ Paul Ashton

Name: Paul Ashton

EXHIBIT A

RELEASE OF CLAIMS

FOR AND IN CONSIDERATION OF the benefits to be provided me in connection with the termination of my employment, as set forth in the Employment Agreement between myself and pSivida Corp. (the “**Company**”) dated as of _____, 2005 (the “**Agreement**”), which benefits are subject to my signing of this Release of Claims and to which I am not otherwise entitled, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, I, on my own behalf and on behalf of my heirs, executors, administrators, beneficiaries, representatives and assigns, and all others connected with me, hereby release and forever discharge the Company, the Subsidiary (as defined in the Agreement), its other subsidiaries and other affiliates and all of their respective past, present and future officers, directors, trustees, shareholders, employees, agents, general and limited partners, members, managers, joint venturers, representatives, successors and assigns, and all others connected with any of them, both individually and in their official capacities, from any and all causes of action, rights and claims of any type or description, known or unknown, which I have had in the past, now have, or might now have, through the date of my signing of this Release of Claims, in any way resulting from, arising out of or connected with my employment by the Company or the Subsidiary or any of its other subsidiaries or other affiliates or the termination of that employment or pursuant to any federal, state or local law, regulation or other requirement (including without limitation Title VII of the Civil Rights Act of 1964, the Age Discrimination in Employment Act, the Americans with Disabilities Act, and the fair employment practices laws of the state or states in which I have been employed by the Company or any of the subsidiaries or other affiliates, each as amended from time to time).

Excluded from the scope of this Release of Claims is (i) any claim arising under the terms of the Agreement and (ii) any right of indemnification or contribution that I have pursuant to the Certificate of Incorporation, Constitution, By-Laws or other governing documents of the Company or the Subsidiary.

In signing this Release of Claims, I acknowledge my understanding that I may not sign it prior to the termination of my employment, but that I may consider the terms of this Release of Claims for up to twenty-one (21) days (or such longer period as the Company may specify) from the later of the date my employment with the Company terminates or the date I receive this Release of Claims. I also acknowledge that I am advised by the Company and its affiliates to seek the advice of an attorney prior to signing this Release of Claims; that I have had sufficient time to consider this Release of Claims and to consult with an attorney, if I wished to do so, or to consult with any other person of my choosing before signing; and that I am signing this Release of Claims voluntarily and with a full understanding of its terms.

I further acknowledge that, in signing this Release of Claims, I have not relied on any promises or representations, express or implied, that are not set forth expressly in the Agreement. I understand that I may revoke this Release of Claims at any time within seven (7) days of the date of my signing by written notice to the General Counsel of the Company and that this Release of Claims will take effect only upon the expiration of such seven-day revocation period and only if I have not timely revoked it.

Intending to be legally bound, I have signed this Release of Claims under seal as of the date written below.

Signature: _____

Name (please print): _____

Date Signed: _____

pSivida Corp.
2008 INCENTIVE PLAN
(as amended in 2009)

1. DEFINED TERMS

Exhibit A, which is incorporated by reference, defines the terms used in the Plan and sets forth certain operational rules related to those terms.

2. PURPOSE

The Plan has been established to advance the interests of the Company by providing for the grant to Participants of Stock-based and other incentive Awards.

3. ADMINISTRATION

The Administrator has discretionary authority, subject only to the express provisions of the Plan, to interpret the Plan; determine eligibility for and grant Awards; determine, modify or waive the terms and conditions of any Award; prescribe forms, rules and procedures; and otherwise do all things necessary to carry out the purposes of the Plan. In the case of any Award intended to be eligible for the performance-based compensation exception under Section 162(m), the Administrator will exercise its discretion consistent with qualifying the Award for that exception. Determinations of the Administrator made under the Plan will be conclusive and will bind all parties.

4. LIMITS ON AWARDS UNDER THE PLAN

(a) **Number of Shares**. The maximum number of shares of Stock that may be delivered in satisfaction of Awards under the Plan shall be: (i) 2,750,000, plus (ii) as of the first day of each of fiscal 2011 through fiscal 2018, inclusive, an additional number of shares equal to the least of (x) 750,000 shares of Stock, (y) 4% of the number of then outstanding shares of Stock, and (z) such lesser number as determined by the Administrator. Up to the maximum number of shares of Stock available to be delivered under the Plan may be delivered upon the exercise or other satisfaction of ISOs. The number of shares of Stock delivered in satisfaction of Awards shall, for purposes of the preceding sentences, be determined net of shares of Stock withheld by the Company in payment of the exercise price of the Award or in satisfaction of tax withholding requirements with respect to the Award. The limits set forth in this Section 4(a) shall be construed to comply with Section 422. To the extent consistent with the requirements of Section 422 and with other applicable legal requirements (including applicable stock exchange requirements), Stock issued under awards of an acquired or reorganized company that are converted, replaced, or adjusted in connection with the acquisition or reorganization shall not reduce the number of shares available for Awards under the Plan.

(b) **Type of Shares**. Stock delivered by the Company under the Plan may be authorized but unissued Stock or previously issued Stock acquired by the Company. No fractional shares of Stock will be delivered under the Plan.

(c) **Section 162(m) Limits**. The maximum number of shares of Stock subject to Awards granted to any person in any calendar year will be 1,062,500 shares. The maximum amount payable to any person in any calendar year under Cash Awards will be \$1,000,000. The foregoing provisions will be construed in a manner consistent with Section 162(m).

5. ELIGIBILITY AND PARTICIPATION

The Administrator will select Participants from among those key Employees and directors of, and consultants and advisors to, the Company or its Affiliates who, in the opinion of the Administrator, are in a position to make a significant contribution to the success of the Company and its Affiliates; *provided*, that, subject to such express exceptions, if any, as the Administrator may establish, eligibility shall be further limited to those persons as to whom the use of a Form S-8 registration statement is permissible. Eligibility for ISOs is limited to employees of the Company or of a "parent corporation" or "subsidiary corporation" of the Company as those terms are defined in Section 424 of the Code.

6. RULES APPLICABLE TO AWARDS

(a) All Awards

(1) **Award Provisions**. The Administrator will determine the terms of all Awards, subject to the limitations provided herein. By accepting (or, under such rules as the Administrator may prescribe, being deemed to have accepted) an Award, the Participant agrees to the terms of the Award and the Plan. Notwithstanding any provision of this Plan to the contrary, awards of an acquired or reorganized company that are converted, replaced or adjusted in connection with the acquisition or reorganization may contain terms and conditions that are inconsistent with the terms and conditions specified herein, as determined by the Administrator.

(2) **Term of Plan**. No Awards may be made after March 30, 2018, but previously granted Awards may continue beyond that date in accordance with their terms.

(3) **Transferability**. Neither ISOs nor, except as the Administrator otherwise expressly provides in accordance with the second sentence of this Section 6(a)(3), other Awards may be transferred other than by will or by the laws of descent and distribution, and during a Participant's lifetime ISOs (and, except as the Administrator otherwise expressly provides in accordance with the second sentence of this Section 6(a)(3), other Awards requiring exercise) may be exercised only by the Participant. The Administrator may permit Awards other than ISOs to be transferred by gift, subject to such limitations as the Administrator may impose.

(4) **Vesting, Etc.** The Administrator may determine the time or times at which an Award will vest or become exercisable and the terms on which an Award requiring exercise will remain exercisable. Without limiting the foregoing, the Administrator may at any time accelerate the vesting or exercisability of an Award, regardless of any adverse or potentially adverse tax consequences resulting from such acceleration. Unless the Administrator expressly provides otherwise, however, the following rules will apply:

(A) immediately upon the cessation of the Participant's Employment, each Award requiring exercise that is then held by the Participant or by the Participant's permitted transferees, if any, will, except as otherwise provided in (B) or (C) below, cease to be exercisable and will terminate, and all other Awards that are then held by the Participant or by the Participant's permitted transferees, if any, to the extent not already vested will be forfeited;

(B) subject to (C) and (D) below, all Stock Options and SARs held by the Participant or the Participant's permitted transferees, if any, immediately prior to the cessation of the Participant's Employment, to the extent then exercisable, will remain exercisable for the lesser of (i) a period of three months or (ii) the period ending on the latest date on which such Stock Option or SAR could have been exercised without regard to this Section 6(a)(4), and will thereupon terminate;

(C) all Stock Options and SARs held by a Participant or the Participant's permitted transferees, if any, immediately prior to the Participant's death, to the extent then exercisable, will remain exercisable for the lesser of (i) the one year period ending with the first anniversary of the Participant's death or (ii) the period ending on the latest date on which such Stock Option or SAR could have been exercised without regard to this Section 6(a)(4), and will thereupon terminate; and

(D) all Stock Options and SARs held by a Participant or the Participant's permitted transferees, if any, immediately prior to the cessation of the Participant's Employment will immediately terminate upon such cessation if the Administrator in its sole discretion determines that such cessation of Employment has resulted for reasons which cast such discredit on the Participant as to justify immediate termination of the Award.

(5) **Taxes**. The delivery or vesting of cash or Stock under an Award shall be conditioned on full satisfaction by the Participant of all applicable tax withholding requirements. The Administrator will make such provision for the withholding of taxes as it deems necessary. The Administrator may, but need not, hold back shares of Stock from an Award or permit a Participant to tender previously owned shares of Stock in satisfaction of tax withholding requirements (but not in excess of the minimum withholding required by law).

(6) **Dividend Equivalents, Etc.** The Administrator may provide for the payment of amounts in lieu of cash dividends or other cash distributions with respect to Stock subject to an Award. Any entitlement to dividend equivalents or similar entitlements shall be established and administered consistent either with exemption from, or compliance with, the requirements of Section 409A.

(7) Rights Limited. Nothing in the Plan will be construed as giving any person the right to continued employment or service with the Company or its Affiliates, or any rights as a stockholder (including, but not limited to, the right to participate in a pro rata offer by the Company to holders of shares of Stock) except as to shares of Stock actually issued under the Plan. The loss of existing or potential profit in Awards will not constitute an element of damages in the event of termination of Employment for any reason, even if the termination is in violation of an obligation of the Company or any Affiliate to the Participant.

(8) Section 162(m). This Section 6(a)(8) applies to any Performance Award intended to qualify as performance-based for the purposes of Section 162(m) other than a Stock Option or SAR. In the case of any Performance Award to which this Section 6(a)(8) applies, the Plan and such Award will be construed to the maximum extent permitted by law in a manner consistent with qualifying the Award for such exception. With respect to such Performance Awards, the Administrator will preestablish, in writing, one or more specific Performance Criteria no later than 90 days after the commencement of the period of service to which the performance relates (or at such earlier time as is required to qualify the Award as performance-based under Section 162(m)). Prior to grant, vesting or payment of the Performance Award, as the case may be, the Administrator will certify whether the applicable Performance Criteria have been attained and such determination will be final and conclusive. No Performance Award to which this Section 6(a)(8) applies may be granted after the first meeting of the stockholders of the Company held in 2013 until the listed performance measures set forth in the definition of "Performance Criteria" (as originally approved or as subsequently amended) have been resubmitted to and reapproved by the stockholders of the Company in accordance with the requirements of Section 162(m) of the Code, unless such grant is made contingent upon such approval.

(9) Coordination with Other Plans. Awards under the Plan may be granted in tandem with, or in satisfaction of or substitution for, other Awards under the Plan or awards made under other compensatory plans or programs of the Company or its Affiliates. For example, but without limiting the generality of the foregoing, awards under other compensatory plans or programs of the Company or its Affiliates may be settled in Stock (including, without limitation, Unrestricted Stock) if the Administrator so determines, in which case the shares delivered shall be treated as awarded under the Plan (and shall reduce the number of shares thereafter available under the Plan in accordance with the rules set forth in Section 4). In any case where an award is made under another plan or program of the Company or its Affiliates and such award is intended to qualify for the performance-based compensation exception under Section 162(m), and such award is settled by the delivery of Stock or another Award under the Plan, the applicable Section 162(m) limitations under both the other plan or program and under the Plan shall be applied to the Plan as necessary (as determined by the Administrator) to preserve the availability of the Section 162(m) performance-based compensation exception with respect thereto.

(10) Section 409A. Each Award shall contain such terms as the Administrator determines, and shall be construed and administered, such that the Award either (i) qualifies for an exemption from the requirements of Section 409A, or (ii) satisfies such requirements.

(11) Certain Requirements of Corporate Law. Awards shall be granted and administered consistent with the requirements of applicable Delaware law relating to the issuance of stock and the consideration to be received therefor, and with the applicable requirements of the stock exchanges or other trading systems on which the Stock is listed or entered for trading, in each case as determined by the Administrator.

(b) Awards Requiring Exercise

(1) Time And Manner Of Exercise. Unless the Administrator expressly provides otherwise, an Award requiring exercise by the holder will not be deemed to have been exercised until the Administrator receives a notice of exercise (in form acceptable to the Administrator) signed by the appropriate person and accompanied by any payment required under the Award. If the Award is exercised by any person other than the Participant, the Administrator may require satisfactory evidence that the person exercising the Award has the right to do so.

(2) Exercise Price. The exercise price (or the base value from which appreciation is to be measured) of each Award requiring exercise shall be 100% (in the case of an ISO granted to a ten-percent shareholder within the meaning of subsection (b)(6) of Section 422, 110%) of the fair market value of the Stock subject to the Award, determined as of the date of grant, or such higher amount as the Administrator may determine in connection with the grant. No such Award, once granted, may be repriced without stockholder approval. Fair market value shall be determined by the Administrator consistent with the applicable requirements of Section 422 and Section 409A.

(3) **Payment Of Exercise Price**. Where the exercise of an Award is to be accompanied by payment, payment of the exercise price shall be by cash or check acceptable to the Administrator, or, if so permitted by the Administrator and if legally permissible, (i) through the delivery of previously acquired unrestricted shares of Stock (subject to such minimum holding period and other requirements, if any, as the Administrator may impose) that have a fair market value equal to the exercise price, (ii) through a broker-assisted exercise program acceptable to the Administrator, (iii) by other means acceptable to the Administrator, or (iv) by any combination of the foregoing permissible forms of payment. The delivery of shares in payment of the exercise price under clause (i) above may be accomplished either by actual delivery or by constructive delivery through attestation of ownership, subject to such rules as the Administrator may prescribe.

(4) **Maximum Term**. Awards requiring exercise will have a maximum term not to exceed ten (10) years from the date of grant.

7. EFFECT OF CERTAIN TRANSACTIONS

(a) **Mergers, etc.** Except as otherwise provided in an Award, the following provisions shall apply in the event of a Covered Transaction:

(1) **Assumption or Substitution**. If the Covered Transaction is one in which there is an acquiring or surviving entity, the Administrator may provide for the assumption of some or all outstanding Awards or for the grant of new awards in substitution therefor by the acquiror or survivor or an affiliate of the acquiror or survivor.

(2) **Cash-Out of Awards**. If the Covered Transaction is one in which holders of Stock will receive upon consummation a payment (whether cash, non-cash or a combination of the foregoing), the Administrator may provide for payment (a “cash-out”), with respect to some or all Awards or any portion thereof, equal in the case of each affected Award or portion thereof to the excess, if any, of (A) the fair market value of one share of Stock (as determined by the Administrator in its reasonable discretion) times the number of shares of Stock subject to the Award or such portion, over (B) the aggregate exercise or purchase price, if any, under the Award or such portion (in the case of an SAR, the aggregate base value above which appreciation is measured), in each case on such payment terms (which need not be the same as the terms of payment to holders of Stock) and other terms, and subject to such conditions, as the Administrator determines; *provided*, that the Administrator shall not exercise its discretion under this Section 7(a)(2) with respect to an Award or portion thereof providing for “nonqualified deferred compensation” subject to Section 409A in a manner that would constitute an extension or acceleration of, or other change in, payment terms if such change would be inconsistent with the applicable requirements of Section 409A.

(3) **Acceleration of Certain Awards**. If an Award will not be assumed, substituted for or cashed out in connection with a Covered Transaction (whether or not there is an acquiring or surviving entity), such Award will become fully exercisable, and the delivery of any shares of Stock remaining deliverable under each outstanding Award of Stock Units (including Restricted Stock Units and Performance Awards to the extent consisting of Stock Units) will be accelerated and such shares will be delivered, prior to the Covered Transaction, in each case on a basis that gives the holder of the Award a reasonable opportunity, as determined by the Administrator, following exercise of the Award or the delivery of the shares, as the case may be, to participate as a stockholder in the Covered Transaction; *provided*, that to the extent acceleration pursuant to this Section 7(a)(3) of an Award subject to Section 409A would cause the Award to fail to satisfy the requirements of Section 409A, the Award shall not be accelerated and the Administrator in lieu thereof shall take such steps as are necessary to ensure that payment of the Award is made in a medium other than Stock and on terms that as nearly as possible, but taking into account adjustments required or permitted by this Section 7, replicate the prior terms of the Award.

(4) **Termination of Awards Upon Consummation of Covered Transaction**. Each Award will terminate upon consummation of the Covered Transaction, other than the following: (i) Awards assumed pursuant to Section 7(a)(1) above; (ii) Awards converted pursuant to the proviso in Section 7(a)(3) above into an ongoing right to receive payment other than Stock; and (iii) outstanding shares of Restricted Stock (which shall be treated in the same manner as other shares of Stock, subject to Section 7(a)(5) below).

(5) **Additional Limitations**. Any share of Stock and any cash or other property delivered pursuant to Section 7(a)(2) or Section 7(a)(3) above with respect to an Award may, in the discretion of the Administrator, contain such restrictions, if any, as the Administrator deems appropriate to reflect any performance or other vesting

conditions to which the Award was subject and that did not lapse (and were not satisfied) in connection with the Covered Transaction. In the case of Restricted Stock that does not vest in connection with the Covered Transaction, the Administrator may require that any amounts delivered, exchanged or otherwise paid in respect of such Stock in connection with the Covered Transaction be placed in escrow or otherwise made subject to such restrictions as the Administrator deems appropriate to carry out the intent of the Plan.

(b) Changes in and Distributions With Respect to Stock

(1) Basic Adjustment Provisions. In the event of a stock dividend, stock split or combination of shares (including a reverse stock split), recapitalization or other change in the Company's capital structure, the Administrator shall make appropriate adjustments to the maximum number of shares specified in Section 4(a) that may be delivered under the Plan and to the maximum share limits described in Section 4(c), and shall also make appropriate adjustments to the number and kind of shares of stock or securities subject to Awards then outstanding or subsequently granted, any exercise prices relating to Awards and any other provision of Awards affected by such change.

(2) Certain Other Adjustments. The Administrator may also make adjustments of the type described in Section 7(b)(1) above to take into account distributions to stockholders other than those provided for in Section 7(a) and 7(b)(1), or any other event, if the Administrator determines that adjustments are appropriate to avoid distortion in the operation of the Plan and to preserve the value of Awards made hereunder, having due regard for the qualification of ISOs under Section 422, the requirements of Section 409A, and for the performance-based compensation rules of Section 162(m), where applicable.

(3) Continuing Application of Plan Terms. References in the Plan to shares of Stock will be construed to include any stock or securities resulting from an adjustment pursuant to this Section 7.

8. LEGAL CONDITIONS ON DELIVERY OF STOCK

The Company will not be obligated to deliver any shares of Stock pursuant to the Plan or to remove any restriction from shares of Stock previously delivered under the Plan until: (i) the Company is satisfied that all legal matters in connection with the issuance and delivery of such shares have been addressed and resolved; (ii) if the outstanding Stock is at the time of delivery listed on any stock exchange or national market system, the shares to be delivered have been listed or authorized to be listed on such exchange or system upon official notice of issuance; and (iii) all conditions of the Award have been satisfied or waived. If the sale of Stock has not been registered under the Securities Act of 1933, as amended, the Company may require, as a condition to exercise of the Award, such representations or agreements as counsel for the Company may consider appropriate to avoid violation of such Act. The Company may require that certificates evidencing Stock issued under the Plan bear an appropriate legend reflecting any restriction on transfer applicable to such Stock, and the Company may hold the certificates pending lapse of the applicable restrictions.

9. AMENDMENT AND TERMINATION

The Administrator may at any time or times amend the Plan or any outstanding Award to comply with applicable law or the applicable rules of any securities exchange or for any purpose which may at the time be permitted by law, and may at any time terminate the Plan as to any future grants of Awards; *provided*, that except as otherwise expressly provided in the Plan the Administrator may not, without the Participant's consent, alter the terms of an Award so as to affect materially and adversely the Participant's rights under the Award, unless the Administrator expressly reserved the right to do so at the time of the Award. Any amendments to the Plan shall be conditioned upon stockholder approval only to the extent, if any, such approval is required by law (including the Code and applicable stock exchange requirements), as determined by the Administrator.

10. OTHER COMPENSATION ARRANGEMENTS

The existence of the Plan or the grant of any Award will not in any way affect the Company's right to Award a person bonuses or other compensation in addition to Awards under the Plan.

11. MISCELLANEOUS

(a) **Waiver of Jury Trial**. By accepting an Award under the Plan, each Participant waives any right to a trial by jury in any action, proceeding or counterclaim concerning any rights under the Plan and any Award, or under any amendment, waiver, consent, instrument, document or other agreement delivered or which in the future may be delivered in connection therewith, and agrees that any such action, proceedings or counterclaim shall be tried before a court and not before a jury. By accepting an Award under the Plan, each Participant certifies that no officer, representative, or attorney of the Company has represented, expressly or otherwise, that the Company would not, in the event of any action, proceeding or counterclaim, seek to enforce the foregoing waivers.

(b) **Limitation of Liability**. Notwithstanding anything to the contrary in the Plan, neither the Company, nor any Affiliate, nor the Administrator, nor any person acting on behalf of the Company, any Affiliate, or the Administrator, shall be liable to any Participant or to the estate or beneficiary of any Participant or to any other holder of an Award by reason of any acceleration of income, or any additional tax, asserted by reason of the failure of an Award to satisfy the requirements of Section 422 or Section 409A or by reason of Section 4999 of the Code; provided, that nothing in this Section 11(b) shall limit the ability of the Administrator or the Company to provide by separate express written agreement with a Participant for a gross-up payment or other payment in connection with any such tax or additional tax.

EXHIBIT A

Definition of Terms

The following terms, when used in the Plan, will have the meanings and be subject to the provisions set forth below:

“Administrator”: The Compensation Committee, except that the Compensation Committee may delegate (i) to one or more of its members such of its duties, powers and responsibilities as it may determine; (ii) to one or more officers of the Company the power to grant rights or options to the extent permitted by Section 157(c) of the Delaware General Corporation Law; and (iii) to such Employees or other persons as it determines such ministerial tasks as it deems appropriate. In the event of any delegation described in the preceding sentence, the term “Administrator” shall include the person or persons so delegated to the extent of such delegation.

“Affiliate”: Any corporation or other entity that stands in a relationship to the Company that would result in the Company and such corporation or other entity being treated as one employer under Section 414(b) and Section 414(c) of the Code.

“Award”: Any or a combination of the following:

- (i) Stock Options.
- (ii) SARs.
- (iii) Restricted Stock.
- (iv) Unrestricted Stock.
- (v) Stock Units, including Restricted Stock Units.
- (vi) Performance Awards.
- (vii) Cash Awards.
- (viii) Awards (other than Awards described in (i) through (vii) above) that are convertible into or otherwise based on Stock.

“Board”: The Board of Directors of the Company.

“Cash Award”: An Award denominated in cash.

“Code”: The U.S. Internal Revenue Code of 1986 as from time to time amended and in effect, or any successor statute as from time to time in effect.

“Company”: pSivida Corp.

“Compensation Committee”: The Compensation Committee of the Board.

“Covered Transaction”: Any of (i) a consolidation, merger, or similar transaction or series of related transactions, including a sale or other disposition of stock, in which the Company is not the surviving corporation or which results in the acquisition of all or substantially all of the Company’s then outstanding common stock by a single person or entity or by a group of persons and/or entities acting in concert, (ii) a sale or transfer of all or substantially all the Company’s assets, or (iii) a dissolution or liquidation of the Company. Where a Covered Transaction involves a tender offer that is reasonably expected to be followed by a merger described in clause (i) (as determined by the Administrator), the Covered Transaction shall be deemed to have occurred upon consummation of the tender offer.

“Employee”: Any person who is employed by the Company or an Affiliate.

“Employment”: A Participant’s employment or other service relationship with the Company and its Affiliates. Employment will be deemed to continue, unless the Administrator expressly provides otherwise, so long as the Participant is employed by, or otherwise is providing services in a capacity described in Section 5 to the Company or its Affiliates. If a Participant’s employment or other service relationship is with an Affiliate and that entity ceases to be an Affiliate, the Participant’s Employment will be deemed to have terminated when the entity ceases to be an Affiliate unless the Participant transfers Employment to the Company or its remaining Affiliates. Notwithstanding the foregoing and the definition of “Affiliate” above, in construing the provisions of any Award relating to payment of “nonqualified deferred compensation” (subject to Section 409A) upon a termination or cessation of Employment, references to termination or cessation of Employment, separation from service, retirement or similar or correlative terms shall be construed to require a “separation from service” (as that term is defined in Section 1.409A-1(h) of the Treasury Regulations) from the Company and from all other corporations and trades or businesses, if any, that would be treated as a single “service recipient” with the Company under Section 1.409A-1(h)(3) of the Treasury Regulations. The Company may, but need not, elect in writing, subject to the applicable limitations under section 409A of the Code, any of the special elective rules prescribed in Section 1.409A-1(h) of the Treasury Regulations for purposes of determining whether a “separation from service” has occurred. Any such written election shall be deemed part of the Plan.

“ISO”: A Stock Option intended to be an “incentive stock option” within the meaning of Section 422. Each option granted pursuant to the Plan will be treated as providing by its terms that it is to be a non-incentive stock option unless, as of the date of grant, it is expressly designated as an ISO.

“Participant”: A person who is granted an Award under the Plan.

“Performance Award”: An Award subject to Performance Criteria. The Committee in its discretion may grant Performance Awards that are intended to qualify for the performance-based compensation exception under Section 162(m) and Performance Awards that are not intended so to qualify.

“Performance Criteria”: Specified criteria, other than the mere continuation of Employment or the mere passage of time, the satisfaction of which is a condition for the grant, exercisability, vesting or full enjoyment of an Award. For purposes of Awards that are intended to qualify for the performance-based compensation exception under Section 162(m), a Performance Criterion will mean an objectively determinable measure of performance relating to any or any combination of the following (measured either absolutely or by reference to an index or indices and determined either on a consolidated basis or, as the context permits, on a divisional, subsidiary, line of business, project or geographical basis or in combinations thereof): sales; revenues; assets; expenses; earnings before or after deduction for all or any portion of interest, taxes, depreciation, or amortization, whether or not on a continuing operations or an aggregate or per share basis; return on equity, investment, capital or assets; one or more operating ratios; borrowing levels, leverage ratios or credit rating; market share; capital expenditures; total shareholder return; cash flow; operating income; stock price; stockholder return; sales of particular products or services; customer acquisition or retention; employee turnover and/or other human resources activities; acquisitions and divestitures (in whole or in part); collaborations, joint ventures and strategic alliances; spin-offs, split-ups and the like; in-licensing and/or out-licensing; patents; product development; product market share; progress on the Company’s product pipeline; research productivity; movement of programs from research to development; cost reductions or savings; government relations; litigation; management and board of directors composition; leadership development and/or talent management; sales of assets and/or subsidiaries; information services; clinical trials; manufacturing; manufacturing capacity; production; inventory; site development; plant, building or facility development; reorganizations; or recapitalizations, restructurings, financings (issuance of debt or equity) or

refinancings. A Performance Criterion and any targets with respect thereto determined by the Administrator need not be based upon an increase, a positive or improved result or avoidance of loss. To the extent consistent with the requirements for satisfying the performance-based compensation exception under Section 162(m), the Administrator may provide in the case of any Award intended to qualify for such exception that one or more of the Performance Criteria applicable to such Award will be adjusted in an objectively determinable manner to reflect events (for example, but without limitation, acquisitions or dispositions) occurring during the performance period that affect the applicable Performance Criterion or Criteria.

“Plan”: The pSivida Corp. 2008 Incentive Plan as from time to time amended and in effect.

“Restricted Stock”: Stock subject to restrictions requiring that it be redelivered or offered for sale to the Company if specified conditions are not satisfied.

“Restricted Stock Unit”: A Stock Unit that is, or as to which the delivery of Stock or cash in lieu of Stock is, subject to the satisfaction of specified performance or other vesting conditions.

“SAR”: A right entitling the holder upon exercise to receive an amount (payable in cash or in shares of Stock of equivalent value) equal to the excess of the fair market value of the shares of Stock subject to the right over the base value from which appreciation under the SAR is to be measured.

“Section 409A”: Section 409A of the Code.

“Section 422”: Section 422 of the Code.

“Section 162(m)”: Section 162(m) of the Code.

“Stock”: Common Stock of the Company, par value \$0.001 per share.

“Stock Option”: An option entitling the holder to acquire shares of Stock upon payment of the exercise price.

“Stock Unit”: An unfunded and unsecured promise, denominated in shares of Stock, to deliver Stock or cash measured by the value of Stock in the future.

“Unrestricted Stock”: Stock not subject to any restrictions under the terms of the Award .

List of Subsidiaries of pSivida Corp.

Subsidiary Name

pSivida US, Inc.

pSiMedica Limited

pSivida Securities Corporation

Jurisdiction of Incorporation

Delaware

United Kingdom

Massachusetts

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-152146 and 333-163208 on Form S-8 and Registration Statement No. 333-185549 on Form S-3 of our reports dated September 10, 2015, 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, 2015.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
September 10, 2015

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 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 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 10, 2015

/ s / **PAUL A SHTON**

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

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

CERTIFICATIONS

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

1. I have reviewed this Annual Report on Form 10-K of **PSIVIDA CORP.** ;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer 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 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 10, 2015

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|---------------|---|
| | / S / L EONARD S. R OSS |
| Name: | Leonard S. Ross |
| Title: | Vice President, Finance (Principal Financial and Accounting Officer) |

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

In connection with the Annual Report of pSivida Corp. (the "Company") on Form 10-K for the year ended June 30, 2015, 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 10, 2015

/ s / **PAUL A SHTON**

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

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

In connection with the Annual Report of pSivida Corp. (the "Company") on Form 10-K for the year ended June 30, 2015, 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 10, 2015

/s/ **Leonard S. Ross**

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