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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, 2016

or

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

For the transition period from to

Commission File Number 000-51122

PSIVIDA CORP.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the common stock held by non-affiliates of the registrant, computed by reference to the closing price of the common stock on the NASDAQ Global Market on December 31, 2015, the last trading day of the registrant's most recently completed second fiscal quarter, was approximately $140,134,000.

There were 34,176,999 shares of the registrant's common stock, $0.001 par value, outstanding as of September 6, 2016.

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 12, 2016, are incorporated by reference into Part III of this Annual Report on Form 10-K.

PSIVIDA CORP.

Form 10-K
For the Fiscal Year Ended June 30, 2016

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Preliminary Note Regarding Forward-Looking Statements

This Form 10-K and our 2016 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 Securities and Exchange Commission (SEC), on our website, www.psivida.com, or otherwise.

ITEM 1. BUSINESS

Introduction

Our Business

We develop sustained-release drug delivery products primarily for the treatment of chronic 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 United States (U.S.) Food and Drug Administration (FDA) for treatment of back-of-the-eye diseases. Medidur™ for posterior segment uveitis, our lead product candidate, is in pivotal Phase 3 clinical trials, and ILUVIEN® for diabetic macular edema (DME), our lead licensed product, is sold in the U.S. and three European Union (EU) countries. Our product development program is focused primarily on utilizing our two core technology platforms to deliver drugs and biologics to treat chronic diseases. Our strategy includes developing products independently while continuing to leverage our technology platforms through collaborations and license agreements as appropriate.

Medidur, our most advanced development product, is designed to treat chronic non-infectious uveitis affecting the posterior segment of the eye (posterior segment uveitis) for three years from a single injection. Injected into the eye in an office visit, Medidur is a tiny micro-insert that delivers a micro-dose of a corticosteroid to the back of the eye on a sustained basis. We are developing Medidur independently.

The first of Medidur’s two Phase 3 trials met its primary efficacy endpoint of prevention of recurrence of disease through six months with high statistical significance (p less than 0.00000001; intent to treat analysis) and achieved encouraging safety results. The same high statistical significance for efficacy and encouraging safety results were maintained through 12 months of follow-up. Due to the high level of statistical significance

achieved, we plan to file our EU marketing approval application (MAA) based on data from the first Phase 3 trial, rather than two trials. The MAA is planned for the first quarter of 2017. Enrollment in the second Phase 3 trial is expected to be completed in October 2016. Assuming favorable results, we plan to file a new drug application (NDA) with the FDA in the third quarter of 2017. A utilization study of our new Medidur inserter with a smaller diameter needle, which is required for both our MAA and NDA, met its primary endpoint, ease of intravitreal administration.

ILUVIEN, our most recently approved product, is an injectable, sustained-release micro-insert that provides three years of treatment of DME from a single injection. ILUVIEN is substantially the same design as Medidur and delivers the same steroid, although it is injected using a larger diameter inserter. ILUVIEN was developed in collaboration with Alimera Sciences, Inc. (Alimera) and is licensed to and sold by Alimera. We are entitled to a share of the net profits (as defined) from Alimera's sales of ILUVIEN on a quarter-by-quarter, country-by-country basis. ILUVIEN has been sold in the U.S. since 2015, 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 (IOP). ILUVIEN has been sold in the United Kingdom (U.K.) and Germany since 2013 and in Portugal since 2015. ILUVIEN has marketing approvals in these and 14 other European countries for the treatment of chronic DME considered insufficiently responsive to available therapies.

FDA-approved Retisert® is an implant that provides sustained treatment of posterior segment uveitis for 30 months. Implanted in a surgical procedure, Retisert delivers the same corticosteroid as Medidur but in a larger dose. Retisert was co-developed with Bausch & Lomb, to which it is licensed. We receive royalties from Retisert sales.

We are seeking to develop products that use our Durasert™ and Tethadur™ technology platforms to deliver drugs and biologics to treat wet and dry age-related macular degeneration (AMD), glaucoma, osteoarthritis and other diseases. The sustained release, surgical implant to treat pain associated with severe knee osteoarthritis (OA) we developed in collaboration with Hospital for Special Surgery (HSS) is in an investigator-sponsored pilot study. We recently commenced the first of two investigational new drug (IND)-enabling studies of an injectable, bioerodible micro-insert we developed to provide sustained delivery of a tyrosine kinase inhibitor (TKI) to treat wet AMD.

Durasert™, Medidur™ and Tethadur™ 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 2016, fiscal 2015 and fiscal 2014 mean the twelve months ended June 30, 2016, 2015 and 2014, respectively, and fiscal 2017 means the twelve months ending June 30, 2017.

Strategy

Our strategy is to use our proprietary Durasert and Tethadur drug delivery technology platforms to independently develop new drug delivery products that use already-approved drugs and biologics to better treat 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 therapeutic agents, resulting in improved therapeutic effectiveness, safer administration and better patient compliance and convenience, with reduced product development risk and cost. Our proven track record of three approved products, all providing sustained release of previously approved drugs, reflects the benefits 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 four years, patent coverage will end on products with world-wide sales aggregating billions of dollars 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 targeted delivery at the treatment site would materially improve the effectiveness, safety or convenience of the original drugs or biologics. By focusing on delivery of already-approved drugs and biologics, particularly those requiring potentially shorter clinical development programs, 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, drugs and biologics that might be more effectively delivered by our platform technologies or may have extended patent protection 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.
- **Expand Beyond Ophthalmology.** While we continue to focus on our core ophthalmic competency, we intend to also use our technology platforms for the treatment of other diseases where sustained delivery could provide a significant advantage, such as osteoarthritis or for sustained systemic release of biologics.

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, the 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 appropriate concentration and that concentration is maintained at the tissue 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 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 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 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 Lucentis® and EYLEA®, 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 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.

As a result of the issues with traditional delivery of drugs and biologics, there is significant market opportunity for delivery of these products on a sustained, controlled basis over an extended period directly to the targeted site.

Our Technology Systems and Products

Our two core technology platforms, Durasert and Tethadur, are designed to address the issues of sustained delivery for ophthalmic and other product candidates:

- *Extended Delivery*. Our Durasert technology platform can deliver drugs for predetermined periods of time ranging from days to years. Our goal is to develop Tethadur to provide sustained delivery of biologics. 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, our late stage product candidate for posterior segment uveitis and earlier stage product candidates for knee OA and AMD, use our Durasert technology platform to provide sustained, localized delivery of small molecule drugs to the back of the eye or the joint. In our Durasert products, a drug core is surrounded with one or more polymer layers, and the permeability of those layers and other design aspects of the product control the rate and duration of drug release. By changing elements of the design, we can alter both the rate and duration of release to meet different therapeutic needs. ILUVIEN is, and our ophthalmic product candidates are designed to be, injected at the target site in an office visit, while earlier ophthalmic products Retisert and Vitrasert are surgically implanted. Our osteoarthritis product candidate is surgically implanted in the joint.

The portfolio of our Durasert approved products and product candidates include:

Product	Disease	Stage of Development	Partner
Retisert	Posterior segment uveitis	FDA-approved; commercialized since 2005	Bausch & Lomb
ILUVIEN	DME	Approved in the U.S. and 17 EU countries; commercialized since 2013 in U.K. and Germany and since 2015 in U.S. and Portugal	Alimera
Medidur	Posterior segment uveitis	Phase 3 clinical trials	Independent development
Steroid implant	Severe knee OA	Investigator-sponsored study	Hospital for Special Surgery
TKI insert	Wet AMD	Pre-clinical	Independent development
Vitrasert	CMV retinitis	FDA-approved; commercialized from 1996 through 2012 (patent expiration)	Bausch & Lomb

Development Product: Medidur for Posterior Segment Uveitis

Medidur, our lead development product, is an injectable, sustained-release micro-insert designed to treat chronic, noninfectious posterior uveitis, intermediate uveitis and panuveitis affecting the posterior segment of the eye for three years from a single injection. Injected in an office visit, Medidur provides sustained release of 0.18 mg of the off-patent corticosteroid fluocinolone acetonide (FAc) at a controlled rate directly to the back of the eye over three years. Medidur is injected with our proprietary inserter that uses a 27-gauge needle. We are developing Medidur independently and have not licensed the rights to Medidur for posterior segment uveitis to Alimera or any other third party.

Posterior segment uveitis is a chronic, non-infectious inflammatory disease affecting the posterior segment of the eye, often involving the retina, and 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 segment 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 segment 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 3 Trials

We are currently conducting two Phase 3 trials to assess the safety and efficacy of Medidur for the treatment of posterior segment uveitis. These are randomized, sham injection-controlled, double-masked trials. The primary endpoint of both trials is recurrence of disease at six months, with patients followed for three years. Our first Phase 3 Medidur trial enrolled 129 patients in 16 centers in the U.S. and 17 centers outside the U.S, with 87 eyes treated with Medidur and 42 eyes randomized to control and receiving sham injections. We expect to complete enrollment of our second Phase 3 trial of approximately 150 patients in 15 centers in India in October 2016.

Our first Phase 3 trial met its primary efficacy endpoint of prevention of recurrence of disease at six months with high statistical significance (p less than 0.00000001; intent to treat analysis) (recurrence of 18.4% for

Medidur versus 78.6% for control). The trial continued to meet its primary efficacy endpoint with the same high statistical significance through 12 months of follow up (p less than 0.00000001) (27.6% Medidur versus 85.7% control). Medidur was generally well tolerated through the latest follow-up visit reported (minimum 12 months, maximum 30 months, average 18 months). The incremental risk of elevated IOP for Medidur-treated eyes compared to control eyes was lower through the last follow up than through six months for over 21mmHg (8.3% versus 10.9%) as well as for the more serious elevation over 25mmHg (5.1% versus 11.3%). Elevated IOP was generally well treated with eye drops. Through the last follow-up, the percentage of eyes requiring incisional surgery was essentially the same in Medidur-treated and control eyes (4.6% versus 4.8%). Of the 64 study eyes with a natural lens at baseline, 45.2% of Medidur-treated eyes compared to 9.5% of control eyes required cataract surgery through the last follow-up visit. Cataracts are both a side effect of treatment with steroids and a natural consequence of posterior segment uveitis.

Our multi-center, randomized, controlled, single-masked study of the safety and utilization of our new proprietary 27-gauge inserter for Medidur met its primary endpoint, ease of intravitreal administration, showing that it facilitated the administration of Medidur compared to the larger diameter, 25-gauge inserter. These study results will form part of our anticipated MAA and NDA filings for Medidur for posterior segment uveitis.

Medidur Regulatory Strategy

In the EU, we plan to submit an MAA to the European Medicines Agency (EMA) in the first quarter of 2017 for Medidur for treatment of posterior segment uveitis. The submission is planned using the Centralized Procedure, which allows submission of a single application that, when approved, authorizes marketing in all EU member states and European Free Trade Association countries rather than requiring separate national approvals. As a result of the high statistical significance achieved in the first Phase 3 trial, we plan to base our MAA on data from only one rather than two Phase 3 trials. The U.K. Medicines and Healthcare Products Regulatory Agency (MHRA) advised us that, consistent with the published Points to Consider (PtC) of the European Agency for Evaluation of Medicinal Products, an application for a product treating a condition like posterior segment uveitis could be based on statistically compelling and clinically relevant results from just one pivotal trial. The submission will also be based on data from our inserter study and ILUVIEN for DME trials.

The European Commission (EC) designated Medidur as an orphan medicinal product. Orphan drug designation provides up to 10 years of market exclusivity in Europe following marketing approval, access to the Centralized Procedure and other regulatory and financial incentives.

In the U.S., we plan to submit an NDA to the FDA seeking approval of the marketing of Medidur for the treatment of posterior segment uveitis. We plan to base the NDA on data from our two Phase 3 trials and the inserter utilization study, as well as data referenced from the ILUVIEN for DME trials. Pending favorable results in our second Phase 3 trial, we expect to file an NDA in the third quarter of 2017. We have not obtained orphan designation for Medidur for posterior segment uveitis in the U.S. and may not do so.

Medidur Marketing Strategy

To be prepared for the potential marketing approvals of Medidur, we have begun the process of evaluating how we could best commercialize Medidur and maximize its value to us. We do not currently have any sales or marketing staff or any in-house expertise on product commercialization, and our resources are limited. We will be reviewing all of our potential options with respect to Medidur commercialization, including whether we should have different approaches in different jurisdictions.

Approved Product: ILUVIEN for DME

ILUVIEN is an injectable, sustained-release micro-insert delivering 0.19 mg of FAc to the back of the eye for treatment of DME. It is substantially the same micro-insert as Medidur. Injected in an office visit using a

larger diameter 25-gauge inserter, 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 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 the working-age population in most developed countries.

We licensed ILUVIEN to Alimera, with which we co-developed the product. Alimera has sold ILUVIEN in the U.K. and Germany since 2013 and in Portugal and the U.S. since 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 sublicensed ILUVIEN in various countries.

Approved Product: Retisert for Posterior Segment Uveitis

Retisert is a sustained-release implant for the treatment of posterior segment uveitis. Surgically implanted, it delivers 0.59 mg of FAc to the back of the eye for approximately 30 months. Retisert is licensed to Bausch & Lomb, with which we co-developed the product. Approved in the U.S., Bausch & Lomb sells the product and pays sales-based royalties to us.

Approved Product: Vitrasert for CMV Retinitis

Our first product Vitrasert was a sustained-release implant for the treatment of CMV retinitis, a blinding eye disease that occurs in individuals with advanced AIDS. Surgically implanted, Vitrasert provided sustained delivery of the anti-viral drug ganciclovir for six to eight months. Approved in the U.S. and EU, Vitrasert was licensed to Bausch & Lomb, which discontinued sales in fiscal 2013 following patent expiration.

Tethadur Technology System

Our Tethadur technology system, currently in pre-clinical development, is designed to provide sustained delivery of large biologic molecules, including peptides, proteins and antibodies. Tethadur utilizes a tunable, biodegradable, biocompatible matrix of nanostructured silica. Biologics are loaded into the matrix and are then released over time as the matrix dissolves. We believe that by varying the pore size and surface area of Tethadur, the release rate of biologics loaded into the Tethadur matrix can be controlled. Our goal with Tethadur is to provide sustained delivery of biologics that currently must be delivered by frequent injections. The Tethadur matrix could also be designed to deliver smaller molecules.

Development Pipeline

Our research is focused on using our Durasert technology platform and developing our Tethadur delivery platform to deliver therapeutic agents to treat wet and dry AMD, glaucoma and osteoarthritis, as well as to provide systemic delivery of biologics.

Development Product: Severe Knee Osteoarthritis Implant.

We have developed an implant for the treatment of pain associated with severe knee OA in collaboration with HSS. This implant is being studied in an investigator-sponsored, pilot study. The implant is composed of a specially manufactured, surgical screw-like device with an embedded Durasert system that delivers dexamethasone directly to the joint on a sustained basis. Dexamethasone is an off-patent corticosteroid that is frequently used for the treatment of OA. Implanted in the non-articulating area of the knee in an outpatient procedure, the implant is designed to provide long-term pain relief and thereby delay the need for knee replacement surgery. This implant represents the first use of our Durasert technology outside of ophthalmology. We believe this design, if successful, could be adapted for severe OA in other joints.

Knee OA is a degenerative joint disease that results from breakdown of joint cartilage and underlying bone, with joint pain and stiffness the most common symptoms. More than 10 million people have knee OA. No cure exists, but pain and movement restriction associated with the disease are currently treated with oral analgesics, non-steroidal anti-inflammatory drugs, corticosteroids taken orally or injected into the knee, or hyaluronic acid injected into the knee. With degeneration, damage and pain from knee OA can become severe, making it the leading cause of total knee replacement surgery. More than 700,000 of these surgeries were performed last year in the U.S. alone, and the number is expected to grow.

Development Product: TKI Insert for Wet AMD. We are developing an injectable, bioerodible, sustained-release Durasert insert delivering a TKI for treatment of wet AMD. AMD, the leading cause of vision loss in people over 65, is most commonly treated with intravitreal injections of biologics that block vascular endothelial growth factor (VEGF) molecules. FDA-approved Lucentis and Eylea and off-label use of the anti-cancer Avastin®, all of which block only VEGF, are the leading treatments for wet AMD. These biologics must be injected into the eye as frequently as monthly and typically lose efficacy over time, resulting in vision loss and return of the disease.

Although the exact cause of AMD is unknown, other growth factors in addition to VEGF such as platelet-derived growth factor (PDGF) are thought to be involved in AMD. Approved for the treatment of cancer, some TKIs, including the one we propose to use in our insert, are known to inhibit PDGF as well as VEGF. In cancer therapy, TKIs are taken orally, but their toxicity prevents their systemic use to treat AMD. By using our Durasert technology, we plan to deliver a TKI directly to the back of the eye with a total dose that is significantly lower than is used in a course of cancer therapy.

Our goal is to provide sustained treatment of wet AMD for six months with a single injection, targeting both VEGF and PDGF while avoiding the toxic systemic side effects of TKIs and the frequent injections of current AMD anti-VEGF biologics. Our completed pre-clinical study data demonstrated that a TKI delivered by a sustained release insert was comparably efficacious to a commercially available biologic indicated for wet AMD delivered by injection in both preventing choroidal neovascularization and reducing vascular leakage. On the basis of these studies, we have commenced the first of two IND-enabling studies.

Feasibility Study Agreements

We enter into feasibility study agreements (some of which are funded by third parties) to evaluate our Durasert and Tethadur technology systems for the treatment of 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 these collaboration agreements, we have retained 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.

In October 2014, Alimera paid us a $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 our 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.

Bausch & Lomb

Under a 2003 amended license agreement, Bausch & Lomb has a worldwide exclusive license to make and sell Retisert and other first generation products defined in the agreement 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 2 clinical trials. If we cease development, or if we commence and complete Phase 2 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 the other party's uncured material breach or upon various bankruptcy events. 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.

Pfizer owned approximately 5.4% of our outstanding stock as of August 31, 2016.

Enigma Therapeutics

Our December 2012 license agreement, amended and restated in March 2013, with Enigma Therapeutics Limited (Enigma) provides Enigma with an exclusive, worldwide, royalty-bearing license for the development of BrachySil (now named OncoSil™), a product candidate for the treatment of pancreatic and other cancers. 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, January 2015 and December 2015. Enigma has the right to terminate this license upon 60 days' prior written notice.

Research and Development

Our clinical and pre-clinical research programs primarily focus on ophthalmic applications of our technology systems. Our research and development expenses totaled $14.4 million in fiscal 2016, $12.1 million in fiscal 2015 and $9.6 million in fiscal 2014. Of these amounts, $12.8 million in fiscal 2016, $10.6 million in fiscal 2015 and $8.2 million in fiscal 2014 were incurred for costs of research and development personnel, clinical and pre-clinical studies, contract services, testing and laboratory facilities. The remaining expense of $1.6 million in fiscal 2016, $1.5 million in fiscal 2015 and $1.4 million in fiscal 2014 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.

During the first quarter of fiscal 2017, we consolidated all of our research and development operations in our facility in Watertown, Massachusetts. We closed our research facility in Malvern, U.K. and have terminated the employment of all of our employees in that location.

Intellectual Property

We own or license patents in the U.S. and other countries. Our patents generally cover the design, formulation, manufacturing methods and use of our sustained release therapeutics, devices and technologies. Patents for individual products extend for varying periods according to the date of patent filing or grant and legal term of patents in the various countries where patent protection is obtained. The actual protection afforded by a patent, which can vary from country to country, depends upon the type of patent, the scope of its coverage and the availability of legal remedies in the country. Patent term extension may be available in various countries to compensate for a patent office delay or a regulatory delay in approval of the product.

The U.S. patent with which Retisert is marked expires in March 2019. The latest expiring patent covering ILUVIEN and Medidur expires in August 2027 in the U.S. and in October 2024 in the EU, although extensions have been obtained or applied for through May 2027 in various EU 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, 2016:

Technology	United States Patents	United States Applications	Foreign Patents	Foreign Applications	Patent Families
Durasert	10	7	82	13	14
Tethadur	27	10	88	49	26
Other	5	4	21	24	13
Total	42	21	191	86	53

Employees

We had 20 employees as of August 31, 2016. None of our employees is covered by a collective bargaining agreement.

Manufacturing

We currently manufacture our product candidates for pre-clinical studies and clinical trials. We purchase raw materials necessary to manufacture Medidur and our other product candidates in the ordinary course of business, and they are available from multiple sources. The manufacture of Retisert and ILUVIEN is the responsibility of our licensees. We do not own or operate manufacturing facilities for the production of commercial quantities of our product candidates. If Medidur is approved, we may perform initial commercial manufacture in our current facility, but we expect to arrange for long-term manufacture by contract manufacturers or licensees.

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

In both domestic and foreign markets, sales of pharmaceutical products depend, in part, on the availability and amount of reimbursement by third-party payers, including governments and private health plans. Governments may regulate coverage, reimbursement and/or pricing of pharmaceutical products or require discounts. Private health plans may also seek to manage cost and utilization by implementing coverage and reimbursement limitations.

U.S. and foreign governments regularly consider reform measures that affect health care coverage and costs. Such reforms may include changes to the coverage and reimbursement of pharmaceutical products. For example, in the U.S., the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (Healthcare Reform Law), was enacted in 2010 and substantially changed the way healthcare is financed by both governmental and private insurers. In the EU, governments may set prices or otherwise regulate pricing. Negotiating prices with governmental authorities can delay commercialization. In recent years, EU governments have considered or implemented various cost-containment measures, such as price freezes, increased price cuts and mandatory rebates, and EU governments likely will continue to use these and other cost-containment measures, including value-based pricing and reference pricing (i.e., referencing prices in other countries and using those reference prices to set a price).

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 diseases targeted by our products and product candidates. 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 or fewer 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, ease of administration, 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 ILUVIEN or Medidur. 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 AG 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 segment uveitis*. Periocular steroid injections and systemic delivery of corticosteroids are used to treat posterior segment uveitis. Ozurdex is approved in the U.S. and EU for posterior segment uveitis. Abbvie recently obtained FDA approval for Humira® for posterior segment uveitis, and other companies have ongoing trials of posterior segment uveitis treatments, including Clearside's CLS-TA and Santen Pharmaceutical Co. Ltd.'s sirolimus drug DE-109.

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,								
	2016			2015			2014		
	U.S.	U. K.	Total	U.S.	U. K.	Total	U.S.	U. K.	Total
	(In thousands)								
Revenues:									
Collaborative research and development	$ 298	$100	$ 398	$25,311	$100	$25,411	$1,930	$225	$2,155
Royalty income	1,222	—	1,222	1,154	—	1,154	1,318	—	1,318
	$1,520	$100	$1,620	$26,465	$100	$26,565	$3,248	$225	$3,473

Government Regulation

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, labeling, storage, record-keeping, approval, distribution, import, export, advertising and promotion of drug products.

Drug Development, Approval, and Regulation in the U.S. The steps required by the FDA under the Federal Food, Drug, and Cosmetic Act before a drug may be approved for marketing in the U.S. generally include the following:

- pre-clinical laboratory and animal tests;
- submission to the FDA of an IND application, which must become effective before human clinical trials may begin;
- adequate and well-controlled human clinical 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;
- FDA pre-approval inspection of the manufacturing sites identified in the NDA; 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. Pre-clinical tests include laboratory evaluation of the product candidate, its chemistry, formulation and stability, as well as animal studies to assess the potential safety and efficacy of the product candidate. Pre-clinical tests intended for submission to the FDA must be conducted in compliance with FDA's current Good Laboratory Practice (GLP) regulations and the U.S.Department of Agriculture's Animal Welfare Act. 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. Pre-clinical trials do not necessarily result in the submission of an IND and submission of an IND does not necessarily result in FDA authorization to commence clinical trials.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators. The conduct of clinical trials is subject to extensive regulation, including compliance with the FDA's bioresearch monitoring regulations and Good Clinical Practice (GCP) requirements, which establish standards for conducting, recording data from, and reporting the results of, clinical trials and are intended to assure that the data and reported results are credible and accurate, and that the rights, safety, and well-being of study participants are protected. Clinical trials must be conducted in accordance with protocols that detail the objectives of the study, the criteria for determining subject eligibility, the dosing plan, patient monitoring requirements, timely reporting of adverse events, and other elements necessary to ensure patient 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 reviewed, approved, and conducted under the auspices of an independent Institutional Review Board (IRB) or Ethics Committee (EComm). The IRB/EComm's role is to protect the rights and welfare of human subjects involved in clinical studies by evaluating, among other things, the potential risks and benefits to subjects, processes for obtaining informed consent, monitoring of data to ensure subject safety, and provisions to protect the subjects' privacy. Foreign studies conducted under an IND application must meet the same requirements that apply to studies being conducted in the U.S. Data from a foreign study not conducted under an IND may be submitted in support of an NDA if the study was conducted in accordance with GCP and the FDA is able to validate the data.

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 in an application for FDA approval, if appropriate, provided that the applicant has contractual rights to use the results.

Human clinical trials are typically conducted in three sequential phases, but the phases may overlap and different trials may be initiated with the same drug candidate within the same phase of development in similar or differing patient populations:

- *Phase 1*: Phase 1 trials are initially conducted in a limited number of human subjects, usually health human subjects, to test the product candidate for safety, dosage tolerance, absorption, distribution, metabolism and excretion.
- *Phase 2*: Phase 2 trials are usually conducted in a larger, but still limited, patient population to evaluate preliminarily the efficacy of the product candidate for specific, targeted indications, to determine dosage tolerance and optimal dosage, and to identify possible short-term adverse effects and safety risks.

- *Phase 3*: Phase 3 trials are typically conducted when Phase 2 clinical trials demonstrate that a dose range of the product candidate is effective and has an acceptable safety profile. Phase 3 clinical trials are commonly referred to as “pivotal” studies, which typically denotes a study that presents the data that the FDA or other relevant regulatory agency will use to determine whether or not to approve the product candidate. Phase 3 clinical trials are generally undertaken with larger numbers of patients to further evaluate dosage, to provide substantial evidence of clinical efficacy and to further test for safety in an expanded and diverse patient population at multiple, geographically-dispersed clinical trial 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 preliminary evidence of efficacy traditionally obtained in Phase 2 trials, and so these trials are frequently referred to as Phase 1/2 or 2a trials.

Clinical trials may be suspended by the sponsor or by the FDA or IRB/EComm at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

The results of pre-clinical studies and clinical trials, together with other detailed information, including information on the manufacture and composition and proposed labeling of the product candidate are submitted to the FDA as part of an NDA for approval of the marketing and commercial shipment of the product for a proposed indication. The fees payable to the FDA for reviewing an NDA, as well as annual fees for commercial manufacturing establishments and for approved products, can be substantial. The FDA has a statutorily mandated goal of responding to standard review NDAs within ten months after the 60-day filing review period, but this timeframe is often extended. The first indication of the FDA’s review progress is provided at the mid-cycle review. This typically occurs approximately five months after the NDA is submitted. However, the review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. 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.

Satisfaction of FDA new drug approval requirements typically takes several years or more, and varies substantially. The FDA may delay approval of product candidates for a considerable period of time or fail to grant approval at all, and may require additional trials or other costly procedures in order to obtain regulatory approval, which delay or render impossible or impractical obtaining FDA approval. The time and expense required to obtain FDA approval for regulated products can exceed the time and expense of the research and development initially required to create the product.. Even if a product receives regulatory approval, the FDA may limit the indications for use or place other conditions on any approvals that could restrict the commercial application of the product. In addition, as a condition of approval, the FDA may require a sponsor to conduct additional post-approval clinical trials to confirm that the drug is safe and effective for its intended uses. The FDA may also require surveillance programs to monitor approved products or changes in labeling. The FDA has the authority to prevent or limit further marketing of a product based on the results of these post-approval programs. FDA approval may also be subject to the manufacturers’ continued adherence to a Risk Evaluation Mitigation Strategies (REMS) program. REMS, which are tailored to specifically address the risks of a given drug, may contain elements that restrict distribution of the drug to certain physicians, pharmacists and patients, or that require the use of communication tools such as letters to healthcare providers and patients detailing the risks associated with the drug.

After approval, certain changes to the approved drug, such as adding new indications, manufacturing changes, or additional labeling claims are subject to further FDA review and approval. Depending on the nature of the change proposed, an NDA supplement must be filed and approved before the change may be implemented.

For many proposed post-approval changes to an NDA, but excluding efficacy supplements to an NDA, the FDA has up to 180 days to review the application. As with new NDAs, the review process is often significantly extended by the FDA and requests for additional information or clarification.

Once a product approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if safety problems are identified after the product reaches the market. Where a withdrawal may not be appropriate, 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 expose us to product liability claims and result in other consequences, including

- revisions to the approved labeling to add new safety information;
- imposition of post-market studies or clinical trials to assess new safety risks;
- imposition of distribution or other restrictions under a Risk Evaluation and Mitigation Strategy (REMS) program;
- 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.

Any drug product manufactured or distributed under FDA 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. Commercial drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies. Drug manufacturers and their subcontractors are also subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including current good manufacturing practices (cGMP), which impose procedural and documentation requirements. Failure to comply with the statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as warning letters, suspension of manufacturing, seizure of product, injunctive action or possible civil penalties. The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

Foreign Regulation of Drug Development, Approval, and Marketing. Countries outside the U.S. also have regulatory requirements governing human clinical trials conducted in and marketing approval for pharmaceutical products sold in their countries. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary widely by country. Whether or not FDA approval is obtained, requisite approvals from regulatory authorities in foreign countries must be obtained prior to the commencement of clinical studies or marketing of a product in those countries. Certain countries outside of the U.S. have a similar process that requires the submission of a clinical study application much like the IND prior to the commencement of human clinical studies.

The drug approval process varies from country to country, can involve additional testing beyond that required by FDA, and the time required for these approvals may be substantially longer or shorter than that required for FDA approval. Clinical trials conducted in one country may not be accepted by other countries, and approval in one country does not assure approval in any other country.

Under the EU regulatory system, marketing authorizations are submitted under either the centralized procedure or one of the national authorization procedures.

- *Centralized procedure*. The centralized procedure provides for the grant of a single marketing authorization for a medicinal product by the EC on the basis of a positive opinion by the EMA. A centralized marketing authorization is valid for all EU member states and Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for human medicines that are derived from biotechnology processes, such as genetic engineering, contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions, and officially designated orphan medicines. For medicines that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the EC following a favorable opinion by the EMA, as long as the medicine concerned is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health.
- *National authorization procedures*. There are also two other routes to obtain marketing authorization of medicinal products in several EU countries, which are available for medicinal products that fall outside the scope of the centralized procedure:
    - *Decentralized procedure.* Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one EU country of medicinal products that have not yet been authorized in any EU country. One national competent authority, selected by the applicant, assesses the application for marketing authorization. The competent authorities of the other EU member states are subsequently required to grant marketing authorization for their territory on the basis of this assessment, except where grounds of potential serious risk to public health require this authorization to be refused.
    - *Mutual recognition procedure.* The mutual recognition procedure provides for mutual recognition of marketing authorizations delivered by the national competent authorities of EU member states by the competent authorities of other EU member states. The holder of a national marketing authorization may submit an application to the competent authority of a EU member state requesting that this authority recognize the marketing authorization delivered by the competent authority of another EU member state for the same medicinal product.

Similar to the U.S., both marketing authorization holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA and the competent authorities of the individual EU member states both before and after grant of the manufacturing and marketing authorizations. This includes control of compliance by the entities with EU cGMP rules, which govern quality control of manufacturing processes, methods and equipment and require documentation policies and procedures. Failure by authorization holders, suppliers, manufacturers and distributors to comply with EU laws, the related national laws of individual EU member states or the laws of other foreign regulatory authorities governing the research, development, testing, manufacture, labeling, storage, record-keeping, approval, distribution, import, export, advertising or promotion of our drug products may result in administrative, civil, or criminal penalties. These penalties could include delays in or refusal to authorize the conduct of clinical trials or to grant marketing authorization, product withdrawals and recalls, product seizures, suspension, or variation of the marketing authorization, total or partial suspension of production, distribution, manufacturing, or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

Orphan Drug Designation. Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which generally is a disease or condition that affects fewer than 200,000 individuals in the U.S., or more than 200,000 individuals in the U.S., but for which there is no reasonable expectation that the cost of developing and making a drug product available in the U.S. for this type of disease or condition will be recovered from sales of the product. Orphan drug designation must be requested before submitting an NDA or supplemental NDA. After the FDA grants orphan drug designation, the identity of

the therapeutic agent and its potential orphan use are publicly disclosed by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. If a product which has an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to an orphan exclusivity period. Orphan exclusivity prevents FDA from approving any other applications to market the same drug for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. This exclusivity does not prevent a competitor from obtaining approval to market a different product that treats the same disease or condition or the same product to treat a different disease or condition.

Medicinal products are eligible for orphan designation in the EU if they meet each of the following requirements:

- the product must be intended for the treatment, prevention or diagnosis of a disease that is life-threatening or chronically debilitating;
- the prevalence of the condition in the EU must not be more than 5 in 10,000 or it must be unlikely that marketing of the medicine would generate sufficient returns to justify the investment needed for its development; and
- no satisfactory method of diagnosis, prevention or treatment of the condition concerned can be authorized, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

The application for orphan designation must be submitted to the EMA and approved before an application is made for marketing authorization for the product. Once authorized, orphan medicinal products are entitled to ten years of market exclusivity during which competent authorities of the EU member states, the EMA and the EC are not permitted to accept applications or grant marketing authorization for other similar medicinal products with the same indication. However, marketing authorization may be granted to a similar medicinal product with the same orphan indication during the ten-year exclusivity period if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities or if the latter product is safer, more effective or otherwise clinically superior to the original orphan medicinal product. The period of market exclusivity may also be reduced to six years if, at the end of the orphan product's fifth year on the market, it can be demonstrated that the product is sufficiently profitable so as not to justify maintenance of market exclusivity.

Healthcare Law and Regulation. Healthcare providers, including physicians, and third-party payers play a primary role in the recommendation and prescription of drug products that are granted marketing approval. Arrangements with healthcare providers, third-party payers 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. 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 payers, 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 healthcare 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.

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 healthcare clearinghouses (which are entities that process or 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 these laws differ from each other in significant ways and they 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.

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 SEC. Further, a copy of this Annual Report on Form 10-K is located at the SEC's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. Information on the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at www.sec.gov.

ITEM 1A. RISK FACTORS

RISKS RELATED TO OUR COMPANY AND OUR BUSINESS

We will need additional capital to fund our operations, which may not be available on favorable terms or at all.

We will need additional capital to fund our operations, including completing Medidur clinical development and obtaining regulatory approvals and continuing our research and development program for other product candidates. In addition, if we decide to commercialize Medidur or any of these product candidates ourselves, we would incur significant expenses related to product manufacturing, marketing, sales, distribution and other commercialization costs. We believe that our capital resources of $29.0 million at June 30, 2016, together with expected revenues from existing collaborations, should enable us to fund our operations as currently planned into the second quarter of fiscal year 2018. This estimate excludes any potential net profits receipts from sales of ILUVIEN or other receipts under the Alimera collaboration agreement. We believe our ability to fund our planned operations beyond that time, including completion of clinical development of Medidur, will require additional capital from the commercialization of ILUVIEN, future collaboration or other agreements and/or financing transactions.

The additional capital we will require will be influenced by many factors, including, but not limited to:

- whether, when and to what extent we receive future revenues with respect to the commercialization of ILUVIEN;
- the timing and cost of clinical development, regulatory approval and commercialization of Medidur for posterior segment uveitis and the manner in which we commercialize Medidur;
- 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 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.

We do not know if additional capital will be available to us when needed or on terms favorable to us or our stockholders. Collaboration, licensing or other agreements may not be available on favorable terms, or at all. We do not know when or if we will receive any substantial funds from the commercialization of ILUVIEN. If we seek to sell shares under our at-the-market (ATM) facility or in another offering, we do not know whether and to what extent we will be able to do so, or on what terms. Further, the rules and regulations of the Australian Securities Exchange (ASX) and the NASDAQ Global Market (NASDAQ) require us to obtain shareholder approval for sales of common stock under certain circumstances, which could delay or prevent us from raising additional capital from such sales. Also, the state of the economy and 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 dilute our existing stockholders' 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, potential independent commercialization of Medidur or other new products, if any, 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.

We have incurred significant losses and may never achieve profitability from operations.

We have a history of operating losses, and at June 30, 2016, we had a total accumulated deficit of $292.2 million. Since inception, we have financed our operations primarily from payments under collaboration agreements and sales of our equity securities. We do not have any assured sources of revenue. To become and remain profitable, we and/or our licensees must succeed in developing and commercializing products that generate significant revenue. This will require us or our licensees to be successful in a range of challenging activities, including completing pre-clinical testing and clinical trials of our product candidates, discovering additional product candidates, obtaining regulatory approval for these product candidates, manufacturing, marketing and selling any products for which we may obtain regulatory approval, satisfying any post-marketing requirements and obtaining reimbursement for our products from private insurance or government payers. To date, none of our approved licensed products, including Retisert and ILUVIEN, has generated significant revenues to us from sales. Of our product candidates, only Medidur is in late-stage clinical trials. We may never succeed in these activities and, even if we do, may never generate revenues significant enough to achieve profitability. Because of the numerous risks and uncertainties associated with pharmaceutical product development and commercialization, we are unable to accurately project when or if we will be able to achieve profitability from operations. Even if we do so, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations.

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

Our Retisert royalty income has ranged between $1.2 million and $1.4 million for each of the last five fiscal years. We do not expect Retisert royalty income to grow materially, if at all, and it may decline or cease. The patent with which Retisert is marked expires in March 2019, and we may not receive any Retisert royalty income after that time. Bausch & Lomb ceased selling Vitrasert on its patent expiration.

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:

- costs of internally funded research and development, including contract research organization (CRO) and other costs related to clinical development and costs of pre-clinical studies and research;
- developments with respect to our products and product candidates, both licensed and independently developed, including pre-clinical and clinical trial data and 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;
- 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.

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

At June 30, 2016, we had $1.1 million of intangible assets relating to our Durasert and Tethadur technologies on our balance sheet. We conduct impairment analyses of our intangible assets as required under U.S. Generally Accepted Accounting Principles (U.S. GAAP) and could take 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. Impairment charges on our intangible assets could have a material adverse effect on our results of operations in the quarter of the impairment.

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

Our success is dependent on our ability to complete clinical development of, obtain marketing approvals for and successfully commercialize Medidur for posterior segment uveitis. If we are unable to do so, either alone or through a collaboration, or experience significant delays in doing so, our business could be materially harmed.

We have invested a significant portion of our efforts and financial resources in the development of Medidur for posterior segment uveitis. Our prospects are substantially dependent on our ability to obtain marketing approval for and successfully commercialize Medidur. Successful commercialization of Medidur will depend on various factors, including:

- Successful completion of the clinical development of Medidur;
- Receipt of marketing approvals in the U.S., Europe and other jurisdictions and appropriate labeling;
- Receipt and maintenance of orphan drug designation and marketing exclusivity;
- The extent of any required post-marketing approval commitments to regulatory authorities;
- Successful arrangements for raw materials, manufacturing and delivery of Medidur;
- Adequate levels of pricing and reimbursement;
- Establishing or contracting for a commercial team or establishing collaborations to successfully market and sell Medidur;
- Commercial acceptance by ophthalmologists, patients and third-party payers;
- Continued acceptable safety profile;
- Competition with other products and therapies;
- Performance of any collaborators; and
- Protection of intellectual property rights.

If, as a result of failure to achieve any of these or other factors, we are unable to receive marketing approval for or successfully commercialize Medidur, or experience significant delays in doing so, our business could be materially harmed.

If our CROs, vendors and investigators do not successfully carry out their responsibilities or if we lose our relationships with them, our development efforts with respect to our product candidates could be delayed.

We are dependent on CROs, vendors and investigators for pre-clinical testing and clinical trials related to our product development programs. These parties are not our employees, and we cannot control the amount or timing of resources that they devote to our programs. If they do not timely fulfill their responsibilities or if their performance is inadequate, the development and commercialization of our product candidates could be delayed. The parties with which we contract for execution of clinical trials play a significant role in the conduct of the trials and the subsequent collection and analysis of data. Their failure to meet their obligations could adversely affect clinical development of our product candidates. If we lose our relationship with any one or more of these parties, we could experience a significant delay in identifying another comparable provider and contracting for its services. We may be unable to retain an alternative provider on reasonable terms, if at all. Even if we locate an alternative provider, this provider may need additional time to respond to our needs and may not provide the same type or level of service as the original provider. In addition, any provider that we retain will be subject to GLP and similar foreign standards, and we do not have control over compliance with these regulations by these providers. Consequently, if these practices and standards are not adhered to by these providers, the development and commercialization of our product candidates could be delayed.

There is no assurance that we will be able to file our MAA or NDA for Medidur for posterior segment uveitis on the schedule we have planned, which could delay the potential marketing approvals and commercialization of Medidur.

We are dependent on third parties to collect and analyze the data from our Medidur Phase 3 trials and Medidur inserter utilization study, and we cannot assure that they will provide the data in time for us to meet the planned filings of our MAA and NDA. Further, we need the results of our second Phase 3 trial, which requires completion of enrollment and six-month final visits with patients. There is no assurance that we will reach the six-month primary endpoint of that trial on the schedule required to meet our planned filing schedule. Failure to file for our applications for marketing approvals on our planned schedule could delay the potential receipt of those approvals and the commercialization of Medidur.

There is no assurance that data we plan to submit in support of our planned MAA and NDA for Medidur for posterior segment uveitis will be acceptable to the EMA or the FDA and accordingly that Medidur's European or U.S. marketing authorization will be granted.

We plan to file our MAA for Medidur for posterior segment uveitis based on data from our first Phase 3 trial rather than two Phase 3 trials as a result of the high statistical significance of the top-line results achieved in our first trial. The MHRA advised us that, consistent with the published PtC of the European Agency for Evaluation of Medicinal Products, an application for a product treating a condition like posterior segment uveitis could be based on statistically compelling and clinically relevant results from just one pivotal trial. The MHRA provided this advice without reviewing the results of our first Phase 3 trial, which had not been completed at the time. There can be no assurance that the results from our first Phase 3 trial will satisfy the standards of the PtC or provide the data necessary for marketing approval in Europe, and data from our second Phase 3 trial or other data could be required.

We plan to file our NDA for Medidur for posterior segment uveitis on results from our two Phase 3 trials. While our first Phase 3 trial of Medidur for posterior segment uveitis met its primary efficacy endpoint with high statistical significance and showed encouraging safety results, there is no assurance that the second trial will achieve the same or comparable results to the first trial or provide the evidence of safety and efficacy required to file an NDA for approval of Medidur by the FDA or other regulatory authorities. Further, we are conducting our second Phase 3 trial of Medidur in India. In general, the FDA accepts data from clinical trials conducted outside the U.S.; however, acceptance of this data is subject to, among other things, the clinical trials being conducted and performed by qualified investigators in accordance with GCP 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 our second Phase 3 clinical trial is subject to applicable local laws, FDA acceptance of the data from the trial will depend on its determination that it also was conducted in accordance with all applicable U.S. laws and regulations.

We plan to submit data from our new inserter utilization study in support of both our MAA and NDA. The EMA or the FDA may require an additional study of our inserter.

The FDA has significant discretion in determining whether to accept an NDA for review and what data to require 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 or to approve the NDA. The EMA has comparable discretion with respect to MAAs. The refusal of the FDA or the EMA to accept our marketing applications for review or their requirements for additional data or trials could delay the timing, increase the expense or render impractical continued pursuit of potential marketing approval of Medidur for posterior segment uveitis. Delay in or inability to obtain marketing approvals for Medidur could materially and adversely affect our business and the price of our common stock.

We may not maintain our European orphan product designation for Medidur for posterior segment uveitis or obtain orphan designation in the U.S. and as a result, may not have the benefits of that designation.

Medidur has been designated as an orphan medicinal product in Europe. However, at the time we apply for marketing authorization, we must also submit a request for maintenance of the orphan designation to determine whether Medidur will maintain its status as an orphan medicine and receive market exclusivity and other benefits. Review of the maintenance of orphan designation is based on data on the then current prevalence of posterior segment uveitis; the then current life-threatening or debilitating nature of posterior segment uveitis; other methods for its diagnosis, prevention or treatment; and if applicable, a justification of Medidur's significant benefit. This review is carried out independently of, but in parallel to, the evaluation of the marketing authorization application. There is no assurance that Medidur will maintain its orphan medicinal status in Europe. Further, our ability to obtain orphan status for Medidur in the U.S. in uncertain, and there is no assurance we will be able to do so.

Off-label sales of ILUVIEN to treat posterior segment uveitis may adversely affect sales of Medidur, if approved.

The micro-inserts that comprise ILUVIEN and Medidur have substantially the same design, polymers and release rate, and both deliver the corticosteroid FAc. Although Medidur is administered with a smaller gauge needle and delivers a somewhat lower dose of FAc than ILUVIEN, ILUVIEN is already approved and marketed. It is possible that physicians will prescribe ILUVIEN for the treatment of posterior segment uveitis on an off-label basis, which could adversely affect the sales of Medidur, if approved.

There is no assurance that Alimera will successfully commercialize ILUVIEN for DME or that we will receive any significant revenues from its commercialization.

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 commercialization of ILUVIEN is a significant undertaking by Alimera, and ILUVIEN for DME is Alimera's first and only commercial product. Alimera's sales of ILUVIEN have not been significant to date, Alimera has continued to incur operating losses, and it has violated and in the future may violate the financial covenants of its loan agreement. We do not know if, when, or to what extent we will receive future revenues from the commercialization of ILUVIEN for DME. The amount and timing of any revenues we receive will be affected by many factors including:

- Alimera's and its distributors' and sublicensees' ability to effectively market and sell ILUVIEN in each country where sold;

- the manner of sale, whether directly by Alimera or by sublicensees or distributors, and the terms of sublicensing and distribution agreements;
- the amount and timing of sales of ILUVIEN in each country;
- commercialization costs;
- regulatory approvals, appropriate labeling, and desirable pricing, insurance coverage and reimbursement;
- competition;
- commencement of marketing in additional countries; and
- Alimera's ability to raise adequate capital as needed to fund its operations and to maintain compliance with its loan agreement.

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

Alimera needs alternative financing to replace its $35.0 million debt facility or additional capital to maintain compliance with the financial covenants under its loan agreement, which Alimera may be unable to obtain, and Alimera's continued losses and financial condition may cast doubt on its ability to continue to operate as a going concern.

Although Alimera launched ILUVIEN in Germany and the U.K. in the second quarter of 2013 and in the U.S. and Portugal in the first quarter of 2015, Alimera had accumulated a deficit of $361.9 million through June 30, 2016. Alimera has not generated revenues that cover its actual or anticipated expenses and cannot project the extent of its future losses. Alimera expects to continue to incur substantial losses, and as a result, is unable to predict when or if it will achieve or sustain profitability. Alimera's ability to achieve profitability and generate net profit payments to us is dependent on its ability to successfully market and sell ILUVIEN.

Alimera failed to meet a revenue threshold in January 2016 and a liquidity threshold as of June 30, 2016 under the financial covenants of its loan agreement. While these failures were subsequently waived by the lender, Alimera was required to pay substantial amounts and grant concessions in connection with these waivers. Alimera reported that based on its financial forecast for the remainder of 2016, it must obtain additional or alternative financing or it is probable that Alimera will not be able to comply with the modified financial covenants under its loan agreement. Alimera is pursuing alternative or additional debt financing (including a recently completed common stock offering raising $25.1 million in net proceeds, which Alimera reported would be used to fund the commercialization of ILUVIEN and other corporate purposes), and has an at-the-market offering in place for possible sales of its common stock. If Alimera is not successful in raising the capital it requires and defaults on its obligations under its loan agreement, its lender may call the loan, which could require Alimera to pay back the entire amount owed and pay an early termination fee, or if the lender does not call the loan, Alimera may have to pay an increased rate of interest, pay additional monetary amounts in exchange for a waiver or modification of the loan agreement, or grant additional equity or warrant coverage and agree to further restrictions on its operations that could hinder it in the future. Alimera's failure to comply with the covenants under the loan agreement could create substantial doubt about Alimera's ability to continue as a going concern and to market and sell ILUVIEN. The termination provisions of our agreement with Alimera include various bankruptcy events.

Further, due to the limited revenue generated by ILUVIEN to date, even if Alimera is able to refinance its loan agreement and maintain compliance with its covenants, Alimera will need to raise additional capital to fund the continued commercialization of ILUVIEN. If Alimera is unable to raise sufficient additional financing, it may need to adjust its commercial plans, which likely would adversely affect Alimera's ability to market ILUVIEN and make any potential payments to us.

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

Prices, coverage and reimbursement to consumers of ILUVIEN for DME, like other drugs, are generally regulated by third-party payers, such as government health administration authorities and plans, private health 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 is associated with certain adverse side effects in the eye, which may affect the success of this micro-insert for treatment of DME and posterior segment 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. These side effects shown in the Phase 3 trials for ILUVIEN resulted in limitations to the approved indications of ILUVIEN, and sales of ILUVIEN may be adversely affected by the potential side effects from FAc relative to other treatments for DME. The extent of ILUVIEN's long-term side-effect profile beyond month 36 is not yet known. Alimera is conducting a five-year post-authorization, open label registry study of the safety of ILUVIEN in 800 patients treated with the European labeled indication, which was a condition of European approval. Data from this study or other commercial experience could result in the withdrawal of ILUVIEN's marketing approval in one or more jurisdictions. Further, delay in the commercial launch of ILUVIEN could result in the withdrawal of marketing or regulatory authorization for ILUVIEN in jurisdictions where ILUVIEN has already received marketing authorization. In addition, the perception by physicians of this benefit of efficacy versus the side-effect profile could adversely affect sales of ILUVIEN.

Medidur achieved encouraging safety results through the last follow-up visit in its first Phase 3 trial. However, there is no assurance that encouraging safety results will continue in that trial, or that the second Phase 3 trial will yield encouraging safety results. There is also no assurance that the overall risk-benefit profile for Medidur will be favorable or that Medidur will be determined to be safe for the treatment of posterior segment uveitis in light of potential 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.

There is no assurance that payment of ILUVIEN net profits to us for 2014 as the result of an independent audit will be upheld or that we will receive any future payments of ILUVIEN net profits to which we believe we are entitled without future independent audits or at all.

While the independent audit firm that audited Alimera's commercialization reporting for 2014 concluded that Alimera over-reported commercialization expenses and accordingly under-reported net profits payable to us, Alimera has sought to challenge those findings in arbitration, and if that challenge is allowed to go forward, may prevail in its efforts to overturn all or part of the audit firm's conclusions. Depending upon the outcome of the arbitration, conclusions of the independent audit firm with respect to some commercialization expenses for 2014 may also affect other periods. As a result, there is no assurance that we will receive net profits payments to

which we believe we are entitled in accordance with the Alimera Agreement. Moreover, we may in the future challenge Alimera's reporting under the Alimera Agreement, which may result in future independent audits and arbitration, the outcome of which may or may not be favorable to us.

There is no assurance that Pfizer will exercise its option with respect to the Latanoprost Product if we initiate and complete Phase 2 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 if we complete Phase 2 clinical trials, which are at our option and expense, or we cease development at any time prior to completion of those trials. There is no assurance that we will commence or complete Phase 2 clinical trials for the Latanoprost Product; that, if completed, the trials will be successful; that Pfizer will exercise its option whether we complete Phase 2 trials or cease development; that, if exercised, Pfizer will commence or complete Phase 3 clinical trials; or that the Latanoprost Product will achieve successful Phase 3 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 have continued to make advances in our development of Tethadur and are optimistic that our Tethadur technology platform can provide sustained delivery of proteins (including antibodies) and peptides, our research continues to be at an early stage, and we face challenges. Development of any product candidates utilizing Tethadur is expected to require significant additional research and funding. There is no assurance that we will continue our development of Tethadur, that 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.

During the first quarter of fiscal year 2017, we consolidated all of our research and development work in our U.S. laboratory facility, closed our U.K. research facility, where much of our Tethadur research was previously conducted, and have terminated the employment of our U.K.-based employees who performed much of the pre-clinical research of Tethadur. There is no assurance that we will successfully transition the research and development of Tethadur to the U.S. or that we will not experience delays as a result of this consolidation.

We do not know if our product candidate for severe knee osteoarthritis in collaboration with HSS will be safe and effective, will ever enter pivotal clinical trials or will become an approved product or be commercialized.

Our product candidate for severe knee osteoarthritis in collaboration with HSS is the subject of an investigator-sponsored, open-label, one-dose, safety and tolerability study. We do not know what the results of that study will be, whether we will be able to develop a product candidate for this indication to eventually enter pivotal Phase 3 trials, whether we will commence or successfully complete any such trials or whether we will obtain regulatory approvals for a product for this indication. Although we believe we will be able to do so, there is no assurance that we will be able to design a product with a longer treatment duration than six months, that we will be able to create a refillable implant or that the product, even if successful for severe knee osteoarthritis, can be extended to treat osteoarthritis of any other joint. In addition, the study for this product candidate is being conducted by an investigator, and we do not control that trial as we would if we were conducting the trial ourselves. We have no agreement with HSS to develop this product beyond the completion of this study, and there is no assurance that we will reach such an agreement. If we do not do so, there is a risk that the intellectual property of HSS and joint intellectual property developed in the course of our collaboration with HSS or future actions by HSS will interfere with our ability to develop and market an OA implant.

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 segment uveitis, which is in pivotal Phase 3 trials, all of our product development is at earlier stages. Product development at all stages involves a high degree of risk, and only a small proportion of research and development programs result in product candidates that advance to pivotal clinical trials or result in approved products. For example, although we have completed favorable pre-clinical tests of a TKI to treat wet AMD, there is additional pre-clinical research to be completed and there is no assurance that we will develop a TKI product to advance to clinical trials. 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 or promote products licensed to them;
- adverse side effects;
- failure of trials to demonstrate 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, CROs, vendors and investigators responsible for pre-clinical testing and clinical trials;
- inability to obtain supplies and/or to manufacture sufficient quantities of materials for use in clinical trials;
- stability issues with clinical materials;
- failure to comply with GLP, 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. In addition, data from one pivotal clinical trial may not be predictive of the results of other pivotal clinical trials for the same product candidate, even if the trial designs are the same or similar. 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.

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 Medidur for posterior segment uveitis or any other products if we seek to do so.

We currently have no marketing and sales capability, our approved products are commercialized by others, and we have no experience in commercializing products. We face the decision of how to commercialize Medidur for posterior segment uveitis, if approved. We do not know if we will decide to directly commercialize Medidur or any other products ourselves. 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 in one or more countries, 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 in any country.

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;
- 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. 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 may 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.

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 payers. 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 and determinations of government and other third-party payers. In particular, if governments, private insurers, governmental insurers and other third-party payers do not recommend our products and product candidates, limit the indications for which they are recommended, do not provide adequate and timely coverage and reimbursement levels for our products or limit the frequency of administration, the market acceptance of our products and product candidates will be limited. Governments, governmental insurers, private insurers and other third-party payers 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, 2016, we had 233 patents and 107 pending patent applications, including patents and pending applications covering our Durasert, Tethadur and other technologies. Intellectual property protection of our technologies is uncertain. We expect to seek to patent and protect our proprietary technologies. However, there is no assurance that any additional patents will be issued to us as a result of our pending or future patent applications or that any of our patents will withstand challenges by others. In addition, we may not have sufficient funds to patent and protect our proprietary technologies to the extent that we would desire, or at all. If we were determined to be infringing any third-party patent, we could be required to pay damages, alter our products or processes, obtain licenses, pay royalties or cease certain operations. We may not be able to obtain any required licenses on commercially favorable terms, if at all. In addition, many foreign country laws may treat the protection of proprietary rights differently from, and may not protect our proprietary rights to the same extent as, laws in the U.S. and Patent Cooperation 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 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 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.

We do not own or operate manufacturing facilities for the production of commercial quantities of our product candidates, including Medidur. If Medidur or any other of our product candidates is approved, we do not intend to build our own commercial manufacturing facilities and would need to arrange for manufacture by contract manufacturers. There is no assurance that we will be able to arrange for the manufacture of Medidur or any other product on satisfactory terms or that any contract manufacturer will supply any such products on a timely manner and in compliance with applicable regulations.

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.

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;
- inadequate protection of intellectual property rights in some countries; and
- obtaining required government approvals.

Economic conditions and regulatory changes leading up to and following the U.K.'s likely exit from the EU could have a material adverse effect on our business and results of operations.

In June 2016, the U.K. held a non-binding referendum in which voters approved an exit from the EU (commonly referred to as "Brexit"), the announcement of which caused significant volatility in global stock markets and currency exchange rate fluctuations that resulted in the strengthening of the U.S. dollar against the Pound Sterling currency in which we conduct certain business activity. As a result of the referendum, it is expected that the U.K. government will begin negotiating the terms of the U.K.'s withdrawal from the EU, which may amplify the adverse effects experienced to date.

Given the lack of comparable precedent, it is unclear what financial, trade and legal implications the withdrawal of the U.K. from the EU may have and how such withdrawal may affect us. Potential volatility of the U.S. dollar relative to the Pound Sterling or other currencies may adversely affect our operating results and expose us to gains and losses on non-U.S. currency transactions. The announcement of Brexit and the withdrawal of the U.K. from the EU may create economic uncertainty, which may reduce sales of our licensed products. A U.K. withdrawal from the EU may, among other things, increase regulatory complexities, disrupt the free movement of goods, services and people between the U.K. and the EU, undermine bilateral cooperation in key policy areas and significantly disrupt trade between the U.K. and the EU. In addition, Brexit could lead to legal uncertainty and potentially divergent national laws and regulations in Europe, as the U.K. determines which EU laws to replace or replicate. It raises uncertainty, for example, as to the regulatory path for marketing approval of Medidur in the U.K.

If the U.K. were to significantly alter its laws or regulations affecting the biotechnology or pharmaceutical industries, we could face significant new costs and uncertainties Altered regulations could add time and expense to the process by which our product candidates receive regulatory approval in the U.K. and the EU. Similarly, it is unclear at this time what impact Brexit will have on our intellectual property rights and the process for obtaining and defending such rights.

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 payers 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 Prescription Drug User Fee Act (PDUFA) extended by two months the period in which the FDA is expected to review and approve certain NDAs. Although the FDA has recently stated that it expects to meet PDUFA's updated timing goals, it has in the past provided its managers discretion to miss them due to heightened agency workload or understaffing in the review divisions. Accordingly, it remains unclear whether and to what extent the FDA will adhere to PDUFA timing goals in the future, which could delay approval and commercialization of our product candidates.

RISKS RELATED TO OUR COMMON STOCK

The price of our common stock may be volatile.

The price of our common stock (including common stock represented by CHESS Depositary Interests (CDIs)) may be affected by developments directly affecting our business, as well as by developments out of our

control or not specific to us. The 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 NASDAQ, including the minimum stock price, and 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, 2016, we had outstanding warrants and options to acquire approximately 6.6 million shares of our common stock, or approximately 16.2% 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We do not own any real property. We lease 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. Our lease of 1,250 square feet of laboratory space and 1,665 square feet of office space in Malvern, U.K. expired in August 2016, but was extended through October 2016 to facilitate closure of the research facility. We believe our leased Watertown facility is adequate for the Company's present needs.

ITEM 3. LEGAL PROCEEDINGS

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market Information, Holders and Dividends

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

	High	Low
Fiscal year ended June 30, 2016:		
First Quarter	$4.52	$3.23
Second Quarter	5.81	3.46
Third Quarter	4.82	2.37
Fourth Quarter	3.87	2.64
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

On August 31, 2016, the last reported sale price of our common stock on the NASDAQ Global Market was $3.87. As of that date, we had approximately 20 holders of record of our common stock and, according to our estimates, approximately 4,888 beneficial owners of our common stock. In addition, as of that date, there were approximately 1,943 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, 2016:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in Column a) (c)
Equity Compensation plans approved by security holders	4,981,421	$ 3.60	1,019,791
Equity Compensation plans not approved by security holders	—	—	—
Total	4,981,421	$ 3.36	1,019,791

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, 2016, the number of shares issuable under the 2008 Incentive Plan was increased by 750,000 shares.

Recent Sales of Unregistered Securities

None.

Issuer Repurchases of Equity Securities

None.

ITEM 6. SELECTED FINANCIAL DATA

The selected historical financial data set forth below as of June 30, 2016, 2015, 2014, 2013 and 2012 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, 2016 and 2015 and for the years ended June 30, 2016 2015 and 2014 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,				
	2016	2015	2014	2013	2012
	(In thousands except per share data)				
Consolidated Statements of Operations Data:					
Revenues:					
Collaborative research and development (1)	$ 398	$25,411	$ 2,155	$ 780	$ 2,080
Royalty income	1,222	1,154	1,318	1,363	1,446
Total revenues	1,620	26,565	3,473	2,143	3,526
Operating expenses:					
Research and development	14,381	12,088	9,573	7,005	7,039
General and administrative	9,013	8,056	7,468	7,169	6,868
Gain on sale of property and equipment	—	—	(78)	—	—
Impairment of intangible assets (2)	—	—	—	—	14,830
Total operating expenses	23,394	20,144	16,963	14,174	28,737
Operating (loss) income	(21,774)	6,421	(13,490)	(12,031)	(25,211)
Other income:					
Change in fair value of derivatives	—	—	—	—	170
Interest and other income, net	72	22	5	14	37
Total other income	72	22	5	14	207
(Loss) income before income taxes	(21,702)	6,443	(13,485)	(12,017)	(25,004)
Income tax benefit (expense)	155	(96)	130	117	169
Net (loss) income	$(21,547)	$ 6,347	$(13,355)	$(11,900)	$(24,835)
Net (loss) income per share:					
Basic	$ (0.68)	$ 0.22	$ (0.49)	$ (0.52)	$ (1.19)
Diluted	$ (0.68)	$ 0.21	$ (0.49)	$ (0.52)	$ (1.19)
Weighted average common shares outstanding:					
Basic	31,623	29,378	27,444	23,044	20,791
Diluted	31,623	30,584	27,444	23,044	20,791

	As of June 30,				
	2016	2015	2014	2013	2012
	(In thousands)				
Consolidated Balance Sheet Data:					
Cash and cash equivalents	$15,313	$19,121	$15,334	$ 6,899	$ 4,625
Marketable securities	13,679	9,414	2,944	3,374	9,946
Total assets	31,619	32,367	22,671	16,249	20,597
Total deferred revenue—current and long-term	5,732	5,629	5,722	5,984	5,959
Total stockholders' equity	20,881	23,368	14,924	7,700	13,636

(1) Includes the following: from our collaboration agreement with Alimera: $233,000 in fiscal 2016, $25.1 million in fiscal 2015, $114,000 in fiscal 2014, $67,000 in fiscal 2013 and $111,000 in fiscal 2012; from our Restated Pfizer Agreement: $368,000 in fiscal 2013 and $754,000 in fiscal 2012; from feasibility study agreements: $33,000 in fiscal 2016, $144,000 in fiscal 2015, $1.9 million in fiscal 2014 and $245,000 in fiscal 2013; from our license agreement with Enigma Therapeutics: $100,000 in fiscal 2016, $100,000 in fiscal 2015, $102,000 in fiscal 2014 and $100,000 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 Tethadur and Durasert intangible assets.

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

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

Overview

We develop sustained-release drug delivery products primarily for the treatment of chronic 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 United States (U.S.) Food and Drug Administration (FDA) for treatment of back-of-the-eye diseases. Medidur™ for posterior segment uveitis, our lead product candidate, is in pivotal Phase 3 clinical trials, and ILUVIEN® for diabetic macular edema (DME), our lead licensed product, is sold in the U.S. and three European Union (EU) countries. Our product development program is focused primarily on utilizing our two core technology platforms to deliver drugs and biologics to treat chronic diseases. Our strategy includes developing products independently while continuing to leverage our technology platforms through collaborations and license agreements as appropriate.

Medidur, our most advanced development product, is designed to treat chronic non-infectious uveitis affecting the posterior segment of the eye (posterior segment uveitis) for three years from a single injection. Injected into the eye in an office visit, Medidur is a tiny micro-insert that delivers a micro-dose of a corticosteroid to the back of the eye on a sustained basis. We are developing Medidur independently.

The first of Medidur's two Phase 3 trials met its primary efficacy endpoint of prevention of recurrence of disease through six months with high statistical significance (p less than 0.00000001; intent to treat analysis) and achieved encouraging safety results. The same high statistical significance for efficacy and encouraging safety results were maintained through 12 months of follow-up. Due to the high level of statistical significance achieved, we plan to file our EU marketing approval application (MAA) based on data from the first Phase 3 trial, rather than two trials. The MAA is planned for the first quarter of 2017. Enrollment in the second Phase 3 trial is expected to be completed in October 2016. Assuming favorable results, we plan to file a new drug application (NDA) with the FDA in the third quarter of 2017. A utilization study of our new smaller diameter 27-gauge Medidur inserter, which is required for both our MAA and NDA, met its primary endpoint, ease of intravitreal administration.

ILUVIEN, our most recently approved product, is an injectable, sustained-release micro-insert that provides three years of treatment of DME from a single injection. ILUVIEN is substantially the same design as Medidur and delivers the same steroid, although it is injected using a 25-gauge inserter. ILUVIEN was developed in collaboration with Alimera Sciences, Inc. (Alimera) and is licensed to and sold by Alimera. We are entitled to a share of the net profits (as defined) from Alimera's sales of ILUVIEN on a quarter-by-quarter, country-by-country basis. ILUVIEN has been sold in the U.S. since 2015, 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 (IOP). ILUVIEN has been sold in the United Kingdom (U.K.) and Germany since 2013 and in Portugal since 2015. ILUVIEN has marketing approvals in these and 14 other European countries for the treatment of chronic DME considered insufficiently responsive to available therapies.

FDA-approved Retisert® is an implant that provides sustained treatment of posterior segment uveitis for 30 months. Implanted in a surgical procedure, Retisert delivers the same corticosteroid as Medidur but in a larger dose. Retisert was co-developed with Bausch & Lomb to which it is licensed. We receive royalties from Retisert sales.

We are seeking to develop products that use our Durasert™ and Tethadur™ technology platforms to deliver drugs and biologics to treat wet and dry age-related macular degeneration (AMD), glaucoma, osteoarthritis and other diseases. A sustained release, surgical implant to treat pain associated with severe knee osteoarthritis (OA) we developed in collaboration with Hospital for Special Surgery is in an investigator-sponsored pilot study. We recently commenced the first of two investigational new drug (IND)-enabling studies of an injectable, bioerodible micro-insert we developed to provide sustained delivery of a tyrosine kinase inhibitor (TKI) to treat wet AMD.

In the first quarter of fiscal 2017, we consolidated all of our research and product development activities in our facility in the U.S. We have terminated the employment of all of our U.K. employees and expect to vacate our research facility in Malvern, U.K. at the end of October. We estimate that this consolidation will reduce pre-tax operating expenses by approximately $900,000 annually, beginning in the second quarter of fiscal 2017. We expect to incur approximately $710,000 in total pre-tax charges, of which approximately $590,000 are cash outlays, as a result of the consolidation. Of these charges, $218,000 was expensed in the fourth quarter of fiscal 2016. See Note 9 of Notes to Consolidated Financial Statements for more information.

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

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

Revenue Recognition

Our business strategy includes entering into collaborative license and development agreements for the development and commercialization of product candidates utilizing our technology systems. The terms of these arrangements typically include multiple deliverables by us (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 and/or 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 years ended June 30, 2016 and 2015, we reported $398,000 and $25.4 million, respectively, 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.

In the fiscal year ended June 20, 2011, we restated our agreement with Pfizer. The balance of the total arrangement consideration of the Restated Pfizer Agreement that was not recognized at the time of the restatement was recorded as deferred revenue and is recognized as revenue using the proportional performance method over the estimated period of our performance obligations under the research and development program provided in the agreement. Revenue is recognized in any period to the extent that we incur costs for the research and development program relative to the aggregate projected costs for the program.

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 3 clinical trial program for Medidur for posterior segment 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, 2016, our CRO agreements provided for two Phase 3 clinical trials and a utilization study of our proprietary inserter at an aggregate remaining cost of approximately $13.5 million, which we expect to increase as a result of pending and contemplated change orders. 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 2016, we recognized approximately $7.3 million of research and development expense attributable to our Medidur Phase 3 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, 2016 and 2015

	Year Ended June 30,		Change	
	2016	2015	Amounts	%
	(In thousands except percentages)			
Revenues:				
Collaborative research and development	$ 398	$25,411	$(25,013)	(98)%
Royalty income	1,222	1,154	68	6%
Total revenues	1,620	26,565	(24,945)	(94)%
Operating expenses:				
Research and development	14,381	12,088	2,293	19%
General and administrative	9,013	8,056	957	12%
Total operating expenses	23,394	20,144	3,250	16%
Operating (loss) income	(21,774)	6,421	(28,195)	(439)%
Interest and other income, net	72	22	50	227%
(Loss) income before income taxes	(21,702)	6,443	(28,145)	(437)%
Income tax benefit (expense)	155	(96)	251	261%
Net (loss) income	$(21,547)	$ 6,347	$(27,894)	(439)%

Revenues

Collaborative research and development revenue totaled $398,000 in fiscal 2016 compared to $25.4 million in fiscal 2015. This decrease was primarily attributable to recognition of the one-time $25.0 million FDA-approval milestone earned for ILUVIEN in September 2014.

Retisert royalty income increased by $68,000, or 6%, to $1.22 million in fiscal 2016 compared to $1.15 million in fiscal 2015. We do not expect Retisert royalty income to increase significantly in the next fiscal year, and it may decline.

We are entitled to share in net profits, on a country-by-country basis, from sales 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 earned $0 and $43,000 of ILUVIEN net profits during fiscal 2016 and 2015, respectively. In addition, during fiscal 2016 we received $157,000 from Alimera attributable to a sublicense arrangement. 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. See Note 14 of Notes to Consolidated Financial Statements with respect to a dispute relating to the computation of ILUVIEN net profits for 2014, which may have implications for other years.

Research and Development

Research and development totaled $14.4 million in fiscal 2016, an increase of $2.3 million, or 19%, compared to $12.1 million in fiscal 2015. This increase was primarily attributable to a $1.4 million increase in CRO and other costs for the Medidur Phase 3 clinical development and regulatory submissions, $475,000 of personnel-related costs, including incentive compensation and contractual severance obligations and $320,000 of pre-clinical studies and other third-party research costs. We currently expect fiscal 2017 research and development expense to increase by approximately 10-15% compared to fiscal 2016, primarily due to our planned regulatory submissions for Medidur, studies of our wet AMD product candidate and increased personnel costs.

General and Administrative

General and administrative totaled $9.0 million in fiscal 2016, an increase of $957,000, or 12%, compared to $8.1 million in fiscal 2015. This increase was primarily attributable to a $564,000 increase in personnel costs, primarily higher incentive compensation accruals and stock-based compensation, and a $302,000 increase in professional fees.

Interest and Other Income

Interest and other income totaled $72,000 in fiscal 2016 compared to $22,000 in fiscal 2015, primarily due to a combination of higher average balances of marketable security investments and improved yields to maturity and higher money market interest rates.

Income Tax Benefit (Expense)

Income tax benefit of $155,000 in fiscal 2016 compared to income tax expense of $96,000 in fiscal 2015. We incurred $4,000 in fiscal 2016 and $263,000 in fiscal 2015 of federal alternative minimum tax expense based on U.S. taxable income for calendar year 2014 primarily attributable to the $25.0 million ILUVIEN FDA-approval milestone. Refundable foreign research and development tax credits totaled $159,000 in fiscal 2016 compared to $167,000 in fiscal 2015.

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	26,565	3,473	23,092	665%
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	na
Total operating expenses	20,144	16,963	3,181	19%
Operating income (loss)	6,421	(13,490)	19,911	148%
Interest and other income, net	22	5	17	340%
Income (loss) before income taxes	6,443	(13,485)	19,928	148%
Income tax (expense) benefit	(96)	130	(226)	(174)%
Net income (loss)	$ 6,347	$(13,355)	$19,702	148%

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 received $43,000 of ILUVIEN net profits during fiscal 2015 and none in fiscal 2014.

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 3 clinical development program and $240,000 of personnel related costs, including stock-based compensation.

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.

Interest and Other Income

Interest and 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 primarily 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.

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 consolidated 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. As a result, ASU 2014-15 will become effective on July 1, 2017, with early adoption permitted. We are evaluating the potential impact of adopting this standard on our consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases*. The new standard establishes a right-of-use (ROU) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. As a result, ASU 2016-02 will become effective on July 1, 2019. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. We are currently evaluating the impact of the pending adoption of the new standard on our consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*. ASU 2016-09 intends to simplify various aspects of how share-based payments are accounted for and presented in the financial statements. The main provisions include: all tax effects related to stock awards will now be recorded through the statement of operations instead of through equity, all tax-related cash flows resulting from stock awards will be reported as operating activities on the cash flow statement, and entities can make an accounting policy election to either estimate forfeitures or account for forfeitures as they occur. The amendments in ASU 2016-09 are effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years, and may be applied prospectively with earlier adoption permitted. As a result, ASU 2016-09 will become effective on July 1, 2017. We are currently evaluating the impact of this guidance on our consolidated financial statements.

Liquidity and Capital Resources

From fiscal 2012 through fiscal 2016, we financed our operations primarily from sales of our equity securities and the receipt of license fees, milestone payments, research and development funding and royalty income from our collaboration partners. At June 30, 2016, our principal sources of liquidity consisted of cash, cash equivalents and marketable securities totaling $29.0 million. Our cash equivalents are primarily invested in an institutional money market fund, and our marketable securities are invested in investment-grade corporate debt and commercial paper with short-term maturities.

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, 2016, we had a total accumulated deficit of $292.2 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 $29.0 million at June 30, 2016, together with expected cash inflows under existing collaboration agreements, will enable us to fund our operations as currently planned into the second quarter of fiscal year 2018. This estimate excludes any potential receipts under our Alimera collaboration agreement. We believe our ability to fund our planned operations beyond that time, including completion of clinical development of Medidur, will require additional capital from the commercialization of ILUVIEN, future collaboration or other agreements and/or financing transactions.

The additional capital we will require will be influenced by many factors, including, but not limited to:

- whether, when and to what extent we receive future revenues with respect to the commercialization of ILUVIEN;
- the timing and cost of development, regulatory approval and commercialization of Medidur for posterior segment uveitis and the manner in which we commercialize Medidur;
- 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 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.

We do not know if additional capital will be available when needed or on terms favorable to us or our stockholders. Collaboration, licensing or other agreements may not be available on favorable terms, or at all. We do not know when or if we will receive any substantial funds from the commercialization of ILUVIEN. If we seek to sell shares under our at-the-market (ATM) facility or in another offering, we do not know whether and to what extent we will be able to do so, or on what terms. Further, the rules and regulations of the Australian Securities Exchange (ASX) and the NASDAQ Global Market require us to obtain shareholder approval for sales of common stock under certain circumstances,, which could delay or prevent us from raising additional capital from such sales. Also, the state of the economy and financial and credit markets at the time or times we seek any additional financing may make it more difficult or expensive to obtain. If available, additional equity financing may be dilutive to stockholders, debt financing may involve restrictive covenants or other unfavorable terms and dilute our existing stockholders' 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, potential independent commercialization of Medidur or other new products, if any, and postpone or cancel the pursuit of product candidates, including pre-clinical and clinical trials and new business opportunities, reduce staff and operating costs, or otherwise significantly curtail our operations to reduce our cash requirements and extend our capital.

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

	Year Ended June 30,		
	2016	2015	2014
	(In thousands)		
Net (loss) income:	$(21,547)	$ 6,347	$(13,355)
Changes in operating assets and liabilities	2,073	1,009	389
Other adjustments to reconcile net (loss) income to cash flows from operating activities	3,158	2,941	2,295
Cash flows (used in) provided by operating activities	$(16,316)	$10,297	$(10,671)
Cash flows (used in) provided by investing activities	$ (4,462)	$ (6,733)	$ 66
Cash flows provided by financing activities	$ 16,990	$ 235	$ 19,044

Sources and uses of operating cash flows for the years ended June 30, 2016, 2015 and 2014 are summarized as follows:

	Year Ended June 30,		
	2016	2015	2014
	(In thousands)		
Operating cash inflows:			
License and collaboration agreements	$ 507	$ 25,317	$ 1,963
Royalty income	1,298	1,086	1,348
Foreign R&D tax credits	163	120	125
Investment interest received, net	176	97	45
	2,144	26,620	3,481
Operating cash outflows:			
Personnel costs	(5,133)	(5,086)	(5,340)
Professional fees	(3,610)	(3,234)	(2,869)
Clinical development and third-party R&D	(7,615)	(5,783)	(3,834)
All other operating cash outflows, net	(2,102)	(2,220)	(2,109)
	(18,460)	(16,323)	(14,152)
Cash flows (used in) provided by operating activities	$(16,316)	$ 10,297	$(10,671)

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 72.4% in fiscal 2016, 99.3% in fiscal 2015 and 5.8% in fiscal 2014, amounts attributable to Enigma represented 19.7% in fiscal 2016, 0.4% in fiscal 2015 and 6.9% in fiscal 2014 and amounts attributable to various feasibility study agreements represented 0.2% in fiscal 2015 and 86.6% in fiscal 2014.

Operating cash outflows increased by $2.1 million, or 13.1%, from fiscal 2015 to fiscal 2016, primarily as a result of increases of: (a) $1.5 million in Medidur clinical development; (b) $376,000 of professional fees; (c) $367,000 of pre-clinical studies and other third-party research and development costs; and (d) $277,000 of personnel and benefit costs, partially offset by decreases of (x) $260,000 of federal alternative minimum taxes attributable to calendar year 2014 U.S. taxable income; and (y) $230,000 in cash incentive compensation awards. 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.

Cash flows from investing activities were primarily attributable to purchases of marketable securities, net of maturities, of $4.3 million for fiscal 2016 and $6.6 million for fiscal 2015 and maturities of marketable securities, net of purchases, of $386,000 for fiscal 2014. Purchases of property and equipment totaled $113,000 in fiscal 2016, $161,000 in fiscal 2015 and $248,000 in fiscal 2014.

Cash flows from financing activities in fiscal 2016 were primarily attributable to an underwritten public offering in January 2016 for gross proceeds of $17.8 million, net of $1.3 million of share issue costs. 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. In addition, cash flows from financing activities included proceeds from the exercise of stock options totaling $490,000 in fiscal 2016, $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, 2016:

	Payments Due by Period				
Contractual Obligations	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
			(In thousands)		
Operating Lease Obligations	$1,227	$ 432	$ 795	$ —	$ —
Purchase Obligations	92	92	—	—	—
Total	$1,319	$ 524	$ 795	$ —	$ —

Our operating lease obligations consist predominantly of office and lab space in Watertown, Massachusetts. 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 segment 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, 2016, our CRO agreements provided for two Phase 3 clinical trials and a utilization study of the newly designed proprietary inserter at an aggregate remaining cost of approximately $13.5 million, which we expect to increase as a result of pending and contemplated change orders. We can terminate the agreements at any time without penalty.

We also have employment agreements with 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.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Foreign Currency Exchange Rates

We have conducted 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 impacted the net operating expenses of our U.K. operations. The strengthening of the U.S. dollar relative to the Pound Sterling in fiscal 2016 compared to fiscal 2015 resulted in a net decrease in research and development expense of approximately $133,000. 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 2016 would have decreased or increased by $101,000, respectively. All cash and cash equivalents, and most other asset and liability balances, are denominated in each entity's functional currency and, accordingly, we do not consider our statement of comprehensive (loss) income exposure to realized and unrealized foreign currency gains and losses to be significant.

Changes in the foreign exchange rate of the Pound Sterling to the U.S. dollar also impacted total stockholders' equity. As reported in the statement of comprehensive (loss) income, the relative strengthening of the U.S. dollar in relation to the Pound Sterling at June 30, 2016 compared to June 30, 2015 resulted in $96,000 of other comprehensive loss due to the translation of £204,000 of net assets of our U.K. operations, predominantly the Tethadur technology intangible asset, into U.S. dollars. For every incremental 5% strengthening or weakening of the U.S. dollar at June 30, 2016 in relation to the Pound Sterling, our stockholders' equity at June 30, 2016 would have decreased or increased, respectively, by approximately $14,000.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by this item may be found on pages F-1 through F-25 of this Annual Report.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2016. The term "disclosure controls and procedures", as defined in Rules 13a-15(e) and 15d-15(e) under 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, 2016, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

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

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

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

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

Our management assessed the effectiveness of our internal control over financial reporting as of June 30, 2016. 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, 2016, which is included below in this Item 9A of our Annual Report on Form 10-K.

(b) Changes in Internal Control over Financial Reporting

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

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the internal control over financial reporting of pSivida Corp. and subsidiaries (the "Company") as of June 30, 2016, 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, 2016, 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, 2016 of the Company and our report dated September 13, 2016 expressed an unqualified opinion on those financial statements.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
September 13, 2016

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, 55

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, 49

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, 66

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.

Dario Paggiarino, M.D., 59

Vice President, Chief Medical Officer

Dr. Paggiarino has served as our Vice President, Chief Medical Officer since August 2016. Prior to that, Dr. Paggiarino served since April 2013 as Senior Vice President and Chief Development Officer of Lpath, Inc., a biotechnology company focused on the discovery and development of lipidomic-based therapeutic antibodies

that target bioactive signaling lipids to treat a wide range of human diseases. Dr. Paggiarino served as Vice President and Therapeutic Unit Head for retina diseases at Alcon, a division of Novartis from 2011 to 2013. He served as Executive Director of Clinical Development and Medical Affairs at Pfizer Global R&D, a division of Pfizer, Inc., from 2001 to 2011. Earlier in his career, he held research and development positions of increasing responsibility at Angelini Pharmaceuticals, Inc., an affiliate of Angelini S.p.A, a privately owned company, ultimately serving as president and later joined Pharmacia Global R&D, a division of Pharmacia Corporation, where he was clinical program director of ophthalmology.

Corporate Governance

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

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

Other Information

The other information required to be disclosed in Item 10 is hereby incorporated by reference to our 2016 Proxy Statement.

ITEM 11. EXECUTIVE COMPENSATION

The information required to be disclosed in Item 11 is hereby incorporated by reference to our 2016 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 2016 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 2016 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 2016 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 our Consolidated Financial Statements or Notes thereto.

(a)(3) Exhibits.

Exhibit No.	Exhibit Description	Incorporated by Reference to SEC Filing		
		Form	SEC Filing Date	Exhibit No.
	Articles of Incorporation and By-Laws			
3.1	Certificate of Incorporation of pSivida Corp.	8-K12G3	06/19/08	3.1
3.2	By-Laws of pSivida Corp.	8-K	07/19/12	3.1
	Instruments Defining the Rights of Security Holders			
4.1	Form of Specimen Stock Certificate for Common Stock	8-K12G3	06/19/08	4.1
4.2+	Form of Warrant to Purchase Common Shares, dated January 24, 2011	8-K	01/19/11	99.3
4.3+	Form of Warrant to Purchase Common Shares, dated August 7, 2012	8-K	08/02/12	4.1
	Material Contracts—Management Contracts and Compensatory Plans			
10.1	Employment Agreement, between pSivida Corp. and Paul Ashton, dated October 31, 2008	10-K	09/10/15	10.1
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	2008 Equity Incentive Plan, as amended on November 19, 2009	10-K	09/10/15	10.6
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
	Material Contracts—Leases			
10.9	Lease Agreement between pSivida Corp. and Farley White Aetna Mills, LLC dated November 1, 2013	10-Q	11/13/13	10.1

Exhibit No.	Exhibit Description	Incorporated by Reference to SEC Filing		
		Form	SEC Filing Date	Exhibit No.
	Material Contracts—License and Collaboration Agreements			
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 pSivda US, Inc. and Bausch & Lomb dated August 1, 2009	10-K	09/25/09	10.13
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, 2016, formatted in eXtensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets at June 30, 2016 and 2015; (ii) Consolidated Statements of Comprehensive (Loss) Income for the years ended June 30, 2016, 2015 and 2014; (iii) Consolidated Statements of Stockholders' Equity for the years ended June 30, 2016, 2015 and 2014; (iv) Consolidated Statements of Cash Flows for the years ended June 30, 2016, 2015 and 2014; and (v) Notes to Consolidated Financial Statements.			

Confidential treatment has been granted for portions of this exhibit

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

(a) Filed herewith

SIGNATURES

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

PSIVIDA CORP.

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

Date: September 13, 2016

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

Name	Title	Date
/S/ DAVID J. MAZZO **David J. Mazzo**	Chairman of the Board of Directors	September 13, 2016
/S/ PAUL ASHTON **Paul Ashton**	President, Chief Executive Officer and Director (Principal Executive Officer)	September 13, 2016
/S/ LEONARD S. ROSS **Leonard S. Ross**	Vice President, Finance (Principal Financial and Accounting Officer)	September 13, 2016
/S/ DOUGLAS GODSHALL **Douglas Godshall**	Director	September 13, 2016
/S/ MICHAEL ROGERS **Michael Rogers**	Director	September 13, 2016
/S/ JAMES BARRY **James Barry**	Director	September 13, 2016

PSIVIDA CORP. AND SUBSIDIARIES

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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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, 2016 and 2015, and the related consolidated statements of comprehensive (loss) income, stockholders' equity, and cash flows for each of the three years in the period ended June 30, 2016. 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, 2016 and 2015, and the results of their operations and their cash flows for each of the three years in the period ended June 30, 2016, 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, 2016, 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 13, 2016 expressed an unqualified opinion on the Company's internal control over financial reporting.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
September 13, 2016

PSIVIDA CORP. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS
(In thousands except share amounts)

	June 30, 2016	June 30, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 15,313	$ 19,121
Marketable securities	13,679	9,414
Accounts and other receivables	488	622
Prepaid expenses and other current assets	483	681
Total current assets	29,963	29,838
Property and equipment, net	290	338
Intangible assets, net	1,102	1,925
Other assets	114	116
Restricted cash	150	150
Total assets	$ 31,619	$ 32,367
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,363	$ 744
Accrued expenses	3,583	2,571
Deferred revenue	147	33
Total current liabilities	5,093	3,348
Deferred revenue, less current portion	5,585	5,596
Deferred rent	60	55
Total liabilities	10,738	8,999
Commitments and contingencies (Note 14)		
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, 34,172,919 and 29,412,365 shares issued and outstanding at June 30, 2016 and 2015, respectively	34	29
Additional paid-in capital	312,208	293,060
Accumulated deficit	(292,213)	(270,666)
Accumulated other comprehensive income	852	945
Total stockholders' equity	20,881	23,368
Total liabilities and stockholders' equity	$ 31,619	$ 32,367

See notes to consolidated financial statements

PSIVIDA CORP. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF COMPREHENSIVE (LOSS) INCOME
(In thousands except per share data)

	Year Ended June 30,		
	2016	2015	2014
Revenues:			
Collaborative research and development	$ 398	$25,411	$ 2,155
Royalty income	1,222	1,154	1,318
Total revenues	1,620	26,565	3,473
Operating expenses:			
Research and development	14,381	12,088	9,573
General and administrative	9,013	8,056	7,468
Gain on sale of property and equipment	—	—	(78)
Total operating expenses	23,394	20,144	16,963
Operating (loss) income	(21,774)	6,421	(13,490)
Interest and other income, net	72	22	5
(Loss) income before income taxes	(21,702)	6,443	(13,485)
Income tax benefit (expense)	155	(96)	130
Net (loss) income	$(21,547)	$ 6,347	$(13,355)
Net (loss) income per share:			
Basic	$ (0.68)	$ 0.22	$ (0.49)
Diluted	$ (0.68)	$ 0.21	$ (0.49)
Weighted average common shares outstanding:			
Basic	31,623	29,378	27,444
Diluted	31,623	30,584	27,444
Net (loss) income	$(21,547)	$ 6,347	$(13,355)
Other comprehensive (loss) income:			
Foreign currency translation adjustments	(96)	(95)	124
Net unrealized gain (loss) on marketable securities	3	(4)	—
Other comprehensive (loss) income	(93)	(99)	124
Comprehensive (loss) income	$(21,640)	$ 6,248	$(13,231)

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, 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	29,412,365	29	293,060	(270,666)	945	23,368
Net loss	—	—	—	(21,547)	—	(21,547)
Other comprehensive loss	—	—	—	—	(93)	(93)
Issuance of stock, net of issue costs	4,440,000	5	16,495	—	—	16,500
Exercise of stock options	320,554	—	490	—	—	490
Stock-based compensation	—	—	2,163	—	—	2,163
Balance at June 30, 2016	34,172,919	$ 34	$312,208	$ (292,213)	$ 852	$ 20,881

See notes to consolidated financial statements

PSIVIDA CORP. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended June 30,		
	2016	2015	2014
Cash flows from operating activities:			
Net (loss) income	$(21,547)	$ 6,347	$(13,355)
Adjustments to reconcile net (loss) income to cash flows (used in) provided by operating activities:			
Amortization of intangible assets	756	770	778
Depreciation of property and equipment	152	112	139
Amortization of bond premium on marketable securities	87	98	45
Stock-based compensation	2,163	1,961	1,411
Gain on sale of property and equipment	—	—	(78)
Changes in operating assets and liabilities:			
Accounts and other receivables	116	(124)	103
Prepaid expenses and other current assets	187	(136)	1,110
Accounts payable	626	292	(213)
Accrued expenses	1,036	1,053	(381)
Deferred revenue	103	(94)	(267)
Deferred rent	5	18	37
Net cash (used in) provided by operating activities	(16,316)	10,297	(10,671)
Cash flows from investing activities:			
Purchases of marketable securities	(17,517)	(10,222)	(2,964)
Maturities of marketable securities	13,168	3,650	3,350
Purchases of property and equipment	(113)	(161)	(248)
Proceeds from sale of property and equipment	—	—	78
Change in restricted cash	—	—	(150)
Net cash (used in) provided by investing activities	(4,462)	(6,733)	66
Cash flows from financing activities:			
Proceeds from issuance of stock, net of issuance costs	16,500	—	18,057
Proceeds from exercise of stock options	490	235	987
Net cash provided by financing activities	16,990	235	19,044
Effect of foreign exchange rate changes on cash and cash equivalents	(20)	(12)	(4)
Net (decrease) increase in cash and cash equivalents	(3,808)	3,787	8,435
Cash and cash equivalents at beginning of year	19,121	15,334	6,899
Cash and cash equivalents at end of year	$ 15,313	$ 19,121	$ 15,334
Supplemental disclosure of cash flow information:			
Cash paid for income taxes	$ 4	$ 263	$ —

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 primarily for the treatment of chronic eye diseases. The Company's 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. Medidur™ for posterior segment uveitis, the Company's lead product candidate, is in pivotal Phase 3 clinical trials, and ILUVIEN® for diabetic macular edema ("DME"), the Company's lead licensed product, is sold in the U.S. and three European Union ("EU") countries. The Company's product development program is focused primarily on utilizing its two core technology platforms to deliver drugs and biologics to treat chronic diseases. Its strategy includes developing products independently while continuing to leverage its technology platforms through collaborations and license agreements as appropriate.

Medidur, the Company's most advanced development product, is designed to treat chronic non-infectious uveitis affecting the posterior segment of the eye ("posterior segment uveitis") for three years from a single injection. Injected into the eye in an office visit, Medidur is a tiny micro-insert that delivers a micro-dose of a corticosteroid to the back of the eye on a sustained basis. The Company is developing Medidur independently.

The first of Medidur's two Phase 3 trials met its primary efficacy endpoint of prevention of recurrence of disease through six months with high statistical significance. The same high statistical significance for efficacy and encouraging safety results was maintained through 12 months of follow-up. Due to the high level of statistical significance achieved, the Company plans to file its EU marketing approval application ("MAA") based on data from the first Phase 3 trial, rather than two trials. The MAA is planned for the first quarter of 2017. Enrollment in the second Phase 3 trial is expected to be completed in October 2016. Assuming favorable results, the Company plans to file a new drug application ("NDA") with the FDA in the third quarter of 2017. A utilization study of the Company's new Medidur inserter with a smaller diameter needle, which is required for both the MAA and NDA, met its primary endpoint, ease of intravitreal administration.

ILUVIEN®, the Company's most recently approved product, is an injectable, sustained-release micro-insert that provides three years of treatment of DME from a single injection. ILUVIEN is substantially the same design as Medidur and delivers the same steroid, although it is injected using a larger diameter inserter. ILUVIEN was developed in collaboration with, and is licensed to and sold by Alimera Sciences, Inc. ("Alimera"). The Company is entitled to a share of the net profits (as defined) from Alimera's sales of ILUVIEN on a quarter-by-quarter, country-by-country basis. ILUVIEN has been sold in the United Kingdom ("U.K.") and Germany since 2013 and in the U.S. and Portugal since 2015, and also has marketing approvals in 14 other European countries.

FDA-approved Retisert® is an implant that provides sustained treatment of posterior segment uveitis for 30 months. Implanted in a surgical procedure, Retisert delivers the same corticosteroid as Medidur but in a larger dose. Retisert was co-developed with, and licensed to, Bausch & Lomb, and the Company receives royalties from its sales.

The Company is seeking to develop products that use its Durasert™ and Tethadur™ technology platforms to deliver drugs and biologics to treat wet and dry age-related macular degeneration ("AMD"), glaucoma, osteoarthritis and other diseases. The sustained release, surgical implant to treat pain associated with severe knee osteoarthritis ("OA") the Company developed in collaboration with Hospital for Special Surgery is in an investigator-sponsored pilot study. The Company has commenced the first of two investigational new drug ("IND")-enabling studies of an injectable, bioerodible micro-insert it developed to provide sustained delivery of a tyrosine kinase inhibitor ("TKI") to treat wet AMD.

The Company has a history of operating losses and has financed its operations primarily from sales of equity securities and the receipt of license fees, milestone payments, research and development funding and royalty income from its collaboration partners. The Company believes that its cash, cash equivalents and marketable securities of $29.0 million at June 30, 2016, together with expected cash inflows under existing collaboration agreements, will enable the Company to maintain its current and planned operations into the second quarter of fiscal year 2018. This estimate excludes any potential receipts under the Alimera collaboration agreement. The Company's ability to fund its planned operations beyond then, including completion of clinical development of Medidur, is expected to depend on the amount and timing of cash receipts from Alimera's commercialization of ILUVIEN, proceeds from any future collaboration or other agreements and/or proceeds from any financing transactions. There is no assurance that the Company will receive significant, if any, revenues from the commercialization of ILUVIEN or financing from any other sources.

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, 2016, 2015 and 2014 may be referred to herein as fiscal 2016, fiscal 2015 and fiscal 2014, respectively.

Use of Estimates

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

Foreign Currency

The functional currency of the Company and each of its subsidiaries is the currency of the primary economic environment in which that entity operates—the U.S. dollar or the Pound Sterling.

Assets and liabilities of the Company's foreign subsidiary are translated at period-end exchange rates. Amounts included in the statements of comprehensive (loss) income 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 $854,000 at June 30, 2016 and $950,000 at June 30, 2015. Foreign currency gains or losses arising from transactions denominated in foreign currencies, whether realized or unrealized, are recorded in interest and other income, net in the consolidated statements of comprehensive (loss) income 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, 2016 and 2015, there were no investments in a significant unrealized loss position. The fair value of marketable securities is determined based on quoted market prices at the balance sheet date of the same or similar instruments. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts through to the earlier of sale or maturity. Such amortization and accretion amounts are included in interest and other income, net in the consolidated statements of comprehensive (loss) income. 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, 2016, $13.0 million, or 93.5% of the Company's interest-bearing cash equivalent balances, 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 have minimal risk. Marketable securities at June 30, 2016 and 2015 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.

Revenues from Alimera accounted for $233,000, or 14% of total revenues in fiscal 2016, $25.1 million, or 95% of total revenues in fiscal 2015 and were inconsequential in fiscal 2014. Revenues from Bausch & Lomb accounted for $1.3 million, or 77% of total revenues in fiscal 2016, $1.2 million, or 5% of total revenues in fiscal 2015 and $1.3 million, or 38% of total revenues in fiscal 2014. A completed feasibility study agreement accounted for $1.7 million, or 49%, of total revenues in fiscal 2014.

Accounts receivable from Bausch & Lomb accounted for $288,000, or 59%, of total accounts receivable at June 30, 2016 and $371,000, or 60%, of total accounts receivable at June 30, 2015.

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 cumulative rent expense over cash payments recorded as a deferred rent liability.

Impairment of Intangible Assets

The Company's finite life intangible assets include its acquired Durasert and 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 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 (Loss) Income per Share

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

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

	Year Ended June 30,		
	2016	2015	2014
Number of common shares—basic	31,623,473	29,378,250	27,443,592
Effect of dilutive securities:			
Stock options	—	956,441	—
Warrants	—	249,449	—
Number of common shares—diluted	31,623,473	30,584,140	27,443,592

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,		
	2016	2015	2014
Options outstanding	4,981,421	2,010,793	3,791,001
Warrants outstanding	623,605	552,500	1,176,105
	5,605,026	2,563,293	4,967,106

Comprehensive (Loss) Income

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

Income Tax

The Company accounts for income taxes under the asset and liability method. Deferred income tax assets and liabilities are computed for the expected future impact of differences between the financial reporting and income tax bases of assets and liabilities and for the expected future benefit to be derived from tax credits and loss carry forwards. Such deferred income tax computations are measured based on enacted tax laws and rates applicable to the years in which these temporary differences are expected to be recovered or settled. A valuation allowance is provided against net deferred tax assets if, based on the available evidence, it is more likely than not that some or all of the net deferred tax assets will not be realized.

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

Recently Adopted and Recently Issued Accounting Pronouncements

New accounting pronouncements are issued periodically by the Financial Accounting Standards Board (“FASB”) and are adopted by the Company as of the specified effective dates. Unless otherwise disclosed below,

the Company believes that the impact of recently issued and adopted pronouncements will not have a material impact on the Company's financial position, results of operations and cash flows or do not apply to the Company's operations.

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers* (Topic 606) ("ASU 2014-09"), which requires an entity to recognize revenue in an amount that reflects the consideration to which the entity expects to be entitled in exchange for the transfer of promised goods or services to customers. The standard will replace most existing revenue recognition guidance in U.S. GAAP. 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 consolidated 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. As a result, ASU 2014-15 will become effective on July 1, 2017. Early adoption is permitted. The Company is evaluating the potential impact of adopting this standard on its consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases*. The new standard establishes a right-of-use ("ROU") model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. As a result, ASU 2016-02 will become effective on July 1, 2019. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company is currently evaluating the impact of its pending adoption of the new standard on its consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*. ASU 2016-09 intends to simplify various aspects of how share-based payments are accounted for and presented in the financial statements. The main provisions include: all tax effects related to stock awards will now be recorded through the statement of operations instead of through equity, all tax-related cash flows resulting from stock awards will be reported as operating activities on the cash flow statement, and entities can make an accounting policy election to either estimate forfeitures or account for forfeitures as they occur. The amendments in ASU 2016-09 are effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years, and may be applied prospectively with earlier adoption permitted. As a result, ASU 2016-09 will become effective on July 1, 2017. The Company is currently evaluating the impact of this guidance on its consolidated 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.

Because the Company has no remaining performance obligations under the Alimera Agreement, all amounts received from Alimera are generally 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 instances when payments are received and subject to a contingency, revenue is deferred until such contingency is resolved—refer to Note 14 regarding net profit share receipts subject to arbitration proceedings.

Revenue under the Alimera Agreement totaled $233,000 for fiscal 2016, $25.1 million for fiscal 2015 and $114,000 for fiscal 2014. These revenues included $157,000 of non-royalty sublicense consideration earned in fiscal 2016 and a $25.0 million milestone earned as a result of the FDA approval of ILUVIEN in the first quarter of fiscal 2015, with the remainder in each year having consisted principally of patent fee reimbursements.

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 dose-escalation study that enrolled and followed six patients to treat ocular hypertension and glaucoma. The Company may, at its option, conduct Phase 2 clinical trials, which to date have not been undertaken, for the purpose of demonstrating Proof-of-Concept ("POC"). If the Company were to issue a final report demonstrating POC, Pfizer would have a 90-day exercise option for an exclusive, worldwide license to further develop and commercialize the Latanoprost Product in return for a $20.0 million payment to the Company and potential double-digit sales-based royalties and prescribed development, regulatory and sales performance milestone payments. If the Company elects to cease development of the Latanoprost Product prior to POC, Pfizer could exercise its option for the same worldwide license upon payment of a lesser option fee, with comparable reductions in any future milestones and royalties. If Pfizer does not exercise its option when available, the Restated Pfizer Agreement will automatically terminate, with any remaining deferred revenue balance recorded as revenue at that time, provided, however, that the Company would retain the right to develop and commercialize the Latanoprost Product.

As a result of the material modification of the Pfizer arrangement, the estimated selling price of the combined deliverables under the Restated Pfizer Agreement of $6.7 million is being recognized as collaborative research and development revenue over the expected performance period using the proportional performance method. As of June 30, 2016, the Company continues to evaluate whether to undertake Phase 2 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, 2016 and 2015. Total deferred revenue was approximately $5.6 million at each of June 30, 2016 and 2015. Collaborative research and development revenue related to the Restated Pfizer Agreement was $0 in each of fiscal 2016 and fiscal 2015, and inconsequential in fiscal 2014. Costs associated with conducting the R&D program are included in operating expenses as incurred.

Pfizer owned approximately 5.4% of the Company's outstanding shares at June 30, 2016.

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 each of fiscal 2016 and fiscal 2015, and $1.3 million in fiscal 2014. Accounts receivable from Bausch & Lomb totaled $288,000 at June 30, 2016 and $371,000 at June 30, 2015.

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 previously developed product candidate for the treatment of pancreatic and other types of cancer. The Company received an upfront fee of $100,000 and is entitled to 8% sales-based royalties, 20% of sublicense consideration and milestone payments based on aggregate product sales. Enigma is obligated to pay an annual license maintenance fee of $100,000 by the end of each calendar year, the most recent of which was received in December 2015. 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 each of fiscal 2016 and fiscal 2015, and $102,000 in fiscal 2014. At June 30, 2016, no deferred revenue was recorded for this agreement.

Evaluation 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 $33,000 in fiscal 2016, $144,000 in fiscal 2015 and $1.9 million in fiscal 2014.

4. Intangible Assets

The reconciliation of intangible assets for the years ended June 30, 2016 and 2015 was as follows (in thousands):

	June 30, 2016	June 30, 2015
Patented technologies		
Gross carrying amount at beginning of year	$ 39,710	$ 41,689
Foreign currency translation adjustments	(3,514)	(1,979)
Gross carrying amount at end of year	36,196	39,710
Accumulated amortization at beginning of year	(37,785)	(38,924)
Amortization expense	(756)	(770)
Foreign currency translation adjustments	3,447	1,909
Accumulated amortization at end of year	(35,094)	(37,785)
Net book value at end of year	$ 1,102	$ 1,925

The net book value of the Company's intangible assets at June 30, 2016 and 2015 is summarized as follows (in thousands):

	June 30, 2016	June 30, 2015	Estimated Remaining Useful Life at June 30, 2016 (Years)
Patented technologies			
Durasert	$ 795	$1,324	1.5
Tethadur	307	601	1.5
	$1,102	$1,925	

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 $756,000 in fiscal 2016, $770,000 in fiscal 2015 and $778,000 in fiscal 2014. The carrying value of intangible assets at June 30, 2016 of $1.1 million is expected to be amortized on a straight-line basis of approximately $735,000 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, 2016 and 2015 were as follows (in thousands):

	June 30, 2016		
	Amortized Cost	Unrealized Loss	Fair Value
Corporate bonds	$ 5,999	$ (2)	$ 5,997
Commercial paper	7,682	—	7,682
	$ 13,681	$ (2)	$13,679

	June 30, 2015		
	Amortized Cost	Unrealized Loss	Fair Value
Corporate bonds	$ 9,419	$ (5)	$9,414

During fiscal 2016, $17.5 million of marketable securities were purchased and $13.2 million matured. At June 30, 2016, the marketable securities had maturities ranging between 5 days and 6.9 months, with a weighted average maturity of 3.0 months.

6. Property and Equipment, Net

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

	June 30,	
	2016	2015
Property and equipment	$ 1,777	$ 1,927
Leasehold improvements	206	217
Gross property and equipment	1,983	2,144
Accumulated depreciation and amortization	(1,693)	(1,806)
	$ 290	$ 338

Depreciation expense was $152,000 in fiscal 2016, $112,000 for fiscal 2015 and $139,000 for fiscal 2014.

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).
- 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, 2016 and 2015 by valuation hierarchy (in thousands):

Description	June 30, 2016 Total Carrying Value	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets:				
Cash equivalents	$ 13,856	$ 12,957	$ 899	$ —
Marketable securities:				
Corporate bonds	5,997	4,596	1,401	—
Commercial paper	7,682	—	7,682	—
	$ 27,535	$ 17,553	$ 9,982	$ —

Description	June 30, 2015 Total Carrying Value	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets:				
Cash equivalents	$ 15,835	$ 15,835	$ —	$ —
Marketable securities:				
Corporate bonds	9,414	7,413	2,001	—
	$ 25,249	$ 23,248	$ 2,001	$ —

8. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	June 30, 2016	June 30, 2015
Clinical trial costs	$1,678	$1,424
Personnel costs	1,314	735
Professional fees	535	384
Other	56	28
	$3,583	$2,571

9. Restructuring

In July 2016, the Company announced its plan to consolidate all of its research and development activities in its U.S. facility. Following employee consultations under local U.K. law, the Company determined to close its U.K. research facility and terminated the employment of all of its U.K. employees. The U.K. facility lease, set to expire on August 31, 2016, was extended through October 31, 2016 to facilitate an orderly transition and the required restoration of the premises.

The Company expects to incur approximately $710,000 of total pre-tax charges in connection with the restructuring. Of this total, $218,000 was charged to research and development expense in the quarter ended June 30, 2016 and included (i) contractual termination benefits of $118,000, which were provided for once it was determined that such costs were both probable and estimable in accordance with the provisions of FASB Accounting Standard Codification ("ASC") 712, *Compensation—Nonretirement Postemployment Benefits*, as well as (ii) other costs totaling $100,000 for asset write-offs, facility restoration costs and professional service fees.

The Company expects to record additional costs of approximately $492,000 during the quarter ending September 30, 2016. These estimated costs consist of (i) $274,000 of additional employee severance for discretionary termination benefits to be expensed upon notification of the affected employees in accordance with ASC 420, *Exit or Disposal Cost Obligations*; (ii) $91,000 of non-cash stock-based compensation expense to be recognized in connection with an extension of the exercise period for all vested stock options held by the U.K. employees at July 31, 2016; and (iii) approximately $127,000 of professional fees, travel and lease extension costs.

The actual amounts of these estimated costs could vary, including due to fluctuations in the Pound Sterling to U.S. dollar currency exchange rate during the quarter. Substantially all of the restructuring costs associated with the plan of consolidation are expected to be paid by October 31, 2016.

10. Stockholders' Equity

Sales of Common Stock

In January 2016, the Company sold 4,440,000 shares of its common stock in an underwritten public offering at a price of $4.00 per share for gross proceeds of $17.8 million. Underwriter discounts and commissions and other share issue costs totaled approximately $1.3 million. At June 30, 2016, an aggregate registered amount of approximately $57.2 million of common stock remains available for sale under the Company's existing shelf registration statement which, under the rules and regulations of the Australian Securities Exchange ("ASX"), could require the Company to obtain shareholder approval for sales of common stock under certain circumstances.

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, of which approximately $17.6 million remains unsold. In connection with execution of the ATM program, the Company incurred transaction costs of $153,000. The Company pays the sales agent a commission of up to 3.0% of the gross proceeds from the sale of such shares. The Company's ability to sell shares under the ATM program is subject to an ASX rule limiting the number of shares the Company may issue in any 12-month period without shareholder approval, as well as other applicable rules and regulations of ASX and the NASDAQ Global Market ("NASDAQ"). During fiscal 2016 and 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.

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.

Warrants to Purchase Common Shares

The following table provides a reconciliation of warrants to purchase common stock for the years ended June 30, 2016 and 2015:

	Year Ended June 30,			
	2016		2015	
	Number of Warrants	Weighted Average Exercise Price	Number of Warrants	Weighted Average Exercise Price
Balance at beginning of year	1,176,105	$ 3.67	1,176,105	$ 3.67
Expired	(552,500)	5.00	—	—
Balance and exercisable at end of year	623,605	$ 2.50	1,176,105	$ 3.67

At June 30, 2016, the remaining term of these warrants was 1.1 years.

11. 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, 2016, a total of 7,091,255 shares of common stock were authorized for issuance under the 2008 Plan, of which 1,019,791 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, 2016.

Options to purchase a total of 854,000 shares were granted during fiscal 2016 at exercise prices equal to the closing market price of the Company's common stock on NASDAQ on the respective option grant dates. Of this total, options to purchase 744,000 shares were issued to employees with ratable annual vesting over 4 years and options to purchase 110,000 shares were issued to non-executive directors with 1-year cliff vesting. A total of 646,605 options vested during fiscal 2016. 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, 2016, 2015 and 2014 were as follows:

	2016	2015	2014
Option life (in years)	5.50 - 6.25	5.50 - 6.25	5.50 - 6.25
Stock volatility	76% - 80%	79% - 93%	94% - 96%
Risk-free interest rate	1.47% - 1.97%	1.70% - 2.00%	1.70% - 1.99%
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, 2016, 2015 and 2014 (in thousands except per share amounts):

	2016	2015	2014
Weighted-average grant date fair value per share	$2.74	$3.33	$2.48
Total cash received from exercise of stock options	490	235	987
Total intrinsic value of stock options exercised	967	257	841

At June 30, 2016, 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 1.8 years.

The following table provides a reconciliation of stock option activity under the 2008 Plan for fiscal 2016:

	Number of options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at July 1, 2015	4,447,975	$ 3.36		
Granted	854,000	4.08		
Exercised	(320,554)	1.53		
Outstanding at June 30, 2016	4,981,421	$ 3.60	5.87	$ 1,009
Outstanding at June 30, 2016—vested or unvested and expected to vest	4,889,785	$ 3.59	5.83	$ 1,006
Exercisable at June 30, 2016	3,220,234	$ 3.37	4.56	$ 950

Stock-Based Compensation Expense

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

	Year Ended June 30,		
	2016	2015	2014
Compensation expense included in:			
Research and development	$ 702	$ 676	$ 516
General and administrative	1,461	1,285	895
	$2,163	$1,961	$1,411

12. 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 operated a defined contribution pension plan for U.K. employees pursuant to which the Company made contributions on behalf of employees plus a matching percentage of elective employee contributions. This pension plan was terminated in the quarter ending September 30, 2016 following termination of employment of all U.K. employees.

The Company contributed a total of $209,000 for fiscal 2016, $187,000 for fiscal 2015 and $189,000 for fiscal 2014 in connection with these retirement plans.

13. Income Taxes

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

	Year Ended June 30,		
	2016	2015	2014
U.S. operations:			
Current income tax expense	$ 4	$ 263	$ —
Deferred income tax benefit	—	—	—
	4	263	—
Non-U.S. operations:			
Current income tax benefit	(159)	(167)	(130)
Deferred income tax benefit	—	—	—
	(159)	(167)	(130)
Income tax (benefit) expense	$(155)	$ 96	$(130)

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, 2016, 2015 and 2014, the Company also recognized a current income tax benefit of $159,000, $167,000 and $130,000, respectively, related to foreign research and development tax credits earned by its U.K. subsidiary.

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

	Year Ended June 30,		
	2016	2015	2014
U.S. operations	$(19,780)	$ 8,120	$(11,712)
Non-U.S. operations	(1,922)	(1,677)	(1,773)
(Loss) income before income taxes	$(21,702)	$ 6,443	$(13,485)

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

	Year Ended June 30,		
	2016	2015	2014
Income tax (benefit) expense at statutory rate	$(7,379)	$ 2,191	$(4,585)
State income taxes, net of federal benefit	(1,044)	435	(693)
Non-U.S. income tax rate differential	778	137	157
Research and development tax credits	(397)	(313)	(169)
Capital loss expiration	—	511	—
Permanent items	216	236	221
Changes in valuation allowance	6,789	(3,572)	4,619
Expiration of state net operating loss carryforwards	—	—	161
Other, net	882	471	159
Income tax (benefit) expense	$ (155)	$ 96	$ (130)

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

	June 30, 2016	June 30, 2015
Deferred tax assets:		
Net operating loss carryforwards	$31,299	$25,736
Deferred revenue	2,198	2,194
Stock-based compensation	4,111	3,431
Tax credits	1,484	1,246
Other	141	110
Total deferred tax assets	39,233	32,717
Deferred tax liabilities:		
Intangible assets	367	640
Deferred tax assets, net	38,866	32,077
Valuation allowance	38,866	32,077
Total deferred tax liability	$ —	$ —

The valuation allowance generally reflects limitations on the Company's ability to use the tax attributes and reduce the value of such attributes to the more-likely-than-not realizable amount. 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, 2016, 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 increased $6.8 million and $4.6 million during the fiscal year ended June 30, 2016 and June 30, 2014, respectively, with such increases attributed to the re-measurement of the net deferred tax assets at the year-end dates. 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 Company has tax net operating loss and tax credit carry forwards in its individual tax jurisdictions. At June 30, 2016, the Company had U.S. federal net operating loss carry forwards of approximately $72.6 million, which expire at various dates between calendar years 2023 and 2036. 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, 2016, the Company had state net operating loss carry forwards of approximately $31.6 million, which expire between 2033 and 2036, as well as U.S. federal and state research and development tax credit carry forwards of approximately $980,000, which expire at various dates between calendar years 2016 and 2036. In addition, at June 30, 2016 the Company had net operating loss carry forwards in the U.K. of £20.5 million (approximately $27.4 million), which are not subject to any expiration dates.

The Company's U.S. federal income tax returns for calendar years 2003 through 2015 remain subject to examination by the Internal Revenue Service. The Company's U.K. tax returns for fiscal years 2006 through 2015 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, 2016, the Company had no unrecognized tax benefits in its consolidated statements of comprehensive (loss) income and no unrecognized tax benefits in its consolidated balance sheets as of June 30, 2016 or 2015.

As of June 30, 2016 and 2015, the Company had no accrued penalties or interest related to uncertain tax positions.

14. Commitments and Contingencies

Operating Leases

The Company leases approximately 13,650 square feet of combined office and laboratory space in Watertown, Massachusetts under a lease with a term from March 2014 through April 2019, with a five-year renewal option at market rates The Company provided a cash-collateralized $150,000 irrevocable standby letter of credit as security for the Company's obligations under the lease. 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. The Company's previous facilities lease expired in April 2014. In addition, the Company occupied approximately 2,200 square feet of laboratory and office space in Malvern, U.K. under a lease with a term that expired on August 31, 2016. The lease term has been extended through October 2016 to facilitate an orderly transition of the closure of the U.K. facility.

At June 30, 2016, the Company's total future minimum lease payments under non-cancellable operating leases were as follows (in thousands):

Fiscal Year:	
2017	$ 432
2018	431
2019	364
2020	—
2021	—
	$1,227

Rent expense related to the Company's real estate and other operating leases charged to operations was approximately $485,000 for fiscal 2016, $494,000 for fiscal 2015 and $485,000 for fiscal 2014.

Arbitration

In December 2014, the Company exercised its right under the Alimera Agreement to conduct an audit by an independent accounting firm of Alimera's commercialization reporting for ILUVIEN for DME for 2014. In April 2016, the independent accounting firm issued its report, which concluded that Alimera under-reported net profits payable to the Company for 2014 by $136,000. In June 2016, Alimera remitted $354,000 to the Company, which consisted of the under-reported net profits plus interest and reimbursement of the audit costs of $204,000. In July 2016, Alimera filed a demand for arbitration with the American Arbitration Association ("AAA") in Boston, Massachusetts to dispute the audit findings and requested a full refund of the $354,000 previously paid to the Company. The Company has filed a motion to dismiss Alimera's demand for arbitration on grounds that Alimera did not object to the independent accounting firm's findings within the time period provided for in the Alimera Agreement and voluntarily paid the amounts due. An arbitrator has been selected, but proceedings have yet to commence. Pending the arbitration outcome, $136,000 of net profits participation has been recorded as deferred revenue and the remaining $218,000 as accrued expenses at June 30, 2016.

Litigation

In addition to the Alimera arbitration referenced above, 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.

15. Segment and Geographic Area Information

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.

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	
	2016	2015	2014	2016	2015
U.S.	$1,520	$26,465	$3,248	$ 277	$ 273
U.K.	100	100	225	13	65
Consolidated	$1,620	$26,565	$3,473	$ 290	$ 338

16. Quarterly Financial Data (unaudited)

The following table summarizes the quarterly results of operations for the years ended June 30, 2016 and 2015 (in thousands except per share amounts):

	Fiscal Year 2016				
	First Quarter Ended September 30, 2015	Second Quarter Ended December 31, 2015	Third Quarter Ended March 31, 2016	Fourth Quarter Ended June 30, 2016	Year Ended June 30, 2016
Total revenues	$ 466	$ 526	$ 324	$ 304	$ 1,620
Operating loss	(4,984)	(5,238)	(5,096)	(6,456)	(21,774)
Net loss	(4,933)	(5,186)	(5,041)	(6,387)	(21,547)
Net loss per share—basic and diluted	$ (0.17)	$ (0.18)	$ (0.15)	$ (0.19)	$ (0.68)
Weighted average common shares—basic and diluted	29,416	29,437	33,538	34,152	31,623

	Fiscal Year 2015				
	First Quarter Ended September 30, 2014 (1)	Second Quarter Ended December 31, 2014	Third Quarter Ended March 31, 2015	Fourth Quarter Ended June 30, 2015	Year Ended June 30, 2015
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

(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).

Exhibit 21.1

List of Subsidiaries of pSivida Corp.

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

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-152146 and 333-163208 on Form S-8 and Registration Statement No. 333-208115 on Form S-3 of our reports dated September 13, 2016, 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, 2016.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
September 13, 2016

Exhibit 31.1

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

CERTIFICATIONS

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

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

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

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

4. The registrant's other certifying officer 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 13, 2016

/S/ PAUL ASHTON

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

Exhibit 31.2

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

CERTIFICATIONS

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

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

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

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

4. The registrant's other certifying officer 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 13, 2016

/S/ LEONARD S. ROSS

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

Exhibit 32.1

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

In connection with the Annual Report of pSivida Corp. (the "Company") on Form 10-K for the year ended June 30, 2016, 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 13, 2016

/S/ PAUL ASHTON

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

Exhibit 32.2

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

In connection with the Annual Report of pSivida Corp. (the "Company") on Form 10-K for the year ended June 30, 2016, 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 13, 2016

/s/ Leonard S. Ross

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