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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, 2011

or

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

For the transition period from to

Commission File Number 000-51122

PSIVIDA CORP.
(Exact name of registrant as specified in Its charter)

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

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

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

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

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

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

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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 ☒
Non-accelerated filer ☐	Smaller reporting company ☒
(Do not check if a smaller reporting company)	

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

The aggregate market value of the common stock held by non-affiliates of the registrant, computed by reference to the closing price of the common stock on the NASDAQ Global Market on December 31, 2010, the last trading day of the registrant's most recently completed second fiscal quarter, was approximately $82,346,000.

There were 20,750,642 shares of the registrant's common stock, $0.001 par value, outstanding as of September 9, 2011.

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 November 29, 2011, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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PSIVIDA CORP.

Form 10-K
For the Fiscal Year Ended June 30, 2011

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PART I

Preliminary Note Regarding Forward-Looking Statements

This Form 10-K and our 2011 Annual Report contain forward-looking statements, within the meaning of Section 27A of the Securities Act of 1933, as amended (Securities Act) and Section 21E of the Securities Exchange Act of 1934, as amended (Exchange Act). Forward-looking statements are inherently subject to risks, uncertainties and potentially inaccurate assumptions. Such statements give our current expectations or forecasts of future events; they do not relate strictly to historical or current facts. All statements other than statements of historical fact could be deemed forward-looking statements, including, without limitation, any expectations of revenue, expenses, cash flows, earnings or losses from operations, capital or other financial items; any statements of the plans, strategies and objectives of management for future operations; any statements concerning product research, development and commercialization timelines; any statements of expectations or belief; and any statements of assumptions underlying any of the foregoing. We often, although not always, identify forward-looking statements by using words or phrases such as the following: “likely”, “expect”, “intend”, “anticipate”, “believe”, “estimate”, “plan”, “project”, “forecast” and “outlook”.

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

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

ITEM 1. BUSINESS

Introduction

We develop tiny, sustained release, drug delivery products designed to deliver drugs at a controlled and steady rate for months or years. We are currently focused on treatment of chronic diseases of the back of the eye utilizing our core technology systems, Durasert™ and BioSilicon™. ILUVIEN® for the treatment of Diabetic Macular Edema (DME), our most advanced product candidate, is currently under review by the U.S. Food and Drug Administration (FDA). An investigator-sponsored Investigational New Drug (IND) opened for an injectable insert designed to treat uveitis affecting the posterior segment of the eye (posterior uveitis) of the same design as ILUVIEN and an investigator-sponsored trial is ongoing for an injectable bioerodible insert designed to treat glaucoma and ocular hypertension. Our two FDA-approved products provide long-term, sustained drug delivery to treat two other chronic diseases of the retina.

ILUVIEN. We licensed the third generation injectable Durasert insert that delivers the corticosteroid fluocinolone acetonide (FAc) over a period of up to 3 years to Alimera Sciences, Inc. (Alimera) for the treatment and prevention of eye diseases in humans (other than uveitis). This insert is being developed by Alimera under its brand name ILUVIEN. Alimera completed two Phase III clinical trials (FAME™ Study) of ILUVIEN for the treatment of DME, a leading cause of vision loss for people under the age of 65 estimated to affect over 1,000,000 people in the United States.

Alimera submitted an NDA for ILUVIEN for DME to the FDA in June 2010 based on month 24 data from the FAME Study, received a Complete Response Letter (CRL) in December 2010 and resubmitted an NDA to the

FDA to respond to the CRL in May 2011. Alimera expects a response from the FDA in November 2011. Alimera stated that if approved, it plans to commercialize ILUVIEN for DME in the U.S. as soon as early 2012. In July 2010, Alimera submitted a Marketing Authorization Application for ILUVIEN for DME to the Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom and to other regulatory authorities in Europe. Alimera reports that it anticipates submitting the final response to the MHRA and the other European regulatory authorities by December 31, 2011.

Under our collaboration agreement with Alimera, in addition to treating DME, ILUVIEN is also being studied in three Phase II clinical trials for the treatment of the dry form of Age-Related Macular Degeneration (AMD), the wet form of AMD and Retinal Vein Occlusion (RVO).

Other Product Development. In September 2011, an investigator-sponsored IND opened for a Phase I/II study of the safety and efficacy of our injectable, sustained release insert delivering FAc for the treatment of posterior uveitis. The insert is the same design as the insert being developed by Alimera for the treatment of DME and delivers the high and low dose of FAc used in the FAME Study. We did not license Alimera the rights to use the insert for uveitis. If successful, we plan to advance this product candidate into pivotal multi-center Phase III trials and reference the NDA for ILUVIEN for DME (including the clinical data from the FAME Study and the manufacturing and stability data) in potential posterior uveitis regulatory filings. We also plan to use a new inserter, with a smaller gauge needle than that used in the FAME Study, in any future posterior uveitis Phase III trials.

Under our recently amended collaborative research and license agreement with Pfizer Inc. (Pfizer), we granted Pfizer an exclusive option under various circumstances to license the development and commercialization worldwide of an injectable, bioerodible sustained release insert delivering latanoprost (Latanoprost Product) for the treatment of human ophthalmic disease or conditions other than uveitis. An investigator-sponsored Phase I/II dose-escalation study has been initiated to assess the safety and efficacy of this insert, which utilizes a fourth generation of our Durasert technology, in patients with elevated IOP.

In August 2011, we entered into an evaluation agreement with Hospital for Special Surgery (HSS) to investigate our Durasert drug delivery technologies in orthopedics.

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

BioSilicon. BioSilicon, the second key technology system we are targeting for sustained drug delivery, utilizes fully-erodible, nanostructured, porous material. Our primary focus is on Tethadur™, which utilizes BioSilicon to deliver large biologic molecules, including peptides and proteins, on a sustained basis. Our BioSilicon technology is also designed to deliver smaller molecules.

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

Market Overview

Drug Delivery Generally

The therapeutic value of a drug depends on its distribution throughout the body, reaction with the targeted site, reaction with other tissues and organs in the body and clearance from the body. In an ideal treatment, the appropriate amount of drug is delivered to the intended site at an adequate concentration and maintained there for

a sufficient period of time without adverse effect to other tissues and organs. Accordingly, the manner in which a drug is delivered can be as important to the ultimate therapeutic value of the treatment as the intrinsic properties of the drug itself.

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

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

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

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

Ophthalmic Drug Delivery

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

Injecting drugs in solution directly into the back of the eye can achieve effective, but often transient, drug levels in the eye, requiring repeated injections. Examples include Macugen® (pegaptanib sodium) and Lucentis® (ranibizumab, formerly RhuFab V2), both of which may be injected into the eye as frequently as approximately every four to six weeks. Apart from inconvenience and cost, repeated intravitreal injections carry risks, including intraocular infection, perforated sclera, vitreous hemorrhage and cataract formation.

Technologies and Products

Our primary technology systems are Durasert and BioSilicon.

Durasert Technology System

ILUVIEN, Retisert and Vitrasert, as well as our latanoprost and posterior uveitis product candidates, use different generations of our proprietary Durasert technology system, which delivers specific quantities of drugs directly to a target site in the body at controlled rates for predetermined periods of time ranging from weeks to

years. The Durasert technology system is designed to provide the benefits of direct delivery of appropriate quantities of drug over an extended period, while addressing the drawbacks of systemic drug delivery, including adverse side effects characteristic of high dosing levels and reduced treatment benefits due to variations in drug levels at the target site. The Durasert technology system has three principal attributes designed to deliver these advantages:

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

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

Our portfolio of Durasert products and product candidates includes:

Product	Disease	Stage of Development	Licensee
Vitrasert	CMV Retinitis	FDA-approved; commercialized since 1996	Bausch & Lomb
Retisert	Posterior uveitis	FDA-approved; commercialized since 2005	Bausch & Lomb
ILUVIEN	Diabetic macular edema (DME)	Phase III clinical trials completed; NDA submitted June 2010 and re-filed May 2011	Alimera
ILUVIEN	Wet age-related macular degeneration (Wet AMD)	Investigator-sponsored pilot clinical trial	Alimera
ILUVIEN	Dry age-related macular degeneration (Dry AMD)	Investigator-sponsored pilot clinical trial	Alimera
ILUVIEN	Retinal vein occlusion (RVO)	Investigator-sponsored pilot clinical trial	Alimera
TBD	Glaucoma	Investigator-sponsored Phase I/II clinical trial	Option by Pfizer
TBD	Posterior Uveitis	Investigator-sponsored Phase I/II clinical trial	None
TBD	Orthopedic Applications	Pre-clinical; Evaluation Agreement	Hospital for Special Surgery

ILUVIEN

ILUVIEN is designed to treat DME, a disease that causes swelling in the macula, the most sensitive part of the retina. DME is a major cause of vision loss in diabetics and a leading cause of vision loss for Americans under 65, and has been estimated to affect over 1,000,000 people in the United States. ILUVIEN, which is inserted via a 25-gauge, transconjunctival delivery system to the back of the eye in an in-office procedure, is

designed to deliver FAc on a sustained basis for up to 36 months. There is currently no FDA-approved drug treatment for DME. The only FDA-approved method for treating DME is laser photocoagulation therapy, which has only modest efficacy and can leave irreversible blind spots.

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

Development Program for ILUVIEN for the Treatment of DME

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

Based on the 24-month clinical data, reflecting the primary end point in the Fame Study, Alimera submitted an NDA for the low dose of ILUVIEN to the FDA in June 2010. In December 2010, Alimera received a CRL from the FDA communicating its decision that the NDA could not be approved in its then present form. In the CRL, the FDA asked for analyses of safety and efficacy data through month 36 of the FAME Study, including exploratory analyses in addition to those previously submitted in the NDA, to further assess the relative benefits and risks of ILUVIEN. The FDA also requested additional information regarding controls and specifications concerning the manufacturing, packaging and sterilization of ILUVIEN and indicated that it had observed deficiencies in current good manufacturing practices (cGMP) during facility inspections of two of Alimera's third-party manufacturers, which were completed in August and September of 2010, and that all facilities and controls will need to comply with cGMP.

Alimera resubmitted an NDA to the FDA on May 12, 2011 to respond to the CRL, including analyses of safety and efficacy data though month 36 of the FAME Study and additional information regarding controls and specifications on the manufacturing, packaging and sterilization of ILUVIEN. The resubmission also included data from analyses of a subgroup of patients in the FAME Study who had DME for 3 or more years at baseline (chronic DME). Alimera reported that the FDA classified the response as a Class 2 resubmission resulting in a six-month review period and a Prescription Drug User Fee Act (PDUFA) date by which Alimera can reasonably expect a response from the FDA of November 12, 2011. Alimera also reported that the FDA subsequently indicated it will not call an advisory committee during its review.

Alimera has reported that it believes the deficiencies in cGMP noted by the FDA in the CRL have been resolved and that no further action is required because the FDA issued letters to both of these third-party manufacturers indicating that the inspections were now closed. Alimera has indicated that the ILUVIEN injection system will not require a separate device application, but it must meet the safety and regulatory requirements of the applicable regulatory authorities when evaluated as part of the drug product marketing application.

If approved by the FDA, Alimera has stated that it plans to commercialize ILUVIEN for DME in the U.S. by marketing and selling it to retinal specialists as soon as early 2012.

In July 2010, using the Decentralized Procedure, Alimera submitted a Marketing Authorization Application for ILUVIEN to the MHRA in the United Kingdom, which serves as the Reference Member State, and to regulatory authorities in Austria, France, Germany, Italy, Portugal and Spain. In November 2010, Alimera received a preliminary assessment report from the MHRA followed by additional comments from other health

authorities in December 2010. In July 2011, Alimera submitted draft responses to the clinical and non-clinical and quality questions to the MHRA. The submission included the additional safety and efficacy data through the final readout at the end of the FAME Study. Alimera reports that the MHRA will provide comments to Alimera's draft response and that Alimera anticipates submitting the final response to the MHRA and other health authorities by December 31, 2011.

FAME Study

The FAME Study, initiated by Alimera in September 2005, was designed as a three year study with the primary efficacy analysis at 2 years. The Fame Study was designed in light of the FDA requirements for registration and approval of drugs being developed for diabetic retinopathy, including DME. The primary efficacy endpoint for the FAME Study was the difference in the percentage of patients whose best corrected visual acuity (BCVA) improved from baseline by 15 or more letters on the Early Treatment Diabetic Retinopathy Study (ETDRS) eye chart between the treatment and control groups at month 24. The ETDRS eye chart is the standard used in clinical trials for measuring sharpness of sight as established by the National Eye Institute's Early Treatment Diabetic Retinopathy Study. In addition, the Fame Study reflected the FDA requirement for a numerical comparison of the percentage of patients with BCVA improvement of 15 or more letters between the month 24 and month 18 data to determine if the month 24 results are equal to or greater than the month 18 results. Patients enrolled in the FAME Study were followed by Alimera for 36 months.

The FAME study was divided into Trial A and Trial B (each having identical protocols) and completed enrollment in October 2007 of 956 patients across 101 academic and private practice centers. Trial A drew patients from sites located in the northern regions of the United States, Europe and India and all sites in Canada, while sites in the southern regions of the United States, India and Europe comprised Trial B.

The FAME Study was designed to assess the safety and efficacy of ILUVIEN in patients with DME involving the center of the macula, and who had at least one prior macular laser treatment 12 weeks or more before study entry. The inclusion criteria for the FAME Study were designed to select DME patients with BCVA between 20/50 (68 letters on the ETDRS eye chart) and 20/400 (19 letters on the ETDRS eye chart) in the study eye and no worse than 20/400 in the non-study eye. Patients who had received steroid drug treatments for DME within three months of screening, or anti-VEGF injections within two months of screening, and patients with glaucoma, ocular hypertension, IOP greater than 21mmHg or concurrent therapy with IOP-lowering agents in the study eye at screening were not eligible to participate in the trial.

Patient characteristics, such as age, gender and baseline BCVA, were balanced across the treatment and control groups. As part of randomization, the patients were divided into two separate groups, those with a baseline BCVA score greater than or equal to 49 letters on the ETDRS eye chart and those with a baseline BCVA score of less than 49 letters on the ETDRS eye chart.

Patients participating in the FAME Study were randomly assigned to one of three groups at a ratio of 2:2:1. The first two of these groups were assigned to an active drug formulation and the third group served as the control group, undergoing a sham insertion procedure designed to mimic an intravitreal insertion. The treatment groups consisted of one group receiving a low dose of ILUVIEN and another group receiving a high dose of ILUVIEN. To reduce potential bias, these trials use a randomized, double-masked study design so that neither the patient nor the investigational staff involved with assessing the patient knew to which group the patient belonged. In order to simulate an insertion and help to maintain proper patient masking, the sham insertion procedure included all steps involved in the insertion procedure, except that a blunt inserter without a needle was used to apply pressure to the anesthetized eye.

As part of the FAME Study, investigators were able to re-treat each patient with ILUVIEN following their month 12 follow-up visit if certain criteria were met. Through month 36, 25.6% of patients were treated with more than one ILUVIEN insert and 4% of patients were treated with more than two ILUVIEN inserts.

Primary Efficacy Endpoint. The primary efficacy endpoint for the FAME Study was the difference in the percentage of patients with improved BCVA from baseline of 15 or more letters on the ETDRS eye chart at month 24 between the treatment and control groups. In December 2009, Alimera received the month 24 clinical readout for the FAME Study and analyzed the full data set consistent with the recommendations regarding the appropriate population for primary analysis as described in the FDA-adopted International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Guidance E9, "Statistical Principles for Clinical Trials". ICH is a joint venture involving regulatory authorities and pharmaceutical industry representatives from Europe, Japan and the United States who discuss scientific and technical aspects of product registration.

The full data set includes all 956 patients randomized into the FAME Study, with data imputation employed, using "last observation carried forward" (LOCF), for data missing because of patients who discontinued the trial or were unavailable for follow-up (the Full Analysis Set). As part of Alimera's analyses, it determined statistical significance based on the Hochberg-Bonferroni procedure (H-B procedure), which is a procedure employed to control for multiple comparisons. Alimera also made a target p-value adjustment of 0.0001 to account for each of the nine instances that the independent data safety monitoring board reviewed unmasked interim clinical data. These adjustments resulted in a required p-value of 0.0491 or lower for each of Trial A and Trial B to demonstrate statistical significance for both the low dose and high dose of ILUVIEN. Based upon the H-B procedure, if either dose of ILUVIEN in a trial did not meet statistical significance, the alternate dose was required to achieve a p-value of 0.02455 or lower in that trial to demonstrate statistical significance.

In the Full Analysis Set, the primary efficacy endpoint was met with statistical significance for both the low dose and the high dose of ILUVIEN in Trial A and Trial B, as well as on a combined basis. The table below summarizes the primary efficacy variable results.

Patients Gaining At Least 15 Letters At Month 24

	Trial A			Trial B			Combined		
Study Group	Individuals	%	p-value	Individuals	%	p-value	Individuals	%	p-value
Control	14/95	14.7%	—	16/90	17.8%	—	30/185	16.2%	—
Low Dose	51/190	26.8%	0.029	57/186	30.6%	0.030	108/376	28.7%	0.002
High Dose	51/196	26.0%	0.034	62/199	31.2%	0.027	113/395	28.6%	0.002

Additionally, as required by the FDA, a numerical comparison of the percentage of ILUVIEN patients gaining 15 or more letters at month 18 and month 24 in the Full Analysis Set demonstrated that the percentage of ILUVIEN patients gaining 15 or more letters for both the low dose and high dose of ILUVIEN at month 24 was numerically greater than at month 18 in both Trial A and Trial B.

Although the primary endpoint for the FAME Study was at month 24, the FDA requested in the CRL analyses of safety and efficacy data through month 36 to further assess the relative benefits and risks of ILUVIEN, which Alimera provided in its resubmitted NDA.

The data through month 36 for the Full Analysis Set in Trial A demonstrated statistically significant therapeutic effects at months 30 and 33 of ILUVIEN patients gaining 15 or more letters compared to the control group. The therapeutic effect was maintained at month 36; however, statistical significance was lost, as more of the control group gained 15 or more letters at this time point**.** The table below summarizes the primary efficacy variable results for Trial A at months 24, 27, 30, 33 and 36:

Patients Gaining At Least 15 Letters in Trial A

	At Month 24			At Month 27			At Month 30		
	Individuals	%	P-Value	Individuals	%	P-Value	Individuals	%	P-Value
Control	14/95	14.7%	—	15/95	15.8%	—	14/95	14.7%	—
Low Dose	51/190	26.8%	0.029	49/190	25.8%	0.076	55/190	28.9%	0.011
High Dose	51/196	26.0%	0.034	54/196	27.6%	0.031	53/196	26.9%	0.023

	At Month 33			At Month 36		
	Individuals	%	P-Value	Individuals	%	P-Value
Control	16/95	16.8%	—	18/95	18.9%	—
Low Dose	54/190	28.4%	0.042	54/190	28.4%	0.106
High Dose	56/196	28.6%	0.034	53/196	27.0%	0.142

Results from Trial B were similar. Statistically significant therapeutic effects at months 30 and 33 of ILUVIEN patients gaining 15 or more letters over baseline were reported compared to the control group. The table below summarizes the primary efficacy variable results for Trial B at months 24, 27, 30, 33 and 36:

Patients Gaining At Least 15 Letters in Trial B

	At Month 24			At Month 27			At Month 30		
	Individuals	%	P-Value	Individuals	%	P-Value	Individuals	%	P-Value
Control	16/90	17.8%	—	12/90	13.3%	—	14/90	15.6%	—
Low Dose	57/186	30.6%	0.030	59/186	31.7%	0.001	63/186	33.9%	0.002
High Dose	62/199	31.2%	0.027	61/199	30.7%	0.003	58/199	29.1%	0.018

	At Month 33			At Month 36		
	Individuals	%	P-Value	Individuals	%	P-Value
Control	16/90	17.8%	—	17/90	18.9%	—
Low Dose	55/186	29.6%	0.046	54/186	29.0%	0.086
High Dose	58/199	29.1%	0.057	57/199	28.6%	0.111

Alimera also provided data for the subgroup of patients with chronic DME in its resubmission of the NDA for ILUVIEN for DME. The subgroup was not specified in the protocol for the FAME Study. For this subgroup, which comprised approximately 55% of the patients in the FAME Study, statistically significant therapeutic effects of ILUVIEN patients gaining 15 or more letters over baseline compared to control were maintained through month 36 in each of Trial A and Trial B separately and in Trials A and B combined. Consistent with the full patient population in the FAME Study, approximately 75% of the patients in this subgroup treated with ILUVIEN were reported to have received only one ILUVIEN insert over the 36 month study. The tables below summarize the percentage of patients with improved BCVA from baseline of 15 or more letters for the low dose for the subgroup of patients with chronic DME for Trials A and B separately at months 24, 27, 30, 33 and 36:

Subgroup Patients Gaining At Least 15 Letters in Trial A

	At Month 24			At Month 27			At Month 30		
	Individuals	%	P-Value	Individuals	%	P-Value	Individuals	%	P-Value
Control	7/58	11.9%	—	8/59	13.6%	—	6/59	10.2%	—
Low Dose	35/110	31.8%	0.004	32/110	29.1%	0.022	37/110	33.6%	<0.001

	At Month 33			At Month 36		
	Individuals	%	P-Value	Individuals	%	P-Value
Control	7/59	11.9%	—	8/59	13.6%	—
Low Dose	38/110	34.5%	0.002	35/110	31.8%	0.010

Subgroup Patients Gaining At Least 15 Letters in Trial B

	At Month 24			At Month 27			At Month 30		
	Individuals	%	P-Value	Individuals	%	P-Value	Individuals	%	P-Value
Control	8/53	15.1%	—	5/53	9.4%	—	6/53	11.3%	—
Low Dose	37/99	37.4%	0.006	38/99	38.4%	<0.001	42/99	42.4%	<0.001

	At Month 33			At Month 36		
	Individuals	%	P-Value	Individuals	%	P-Value
Control	8/53	15.1%	—	7/53	13.2%	—
Low Dose	37/99	37.4%	0.006	36/99	36.4%	0.004

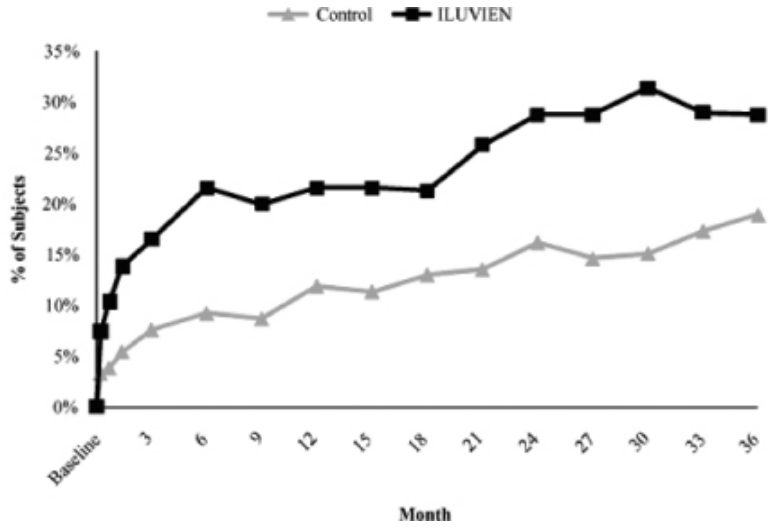
Additional Clinical Observations – Combined Basis. In addition to the primary efficacy variable, Alimera also reported that it observed a number of other clinically relevant results in the final readout from the FAME Study through month 36. These observations included, among others, the following:

- patients with improved BCVA of 15 or more letters at each follow up visit;
- BCVA improvement of 15 or more letters relative to baseline BCVA;
- Mean change in BCVA letter score; and
- decrease in excess foveal thickness.

The analyses of these Full Analysis Set observations set forth below are presented for Trial A and Trial B on a combined basis for patients who received the low dose of ILUVIEN in comparison to the control group. Statements regarding statistical significance do not reflect any adjustments to the p-values calculated for multiple comparisons and analyses.

Patients With Improved BCVA of 15 Letters or More at Each Follow-Up Visit. Alimera's analysis of the results of the FAME Study through month 36 indicates that the low dose of ILUVIEN provides an improvement in BCVA as early as three weeks after insertion. The low dose of ILUVIEN was statistically significantly better

than the control group in the FAME Study by week 3 of patient follow-up, and maintained a statistically significant advantage over the control through month 36, with a peak efficacy of 31.4% achieving BCVA of 15 or more letters from baseline at month 30. The chart below demonstrates the treatment effect of the low dose of ILUVIEN versus the control group, as measured by an improvement in BCVA of 15 letters or more, at each scheduled follow-up visit during the FAME Study.



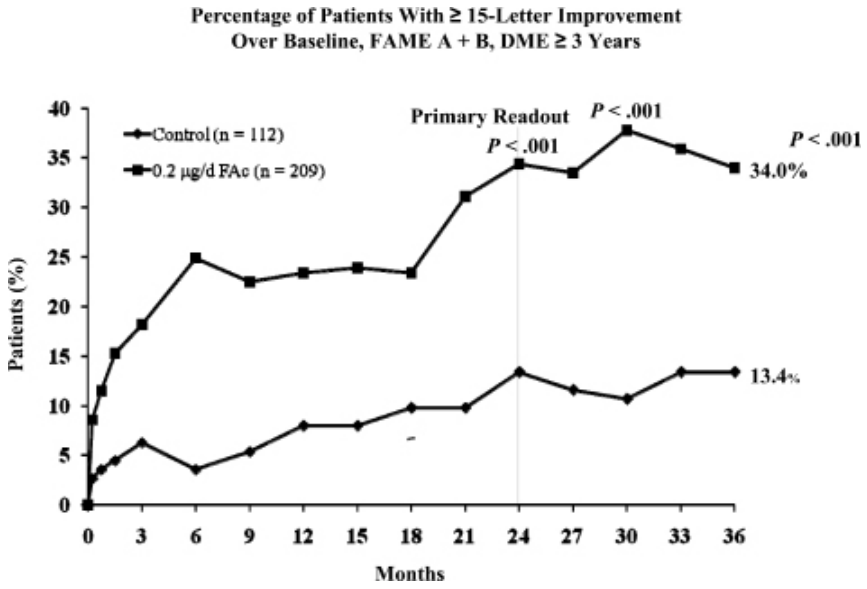
The table below summarizes the primary efficacy variable results for Trials A and B combined at months 24, 27, 30, 33 and 36:

Patients Gaining At Least 15 Letters in Trial A & Trial B Combined

	At Month 24			At Month 27			At Month 30		
	Individuals	%	P-Value	Individuals	%	P-Value	Individuals	%	P-Value
Control	30/185	16.2%	—	27/185	14.6%	—	28/185	15.1%	—
Low Dose	108/376	28.7%	0.002	108/376	28.7%	<.001	118/376	31.4%	<0.001

	At Month 33			At Month 36		
	Individuals	%	P-Value	Individuals	%	P-Value
Control	32/185	17.3%	—	35/185	18.9%	—
Low Dose	109/376	29.0%	0.004	108/376	28.7%	0.018

Alimera's analysis of the results of the FAME study through month 36 for the subgroup of patients with chronic DME on a combined basis also demonstrates that the low dose of ILUVIEN had greater efficacy than the control group with peak efficacy of 37.8% of patients receiving low dose gaining 15 or more letters in BCVA from baseline at month 30 compared to 10.7% of patients randomized to control. The chart below demonstrates the treatment effect of the low dose of ILUVIEN versus the control group on a combined basis in the subgroup of patients with chronic DME, as measured by an improvement in BCVA of 15 letters or more, at each scheduled follow-up visit during the FAME Study.



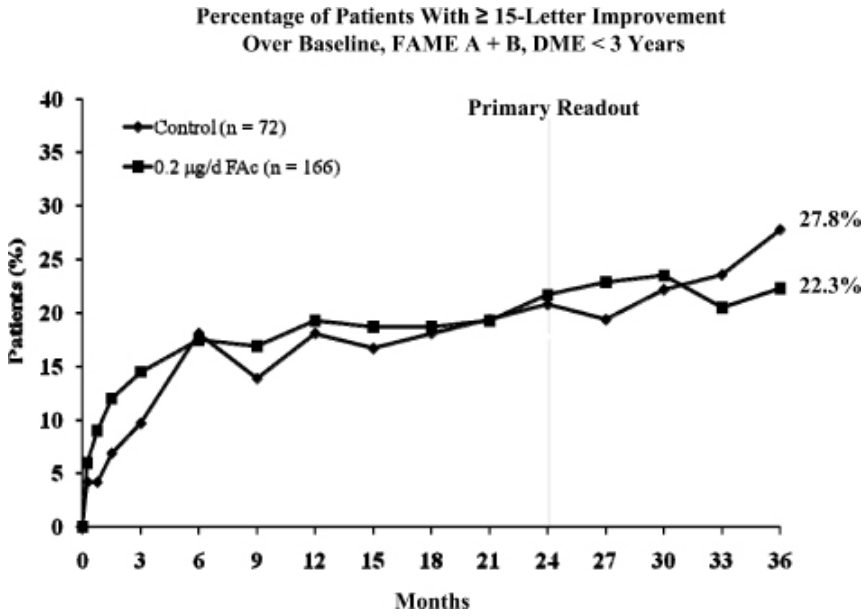
The table below summarizes the percentage of patients with improved BCVA from baseline of 15 or more letters for the low dose for the subgroup of patients with chronic DME for Trials A and B combined at months 24, 27, 30, 33 and 36:

Subgroup Patients Gaining At Least 15 Letters in Trial A & Trial B Combined

	At Month 24			At Month 27			At Month 30		
	Individuals	%	P-Value	Individuals	%	P-Value	Individuals	%	P-Value
Control	15/112	13.4%	—	13/112	11.6%	—	12/112	10.7%	—
Low Dose	72/209	34.4%	<0.001	70/209	33.5%	<0.001	79/209	37.8%	<0.001

	At Month 33			At Month 36		
	Individuals	%	P-Value	Individuals	%	P-Value
Control	15/112	13.4%	—	15/112	13.4%	—
Low Dose	75/209	35.9%	<0.001	71/209	34.0%	<0.001

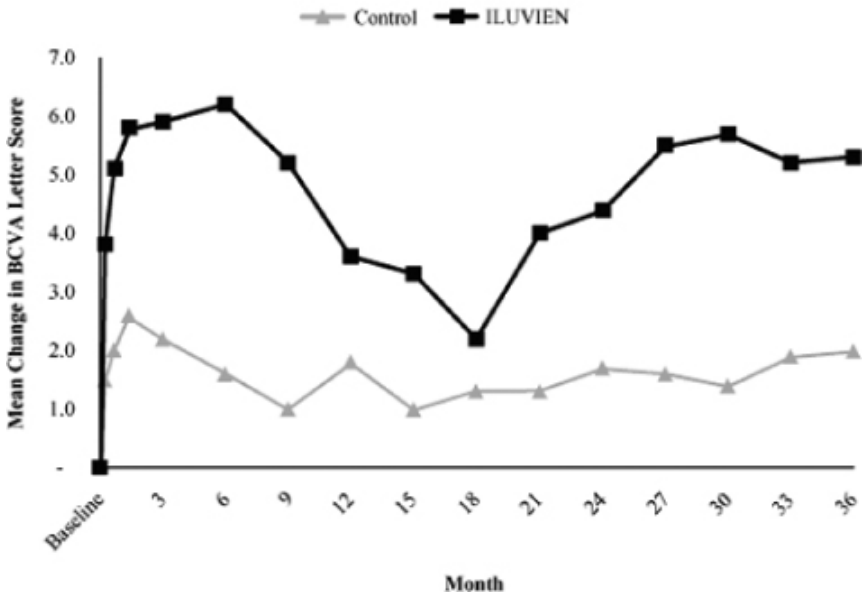
In patients with relatively recently diagnosed DME (that is, less than three years duration of DME at entry), there was no statistically significant difference in BCVA improvement in the low dose of ILUVIEN compared to control. The chart below shows the treatment effect of the low dose of ILUVIEN versus the control group on a combined basis in the subgroup of patients with less than three years' duration of DME at entry, as measured by an improvement in BCVA of 15 letters or more, at each scheduled follow-up visit during the FAME Study.



BCVA Improvement of 15 or More Letters Relative to Baseline BCVA. Alimera's analysis of the results of the FAME Study at month 36 indicates that ILUVIEN has a statistically significant advantage over the control group in patients with more severe disease. The table below demonstrates the treatment effect at month 24 and at month 36 of ILUVIEN versus the control group in patients with baseline BCVA of more than 49 letters on the EDTRS eye chart, and patients with BCVA of 49 letters or less on the EDTRS eye chart at baseline.

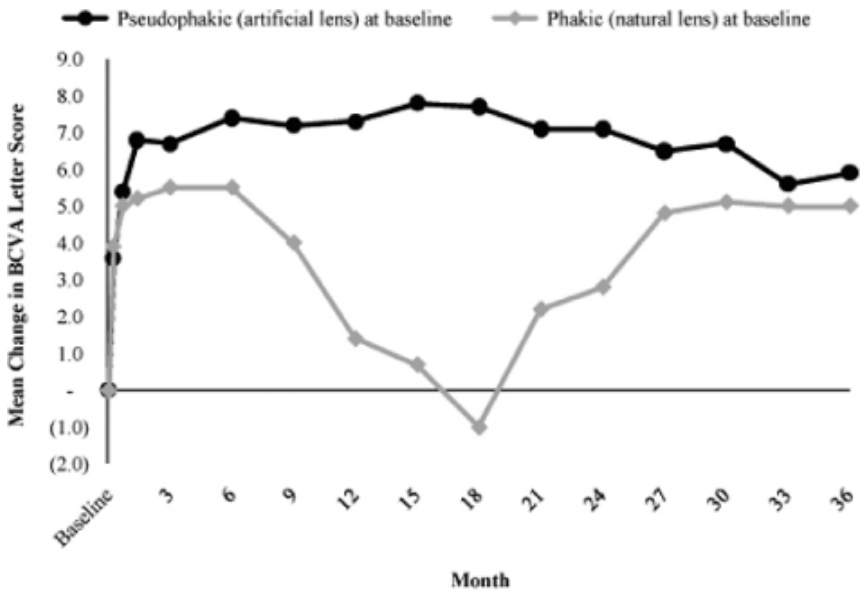
	Trial A & Trial B Combined					
	At 24 Months			At 36 Months		
Baseline BCVA	Control	Low Dose	p-value	Control	Low Dose	p-value
Greater than 49 Letters	11.8%	21.1%	0.027	16.9%	21.8%	0.292
49 Letters or Less	28.6%	46.1%	0.039	24.5%	44.3%	0.022

Mean Change in BCVA Letter Score. Alimera's analysis of the results of the FAME Study through month 36 indicates that the low dose of ILUVIEN provided a more beneficial improvement in visual acuity than the control group as analyzed by the mean change in the BCVA letter score from baseline. As demonstrated in the graph below, the mean change in BCVA for the patients receiving the low dose of ILUVIEN was an increase of 5.3 letters at month 36, peaking at an increase of 6.0 letters at month 6, compared to an increase of 2.0 letters in the control group, peaking at an increase of 2.6 letters at week 6. The low dose of ILUVIEN was statistically significantly better than the control group at month 36 (p-value 0.007).

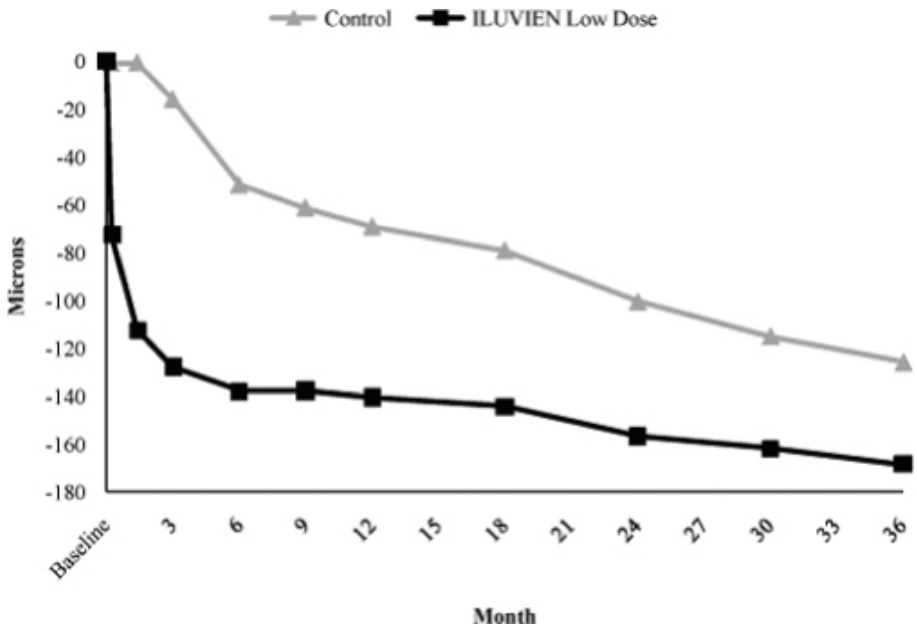


During the FAME Study, Alimera reported that, of patients who were phakic (had a natural lens and no prior cataract surgery) at baseline, 61 of 121, or 50.4% of the control group and 192 of 235, or 81.7% of the low dose of ILUVIEN, had cataract formation reported as an adverse event through month 36. For these same phakic patients, Alimera reported that 27.3% of the control group and 80.0% of the low dose group underwent cataract surgery through month 36. For the patients in the low dose group the median time to reporting cataract formation as an adverse event was approximately 12 months from randomization into the FAME Study. The median time to cataract surgery was approximately 18 months. This interval between the report of cataract formation as an adverse event and cataract surgery may account for the decrease in the mean change in BCVA in patients receiving the low dose of ILUVIEN from the month 6 follow-up visit to the month 18 follow-up visit.

The temporary effect of cataract progression on BCVA reported by Alimera is illustrated by comparing the mean change in BCVA of the 140 low dose patients that were pseudophakic (had already undergone cataract surgery and received an artificial lens) at baseline to the 235 that were phakic at baseline. The chart below shows the pseudophakic subset (those who would not have vision affected by a cataract) achieved a mean change in BCVA of more than 7 letters by month 6 and substantially maintained this mean change through month 36 while the phakic subset experienced a decrease in the mean change in BCVA from the month 6 follow-up visit to the month 18 follow-up visit. The temporary decrease in mean change in BCVA in the phakic population is consistent with the total low dose population.



Decrease In Excess Foveal Thickness. In addition to the functional measures of BCVA, Alimera assessed the ability of ILUVIEN to effect a decrease in excess foveal thickness, an anatomic outcome, as measured by optical coherence tomography. Excess foveal thickness is a measurement of the swelling of the macula at its center point (known as the fovea). Alimera reported that it considers any measurement above 180 microns to represent excess foveal thickness. Based on a review of the final clinical readout through month 36 as summarized in the chart below, Alimera reported that patients receiving the low dose of ILUVIEN demonstrated a statistically significant difference versus the control group in decreasing excess foveal thickness by week 1 of patient follow-up of the FAME Study, and maintained a statistically significant advantage through month 36. At month 36, patients receiving the low dose of ILUVIEN demonstrated a mean decrease in excess foveal thickness of 168.3 microns versus 125.9 microns for the control group.



Safety. Alimera reported that its safety assessment in connection with the month 24 clinical readout of the FAME Study included all reported adverse events at that time, regardless of a patient's progression in the FAME Study. Some reported adverse events occurred beyond patients' month 24 follow-up visits. Alimera also assessed safety through the completion of the FAME study in month 36. Alimera reported that ILUVIEN was well tolerated through this readout in both the low and high dose patient populations. Alimera's preliminary assessment of adverse event data indicates that there is no apparent risk of systemic adverse events to patients as a result of the use of ILUVIEN. The use of corticosteroids in the eye is primarily associated with two undesirable side effects: increased IOP, which may increase the risk of glaucoma and require additional procedures to manage, and cataract formation. Excluding IOP-related side effects and cataracts, Alimera reported that it observed no significant eye-related adverse events when comparing both the low dose and high dose patient populations to control. Thus, Alimera has stated that it believes the adverse events associated with the use of ILUVIEN are within the acceptable limits of a drug for the treatment of DME.

According to the CDC, diabetic individuals aged 50 or older are 1.5 times more likely to develop cataracts than non-diabetic individuals. A review of the baseline characteristics of the FAME patient population reflects this increased risk of cataracts for diabetic patients, with 34.8% of the patients treated in the FAME Study having previously undergone a cataract surgery in the study eye. Alimera reported that the month 24 clinical readout from the FAME study (which includes reported adverse events that occurred beyond patients' month 24 follow-up visits) indicated that, of patients who had a natural lens (no prior cataract surgery) at baseline, 46.3% of the control group, 80.0% of the low dose and 87.5% of the high dose had cataract formation reported as an adverse event through month 24. Additionally, of the patients who had a natural lens at baseline, 23.1% of the control group, 74.9% of the low dose and 84.5% of the high dose underwent cataract surgery**.** The final 36 month clinical readout indicated that, of patients who had a natural lens at baseline, 50.4% of the control group and 81.7% of the low dose had cataract formation reported as an adverse event through month 36. Additionally, of the patients who had a natural lens at baseline, 27.3% of the control group and 80% of the low dose group underwent cataract surgery.

Alimera assessed safety through completion of the FAME study for the subgroup of patients with chronic DME. The tables below show IOP and cataract related adverse events at the time of the 36 month clinical readout for the low dose for the full patient population and the subgroup of patients with chronic DME.

	IOP Related Events			
	DME ≥ 3 year subgroup		Full Population	
	Control N=112	Low Dose N=209	Control N=185	Low Dose N=375
IOP > 30 mmHg (1)	5.4%	14.8%	4.3%	18.4%
Trabeculoplasty	0.0%	1.9%	0.0%	1.3%
IOP-Lowering Surgeries	0.0%	5.3%	0.5%	4.8%

(1) An IOP of 30 mmHg is a clinically significant level that Alimera used in assessing adverse events.

	Cataract Related Events			
	DME ≥ 3 year subgroup		Full Population	
	Control N=66	Low Dose N=114	Control N=121	Low Dose N=235
Cataract (phakic patients)	51.5%	86.0%	50.4%	81.7%
Cataract Extraction (phakic patients)	36.4%	85.1%	27.3%	80.0%

PK Study

Regulatory agencies require carcinogenicity studies in animals to identify tumorigenic potential in animals to assess the relevant risk in humans as a result of systemic exposure. Alimera initiated an open-label Phase 2 human pharmacokinetic clinical study (PK Study) in August 2007 to assess the systemic exposure of FAc by measuring plasma levels of FAc. Analysis of plasma levels through month 18 in September 2009 demonstrated no systemic exposure of FAc (plasma levels were below the limit of detection of 100 picograms per milliliter). Based on the month 18 readouts, Alimera reported that it submitted a carcinogenicity waiver in its submissions to the FDA and European health authorities. Although the FDA did not specifically state in the CRL that the waiver has been granted, the CRL did not include any requirement to conduct a carcinogenicity study. In the Preliminary Assessment Report issued by the MHRA, the MHRA stated that the lack of single-dose, carcinogenicity and reproductive and developmental toxicity studies with ILUVIEN is acceptable. Alimera reported that if it is required to perform carcinogenicity studies of ILUVIEN in animals, the approval of ILUVIEN could be delayed by up to 36 months.

Alimera reported that a total of 37 patients were enrolled in the PK Study, 17 patients on the high dose and 20 patients on the low dose of ILUVIEN, that the last patient was enrolled in the study at the end of February 2008, and that data from the PK Study were evaluated on an ongoing basis with interim evaluations at months 3, 6, 12, 18, 24, 30 and 36.

Approved Durasert Products

Retisert. Retisert is approved by the FDA for the treatment of posterior uveitis, an autoimmune condition characterized by inflammation of the posterior of the eye that can cause sudden or gradual vision loss. In the United States, this disease has been estimated to affect 175,000 people and to have resulted in blindness in approximately 30,000 people. Retisert, which is about the size of a grain of rice, is surgically implanted through a 3-4 mm incision and delivers sustained levels of the anti-inflammatory corticosteroid FAc for approximately 30 months. Clinical trials have shown that many patients treated with Retisert experience improved vision. Retisert was approved as an orphan drug in 2005, which provided for seven-year exclusive marketing rights. Retisert is marketed and sold in the United States by Bausch & Lomb.

Vitrasert. Vitrasert treats CMV retinitis, a blinding eye disease that occurs in individuals with advanced AIDS. Vitrasert, which is surgically implanted through a 5-6 mm incision, provides sustained treatment for six to eight months through the intravitreal delivery of the anti-viral drug ganciclovir. Studies have shown that Vitrasert is one of the most effective approved treatments for CMV retinitis. Vitrasert has been sold since 1996 in the United States and abroad, first by Chiron Corporation and subsequently by Bausch & Lomb. Although CMV retinitis was relatively common in AIDS patients in the early 1990s, improvements in the treatment of AIDS/HIV

have since significantly decreased the incidence of the disease in more developed countries. Accordingly, sales of Vitrasert have decreased significantly.

Other Durasert Product Candidates

Latanoprost Glaucoma Product Candidate.

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

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

Posterior Uveitis Product Candidate

In September 2011, an investigator-sponsored IND opened for a Phase I/II study of the safety and efficacy of our injectable, sustained release insert delivering FAc for the treatment of posterior uveitis. The insert is the same design as the insert being developed by Alimera for the treatment of DME and delivers the high and low dose of FAc used in the FAME Study. We did not license Alimera the rights to use the insert for uveitis. If successful, we plan to advance this product candidate into pivotal multi-center Phase III trials and reference the NDA for ILUVIEN for DME (including the clinical data from the FAME Study and the manufacturing and stability data) in potential posterior uveitis regulatory filings. We also plan to use a new inserter, with a smaller gauge needle than that used in the FAME Study, in any future posterior uveitis Phase III trials.

BioSilicon Technology System

Our BioSilicon technology system utilizes a “honeycomb” structure of nano-porous, elemental silicon to deliver therapeutics. Products utilizing this system are biocompatible and biodegradable. Our primary focus is on Tethadur, which utilizes BioSilicon to deliver large biologic molecules, including peptides and proteins, on a sustained basis. Our BioSilicon technology can also be tailored to deliver smaller molecules. Based on results of our preliminary studies, we are currently targeting the BioSilicon technology as a key second prong of our drug delivery technology platform.

Strategic Collaborations

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

Alimera

Under a collaboration agreement with Alimera, as amended in March 2008 (the “Restated Alimera Agreement”), we granted Alimera an exclusive worldwide license to manufacture, develop, market and sell ILUVIEN for the treatment and prevention of eye diseases in humans other than uveitis. The Restated Alimera Agreement also provides Alimera a worldwide non-exclusive license to manufacture, develop, market and sell certain additional Durasert-based products (1) to deliver a corticosteroid and no other active ingredient by a direct delivery method to the back of the eye or (2) to treat DME by delivering a compound through a direct delivery method through an incision no smaller than that required for a 25-gauge or larger needle, in each case solely for the treatment and prevention of eye diseases in humans other than uveitis. The non-exclusive license is

limited to those products that (i) are not an implant required to be surgically inserted through an incision of at least 2 mm in the scelera into the vitreous, are secured in the posterior of the eye, cannot be injected, and use a certain reservoir design, (ii) have a drug core within a polymer layer (with certain limitations regarding chemically bonded combinations of active agents), and (iii) are approved or designed to be approved to deliver a corticosteroid and no other active ingredient by a direct delivery method to the posterior portion of the eye or to treat DME by delivering a compound by a direct delivery method through an incision required for a 25 gauge or larger needle. With the exception of the licenses to Bausch & Lomb, during the term of the agreement we are not permitted to use, or grant a license to any third party to use, such technologies to make or sell any products that are or would be (but for delivering a corticosteroid in combination with another active ingredient) subject to the non-exclusive license granted to Alimera.

Under our original collaboration agreement entered into in February 2005, we and Alimera agreed to collaborate on the development of ILUVIEN for DME and share the development expenses equally. In connection with the March 2008 Restated Alimera Agreement, we received consideration of $12.0 million in cash, and Alimera cancelled $5.7 million of accrued development cost liabilities, including related penalties and accrued interest, we owed Alimera as of March 14, 2008. In addition, Alimera gave us an interest-bearing $15.0 million conditional note, agreed to pay us a $25.0 million milestone payment upon FDA approval of ILUVIEN for DME and assumed all financial responsibility for the development of licensed products under the Restated Alimera Agreement (including reimbursement of approved development costs incurred by us in support of the ongoing clinical studies of ILUVIEN) and anticipated regulatory submissions. In exchange, we decreased our share in any future profits, as defined, on sales of ILUVIEN by Alimera from 50% to 20%, subject to an offset of 20% of pre-profitability commercialization costs, as defined, incurred by Alimera. In the event Alimera sublicenses commercialization, we are entitled to receive 20% of royalties and 33% of non-royalty consideration received by Alimera, less certain permitted deductions. Alimera has indicated that it intends to commercialize ILUVIEN, if approved, through a direct sales force in the United States and to seek marketing collaboration partners for the commercialization of ILUVIEN outside of the United States.

Through March 31, 2010, we received total interest payments of approximately $2.5 million on the conditional note. In April 2010, following consummation of its initial public offering, Alimera paid the $15.0 million conditional note in full, together with an additional $225,000 of accrued and unpaid interest.

We derived revenues of $192,000 in the year ended June 30, 2011 (fiscal 2011), $22.3 million in the year ended June 30, 2010 (fiscal 2010) and $11.8 million in the year ended June 30, 2009 (fiscal 2009) under the Restated Alimera Agreement.

Either party may terminate the agreement for the other party’s uncured material breach. We may terminate the Restated Alimera Agreement with respect to a particular product if Alimera notifies us that it is abandoning or has abandoned such product, in which case the agreement provides for specific, exclusive remedies.

Pfizer

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

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

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

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

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

Pfizer owns approximately 9.0% of pSivida's total shares outstanding as of August 31, 2011.

Bausch & Lomb

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

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

Intrinsiq

In January 2008, we granted an exclusive field-of-use license to Intrinsiq Materials Cayman Limited (Intrinsiq) for the development and commercialization of nutraceutical and food science applications of BioSilicon, under which we received aggregate license fee and minimum royalty payments of $1.7 million through June 2011. In February 2009, we entered into a 2-year supply agreement with Intrinsiq under which we

leased certain equipment to Intrinsiq for their use in manufacturing BioSilicon material for total payments of $122,000. In July 2011, we purchased BioSilicon-related capital equipment and intellectual property assets of Intrinsiq for $223,000, and assumed four Intrinsiq employees. In connection with this asset purchase agreement, Intrinsiq terminated its field-of-use license agreement.

Research and Development

Our primary activity is the development of products based on our technology systems. Our research and development expenses were $6.9 million in fiscal 2011, $7.0 million in fiscal 2010 and $8.0 million in fiscal 2009. Of these amounts, $3.2 million in fiscal 2011, $3.4 million in fiscal 2010 and $4.4 million in fiscal 2009 were incurred for costs of research and development personnel, clinical trials, contract services, testing and laboratory facilities. Fiscal 2011 costs were reduced by a one-time IRS grant award of $208,000. All such costs were charged to operations as incurred. The remaining expense of $3.7 million in fiscal 2011 and $3.6 million in each of fiscal 2010 and fiscal 2009 consisted of non-cash charges for amortization of intangible assets, depreciation of property, plant and equipment and stock-based compensation expense specifically allocated to research and development personnel.

Intellectual property

Our intellectual property rights are crucial to our business. We hold or are licensed patents relating to our core technology systems in the United States and international markets. The following table provides general details relating to our owned and licensed patents (including both patents that have been issued and applications that have been accepted for issuance) and patent applications as of August 31, 2011:

Technology	United States Patents	United States Applications	Foreign Patents	Foreign Applications	Patent Families
Durasert	12	23	88	77	26
BioSilicon	12	9	64	33	22
CODRUG	3	9	14	12	12
Other	—	4	—	3	4
Total	**27**	**45**	**166**	**125**	**64**

Employees

We had 26 employees as of August 31, 2011. None of our employees is covered by a collective bargaining agreement.

Sales and Marketing

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

Reimbursement

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

Competition

We are engaged in healthcare product development, an industry that is characterized by extensive research efforts and rapid technological progress. 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 and novel delivery methods to treat our targeted diseases. We have, or expect to face, significant competition for all of our products and product candidates. Most of our competitors and potential competitors are larger, more well established and experienced and have substantially more resources than us or Alimera.

Many companies are pursuing products to treat back-of-the-eye diseases. These include the following:

- Genentech Inc.'s products Lucentis (ranibizumab injection) and Avastin® (bevacizumab) block all isoforms of vascular endothelial growth factor (VEGF) and are being studied for the treatment of DME. Two-year results from Phase III clinical trials of Lucentis have shown that this drug is effective in the treatment of DME. Lucentis is currently approved in the United States and the European Union for the treatment of patients with neovascular wet AMD and approved in the European Union for the treatment of DME. Avastin is currently marketed as an oncology product but is believed to be widely prescribed for ophthalmic treatment. Genentech is a wholly-owned member of the Roche Group.
- Allergan, Inc.'s product Ozurdex® (dexamethasone intraveal implant) is a bioerodible extended release implant that delivers the corticosteroid dexamethasone. Ozurdex is approved for macular edema following branch or central RVO and posterior uveitis, and has a duration of therapy of three to five months. In addition, Allergan's product Trivaris™ (triamcinolone acetonide injectable suspension) is approved for sympathetic ophthalmia, temporal arteritis, uveitis and other inflammatory conditions unresponsive to topical corticosteroids.
- Eyetech, Inc.'s product Macugen (pegaptanib sodium injection) is an anti-VEGF aptamer against VEGF 165. It has been FDA-approved for treatment of all subtypes of choroidal neovascularization in patients with AMD.
- Regeneron Pharmaceuticals, Inc. is developing a drug for wet-AMD and DME. This drug (VEGF-trap) is designed, like Lucentis and Macugen, to be injected directly into the vitreous on a regular basis. Regeneron has completed Phase III clinical trials for wet-AMD and was recommended for approval at a recent FDA advisory panel meeting. Phase II trials of VEGF-trap for DME are underway.
- Treatments involving the systemic delivery of ganciclovir, a Roche Holdings AG product, and other drugs are used to treat CMV Retinitis and systemic delivery of corticosteroids is used to treat intermediate and posterior uveitis.

QLT Inc. is developing a punctal plug latanoprost implant for sustained release for more than one month. This product recently completed a Phase II clinical trial.

Other companies, including Glaxo SmithKline (GSK), MacuSight, Inc., Thrombogenics NV and Novagali Pharma S.A., are developing drug therapies or sustained delivery platforms for the treatment of ocular disease.

We believe that competition for treatments of back-of-the-eye diseases is based upon the effectiveness of the treatment, potential side effects, time to market, reimbursement and price.

Revenues

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

	Year Ended June 30,								
	2011			2010			2009		
	United States	United Kingdom	Total	United States	United Kingdom	Total	United States	United Kingdom	Total
	(In thousands)								
Revenue:									
Collaborative research and development	$3,529	$ 83	$3,612	$22,449	$ 121	$22,570	$11,925	$ 77	$12,002
Royalty income	1,353	—	1,353	483	—	483	160	—	160
	$4,882	$ 83	$4,965	$22,932	$ 121	$23,053	$12,085	$ 77	$12,162

Government Regulation

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

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

The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approval will be granted on a timely basis, if at all.

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

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

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

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

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

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

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

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

The results of product development, pre-clinical studies and clinical studies are submitted to the FDA as part of an NDA for approval of the marketing and commercial shipment of the product. The FDA may deny an NDA if the applicable regulatory criteria are not satisfied, or may require additional clinical data. Even if the additional data are submitted, the FDA ultimately may decide that the NDA does not satisfy the criteria for approval. As a condition of approval, the FDA may require post-marketing "Phase IV" clinical trials to confirm that the drug is safe and effective for its intended uses. Once issued, the FDA may withdraw product approval for non-compliance with regulatory requirements or if safety or efficacy problems occur after the product reaches the market. The FDA may also require surveillance programs to monitor approved products which have been commercialized. The FDA also has the power to require changes in labeling or to prevent further marketing of a product based on the results of these post-marketing programs.

Satisfaction of FDA requirements or similar requirements of foreign regulatory agencies typically takes several years, and the actual time required may vary substantially based upon various factors, including the type, complexity and novelty of the pharmaceutical product. Such government regulation may delay or prevent marketing of potential products for a considerable period of time, and may impose costly procedures upon our activities. Success in pre-clinical or early stage clinical trials does not assure success in later stage clinical trials. Data from pre-clinical and clinical activities is not always conclusive, and may be susceptible to varying interpretations which could delay or prevent regulatory approval. Even if a product receives regulatory approval, the approval may be subject to significant limitations based on data from pre-clinical and clinical activities. Further, discovery of previously unknown problems in connection with a product's use may result in restrictions on the product, or even complete withdrawal of the product from the market.

Any product manufactured or distributed under FDA approval is subject to pervasive and continuing regulation by the FDA, including requirements for record-keeping and reporting adverse experiences with the product. Drug manufacturers and their subcontractors are required to register with the FDA and state agencies. Drug manufacturers and their subcontractors are also subject to periodic unannounced inspections by the FDA and state agencies for compliance with good manufacturing practices, which impose procedural and documentation requirements upon us and our third-party manufacturers.

The passage of the FDAAA significantly enhanced the FDA's authority to regulate drugs post-approval. For certain drugs that the FDA determines pose risks that outweigh the benefits, FDA approval may be subject to the manufacturers' continued adherence to a Risk Evaluation Mitigation Strategy (REMS). REMS, which are tailored to specifically address the risks of a given drug, may contain elements that restrict distribution of the drug to certain physicians, pharmacists and patients or that require the use of communication tools such as letters to healthcare providers and patients detailing the risks associated with the drug. In addition to REMS, the FDAAA also provides the FDA with increased authority to require the manufacturer to conduct post-approval clinical trials and to submit drug advertisements to the FDA for review before dissemination.

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

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

The time and expense required to perform the clinical testing necessary to obtain FDA clearance or approval for regulated products can frequently exceed the time and expense of the research and development initially required to create the product. Even after initial FDA approval has been obtained, we or our collaborative partners could be required to conduct further studies to provide additional data on safety or efficacy or, should we desire, to gain approval for the use of a product as a treatment for additional clinical indications. In addition, use of a product during testing and after marketing approval has been obtained could reveal side effects which, if serious, could limit uses, or in the most serious cases, result in a market withdrawal of the product or expose us to product liability claims.

Corporate Information

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

Additional Information

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

ITEM 1A. RISK FACTORS

RISKS RELATED TO OUR COMPANY AND OUR BUSINESS

We may be required to seek additional capital in order to fund our operations, and our ability to obtain additional capital is uncertain.

Our cash, cash equivalents and marketable securities totaled $24.1 million at June 30, 2011. We believe we can fund our operations as currently conducted into at least calendar year 2013. Whether we will require, or desire, additional capital will be influenced by many factors, including, but not limited to:

- the timely development and regulatory approval and successful commercialization of ILUVIEN and receipt of milestone, royalty and other payments;
- the scope and extent of our internally funded operations and programs, including the clinical trials for the Latanoprost Product and the posterior uveitis insert, and any new product candidates and any new business opportunities;
- our ability to establish and maintain strategic arrangements for products and product candidates for research, development, clinical testing, manufacturing and marketing;
- the success of our products and product candidates, including the timing and costs of regulatory approvals and the commercial success of approved products;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing any patent claims; and
- changes in our operating plan, including the pursuit of any new business opportunities, which may affect our need for capital.

In particular, our future cash position depends significantly on approval of ILUVIEN by the FDA and foreign regulatory authorities and the initiation and success of marketing of ILUVIEN. Alimera has agreed to pay us $25 million upon FDA approval of ILUVIEN for DME. In addition, we will be entitled to 20% of any future profits, as defined, on sales of ILUVIEN by Alimera, subject to an offset of 20% of defined pre-profitability commercialization costs incurred by Alimera. In the event Alimera sublicenses commercialization, we would receive 20% of royalties and 33% of non-royalty consideration received by Alimera, less certain permitted deductions. However, there is no assurance that the FDA or other regulatory authorities will approve ILUVIEN or that ILUVIEN will achieve market acceptance even if it is approved. If we determine that it is desirable or necessary to raise additional capital in the future, we do not know if it will be available when needed or on terms favorable to us or our stockholders. The state of the economy and the financial and credit markets at the time we seek additional financing may make it more difficult and more expensive to obtain. If available, additional equity financing may be dilutive to stockholders, debt financing may involve restrictive covenants or other unfavorable terms and potential dilutive equity, and funding through collaboration agreements may be on unfavorable terms, including requiring us to relinquish rights to certain of our technologies or products. If adequate financing is not available if and when needed, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs, postpone the pursuit of product candidates and new business opportunities, or otherwise reduce our cash requirements.

We have a history of losses and may incur losses in the future.

We have incurred operating losses since our inception in 2000 except for fiscal 2010. For fiscal 2010, we recorded net income of $8.8 million, primarily due to the accelerated payment in full by Alimera of its $15.0 million conditional note. For fiscal 2011 and 2009, we incurred net losses of $8.6 million and $2.5 million, respectively. We expect to incur net losses for the foreseeable future unless ILUVIEN is approved and successfully commercialized. Even if ILUVIEN is approved and marketed, our profit share on sales of ILUVIEN, combined with any royalty income from our current products, and any other sources of revenue, may not be sufficient to result in profitability on an ongoing basis.

If we are required to impair the value of our intangible assets under GAAP, our financial results could be adversely affected, which could adversely affect the price of our securities.

Impairment charges on our intangible assets could have a material effect on our results of operations, which could, in turn, adversely affect the price of our securities. We recorded significant amounts of intangible assets in connection with earlier acquisitions. We took a $60.1 million impairment charge on goodwill as of June 30, 2008 (which reduced the carrying value of our goodwill to zero) and a $45.3 million impairment charge on the recorded value of our Durasert intangible asset as of June 30, 2007. We still had $21.6 million of intangible assets on our balance sheet as of June 30, 2011, of which $14.7 million related to our BioSilicon technology and $6.9 million related to our Durasert technology. We will continue to conduct impairment analyses of our intangible assets as required, and we may be required to take impairment charges in the future, which could be significant. If there is a significant change in the estimation of the projected undiscounted net cash flows for the products and product candidates utilizing the Durasert and BioSilicon technology systems, the carrying value of the respective assets could be impaired. We expect to have further information about whether we will advance the Latanoprost Product utilizing BioSilicon technology into more advanced clinical trials in late fiscal 2012, and if we do not do so, the BioSilicon intangible asset could become fully impaired.

Our results could be adversely affected by non-cash charges due to fluctuations in the fair values of certain of our outstanding warrants, which could adversely affect the price of our securities.

We previously issued warrants denominated in Australian dollars (A$). The fair values of these warrants have been recorded as derivative liabilities on our balance sheet. We are required to assess the fair value of these warrants at each balance sheet date, and changes in their fair values result in adjustments to our recorded derivative liabilities, and corresponding income or expense in our statements of operations. The fair values of these warrants are sensitive to changes in our share price, among other factors, and are measured using the Black-Scholes valuation model. Fluctuations in the fair values of these warrants will continue to affect our operating results until these warrants expire in July 2012.

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:

- the timing, receipt and amount of payments, if any, from current and potential future collaboration partners, including, without limitation, collaborative research, milestone and royalty payments, and the revenue recognition policies related thereto;
- changes in accounting estimates, policies or principles;
- the entry into, or termination of, collaboration agreements;
- the scope, duration and effectiveness of our collaboration arrangements;
- the quarterly income or expense amounts recorded from the revaluation of our derivative liabilities;
- the amount of research and development costs, including pre-clinical studies and clinical trials, that we fund internally;
- general and industry-specific adverse economic conditions that may affect, among other things, our and our collaborators' operations and financial results; and
- impairment write-downs of one or more of our intangible assets.

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 a decrease in our stock price.

Our royalty income from Bausch & Lomb may continue to decline.

The annual trend of the royalties from Bausch & Lomb for Retisert (including the historical amounts previously retained by Bausch & Lomb) and Vitrasert has declined and may continue to do so. There is no assurance that Bausch & Lomb will continue to market either or both of these products. We do not expect that our royalty payments from Bausch & Lomb for these products will ever become a material source of revenue for us.

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

We do not know if the FDA or other regulatory authorities will approve ILUVIEN for DME. If Alimera is unable to obtain regulatory approval for and successfully commercialize ILUVIEN, or if Alimera experiences significant delays in doing so, our business will be materially harmed.

Alimera will not be able to market ILUVIEN for DME in the U.S. unless and until it receives FDA approval and in foreign jurisdictions until it receives necessary regulatory approvals. Our ability to generate significant revenues from this product depends on the ability of Alimera to obtain regulatory approval for and successfully commercialize ILUVIEN. In December 2010, Alimera received a CRL from the FDA in response to Alimera's NDA filed on the basis of 24-month clinical readout data from the Fame Study, which communicated the FDA's decision that the NDA for ILUVIEN for DME could not be approved in its then present form. In the CRL, the FDA asked for analyses of safety and efficacy of the clinical readout of data from the FAME Study through month 36 ("36 Month Data"), including certain exploratory analyses in addition to analyses previously submitted in the NDA, to further assess the relative benefits and risks of ILUVIEN. In the CRL, the FDA also requested additional information regarding controls and specifications concerning the manufacturing, packaging and sterilization of ILUVIEN and indicated that the FDA had observed deficiencies in cGMP during facility inspections of two of Alimera's third-party manufacturers, which were completed in August and September of 2010, and that all facilities and controls will need to comply with cGMP.

Alimera resubmitted an NDA to the FDA on May 12, 2011 to respond to the CRL, including analyses of safety and efficacy data through month 36 of the FAME Study, and additional information regarding controls and specifications on the manufacturing, packaging and sterilization of ILUVIEN. The resubmission also included data from analyses of a subgroup of chronic DME patients in the FAME Study. The subgroup was not specified in the protocol for the FAME Study. Alimera reported that the FDA classified the response as a Class 2 resubmission, resulting in a six-month review period and a PDUFA date by which Alimera can reasonably expect a response from the FDA of November 12, 2011. Alimera also reported that the FDA has subsequently indicated it will not call an advisory committee during its review.

Alimera has reported that it believes the deficiencies in cGMP noted by the FDA in the CRL have been resolved and that no further action is required because the FDA issued letters to both of these third-party manufacturers indicating that the inspections were now closed. Alimera has indicated that the ILUVIEN injection system will not require a separate device application, but it must meet the safety and regulatory requirements of the applicable regulatory authorities when evaluated as part of the drug product marketing application.

In the NDA, Alimera included analyses of the 24 Month Data utilizing the full data set of all 956 patients randomized into Alimera's FAME Study, with data imputation employed using LOCF for data missing because of patients who discontinued the trial or were unavailable for follow-up (the "Full Analysis Set") as well as other data sets including one that excludes from the Full Analysis Set three patients who were enrolled but never treated, excludes data collected for patients subsequent to their use of treatments prohibited by Alimera's FAME

Study protocol and imputes the last observation prior to the protocol violation forward to month 24 using the LOCF method (the "Modified ART Data Set"). Both Alimera and we believed that the FDA would consider the Full Analysis Set the most relevant population for determining the safety and efficacy of ILUVIEN based on the 24 Month Data. The primary efficacy endpoint at month 24 was met with statistical significance for both the low dose and the high dose of ILUVIEN in both trials using the Full Analysis Set. However, Alimera's FAME Study protocol did not include the Full Analysis Set. The FAME Study protocol provides that the primary assessment of efficacy will be based on the Modified ART Data Set. Statistical significance was not achieved at month 24 for either the low dose or the high dose of ILUVIEN in one trial using the Modified ART Data Set. Although the CRL requested certain exploratory analyses with respect to the 36 Month Data, it did not specify what data set or sets Alimera should utilize to analyze the 36 Month Data. Based on Alimera's communication with the FDA that the Full Analysis Set is the same as the FDA definition of Intent-to-Treat with Last Observation Carried Forward ("ITT with LOCF"), Alimera analyzed the 36 Month Data utilizing the Full Analysis Set and provided those analyses to the FDA in Alimera's resubmission of the NDA for ILUVIEN. However, there is no assurance that the FDA will utilize the Full Analysis Set and not require the use of the Modified ART Data Set or another data set in determining whether ILUVIEN is safe and effective.

In order to obtain approval to market ILUVIEN for DME in the U.S., Alimera will need to demonstrate to the FDA that ILUVIEN for DME is safe and efficacious and satisfy the FDA on each of the issues raised in the CRL. There is no assurance that the 36 Month Data for the full patient population or for the subgroup with chronic DME or other responses provided by Alimera and its third-party manufacturers will be sufficient to satisfy the FDA. The FDA may not grant marketing approval or it may request additional information from Alimera, including requesting data from additional clinical trials (which could include new clinical trials consisting solely of patients with chronic DME), and ultimately may not grant marketing approval for ILUVIEN. The FDA may limit the approval for ILUVIEN to a subgroup of DME patients such as those diagnosed with DME for three or more years.

We manufactured the clinical materials for Alimera's FAME Study and PK Study and the Phase II clinical trials being conducted for the use of ILUVIEN for the treatment of dry AMD and wet AMD. Alimera plans to use a third-party contract manufacturer to manufacture ILUVIEN for DME for commercial sales. Alimera reports that it has discussed its approach to show equivalency of our manufacturing process to the commercial manufacturing process with the FDA, the MHRA and the German Bundeninstitut fur Arneimittel und Medizinprodukte and that the CRL and the assessment reports received from the European Health Authorities did not raise an issue with respect to the demonstration of equivalency between the manufacturing processes. However, there is no assurance that they will not raise such an issue.

In addition to approval in the U.S., Alimera will also require regulatory approvals to sell ILUVIEN for DME in other countries, and there is no assurance that Alimera will receive those approvals. In July 2010, using the Decentralized Procedure, Alimera submitted a Marketing Authorization Application for ILUVIEN to the MHRA in the United Kingdom, which serves as the Reference Member State, and to regulatory authorities in Austria, France, Germany, Italy, Portugal and Spain. In November 2010, Alimera received a preliminary assessment report from the MHRA followed by additional comments from other health authorities in December 2010. In July 2011, Alimera submitted draft responses to the clinical and non-clinical and quality questions to the MHRA. The submission included the additional safety and efficacy data through the final readout at the end of the FAME Study. Alimera reports that the MHRA will provide comments to Alimera's draft response and that Alimera anticipates submitting the final response to the MHRA and other health authorities by December 31, 2011.

If Alimera is not successful in obtaining regulatory approval for and commercializing ILUVIEN for DME, or is significantly delayed in doing so, our business will be materially harmed. Alimera's ability to commercialize ILUVIEN will depend on, among other things, its ability to:

- receive marketing approval from the FDA and similar foreign regulatory authorities;

- maintain commercial manufacturing arrangements with third-party manufacturers;
- produce, or have its third-party manufacturers produce, sufficient quantities of ILUVIEN in a validated process and in compliance with cGMP and relevant foreign standards to permit successful commercialization;
- launch commercial sales of ILUVIEN; and
- secure acceptance of ILUVIEN in the medical community and with third-party payors.

Regulatory agencies require carcinogenicity studies in animals to identify tumorigenic potential in order to assess the relevant risk in humans as a result of systemic exposure. Alimera reported that based on month 18 readouts from its open-label Phase II human pharmacokinetic clinical trial (PK Study), which indicated that there was negligible systemic absorption of FAc in patients being treated with ILUVIEN, Alimera submitted a carcinogenicity waiver in its submissions to the FDA and European health authorities. Although the FDA did not specifically state in the CRL that the waiver has been granted, the CRL did not include any requirement to conduct a carcinogenicity study. The Preliminary Assessment Report issued by the MHRA stated that the lack of single-dose, carcinogenicity and reproductive and developmental toxicity studies with ILUVIEN is acceptable. Alimera reported that if it is required to perform carcinogenicity studies of ILUVIEN in animals, the approval of ILUVIEN could be delayed by up to 36 months.

ILUVIEN utilizes FAc, a corticosteroid used in ILUVIEN that has demonstrated undesirable side effects in the eye, and the success of ILUVIEN, therefore, will be dependent upon achieving an acceptable risk/benefit profile.

ILUVIEN utilizes FAc, a corticosteroid whose use in the eye has been associated with undesirable side effects such as cataract formation and increased incidence of elevated IOP, which may increase the risk of glaucoma. Upon review of Alimera's NDA for the low dose of ILUVIEN in the treatment of DME as well as the analysis of the 36 Month Data, including the subgroup data, the FDA may conclude that Alimera's FAME Study did not demonstrate that ILUVIEN has sufficient levels of efficacy to outweigh the risks associated with its side-effect profile. Conversely, the FDA may conclude that ILUVIEN's side-effect profile does not demonstrate an acceptable risk/benefit relationship in line with ILUVIEN's demonstrated efficacy. In the event of such conclusions, Alimera may not receive regulatory approval from the FDA or from similar regulatory agencies in other countries.

Even if Alimera receives regulatory approval for ILUVIEN, the FDA and other regulatory agencies may impose limitations on the indicated uses for which ILUVIEN may be marketed, may subsequently withdraw approval for ILUVIEN or may take other actions against ILUVIEN that would be adverse to our business.

Regulatory agencies generally approve products for particular indications. Alimera has indicated that it filed the subgroup data with respect to patients diagnosed with DME for three or more years in support of the pending NDA. It is possible that the FDA would approve ILUVIEN only for this subgroup of patients, which may reduce the size of the potential market for ILUVIEN. The FDA or another regulatory authority may further limit the indications of use.

Additionally, product approvals, once granted, may be withdrawn if problems occur after initial marketing. If and when ILUVIEN does receive regulatory approval or clearance, the marketing, distribution and manufacture of ILUVIEN will be subject to regulation by the FDA in the United States and by similar entities in other countries. Alimera will need to comply with facility registration and product listing requirements of the FDA and similar entities in other countries, and will need to adhere to the FDA's Quality System Regulations. Noncompliance with applicable FDA and similar entities' requirements could result in warning letters, fines, injunctions, civil penalties, recall or seizure of ILUVIEN, total or partial suspension of production, refusal of regulatory agencies to grant approvals, withdrawal of approvals by regulatory agencies or criminal prosecution. Alimera also will need to maintain compliance with federal, state and foreign laws regarding sales incentives, referrals and other programs.

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

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

Our product candidates, other than ILUVIEN for DME, are in early stages of development. Product development at all stages involves a high degree of risk, and only a small proportion of research and development programs result in an approved product. If clinical trials conducted by or for us or our licensees for any of our product candidates do not provide the necessary evidence of safety and efficacy, those product candidates could not be manufactured and sold, and would not generate revenues. Initial and subsequent clinical trials initiated by or for us or our licensees for product candidates may be delayed, or fail due to many factors, including the following:

- our (or licensees') lack of sufficient funding to pursue trials rapidly or at all;
- our (or our licensees') inability to attract clinical investigators for trials;
- our (or our licensees') inability to recruit patients in sufficient numbers or at the expected rate;
- our inability to find or reach agreement with licensees to undertake the clinical trials;
- decisions by licensees not to exercise options for products and not to pursue products licensed to them;
- adverse side effects;
- failure of the trials to demonstrate a product's safety and efficacy;
- our (or our licensees') failure to meet FDA or other regulatory agency requirements for clinical trial design;
- our (or our licensees') inability to follow patients adequately after treatment;
- changes in the design or manufacture of a product;
- failures by, or changes in, our (or our licensees') relationship with contract research organizations, third-party vendors and investigators responsible for pre-clinical testing and clinical trials;
- our (or our licensees') inability to manufacture sufficient quantities of materials for use in clinical trials;
- stability issues with materials;
- failure to comply with cGMP or other manufacturing issues;
- requests by regulatory authorities for additional clinical trials;
- governmental or regulatory agency assessments of pre-clinical or clinical testing that differs from our (or our licensees') interpretations or conclusions that product candidates meet quality standards for stability, quality, purity and potency; and
- governmental or regulatory delays, or changes in approval policies or regulations.

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

The FDA or other relevant regulatory agencies may not approve our product candidates for manufacture and sale, and any approval by the FDA does not ensure approval by other regulatory agencies or vice versa (which

could require us to comply with numerous and varying regulatory requirements, possibly including additional clinical testing). Any product approvals we or our licensees achieve could also be withdrawn for failure to comply with regulatory standards or due to unforeseen problems after the products' marketing approval. In either case, marketing efforts with respect to the affected product would have to cease. In addition, the FDA or other regulatory agencies may impose limitations on the indicated uses for which a product may be marketed.

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

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

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

Our business strategy includes entering into collaborative and licensing arrangements for the development and commercialization of our product candidates, and we currently have collaboration and licensing arrangements with Alimera, Pfizer and Bausch & Lomb. The curtailment or termination of any of these arrangements could adversely affect our business, our ability to develop and commercialize our products, product candidates and proposed products and our ability to fund operations.

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

- our collaborative and licensing arrangements are, and are expected to be, subject to termination under various circumstances, including on short notice and without cause;
- we are required, and expect to be required, under our collaborative and licensing arrangements not to conduct specified types of research and development in the field that is the subject of the arrangement, limiting the areas of research and development 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, consistent with other pharmaceutical and biotechnology companies that have historically acted similarly, may for a variety of reasons change the focus of their development and commercialization efforts or decrease or fail to increase spending related to our products or product candidates, thereby limiting the ability of these products to reach their potential;
- our licensees may lack the funding, personnel or experience to develop and commercialize our products successfully or may otherwise fail to do so; and
- our licensees may not perform their obligations, in whole or in part.

To the extent that we choose not to, or we are unable to, enter into future license agreements with marketing and sales partners and, alternatively, seek to market and sell products ourselves, we would experience increased

capital requirements to develop the ability to manufacture, market and sell future products. We may not be able to manufacture, market or sell our products or future products independently in the absence of such agreements.

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

Our licensees have rights of termination under our agreements with them. Exercise of termination rights by one or more of our licensees may leave us without the financial benefits and development, marketing or sales resources provided under the terminated agreement, which may have an adverse effect on our business, financial condition and results of operations. Additionally, our interests may not continue to coincide with those of our partners, and our partners may develop, independently or with third parties, products or technologies that could compete with our products. Further, disagreements over rights or technologies or other proprietary interests may occur.

In June 2011, we amended and restated our Original Pfizer Agreement to focus solely on the development of the Latanoprost Product. Pfizer may terminate the Restated Pfizer Agreement without penalty at any time and for any reason upon 60 days' written notice. We have exclusively licensed our technology underlying Vitrasert and Retisert to Bausch & Lomb, which can terminate its agreement with us without penalty at any time upon 90 days' written notice. We have licensed the technology underlying ILUVIEN for DME and certain ophthalmic applications to Alimera. Alimera has financial responsibility for the development of ILUVIEN and any other licensed products developed under our collaboration agreement, along with sole responsibility for the commercialization of such licensed products. Alimera may abandon the development and commercialization of any licensed product at any time.

Any of Pfizer, Alimera or Bausch & Lomb may decide not to continue to develop, exercise options or commercialize any or all of the licensed products under their respective agreements, change strategic focus, pursue alternative technologies or develop competing products. While Pfizer and Bausch & Lomb have significant experience in the ophthalmic field and have substantial resources, there is no assurance whether, and to what extent, that experience and those resources will be devoted to our technologies. Alimera has limited experience, and if approved, ILUVIEN would be its first product. Because we do not currently have sufficient funding or internal capabilities to develop and commercialize our products and product candidates, decisions, actions, breach or termination of these agreements by Pfizer, Bausch & Lomb or Alimera could delay or stop the development or commercialization of any of the products or product candidates licensed to such entities.

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

We believe that pharmaceutical, drug delivery and biotechnology companies, research organizations, governmental entities, universities, hospitals, other nonprofit organizations and individual scientists are seeking to develop drugs, therapies, products, approaches or methods to treat our targeted diseases or their underlying causes. For many of our targeted diseases, competitors have alternate therapies that are already commercialized or are in various stages of development ranging from discovery to advanced clinical trials. For example, Novartis announced earlier this year that the European Commission granted Novartis a new indication for Lucentis to treat patients with visual impairment due to DME. Any of these drugs, therapies, products, approaches or methods may receive government approval or gain market acceptance more rapidly than our products and product candidates, may offer therapeutic or cost advantages, or may cure our targeted diseases or their underlying causes completely, which could reduce demand for our products and product candidates and could render them noncompetitive or obsolete. For example, sales of Vitrasert for the treatment of CMV retinitis, a disease that affects people with late-stage AIDS, declined significantly because of treatments that delay the onset of late-stage AIDS.

Many of our competitors and potential competitors have substantially greater financial, technological, research and development, marketing and personnel resources than us. 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; or
- may otherwise render our products less competitive or obsolete.

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

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

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

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

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

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

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

Our success is dependent on whether we can obtain patents, defend our existing patents and operate without infringing on the proprietary rights of third parties. As of August 31, 2011, we had 193 patents and 170 pending patent applications, including patents and pending applications covering our Durasert, BioSilicon and CODRUG

technologies. Intellectual property protection of our technologies is uncertain. We expect to seek to patent and protect our proprietary technologies. However, there is no assurance that any additional patents will be issued to us as a result of our pending or future patent applications or that any of our patents will withstand challenges by others. In addition, we may not have sufficient funds to patent and protect our proprietary technologies to the extent that we would desire, or at all. If we were determined to be infringing any third party patent, we could be required to pay damages, alter our products or processes, obtain licenses, pay royalties or cease certain operations. We may not be able to obtain any required licenses on commercially favorable terms, if at all. In addition, many foreign country laws may treat the protection of proprietary rights differently from, and may not protect our proprietary rights to the same extent as, laws in the United States and Patent Co-operation Treaty countries.

Prior art may reduce the scope or protection of, or invalidate, our patents. Previously conducted research or published discoveries may prevent our patents from being granted, invalidate issued patents or narrow the scope of any protection obtained. Reduction in scope of protection or invalidation of our licensed or owned patents, or our inability to obtain patents, may enable other companies to develop products that compete with our products and product candidates on the basis of the same or similar technology. As a result, our patents and those of our licensors may not provide any or sufficient protection against competitors. While we have not been, and are not currently involved in, any litigation over intellectual property, such litigation may be necessary to enforce any patents issued or licensed to us or to determine the scope and validity of third party proprietary rights. We may also be sued by one or more third parties alleging that we infringe their intellectual property rights. Any intellectual property litigation would be likely to result in substantial costs to us and diversion of our efforts, and could prevent or delay our discovery or development of product candidates. If our competitors claim technology also claimed by us, and if they prepare and file patent applications in the U.S. or other jurisdictions, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office or the appropriate foreign patent office to determine priority of invention, which could result in substantial cost to us and diversion of our efforts. Any such litigation or interference proceedings, regardless of the outcome, could be expensive and time consuming. Litigation could subject us to significant liabilities to third parties, requiring disputed rights to be licensed from third parties and/or requiring us to cease using certain technologies.

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

RISKS RELATED TO OUR BUSINESS, INDUSTRY, STRATEGY AND OPERATIONS

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

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

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

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

The trend towards consolidation in the pharmaceutical and biotechnology industries may adversely affect us.

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

If we fail to comply with environmental laws and regulations, our 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 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 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 for injury or contamination that results from our use or the use by third parties of these materials, and our liability may exceed our total assets. Compliance with environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development or production efforts or harm our operating results.

If we encounter problems with product manufacturing, we could experience delays in product development and commercialization, which would adversely affect our future profitability.

Our ability to conduct timely pre-clinical and clinical research and development programs, obtain regulatory approvals, develop and commercialize our product candidates will depend, in part, upon our and our collaborative partners' 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. 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 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 regulations that are both capable of manufacturing our products and product candidates and are willing to do so. Failure by us, our collaborative partners, or our or their third-party manufacturers, to comply with applicable manufacturing requirements could

result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product, operating restrictions and criminal prosecutions. In addition, we or our collaborative partners may not be able to manufacture our product candidates successfully or have a third party manufacture them in a cost-effective manner. If we or our collaborative partners are unable to develop our own manufacturing facilities or to obtain or retain third-party manufacturing on acceptable terms, we may not be able to conduct certain future pre-clinical and clinical testing or to supply commercial quantities of our products.

We manufacture supplies in connection with pre-clinical or clinical studies conducted by us or our collaboration partners. Under our collaboration agreements with Alimera, Pfizer and Bausch & Lomb, we have provided our licensees the exclusive rights to manufacture commercial quantities of products, once approved for marketing. Our current reliance on third-party manufacturers entails risks, including:

- the possibility that third parties may not comply with the FDA's cGMP regulations, other regulatory requirements, and those of similar foreign regulatory bodies, and may not employ adequate quality assurance practices;
- supply disruption, deterioration in product quality or breach of a manufacturing or license agreement by the third party because of factors beyond our control;
- the possible termination or non-renewal of a manufacturing or licensing agreement with a third party at a time that is costly or inconvenient to us; and
- our inability to identify or qualify an alternative manufacturer in a timely manner, even if contractually permitted to do so.

Alimera has contracted with third-party manufacturers with respect to the manufacture of components of ILUVIEN. Our business could be significantly harmed if these third parties are not able to manufacture ILUVIEN in compliance with cGMP or to satisfy demand for ILUVIEN and alternative sources are not available. In addition, the materials necessary to produce ILUVIEN or to formulate the active pharmaceutical ingredient may not be available on commercially reasonable terms, or at all, which could affect the development and commercialization of ILUVIEN.

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

We currently maintain offices and research and development facilities in the U.S. and the U.K., and we intend to license products for sale and/or sell products in most major world healthcare markets. A number of risks are inherent in our international strategy. In order for us to license and manufacture our products, we must obtain country and jurisdiction-specific regulatory approvals or clearances to comply with regulations regarding safety and quality. We may not be able to obtain or maintain regulatory approvals or clearances in such countries, and we may be required to incur significant costs in obtaining or maintaining foreign regulatory approvals or clearances. In addition, our operations and revenues may be subject to a number of risks associated with foreign commerce, including the following:

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

- obtaining required government approvals.

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

Sales of our products depend on the availability and extent of reimbursement from government and other third-party payors. Difficult credit and financial market conditions may increase the risk that government and other third-party payors will reduce the availability or extent of reimbursement for our products, and the risk that third-party payors will delay or default on reimbursement obligations.

Development and sales of our products and product candidates also heavily depend on collaborative partners and third-party suppliers. Difficult credit and financial market conditions may increase the risk that there are delays, disruptions or defaults in the performance of these third parties' obligations to us.

Legislative or regulatory changes may adversely affect our business, operations and financial results.

Our industry is highly regulated and new laws, regulations and judicial decisions, and new interpretations of existing laws, regulations and judicial decisions, may adversely affect our business, operations and financial results.

The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (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 this new law could significantly reduce payments from Medicare and Medicaid for our products and product candidates over the next 10 years, resulting in potentially significant reductions of our revenues. The PPACA's effects cannot be fully known until its provisions are implemented, and the Centers for Medicare & Medicaid Services, and other federal and state agencies, issue applicable regulations or guidance. Proposed U.S. state healthcare reforms, and any foreign healthcare reforms, also could alter the availability, methods and rates of reimbursements from the government and other third-party payors for our products and product candidates, and could adversely affect our business strategy, operations and financial results.

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

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 and by developments out of our control or unrelated 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 volume of companies in the biotechnology industry, including ours, can swing dramatically in ways unrelated to, or that bear a disproportionate relationship to, operating 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 trial results and other product and technological developments and innovations;
- FDA and other governmental regulatory actions, receipt and timing of approvals of our (or our licensees') 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 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 the royalties payable to us;
- availability and cost of capital and our financial and operating results;
- changes in reimbursement policies or other practices relating to our product candidates or the pharmaceutical industry generally;
- meeting, exceeding or failing to meet analysts' or investors' expectations, and changes in evaluations and recommendations by securities analysts;
- economic, industry and market conditions, changes or trends; and
- other factors unrelated to us or the biotechnology industry.

In addition, low trading volume in our common stock or our CDIs may increase their price volatility. Holders of our common stock and CDIs may not be able to liquidate their positions at the desired time or price.

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, 2011, we had outstanding approximately 7.8 million investor warrants and 3.4 million employee and director options to acquire shares of our common stock, or approximately 35.1% of our shares on a fully diluted basis. Certain of the options are subject to shareholder approval and/or performance conditions, and the exercise prices of all of these warrants and a small portion of the stock options were above the market price at that date. The issuance of shares of our common stock upon exercise of our outstanding warrants and stock options could result in dilution to the interests of other holders of our common stock and could adversely affect our stock price. The overhang of outstanding warrants and options may adversely affect our stock price. The warrant exercise prices may be adjusted under certain circumstances.

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

Pfizer owned approximately 9.0% of our outstanding shares as of August 31, 2011 and is a collaborative partner. As a result, Pfizer may be able to exert significant influence over our board of directors and how we operate our business. The concentration of ownership may also have the effect of delaying or preventing a change in control of our company.

We have paid penalties pursuant to registration agreements with securities holders relating to resale registration statements, and any requirement to pay such penalties in the future may have a material adverse effect on our financial condition.

We have registration rights agreements that require us to file and maintain the effectiveness of registration statements for the resale of our common stock, which provide for monetary penalties in the event of our failure to do so. During the year ended June 30, 2007, we paid registration delay penalties of approximately $2.3 million in connection with then outstanding convertible notes. Our failure or inability to maintain the effectiveness of any of our required registration statements or to adequately update information in the related prospectuses may subject us to additional penalties under our current registration rights agreements. Payment of additional

penalties may have a material adverse effect on our financial condition and may require us to suspend, curtail or terminate our operations or delay, reduce the scope of or eliminate one or more of our research and development programs, any of which could have a material adverse effect on our business.

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

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

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

- 3,940 square feet of laboratory space, 1,582 square feet of clean room space and 7,890 square feet of office space in Watertown, Massachusetts under a lease agreement that expires in April 2014; and
- 1,500 square feet of laboratory space and 1,800 square feet of office space in Malvern, United Kingdom under lease agreements that expire in June 2012.

ITEM 3. LEGAL PROCEEDINGS

None.

ITEM 4. [REMOVED AND RESERVED]

ITEM 4A. EXECUTIVE OFFICERS OF THE REGISTRANT

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, 50
President and Chief Executive Officer

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

Lori Freedman, 44
Vice President of Corporate Affairs, General Counsel and Company Secretary

Ms. Freedman has served as our Vice President of Corporate Affairs, General Counsel and Secretary since May 2006, and held the same positions at CDS from 2001 to May 2006. Prior to that, Ms. Freedman served as Vice President, Business Development, and Counsel of Macromedia, Inc., a provider of software for creating

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

Leonard S. Ross, 61
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.

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, 2011:		
First Quarter	$4.54	$3.16
Second Quarter	7.22	4.26
Third Quarter	5.15	3.75
Fourth Quarter	4.68	3.50
Fiscal year ended June 30, 2010:		
First Quarter	$6.25	$1.51
Second Quarter	6.06	2.86
Third Quarter	4.72	3.08
Fourth Quarter	5.14	3.26

On September 8, 2011, the last reported sale price of our common stock on the NASDAQ Global Market was $4.53. As of that date, we had approximately 424 holders of record of our common stock and, according to our estimates, approximately 3,450 beneficial owners of our common stock. In addition, as of that date, there were 2,473 registered owners of our CDIs.

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

Equity Compensation Plan Information

The following table provides information about the securities authorized for issuance under the Company's equity compensation plans as of June 30, 2011:

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	2,740,895	$ 2.85	709,063
Equity Compensation plans not approved by security holders	—	—	—
Total	2,740,895	$ 2.85	709,063

(*) Of the total outstanding options, 135,000 are denominated in A$ and were translated at the June 30, 2011 exchange rate of A$1.00 = US$1.0595.

On July 1, 2011 and each subsequent anniversary date through 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, 2011, the number of shares issuable under the 2008 Incentive Plan was increased by 600,000 shares, representing such lesser amount as approved by the Board of Directors.

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

None.

ITEM 6. SELECTED FINANCIAL DATA

The selected historical financial data set forth below as of June 30, 2011, 2010, 2009, 2008 and 2007 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, 2011 and 2010 and for the years ended June 30, 2011, 2010 and 2009 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,				
	2011 (1)	2010 (1)	2009 (1)	2008 (1,2)	2007 (3,4)
	(In thousands except per share data)				
Consolidated Statements of Operations Data:					
Revenues:					
Collaborative research and development	$ 3,612	$ 22,570	$ 12,002	$ 3,328	$ 733
Royalty income	1,353	483	160	148	1,052
Total revenues	4,965	23,053	12,162	3,476	1,785
Operating expenses:					
Research and development	6,864	6,994	8,007	14,426	21,065
General and administrative	8,104	6,968	8,791	13,951	11,204
Impairment of goodwill	—	—	—	60,106	—
Impairment of intangible assets	—	—	—	—	45,278
Total operating expenses	14,968	13,962	16,798	88,483	77,547
Operating (loss) income from continuing operations	(10,003)	9,091	(4,636)	(85,007)	(75,762)
Other income (expense):					
Change in fair value of derivatives	1,140	(339)	959	8,357	11,434
Interest income	30	27	162	648	277
Interest and finance costs	—	—	—	(507)	(9,491)
Loss on extinguishment of debt	—	—	—	—	(23,361)
Other (expense) income, net	(13)	(3)	53	356	153
Total other income (expense)	1,157	(315)	1,174	8,854	(20,988)
(Loss) income from continuing operations before income taxes	(8,846)	8,776	(3,462)	(76,153)	(96,750)
Income tax benefit (expense)	218	(23)	951	483	13,225
(Loss) income from continuing operations	(8,628)	8,753	(2,511)	(75,670)	(83,525)
Discontinued operations:					
Loss from discontinued operations	—	—	—	—	(1,318)
Gain on sale of discontinued operations	—	—	—	—	3,640
Income from discontinued operations	—	—	—	—	2,322
Net (loss) income	$ (8,628)	$ 8,753	$ (2,511)	$ (75,670)	$ (81,203)
Basic net (loss) income per share:					
(Loss) income from continuing operations	$ (0.44)	$ 0.48	$ (0.14)	$ (4.17)	$ (7.57)
Income from discontinued operations	—	—	—	—	0.21
Net (loss) income	$ (0.44)	$ 0.48	$ (0.14)	$ (4.17)	$ (7.36)
Diluted net (loss) income per share:					
(Loss) income from continuing operations	$ (0.44)	$ 0.46	$ (0.14)	$ (4.17)	$ (7.57)
Income from discontinued operations	—	—	—	—	0.21
Net (loss) income	$ (0.44)	$ 0.46	$ (0.14)	$ (4.17)	$ (7.36)
Weighted average common shares outstanding:					
Basic	19,489	18,405	18,263	18,166	11,038
Diluted	19,489	18,895	18,263	18,166	11,038

	As of June 30,				
	2011	2010	2009	2008	2007
			(In thousands)		
Consolidated Balance Sheet Data:					
Cash and cash equivalents	$12,912	$15,514	$ 6,899	$15,609	$ 2,670
Marketable securities	11,216	2,051	—	—	—
Total assets	47,113	43,014	37,104	55,784	107,220
Total deferred revenue	7,847	6,896	10,534	18,590	1,702
Total stockholders' equity	37,433	33,041	23,541	30,078	88,265

(1) We recognized $3.3 million of collaborative research and development revenue in fiscal 2011 under our Restated Pfizer Agreement. We recognized $0.2 million in fiscal 2011, $22.3 million in fiscal 2010, $11.8 million in fiscal 2009 and $3.3 million in fiscal 2008 of collaborative research and development revenue under our collaboration agreement with Alimera. See Note 3 to the accompanying audited consolidated financial statements for additional information.

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

(3) At June 30, 2007, we recorded a $45.3 million impairment charge related to our Durasert intangible asset.

(4) In April 2007, we sold the stock of our AION Diagnostics, Inc. subsidiary for a pre-tax and after-tax gain of $3.6 million.

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

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

Overview

We develop tiny, sustained release, drug delivery products designed to deliver drugs at a controlled and steady rate for months or years. We are currently focused on treatment of chronic diseases of the back of the eye utilizing our core technology systems, Durasert and BioSilicon. ILUVIEN for the treatment of DME, our most advanced product candidate, is currently under review by the FDA. An investigator-sponsored IND opened for an injectable insert designed to treat uveitis affecting the posterior segment of the eye (posterior uveitis) of the same design as ILUVIEN and an investigator-sponsored trial is ongoing for an injectable bioerodible insert designed to treat glaucoma and ocular hypertension. Our two FDA-approved products provide long-term, sustained drug delivery to treat two other chronic diseases of the retina.

ILUVIEN. We licensed the third generation injectable Durasert insert that delivers FAc over a period of up to 3 years to Alimera for the treatment and prevention of eye diseases in humans (other than uveitis). This insert is being developed by Alimera under its brand name ILUVIEN. Alimera completed two Phase III clinical trials (FAME Study) of ILUVIEN for the treatment of DME, a leading cause of vision loss for people under the age of 65 estimated to affect over 1,000,000 people in the United States.

Alimera submitted an NDA for ILUVIEN for DME to the FDA in June 2010 based on month 24 data from the FAME Study, received a CRL in December 2010 and resubmitted an NDA to the FDA to respond to the CRL in May 2011. Alimera expects a response from the FDA in November 2011. Alimera stated that if approved, it plans to commercialize ILUVIEN for DME in the U.S. as soon as early 2012. In July 2010, Alimera submitted a Marketing Authorization Application for ILUVIEN for DME to the MHRA in the United Kingdom and to other regulatory authorities in Europe. Alimera reports that it anticipates submitting the final response to the MHRA and the other European regulatory authorities by December 31, 2011.

Under our collaboration agreement with Alimera, in addition to treating DME, ILUVIEN is also being studied in three Phase II clinical trials for the treatment of the dry form of AMD, the wet form of AMD and RVO.

Other Product Development. In September 2011, an investigator-sponsored IND opened for a Phase I/II study of the safety and efficacy of our injectable, sustained release insert delivering FAc for the treatment of uveitis affecting the posterior segment of the eye (posterior uveitis). The insert is the same design as the insert being developed by Alimera for the treatment of DME and delivers the high and low dose of FAc used in the FAME Study. We did not license Alimera the rights to use the insert for uveitis. If successful, we plan to advance this product candidate into pivotal multi-center Phase III trials and reference the NDA for ILUVIEN for DME (including the clinical data from the FAME Study and the manufacturing and stability data) in potential posterior uveitis regulatory filings. We also plan to use a new inserter, with a smaller gauge needle than that used in the FAME Study, in any future posterior uveitis Phase III trials.

Under our Restated Pfizer Agreement, we granted Pfizer an exclusive option under various circumstances to license the development and commercialization worldwide of an injectable, bioerodible sustained release insert delivering latanoprost (Latanoprost Product) for the treatment of human ophthalmic disease or conditions other than uveitis. An investigator-sponsored Phase I/II dose-escalation study has been initiated to assess the safety and efficacy of this insert, which utilizes a fourth generation of our Durasert technology, in patients with elevated IOP. We are currently developing a prototype of this implant that contains BioSilicon to assist in the delivery of latanoprost. If successful, we plan to advance the new prototype into a multi-center Phase II trial.

In August 2011, we entered into an evaluation agreement with (HSS) to investigate our Durasert drug delivery technologies in orthopedics.

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

BioSilicon. BioSilicon, the second key technology system we are targeting for sustained drug delivery, utilizes fully-erodible, nanostructured, porous material. Our primary focus is on Tethadur, which utilizes BioSilicon to deliver large biologic molecules, including peptides and proteins, on a sustained basis. Our BioSilicon technology is also designed to deliver smaller molecules.

Equity Financings

In January 2011, we sold 2,210,000 units at a price of $5.00 per unit for gross proceeds of $11.1 million. Each unit consisted of (i) one share of common stock and (ii) one warrant to purchase 0.25 share of common stock at $5.00 per share.

License and Collaboration Agreements

Alimera

Upon execution of the Restated Alimera Agreement in March 2008, we received consideration of $12.0 million in cash and Alimera cancelled $5.7 million of accrued development cost liabilities, including related penalties and accrued interest, owed by us to Alimera as of March 14, 2008. In addition, we received a $15.0 million conditional note (subject to acceleration upon the occurrence of certain defined liquidity events), Alimera agreed to pay us a $25.0 million milestone payment upon FDA approval of Iluvien for DME and Alimera assumed all financial responsibility for the development of licensed products under the Restated Alimera Agreement, which had previously been shared equally, including reimbursement of approved development costs incurred by us in support of the ongoing clinical studies of Iluvien and anticipated regulatory submissions. In exchange, we decreased our share in any future profits, as defined, on sales of Iluvien by Alimera from 50% to 20%, subject to an offset of 20% of pre-profitability commercialization costs, as defined, incurred by Alimera. In the event Alimera sublicenses commercialization, we are entitled to receive 20% of royalties and 33% of non-royalty consideration received by Alimera, less certain permitted deductions. Alimera has indicated that it intends to commercialize Iluvien, if approved, through a direct sales force in the United States and to seek marketing collaboration partners for the commercialization of Iluvien outside of the United States.

Pursuant to the Restated Alimera Agreement, a total of $18.3 million of deferred revenue was recognized as revenue on a straight-line basis over the 21.5 month performance obligation period from the amendment effective date through December 31, 2009. Following consummation of the Restated Alimera Agreement, we received conditional note interest payments and reimbursements of approved development and patent maintenance costs totaling $247,000, $1.5 million and $1.9 million during the years ended June 30, 2011, 2010 and 2009, respectively. In addition, on April 27, 2010, following consummation of its initial public offering, Alimera paid the $15.0 million conditional note in full. Cash consideration received from Alimera during the performance period was recognized as revenue ratably over the performance period, including immediate revenue recognition catch-up for the pro rata period from the amendment effective date to the date of each receipt. Cash consideration received subsequent to December 31, 2009 has been recognized as revenue upon receipt or at such earlier date, if applicable, on which any such amount is both fixed and determinable and reasonably assured of collection.

Pfizer

Under the Original Pfizer Agreement, beginning in calendar year 2008 Pfizer paid us $500,000 quarterly in consideration of our costs in performing the research program. Because we were unable to define the period of our performance obligations under this agreement, all payments received from Pfizer, totaling $7.75 million, were classified in non-current deferred revenue.

In June 2011, we entered into the Restated Pfizer Agreement to focus solely on the development of a sustained-release bioerodible implant designed to deliver latanoprost by subconjuntival injection. The Original Pfizer Agreement was effectively terminated, including the cessation of Pfizer's $500,000 quarterly funding of the research program. In addition, we regained all rights to our intellectual property in ophthalmic applications previously included in the Original Pfizer Agreement other than pursuant to the Restated Pfizer Agreement. Upon execution of the Restated Pfizer Agreement, Pfizer made an upfront payment of $2.3 million and we agreed to use commercially reasonable efforts to fund development of the Latanoprost Product for at least one year and, thereafter, at our option, through completion of Phase II clinical trials, as defined. Upon completion of Phase II clinical trials, Pfizer has the option to acquire, upon payment of $20 million, an exclusive, worldwide license to develop and commercialize the Latanoprost Product for the treatment of human ophthalmic disease and conditions other than uveitis and we would be eligible to receive development, regulatory and commercial milestone payments of up to $146.5 million and double-digit sales-based royalties. If Pfizer does not exercise this option, we will be able to develop and commercialize the Latanoprost Product on our own or with a partner, with rights to Pfizer intellectual property as necessary.

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

Our deliverables under the Restated Pfizer Agreement include conducting the research and development program for the Latanoprost Product through completion of Phase II (the "R&D program") and participation on a Joint Steering Committee (JSC). We concluded that the Pfizer exercise option for the worldwide exclusive license is not a deliverable of the arrangement, due to it being a substantive option and not being priced at a significant and incremental discount. We determined that the JSC does not have standalone value from the R&D program and therefore we have combined these deliverables into a single unit of accounting. The performance period is the expected period over which the services of the combined unit are performed, and we have estimated that period to be 3 years.

The total arrangement consideration of the Restated Pfizer Agreement totaled $10.05 million, which consisted of the $7.75 million of deferred revenue on the Company's balance at the effective date plus the $2.3 million upfront payment. The difference between the total arrangement consideration and the estimated selling price of the combined deliverables, or $3.3 million, has been recognized as collaborative research and development revenue in the quarter ended June 30, 2011, the period of the modification. To determine the estimated selling price of the combined deliverable, we applied an acceptable margin to our cost projections for the combined deliverable. The estimated selling price of $6.7 million will be recognized as collaborative research and development revenue over the expected 3-year performance period using the proportional performance method. The costs associated with conducting the research program for the Latanoprost Product will be reflected in operating expenses in the period in which they are incurred.

To the extent that any subsequent payment is received from Pfizer, including exercise option, milestone and sales-based royalty consideration, which would occur after completion of our performance period under the Restated Pfizer Agreement, such amount would be recognized as revenue when all the revenue criteria are met.

Bausch & Lomb

Bausch & Lomb sells Vitrasert and Retisert. Our collaboration agreement with Bausch & Lomb provides for royalties on such sales. In June 2005 we received a $3.0 million advance from Bausch & Lomb in consideration

of $6.25 million of future Retisert royalties that otherwise would be payable to us. Bausch & Lomb retained $1.2 million in fiscal 2010, and $1.6 million in fiscal 2009 of Retisert royalties that otherwise would have been payable to us. During the quarter ended June 30, 2010, Bausch & Lomb retained the final portion of these royalties otherwise payable and we recorded an incremental $342,000 of royalty income, which was paid by Bausch & Lomb. Subsequent to June 30, 2010, we were entitled to receive 100% of the Retisert royalties pursuant to the collaboration agreement, and Retisert royalty income was $1.2 million in fiscal 2011. Vitrasert royalties were $112,000 in fiscal 2011, $141,000 in fiscal 2010 and $160,000 in fiscal 2009.

Intrinsiq

In January 2008 Intrinsiq acquired an exclusive field of use license for nutraceutical and food science applications of BioSilicon, and certain related assets, for which we received aggregate license fee payments of $1.2 million through fiscal 2009. During fiscal 2010, we received the first contractual minimum royalty payment of $450,000. Subject to continuation of the license agreement, which was cancellable by Intrinsiq on 90 days advance notice, we were entitled to receive additional scheduled minimum royalty payments totaling approximately $3.1 million from January 2012 through April 2014, creditable against quarterly royalties earned, if any.

In February 2009, we entered into a 2-year manufacture and supply agreement, pursuant to which we leased certain equipment to Intrinsiq for use in manufacturing BioSilicon material, and title to the equipment passed upon our receipt of lease payments totaling $122,000.

On July 22, 2011, we consummated an asset purchase agreement pursuant to which we acquired porous BioSilicon-related capital equipment and intellectual property assets of Intrinsiq for $223,000, and assumed four Intrinsiq employees. As part of the transaction, Intrinsiq terminated the agreements underlying its original 2008 exclusive field-of-use license. The license termination will result in the recognition of collaborative research and development revenue of $1.1 million in the quarter ending September 30, 2011, representing the total Intrinsiq deferred revenue balance at June 30, 2011, which is classified as a current liability.

Summary of Critical Accounting Policies and Estimates

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

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

Revenue Recognition

Our business strategy includes entering into collaborative license and development agreements for the development and commercialization of product candidates utilizing our technology systems.

The terms of these arrangements typically include multiple deliverables by us (for example, granting of license rights, providing research and development services and manufacturing of clinical materials, participating on joint research committee) in exchange for consideration to us of some combination of non-refundable license fees, funding of research and development activities, payments based upon achievement of clinical development, regulatory and sales milestones and royalties in the form of a designated percentage of product sales or profits.

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

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

For the year ended June 30, 2011, we reported $3.6 million of collaborative research and development revenue. Revenue is recognized when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable and collection is reasonably assured.

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

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

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

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

Valuation of Intangible Assets

At June 30, 2011, we reported $21.6 million of intangible assets, which consisted of $6.9 million and $14.7 million of capitalized costs related to patents, intellectual property and technology rights underlying our Durasert and BioSilicon technology systems, respectively, net of accumulated amortization. We amortize these intangible assets using the straight-line method over their estimated economic lives, which currently extend through calendar year 2017 and results in a charge to operations of approximately $3.3 million per year. We believe that the carrying value of our intangible assets will be recouped primarily through expected net cash flows from our existing collaboration agreements described under License and Collaboration Agreements above.

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

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

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

If there is a significant change in the estimation of the projected undiscounted net cash flows for the products and product candidates utilizing the Durasert and BioSilicon technology systems, the carrying value of the respective assets could be impaired. We expect to have further information about whether we will advance the Latanoprost Product utilizing BioSilicon technology into more advanced clinical trials in late fiscal 2012, and if we do not do so, the BioSilicon intangible asset could become fully impaired.

Results of Operations

Years Ended June 30, 2011 and 2010

	Year ended June 30,		Change	
	2011	2010	Amounts	%
	(In thousands except percentages)			
Revenues	$ 4,965	$23,053	$(18,088)	(78)%
Operating expenses:				
Research and development	6,864	6,994	(130)	(2)%
General and administrative	8,104	6,968	1,136	16%
Total operating expenses	14,968	13,962	1,006	7%
Operating (loss) income	(10,003)	9,091	(19,094)	(210)%
Other income (expense):				
Change in fair value of derivatives	1,140	(339)	1,479	436%
Interest income	30	27	3	11%
Other expense, net	(13)	(3)	(10)	(333)%
Total other income (expense)	1,157	(315)	1,472	467%
(Loss) income before income taxes	(8,846)	8,776	(17,622)	(201)%
Income tax benefit (expense)	218	(23)	241	1048%
Net (loss) income	$ (8,628)	$ 8,753	$(17,381)	(199)%

Revenues

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

Collaborative research and development revenue for fiscal 2011 of $3.6 million was predominantly related to the June 2011 Restated Pfizer Agreement. At the effective date of the Restated Pfizer Agreement, we had $7.75 million of deferred revenue from the Original Pfizer Agreement on our balance sheet, and we received $2.3 million of upfront consideration upon execution of the Restated Pfizer Agreement. The $6.7 million balance of Pfizer deferred revenue at June 30, 2011, after revenue recognition of $3.3 million, will be recognized as revenue using the proportional performance method over the 3-year estimated period of our performance obligations under the Restated Pfizer Agreement. Of that total, approximately $2.1 million is currently expected to be recognized as revenue during fiscal 2012.

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

We are entitled to receive a $25 million milestone payment from Alimera within 30 days following an FDA approval of ILUVIEN for DME. However, absent an FDA approval of ILUVIEN for DME during fiscal 2012, we currently expect to record an insignificant amount of collaborative research and development revenue attributable to the Restated Alimera Agreement in fiscal 2012.

For fiscal 2011, we earned $1.2 million of Retisert royalties. For fiscal 2010, we recognized $342,000 in Retisert royalty income and $1.2 million of Retisert royalties otherwise payable to us was retained by Bausch &

Lomb as the result of a 2005 advance payment from Bausch & Lomb, thereby completing an advance royalty agreement. Retisert royalty income for fiscal 2011 represented a 19.3% decrease compared to the aggregate of fiscal 2010 royalty income and amounts retained by Bausch & Lomb. For fiscal 2012, we expect Retisert royalty income to continue its historical downward trend.

Research and Development

Research and development decreased by $130,000, or 2%, to $6.9 million for fiscal 2011 from $7.0 million for fiscal 2010. This decrease was primarily attributable to a federal therapeutic discovery grant, partially offset by a small increase in research and development costs. We may significantly increase our research and development expense in fiscal 2012, primarily dependent upon whether we initiate clinical trials and other product development activities that we fund internally.

General and Administrative

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

Change in Fair Value of Derivatives

Change in fair value of derivatives represented income of $1.1 million for fiscal 2011 compared to expense of $339,000 for fiscal 2010. Detachable warrants issued in share offerings denominated in A$ were recorded as derivative liabilities, subject to revaluation at subsequent reporting dates. The change in fair value of derivatives for fiscal 2011, determined using the Black-Scholes valuation model, was predominantly due to the expiration of approximately 3.7 million, or 95%, of the A$-denominated warrants during the year. The corresponding net expense in fiscal 2010 was primarily due to a substantial increase in the market price of our shares in fiscal 2010 (resulting in a smaller spread between the market price and the US$-equivalent exercise prices of the warrants), partially offset by the decrease in the weighted average remaining life of the underlying warrants during the period.

We are required to re-value these warrants at each subsequent balance sheet date, and changes in their fair values will result in adjustments to our recorded derivative liabilities ($170,000 at June 30, 2011) and a corresponding income or expense in our statement of operations. Although fluctuations in the fair value of the warrants will continue to impact our future quarterly and annual operating results until the last-to-expire of these warrants in July 2012, we expect the significantly lower number of outstanding warrants and short remaining duration to result in less significant income and expense fluctuations as compared to the prior two years.

Income Tax (Expense) Benefit

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

Years Ended June 30, 2010 and 2009

	Year ended June 30,		Change	
	2010	2009	Amounts	%
	(In thousands except percentages)			
Revenues	$23,053	$12,162	$10,891	90%
Operating expenses:				
Research and development	6,994	8,007	(1,013)	(13)%
General and administrative	6,968	8,791	(1,823)	(21)%
Total operating expenses	13,962	16,798	(2,836)	(17)%
Operating income (loss)	9,091	(4,636)	13,727	296%
Other (expense) income:				
Change in fair value of derivatives	(339)	959	(1,298)	(135)%
Interest income	27	162	(135)	(83)%
Other (expense) income, net	(3)	53	(56)	(106)%
Total other (expense) income	(315)	1,174	(1,489)	(127)%
Income (loss) before income taxes	8,776	(3,462)	12,238	353%
Income tax (expense) benefit	(23)	951	(974)	(102)%
Net income (loss)	$ 8,753	$ (2,511)	$11,264	449%

Revenues

Revenues increased by approximately $10.9 million, or 90%, to $23.1 million for fiscal 2010 from $12.2 million for fiscal 2009. In each fiscal year, revenues were almost entirely attributable to our collaboration agreement with Alimera, consisting of (i) the portion of the upfront license consideration that we recognized in the given year; and (ii) the aggregate of conditional note payments and reimbursement of our development costs received from Alimera that we recognized in the given fiscal year. For fiscal 2010, the Alimera-related revenues included payment in full by Alimera of the $15.0 million conditional note plus interest.

During fiscal 2010, $1.2 million of Retisert royalties otherwise payable were retained by Bausch & Lomb, thereby completing the advance royalty agreement, and $342,000 were recorded as royalty income compared to $1.6 million retained by Bausch & Lomb in fiscal 2009 and $0 recorded as royalty income. The fiscal 2010 total of royalty income and amounts otherwise payable of approximately $1.5 million compared to approximately $1.6 million of royalties otherwise payable for fiscal 2009, a decrease of 6.1%.

Research and Development

Research and development decreased by approximately $1.0 million, or 13%, to $7.0 million for fiscal 2010 from $8.0 million for fiscal 2009. This decrease was primarily attributable to an approximate $1.1 million reduction of U.K.-based research and development costs, primarily related to third party costs of our BrachySil clinical program and third party BioSilicon manufacturing development for the period prior to consummation of our Intrinsiq supply agreement. Approximately $82,000 of the total decrease was attributable to the relative strengthening of the U.S. dollar against the Pound Sterling.

General and Administrative

General and administrative costs decreased by approximately $1.8 million, or 21%, to approximately $7.0 million for fiscal 2010 from $8.8 million for fiscal 2009. This net decrease was primarily attributable to the following factors:

- the absence of a $1.3 million provision for losses in fiscal 2009 on a note receivable,

- the elimination of approximately $400,000 of legal fees and consulting services incurred in fiscal 2009 directly related to the June 2008 Reincorporation,
- an approximate $500,000 reduction in U.S. salaries and benefits, primarily related to fiscal 2009 salary and severance agreement costs of a former executive officer,

partially offset by:

- an approximate $480,000 increase in stock-based compensation.

Change in Fair Value of Derivatives

Change in fair value of derivatives represented an expense of $339,000 for fiscal 2010 compared to income of $959,000 for fiscal 2009, primarily due to a net increase in the market price of our shares in fiscal 2010 (resulting in a smaller spread between the market price and the US$-equivalent exercise prices of the warrants) compared to a net decrease in the market price of our shares in fiscal 2009.

Interest Income

Interest income decreased by $135,000, or 83%, to $27,000 for fiscal 2010 from $162,000 for fiscal 2009, primarily due to sharply lower weighted average interest rates earned on money market funds.

Other (Expense) Income

Other expense, net of $3,000 for fiscal 2010 compares to other income of $53,000 for fiscal 2009. This change was primarily attributable to the absence in fiscal 2010 of foreign exchange gains recognized in fiscal 2009.

Income Tax (Expense) Benefit

Income tax expense of $23,000 in fiscal 2010 compares to $951,000 of income tax benefit for fiscal 2009. The net change was primarily attributable to an approximate $706,000 decrease of foreign research and development tax credits earned by our U.K. subsidiary and an approximate $186,000 increase in U.S. federal alternative minimum taxes resulting from payment of the Alimera conditional note.

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 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 October 2009, the FASB issued ASU 2009-13, *Multiple-Deliverable Revenue Arrangements*. We adopted ASU 2009-13 for revenue arrangements entered into or materially modified on or after July 1, 2010. Adoption of this guidance had a material impact on our fiscal 2011 consolidated financial statements as a result of a materially modified research and collaboration agreement with Pfizer.

In June 2011, the FASB issued new guidance on the presentation of comprehensive income that will require us to present components of net income and other comprehensive income in one continuous statement or in two

separate, but consecutive statements. There are no changes to the components that are recognized in net income or other comprehensive income under current GAAP. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2011, with early adoption permitted. It is applicable to our fiscal quarter beginning July 1, 2012. We have not yet determined which method we will elect to present comprehensive income under the new standard.

Liquidity and Capital Resources

During fiscal 2009 to 2011, we financed our operations primarily from license fees, research and development funding and contingent cash payments from our collaboration partners and, to a lesser degree, from a January 2011 registered direct offering of our equity securities. At June 30, 2011, our principal sources of liquidity consisted of cash, cash equivalents and marketable securities totaling $24.1 million. Our cash equivalents are invested in institutional money market funds and our marketable securities are invested in investment-grade corporate debt, government agency securities and commercial paper with maturities at June 30, 2011 ranging from one to nine months.

With the exception of fiscal 2010, we have incurred operating losses since inception and, at June 30, 2011, we had a total accumulated deficit of $226.9 million. We generally expect negative cash flows from operations on a quarterly basis at least until such time as one or more of our product candidates achieves regulatory approval and achieves sufficient sales. We believe we can fund our operations as currently conducted into at least calendar year 2013. Whether we will require, or desire, to raise additional capital will be influenced by many factors, including, but not limited to:

- the timely development and regulatory approval and successful commercialization of ILUVIEN and receipt of milestone, royalty and other payments;
- the scope and extent of our internally funded operations and programs, including the clinical trials for the Latanoprost Product and the posterior uveitis insert, any new product candidates and any new business opportunities;
- our ability to establish and maintain strategic arrangements for products and product candidates for research, development, clinical testing, manufacturing and marketing;
- the success of our products and product candidates, including the timing and costs of regulatory approvals and the commercial success of approved products;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing any patent claims; and
- changes in our operating plan, including the pursuit of any new business opportunities, which may affect our need for capital.

Absent adequate levels of funding from new and existing collaboration agreements and/or financing transactions, management currently believes that our cash position thereafter depends significantly on approval of ILUVIEN for DME by the FDA and foreign regulatory authorities and the initiation and success of marketing of ILUVIEN for DME. However, there is no assurance that the FDA or other regulatory authorities will approve ILUVIEN for DME or that it will achieve market acceptance even if it is approved.

If we determine that it is desirable or necessary to raise additional capital in the future, we do not know if it will be available when needed or on terms favorable to us or our stockholders. The state of the economy and the financial and credit markets at the time we seek additional financing may make it more difficult and more expensive to obtain. If available, additional equity financing may be dilutive to stockholders, debt financing may involve restrictive covenants or other unfavorable terms and potential dilutive equity, and funding through collaboration agreements may be on unfavorable terms, including requiring us to relinquish rights to certain of our technologies or products. If adequate financing is not available if and when needed, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs, postpone the pursuit of product candidates and new business opportunities, or otherwise reduce our cash requirements.

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

	Year Ended June 30,		
	2011	2010	2009
	(In thousands)		
Net (loss) income:	$ (8,628)	$ 8,753	$ (2,511)
Changes in operating assets and liabilities	1,211	(4,015)	(10,452)
Other adjustments to reconcile net (loss) income to cash flows from operating activities	4,247	5,161	4,527
Cash flows (used in) provided by operating activities	$ (3,170)	$ 9,899	$ (8,436)
Cash flows used in investing activities	$ (9,498)	$(2,069)	$ (195)
Cash flows provided by financing activities	$10,060	$ 802	$ —

Sources and uses of operating cash flows for the years ended June 30, 2011, 2010 and 2009 are summarized as follows:

	Year Ended June 30,		
	2011	2010	2009
	(In thousands)		
Operating cash inflows:			
License and collaboration agreements	$ 4,665	$19,123	$ 4,315
Royalty income	1,360	127	181
Foreign R&D tax credits	142	130	588
Federal R&D grants	208	—	—
Investment interest received (paid)	129	(22)	188
	6,504	19,358	5,272
Operating cash outflows:			
Reincorporation costs	—	—	(1,401)
Legal and audit fees	(2,388)	(1,770)	(2,737)
All other operating cash outflows, net	(7,286)	(7,689)	(9,570)
	(9,674)	(9,459)	(13,708)
Cash flows (used in) provided by operating activities	$(3,170)	$ 9,899	$ (8,436)

Operating cash inflows for each year consisted primarily of payments received pursuant to license and collaboration agreements, predominantly with Alimera and Pfizer. As a percentage of total license and collaboration agreement payments received, amounts attributable to Pfizer represented 92.2% in fiscal 2011, 10.5% in fiscal 2010 and 34.8% in fiscal 2009 and amounts attributable to Alimera represented 5.3% in fiscal 2011, 86.9% in fiscal 2010 and 44.5% in fiscal 2009.

Operating cash outflows increased by $215,000, or 2.3%, from fiscal 2010 to fiscal 2011, primarily as a result of increased professional fees, and decreased by $4.2 million, or 31%, from fiscal 2009 to fiscal 2010, primarily due to decreased professional fees related to, and resulting from, the Reincorporation, the related closure of our Australian office and decreased U.K. research and development costs, including completion of internally funded Phase II clinical studies of a product candidate.

Cash used in investing activities were primarily attributable to purchases of marketable securities, net of maturities, totaling $9.4 million for fiscal 2011 and $2.1 million for fiscal 2010. There were no transactions involving marketable securities during fiscal 2009.

Net cash flows from financing activities were predominantly attributable to $11.0 million of gross proceeds from the January 2011 registered direct share offering of 2,210,000 common shares and 552,500 warrants to purchase common shares at a price per unit of $5.00, net of $1.0 million of stock issuance costs. In addition, cash flows from financing activities included proceeds from the exercise of stock options and warrants totaling $17,000 in fiscal 2011 and $802,000 in fiscal 2010. There were no cash flows from financing activities in fiscal 2009.

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, 2011:

	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	$1,078	$ 408	$ 370	$ 300	$ —
Purchase Obligations	438	438	—	—	—
Total	$1,516	$ 846	$ 370	$ 300	$ —

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

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

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

Derivative Liabilities

At June 30, 2011, the balance of our derivative liabilities, which relate to warrants denominated in A$, totaled $170,000 and was determined using the Black-Scholes valuation model. The change in fair value of derivatives resulted in income of $1.1 million for fiscal 2011, expense of $339,000 for fiscal 2010 and income of $959,000 for fiscal 2009.

During fiscal 2011, approximately 3.7 million A$ warrants expired. At June 30, 2011, there were 205,000 A$ warrants outstanding with a remaining contractual life of approximately 1.05 years and a US$-equivalent exercise price of $8.14 per share compared to the $4.28 NASDAQ closing price of our common shares. Fluctuations in our share price and the US$-equivalent exercise price of the warrants as a result of currency rate change are the primary factors that change the fair value of these derivatives. The following table summarizes the sensitivity of our consolidated statements of operations for fiscal 2011 to assumed increases or decreases of our share price at June 30, 2011:

	Decrease in Share Price			Current Price	Increase in Share Price		
	-15%	-10%	-5%		+5%	+10%	+15%
	(In thousands)						
Change in fair value of derivatives—income (expense)	$ 63	$ 46	$ 28	$ —	$(10)	$(30)	$(51)

Foreign Currency Exchange Rates

We conduct operations in two principal currencies, the U.S. dollar and the Pound Sterling (£). The U.S. dollar is the functional currency for our U.S. operations, and the Pound Sterling is the functional currency for our U.K. operations. Changes in the foreign exchange rate of the U.S. dollar and Pound Sterling impact the net operating expenses of our U.K. operations. The weakening of the U.S. dollar in fiscal 2011 compared to fiscal 2010 resulted in a net increase in research and development expense of approximately $20,000. All cash and cash equivalents, and most other asset and liability balances, are denominated in each entity's functional currency and, accordingly, we do not consider our statement of operation exposure to realized and unrealized foreign currency gains and losses to be significant.

Changes in the foreign exchange rate of the U.S. dollar and Pound Sterling also impact total stockholders' equity. During fiscal 2011, the relative weakening of the U.S. dollar in relation to the Pound Sterling resulted in a net increase of $919,000 in stockholders' equity due to the translation of approximately £8.6 million of net assets of our U.K. operations, predominantly the BioSilicon technology intangible asset, into U.S. dollars. For every incremental 5% strengthening or weakening of the U.S. dollar at June 30, 2011 in relation to the Pound Sterling, our stockholders' equity at June 30, 2011 would have decreased or increased, respectively, by approximately $690,000.

Interest Rates

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2011. The term "disclosure controls and procedures", as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act'), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their desired objectives, and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2011, 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, 2011. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in *Internal Control—Integrated Framework*. Based on this assessment, our management concluded that, as of such date, our internal control over financial reporting was effective based on those criteria.

Our independent registered public accounting firm has issued its attestation report on our internal control over financial reporting. This report appears below.

(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, 2011, based on criteria established in *Internal Control—Integrated Framework* 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, 2011, based on the criteria established in *Internal Control—Integrated Framework* 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, 2011 of the Company and our report dated September 13, 2011 expressed an unqualified opinion on those financial statements and included an explanatory paragraph relating to the adoption of Accounting Standards Update No. 2009-13, *Multiple-Deliverable Revenue Arrangements*, effective July 1, 2010.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
September 13, 2011

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

Corporate Governance

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

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

Other Information

The other information required to be disclosed in Item 10 is hereby incorporated by reference to our 2011 Proxy Statement.

ITEM 11. EXECUTIVE COMPENSATION

The information required to be disclosed in Item 11 is hereby incorporated by reference to our 2011 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 2011 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 2011 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 2011 Proxy Statement.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENTS

(a)(1) Financial Statements

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

(a)(2) Financial Statement Schedules

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

(a)(3) Exhibits.

Exhibit No.	Exhibit Description	Incorporated by Reference to SEC Filing		
		Form	SEC Filing Date	Exhibit No.
	Articles of Incorporation and By-Laws			
3.1	Certificate of Incorporation of pSivida Corp.	8-K12G3	06/19/08	3.1
3.2	By-Laws of pSivida Corp.	8-K12G3	06/19/08	3.2
	Instruments Defining the Rights of Security Holders			
4.1	Form of Specimen Stock Certificate for Common Stock	8-K12G3	06/19/08	4.1
4.2 +	Form of Warrant, dated as of November 15, 2005	6-K	11/15/05	99.3
4.3 +	Form of Series A Warrant	6-K/A	07/31/06	99.4
4.4	Registration Rights Agreement, dated as of September 26, 2006, by and among pSivida Limited, Australian IT Investments Limited, Absolute Octane Fund and European Catalyst Fund	6-K	09/26/06	99.5
4.5 +	Form of pSivida Limited Warrants to Purchase ADRs, dated September 26, 2006	6-K	09/26/06	99.4
4.6	pSivida Limited Series C Warrants to Purchase ADRs	6-K	01/03/07	99.2
4.7	Series D Warrants	6-K	05/16/07	99.4
4.8	Series E Warrants	6-K	05/16/07	99.5
4.9	Series F Warrants	6-K	05/16/07	99.6
4.10	Series G Warrants	6-K	05/16/07	99.7
4.11	Second Amended and Restated Registration Rights Agreement dated May 15, 2007 by and among pSivida Limited and Castlerigg Master Investments Ltd	6-K	05/16/07	99.3
4.12 +	Form of Investor Warrant	6-K	07/02/07	99.4
4.13 +	Form of Placement Agents Warrant	6-K	07/02/07	99.5
4.14 +	Form of Application for Shares and Options	8-K	06/19/08	4.16
4.15 +	Form of Investor Warrant	8-K	01/19/11	99.3
4.16 +	Form of Securities Purchase Agreement between pSivida Corp and certain investors	8-K	01/19/11	99.4
	Material Contracts—Management Contracts and Compensatory Plans (*)			
10.1	Employment Agreement, between pSivida Limited and Paul Ashton, dated January 1, 2006	20-F	12/08/06	4.35
10.2	Non-Competition Agreement, between pSivida Limited and Paul Ashton, dated October 3, 2005	20-F	01/18/06	4.35
10.3	Employment Agreement, between pSivida Limited and Lori Freedman, dated as of May 16, 2006	6-K	05/23/06	99.3
10.4	Employment Agreement, between pSivida Corp and Leonard S. Ross, dated December 17, 2010	8-K	12/21/10	10.1
10.5	Option Amendment Agreement, between pSivida Corp and Leonard S. Ross, dated December 17, 2010	8-K	12/21/10	10.2
10.6	Rules of the pSivida Corp. Employee Share Option Plan	8-K	06/19/08	10.40
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

Exhibit No.	Exhibit Description	Incorporated by Reference to SEC Filing		
		Form	SEC Filing Date	Exhibit No.
	Material Contracts—Leases			
10.9	Commercial Sublease, between Exergen Corporation and Control Delivery Systems, Inc., dated as of April 6, 2005	20-F	01/18/06	4.19
10.10	Lease Renewal Agreement between pSivida Inc. and Exergen Corporation dated October 18, 2007	10-Q	02/11/08	10.1
	Material Contracts—License and Collaboration Agreements			
10.11 #	Amended and Restated License Agreement between Control Delivery Systems, Inc. and Bausch & Lomb Incorporated dated December 9, 2003, as amended on June 28, 2005	20-F	01/18/06	4.12
10.12 #	Second Amendment to Amended and Restated License Agreement between pSivda US, Inc. and Bausch & Lomb dated August 1, 2009	10-K	09/25/09	10.13
10.13 (a) ##	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.			
10.14 #	Amended and Restated Collaboration Agreement by and between pSivida Inc. and Alimera Sciences, Inc. dated March 14, 2008	8-K	04/26/10	9.01
	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			

Confidential treatment has been granted for portions of this exhibit

Confidential treatment has been requested for portions of this exhibit

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

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

(a) Filed herewith

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, 2011

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, 2011
/s/ PAUL ASHTON **Paul Ashton**	President, Chief Executive Officer and Director (Principal Executive Officer)	September 13, 2011
/s/ LEONARD S. ROSS **Leonard S. Ross**	Vice President, Finance (Principal Financial and Accounting Officer)	September 13, 2011
/s/ PAUL A. HOPPER **Paul Hopper**	Director	September 13, 2011
/s/ MICHAEL ROGERS **Michael Rogers**	Director	September 13, 2011
/S/ PETER SAVAS **Peter Savas**	Director	September 13, 2011

PSIVIDA CORP. AND SUBSIDIARIES

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Consolidated Financial Statements:

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of pSivida Corp. and subsidiaries (the "Company") as of June 30, 2011 and 2010, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended June 30, 2011. 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 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, 2011 and 2010, and the results of their operations and their cash flows for each of the three years in the period ended June 30, 2011, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 2 to the consolidated financial statements, the Company adopted Accounting Standards Update No. 2009-13, *Multiple-Deliverable Revenue Arrangements*, on July 1, 2010.

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, 2011, based on the criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated September 13, 2011, expressed an unqualified opinion on the Company's internal control over financial reporting.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
September 13, 2011

PSIVIDA CORP. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS
(In thousands except share amounts)

	June 30, 2011	June 30, 2010
Assets		
Current assets:		
Cash and cash equivalents	$ 12,912	$ 15,514
Marketable securities	11,216	2,051
Accounts and other receivables	843	1,111
Prepaid expenses and other current assets	395	358
Total current assets	25,366	19,034
Property and equipment, net	123	43
Intangible assets, net	21,564	23,877
Other assets	60	60
Total assets	$ 47,113	$ 43,014
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 328	$ 387
Accrued expenses	1,322	1,158
Deferred revenue	3,212	79
Derivative liabilities	170	1,310
Total current liabilities	5,032	2,934
Deferred revenue	4,635	6,817
Deferred tax liabilities	13	222
Total liabilities	9,680	9,973
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Preferred stock, $.001 par value, 5,000,000 shares authorized, no shares issued and outstanding	—	—
Common stock, $.001 par value, 60,000,000 shares authorized, 20,748,642 and 18,531,392 shares issued and outstanding at June 30, 2011 and 2010, respectively	21	19
Additional paid-in capital	262,906	250,796
Accumulated deficit	(226,923)	(218,295)
Accumulated other comprehensive income	1,429	521
Total stockholders' equity	37,433	33,041
Total liabilities and stockholders' equity	$ 47,113	$ 43,014

See notes to consolidated financial statements

PSIVIDA CORP. AND SUBSIDIARIES

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

	Year Ended June 30,		
	2011	2010	2009
Revenues:			
Collaborative research and development	$ 3,612	$22,570	$12,002
Royalty income	1,353	483	160
Total revenues	4,965	23,053	12,162
Operating expenses:			
Research and development	6,864	6,994	8,007
General and administrative	8,104	6,968	8,791
Total operating expenses	14,968	13,962	16,798
Operating (loss) income	(10,003)	9,091	(4,636)
Other income (expense):			
Change in fair value of derivatives	1,140	(339)	959
Interest income, net	30	27	162
Other (expense) income, net	(13)	(3)	53
Total other income (expense)	1,157	(315)	1,174
(Loss) income before income taxes	(8,846)	8,776	(3,462)
Income tax benefit (expense)	218	(23)	951
Net (loss) income	$ (8,628)	$ 8,753	$ (2,511)
Net (loss) income per share:			
Basic	$ (0.44)	$ 0.48	$ (0.14)
Diluted	$ (0.44)	$ 0.46	$ (0.14)
Weighted average common shares outstanding:			
Basic	19,489	18,405	18,263
Diluted	19,489	18,895	18,263

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, 2008	18,262,345	$ 18	$247,628	$ (224,537)	$ 6,969	$ 30,078
Comprehensive loss:						
Net loss	—	—	—	(2,511)	—	(2,511)
Reclassification of foreign currency translation gains to earnings upon dissolution of subsidiaries					(69)	(69)
Foreign currency translation adjustments	—	—	—	—	(4,829)	(4,829)
Total comprehensive loss						$ (7,409)
Issuance of fully vested shares	31,616	—	57	—	—	57
Stock-based compensation	—	—	815	—	—	815
Balance at June 30, 2009	18,293,961	18	248,500	(227,048)	2,071	23,541
Comprehensive income:						
Net income	—	—	—	8,753	—	8,753
Foreign currency translation adjustments	—	—	—	—	(1,548)	(1,548)
Net unrealized loss on marketable securities	—	—	—	—	(2)	(2)
Total comprehensive income						$ 7,203
Exercise of warrants	100,000	—	484	—	—	484
Exercise of stock options	110,000	1	317	—	—	318
Issuance of fully vested shares	27,431	—	110	—	—	110
Stock-based compensation	—	—	1,385	—	—	1,385
Balance at June 30, 2010	18,531,392	19	250,796	(218,295)	521	33,041
Comprehensive loss:						
Net loss	—	—	—	(8,628)	—	(8,628)
Foreign currency translation adjustments	—	—	—	—	919	919
Net unrealized loss on marketable securities	—	—	—	—	(11)	(11)
Total comprehensive loss						$ (7,720)
Issuance of stock, net of issue costs	2,210,000	2	10,041	—	—	10,043
Exercise of stock options	7,250	—	17	—	—	17
Stock-based compensation	—	—	2,052	—	—	2,052
Balance at June 30, 2011	20,748,642	$ 21	$262,906	$ (226,923)	$ 1,429	$ 37,433

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See notes to consolidated financial statements

PSIVIDA CORP. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended June 30,		
	2011	2010	2009
Cash flows from operating activities:			
Net (loss) income	$ (8,628)	$ 8,753	$ (2,511)
Adjustments to reconcile net (loss) income to cash flows from operating activities:			
Amortization of intangible assets	3,302	3,289	3,336
Depreciation of property and equipment	53	37	102
Change in fair value of derivatives	(1,140)	339	(959)
Amortization of bond premium on marketable securities	189	1	—
Stock-based compensation	2,052	1,495	872
Loss on sale of equipment	—	—	39
Provision for losses on note receivable	—	—	1,300
Deferred income tax benefit	(209)	—	(94)
Foreign currency translation gains upon dissolution of subsidiaries	—	—	(69)
Changes in operating assets and liabilities:			
Accounts and other receivables	285	(290)	124
Prepaid expenses and other current assets	(36)	52	117
Accounts payable	(64)	110	(2,156)
Accrued expenses	146	(360)	(649)
Deferred revenue	880	(3,527)	(7,888)
Net cash (used in) provided by operating activities	(3,170)	9,899	(8,436)
Cash flows from investing activities:			
Purchases of marketable securities	(15,963)	(2,054)	—
Maturities of marketable securities	6,598	—	—
Purchases of property and equipment	(133)	(15)	(195)
Net cash used in investing activities	(9,498)	(2,069)	(195)
Cash flows from financing activities:			
Proceeds from issuance of stock, net of issuance costs	10,043	—	—
Proceeds from exercise of stock options and warrants	17	802	—
Net cash provided by financing activities	10,060	802	—
Effect of foreign exchange rate changes on cash and cash equivalents	6	(17)	(79)
Net (decrease) increase in cash and cash equivalents	(2,602)	8,615	(8,710)
Cash and cash equivalents at beginning of year	15,514	6,899	15,609
Cash and cash equivalents at end of year	$ 12,912	$15,514	$ 6,899
Supplemental disclosure of cash flow information:			
Cash paid for income taxes	$ 56	$ 266	$ —

See notes to consolidated financial statements

PSIVIDA CORP. AND SUBSIDIARIES

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

1. Nature of the Business

pSivida Corp. (together with its subsidiaries, the "Company"), incorporated in Delaware, develops tiny, sustained release, drug delivery products that are administered by implantation, injection or insertion and designed to deliver drug at a controlled and steady rate for months or years. The Company is currently focused on the treatment of chronic eye diseases utilizing its cored technology systems, Durasert™ and BioSilicon™. ILUVIEN® for the treatment of diabetic macular edema ("DME"), the Company's lead product candidate, is under U.S. Food and Drug Administration ("FDA") review, and uses the third generation of the Durasert™ technology system to deliver the corticosteroid fluocinolone acetonide ("FAc") over a period of up to 3 years. The Company's two FDA-approved products provide sustained release drug delivery to treat other back-of-the-eye diseases. An investigator-sponsored trial is ongoing for an injectable bioerodible insert delivering latanoprost designed to treat glaucoma and ocular hypertension and an investigator-sponsored Investigational New Drug ("IND") opened for an injectable insert of the same design as ILUVIEN designed to treat posterior uveitis.

ILUVIEN is licensed to Alimera Sciences, Inc. ("Alimera"), which completed two Phase III clinical trials (the FAME Study) in October 2010. Alimera submitted a New Drug Application ("NDA") for ILUVIEN for DME to the FDA in June 2010 based on month 24 data from the FAME Study, received a Complete Response Letter ("CRL") in December 2010, and resubmitted an NDA to the FDA in response to the CRL in May 2011. Alimera expects a response from the FDA in November 2011. If approved, Alimera has indicated that it plans to commercialize ILUVIEN for DME in the U.S. as soon as early calendar year 2012. In July 2010, Alimera submitted a Marketing Authorization Application for ILUVIEN to the Medicines and Healthcare products Regulatory Agency ("MHRA") in the United Kingdom and to other regulatory authorities in Europe. Alimera has reported that it expects to submit the final response to the MHRA and other regulatory authorities by December 2011.

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

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

BioSilicon, the Company's other principal technology system, is a fully-erodible, nanostructured, porous silicon designed to provide sustained delivery of various therapeutics, including small drug molecules, proteins and peptides. Based on results of its preliminary studies, the Company is currently targeting BioSilicon as a second key drug delivery technology.

The Company is subject to risks common to companies in the biotechnology industry, including, but not limited to, its ability, and that of its collaboration partners, to successfully advance research, pre-clinical and clinical development, obtain regulatory approvals and commercialize product candidates utilizing the Company's technologies, development by its competitors and others of alternative products and disease treatments, ability to protect its proprietary technologies, dependence on key personnel, compliance with FDA and other governmental regulations and approval requirements as well as its ability to execute on its business strategies and obtain adequate financing to fund its operations through collaborations, sales of equity or otherwise.

The Company expects its future operating results will vary from year to year and quarter to quarter, and such variations could be significant. Future operating results are expected to depend, among other things, upon the amounts of payments received from, and revenue recognition associated with, the Company's current and any potential future collaboration arrangements, its clinical research and development and other costs and outcomes of its product candidates. The Company anticipates that existing capital resources of $24.1 million at June 30, 2011 should enable it to maintain its current and planned operations into at least calendar year 2013. The Company's ability to fund its planned operations internally beyond then may be substantially dependent upon whether and when the FDA approves ILUVIEN for DME, which would result in a $25.0 million milestone payment due from Alimera, as well as the extent to which Alimera is able to successfully commercialize ILUVIEN for DME.

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, 2011, 2010 and 2009 may be referred to herein as fiscal 2011, fiscal 2010 and fiscal 2009, respectively. Throughout these financial statements, references to "US$" and "$" are to U.S. dollars and references to "A$" are to Australian dollars.

2. Significant Accounting Policies

Use of Estimates

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

Foreign Currency

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

Assets and liabilities of the Company's foreign subsidiary are translated at period end exchange rates. Amounts included in the statements of operations are translated at the weighted average exchange rates for the period. Gains and losses from currency translation are included in accumulated other comprehensive income as a separate component of stockholders' equity in the consolidated balance sheets. The balance of accumulated other comprehensive income attributable to foreign currency translation was $1.4 million at June 30, 2011 and $523,000 at June 30, 2010. Foreign currency gains or losses arising from transactions denominated in foreign currencies, whether realized or unrealized, are recorded in other income, net in the consolidated statements of operations and were not significant for all periods presented.

Cash Equivalents

Cash equivalents represent highly liquid investments with maturities of three months or less at the date of purchase, principally consisting of institutional money market funds. Cash equivalents are stated at amortized cost, which approximates fair value.

Marketable Securities

Marketable securities consist of investments with an original or remaining maturity of greater than ninety days at the date of purchase. The Company has classified its marketable securities as available-for-sale and, accordingly, records these investments at fair value, with unrealized gains and temporary losses excluded from earnings and reported, net of tax, in accumulated other comprehensive income, which is a component of stockholders' equity. If it is determined that a decline of any investment is other-than-temporary, the investment would be written down to fair value. As of June 30, 2011 and 2010, there were no investments in a significant unrealized loss position. The fair value of marketable securities is determined based on quoted market prices at the balance sheet dates of the same or similar instruments. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts through to the earlier of sale or maturity. Such amortization and accretion amounts are included in interest income net in the consolidated statements of operations. The cost of marketable securities sold is determined by the specific identification method.

Concentrations of Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash, cash equivalents and marketable securities. At June 30, 2011, substantially all of the Company's interest-bearing cash equivalent balances, aggregating approximately $8.7 million, were concentrated in one institutional money market fund that has investments consisting primarily of certificates of deposit, commercial paper, time deposits, U.S. government agency securities, treasury bills and treasury repurchase agreements. Generally, these deposits may be redeemed upon demand and, therefore, bear minimal risk. Marketable securities at June 30, 2011 consist of high-grade corporate bonds, U.S. Government obligations and commercial paper. The Company's investment policy, approved by the Board of Directors, includes guidelines relative to diversification and maturities to preserve principal and liquidity.

In fiscal 2011, Pfizer accounted for $3.3 million, or 67%, of total revenues and Bausch & Lomb accounted for $1.4 million, or 27%, of total revenues. Alimera accounted for approximately $22.3 million, or 97%, of total revenues in fiscal 2010 and $11.8 million, or 97%, of total revenues in fiscal 2009.

Fair Value of Financial Instruments

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

Accounts and Other Receivables

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

Debt and Equity Instruments

Debt and equity instruments are classified as either liabilities or equity in accordance with the substance of the contractual arrangement. Warrants issued in connection with share issues that are denominated in a currency (A$) other than the Company's functional currency (US$) are treated as derivative liabilities, reflecting the variable amount of functional currency to be received upon potential exercise. After initial recognition, subsequent changes in the fair value of the derivative liabilities are recorded in the consolidated statements of operations in each reporting period. Fair value is determined using a Black-Scholes valuation model.

Property and Equipment

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

Leases

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

Impairment of Intangible Assets

The Company's finite life intangible assets include its acquired Durasert and BioSilicon patented technologies that 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, and considered the effects of legal, regulatory, contractual, competitive and other economic factors. The Company continually monitors whether events or circumstances have occurred that indicate that the remaining estimated useful life of its intangible assets may warrant revision. The Company assesses potential impairments to its intangible assets when there is evidence that events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An impairment loss is recognized when the future undiscounted net cash flows expected to result from the use of an asset is less than its carrying value. If an asset is considered to be impaired, the impairment charge to be recognized is measured by the amount by which the carrying value of the asset exceeds its estimated fair value.

Revenue Recognition

Collaborative Research and Development and Multiple-Deliverable Arrangements

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

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

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

The Company prospectively adopted the provisions of Accounting Standards Update No. 2009-13, Revenue Recognition (Topic 605); *Multiple-Deliverable Revenue Arrangements* ("ASU 2009-13") for new and materially modified arrangements originating on or after July 1, 2010. ASU 2009-13 provides updated guidance on how the

deliverables in an arrangement should be separated, and how consideration should be allocated, and it changes the level of evidence of standalone selling price required to separate deliverables by allowing a vendor to make its best estimate of the standalone selling price of deliverables when vendor-specific objective evidence or third-party evidence of selling price is not available.

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

Royalties

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

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

Reimbursement of Costs

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

Deferred Revenue

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

Research and Development

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

Stock-Based Compensation

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

Net (Loss) Income per Share

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

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

	Year Ended June 30,		
	2011	2010	2009
Number of common shares—basic	19,489,154	18,404,823	18,262,865
Effect of dilutive securities:			
Stock options	—	489,783	—
Number of common shares—diluted	19,489,154	18,894,606	18,262,865

The following potentially dilutive securities outstanding, prior to the application of the treasury stock method, have been excluded from the computation of diluted weighted-average shares outstanding for the years ended June 30, 2011, 2010 and 2009, as they would be anti-dilutive:

	June 30,		
	2011	2010	2009
Options	2,740,895	907,219	2,078,397
Warrants	7,820,227	10,997,681	11,097,681
	10,561,122	11,904,900	13,176,078

Comprehensive (Loss) Income

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

Income Tax

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

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

Recently Adopted and Recently Issued Accounting Pronouncements

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

the Company believes that the impact of recently issued 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 October 2009, the FASB issued ASU 2009-13, *Multiple-Deliverable Revenue Arrangements*. The Company adopted ASU 2009-13 for revenue arrangements entered into or materially modified on or after July 1, 2010. Adoption of this guidance had a material impact on the Company's fiscal 2011 consolidated financial statements as a result of a materially modified research and collaboration agreement with Pfizer.

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

3. License and Collaboration Agreements

Alimera

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

Upon execution of the Alimera Agreement, the Company received consideration of $12.0 million in cash and Alimera cancelled $5.7 million of accrued development cost liabilities, including related penalties and accrued interest, owed by the Company to Alimera as of March 14, 2008. In addition, the Company received a $15.0 million conditional note (subject to acceleration upon the occurrence of certain defined liquidity events), Alimera agreed to pay a $25.0 million milestone payment upon FDA approval of ILUVIEN for DME, and Alimera assumed all financial responsibility for the development of licensed products under the Alimera Agreement, which had previously been shared equally, including reimbursement of approved development costs incurred by the Company in support of the ongoing clinical studies of ILUVIEN and anticipated regulatory submissions. In exchange, the Company decreased its share in any future profits, as defined, on sales of ILUVIEN by Alimera from 50% to 20%, subject to an offset of 20% of pre-profitability commercialization costs, as defined, incurred by Alimera. In the event Alimera sublicenses commercialization, the Company is entitled to receive 20% of royalties and 33% of non-royalty consideration received by Alimera, less certain permitted deductions.

The scheduled payment terms on the $15.0 million conditional note consisted of (i) interest only at an annual rate of 8% payable quarterly through March 2010 and (ii) principal payments of $500,000 per month commencing April 30, 2010 together with interest payable quarterly at an annual rate of 20%. Through March 31, 2010, the Company received total interest payments of approximately $2.5 million under the terms of the note. On April 27, 2010, following consummation of its initial public offering, Alimera paid the $15.0 million conditional note in full together with $225,000 of accrued and unpaid interest.

The Company considered the Alimera Agreement to be a revenue arrangement with multiple deliverables. The Company's deliverables under this collaboration included the exclusive license to ILUVIEN, future "know-how", a non-exclusive license for certain other products using the same technology, and certain prescribed research and development. The Company assessed each of these elements against the separation criteria for multiple element arrangements and concluded that the licenses did not have stand-alone value to Alimera and the Company did not have objective and reliable evidence of fair value for all undelivered elements of the arrangement. Accordingly, the Company concluded that the deliverables represented a single unit of accounting. The terms of the collaboration agreement specifically defined the end period of any and all of the Company's performance obligations as (i) December 31, 2009 for ILUVIEN and (ii) the effective date of the Alimera Agreement for any other licensed product. Accordingly, the services related to ILUVIEN were provided through the December 31, 2009 performance period and no further obligations existed after this date.

The Company incurred costs related to the Alimera Agreement to provide services, as requested. The Company was the primary obligor under these arrangements and, upon the amendment in March 2008, was no

longer sharing in the costs of product development. Accordingly, costs associated with development activities have been recorded as expense as incurred and payments received have been recorded as revenue.

Based upon the above analysis, the initial $18.3 million of deferred revenue, which consisted of the $12.0 million in cash, the $5.7 million cancellation of accrued development cost liabilities and $650,000 of previously received but unamortized milestone payments, was recognized as revenue on a straight-line basis over the 21.5 month performance period from the effective date of the Alimera Agreement through December 31, 2009. Because the $15.0 million note did not represent an unconditional payment obligation of Alimera, it was not recorded as an asset but instead treated by the Company as contingent future revenue consideration. All additional cash consideration received from Alimera during the performance period, which consisted of conditional note payments and development cost reimbursements, was recognized as revenue during the performance period using the cumulative catch-up method. Amounts received from Alimera subsequent to December 31, 2009, including any note, milestone and profit share payments, are recognized as revenue upon receipt or at such earlier date, if applicable, on which any such amount is both fixed and determinable and reasonably assured of collectability.

Revenue related to the Alimera Agreement totaled $192,000 for fiscal 2011, $22.3 million for fiscal 2010 and $11.8 million for fiscal 2009. These revenues represented substantially all of the Company's collaborative research and development revenue for each of fiscal 2010 and fiscal 2009. There was no deferred revenue balance at June 30, 2011 and 2010.

Pfizer

In April 2007, the Company entered into a worldwide Collaborative Research and License Agreement (the "Original Pfizer Agreement") with Pfizer for the use of certain of its technologies in ophthalmic applications that were not licensed to others. Commencing in calendar 2008, Pfizer paid the Company a minimum of $500,000 quarterly in consideration of the Company's costs in performing the research program. The Company was unable to define the time period of its overall deliverables and other obligations under the Original Pfizer Agreement and, as a result, all payments received from Pfizer through June 30, 2011 totaling $7.75 million were classified in non-current deferred revenue.

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

Based upon the significant changes to the terms of the Original Pfizer Agreement, which included (i) changes in the consideration payable by Pfizer; (ii) changes in the deliverables; and (iii) changes in the

research program, which now is solely related to the Latanoprost Product, the Company considered the Restated Pfizer Agreement a material modification and applied the guidance of ASU 2009-13 to this arrangement.

The Company's deliverables under the Restated Pfizer Agreement include conducting the research and development program for the Latanoprost Product through completion of Phase II (the "R&D program") and participation on a Joint Steering Committee (JSC). The Company concluded that the Pfizer exercise option for the worldwide exclusive license is not a deliverable of the arrangement, due to it being a substantive option and not being priced at a significant and incremental discount. The Company determined that the JSC does not have standalone value from the R&D program and therefore the Company has combined these deliverables into a single unit of accounting. The performance period is the expected period over which the services of the combined unit are performed, and the Company has estimated that period to be 3 years.

The total arrangement consideration of the Restated Pfizer Agreement totaled $10.05 million, which consisted of the $7.75 million of deferred revenue on the Company's balance sheet at the effective date plus the $2.3 million upfront payment. The difference between the total arrangement consideration and the estimated selling price of the combined deliverables, or $3.3 million, has been recognized as collaborative research and development revenue in the quarter ended June 30, 2011, the period of the modification. An increase of 10% in the estimated selling price of the combined deliverable would have reduced revenue recognized in fiscal 2011 by $673,000. To determine the estimated selling price of the combined deliverable, the Company applied an estimated margin to its cost projections for the combined deliverable. The estimated selling price of $6.7 million will be recognized as collaborative research and development revenue over the expected 3-year performance period using the proportional performance method. The costs associated with conducting the research program for the Latanoprost Product will be reflected in operating expenses in the period in which they are incurred.

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

Intrinsiq

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

Under the original agreement, the parties were obligated to enter into a manufacture and supply agreement, which was consummated effective as of February 1, 2009. Pursuant to the supply agreement, the Company leased to Intrinsiq certain equipment for its use in manufacturing BioSilicon material. Subject to its right to terminate the lease, Intrinsiq would acquire title to the equipment upon the remittance of lease payments totaling $122,000 over the 2-year lease term, the final payment of which was received in May 2011.

The Company determined that the equipment lease component represented a separate element of this arrangement. Using the relative fair value method prescribed under the authoritative guidance, the Company allocated the arrangement consideration between the lease and license deliverables. The Company determined the performance period of the license arrangement to be 17 years, coinciding with the last to expire of the patents licensed to Intrinsiq, and is recognizing consideration allocated to the license arrangement on a straight-line basis over this period. The Company recognized collaborative research and development revenue of $83,000 in fiscal 2011, $121,000 in fiscal 2010 and $77,000 in fiscal 2009, and the remaining balance of payments received, including minimum royalties, of approximately $1.1 million was recorded as deferred revenue at June 30, 2011.

On July 22, 2011, the Company consummated an asset purchase agreement pursuant to which it acquired porous BioSilicon-related capital equipment and intellectual property assets of Intrinsiq for $223,000, and

assumed four Intrinsiq employees. As part of the transaction, Intrinsiq terminated the agreements underlying its original 2008 exclusive field-of-use license to develop and commercialize nutraceutical and food science applications of BioSilicon. The license termination will result in the recognition of collaborative research and development revenue of approximately $1.1 million in the quarter ending September 30, 2011, representing the total Intrinsiq deferred revenue balance at June 30, 2011, which was classified as a current liability.

Bausch & Lomb

The Company's Retisert and Vitrasert products have been commercialized under a 1992 licensing and development agreement with Bausch & Lomb. Pursuant to a subsequent collaboration agreement, Bausch & Lomb has a worldwide exclusive license to make and sell Vitrasert and our first-generation products (as defined in the agreement, including Retisert) in return for royalties based on sales.

In June 2005, the Company received a $3.0 million advance from Bausch & Lomb in consideration of $6.25 million of future Retisert royalties that otherwise would be payable to the Company. During the quarter ended June 30, 2010, Bausch & Lomb retained the final portion of these royalties otherwise payable and the Company recorded $342,000 of royalty income. During fiscal 2011, the Company recorded $1.2 million of royalty income, representing 100% of the Retisert royalties earned pursuant to the collaboration agreement. Accounts receivable from Bausch & Lomb totaled $290,000 at June 30, 2011 and $342,000 at June 30, 2010.

4. Intangible Assets

The reconciliation of intangible assets for the years ended June 30, 2011 and 2010 is as follows:

	June 30, 2011	June 30, 2010
Patented technologies		
Gross carrying amount at beginning of year	$ 53,275	$ 56,559
Foreign currency translation adjustments	2,147	(3,284)
Gross carrying amount at end of year	55,422	53,275
Accumulated amortization at beginning of year	(29,398)	(27,757)
Amortization expense	(3,302)	(3,289)
Foreign currency translation adjustments	(1,158)	1,648
Accumulated amortization at end of year	(33,858)	(29,398)
Net book value at end of year	$ 21,564	$ 23,877

The net book value of the Company's intangible assets at June 30, 2011 and 2010 is summarized as follows:

	June 30, 2011	June 30, 2010	Estimated Remaining Useful Life at June 30, 2011 (Years)
Patented technologies			
Durasert	$ 6,845	$ 7,898	6.5
BioSilicon	14,719	15,979	6.5
	$21,564	$23,877	

The Company amortizes its intangible assets with finite lives on a straight-line basis over their respective estimated useful lives. The aggregate annual amortization expense for intangible assets was $3.3 million for each of the three years in the period ended June 30, 2011. Based upon intangible assets in service as of June 30, 2011, amortization expense for each of the next five years is estimated to be approximately $3.3 million per year.

5. Marketable Securities

The amortized cost, unrealized gains or losses and fair value of the Company's available-for-sale marketable securities at June 30, 2011 and 2010 were as follows:

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

	June 30, 2010		
	Amortized Cost	Unrealized (Loss)	Fair Value
Corporate bonds	$ 1,304	$ (2)	$ 1,302
U.S. Government obligations	449	—	449
Commercial Paper	300	—	300
Total marketable securities	$ 2,053	$ (2)	$ 2,051

During fiscal 2011, $16.0 million of marketable securities were purchased and $6.6 million matured. The marketable securities at June 30, 2011 have maturity dates ranging between one and nine months, with a weighted average maturity of 5.2 months.

6. Property and Equipment, Net

	June 30,	
	2011	2010
Property and equipment	$ 3,755	$ 3,470
Leasehold improvements	194	192
Gross property and equipment	3,949	3,662
Accumulated depreciation and amortization	(3,826)	(3,619)
	$ 123	$ 43

Depreciation expense was $53,000 for fiscal 2011, $37,000 for fiscal 2010 and $102,000 for fiscal 2009.

7. Fair Value Measurements

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

- Level 1—Inputs are quoted prices in active markets that are accessible at the measurement date for identical assets and liabilities.
- Level 2—Inputs are directly or indirectly observable in the marketplace, such as quoted prices for similar assets or liabilities in active markets or quoted prices for identical assets or liabilities with insufficient volume or infrequent transaction (less active markets).

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

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

The following table summarizes the Company's assets and liabilities carried at fair value measured on a recurring basis at June 30, 2011 and 2010 by valuation hierarchy:

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

	June 30, 2010			
Description	Total Carrying Value	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets:				
Cash equivalents	$ 15,055	$ 15,055	$ —	$ —
Marketable securities:				
Corporate bonds	1,302	1,302	—	—
U.S. Government obligations	449	—	449	—
Commercial Paper	300	—	300	—
	$ 17,106	$ 16,357	$ 749	$ —
Liabilities:				
Derivative liabilities	$ 1,310	$ —	$ —	$ 1,310

The Company's derivative liabilities were classified as Level 3 and valued using the Black-Scholes model. At June 30, 2011 and 2010, the fair values were derived by applying the following assumptions:

	June 30,	
	2011	2010
Expected term (in years)	1.05	0.50 - 2.04
Stock volatility	95%	95%
Risk-free interest rate	0.19%	0.22% - 0.63%
Expected dividends	0%	0%

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

	June 30,	
	2011	2010
Balance at beginning of year	$1,310	$ 971
Change in fair value of derivatives—other income (expense)	1,140	(339)
Balance at end of year	$ 170	$1,310

8. Accrued Expenses

	June 30,	
	2011	2010
Personnel costs	$ 711	$ 592
Professional fees	434	282
Clinical	140	242
Other	37	42
	$1,322	$1,158

9. Stockholders' Equity

Sales of Common Stock and Warrants

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

In July 2007, the Company completed a sale of 3,600,500 units at a per unit price of $5.00 for gross proceeds of $18.0 million. Each unit consisted of (i) one common share; and (ii) one warrant to purchase 0.40 common share, with a warrant exercise price of $6.60 per share. Of the total offering, 1,300,000 units were purchased by Pfizer in accordance with the terms of the Pfizer Agreement. A total of 72,010 warrants, with a warrant exercise price of $6.60 per share, were issued to the placement agents in connection with the offering. In addition, the Company simultaneously completed a sale of 513,699 units at the equivalent price of A$5.84 per unit for additional gross proceeds of approximately $2.6 million. Aggregate share issue costs for these transactions totaled approximately $2.2 million.

Warrants to Purchase Common Shares

The following table provides a reconciliation of all US$ warrants for the years ended June 30, 2011 and 2010:

	Year Ended June 30,			
	2011		2010	
	Number of Warrants	Weighted Average Exercise Price	Number of Warrants	Weighted Average Exercise Price
Balance at beginning of year	7,062,248	$ 7.53	7,162,248	$ 7.50
Issued	552,500	5.00	—	—
Exercised	—	—	(100,000)	4.84
Balance and exercisable at end of year	7,614,748	$ 7.35	7,062,248	$ 7.53

At June 30, 2011, the remaining lives of these outstanding warrants ranged from 0.2 to 4.6 years, representing a weighted average term of approximately 1.0 year.

The following table provides a reconciliation of all A$ warrants for the years ended June 30, 2011 and 2010:

	Year Ended June 30,			
	2011		2010	
	Number of Warrants	Weighted Average Exercise Price A$	Number of Warrants	Weighted Average Exercise Price A$
Balance at beginning of year	3,935,433	9.54	3,935,433	9.54
Expired	(3,729,954)	9.65	—	—
Balance and exercisable at end of year	205,479	7.68	3,935,433	9.54

The weighted average exercise price of these warrants translated to US$ was $8.14 at June 30, 2011 and $8.17 at June 30, 2010. At June 30, 2011, these outstanding warrants had a weighted average remaining life of 1.05 years.

Because the potential exercise of the A$-denominated warrants would result in a variable amount of proceeds in the Company's functional currency, the fair value of the warrants was recorded as a derivative liability, subject to revaluation of the liability on a recurring basis through the statement of operations.

Registration Rights Agreements

The Company has entered into registration rights agreements with purchasers of certain of its equity and debt securities. These registration rights agreements required the Company to register with the SEC the resale of shares issued or issuable to such persons. The Company's obligations to register shares in such transactions were subject to various deadlines, and the Company's failure to maintain the registration of these securities would result in financial penalties against the Company. All required registration statements related to these underlying securities have been filed, declared effective by the SEC and remain in effect as of June 30, 2011.

10. Stock-Based Compensation

2008 Incentive Plan

The pSivida Corp. 2008 Incentive Plan (the "2008 Plan") provides for the issuance of shares of common stock in satisfaction of stock-based awards to directors, executives, employees and consultants. Awards may include stock options, stock appreciation rights, restricted and unrestricted stock, deferred stock, performance awards, convertible securities and cash grants. At June 30, 2011, the number of shares reserved for issuance

under the 2008 Plan was 3,491,255, of which 709,063 shares were available for grant under the 2008 Plan. The 2008 Plan includes an "evergreen provision" that allows for an annual increase in the number of shares of common stock available for issuance under the 2008 Plan. Beginning on July 1, 2010, and on each subsequent anniversary date through July 1, 2017, the number of shares reserved for issuance under the 2008 Plan will be increased by the least of (i) 750,000 shares; (ii) 4% of the then outstanding shares of common stock; and (iii) any such lesser amount of shares of common stock as is determined by the Compensation Committee of the Board of Directors. On July 1, 2010, the number of shares reserved for issuance was increased by 741,255 shares, representing 4% of the outstanding shares at June 30, 2010. On July 1, 2011, the number of shares reserved for issuance was increased by 600,000.

A total of 762,980 options were granted during fiscal 2011 at exercise prices equal to the closing market price of the Company's common stock on the NASDAQ Global Market ("NASDAQ") on the respective option grant dates. Of this total, 371,705 options were issued to employees with ratable annual vesting over 4 years and 135,000 options were issued to non-employee directors with 1-year cliff vesting. The remaining 256,275 option are subject to both performance and service condition vesting. All option grants have a 10-year life.

The Company measures the fair value of options on their grant date using the Black-Scholes option-pricing model. Based upon limited option exercise history, the Company has generally used the "simplified" method outlined in SEC Staff Accounting Bulletin No. 107 to estimate the expected life of stock option grants. Management believes that the historical volatility of the Company's stock price on NASDAQ, for which there has been trading history for approximately 6.5 years, best represents the expected volatility over the estimated life of the option. The risk-free interest rate is based upon published U.S. Treasury yield curve rates at the date of grant corresponding to the expected life of the stock option. An assumed dividend yield of zero reflects the fact that the Company has never paid cash dividends and has no intentions to pay dividends in the foreseeable future.

The key assumptions used to apply the option pricing model for options granted under the 2008 Plan during the years ended June 30, 2011, 2010 and 2009 were as follows:

	2011	2010	2009
Option life (in years)	3.50 - 6.25	5.50 - 6.25	5.50 - 6.25
Stock volatility	95%	95%	80% - 95%
Risk-free interest rate	1.13% - 2.35%	2.36% - 2.62%	2.36% - 3.10%
Expected dividends	0.0%	0.0%	0.0%

The Company recognizes compensation expense for only the portion of options that are expected to vest. Based on historical trends, the Company applies estimated forfeiture rates to determine the numbers of awards that are expected to vest. Additional expense is recorded if the actual forfeiture rate for each tranche of option grants is lower than estimated, and a recovery of prior expense is recorded if the actual forfeiture rate is higher than estimated. The Company assesses the forfeiture rate at the end of each reporting period. The Company begins to record stock-based compensation expense for performance-based options at the time it becomes probable that the respective performance conditions will be achieved. The Company will continue to recognize the grant date fair value of performance-based options through the vesting date of the respective awards so long as it remains probable that the related performance conditions will be satisfied. The Company recorded $121,000 of stock-based compensation expense for the year ended June 30, 2011 related to performance-based options.

The following table summarizes information about stock options for the years ended June 30, 2011, 2010 and 2009:

	2011	2010	2009
Weighted-average grant date fair value, per share	$3.24	$3.10	$1.43
Total cash received from exercise of stock options	17	318	—
Total intrinsic value of stock options exercised	12	78	—

At June 30, 2011, there was approximately $1.35 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 1.6 years.

The following table provides a reconciliation of stock option activity under the 2008 Plan for fiscal 2011:

	Number of options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at July 1, 2010	1,966,000	$ 2.36		
Granted	762,980	3.45		
Exercised	(7,250)	2.38		
Forfeited	(112,085)	3.33		
Cancelled	(3,750)	2.50		
Outstanding at June 30, 2011	2,605,895	$ 2.63	8.05	$ 4,290
Outstanding at June 30, 2011—vested or unvested and expected to vest	2,479,303	$ 2.61	8.02	$ 4,142
Exercisable at June 30, 2011	1,088,250	$ 2.19	7.66	$ 2,272

Employee Share Option Plan

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

The following table provides a reconciliation of stock option activity under the Plan for fiscal 2011:

	Number of options	Weighted Average Exercise Price A$	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value A$
Outstanding at July 1, 2010	185,312	14.91		
Granted	—	—		
Forfeited	(9,219)	36.80		
Cancelled	(41,093)	36.80		
Outstanding and exercisable at June 30, 2011	135,000	6.75	1.09	—

At June 30, 2011 the weighted average exercise price of outstanding and exercisable options translated into US$ was $7.15.

Stock-Based Compensation Expense

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

	Year ended June 30,		
	2011	2010	2009
Compensation expense from:			
Stock options	$2,052	$1,385	$815
Issuance of fully vested shares	—	110	57
	$2,052	$1,495	$872
Compensation expense included in:			
Research and development	$ 400	$ 306	$216
General and administrative	1,652	1,189	656
	$2,052	$1,495	$872

11. Retirement Plans

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

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

The Company contributed a total of $160,000 for fiscal 2011, $153,000 for fiscal 2010 and $155,000 for fiscal 2009 in connection with these retirement plans.

12. Income Taxes

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

	Year Ended June 30,		
	2011	2010	2009
U.S. operations:			
Current income tax provision (benefit)	$ 96	$ 156	$ (19)
Deferred income tax benefit	(209)	—	(94)
	(113)	156	(113)
Non-U.S. operations:			
Current income tax benefit	(105)	(133)	(838)
Deferred income tax benefit	—	—	—
	(105)	(133)	(838)
Income tax (benefit) provision	$(218)	$ 23	$(951)

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

	Year Ended June 30,		
	2011	2010	2009
U.S. operations	$(5,519)	$12,353	$ 1,183
Non-U.S. operations	(3,327)	(3,577)	(4,645)
(Loss) income before income taxes	$(8,846)	$ 8,776	$(3,462)

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

	Year Ended June 30,		
	2011	2010	2009
Income tax (benefit) provision at statutory rate	$(3,008)	$ 2,984	$(1,177)
State income taxes, net of federal benefit	(350)	953	20
Non-U.S. income tax rate differential	228	180	218
Research and development tax credits	(106)	(132)	(838)
Changes in valuation allowance, including revisions of prior year estimates	3,045	(4,219)	771
Other, net	(27)	257	55
Income tax (benefit) provision	$ (218)	$ 23	$ (951)

The components of deferred income taxes are as follows:

	June 30,	
	2011	2010
Deferred tax assets:		
Net operating loss carryforwards	$23,799	$21,652
Deferred revenue	555	1,300
Stock-based compensation	1,608	842
Provision for losses on note receivable	511	520
Other	620	590
Total deferred tax assets	27,093	24,904
Deferred tax liabilities:		
Intangible assets	6,516	7,581
Deferred tax assets, net	20,577	17,323
Valuation allowance	20,590	17,545
Net deferred tax liability	$ 13	$ 222

The valuation allowances generally reflect limitations on the Company's ability to use the tax attributes and reduce the value of such attributes to the more likely than not realizable amount. The valuation allowance increased by $3.0 million during fiscal 2011 and decreased by $4.2 million during fiscal 2010.

The Company has tax loss carry forwards in its individual tax jurisdictions. At June 30, 2011, the Company had U.S. federal net operating loss carry forwards of approximately $44.8 million which expire at various dates between calendar years 2023 and 2028. The utilization of certain of these loss carry forwards may be limited by Section 382 of the Internal Revenue Code as a result of historical or future changes in the Company's ownership. At June 30, 2011, the Company had state net operating loss carry forwards of approximately $20.4 million, of

which approximately $13.3 million expires in 2012, $3.1 million expires in 2013 and $4.0 million expires in 2031. Additionally, at June 30, 2011 the Company had loss carry forwards in the U.K. of £18.0 million (approximately $28.8 million). During fiscal 2011, the Company recognized a current income tax benefit of $106,000 related to foreign research and development tax credits earned by its U.K. subsidiary.

The Company's U.S. federal income tax returns for calendar years 2002 through 2010 remain subject to examination by the Internal Revenue Service. The Company's U.K. tax returns for fiscal 2006 to 2010 remain subject to examination. The Australian tax returns for the former parent company for fiscal 2004 through 2008 remain subject to examination.

Through June 30, 2011, the Company had no unrecognized tax benefits in its consolidated statements of operations and no unrecognized tax benefits in its consolidated balance sheets as of June 30, 2011 or 2010.

As of June 30, 2011 and 2010, the Company had no accrued penalties or interest related to uncertain tax positions.

13. Commitments and Contingencies

Operating Leases

The Company leases its office and research laboratory space in Watertown, Massachusetts through April 6, 2014. In addition to base rent, the lease agreement requires the Company to pay for utilities, taxes, insurance, maintenance and other operating expenses. The Company leases laboratory and office space in Malvern, U.K. through June 2012, subject to a 6-month advance notice of cancellation by either party at any time. The Company also leases certain office equipment under operating lease agreements that expire through calendar year 2013.

At June 30, 2011, the Company's total future minimum lease payments under non-cancellable operating leases were as follows:

Fiscal Year:	
2012	$ 408
2013	370
2014	300
Thereafter	—
	$1,078

Rent expense related to operating leases charged to operations was approximately $449,000 for fiscal 2011, $449,000 for fiscal 2010 and $463,000 for fiscal 2009.

Litigation

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

14. Segment and Geographic Area Information

(a) Business Segment

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

(b) Geographic Area Information

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

	Revenues			Long-lived assets		
	2011	2010	2009	2011	2010	2009
United States	$4,882	$22,932	$12,085	$ 62	$29	$36
United Kingdom	83	121	77	61	14	30
Consolidated	$4,965	$23,053	$12,162	$123	$43	$66

15. Related Party Transactions

As of June 30, 2011, Pfizer owned approximately 9.0% of the Company's outstanding shares. The Company received research and development program payments from Pfizer under the Original Pfizer Agreement of $2.0 million during fiscal 2011, $2.0 million during fiscal 2010 and $1.5 million during fiscal 2009. In addition, in connection with consummation of the Restated Pfizer Agreement in June 2011, the Company received an upfront license fee of $2.3 million.

16. Quarterly Financial Data (unaudited)

The following table summarizes the quarterly results of operations for the years ended June 30, 2011 and 2010:

	Fiscal Year 2011				
	First Quarter Ended September 30, 2010	Second Quarter Ended December 31, 2010	Third Quarter Ended March 31, 2011	Fourth Quarter Ended June 30, 2011 (1)	Year Ended June 30, 2011 (1)
Total revenues	$ 476	$ 414	$ 360	$ 3,715	$ 4,965
Loss from operations	(3,435)	(3,121)	(3,139)	(308)	(10,003)
Net loss	(3,108)	(2,695)	(2,685)	(140)	(8,628)
Net loss per share:					
Basic and diluted	$ (0.17)	$ (0.15)	$ (0.13)	$ (0.01)	$ (0.44)
Weighted average common shares:					
Basic and diluted	18,531	18,531	20,177	20,745	19,489

	Fiscal Year 2010				
	First Quarter Ended September 30, 2009	Second Quarter Ended December 31, 2009	Third Quarter Ended March 31, 2010	Fourth Quarter Ended June 30, 2010 (2)	Year Ended June 30, 2010 (2)
Total revenues	$ 3,383	$ 3,433	$ 515	$ 15,722	$ 23,053
(Loss) income from operations	(107)	(113)	(2,863)	12,174	9,091
Net (loss) income	(1,591)	(24)	(2,705)	13,073	8,753
Net (loss) income per share:					
Basic	$ (0.09)	$ —	$ (0.15)	$ 0.71	$ 0.48
Diluted	$ (0.09)	$ —	$ (0.15)	$ 0.68	$ 0.46
Weighted average common shares:					
Basic	18,294	18,317	18,480	18,531	18,405
Diluted	18,294	18,317	18,480	19,217	18,895

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

(2) Results for the fourth quarter of fiscal 2010 included $15.2 million of revenue related to the payment in full by Alimera of a conditional note (see Note 3).

CONFIDENTIAL TREATMENT REQUESTED

Final Execution Version

AMENDED AND RESTATED

COLLABORATIVE RESEARCH AND LICENSE AGREEMENT

By and Among

pSivida Corp.

pSivida US, Inc.

pSiMedica Limited

and

Pfizer Inc.

Dated June 14, 2011

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CONFIDENTIAL TREATMENT REQUESTED

AMENDED AND RESTATED

COLLABORATIVE RESEARCH AND LICENSE AGREEMENT

This Amended and Restated Collaborative Research and License Agreement (the "Agreement"), dated as of June 14, 2011 (the "Effective Date"), is made by and among pSivida Corp., a Delaware corporation with offices located at 400 Pleasant Street, Watertown, Massachusetts, 02472, pSivida US, Inc., a Delaware corporation with offices located at 400 Pleasant Street, Watertown, Massachusetts 02472, pSiMedica Limited, a United Kingdom limited company with offices located at Malvern Hills Science Park, Geraldine Road, Malvern, Worcestershire, WR14 3SZ (collectively, "PSIVIDA") and Pfizer Inc., a Delaware corporation with offices located at 235 East 42nd Street, New York, New York, 10017 ("PFIZER"). PSIVIDA and PFIZER are sometimes referred to herein individually as a "Party" and collectively as the "Parties."

WHEREAS, PSIVIDA owns or otherwise controls certain patents, patent applications, technology, know-how and scientific and technical information relating to formulations for drug delivery and compatible devices;

WHEREAS PFIZER has extensive experience and expertise in the development and commercialization of pharmaceutical products;

WHEREAS, PFIZER and pSivida Inc. (now pSivida US Inc.) and pSivida Corp. (as successor to pSivida Limited) are currently party to a Collaborative Research and License Agreement dated April 3, 2007 (the "Prior Agreement");

WHEREAS PFIZER and PSIVIDA wish to enter into this Agreement to amend and restate the Prior Agreement as of the Effective Date;

NOW, THEREFORE, in consideration of the mutual covenants and agreements provided herein, PSIVIDA and PFIZER hereby agree as follows:

1. **Definitions.**

1.1 "Accused Device" shall have the meaning assigned to it in Section 8.3.2.

1.2 "Affiliate" means any entity directly or indirectly controlled by, controlling, or under common control with, a Party to this Agreement, but only for so long as such control shall continue. For purposes of this definition, "control" (including, with correlative meanings, "controlled by", "controlling" and "under common control with") means (a) possession, direct or indirect, of the power to direct or cause direction of the management or policies of an entity (whether through ownership of securities or other ownership interests, by contract or otherwise), or (b) beneficial ownership of at least fifty percent (50%) of the voting securities or other ownership interest (whether directly or pursuant to any option, warrant or other similar arrangement) or other comparable equity interests of an entity.

1.3 "Alimera" means Alimera Sciences, Inc.

1.4 "Alimera Agreement" means the Amended and Restated Collaboration Agreement between pSivida, Inc. (f/k/a Control Delivery Systems, Inc.) and Alimera dated as of March 14, 2008 as in existence and effect as of the Effective Date.

1.5 "Antecedent Product" means, with respect to a specific Generic Product, (a) in the United States, the Product referenced as the listed drug for a new drug application that is submitted pursuant to Section 505(j) of the FDCA and (b) in any country outside the United States, the Product referenced in an analogous manner under an analogous application process.

1.6 "B&L" means Bausch & Lomb Incorporated.

1.7 "B&L Agreement" means the Amended and Restated License Agreement between Control Delivery Systems, Inc. (presently, PSIVIDA) and B&L dated as of December 9, 2003 as in existence and effect on the Effective Date.

1.8 "Business Day" means a day other than a Saturday, Sunday, or bank or other public holiday in New York, New York or Boston, Massachusetts.

1.9 "Change of Control" means, with respect to a Party or its parent corporation, (a) a merger or consolidation of such Party or such parent corporation with a Third Party which results in the voting securities of such Party or such parent corporation outstanding immediately prior thereto ceasing to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger or consolidation, or (b) a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the beneficial owner of fifty percent (50%) or more of the combined voting power of the outstanding securities of such Party or such parent corporation, or (c) the sale or other transfer to a Third Party of all or substantially all of such Party's assets or business or substantially all of such Party's ophthalmic assets or business.

1.10 "Clinical IP" means (a) all preclinical and clinical protocols, studies, data, results, study-related forms, materials (excluding solely the Compound) and reports (e.g., investigator brochures, informed consent forms, data safety monitoring board related documents, patient recruitment related materials, biocompatibility studies, animal studies, safety studies, and chemistry, manufacturing and control data) resulting from any preclinical or clinical study or trial of the Product or generated in the course of the Development Program, (b) any certificates of any audit of any such preclinical or clinical study or trial, any record or report of any audit of such preclinical or clinical study or trial containing a finding that involves the absence or failure of a critical process, system or related component, a key internal control and/or an issue with considerable risk to a Party and which warrants immediate remediation to address, and any other audit record or report of such preclinical or clinical study to the extent necessary to respond to a request, requirement, or order by a Government Authority, upon the request of the Party that is the subject of the Government Authority's request, requirement, or order, and (c) all INDs, NDAs, any unfiled applications, components or materials normally associated with an IND or NDA, regulatory filings or applications comparable to INDs or NDAs in any foreign jurisdictions, drug master files, and other regulatory applications and Regulatory Approvals regarding the Product (excluding any of the foregoing relating to the Compound apart from the Product).

1.11 "Clinical Trials" means all Phase I/II Clinical Trials, Phase II Clinical Trials and Phase III Clinical Trials, or such analogous studies and trials of a medical device as are intended to establish scientifically valid evidence to be submitted in an application to a Regulatory Authority for the Product.

1.12 "Clinical Supply Requirements" means the quantities of the Compound or Product that are required for the conduct of Clinical Trials or Non-NDA Trials.

1.13 "Cost of Clinical Supplies" means the out-of-pocket costs that a Party pays to Third Parties for the manufacture and supply of Clinical Supply Requirements pursuant to this Agreement.

1.14 "Commence" or "Commencement" when used with respect to a clinical trial, means the first dosing of the first patient for such trial.

1.15 "Commercially Reasonable Efforts" means those efforts and resources consistent with the usual practice of a Party in pursuing the development or commercialization of its own products that are of similar market potential as the Product in the Field, taking into account all relevant factors including resource and workload constraints, product labeling or anticipated labeling, present and future market potential, past performance of the Product in the Field and such Party's own products that are of similar market potential, financial return, medical and clinical considerations, present and future regulatory environment and competitive market conditions, all as measured by the facts and circumstances at the time such efforts are due.

1.16 "Compound" means latanoprost, which has the chemical name: isopropyl-(Z)-7[(1R,2R,3R,5S)3,5-dihydroxy-2-[(3R)-3-hydroxy-5-phenylpentyl]cyclopentyl]-5-heptenoate) and is also known as 13, 14-dihydro-17-phenyl-18, 19, 20-trinor PGF2alpha isopropyl ester, and free acid(s) and salt(s) thereof.

1.17 "Confidential Information" means either the PFIZER Confidential Information or the PSIVIDA Confidential Information, or both, as the context may require.

1.18 "Control" or "Controlled" means, with respect to any intellectual property right, that the Party (i) owns or (ii) has a license to such intellectual property right and has the ability to grant the other Party access, a license, or a sublicense (as applicable) to such intellectual property right as provided herein, without violating the terms of any agreement or other arrangement with any Third Party existing at the time such Party would be first required hereunder to grant the other Party such access, license or sublicense (such ability, the "Right to Grant a Sublicense").

1.19 "Courts" shall have the meaning assigned to it in Section 15.2.

1.20 "Development Plans" means the Pre-POC Development Plan and the PFIZER Development Plan.

1.21 "Development Program" means the clinical, regulatory, development and associated activities for a Product conducted under this Agreement and the Prior Agreement.

1.22 "Development Term" means the period commencing on the Effective Date and ending on the date of the First Commercial Sale.

1.23 "Device" means a bioerodible device for injection or implantation in or adjacent to the eye that has a core, which core contains a drug, and which core is completely or partially surrounded by a polymer layer or tube.

1.24 "Excluded PSIVIDA Affiliate IP" shall mean any Patent Rights and Technology Controlled by any Third Party that becomes an Affiliate of PSIVIDA following a Change of Control of PSIVIDA, to the extent, but only to the extent, that such Patent Rights or Technology: (i) are Controlled by such future Affiliate of PSIVIDA at the time such Affiliate becomes an Affiliate of PSIVIDA (other than pursuant to any license or other grant of rights by PSIVIDA or any other Affiliate of PSIVIDA to such future Affiliate) or (ii) are subsequently Controlled by such Affiliate but are developed independently of and without the use of any Patent Rights and Technology Controlled by PSIVIDA as of or prior to the time such Affiliate becomes an Affiliate of PSIVIDA.

1.25 "Faber" means Faber Research LLC.

1.26 "Faber Agreement" means the License Agreement by and between Faber Research LLC and pSivida Limited dated January 3, 2007 and as in existence and effect as of the Effective Date.

1.27 "FDA" means the United States Food and Drug Administration or any successor agency thereto.

1.28 "FDCA" means the U.S. Federal Food, Drug and Cosmetic Act, as amended, and the regulations promulgated thereunder.

1.29 "Field" means the treatment, control or prevention of any ophthalmic disease or condition in humans excluding uveitis.

1.30 "Firm Order" has the meaning assigned to it in Section 5.5.2.

1.31 "Final Report" has the meaning assigned to it in Section 3.4.

1.32 "Formulation" means a solid, solution or suspension suitable for the ocular delivery of the Compound for use with the Device.

1.33 "First Commercial Sale" means the first shipment of a Product in commercial quantities for commercial sale by PFIZER, its Affiliates or its sublicensees to a Third Party in an arm's length transaction in a country in the Territory after receipt by PFIZER of the first Regulatory Approval for such Product in such country.

1.34 "Funding Option Notice" has the meaning assigned to it in Section 3.5.

1.35 "Generic Product" means a Device that (i) is sold by a Third Party that is not a licensee or sublicensee of a Party or its Affiliates, or any of their licensees or sublicensees, under

a marketing authorization granted by a Regulatory Authority to such Third Party; (ii) contains the Compound as its sole active pharmaceutical ingredient; and (x) for purposes of the United States, is approved under an abbreviated new drug application that is submitted pursuant to Section 505(j) of the FDCA (or any successor thereto) and that references a Product as its listed drug or (y) for purposes of a country outside the United States, is approved by the applicable Regulatory Authority under an analogous application process.

1.36 "Glaucoma" means any of a group of neuropathies (including without limitation primary open angle glaucoma, angle closure glaucoma and normal tension glaucoma) or conditions where the goal of treatment is to reduce intraocular pressure.

1.37 "Governmental Authority" means any court, agency, department, authority or other instrumentality of any nation, state, county, city or other political subdivision.

1.38 "Government Official" has the meaning assigned to it in Section 10.1.9.

1.39 "HSR Act" shall mean the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the rules and regulations promulgated thereunder.

1.40 "HSR Filing" shall mean filings by PFIZER and PSIVIDA with the United States Federal Trade Commission and the Antitrust Division of the United States Department of Justice of a Notification and Report Form for Certain Mergers and Acquisitions (as that term is defined in the HSR Act) with respect to the matters set forth in this Agreement, together with all required documentary attachments thereto.

1.41 "HSR Clearance Date" shall mean the earliest date on which the Parties have actual knowledge that all applicable waiting periods under the HSR Act with respect to the transactions contemplated hereunder have expired or have been terminated.

1.42 "IND" means the Investigational New Drug Application or, if applicable, the Investigational Device Exemption application, filed with FDA, or a similar application filed with an applicable Regulatory Authority outside of the United States.

1.43 "Indemnified Party" shall have the meaning assigned to it in Section 14.4.

1.44 "Indemnifying Party" shall have the meaning assigned to it in Section 14.4.

1.45 "Infringer" has the meaning assigned to it in Section 8.3.2.

1.46 "Joint Steering Committee" and "JSC" have the meaning assigned to them in Section 2.1.

1.47 "Kentucky Study Agreement" means the means the Investigator Initiated Research Agreement dated as of June 1, 2010 among PFIZER, PSIVIDA and the University of Kentucky Research Foundation.

1.48 "Laws" means all laws, statutes, rules, regulations, orders, judgments and/or ordinances of any Governmental Authority.

1.49 "Litigation Condition" shall have the meaning assigned to it in Section 14.4.1.

1.50 "Losses" shall have the meaning assigned to it in Section 14.2.

1.51 "Major EU Countries" means the United Kingdom, Spain, Italy, France and Germany.

1.52 "Market Penetration" shall mean, with respect to a Product, on a country-by-country and Product-by-Product basis, (a) the quantity of all Generic Products for which such Product is the Antecedent Product sold in the applicable country divided by (b) the total quantity of such Antecedent Product and all such Generic Product sold in the applicable country (quantity of product sold based on data provided by IMS International or, if such data is not available from IMS International, such other reliable data source as reasonably determined by PFIZER and reasonably agreed by PSIVIDA).

1.53 "NDA" means a New Drug Application or a Biological License Application filed with the FDA in accordance with the FDCA with respect to a pharmaceutical or biologic product or a similar application filed with an applicable Regulatory Authority outside of the United States (including any supra national agency such as the European Union) for the purpose of obtaining approval to market and sell a pharmaceutical or biological product in such jurisdiction in the Territory.

1.54 "Net Sales" means with respect to a Product, the gross amount invoiced by PFIZER, its Affiliates and its sublicensees of such Product to Third Parties, less, without duplication, the following to the extent actually invoiced, paid, granted or accrued: sales returns and allowances, trade, quantity and cash discounts and adjustments granted on account of billing errors, rejected goods, damaged or defective goods, recalls, returns, rebates, chargeback rebates, reimbursements or similar payments granted or given to wholesalers or other distributors, buying groups, health care insurance carriers or other institutions; adjustments arising from consumer discount programs or other similar programs; customs or excise duties, sales tax, consumption tax, value added tax, and other taxes (except income taxes) or duties relating to sales; any reductions of payment in respect of sales to the United States government, any state government or any foreign government, or to any other Governmental Authority, or with respect to any government-subsidized program or managed care organization (provided that any reductions, discounts or adjustments that apply collectively to multiple products including the Product shall be allocated pro rata to the amounts invoiced for Products); and freight and insurance (to the extent that PFIZER bears the cost of freight and insurance for a Product). Net Sales shall be determined from books and records maintained in accordance with generally acceptable accounting principles in the United States, as consistently applied by PFIZER with respect to sales of all its pharmaceutical or biologic products.

If the Product is sold as part of a bundle of distinct products (i.e., one price is charged for a number of distinct products), the Net Sales for the Product shall be, on a country-by-country basis, the greater of (a) the gross amount invoiced by PFIZER its Affiliates and its sublicensees of such bundle to Third Parties in such country, multiplied by the ratio of the list price for such Product in such country to the sum of the list prices for each product in such bundle in such country (by way of example, if the list price for such Product when sold separately is $10, and

the sum of the list prices for each product in such bundle when sold separately is $40, then the Net Sales attributable to the Product when sold as part of the bundle would be twenty five percent (25%) of the Net Sales of the bundle of products sold) and (b) the number of units of the Product sold by PFIZER, its Affiliates and its sublicensees in such country to Third Parties as part of a bundle, multiplied by the average gross amount invoiced to Third Parties during the relevant PFIZER Quarter for a unit of the Product sold separately in such country (i.e., on a stand-alone basis solely for monetary consideration), or, in the absence of such transactions, the fair market value for the Product, in each case less, without duplication, the deductions described above.

1.55 "Non-NDA Trial" means any clinical trial, or part of a clinical trial, for the Product that is not designed or required to procure data necessary for the acceptance of filing an NDA. Non-NDA Trials may be conducted before or after the filing of an NDA, before Regulatory Approval for the Product or at any time after Regulatory Approval for the Product.

1.56 "Non-Sequential Milestone" shall have the meaning assigned to it in Section 6.3.1.

1.57 "Patent Costs" means the fees and costs associated with filing, prosecution and maintenance of Patent Rights in the Territory.

1.58 "Patent Rights" means all patents and patent applications, whether domestic or foreign, including all continuations, continuations-in-part, divisionals, provisionals and renewals, and letters of patent granted with respect to any of the foregoing, patents of addition, supplementary protection certificates, registration or confirmation patents and all reissues, re-examination and extensions thereof. In all cases, inventorship will be determined in accordance with U.S. law.

1.59 "Patient Outcomes Tool" means a method for identifying clinical trial subjects, which method meets the following criteria: (a) such method is intended to be used in both a clinical trial and clinical use setting; (b) such method does not require the performance of significant additional activities besides completion of a brief questionnaire and clinical status observations; (c) such method is actually used in a Phase II Clinical Trial of the Product except as otherwise provided in this Section 1.59; and (d) if such method is used in a Phase II Clinical Trial, the use of such method in such Phase II Clinical Trial is intended to (i) demonstrate the utility of such method and (ii) provide evidence of the validity of such method and its appropriateness for use in a Phase III Clinical Trial. Notwithstanding anything to the contrary in this Agreement, the foregoing requirements shall not apply if (x) compliance with applicable Law renders compliance with such requirement impracticable or impossible; (y) compliance with such requirement is not authorized by any Governmental Authority or Regulatory Authority or is not consistent with a Regulatory Approval; or (z) compliance with such requirement is prohibited by, or would impede, delay or adversely impact the approval of the Product by, any Governmental Authority or Regulatory Authority.

1.60 "Person" means an individual, corporation, partnership, company, joint venture, unincorporated organization, limited liability company or partnership, sole proprietorship,

association, bank, trust company or trust, whether or not legal entities, or any Governmental Authority.

1.61 "PFIZER Confidential Information" means all information relating to PFIZER Technology or PFIZER Program Technology, as well as any other information regarding the technology, business and operations of PFIZER of any of its Affiliates, that is or has been disclosed (whether orally or in writing) by PFIZER or its Affiliates to PSIVIDA or its Affiliates to the extent that such information is not (i) as of the date of disclosure known to PSIVIDA or its Affiliates; or (ii) disclosed in published literature, or otherwise generally known to the public through no breach by PSIVIDA of this Agreement; or (iii) obtained by PSIVIDA or its Affiliates from a Third Party free from any obligation of confidentiality to PFIZER; or (iv) independently developed by PSIVIDA or its Affiliates without use of the PFIZER Confidential Information; or (v) required to be disclosed under Law; provided that, in the case of (v), PSIVIDA provides PFIZER prior notice (to the extent practicable) of such disclosure and agrees to cooperate, at the request and sole expense of PFIZER, with PFIZER's efforts to preserve the confidentiality of such information.

1.62 "PFIZER Controlled Intellectual Property" means the Patent Rights and Technology Controlled by PFIZER or any of its Affiliates as of the date of a termination described in Section 13.3.2 that are necessary to develop, make, sell, offer for sale, use and import the Product in substantially the form the Product exists on such date of termination, but not including PFIZER Technology, the PFIZER Program Technology, the PFIZER Program Patent Rights, the PFIZER Patent Rights, and Clinical IP Controlled by PFIZER or any of its Affiliates.

1.63 "PFIZER Development Plan" means, with respect to the Product, a strategy and planning document for all research and development activities to be conducted pursuant to this Agreement up to and including filing an NDA, which document shall describe in reasonable detail the Commercially Reasonable Efforts activities to be undertaken by PFIZER (including Clinical Trials, seeking Regulatory Approvals and manufacturing activities) and the expected timing of each activity.

1.64 "PFIZER Option Date" shall have the meaning assigned to it in Section 3.6.1.

1.65 "PFIZER Patent Rights" means the Patent Rights set forth on Schedule 1.65 and any Patent Rights that may issue from or claim priority to or through the Patent Rights set forth on Schedule 1.65.

1.66 "PFIZER Program Patent Rights" means Program Patent Rights (other than PSIVIDA Program Patents Rights) that are determined by United States law to be owned by PFIZER or any of its Affiliates, including without limitation the Program Patent Rights set forth on Schedule 1.66 and any Program Patent Rights that may issue from or claim priority to or through the Program Patent Rights set forth on Schedule 1.66.

1.67 "PFIZER Program Technology" means Program Technology (other than PSIVIDA Program Technology) that is determined by United States law to be owned by PFIZER or any of its Affiliates and includes relevant PFIZER Confidential Information.

1.68 "PFIZER Quarter" means (A) for the first three (3) quarters in any calendar year, the three (3) successive thirteen (13) week periods (i) with respect to the United States, commencing on January 1 of any calendar year, and (ii) with respect to any country in the Territory other than the United States, commencing on December 1 of any calendar year, and (B) for the fourth (4th) quarter in any calendar year, the period commencing on the day after the end of the third successive thirteen (13) week period in (A) above and (i) with respect to the United States, ending on December 31 of any calendar year, and (ii) with respect to any country in the Territory other than the United States, ending on November 30 of any calendar year.

1.69 "PFIZER Technology" means any Technology and know-how (including Pfizer Confidential Information) owned, licensed or otherwise Controlled by PFIZER or any of its Affiliates as of the Effective Date.

1.70 "PFIZER Year" means the twelve (12) month period (i) with respect to the United States, commencing on January 1 of any calendar year, and (ii) with respect to any country in the Territory other than the United States, commencing on December 1 of any calendar year.

1.71 "Phase I/II Clinical Trial" means a first in human clinical trial that is primarily intended to test the safety of the Product for a specific indication in patients with the disease or condition under study, or an analogous study or trial of a medical device intended to evaluate scientifically valid evidence to be submitted in an application to a Regulatory Authority for the applicable Product.

1.72 "Phase II Clinical Trial" means a Phase II Clinical Trial that is primarily intended to evaluate the effectiveness and dosing regimen for use in a Phase III Clinical Trial of a Product for a specific indication or an analogous study or trial of a medical device intended to establish scientifically valid evidence to be submitted in an application to a Regulatory Authority for the applicable Product.

1.73 "Phase III Clinical Trial" means a clinical trial intended to meet the requirements for approval of an NDA for the Product, or an analogous study or trial of a medical device intended to establish scientifically valid evidence to be submitted in an application to a Regulatory Authority for the Product.

1.74 "Pre-POC Development Plan" means the plan prepared by PSIVIDA setting forth research and development activities to be conducted prior to and including Proof-of-Concept. Such plan will include details regarding the development activities for the Phase II Clinical Trials for the Product and the development of the Patient Outcomes Tool, which activities will include those summarized on Schedule 1.74.

1.75 "Price Approval" means, in any country where a Governmental Authority authorizes reimbursement for, or approves or determines pricing for, pharmaceutical products, receipt (or, if required to make such authorization, approval or determination effective, publication) of such reimbursement authorization or pricing approval or determination (as the case may be).

1.76 "Product" means a Device that meets all of the following criteria: (A) it has a core within a polymer tube, which core contains the Compound and no other active ingredient, (B) it

receives Regulatory Approval or is designed to receive Regulatory Approval to deliver the Compound and no other active ingredient by subconjunctival injection and no other delivery method, (C) it is bioerodible, and (D) [*]. For the avoidance of doubt, Product shall not include the following: (i) the "First Generation Exclusive Licensed Product" and the "Vitrasert Licensed Product," each as defined under the B&L Agreement, and (ii) the "First Product," "Product," "Excluded Product," or "Option Product" (to the extent PSIVIDA has granted a license covering such Option Product pursuant to Section 5.8 of the Alimera Agreement), each as defined under the Alimera Agreement.

1.77 "Program Patent Rights" means all Patent Rights that cover Program Technology and includes PSIVIDA Program Patent Rights and PFIZER Program Patent Rights. For the avoidance of doubt, Program Patent Rights shall not include CDS Improvements (as defined in the Alimera Agreement).

1.78 "Program Technology" means Technology relating to the Product that is or was (a) invented, created or developed by officers, employees or agents of, or consultants to, PSIVIDA or any of its Affiliates, alone or jointly with Third Parties, in the course of conducting activities under the Development Program, (b) jointly invented, created or developed by officers, employees or agents of, or consultants to, both PSIVIDA and PFIZER or any of their respective Affiliates or sublicensees, in each case, alone or jointly with Third Parties, in the course of conducting activities under the Development Program, (c) invented, created or developed by officers, employees or agents of, or consultants to, PFIZER or any of its Affiliates or sublicensees, alone or jointly with Third Parties, in the course of conducting activities under the Development Program, or (d) acquired by purchase, license, assignment or other means from Third Parties by PSIVIDA or any of its Affiliates, by PSIVIDA and PFIZER or any of their respective Affiliates or by PFIZER or any of its Affiliates, in each case, alone or jointly with Third Parties, in order for such Party (or Parties) to perform obligations under the Development Program. For the avoidance of doubt, Program Technology shall not include CDS Improvements (as defined in the Alimera Agreement).

1.79 "Proof-of-Concept" means the time when a Phase II Clinical Trial for the Product that includes the activities set forth in Schedule 1.74 has been completed.

1.80 "PSIVIDA Confidential Information" means all information relating to PSIVIDA Technology or PSIVIDA Program Technology, as well as any other information regarding the technology, business and operations of PSIVIDA or any of its Affiliates, that is or has been disclosed (whether orally or in writing) by PSIVIDA or any of its Affiliates to PFIZER or its Affiliates to the extent that such information is not (i) as of the date of disclosure to PFIZER, known to PFIZER or its Affiliates; or (ii) disclosed in published literature, or otherwise generally known to the public through no breach by PFIZER of this Agreement; or (iii) obtained by PFIZER or its Affiliates from a Third Party free from any obligation of confidentiality to PSIVIDA; or (iv) independently developed by PFIZER or its Affiliates without use of the PSIVIDA Confidential Information; or (v) required to be disclosed under Law; provided that, in the case of (v), PFIZER provides PSIVIDA prior notice (to the extent practicable) of such disclosure and agrees to cooperate, at the request and sole expense of PSIVIDA, with PSIVIDA's efforts to preserve the confidentiality of such information.

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1.81 "PSIVIDA Controlled Intellectual Property" means the Patent Rights and Technology Controlled by PSIVIDA or any of its Affiliates as of the PFIZER Option Date that are necessary to develop, make, sell, offer for sale, use and import the Product in substantially the form the Product exists on the PFIZER Option Date, but not including the Excluded PSIVIDA Affiliate IP, PSIVIDA Technology, the PSIVIDA Program Technology, the PSIVIDA Program Patent Rights, the PSIVIDA Patent Rights, Clinical IP Controlled by PSIVIDA or any of its Affiliates and the PSIVIDA Confidential Information.

1.82 "PSIVIDA Patent Rights" means the Patent Rights set forth on Schedule 1.82 and any Patent Rights that may issue from or claim priority to or through the Patent Rights listed on Schedule 1.82.

1.83 "PSIVIDA Program Patent Rights" means (a) all Program Patent Rights to the extent that that they claim (i) modifications, improvements and advancements to the Device (but not including Program Patent Rights that solely and specifically claim improvements to the Device with the Compound), (ii) methods of manufacture or monitoring the Device (but not including Program Patent Rights that solely and specifically claim methods of manufacturing or monitoring the Device with the Compound); (iii) the Device with any composition of matter (but not including Program Patent Rights that solely and specifically claim the Device with the Compound); and (iv) method of use claims except for method of use claims that solely and specifically claim (A) the Device with the Compound or (B) Formulations with respect to the Compound, in each case (i)-(iv) regardless of the identity of the inventors; and (b) Program Patent Rights that are determined by United States law to be owned by PSIVIDA or any of its Affiliates, and including without limitation the Program Patent Rights set forth on Schedule 1.83.

1.84 "PSIVIDA Program Technology" means (a) all Program Technology to the extent that it relates to (i) modifications, improvements and advancements to the Device (but not including Program Technology that solely and specifically relates to improvements to the Device with the Compound), (ii) methods of manufacture or monitoring the Device (but not including Program Technology that solely and specifically relates to methods of manufacturing or monitoring the Device with the Compound); (iii) the Device with any composition of matter (but not including Program Technology that solely and specifically relates to the Device with the Compound); and (iv) method of use claims except for method of use claims that solely and specifically claim (A) the Device with the Compound or (B) Formulations with respect to the Compound, in each case (i)-(iv) regardless of the identity of the inventors; and (b) Program Technology that is determined by United States law to be owned by PSIVIDA or any of its Affiliates.

1.85 "PSIVIDA Reserved Interests" shall have the meaning assigned to it in Section 16.3.1.

1.86 "PSIVIDA Technology" means any Technology owned or otherwise Controlled by PSIVIDA or any of its Affiliates as of the Effective Date.

1.87 "PSIVIDA Valid Claim" means any claim from (a) an issued and unexpired patent included within the PSIVIDA Patent Rights or PSIVIDA Program Patent Rights that has not been revoked or held unenforceable or invalid by a final decision of a court or other

Governmental Authority of competent jurisdiction, unappealable or unappealed within the time allowed for appeal or that has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer or otherwise; or (b) a patent application included within the PSIVIDA Patent Rights or PSIVIDA Program Patent Rights; provided however, that such a claim from a patent application has not been canceled, withdrawn, or abandoned [*]. If a claim of a patent application ceases to be a PSIVIDA Valid Claim under item (b) because of the passage of time and later issues as part of a patent within item (a), then it shall again be considered to be a PSIVIDA Valid Claim effective as of the earlier of the grant, allowance or issuance of such patent.

1.88 "Regulatory Approval" means any and all approvals, with respect to any jurisdiction, or authorizations (other than Price Approvals) of a Regulatory Authority, that are necessary for the commercial manufacture, distribution, use, marketing or sale of a pharmaceutical product in such jurisdiction.

1.89 "Regulatory Authority" means, in respect of a particular country or jurisdiction, the Governmental Authority having responsibility for granting Regulatory Approvals in such country or jurisdiction.

1.90 "Representatives" shall have the meaning assigned to it in Section 14.1.1.

1.91 "Right of Reference" means the right of a Party and its licensees or designees to reference or cross-reference Clinical IP in any regulatory applications or filings.

1.92 "Right to Grant a Sublicense" shall have the meaning assigned to it in Section 1.18.

1.93 "Royalty Term" means, on a country-by-country and Product-by-Product basis, the period commencing upon First Commercial Sale of a Product in a country and ending upon the later to occur of: (i) the date on which such Product is no longer covered by a PSIVIDA Valid Claim in such country; and (ii) [*] from the date of First Commercial Sale of such Product in such country.

1.94 "Technology" means all inventions, materials, technology, data, technical and scientific information, know-how, expertise and trade secrets, and intellectual property rights embodying any of the foregoing, but excluding any Patent Rights.

1.95 "Term" means the period of time commencing on the Effective Date and ending on the earlier of (a) the last to expire Royalty Term or (b) the effective date of termination of this Agreement pursuant to the terms hereof.

1.96 "Territory" means the entire world.

1.97 "Third Party" means any person or entity other than PFIZER, PSIVIDA, or any of their respective Affiliates.

1.98 "Third Party Claim" shall have the meaning assigned to it in Section 14.4.

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1.99 Construction. Except where expressly stated otherwise in this Agreement, the following rules of interpretation apply to this Agreement: (i) "include", "includes" and "including" are not limiting and mean include, includes and including, without limitation; (ii) definitions contained in this Agreement are applicable to the singular as well as the plural forms of such terms; (iii) references to an agreement, statute or instrument mean such agreement, statute or instrument as from time to time amended, modified or supplemented; (iv) references to a person are also to its permitted successors and assigns; (v) references to an "Article", "Section", "Exhibit" or "Schedule" refer to an Article or Section of, or any Exhibit or Schedule to, this Agreement unless otherwise indicated; (vi) the word "will" shall be construed to have the same meaning and effect as the word "shall"; (vii) the word "any" shall mean "any and all" unless otherwise indicated by context and (viii) references to "dollars" or "$" shall refer to United States Dollars.

2. **Management of the Development Program.**

2.1. Joint Steering Committee. The research and development activities conducted under this Agreement shall be overseen by a joint research committee composed of two (2) (or such larger number mutually agreed to by the Parties) representatives from each Party (the "Joint Steering Committee" or "JSC"). An alternate member designated by a Party may serve temporarily in the absence of a permanent member of the JSC for such Party. Each Party shall designate one of its representatives as a co-chair of the JSC. The co-chairs of the JSC shall be jointly responsible for setting the agenda for each meeting, and each co-chair will be responsible for chairing alternating JSC meeting. From time to time, the JSC may establish subcommittees or subordinate committees (that may or may not include members of the JSC itself) to oversee particular projects or activities, and such subcommittees or subordinate committee shall be constituted and shall operate as the JSC agrees. After the First Commercial Sale of the Product the JSC shall be disbanded. The initial members of the JSC shall be designated by each Party promptly after the Effective Date. For the avoidance of doubt, following the PFIZER Option Date, the Parties agree that PSIVIDA's participation in the JSC is not an obligation, and PSIVIDA may, in its discretion, participate or not participate from time to time.

2.2. Decision-Making. Except as otherwise set forth in this Agreement, all decisions of the JSC made pursuant to this Agreement shall be made by consensus; provided, however, that:

2.2.1. PSIVIDA shall have final decision-making authority (if unresolved after escalation to members of senior management as set forth in Section 2.3) with respect to research and development activities for the Product at any time prior to the PFIZER Option Date.

2.2.2. Following the PFIZER Option Date, PFIZER shall have final decision-making authority (if unresolved after escalation to members of senior management as set forth in Section 2.3) with respect to research and development activities for the Product.

2.3. Dispute Resolution. The representatives of each Party on the JSC shall each have one vote and no vote shall be taken at a meeting of the JSC unless all members of the JSC are present and participating in the vote. In the event a matter is not resolved by unanimous consent of the JSC, or in the event the Parties are unable to agree upon matters relating to a Development Plan, the matter shall be referred to senior management of the Parties for resolution. In the event such members of senior management are unable to resolve the dispute within fifteen (15) days of such referral, the Party having final decision-making authority pursuant to Section 2.2 shall make the final decision on such matter.

2.4. Meetings. The JSC shall hold meetings at such times and places as shall be determined by the co-chairs of the JSC (it being expected that any in-person meetings will alternate between the appropriate offices of each Party), but in no event shall such meetings be held less frequently than once every calendar quarter during the Development Term. The JSC may:

2.4.1. conduct meetings in person, by videoconference or by telephone conference; and

2.4.2. invite other personnel of the Parties to attend meetings of the JSC as appropriate to the agenda for such meeting, after giving advance notice to the other Party.

2.5. Minutes. At each meeting, the JSC shall elect a secretary who will prepare minutes after each meeting, reporting in reasonable detail the actions taken by the JSC during such meeting, issues requiring resolution, and resolutions of previously reported issues. Such minutes are to be reviewed and, if reasonably complete and accurate, signed by one JSC member from each Party. The secretary shall revise such minutes as necessary to obtain such signatures.

2.6. JSC Functions and Powers. The research and development activities of the Parties performed in accordance with this Agreement shall be managed only to the extent set forth herein, unless otherwise agreed to by the Parties in writing. The JSC shall foster the collaborative relationship between the Parties in order to assist each Party in fulfilling its obligations under the Development Plans, and shall in particular have the functions and powers set forth below.

2.6.1. With respect to the Product, the JSC shall:

(a) encourage and facilitate ongoing cooperation and information exchange between the Parties;

(b) monitor the progress of the Development Plans and the Parties' diligence in carrying out their responsibilities thereunder; provided, however, that the JSC shall not have the authority to make any determination that either Party is in breach of its obligations under a Development Plan or this Agreement;

(c) review and comment on the Development Plans; and

(d) perform such other functions as appropriate to further the purposes of this Agreement as mutually determined by the Parties.

2.6.2. For the avoidance of doubt, the JSC shall have no power to amend this Agreement or a Development Plan and shall have only such powers as are specifically delegated to it in this Agreement.

2.7. Independence. Subject to the terms of this Agreement, the activities and resources of each Party shall be managed by such Party, acting independently and in its individual capacity. The relationship between PSIVIDA and PFIZER is that of independent contractors and neither Party shall have the power to bind or obligate the other Party in any manner, other than as is expressly set forth in this Agreement. PSIVIDA and PFIZER are not joint venturers, partners, principal and agent, employer and employee, and have no other relationship other than independent contracting parties.

3. **Development**.

3.1. Pre-POC Development Plan. Commencing on the first anniversary of the Effective Date and on or prior to each anniversary thereafter until the PFIZER Option Date, and at such additional times as PSIVIDA in its sole discretion may choose, PSIVIDA shall update the Pre-POC Development Plan.

3.2. Development Costs Prior to Proof-of-Concept. PSIVIDA shall use Commercially Reasonable Efforts to conduct, directly or through its agents and contractors, the activities set forth in the Pre-POC Development Plan at PSIVIDA's sole expense, unless PSIVIDA elects to cease development under Section 3.3.

3.3. Ceasing Development Prior to Proof of Concept. PSIVIDA may elect to cease development at any time after the first anniversary of the Effective Date but prior to Proof-of-Concept. PSIVIDA shall notify PFIZER of such election. After providing such notice, PSIVIDA shall have no further obligations with respect to the Product under this Agreement. PFIZER shall have the right to elect to solely fund further development and commercialization of the Product, provided that PFIZER makes such election and notifies PSIVIDA no later than sixty (60) days after receiving notice from PSIVIDA pursuant to this Section 3.3, such notice by PFIZER to be deemed a Funding Option Notice. In the event PFIZER submits a Funding Option Notice as set forth in the preceding sentence, the terms of Section 3.6 shall apply, including the obligation to make the payments pursuant to Section 3.6.1, as well as all other terms of this Agreement that apply to the Product; provided, however, that if PSIVIDA elects to cease development prior to achieving Proof-of-Concept for the Product and PFIZER submits such Funding Option Notice, all amounts otherwise payable by PFIZER under Section 3.6.1 or Section 6 shall be reduced by [*]. In the event PFIZER does not submit a Funding Option Notice with respect to the Product, neither Party shall have any further rights or obligations under this Agreement and the Agreement shall automatically terminate at the end of the sixty-day election period, after which termination nothing in this Agreement shall be construed as limiting PSIVIDA's right, alone or with or through other Persons, to develop, manufacture and commercialize the Product, which development, manufacturing and commercialization activities shall not be subject to this Agreement; provided, however, that if PSIVIDA provides the notice referred to

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in this Section 3.3 but does not actually cease all development activities with respect to the Product for at least one year, this Agreement shall not terminate as set forth above and all rights of PFIZER under this Agreement shall remain in effect notwithstanding the foregoing.

3.4. Achievement of Proof-of-Concept. Promptly after PSIVIDA determines that the Product has reached Proof-of-Concept, PSIVIDA shall provide to PFIZER a written report (a "Final Report") setting forth the following information for such Product:

(a) A statement that the Product has achieved Proof-of-Concept;

(b) A summary of relevant Clinical IP for the Product in PSIVIDA's possession and Control (including Clinical IP generated by Third Parties under any services arrangement with PSIVIDA);

(c) Copies of any correspondence and official meeting minutes with Regulatory Authorities with respect to the Product;

(d) All pre-specified safety and efficacy analyses as outlined in the Clinical Trial protocols and statistical analysis plans; and

(e) A summary of any research or development programs in Glaucoma then being conducted by PSIVIDA itself or through a contract service provider or consultant, but excluding programs being conducted by PSIVIDA with a Third Party to which PSIVIDA has granted development and commercialization rights or licenses.

Notwithstanding any other provisions of this Agreement, in the event the Parties disagree whether the Product has achieved Proof-of-Concept, PSIVIDA may elect to continue developing the Product, and, if PSIVIDA so elects and Commences a Phase III Clinical Trial, then the Product will be deemed to have achieved Proof-of-Concept for purposes of this Section 3.4 and PSIVIDA will deliver another or an updated Final Report to PFIZER, in which case Section 3.5 shall apply, and if PFIZER subsequently submits a Funding Option Notice, PFIZER shall pay to PSIVIDA both the Event Milestone payment of [*] for Commencement of the first Phase III Clinical Trial for the Product described in Section 6.2.1 and the payment of $20 million described in Section 3.6.1, both at such time as the payment under Section 3.6.1 is due.

3.5. Funding Option Notice. Within ninety (90) days following

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PFIZER's receipt of a Final Report, PFIZER shall notify PSIVIDA in writing of (a) PFIZER's election to solely fund further development and commercialization of the Product as further set forth in this Agreement (the "Funding Option Notice"); or (b) PFIZER's determination that it will not solely fund such further development and commercialization of the Product. From the Effective Date until the earlier of the end of such ninety (90) day time period (the "Option Notice Period") or PFIZER providing notification pursuant to Section 3.5(a) or 3.5(b), PSIVIDA shall not (x) disclose the Final Report or any of its contents to any Third Party except as may be required by applicable Law or (y) enter into any agreement with a Third Party pursuant to which PSIVIDA grants or conveys to such Third Party licenses, rights, options or other legal interests to develop and or commercialize the Product in the Field or uveitis or engage in any discussions with any Third Party with respect to any such agreement. In the event PFIZER fails to submit a Funding Option Notice during the Option Notice Period, this Agreement shall automatically terminate at the end of the Option Notice Period, after which time nothing in this Agreement shall be construed as limiting PSIVIDA's right, alone or with or through other Persons, to develop, manufacture and commercialize the Product, which development, manufacturing and commercialization activities shall not be subject to this Agreement.

3.6. PFIZER Funding Option. The terms of this Section 3.6 shall apply if PFIZER submits to PSIVIDA a Funding Option Notice.

3.6.1. Within forty-five (45) days of PFIZER submitting to PSIVIDA a Funding Option Notice, PFIZER shall pay to PSIVIDA Twenty Million Dollars ($20,000,000), provided, however, that if PFIZER determines that an HSR Filing with respect to this Agreement is required to be made under the HSR Act, it shall so notify PSIVIDA and in such case PFIZER shall make such payment within forty-five (45) days after the HSR Clearance Date. The date on which PFIZER makes such payment in full shall be the "PFIZER Option Date."

3.6.2. Following the submission of the Funding Option Notice, PFIZER shall have sole authority and discretion with respect to developing and commercializing the Product at PFIZER's sole expense, subject to Section 5.1.

3.6.3. Within fifteen (15) days after the PFIZER Option Date, PSIVIDA shall (i) use Commercially Reasonable Efforts to transfer ownership of all regulatory filings and Regulatory Approvals that relate solely to the Product to PFIZER; (ii) deliver to PFIZER a copy of all Clinical IP in PSIVIDA's (or any of its Affiliates') possession and Control (including Clinical IP generated by Third Parties under any services arrangement) related to the Product, if any, in the same form in which PSIVIDA (or such Affiliate) maintains such data; (iii) provide PFIZER

with copies of any then-existing documentation and technical information, in the form and format in which such materials are maintained by PSIVIDA or any of its Affiliates in the ordinary course of its business, that are necessary for the manufacture of the Product, which documentation and technical information shall include (A) copies of flow charts of the manufacturing procedures and work instructions related to manufacturing the Product, (B) a list of all equipment, including the source of the equipment, utilized in the production of the Product, (C) copies of all current specifications for the Product, (D) copies of all standard operating procedures for the manufacturing procedures to be transferred, (E) all environmental conditions necessary to manufacture the Product and copies of any existing external environmental impact studies based on the materials or methods employed in the manufacturing method to be transferred, and (F) such other documentation as the Parties may mutually agree, in each case of the foregoing subsections (iii) and (A) through (F), that are in PSIVIDA's or any of its Affiliates' possession and Control (including any of the foregoing that are generated by Third Parties under any services arrangement) and are necessary to manufacture Products; and (iv) deliver to PFIZER, in the same form in which PSIVIDA or any of its Affiliates maintains such items, copies of all regulatory reports, records, correspondence and other regulatory materials in PSIVIDA's or any of its Affiliates' possession and Control related solely to such Product and any Regulatory Approval therefor (including any of the foregoing that are generated by Third Parties under any services arrangement), including, if applicable, any information contained in the global safety database established and maintained by PSIVIDA or any of its Affiliates.

3.6.4. Within sixty (60) days after the PFIZER Option Date, PFIZER shall prepare and deliver to PSIVIDA the PFIZER Development Plan. PFIZER shall update the PFIZER Development Plan and deliver such updated PFIZER Development Plan to PSIVIDA on each anniversary date of the PFIZER Option Date up to the date of the First Commercial Sale of the Product if PFIZER has made any material changes to such plan during the prior year. PFIZER shall also deliver a copy of the then-current PFIZER Development Plan to PSIVIDA promptly after PSIVIDA's request. In the event of an inconsistency or discrepancy between the PFIZER Development Plan and this Agreement, the terms of this Agreement shall prevail.

3.6.5. If PFIZER notifies PSIVIDA pursuant to Section 3.6.1 that an HSR Filing is required, each of PFIZER and PSIVIDA shall, within fifteen (15) Business Days after such notice from PFIZER (or such later time as may be agreed to in writing by the Parties), file with the United States Federal Trade Commission and the Antitrust Division of the United States Department of Justice, any HSR Filing required of it

with respect to the transactions contemplated hereby. The Parties shall cooperate with one another to the extent necessary in the preparation of any such HSR Filing. Each Party shall be responsible for its own costs and expenses (other than filing fees, which shall be paid by PFIZER) associated with any HSR Filing.

3.7. Cooperation. Each Party shall use Commercially Reasonable Efforts to cooperate with the other Party in connection with all activities to be performed pursuant to this Section 3. PFIZER will provide reasonable support to PSIVIDA with respect to the development of the Patient Outcomes Tool, including by making available (through telephonic or electronic means) to PSIVIDA a PFIZER employee who is expert in the development of patient outcomes tools for consultation and review of documents for up to one hundred hours prior to the delivery of a Funding Option Notice by PSIVIDA.

3.8. Conduct of Development. The Parties shall perform all activities under this Agreement and the Development Plans in compliance in all material respects with the requirements of applicable Laws and each Party will use Commercially Reasonably Efforts to achieve the objectives of the Development Plans efficiently and expeditiously. For the avoidance of doubt, a Party, unless it agrees otherwise, shall have no obligation to undertake any development activity allocated to it in any Development Plan prepared by the other Party.

3.9. Development Plan Records. Each Party shall maintain complete and accurate records of all work conducted under the Development Plans and all results, data and developments made pursuant to its efforts under the Development Plans. Such records shall reflect work done and results achieved in the performance of the Development Plans in sufficient detail and in a manner appropriate for patent and regulatory purposes. Subject to bona fide confidentiality obligations to a Third Party, the other Party shall have the right to request copies of such records at reasonable times and upon reasonable notice to the extent necessary or useful for such Party to perform its other obligations under this Agreement, or to secure or enforce patents licensed under this Agreement as permitted under this Agreement.

3.10. Reports. Each Party shall report to the JSC no less than once per calendar quarter, and such reports shall consist of a written progress report summarizing the work performed under the Development Plans, data obtained in connection with the Product and other material information regarding the Product since the previous report. The JSC shall define the format and the nature of the content of such quarterly reports, which format and nature shall be reasonably acceptable to both Parties. Beginning six months after the date

of the First Commercial Sale of the Product and once per year thereafter, PFIZER shall provide PSIVIDA with a written report describing development and regulatory activities for the Product undertaken during the previous year, if any, and such activities planned for the next year, if any, including any planned and actual submissions for Regulatory Approval.

3.11. Termination of Development Plans. The Development Plans shall automatically terminate on the effective date of any termination of this Agreement. Additionally, the Pre-POC Development Plan may terminate as specifically set forth in this Section 3.

4. Licenses.

4.1. License to PFIZER. Subject to the terms of this Agreement and except to the extent rights granted hereunder were granted under Sections 2.1.1 or 2.1.2 of the B&L Agreement, or under Sections 4.1, 5.1, 5.4 and 5.8 of the Alimera Agreement, or include rights that PSIVIDA is otherwise obligated not to convey to a Third Party under Sections 2.3, 2.4 and 2.5 of the B&L Agreement, or under Sections 4.1, 5.1, 5.4 and 5.8 of the Alimera Agreement, PSIVIDA hereby grants, and shall cause its Affiliates to grant, to PFIZER, and PFIZER hereby accepts:

4.1.1. subject to PSIVIDA's retained rights pursuant to Section 4.3, an exclusive (even as to PSIVIDA and its Affiliates), royalty-bearing license, with the right to sublicense, under the PSIVIDA Technology, the PSIVIDA Program Technology, the PSIVIDA Program Patent Rights, the PSIVIDA Patent Rights, the Clinical IP Controlled by PSIVIDA or any of its Affiliates and the PSIVIDA Confidential Information, to research, develop, make, have made, use, sell, import or otherwise exploit the Product only in the Field in the Territory following the PFIZER Option Date; and

4.1.2. a non-exclusive, royalty-free, worldwide license, with the right to sublicense, under the PSIVIDA Technology, the PSIVIDA Program Technology, the PSIVIDA Program Patent Rights, the PSIVIDA Patent Rights, the Clinical IP Controlled by PSIVIDA or any of its Affiliates and the PSIVIDA Confidential Information, solely for PFIZER to perform its obligations hereunder that are required to be performed prior to the PFIZER Option Date.

4.1.3. following the PFIZER Option Date, a non-exclusive, royalty-free (except as set forth below), world-wide license, with the right to sublicense, under and to all PSIVIDA Controlled Intellectual Property, solely to develop, make, have made, sell, offer for sale, use and import the Product; provided that such license shall continue only so long as

(a) PFIZER elects to accept such license, and (b) if any such PSIVIDA Controlled Intellectual Property is licensed to PSIVIDA from a Third Party ("Third Party Licensor"), PFIZER agrees in writing to comply with, and thereafter fulfills, all non-financial obligations of PSIVIDA to such Third Party Licensors applicable to sublicensees under the applicable license agreements and all royalties and other payments payable to such Third Party Licensors under the applicable Third Party license arising solely from the sublicense grant under this Section or from activities conducted by PFIZER or its Affiliates or its sublicensees pursuant to such sublicenses. Without limiting the foregoing, PSIVIDA shall disclose such obligations, royalties and other payments to PFIZER in advance of PFIZER taking such sublicense and, if PFIZER elects to take such sublicense, PFIZER shall pay such disclosed royalties and other payments that become payable on and after the PFIZER Option Date either, at PSIVIDA's option and direction, to PSIVIDA reasonably before the amounts are due so that PSIVIDA can make timely payment to the Third Party Licensor, or to the Third Party Licensor in a timely fashion, provided if PFIZER fails at any time to make timely payment of such disclosed royalties and other payments to PSIVIDA or the Third Party Licensor, PFIZER's license rights hereunder shall terminate upon thirty (30) days notice from PSIVIDA unless PFIZER cures such non-payment during such period. PFIZER's payment of such disclosed royalties and other payments under this Section 4.1.3 shall be limited to only those attributable to the development, making, having made, selling, offering for sale, using and importing the Product. In addition, PFIZER shall be responsible for the payment of such disclosed royalties and other payments under this Section 4.1.3 on a pro-rata basis as may be appropriate in the case where PSIVIDA has granted sublicenses to additional Third Party sublicensees. To the extent certain rights would be PSIVIDA Controlled Intellectual Property but for the fact that PSIVIDA does not have a Right to Grant a Sublicense with respect to such rights, PSIVIDA shall not bring (and shall not authorize or directly assist an Affiliate of PSIVIDA or a Third Party to bring, except as may be required under any contractual obligation of PSIVIDA) any action against PFIZER or any of its Affiliates, or a sublicensee of PFIZER's rights related to the Product, alleging misappropriation, misuse, or infringement of such rights arising from PFIZER or such Affiliate or sublicensee researching, developing, making, having made, using, selling, importing or otherwise exploiting the Product. For the purpose of clarity, PSIVIDA has no obligation to maintain Control of any rights for the purposes of this Section.

Notwithstanding anything to the contrary in this Agreement, (i) the Parties agree and acknowledge that, under the B&L Agreement and the Alimera Agreement, PSIVIDA has granted certain rights to B&L and Alimera, respectively, both exclusively and nonexclusively, and has agreed not to grant

certain licenses or other rights to Third Parties; and (ii) to the extent any rights granted hereunder have been granted under the B&L Agreement or the Alimera Agreement or are restricted pursuant to a covenant not to convey under the B&L Agreement or Alimera Agreement, such rights shall not be and are not granted to PFIZER under this Agreement.

4.2. License to PSIVIDA. Subject to the terms of this Agreement, PFIZER hereby grants, and shall cause its Affiliates to grant, to PSIVIDA, and PSIVIDA hereby accepts a non-exclusive, royalty-free (except as set forth below), worldwide license, with the right to sublicense, under and to (a) the Clinical IP Controlled by PFIZER or any of its Affiliates, PFIZER Technology, the PFIZER Program Technology, the PFIZER Program Patent Rights, the PFIZER Patent Rights and the PFIZER Confidential Information, solely for PSIVIDA to perform or have others perform activities and exercise its rights under the Development Plans, and (b) the Clinical IP Controlled by PFIZER or any of its Affiliates (i) to research, develop, make, have made, use, sell, import or otherwise exploit any product in any country in the world (other than a product prohibited under Section 11.3), and (ii) to incorporate, disclose, use or exercise a Right of Reference to such Clinical IP for any research, development or commercial purpose (other than for a product prohibited under Section 11.3); provided that in the case of (i) and (ii) such license shall not grant any rights under or to the Product in the Territory in the Field or for uveitis for so long as PFIZER has an exclusive license to the Product in the Field in the Territory under this Agreement; provided further that, if PSIVIDA exercises its right under this Section to sublicense such Clinical IP to a Third Party, the rights granted under such sublicense may include only such Clinical IP as existed on the first effective date of such sublicense between PSIVIDA and such Third Party and PSIVIDA shall not provide or disclose to such Third Party or use for the benefit or on behalf of such Third Party, directly or indirectly, any Clinical IP arising or created after such date. With respect to the license granted under clause (b) above, if any of the foregoing Clinical IP is licensed to Pfizer from a Third Party ("Third Party Licensor"), PSIVIDA must agree in writing to comply with, and thereafter must fulfill, all non-financial obligations of PFIZER to such Third Party Licensors applicable to sublicensees under the applicable license agreements and all royalties and other payments payable to such Third Party Licensors under the applicable Third Party license arising solely from the sublicense grant under this Section or from activities conducted by PSIVIDA or its Affiliates or its sublicensees pursuant to such sublicenses. Without limiting the foregoing, PFIZER shall disclose such obligations, royalties and other payments to PSIVIDA in advance of PSIVIDA taking such sublicense and, if PSIVIDA elects to take such sublicense, PSIVIDA shall pay such disclosed royalties and other payments that become payable on and after the PFIZER Option Date either, at PFIZER's option and direction, to PFIZER reasonably before the amounts are due so that PFIZER can make timely payment to the Third Party Licensor, or to the Third Party Licensor in a timely fashion, provided if PSIVIDA fails at any time to make

timely payment of such disclosed royalties and other payments to PFIZER or the Third Party Licensor, PSIVIDA's license rights hereunder shall terminate upon thirty (30) days notice from PFIZER unless PSIVIDA cures such non-payment during such period. PSIVIDA's payment of such disclosed royalties and other payments under this Section 4.2 shall be limited to only those attributable to the development, making, having made, selling, offering for sale, using and importing the Product. In addition, PSIVIDA shall be responsible for the payment of such disclosed royalties and other payments under this Section 4.2 on a pro-rata basis as may be appropriate in the case where PFIZER has granted sublicenses to additional Third Party sublicensees. From time to time upon PSIVIDA's request, PFIZER shall deliver to PSIVIDA a copy of all Clinical IP in PFIZER's or any of its Affiliates' possession and Control (including Clinical IP generated by Third Parties under any services arrangement) covered by the foregoing grant but not previously provided to PSIVIDA, if any, in the same form in which PFIZER or such Affiliate maintains such data.

4.3. Retained Rights. Notwithstanding anything to the contrary in this Section 4, each Party shall retain such rights as are necessary for such Party to perform its obligations under this Agreement, including the Development Plans.

5. **Diligence, Regulatory Approvals and Manufacturing/Supply**.

5.1. Diligence.

5.1.1. After the PFIZER Option Date, PFIZER shall use Commercially Reasonable Efforts to develop the Product in accordance with the PFIZER Development Plan for the Product, and to seek Regulatory Approval for and commercialize the Product in the United States and the Major EU Countries.

5.2. Regulatory Affairs.

5.2.1. Until the PFIZER Option Date, PSIVIDA shall determine all regulatory plans and strategies for the Product and will own and be responsible for preparing, seeking, submitting and maintaining all regulatory filings and Regulatory Approvals for the Product, including preparing all reports necessary as part of a regulatory filing or Regulatory Approval. Without limiting the generality of the foregoing, PSIVIDA shall have the right, consistent with applicable law, to amend the protocol for any Phase I/II Clinical Trial or Phase II

Clinical Trial conducted in connection with the Pre-POC Development Plan. Notwithstanding the foregoing, in addition to or in lieu of Clinical Trials sponsored by PSIVIDA, PSIVIDA may, in its sole discretion, authorize a Third Party to sponsor Clinical Trials and to prepare and submit an IND to the FDA for the Product.

5.2.2. Following the PFIZER Option Date, PFIZER shall determine all regulatory plans and strategies for the Product in the Territory and will own and be responsible for preparing, seeking, submitting and maintaining all regulatory filings and Regulatory Approvals for the Product, including preparing all reports necessary as part of a regulatory filing or Regulatory Approval.

5.2.3. During the Term of this Agreement, the Party responsible for submitting regulatory filings (the "Regulatory Submission Party") shall provide the other Party (the "Regulatory Non-Submission Party") with drafts of substantive submissions it plans to make to FDA or other Regulatory Authority with respect to the Product. The Regulatory Non-Submission Party may provide comments regarding such submission prior to its submission, and the Regulatory Submission Party shall consider in good faith incorporating such comments into the submission. The Regulatory Submission Party shall provide the Regulatory Non-Submission Party with copies of all substantive submissions it makes to, and all correspondence it receives from, FDA or other Regulatory Authority with respect to the Product. The Regulatory Submission Party shall provide the Regulatory Non-Submission Party with reasonable advance notice of all meetings, conferences, and discussions, whether in person or by teleconference (including, but not limited to, advisory committee meetings and any other meeting of experts convened by FDA or other regulatory authorities concerning any topic relevant to such Product), scheduled with FDA or such other regulatory authorities concerning any regulatory matters relating to such Product, and the Regulatory Non-Submission Party shall have the right to participate in such meetings, conferences or discussions and to confer with the Regulatory Submission Party in advance on the scheduling of, the objectives to be accomplished at, and the agenda and strategy for, such meetings, conferences, and discussions with FDA or other regulatory authorities; provided, however, that, in the event that the Parties have disagreement relating to such meetings, conferences and discussions, the Regulatory Submission Party shall have the final decision-making authority.

5.2.4. The Regulatory Submission Party shall provide the Regulatory Non-Submission Party with a summary of any such meeting, conference or discussion the Regulatory Non-Submission Party does not attend, or of any other material verbal communication with a Regulatory Authority

with respect to the Product, promptly (and in any case within three (3) Business Days) after it occurs, and generally shall keep the Regulatory Non-Submission Party reasonably informed about the progress of the regulatory approval process for the Product.

5.3. Recalls or Other Corrective Action. After the PFIZER Option Date, PFIZER shall promptly notify PSIVIDA of any material actions to be taken by PFIZER in the Territory with respect to any recall or market withdrawal or other corrective action related to the Product prior to such action, and, if reasonably practicable under the circumstances, to permit PSIVIDA a reasonable opportunity to consult with PFIZER with respect thereto. After the PFIZER Option Date all costs and expenses with respect to a recall, market withdrawal or other corrective action shall be borne by PFIZER.

5.4. Manufacturing and Supply—General. The terms of this Section 5.4 shall apply to the Party manufacturing or supplying Clinical Supply Requirements pursuant to Section 5.5 (the "Manufacturing Party").

5.4.1. Capacity. The Manufacturing Party's obligations to supply Products or Compounds pursuant to Section 5.5 shall be limited to the supply of Clinical Supply Requirements as specified in Section 5.5.1 or 5.5.2 and in each case shall be subject to such Party's actual capacity for the manufacture and supply of such Products or Compounds. The Manufacturing Party shall use Commercially Reasonable Efforts to notify the other Party in the event the forecasted or ordered amount of Product or Compound is likely to exceed the Manufacturing Party's then-existing capacity for manufacturing such Product or Compound.

5.4.2. Conforming Product. Upon delivery to the other Party, all Products and Compounds supplied by the Manufacturing Party shall meet the reasonable specifications provided in advance (in writing) by the other Party. For purposes of this Section 5.4.2, "reasonable specifications" shall mean specifications that may be met with the Manufacturing Party's then-existing manufacturing capabilities. In the event the Manufacturing Party is unable to provide Products or Compounds meeting the reasonable specifications provided in advance in writing by the other Party, the Manufacturing Party shall have the right to obtain Compounds or Products, as applicable, from a Third Party supplier. The non-Manufacturing Party shall provide reasonable cooperation, information and assistance necessary in order for the Manufacturing Party to do so.

5.4.3. Title and Delivery. All Products and Compounds to be supplied pursuant to Section 5.5 shall be delivered FCA (Manufacturing Party's loading dock). The receiving Party shall have the right to designate

the common carrier for shipments of Products and Compounds. Title, possession and risk of loss for Products and Compounds shall pass to the receiving Party upon delivery of Products and Compounds to the receiving Party's designated carrier.

5.5. Manufacture and Supply—Clinical Supplies.

5.5.1. Supply for Pre-POC Activities. PFIZER shall supply to PSIVIDA, at PFIZER's sole expense, [*] of Compound with a remaining shelf life expiring no earlier than [*], for conducting activities under the Pre-POC Development Plan. Such supply of Compound shall be shipped to PSIVIDA at a time and to a destination that are mutually acceptable to the Parties.

5.5.2. Supply of Product. After the PFIZER Option Date, PSIVIDA shall supply to PFIZER, at PSIVIDA's Cost of Clinical Supplies, all or a portion of PFIZER's Clinical Supply Requirements for the Product, in accordance with the PFIZER Development Plan. For the avoidance of doubt, and subject to PFIZER's obligation to purchase such Clinical Supply Requirements as are set forth in the binding portion of the rolling forecast for such Clinical Supply Requirements, PFIZER shall have the right to procure all or any portion of its Clinical Supply Requirements at its sole expense for the Product from a Third Party. On the first Business Day of the second calendar month after the PFIZER Option Date and thereafter on a monthly basis on the first Business Day of each calendar month until PFIZER completes clinical trials for the Product (or such earlier date that PFIZER notifies PSIVIDA that it no longer requires PSIVIDA to supply PFIZER with Clinical Supply Requirements), PFIZER shall provide to PSIVIDA a twelve (12) month rolling forecast for such Clinical Supply Requirements, the first three (3) months of each forecast shall be binding. Along with each forecast PFIZER shall deliver to PSIVIDA a purchase order in a form to be agreed by the parties for the third (3rd) month of the forecast (each a "Firm Order") (for clarity, the first and second months of each forecast will be covered by earlier submitted Firm Orders) this Section 5.5.2. provided however the quantity in each Firm Order shall not be less than eighty percent (80%) nor more than one hundred twenty percent (120%) of the quantity for any calendar month as most recently updated in the Firm Order period of the most recent forecast, and, that PSIVIDA's obligations under this Section 5.5.2 are conditioned on PFIZER's timely supply of Compound to

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PSIVIDA at PFIZER's sole expense. PFIZER may terminate the supply arrangement described in this Section 5.5.2 upon ninety (90) days prior written notice

5.6. Commercialization/Pricing. After the PFIZER Option Date, PFIZER shall be solely responsible for commercial manufacturing, marketing, promoting, selling, distributing and determining pricing and other terms of sale for the Product.

5.7. Disclosure of Technology by PSIVIDA. During the Term at PFIZER's reasonable request, but in no event later than ten business (10) days following such request, PSIVIDA will disclose to PFIZER or its designated Affiliates, all documentation, manuals, tangible materials, protocols or standard operating procedures or Clinical IP embodying PSIVIDA Technology relating to the Product and PSIVIDA Program Technology relating to the Product that is reasonably necessary for PFIZER to practice the licenses under this Agreement, including such information from Third Parties to the extent permitted under any applicable agreements.

5.8. Disclosure of Technology by PFIZER. During the Term at PSIVIDA's reasonable request, but in no event later than ten business (10) days following such request, PFIZER will disclose to PSIVIDA or its designated Affiliates, all documentation, manuals, tangible materials, protocols, standard operating procedures or Clinical IP embodying PFIZER Technology relating to the Product and PFIZER Program Technology relating to the Product that is reasonably necessary for PSIVIDA to practice the licenses under this Agreement, including such information from Third Parties to the extent permitted under any applicable agreements.

6. **Fees, Milestones and Royalties.**

6.1. Upfront Payment. Within fifteen (15) days after the Effective Date, PFIZER shall pay to PSIVIDA $2,300,000, which constitutes a payment for rights granted with respect to the Product pursuant to this Agreement.

6.2. Product Milestone Payments.

6.2.1. Event Milestone Payments. In consideration of the rights granted hereunder with respect to the Product, and subject to the terms and conditions of this Agreement, PFIZER shall pay to PSIVIDA

the amount set forth in the table below opposite the corresponding event milestone (each an "Event Milestone") within forty-five (45) days after the occurrence of such Event Milestone under this Agreement (each amount payable one time only):

Event Milestone	Event Milestone Payment
Commencement of the first Phase III Clinical Trial for the Product	$[*] million
First date of acceptance by FDA of the first NDA for the Product (the "FDA Filing Milestone")	$[*] million
Receipt of the first Regulatory Approval from the FDA for the Product (the "FDA First Indication Approval Milestone")	$[*] million
Receipt of the first Regulatory Approval from the FDA for the Product for the first indication that (a) is different from any indication included in the Regulatory Approval from the FDA with respect to which the FDA First Indication Approval Milestone became payable and (b) is not Glaucoma	$[*] million
Receipt of the first Regulatory Approval and Price Approval, where applicable, for the Product in the first Major EU Country (the "EU First Indication Approval")	$[*] million
Receipt of the first Regulatory Approval and Price Approval, where applicable, for the Product in the first Major EU Country for the first indication that (a) is different from any indication included in the Regulatory Approval in the Major EU Country with respect to which the EU First Indication Approval Milestone became payable and (b) is not Glaucoma	$[*] million

6.2.2. Sales Milestones. In addition to the Event Milestone Payments for the Product, in consideration of the rights granted hereunder, and subject to the terms and conditions of this Agreement, PFIZER shall pay to PSIVIDA the following one-time payments within forty-five (45) days

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after the end of the calendar year that most nearly coincides with the applicable PFIZER Year in which aggregate Net Sales of the Product for all indications in the Territory first reach the respective thresholds (each, a "Sales Milestone") indicated below:

Product Annual Net Sales in the Territory	**Sales Milestone Payment**
Net Sales in a PFIZER Year exceed $[*] million	$ [*] million
Net Sales in a PFIZER Year exceed $[*] billion	$ [*] million
Net Sales in a PFIZER Year exceed $[*] billion	$ [*] million
Net Sales in a PFIZER Year exceed $[*] billion	$ [*] million

6.3. Milestone Payments Generally.

6.3.1. The milestone payments set forth in this Section 6 shall be cumulative rather than mutually exclusive. For the avoidance of doubt, if at any time the FDA Filing Milestone or the FDA First Indication Approval Milestone (each a "Non-Sequential Milestone") for the Product occurs prior to the occurrence of all Event Milestones set forth in the rows preceding such Non-Sequential Milestone for the Product in the tables set forth above, PFIZER shall pay to PSIVIDA the sum of (a) all Event Milestone Payments associated with Event Milestones in rows preceding the Non-Sequential Event Milestone which have not otherwise been paid by PFIZER, and (b) the FDA Filing Milestone or the FDA First Indication Approval Milestone associated with the Non-Sequential Milestone.

6.3.2. PFIZER's payment of any Sales Milestone payment shall be accompanied by a report identifying the Net Sales of the Product and the amount payable to PSIVIDA. All such reports shall be kept confidential by PSIVIDA and not disclosed to any other party, other than PSIVIDA's accountants which shall be obligated to keep such information confidential, and such information and reports shall only be used for purposes of this Agreement.

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6.4. PFIZER Royalty Payments. In addition to the payments under Sections 6.1-6.3, in consideration of the rights granted hereunder, and subject to the terms and conditions of this Agreement, on a country-by-country basis during the Royalty Term for each country in the Territory, PFIZER shall pay to PSIVIDA an amount equal to [*] of Net Sales of the Product in a PFIZER Quarter in such country. The Parties agree and acknowledge that the payment of royalties by PFIZER to PSIVIDA for sales when there is no PSIVIDA Valid Claim covering the Product shall represent consideration for the license granted to PFIZER for PSIVIDA Technology pursuant to this Agreement.

6.5. Generic Products. Any payments owed with respect to sales of a Product pursuant to Section 6.4 shall be reduced by [*] for so long as one or more Generic Products for which the Product is the Antecedent Product together maintain [*] or greater Market Penetration in the Territory; with any such reduction to be prorated appropriately for the then-current PFIZER Quarter.

6.6. Duration of Royalty Payments. Payments under Section 6.4 shall continue until the expiration of the Royalty Term. Thereafter PFIZER shall have a non-exclusive, royalty-free, perpetual, irrevocable, worldwide license, with the right to sublicense, under the PSIVIDA Technology and PSIVIDA Program Technology to research, develop, make, have made, use, sell, import or otherwise exploit the Product only in the Field in the Territory.

6.7. Notices of Termination. In the event that this Agreement has been terminated as permitted under Section 3 or Section 13, no further payments that have not yet accrued under Section 6 shall become due following the effective date of such termination.

7. **Accounting and Procedures for Payment**.

7.1. Inter-Company Sales. Sales between or among PFIZER, its Affiliates or sublicensees shall not be subject to royalties under Section 6.4. PFIZER shall be responsible for the payment of royalties on Net Sales by or on behalf of its Affiliates or sublicensees to Third Parties.

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7.2. Currency. All royalty payments shall be computed and paid in United States dollars. For the purposes of determining the amount of any Sales Milestone Payments or royalties due for the relevant PFIZER Quarter, the amount of Net Sales in any foreign currency shall be converted into United States dollars in a manner consistent with the paying Party's customary practices used to prepare its audited financial reports; provided that such practices use a widely accepted source of published exchange rates.

7.3. Royalty Payments. PFIZER shall make royalty payments to PSIVIDA with respect to each PFIZER Quarter within forty-five (45) days after the end of the calendar quarter that most nearly coincides with such PFIZER Quarter, and each payment shall be accompanied by a report identifying Net Sales and the amount payable, as well as the computation thereof and the basis of any reductions allowable under Section 6. Said reports shall be kept confidential by the Parties and not disclosed to Third Parties, other than the Parties' certified public accountants which shall be obligated to keep such information confidential, and such information and reports shall only be used for purposes of this Agreement.

7.4. Method of Payments. Each payment hereunder shall be made by electronic transfer in immediately available funds via either a bank wire transfer, an ACH (automated clearing house) mechanism, or any other means of electronic funds transfer, at the paying Party's election, to such bank account as the receiving Party shall designate in a notice at least five (5) Business Days before the payment is due. All payments under this Agreement shall bear interest from the fifteenth (15th) day after the date due until paid at a rate equal to the thirty (30)-day United States dollar LIBOR rate in effect on the date that payment was due, as published by The Financial Times.

7.5. Inspection of Records. PFIZER shall, and shall cause its Affiliates and sublicensees to, keep accurate books and records setting forth gross sales of the Product, Net Sales of the Product, and amounts payable hereunder to PSIVIDA for the Product. Each Party shall, and shall cause its Affiliates and sublicensees to, keep accurate books and records setting forth all other payments and reimbursements due hereunder by one Party to the other. Each Party shall permit, and shall cause its Affiliates and sublicensees to permit, the other Party and independent certified public accountants employed by the other Party (reasonably acceptable to the Party providing access to records) to examine such books and records at any reasonable time, upon reasonable notice, but not later than [*] years following the rendering date the

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applicable payment under this Agreement is due. The foregoing right of examination may be exercised only once during each twelve (12)-month period of the Term. The Party being examined may require such accountants to enter into a reasonably acceptable confidentiality agreement and such accountants shall disclose to the examining Party only information that relates to the accuracy of the payments due under this Agreement. The opinion of said independent accountants regarding such reports and related payments shall be binding on the Parties, other than in the case of manifest error. The examining Party shall bear the cost of any such examination and review; provided that if the examination shows an underpayment of royalties or other payments due under this Agreement or an overstatement of amounts invoiced of more than ten percent (10%) of the amount due for the applicable period, then the Party being examined shall promptly reimburse the examining Party for all costs incurred in connection with such examination. If any such examination reveals an underpayment, the underpaying Party shall promptly pay the other Party the amount of such underpayment. Any overpayment of royalties or other payments due under this Agreement revealed by an examination shall be fully-creditable against future payments due under this Agreement or if no future payments will become due, the Party that received such overpayment shall promptly refund such overpayment to the paying Party.

7.6. Tax Matters.

7.6.1. VAT. It is understood and agreed between the Parties that any payments made under this Agreement are inclusive of any value added or similar tax imposed upon such payments.

7.6.2. Tax Cooperation. The Parties agree to cooperate and produce on a timely basis any tax forms or reports, including an IRS Form W-8BEN, reasonably requested by the other Party in connection with any payment made under this Agreement. Each Party further agrees to provide reasonable cooperation to the other Party, at the other Party's expense, in connection with any official or unofficial tax audit or contest relating to payments made under this Agreement.

7.6.3. Withholding Tax Matters. In addition, in the event any of the payments made by PFIZER pursuant to Section 6 become subject to withholding taxes under the Laws of any jurisdiction, PFIZER shall deduct and withhold the amount of such taxes for the account of PSIVIDA to the extent required by Law, such payment shall be reduced by the amount of taxes deducted and withheld, and PFIZER shall pay the amount of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to PSIVIDA an official tax certificate or other evidence of such tax obligations, together with proof of payment from the relevant Governmental Authority of all amounts deducted and withheld sufficient to enable

PSIVIDA to claim such payment of taxes. PFIZER shall act in good faith to withhold taxes at the lowest rate allowed by the tax treaties applicable to the payments made by PFIZER. PSIVIDA shall act in good faith to provide PFIZER with any required documentation to enable PFIZER to withhold taxes at such rate. Any such withholding taxes required under applicable Law to be paid or withheld shall be an expense of, and borne solely by, PSIVIDA. Each Party will provide the other Party with reasonable assistance, at such Party's expense, to enable a Party to recover such taxes as permitted by Law.

8. **Patents and Infringement**.

8.1. Disclosure and Ownership of Program Technology and Program Patent Rights. Each Party shall (and shall cause its Affiliates to) disclose to the other Party all Program Technology or Program Patent Rights in writing promptly after they are invented, created or developed or their significance is first appreciated, and in any event no later than sixty (60) days prior to any public disclosure or filing of a United States or international provisional or non-provisional patent application disclosing or claiming such Program Technology or Program Patent Rights. PSIVIDA shall have sole ownership of, and PFIZER shall and hereby does assign to PSIVIDA, all rights, title and interest in any PSIVIDA Program Technology and PSIVIDA Program Patent Rights, regardless of the identity of the inventors. Inventorship and ownership of Program Technology and Program Patent Rights other than PSIVIDA Program Technology and PSIVIDA Program Patent Rights shall be determined by United States law. The Parties shall provide each other with reasonable assistance to evidence, perfect or defend ownership of Program Technology or Program Patent Rights as set forth in this Agreement, including (i) executing any assignments and other documents requested by the other Party, (ii) providing good faith testimony by affidavit, declaration or in person, and (iii) assisting with filing or maintaining patents.

8.2. Prosecution and Maintenance of PSIVIDA Patent Rights and PSIVIDA Program Patent Rights in the Territory.

8.2.1. Filing, Prosecution, and Maintenance of PSIVIDA Patent Rights. PSIVIDA shall have primary responsibility for and control over the preparation, filing, prosecution, and maintenance of PSIVIDA Patent Rights and PSIVIDA Program Patent Rights in the Territory. PSIVIDA shall have the authority to select patent counsel, and to determine the form and content of such prosecution documents and to make all decisions regarding whether to file, prosecute and maintain

patents and patent applications, and in which countries to do so. PSIVIDA shall be [*] of the Patent Costs associated with the PSIVIDA Patent Rights and PSIVIDA Program Patent Rights. PSIVIDA shall keep PFIZER reasonably informed regarding the status of each patent or patent application included within PSIVIDA Patent Rights and PSIVIDA Program Patent Rights in the Territory and shall provide PFIZER with copies of all official correspondence (including, but not limited to, applications, office actions, responses, etc.) relating to prosecution and maintenance of these Patent Rights. PFIZER shall have the right to review pending patent applications and other proceedings for, and to make recommendations to PSIVIDA regarding, the prosecution of PSIVIDA Patent Rights and PSIVIDA Program Patent Rights in the Territory relating to the Product; provided that all final decisions regarding the prosecution and maintenance of PSIVIDA Patent Rights and PSIVIDA Program Patent Rights shall be made by PSIVIDA. Notwithstanding the foregoing, with respect to the PSIVIDA Program Patent Rights, on and after the date that PFIZER submits a Funding Option Notice, PSIVIDA agrees to act in good faith to cooperate and coordinate with PFIZER, as reasonably requested, on the prosecution and maintenance of such PSIVIDA Program Patent Rights.

8.2.2. Abandonment of PSIVIDA Patent Rights or PSIVIDA Program Patent Rights. PSIVIDA may, at its sole discretion, abandon any patent or pending patent application, on a patent-by-patent or application-by-application basis, within the PSIVIDA Patent Rights and PSIVIDA Program Patent Rights. PSIVIDA shall not abandon prosecution or maintenance of any PSIVIDA Patent Rights or PSIVIDA Program Patent Rights relating to the Product in the Territory without notifying PFIZER in a timely manner of PSIVIDA's intention and reason therefor and providing PFIZER with reasonable opportunity to comment upon such abandonment and to assume responsibility for prosecution or maintenance in the Territory of such PSIVIDA Patent Rights and/or PSIVIDA Program Patent Rights at PFIZER's sole expense, provided, however, that such abandoned PSIVIDA Patent Rights or PSIVIDA Program Patent Rights shall be excluded from the definition of PSIVIDA Valid Claim for the purposes of the Royalty Term. The cancellation or amendment of a claim or claims during the prosecution of a patent application, or during a reissue or reexamination proceeding with respect to an issued patent, within the PSIVIDA Patent Rights or PSIVIDA Program Patent Rights shall not in and of itself constitute a discontinuance or abandonment under this Section. Notwithstanding the foregoing, PFIZER's rights under this

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Section 8.2.2 with respect to PSIVIDA Patent Rights and PSIVIDA Program Patent Rights shall be subject to rights granted to Faber under the Faber Agreement, including Section 4.1 thereof, to Alimera under the Alimera Agreement, including the rights set forth in Section 7.1 and 7.2 thereof, and to B&L under the B&L Agreement, including the rights set forth in Article 9 thereof.

8.2.3. Information Disclosure; Cooperation. Subject to any limitations imposed by the confidentiality obligations set forth in the Faber Agreement, Alimera Agreement and the B&L Agreement, upon PFIZER's request PSIVIDA shall disclose and make available to PFIZER all material information controlled by PSIVIDA or any of its Affiliates that is reasonably necessary for PFIZER to perform its obligations and to exercise its rights under this Section 8. PSIVIDA agrees to cooperate with PFIZER with respect to the preparation, filing, prosecution and maintenance of patents and patent applications pursuant to this Section 8.

8.3. Enforcement of PSIVIDA Patent Rights and PSIVIDA Program Patent Rights.

8.3.1. Notification. During the Term, each of the Parties shall promptly notify the other in the event they learn of any known infringement or suspected infringement of any of the PSIVIDA Patent Rights or PSIVIDA Program Patent Rights that cover the Product and shall provide the other Party with all available evidence supporting said infringement or suspected infringement.

8.3.2. Enforcement. [*], but not the obligation, to initiate or prosecute an infringement or other appropriate suit or action against any Third Party who at any time has infringed or is suspected of infringing (an "Infringer") any of the PSIVIDA Patent Rights or PSIVIDA Program Patent Rights. [*] shall give [*] advance notice of its intent to file a suit against an Infringer of PSIVIDA Patent Rights or PSIVIDA Program Patent Rights relating to the Product in the Territory and the reasons therefor, and shall provide [*] with an opportunity to make suggestions and comments regarding such filing; provided, however, that [*] shall provide any such comments sufficiently in advance of any filing dates to allow for consideration by [*], and further provided that it shall be within [*] sole discretion whether to incorporate such suggestions or comments. [*] shall keep [*] reasonably informed of the status and progress of such litigation. [*] shall have the sole and exclusive right to select counsel for any such suit and action and shall pay all expenses of

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the suit, including, but not limited to, attorneys' fees and court costs. With respect to PSIVIDA Patent Rights and PSIVIDA Program Patent Rights relating to the Product in the Territory, if [*] has not taken legal action or been successful in obtaining cessation of the infringement within (a) ninety (90) days from the date of notice by either Party under Section 8.3.1; or (b) thirty (30) days after [*] notifies [*] that [*] would like to move for injunctive relief; or (c) ten (10) days before the expiration of a period of time set by applicable Law in which action must be taken with respect to the alleged infringement (e.g., as may be required under the Hatch-Waxman Act and 35 USC §271), then, subject to the rights with respect to the PSIVIDA Patent Rights granted to Faber under the Faber Agreement, including 4.2 thereof, to Alimera under the Alimera Agreement, including Section 7.6 thereof, and to B&L under the B&L Agreement, including Article 10 thereof, [*] shall have the right to bring suit against an Infringer at [*] own expense. [*]

[*]

8.3.3. Upon request of the other Party, either Party shall join as a party to or shall commence the suit on behalf of the other Party if required for standing, at the other Party's expense, and shall offer reasonable assistance to the other Party in connection therewith at its own expense. Any damages, royalties, settlement fees or other consideration for infringement resulting from the suit shall be distributed as follows: (i) first, each Party shall be reimbursed for its reasonable out-of-pocket costs paid in connection with the proceeding; and (ii) thereafter, PFIZER will receive [*] and PSIVIDA will receive [*] of any damages, royalties, settlement fees or other consideration. Neither Party shall settle any such suit or otherwise consent to an adverse judgment in any such suit that adversely affects the rights or interests of the other Party under this Agreement, including, issues of validity of the PSIVIDA Patent Rights or PSIVIDA Program Patent Rights, without the prior written consent of the other Party.

8.4. Prosecution and Maintenance of PFIZER Program Patent Rights in the Territory.

8.4.1. Filing, Prosecution, and Maintenance of PFIZER Program Patent Rights. PFIZER shall have primary responsibility for and control over the preparation, filing, prosecution, and maintenance of PFIZER Program Patent Rights. PFIZER shall have the authority to select patent counsel, and to determine the form and content of such prosecution documents

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and to make all decisions regarding whether to file, prosecute and maintain patents and patent applications, and in which countries to do so. PFIZER shall be [*] of the Patent Costs associated with the PFIZER Program Patent Rights. PFIZER shall keep PSIVIDA reasonably informed regarding the status of each patent or patent application included within the PFIZER Program Patent Rights and shall provide PSIVIDA with copies of all official correspondence (including, but not limited to, applications, office actions, responses, etc.) relating to prosecution and maintenance of these Patent Rights. PSIVIDA shall have the right to review pending patent applications and other proceedings for, and to make recommendations to PFIZER regarding the prosecution of PFIZER Program Patent Rights; provided that all final decisions regarding the prosecution and maintenance of PFIZER Program Patent Rights shall be made by PFIZER.

8.4.2. Abandonment of PFIZER Program Patent Rights. PFIZER may, at its sole discretion, abandon any patent or pending patent application, on a patent-by-patent or application-by-application basis, within the PFIZER Program Patent Rights. PFIZER shall not abandon prosecution or maintenance of any PFIZER Program Patent Rights without notifying PSIVIDA in a timely manner of PFIZER's intention and reason therefor and providing PSIVIDA with reasonable opportunity to comment upon such abandonment and to assume responsibility for prosecution or maintenance of PFIZER Program Patent Rights at PSIVIDA's sole expense. The cancellation or amendment of a claim or claims during the prosecution of a patent application, or during a reissue or reexamination proceeding with respect to an issued patent, within the PFIZER Program Patent Rights shall not in and of itself constitute a discontinuance or abandonment under this Section.

8.4.3. Information Disclosure; Cooperation. Upon PSIVIDA's request, PFIZER shall disclose and make available to PSIVIDA all material information controlled by PFIZER or any of its Affiliates that is reasonably necessary for PSIVIDA to perform its obligations and to exercise its rights under this Section 8. PFIZER agrees to cooperate with PSIVIDA with respect to the preparation, filing, prosecution and maintenance of patents and patent applications pursuant to this Section 8.

8.5. Enforcement of PFIZER Program Patent Rights.

8.5.1. Notification. During the Term, each of the Parties shall promptly notify the other in the event they learn of any known infringement or suspected infringement of any of the PFIZER Program Patent Rights that cover the

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Product and shall provide the other Party with all available evidence supporting said infringement or suspected infringement.

8.5.2. Enforcement. PFIZER shall have the initial right, but not the obligation, to initiate or prosecute an infringement or other appropriate suit or action against an Infringer of any of the PFIZER Program Patent Rights. PFIZER shall give PSIVIDA advance notice of its intent to file a suit against an Infringer of PFIZER Program Patent Rights relating to the Product, and shall provide PSIVIDA with an opportunity to make suggestions and comments regarding such filing; provided, however, that PSIVIDA shall provide any such comments sufficiently in advance of any filing dates to allow for consideration by PFIZER, and further provided that it shall be within PFIZER's sole discretion whether to incorporatesuch suggestions or comments. PFIZER shall keep PSIVIDA reasonably informed of the status and progress of such litigation. PFIZER shall have the sole and exclusive right to select counsel for any such suit and action and shall pay all expenses of the suit, including, but not limited to, attorneys' fees and court costs. With respect to PFIZER Program Patent Rights relating to the Product, if PFIZER has not taken legal action or been successful in obtaining cessation of the infringement within (a) ninety (90) days from the date of notice by either Party under Section 8.5.1; or (b) thirty (30) days after PSIVIDA notifies PFIZER that PSIVIDA would like to move for injunctive relief; or (c) ten (10) days before the expiration of a period of time set by applicable Law in which action must be taken with respect to the alleged infringement (e.g., as may be required under the Hatch-Waxman Act and 35 USC §271), then, PSIVIDA shall have the right to bring suit against an Infringer at PSIVIDA's own expense. This right of PSIVIDA to bring suit, as well as to continue an existing suit, is also conditioned on all of the following requirements:

[*]

8.5.3. Upon request of the other Party, either Party shall join as a party to or shall commence the suit on behalf of the other Party if required for standing, at the other Party's expense, and shall offer reasonable assistance to the other Party in connection therewith at its own expense. Any damages, royalties, settlement fees or other consideration for infringement resulting from the suit shall be distributed as follows: (i) first, each Party shall be reimbursed for its reasonable out-of-pocket costs paid in connection with the proceeding; and (ii) thereafter, PSIVIDA will receive [*] and PFIZER will receive [*] of any damages, royalties, settlement fees or other consideration.

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Neither Party shall settle any such suit or otherwise consent to an adverse judgment in any such suit that adversely affects the rights or interests of the other Party under this Agreement, including, issues of validity of the PFIZER Program Patent Rights, without the prior written consent of the other Party

8.6. Patent Term Extension. PFIZER shall have the exclusive right to seek, at PFIZER's expense, patent term extensions or supplemental patent protection, including supplementary protection certificates, in the Territory in relation to the Product under any of the PFIZER Patent Rights and PFIZER Program Patent Rights. PFIZER and PSIVIDA shall cooperate in connection with all such activities, and PFIZER, its agents and attorneys will give due consideration to all timely suggestions and comments of PSIVIDA regarding any such activities; provided that all final decisions shall be made by PFIZER.

8.7. Orange Book Listings. With respect to filings of patent information with FDA on Form 3542a or Form 3542 (and foreign equivalents) for issued patents for the Product for which PFIZER applies for or holds an NDA, PFIZER shall have the exclusive right and shall be solely responsible at its expense for fulfilling its obligations under applicable Laws to list any applicable PSIVIDA Patent Rights and PSIVIDA Program Patent Rights. PFIZER will be solely responsible for any such filings and listings, and for any and all decisions with respect to such filings and listings. Notwithstanding the foregoing, with respect to any such form to be filed concerning any PSIVIDA Patent Rights, PFIZER shall provide PSIVIDA with the opportunity to comment on the filing of such form by providing a draft of such form to PSIVIDA at least five Business Days in advance of filing such form with FDA and by making a good faith effort to incorporate any comments received from PSIVIDA prior to filing such form with FDA.

8.8. Patent Invalidity Claim with Respect to PSIVIDA Patent Rights and PSIVIDA Program Patent Rights. During the Term, each of the Parties shall promptly notify the other in the event of any legal or administrative action by any Third Party against a PSIVIDA Patent Right or a PSIVIDA Program Patent Right of which it becomes aware, including any nullity, revocation, reexamination or compulsory license proceeding. [*] shall have the first right, but not the obligation, to defend against any such action involving a PSIVIDA Patent Right or a PSIVIDA Program Patent Right, [*].

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8.9. Patent Invalidity Claim with Respect to PFIZER Program Patent Rights. During the Term, each of the Parties shall promptly notify the other in the event of any legal or administrative action by any Third Party against a PFIZER Program Patent Right of which it becomes aware, including any nullity, revocation, reexamination or compulsory license proceeding. PFIZER shall have the first right, but not the obligation, to defend against any such action involving PFIZER Program Patent Right, in its own name, and the costs of any such defense shall be at PFIZER's expense. PSIVIDA, upon request of PFIZER, agrees to join in any such action and to cooperate reasonably with PFIZER; provided that PFIZER shall promptly reimburse all out-of-pocket expenses (including reasonable counsel fees and expenses) actually incurred by PSIVIDA in connection with such cooperation. [*] PFIZER, upon request of PSIVIDA, agrees to join in any such action and to cooperate reasonably with PSIVIDA; provided that PSIVIDA shall promptly reimburse all out-of-pocket expenses (including reasonable counsel fees and expenses) actually incurred by PFIZER in connection with such cooperation.

8.10. Notification of Third Party Claim. Each Party shall promptly report in writing to the other Party during the Term of this Agreement any claim or allegation by any Third Party that the development or commercialization of the Product infringes the intellectual property rights of any Third Party and shall provide the other Party with all available evidence supporting said infringement or suspected infringement.

(a) PFIZER shall have the initial right, but not the obligation, to defend any suit or action initiated by any Third Party alleging solely that the Product has infringed, or is suspected of infringing any Third Party intellectual property rights in the Territory. Upon PFIZER's request, PSIVIDA shall join such suit or action and shall offer reasonable assistance to PFIZER in connection therewith at PFIZER's expense. PFIZER shall give PSIVIDA advance notice of its intent to defend any said suit and shall provide PSIVIDA with an opportunity to make suggestions and comments regarding such defense; provided, however, that PSIVIDA shall provide any such comments sufficiently in advance of any filing dates to allow for consideration by PFIZER, and further provided that it shall be within PFIZER's sole discretion whether to incorporate such suggestions or comments. PFIZER shall keep PSIVIDA reasonably informed of the status and progress of the litigation. PFIZER shall have the sole and exclusive right to select counsel for any such suit and action and shall pay all expenses of the suit, including, but not limited to, attorneys' fees and court costs. PFIZER shall have the right to settle any such litigation and shall specifically have the

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right, whether or not litigation commences, to negotiate a license or other rights from any Third Party authorizing the use of Third Party intellectual property rights in connection with the Product; provided, however, that PFIZER shall not settle any such action, or otherwise consent to an adverse judgment in any such action, or make any admission in any such license and negotiation that adversely affects the rights or interests of PSIVIDA under this Agreement, including, issues of validity of the PSIVIDA Patent Rights or PSIVIDA Program Patent Rights, without the prior written consent of PSIVIDA. Any such license shall be at arm's length and otherwise on terms and conditions as may be deemed appropriate in the reasonable business judgment of PFIZER. PFIZER shall provide PSIVIDA with a copy of any such license promptly after its execution.

(b) If PFIZER does not defend a claim, suit or proceeding as set forth above within ninety (90) days of the date PFIZER was reasonably aware or notified of the Third Party claim alleging infringement (or within such shorter period as may be necessary for submitting or filing a response), then PSIVIDA may, in its sole discretion, elect to defend such claim, suit or proceeding, using counsel of its own choice and the provisions of Section 8.10(a) shall apply as if the term "PSIVIDA" were changed to "PFIZER" and the term "PFIZER" were changed to "PSIVIDA".

8.11. Third Party Royalty Obligations. If PFIZER reasonably determines in good faith that, in order to exercise the license granted by PSIVIDA in this Agreement without infringing the Patent Rights of a Third Party, it is necessary to obtain a license of Patent Rights from such Third Party (excluding any license that is required to make, use, sell, offer for sale, supply, cause to be supplied, or import the Compound in such country or to practice PFIZER Technology or PFIZER Patent Rights), then the amount of PFIZER's royalty payments under Section 6.4 with respect to Net Sales for the Product in such country shall be reduced by [*] of the amount of royalties on Net Sales payable by PFIZER to such Third Party [*].

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9. **Confidentiality; Publication**.

9.1. Confidential Information.

9.1.1. PFIZER and PSIVIDA each agree that, except as permitted in this Agreement, during the Term and for five (5) years after the Term, it will keep confidential, and will cause its Affiliates to keep confidential, all of the other Party's Confidential Information that is disclosed to it, or to any of its Affiliates. PFIZER and PSIVIDA each agree to take such action, and to cause its Affiliates to take such action, to preserve the confidentiality of PSIVIDA Confidential Information and PFIZER Confidential Information, respectively, as it would customarily take to preserve the confidentiality of its own similar types of confidential information.

9.1.2. Each of PFIZER and PSIVIDA, agree, and agree to cause their respective Affiliates, (i) to use PSIVIDA Confidential Information and PFIZER Confidential Information, respectively, only as expressly permitted in this Agreement and (ii) not to disclose PSIVIDA Confidential Information and PFIZER Confidential Information, respectively, to any Third Parties under any circumstance without the prior consent of the other Party, except as expressly permitted in this Agreement.

9.1.3. Notwithstanding anything to the contrary in this Section 9, each Party or any of its Affiliates may disclose the other Party's Confidential Information (i) to Governmental Authorities (a) to the extent desirable to obtain or maintain INDs or Regulatory Approvals, and (b) in order to respond to inquiries, requests or investigations relating to this Agreement; (ii) to such Party's attorneys and accountants; (iii) to other outside consultants, contractors, advisory boards, managed care or other health care providers or organizations, and non-clinical and clinical investigators, in each case to the extent desirable to develop, register or market any Compound or Product pursuant to this Agreement or in connection with the exercise of rights or performance of obligations under this Agreement, provided that such Party shall obtain the same confidentiality obligations from such Third Parties as it obtains with respect to its own similar types of confidential information; (iv) in connection with filing or prosecuting Patent Rights or trademark rights as permitted by this Agreement, (v) in connection with prosecuting or defending litigation as permitted by this Agreement, (vi) in connection with or included in scientific presentations and publications relating to Compounds or Products, including abstracts, posters, journal articles and the like, and (vii) to the extent necessary or desirable in order to enforce its rights under

this Agreement.

9.2. Disclosure of Agreement Terms. PSIVIDA or any of its Affiliates may issue mutually acceptable press releases in connection with the execution of this Agreement. Disclosure of the financial terms of this Agreement shall be made in the form of a mutually acceptable press release on the Effective Date. Neither Party nor any of its Affiliates shall disclose or describe the financial terms of this Agreement in any way that is contrary to or inconsistent with the substance of such press release or the Agreement, and neither Party nor any of its Affiliates shall otherwise publically disclose any other terms of this Agreement except as expressly set forth herein. Notwithstanding the foregoing and notwithstanding Section 9.1, each Party or any of its Affiliates may disclose this Agreement or its terms (a) to the extent required by Law, provided that the disclosing Party provides the other Party notice (to the extent practicable) of such disclosure and agrees to cooperate, at the request and sole expense of the other Party, with the other Party's efforts to preserve the confidentiality of such information and (b) to any investors or potential investors, lenders, and other potential financing sources, or to a Third Party in connection with an investment or proposed investment, financing or proposed financing, merger or acquisition, proposed merger or acquisition, a license or proposed license of the technology or intellectual property licensed hereunder and not prohibited hereunder, sale of assets or other similar transaction, and to Affiliates, attorneys, accountants, stockholders, investment bankers, advisers or other consultants in connection with the foregoing permitted disclosures, in each case provided that the Person to which such disclosure is made agrees to keep such information confidential on essentially the same terms as set forth herein and to use such Confidential Information solely to evaluate such investment, financing, acquisition, merger, license, sale or other transaction, (c) to any stock exchange on which its stock is then listed to the extent required by such exchange, provided that the disclosing Party shall notify the other Party in advance of such disclosure to the extent reasonably possible and otherwise complies with the provisions of Section 9.4, (d) to its attorneys and accountants, and (e) to its consultants, advisors, contractors and agents in connection with any of the foregoing permitted purposes, provided that the Person to which such disclosure is made agrees, or is otherwise bound by professional standards of conduct, to keep such information confidential on essentially the same terms as set forth herein.

9.3. Other Disclosures. Notwithstanding anything else herein but subject to Section 3.5, both Parties and their respective Affiliates shall be entitled to publicly disclose significant Product achievements of the type and by the means customary for similarly situated companies. For the purpose of clarity, such public disclosures with respect to a Product by PSIVIDA or any of its Affiliates may include, (i) prior to the Pfizer Option Date, Commencement of Clinical Trials, significant factual information with respect to Clinical Trials including numbers of patients, centers, investigators, descriptions of protocols, completion of enrollment and of treatment under Clinical Trials, safety and efficacy data and other results of Clinical Trials, and filings with and actions by Regulatory Authorities, and (ii) following the Pfizer Option Date, Commencement of Clinical Trials, significant factual information with respect to Clinical Trials including numbers of patients, number of centers, number of investigators, high level descriptions of study design, completion of enrollment and of treatment under Clinical Trials, top line safety and efficacy data, and significant actions by Regulatory Authorities. For the purpose of clarity, such public disclosures described in the first sentence of this Section with respect to a Product by PFIZER or any of its Affiliates following the PFIZER Option Date may include any of the disclosures described in the preceding sentence. Prior to making public disclosure of the achievement of any such event relating to a Product, including any results of Clinical Trials, the disclosing Party will provide the other Party with a copy of such disclosure five (5) Business Days in advance, or if such advance notice is not practicable under the circumstances, as much advance notice as the disclosing Party practicably can provide and shall take into account the good faith and reasonable comments made by the other Party within such five (5) day period. Subject to the foregoing provisions of this Section 9.3, and without limiting any rights under Sections 9.2 and 9.4, each Party shall submit to the other Party for review and approval (such approval not to be unreasonably be withheld or delayed) any proposed academic, scientific or medical publication or public presentation (for the purpose of clarity, not including public disclosures as described in the first three sentences of this Section or filings with a Governmental Authority) which contains the other Party's Confidential Information. Such review and approval will be conducted for the purposes of preserving the value of intellectual property rights and determining whether any portion of the proposed publication or presentation containing the other Party's Confidential Information should be modified or deleted for such purpose. Written copies of such proposed publication or presentation required to be submitted hereunder shall be submitted to the other Party no later than twenty (20) days before submission for publication or presentation. The non-disclosing Party shall provide its comments with respect to such publications and presentations within fifteen (15) days of its receipt of such written copy. The review period may be extended for an additional fifteen (15) days in the event the non-disclosing Party can demonstrate reasonable need for such extension including for the preparation and filing of patent applications. PSIVIDA and PFIZER will each comply with standard academic practice regarding authorship of

scientific publications and recognition of contribution of other parties in any publication.

9.4. Filing, Registration or Notification of the Agreement. If a Party or any of its Affiliates determines that it is required by Law to publicly file, register or notify this Agreement with a Governmental Authority (it being agreed that PSIVIDA or any of its Affiliates may file this Agreement with the Securities & Exchange Commission), such Party or such Affiliate shall (i) initially file a copy of this Agreement in form redacting the financial terms and such other terms as are reasonably requested by the other Party (the "Redacted Agreement"), (ii) request, and use Commercially Reasonable Efforts to obtain, confidential treatment of all terms redacted from this Agreement, as reflected in the Redacted Agreement, for a period of at least ten (10) years, (iii) permit the other Party to review and comment upon such request for confidential treatment and any subsequent correspondence with respect thereto at least five (5) Business Days prior to its submission to such Governmental Authority, provided that any comments shall be made within three (3) Business Days of receipt, (iv) promptly deliver to the other Party any written correspondence received by it or its representatives from such Governmental Authority with respect to such confidential treatment request and promptly advise the other Party of any other communications between it or its representatives with such Governmental Authority with respect to such confidential treatment request, (v) upon the written request of the other Party, request an appropriate extension of the term of the confidential treatment period, and (vi) if such Governmental Authority requests any changes to the redactions set forth in the Redacted Agreement, use Commercially Reasonable Efforts to support the redactions in the Redacted Agreement as originally filed and shall not agree to any changes to the Redacted Agreement without first discussing such changes with the other Party and taking the other Party's comments into consideration when deciding whether to agree to such changes. Each Party and its Affiliates shall be responsible for its own legal and other external costs in connection with any such filing, registration or notification.

10. **Representations and Warranties**.

10.1. PSIVIDA Representations and Warranties. As of the Effective Date, PSIVIDA hereby represents and warrants to PFIZER as follows:

10.1.1. PSIVIDA has the corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder, and the execution, delivery and performance of this Agreement by PSIVIDA have been duly and validly authorized and approved by proper

corporate action on the part of PSIVIDA, and PSIVIDA has taken all other action required by Law, its certificate of incorporation, by-laws or other organizational documents or any agreement to which it is a party or to which it may be subject required to authorize such execution, delivery and performance. Assuming due authorization, execution and delivery on the part of PFIZER, this Agreement constitutes a legal, valid and binding obligation of PSIVIDA, enforceable against PSIVIDA in accordance with its terms.

10.1.2. The execution and delivery of this Agreement by PSIVIDA and the performance by PSIVIDA contemplated hereunder does not and will not violate any Laws or any order of any court or Governmental Authority.

10.1.3. Neither the execution and delivery of this Agreement nor the performance hereof by PSIVIDA requires PSIVIDA to obtain any permits, authorizations or consents from any Governmental Authority (other than any Regulatory Approvals relating to performance of the Development Plan or the manufacture, use, importation or sale of the Product) or from any other person, firm or corporation, and such execution, delivery and performance will not result in the breach of or give rise to any right of termination under any agreement or contract to which PSIVIDA or any of its Affiliates is a party or to which it may be subject, except for those breaches or rights that would not adversely affect the ability of PSIVIDA to perform its obligations under this Agreement.

10.1.4. [*], the patents encompassed within the PSIVIDA Patent Rights and the PSIVIDA Program Patent Rights as of the Effective Date, are, or, upon issuance, will be, valid and enforceable patents and no Third Party is (i) infringing any such Patent Rights relating to the Device as of the Effective Date or (ii) has challenged the extent, validity or enforceability of such Patent Rights (including by way of example through the institution or written threat of institution of interference, nullity or similar invalidity proceedings before the United States Patent and Trademark Office or any analogous foreign entity).

10.1.5. Schedule 10.1.5 contains a complete and correct list of all patents and patent applications owned by or otherwise Controlled by PSIVIDA or any of its Affiliates (and indicating which entity owns or Controls each patent and patent application and which are owned and which are Controlled) that are included within PSIVIDA Patent Rights and PSIVIDA Program Patent Rights.

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10.1.6. To the knowledge of PSIVIDA, PSIVIDA or its relevant Affiliate is the sole legal and beneficial owner of all the PSIVIDA Patent Rights and PSIVIDA Technology, free of any lien, encumbrance, charge, security interest, mortgage or other similar restriction, and no person, firm, corporation, governmental agency, or other entity (including any Affiliate of PSIVIDA) has any right, interest or claim in or to, and neither PSIVIDA nor any of its Affiliates has entered into any agreement granting to any Third Party (including any academic, governmental organization or agency) any right, interest or claim in or to, any PSIVIDA Patent Rights or PSIVIDA Technology, which would conflict with the licenses and rights granted to Pfizer hereunder.

10.1.7. Neither PSIVIDA nor any of its respective employees nor, to the best knowledge of PSIVIDA, its agents, in their capacity as such, have been debarred by the FDA, pursuant to 21 U.S.C. §§ 335(a) or (b), or been charged with or convicted under United States law for conduct relating to the development or approval, or otherwise relating to the regulation of Product under the Generic Drug Enforcement Act of 1992, disqualified from receiving investigational new drugs or devices under 21 CFR 312.70 or 812.119, or debarred, disqualified, or convicted under or for any equivalent or similar applicable foreign law, rule, or regulation.

10.1.8. There is no action, claim, demand, suit, proceeding, arbitration, grievance, citation, summons, subpoena, inquiry or investigation of any nature, civil, criminal, regulatory or otherwise, in law or in equity, pending or, to the knowledge of PSIVIDA, threatened against PSIVIDA or any of its Affiliates in connection with the PSIVIDA Patent Rights, PSIVIDA Technology, PSIVIDA Program Patent Rights or PSIVIDA Program Technology or relating to the transactions contemplated by this Agreement.

10.1.9. PSIVIDA has not and will not directly or indirectly offer or pay, or authorize such offer or payment, of any money or anything of value to improperly seek, or corruptly seek to influence any Government Official, and, if PSIVIDA is itself a Government Official, has not accepted, and will not accept in the future, such a payment. Further, PSIVIDA undertakes to update the representations and warranties herein if (during the term of this Agreement) PSIVIDA, or any of the employees, individuals, or subcontractors who will be primarily responsible for performing under this Agreement, or a relative of such an employee or individual or subcontractor, becomes a Government Official. PSIVIDA will comply with Pfizer Inc.'s Anti-Bribery and Anti-Corruption Principles as set out in Exhibit A attached hereto in connection with its activities pursuant to this Agreement. For purposes of this Agreement, a "Government Official" is defined as: (i) any elected or appointed Government Official (e.g., a member of a

ministry of health); (ii) any employee or person acting for or on behalf of a government official, agency, or enterprise performing a governmental function; (iii) any political party, officer, employee, or person acting for or on behalf of a political party or candidate for public office; or (iv) an employee or person acting for or on behalf of a public international organization; where "government" is meant to include all levels and subdivisions of non-US governments (i.e., local, regional, or national and administrative, legislative, or executive).

10.1.10. PSIVIDA is not a healthcare professional and is not an appointed agent or expert of any public authority.

10.2. PFIZER Representations and Warranties. As of the Effective Date, PFIZER hereby represents and warrants to PSIVIDA as follows:

10.2.1. PFIZER has the corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder, and the execution, delivery and performance of this Agreement by PFIZER have been duly and validly authorized and approved by proper corporate action on the part of PFIZER, and PFIZER has taken all other action required by Law, its certificate of incorporation or by-laws, or any agreement to which it is a party or to which it may be subject, required to authorize such execution, delivery and performance. Assuming due authorization, execution and delivery on the part of PSIVIDA, this Agreement constitutes a legal, valid and binding obligation of PFIZER, enforceable against PFIZER in accordance with its terms.

10.2.2. The execution and delivery of this Agreement by PFIZER and the performance by PFIZER contemplated hereunder does not and will not violate any Laws or any order of any court or Governmental Authority.

10.2.3. Neither the execution and delivery of this Agreement nor the performance hereof by PFIZER requires PFIZER to obtain any permits, authorizations or consents from any Governmental Authority (other than any Regulatory Approvals relating to the manufacture, use, importation or sale of the Product) or from any other person, firm or corporation, and such execution, delivery and performance will not result in the breach of or give rise to any right of termination under any agreement or contract to which PFIZER or any of its Affiliates is a party or to which it may be subject, except for those breaches or rights that would not adversely affect the ability of PFIZER to perform its obligations under this Agreement.

10.2.4. [*], the patents encompassed within the PFIZER Program Patent Rights are, or upon issuance will be, valid and enforceable patents and no Third Party (i) is infringing any such Patent Rights relating to the Device as of the Effective Date or (ii) has challenged the extent, validity or enforceability of such Patent Rights (including by way of example through the institution or written threat of institution of interference, nullity or similar invalidity proceedings before the United States Patent and Trademark Office or any analogous or foreign entity).

10.2.5. To the knowledge of PFIZER, PFIZER or its relevant Affiliate is the sole legal and beneficial owner of all the PFIZER Patent Rights and PFIZER Technology, free of any lien, encumbrance, charge, security interest, mortgage or other similar restriction, and no person, firm, corporation, governmental agency, or other entity (including any Affiliate of PFIZER) has any ownership right, interest or claim in or to, any PFIZER Patent Rights or PFIZER Technology.

10.2.6. Neither PFIZER nor any of its respective employees nor, to the best knowledge of PFIZER, its agents, in their capacity as such, have been debarred by the FDA, pursuant to 21 U.S.C. §§ 335(a) or (b), or been charged with or convicted under United States law for conduct relating to the development or approval, or otherwise relating to the regulation of Product under the Generic Drug Enforcement Act of 1992, disqualified from receiving investigational new drugs or devices under 21 CFR 312.70 or 812.119, or debarred, disqualified, or convicted under or for any equivalent or similar applicable foreign law, rule, or regulation.

10.2.7. There is no action, claim, demand, suit, proceeding, arbitration, grievance, citation, summons, subpoena, inquiry or investigation of any nature, civil, criminal, regulatory or otherwise, in law or in equity, pending or, to the knowledge of PFIZER threatened against PFIZER or any of its Affiliates (except to the extent disclosed pursuant to Section 10.2.4) relating to the PFIZER Program Patent Rights, PFIZER Program Technology, PFIZER Technology or transactions contemplated by this Agreement.

10.2.8. PFIZER has not and will not directly or indirectly offer or pay, or authorize such offer or payment, of any money or anything of value to improperly seek, or corruptly seek to influence any Government Official, and, if PFIZER is itself a Government Official, has not accepted, and will not accept in the future, such a payment. Further, PFIZER undertakes to update the representations and warranties herein

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if (during the term of this Agreement) PFIZER, or any of the employees, individuals, or subcontractors who will be primarily responsible for performing under this Agreement, or a relative of such an employee or individual or subcontractor, becomes a Government Official. PFIZER will comply with its Anti-Bribery and Anti-Corruption Principles as set out in Exhibit A attached hereto in connection with its activities pursuant to this Agreement.

10.3. Disclaimer of Warranty. EXCEPT AS OTHERWISE EXPRESSLY STATED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY OF ANY KIND WITH RESPECT TO COMPOUNDS, DEVICES, FORMULATIONS, PRODUCTS, PATENT RIGHTS, OR TECHNOLOGY. EXCEPT AS OTHERWISE PROVIDED IN THIS SECTION 10, EACH PARTY EXPRESSLY DISCLAIMS ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT.

11. **Additional Covenants**.

11.1. Each of PSIVIDA and PFIZER shall conduct, and shall use Commercially Reasonable Efforts to cause its Affiliates to conduct, all its activities contemplated under this Agreement in accordance with all applicable Laws of the country in which such activities are conducted.

11.2. [*]

11.3. Non-Compete. Subject to the BMP Agreement, the B&L Agreement, the Alimera Agreement, and Section 13.5, during the Royalty Term in any country, PSIVIDA shall not, and shall cause its Affiliates not to, alone or in collaboration with any Third Party, promote, sell, distribute or otherwise commercialize in such country (a) any bioerodible Device delivering by subconjunctival implant or injection the Compound, alone or together with another active ingredient, in humans, (b) any bioerodible Device for the treatment of Glaucoma in humans by a subconjunctival implant or injection that contains a prostaglandin, or (c) any Product for uveitis, or grant any Third Party the right to do any of the foregoing; provided, however, that the foregoing shall not apply to prevent a Person that first becomes an Affiliate of PSIVIDA after the Effective Date from developing, promoting, selling, distributing or otherwise commercializing such a Device as long as such developing, promoting, selling, distributing or otherwise commercializing does not infringe PSIVIDA Patent Rights or PSIVIDA Program Patent Rights.

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11.4. Kentucky Study Agreement. As soon as practicable after the Effective Date, (a) PFIZER shall assign to PSIVIDA and PSIVIDA shall accept and assume all of the rights and obligations of PFIZER under the Kentucky Study Agreement with effect from and after the Effective Date and (b) the Parties shall take such actions and execute such documents as are necessary to carry out such assignment and assumption.

12. **Term**. This Agreement shall be effective as of the Effective Date and shall, unless earlier terminated in accordance with Section 13, remain in effect until the expiration of the Royalty Term.

13. **Termination**.

13.1. Termination Rights. This Agreement may be terminated as follows:

13.1.1. If either PFIZER or PSIVIDA materially breaches or materially defaults in the performance or observance of any of its respective obligations under this Agreement, and such breach or default is not cured within (a) in the event of a failure of a Party to make a required payment under this Agreement, thirty (30) days and (b) for all other breaches or defaults, sixty (60) days after the giving of written notice by the other Party specifying such breach or default, then such other Party shall have the right to terminate this Agreement by providing the breaching Party written notice within thirty (30) days following the expiration of such period (such termination to be effective upon receipt of such termination notice). For the purpose of this Section 13.1.1, a material breach or material default shall include a material inaccuracy in any warranty or representation contained herein. In addition, PSIVIDA may terminate this Agreement pursuant to Section 11.2.

13.1.2. PFIZER may terminate this Agreement effective immediately upon notice to PSIVIDA, if PSIVIDA breaches any of the representations and warranties set forth in Section 10.1.9 or if PFIZER learns that improper payments are being or have been made to Government Officials (as defined in Section 10.1.9) by PSIVIDA with respect to services performed or activities undertaken either on behalf of PSIVIDA or in connection with PSIVIDA's provision of services to any other party. Further, in the event of any termination referred to in the preceding sentence, PSIVIDA shall not be entitled to any further payment, regardless of any activities undertaken or agreements with additional Third Parties entered into prior to termination, and PSIVIDA shall be liable for damages or remedies as provided by law.

13.1.3. PSIVIDA may terminate this Agreement effective immediately upon notice to PFIZER, if PFIZER breaches any of the representations and warranties set forth in Section 10.2.8 or if PSIVIDA learns that improper payments are being or have been made to Government Officials (as defined in Section 10.2.8) by PFIZER with respect to services performed or activities undertaken either on behalf of PFIZER or in connection with PFIZER's provision of services to any other party. Further, in the event of any termination referred to in the preceding sentence, PFIZER shall not be entitled to any further payment, regardless of any activities undertaken or agreements with additional Third Parties entered into prior to termination, and PFIZER shall be liable for damages or remedies as provided by law.

13.1.4. If either Party is generally unable to meet its debts when due, or makes a general assignment for the benefit of its creditors, or there shall have been appointed a receiver, trustee or other custodian for such Party for all or a substantial part of its assets, or any case or proceeding shall have been commenced or other action taken by or against such Party in bankruptcy or seeking the reorganization, liquidation, dissolution or winding-up of such Party or any other relief under any bankruptcy, insolvency, reorganization or other similar act or Law, and any such event shall have continued for sixty (60) days undismissed, unstayed, unbonded and undischarged, then the other Party may, upon notice to such Party, terminate this Agreement, such termination to be effective upon such Party's receipt of such notice.

13.1.5. PFIZER, upon sixty (60) days' written notice to PSIVIDA, shall have the right, at PFIZER's sole discretion, to terminate this Agreement.

13.1.6. This Agreement shall terminate under the circumstances set forth in Section 3.3 or Section 3.5

13.1.7. In the event that the Parties make an HSR Filing under Section 3.6.5 hereof, this Agreement shall terminate (a) at the election of either Party immediately upon notice to the other Party, in the event that the United States Federal Trade Commission and/or the United States Department of Justice shall seek or threaten or shall obtain a preliminary injunction under the HSR Act against PFIZER and PSIVIDA to enjoin the transactions contemplated by this Agreement, or (b) at the election of either Party, immediately upon notice to the other Party, in the event that the HSR Clearance Date shall not have occurred on or prior to ninety (90) days after the effective date of the HSR Filing. Notwithstanding the foregoing, this Section 13.1.7 shall not apply in the event that an HSR Filing is not required.

13.2. Accrued Obligations. Expiration or termination of this

Agreement for any reason (x) shall be without prejudice to a Party's right to receive all royalties accrued under Section 6 prior to the effective date of such termination and to any other remedies that either Party may otherwise have and (y) shall not release a Party hereto from any indebtedness, liability or other obligation incurred hereunder by such Party prior to the date of termination or expiration.

13.3. Effect of Termination.

13.3.1. Upon any termination of this Agreement pursuant to Section 13.1.1, 13.1.3, 13.1.4, 13.1.5, 13.1.6 or 13.1.7, all licenses granted herein to PFIZER shall terminate. Upon any termination of this Agreement by PFIZER pursuant to Section 13.1.1, 13.1.2 or 13.1.4 or upon any termination of this Agreement pursuant to Section 13.1.6 or 13.1.7, all licenses granted herein to PSIVIDA shall terminate, except for such licenses that survive as provided by Section 16.7, and except as expressly set forth in Section 13.3.2.

13.3.2. If PFIZER terminates this Agreement pursuant to Section 13.1.5 (other than in the event (A) of any safety issue that would reasonably be expected to have a material adverse effect on PFIZER's ability to develop, manufacture or commercialize the Product, as determined in good faith in the reasonable judgment of PFIZER's internal safety committee in accordance with PFIZER's standard internal procedures for evaluating such safety issues or (B) that a Regulatory Authority or data monitoring review board has required termination or suspension of a Clinical Trial for the Product or withdrawal of the Product from any market on account of a safety issue), or this Agreement terminates pursuant Section 13.1.6 or 13.1.7, or PSIVIDA terminates this Agreement pursuant to Section 13.1.1 or 13.1.3 (but in no event if (x) any such termination results, arises from or relates to, or is deemed to result, arise from or relate to, by operation of law or otherwise, any termination or deemed termination hereof that occurs during the course of any bankruptcy or other insolvency proceeding involving PSIVIDA or (y) PSIVIDA rejects this Agreement pursuant to Sections 363, 365 or 1123 of Title 11 of the United States Code, as amended):

(a) PFIZER shall at PSIVIDA's request, (i) use Commercially Reasonable Efforts to transfer ownership of all regulatory filings and Regulatory Approvals that relate solely to the Product to PSIVIDA or its designee; (ii) deliver to PSIVIDA a copy of all Clinical IP in PFIZER's or any of its Affiliates' possession and Control (including Clinical IP generated by Third Parties under any services arrangement) related to the Product (and that does not relate solely to the Compound), if any, in the same form in which PFIZER or such Affiliate maintains such data; (iii) provide

PSIVIDA with copies of any then-existing documentation and technical information, in the form and format in which such materials are maintained by PFIZER or any of its Affiliates in the ordinary course of its business, that are necessary for the manufacture of the Product, which documentation and technical information shall include (A) [*], (B) [*], (C) [*], (D) [*], (E) [*] and (F) such other documentation as the Parties may mutually agree, in each case of the foregoing subsections (iii) and (A) through (F), that are in PFIZER's or any of its Affiliates' possession and Control (including any of the foregoing that are generated by Third Parties under any services arrangement) and are necessary to manufacture Products; and (iv) deliver to PSIVIDA, in the same form in which PFIZER or any of its Affiliates maintains such items, copies of all regulatory reports, records, correspondence and other regulatory materials in PFIZER's or any of its Affiliates' possession and Control related solely to such Product (and not related solely to the Compound) and any Regulatory Approval therefor (including any of the foregoing that are generated by Third Parties under any services arrangement), including, if applicable, any information contained in the global safety database established and maintained by PFIZER or any of its Affiliates (provided that any good faith failure by PFIZER to provide immaterial data, information, reports, records, correspondence or other materials to PSIVIDA shall not be a breach of PFIZER's obligations under this Section 13.3.2).

(b) PFIZER shall and hereby does grant to PSIVIDA (i) a non-exclusive, royalty-free (except as set forth below in this paragraph), perpetual, irrevocable, world-wide license, with the right to sublicense, under and to the Clinical IP Controlled by PFIZER or any of its Affiliates, the PFIZER Patent Rights, the PFIZER Technology, the PFIZER Program Technology and the PFIZER Program Patent Rights, and (ii) the non-exclusive right to [*], in the case of (i) and (ii) solely to develop, make, have made, sell, offer for sale, use and import the Product. It is understood that

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upon any termination, PSIVIDA will not obtain any rights to PFIZER Compounds, PFIZER Patent Rights, PFIZER Technology, PFIZER Program Patent Rights or PFIZER Program Technology except as expressly set forth in this Agreement. If any of the foregoing are licensed to Pfizer from a Third Party ("Third Party Licensor"), [*]. Without limiting the foregoing [*].

(c) PFIZER shall and hereby does grant to PSIVIDA a non-exclusive, royalty-free (except as set forth below in this paragraph), perpetual, irrevocable, world-wide license, with the right to sublicense, under and to all PFIZER Controlled Intellectual Property, solely to develop, make, have made, sell, offer for sale, use and import the Product; provided that such license shall continue only so long as (a) PSIVIDA elects to accept such license, and (b) [*]

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[*]. Without limiting the foregoing, [*].

13.3.3. Following any termination of this Agreement but subject to the foregoing provisions of Section 13.3.2 each Party shall, upon request of the other Party, return or destroy all Confidential Information

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disclosed to it by the other Party pursuant to this Agreement or the Prior Agreement, including all copies and extracts of documents, as promptly as practicable following receipt of such request, except that one (1) copy may be kept for the purpose of complying with continuing obligations under this Agreement.

13.3.4. In order to ensure the smooth transition of the development and/or commercialization of the Product from PFIZER to PSIVIDA or a Third Party designated by PSIVIDA, at PSIVIDA's request, representatives of PFIZER and PSIVIDA will meet to discuss in good faith a transition plan with respect to all then-current as well as planned activities relating to the Product, consistent with Section 13.3.2.

13.4. Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by PSIVIDA are, and shall otherwise be deemed to be, for purposes of Article 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined under Article 101 of the U.S. Bankruptcy Code. The Parties agree that PFIZER, as licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code. The Parties further agree that, in the event of the commencement of any proceeding by or against PSIVIDA or any of its Affiliates under the U.S. Bankruptcy Code, PFIZER shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, and, if not already in its possession, PSIVIDA shall promptly deliver to PFIZER all such intellectual property and all embodiments of such intellectual property (a) upon PFIZER's request any time following commencement of any such proceeding, unless PSIVIDA elects to continue to perform all of its obligations under this Agreement or (b) if not delivered under (a) above, upon PFIZER's request any time following the rejection of this Agreement by or on behalf of PSIVIDA.

13.5. Change of Control. PSIVIDA shall notify PFIZER promptly, but in no event later than five (5) Business Days, following approval by PSIVIDA's (or its parent corporation's) board of directors of any transaction that constitutes a Change of Control; provided, however, that in the event such disclosure is prohibited by applicable Law or PSIVIDA's contractual obligations to a Third Party, PSIVIDA shall have the right to delay such notification until five (5) Business Days following the consummation of the applicable Change of Control. Effective upon the consummation of such Change of Control, Section 3.4(e) shall be automatically deleted from this Agreement and shall cease to be of any further force or effect. PFIZER shall have the right upon sixty (60) days' notice following any such Change of Control, to elect that any one or more of the following shall be deleted, in

whole or in part, from this Agreement: Sections 2.1 through 2.6 and 3.6.4, and PFIZER's obligations under Sections 3.9, 3.10, 5.2.3, 5.2.4, and 5.5.1. If PFIZER makes any election as provided in this Section 13.5 to delete any Section, each of the Parties hereto will enter into an appropriate and customary written amendment and no Party shall have any further obligations with respect to any such deleted Section. In the event that a transaction that constitutes a Change of Control is approved by PSIVIDA's board of directors but is not consummated, any Section deleted by PFIZER pursuant to the foregoing shall immediately and automatically be reinstated upon notice thereof by PSIVIDA to PFIZER. For the avoidance of doubt, PFIZER shall be entitled, in its sole discretion, to make the elections provided for in this Section 13.5 upon each occurrence of a Change of Control.

13.6. Breach Remedy. If an event occurs that gives rise to a right of termination by PFIZER under Section 13.1.1 (as a result of an uncured breach by PSIVIDA) and if PFIZER elects not to terminate this Agreement, any amounts payable by PFIZER to PSIVIDA pursuant to Section 3.6.1 or Section 6 shall be reduced to seventy percent (70%) (i.e., a thirty percent (30%) reduction) of the amount that would otherwise have been payable under the terms of the Agreement during the Term and PFIZER may elect that any one or more of the following shall be deleted, in whole or in part, from this Agreement: Sections 2.1 through 2.6, 3.6.3 and 3.10, and PFIZER's obligations under Sections 3.9, 5.2.3, 5.2.4 and 5.5.1. If PFIZER makes any election as provided in this Section 13.6 to delete any Section, each of the Parties hereto will enter into an appropriate and customary written amendment and no Party shall have any further obligations with respect to any such deleted Section.

14. **Indemnification and Insurance**.

14.1. Indemnification.

14.1.1. PSIVIDA will indemnify, defend and hold PFIZER and PFIZER's Affiliates, and their respective directors, officers and employees (collectively, "Representatives"), harmless from any and all Losses (as defined below) incurred by any of them and which are not covered by an insurance policy that result from:

(a) the breach of any covenant, warranty or representation made by PSIVIDA under this Agreement;

(b) the negligence, recklessness, or willful misconduct of PSIVIDA or any of its Affiliates; or

(c) any acts or omissions of PSIVIDA or any of its Affiliates, agents or licensees in connection with the research, development or commercialization of the Product.

PSIVIDA shall only be obligated to so indemnify, defend and hold PFIZER harmless to the extent that such Losses do not result from the negligence, recklessness or willful misconduct of PFIZER or its Affiliates, agents or licensees.

14.1.2. PFIZER will indemnify, defend and hold PSIVIDA and PSIVIDA's Representatives, harmless from any and all Losses incurred by any of them and which are not covered by an insurance policy that result from:

(a) the breach of any covenant, warranty or representation made by PFIZER under this Agreement;

(b) the negligence, recklessness, or willful misconduct of PFIZER or any of its Affiliates;

(c) any acts or omissions of PFIZER or any of its Affiliates, agents or licensees in connection with the research, development or commercialization of the Product.

PFIZER shall only be obligated to so indemnify, defend and hold PSIVIDA harmless to the extent that such Losses do not result from the negligence, recklessness or willful misconduct of PSIVIDA or its Affiliates, agents or licensees.

14.2. Losses. For purposes of this Agreement, "Losses" means any and all costs, expenses, claims, losses, liabilities, damages, fines, royalties, governmental penalties or punitive damages, deficiencies, interest, settlement amounts, awards, and judgments, including any and all reasonable, out-of-pocket costs and expenses properly incurred, as a result of a Third Party claim (including reasonable, out-of-pocket attorneys' fees and all other expenses reasonably incurred in investigating, preparing or defending any litigation or proceeding, commenced or threatened), in each case, net of any insurance recovery received as a result of such Loss.

14.3. Insurance. Each Party shall maintain, and shall cause its Affiliates and each sublicensee conducting activities under this Agreement to maintain, at such Party's, an Affiliate's, or sublicensee's sole expense, appropriate product liability insurance coverage in amounts reasonably determined by the Party from time to time but at least sufficient to insure against claims which may arise from the performance of obligations or exercise of rights granted under this Agreement or from indemnification obligations under this Section 14, but

in no event shall a Party's insurance coverage be in an amount less than $5,000,000 per occurrence and $10,000,000 annual aggregate (provided that (i) in the case of PFIZER such coverage may be pursuant to a program of self-insurance and (ii) in the case of an Affiliate that becomes an Affiliate of PSIVIDA following the Effective Date, such Affiliate may (a) continue to operate under a self-insurance plan that was in place at the time it became an Affiliate or (b) adopt a self-insurance plan to the extent such plan is reasonable in light of industry practices of Persons similarly situated to such Affiliate). The policy of insurance shall contain a provision of non-cancellation except upon the provision of thirty (30) days notice to the other Party. Each Party shall maintain such insurance commencing on the Effective Date and for so long as it continues to research, produce, develop, manufacture, distribute, sell or use the Products, and thereafter for so long as each Party maintains insurance for itself covering such manufacture or sales.

14.4. Defense Procedures; Procedures for Third Party Claims. In the event that any Third Party (in no event to include any Affiliate of any of the Parties) asserts a claim with respect to any matter for which a Party (the "Indemnified Party") is entitled to indemnification hereunder (a "Third Party Claim"), then the Indemnified Party shall promptly notify the Party obligated to indemnify the Indemnified Party (the "Indemnifying Party") thereof; provided, however, that no delay on the part of the Indemnified Party in notifying the Indemnifying Party shall relieve the Indemnifying Party from any obligation hereunder unless (and then only to the extent that) the Indemnifying Party is prejudiced thereby.

14.4.1. The Indemnifying Party shall have the right, exercisable by notice to the Indemnified Party within ten (10) Business Days after receipt of notice from the Indemnified Party of the commencement of or assertion of any Third Party Claim, to assume direction and control of the defense, litigation, settlement, appeal or other disposition of the Third Party Claim (including the right to settle the claim solely for monetary consideration) with counsel selected by the Indemnifying Party and reasonably acceptable to the Indemnified Party; provided that (i) the Indemnifying Party has sufficient financial resources, in the reasonable judgment of the Indemnified Party, to satisfy the amount of any adverse monetary judgment that is sought, (ii) the Third Party Claim seeks solely monetary damages and (iii) the Indemnifying Party expressly agrees in writing that as between the Indemnifying Party and the Indemnified Party, the Indemnifying Party shall be solely obligated to satisfy and discharge the Third Party Claim in full (the conditions set forth in clauses (i), (ii) and (iii) above are collectively referred to as the "Litigation Conditions").

14.4.2. Within ten (10) Business Days after the Indemnifying Party has given notice to the Indemnified Party of its exercise of its right to defend a

Third Party Claim, the Indemnified Party shall give notice to the Indemnifying Party of any objection thereto based upon the Litigation Conditions. If the Indemnified Party reasonably so objects, the Indemnified Party shall continue to defend the Third Party Claim, at the expense of the Indemnifying Party, until such time as such objection is withdrawn. If no such notice is given, or if any such objection is withdrawn, the Indemnifying Party shall be entitled, at its sole cost and expense, to assume direction and control of such defense, with counsel selected by the Indemnifying Party and reasonably acceptable to the Indemnified Party. During such time as the Indemnifying Party is controlling the defense of such Third Party Claim, the Indemnified Party shall cooperate, and shall cause its Affiliates and agents to cooperate upon request of the Indemnifying Party, in the defense or prosecution of the Third Party Claim, including by furnishing such records, information and testimony and attending such conferences, discovery proceedings, hearings, trials or appeals as may reasonably be requested by the Indemnifying Party. In the event that the Indemnifying Party does not satisfy the Litigation Conditions or does not notify the Indemnified Party of the Indemnifying Party's intent to defend any Third Party Claim within ten (10) Business Days after notice thereof, the Indemnified Party may (without further notice to the Indemnifying Party) undertake the defense thereof with counsel of its choice and at the Indemnifying Party's expense (including reasonable, out-of-pocket attorneys' fees and costs and expenses of enforcement or defense). The Indemnifying Party or the Indemnified Party, as the case may be, shall have the right to join in (including the right to conduct discovery, interview and examine witnesses and participate in all settlement conferences), but not control, at its own expense, the defense of any Third Party Claim that the other Party is defending as provided in this Agreement.

14.4.3. The Indemnifying Party shall not, without the prior written consent of the Indemnified Party, enter into any compromise or settlement or consent to the entry of any judgment with respect to any claim or Loss (a) that does not release Indemnified Party from all liability with respect to such claim or Loss or (b) which may materially adversely affect Indemnified Party or under which Indemnified Party would incur any obligation, commitment to act or forbear from taking any action, or liability, other than one as to which Indemnifying Party has an indemnity obligation hereunder. The Indemnified Party shall have the sole and exclusive right to settle any Third Party Claim, on such terms and conditions as it deems reasonably appropriate, to the extent such Third Party Claim involves equitable or other non-monetary relief, but shall not have the right to settle such Third Party Claim to the extent such Third Party Claim involves monetary damages without the prior written consent of the Indemnifying Party. Each of the Indemnifying Party and the Indemnified Party shall not make any

admission of liability in respect of any Third Party Claim without the prior consent of the other Party, and the Indemnified Party shall use Commercially Reasonable Efforts to mitigate losses arising from the Third Party Claim.

14.5. Disclaimer of Liability for Consequential Damages. IN NO EVENT SHALL ANY PARTY OR ANY OF ITS RESPECTIVE AFFILIATES BE LIABLE UNDER THIS AGREEMENT FOR SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, INCLUDING LOSS OF PROFITS OR REVENUE, SUFFERED BY PFIZER, PSIVIDA OR ANY OF THEIR RESPECTIVE REPRESENTATIVES, EXCEPT TO THE EXTENT OF ANY SUCH DAMAGES PAID TO A THIRD PARTY IN CONNECTION WITH A THIRD PARTY CLAIM; PROVIDED THAT THIS SECTION SHALL NOT RELIEVE EITHER PARTY FROM ITS PAYMENT OBLIGATIONS UNDER THIS AGREEMENT.

14.6. SOLE REMEDY. EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT AND EXCEPT FOR ANY EQUITABLE REMEDIES THAT MAY BE AVAILABLE TO A PARTY, INDEMNIFICATION PURSUANT TO THIS SECTION 14 SHALL BE THE SOLE AND EXCLUSIVE REMEDY (WHETHER BASED ON CONTRACT, TORT OR ANY OTHER LEGAL THEORY) AVAILABLE TO PSIVIDA OR PFIZER FOR THE MATTERS COVERED THEREIN.

15. **Governing Law and Jurisdiction**.

15.1. Governing Law. This Agreement shall be governed by and construed in accordance with the substantive laws of the State of New York, without regard to conflicts of law rules.

15.2. Jurisdiction. With the exception of those matters referred for resolution by independent accountants under Section 7.5, in the event of any controversy, claim or counterclaim arising out of or relating to this Agreement, the Parties shall first attempt to resolve such controversy or claim through good faith negotiations for a period of not less than thirty (30) days following notification of such controversy or claim to the other Party. If such controversy or claim cannot be resolved by means of such negotiations during such period, then such controversy or claim shall be resolved by the United States District Court for the Southern District of New York or a local court sitting in New York, New York (collectively, the "Courts"). Each Party (a) irrevocably submits to

the exclusive jurisdiction in the Courts for purposes of any action, suit or other proceeding relating to or arising out of this Agreement and (b) agrees not to raise any objection at any time to the laying or maintaining of the venue of any such action, suit or proceeding in any of the Courts, irrevocably waives any claim that such action, suit or other proceeding has been brought in an inconvenient forum and further irrevocably waives the right to object, with respect to such action, suit or other proceeding, that such Court does not have any jurisdiction over such party. In the event of any action, suit or other proceeding pursuant to this Section 15.2, either Party may effect service of process by providing a complaint and/or summons or other court filing to the other Party pursuant to Section 16.10. Any defenses based on adequacy of service of process, other than breach of Section 16.10 are waived.

16. **Miscellaneous**.

16.1. Termination of Prior Agreements. The Parties agree that: (a) this Agreement shall supersede the Prior Agreement, which shall be and hereby is terminated as of the Effective Date; (b) notwithstanding any provisions of the Prior Agreement to the contrary, no rights, obligations or liabilities of the Parties under the Prior Agreement shall survive this termination except for rights, obligations and liabilities of both Parties under Section 9 (Confidentiality), Section 14 (Indemnification), and other sections, exhibits, or definitions referenced therein; and (c) as of the Effective Date, all payment and performance obligations, except for the assignment of rights from PSIVIDA to PFIZER related to United States Provisional Patent Application [*], owed by each Party under the Prior Agreement (including any payments that were due and payable prior to the Effective Date) to the other Party are hereby deemed fully paid and performed by such owing Party.

16.2. Force Majeure. Neither Party hereto shall be liable to the other Party (except for payment obligations set forth in this Agreement, each of which shall remain in effect) for any losses or damages attributable to a default in or breach of this Agreement that is the result of war (whether declared or undeclared), acts of God, revolution, acts of terror, fire, earthquake, flood, pestilence, riot, enactment or change of Law (following the Effective Date), accident(s), labor trouble, or shortage of or inability to obtain material equipment or transport or any other cause beyond the reasonable control of such Party; provided that if such a cause occurs, then the Party affected will promptly notify the other Party of the nature and likely result and duration (if known) of such cause and use Commercially Reasonable Efforts to reduce the

* Confidential information has been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request.

effect. If the event lasts for a period of longer than three (3) months, the Parties shall meet and discuss appropriate remedial measures.

16.3. Reserved Rights; Non-Exclusivity.

16.3.1. All rights and interests not expressly granted to PFIZER are reserved by PSIVIDA (the "PSIVIDA Reserved Interests") for itself, its Affiliates and partners (other than PFIZER) and other licensees and sublicensees, including, but not limited to, the rights to use, enter into agreements or grant licenses under the PSIVIDA Patent Rights, PSIVIDA Program Patent Rights, PSIVIDA Technology, PSIVIDA Program Technology or any other technology owned, licensed or controlled by PSIVIDA or any of its Affiliates to make, have made, use, offer to sell, sell, have sold and import products (other than the Product in the Territory in the Field or for uveitis for so long as PFIZER has an exclusive license to the Product in the Field in the Territory under this Agreement). It shall not be a breach of this Agreement for PSIVIDA, acting directly or indirectly, to exploit the PSIVIDA Reserved Interests in any manner anywhere in or outside of the Territory, whether or not such activity is competitive with the activities of PFIZER, including the research, development and commercialization or licensing to others to research, develop and commercialize products (other than the Product in the Territory in the Field or for uveitis in the Territory for so long as PFIZER has an exclusive license to the Product in the Field in the Territory under this Agreement).

16.3.2. Subject to Section 13.3.3, except as otherwise expressly provided in this Agreement, for the avoidance of doubt, PFIZER shall be free to use, enter into an agreement with and grant licenses to any Third Party or Third Parties under the PFIZER Patent Rights, the PFIZER Program Patent Rights, the PFIZER Technology or the PFIZER Program Technology or any other technology owned, licensed or Controlled by PFIZER or any of its Affiliates to research, develop and commercialize any and all products, and it shall not be a breach of this Agreement for PFIZER, acting directly or indirectly, to engage in any activities competitive with the activities of PSIVIDA, including the research, development and commercialization of products and other drug delivery devices.

16.4. Severability. If and solely to the extent that any provision of this Agreement shall be invalid or unenforceable, or shall render this entire Agreement to be unenforceable or invalid, such offending provision shall be of no effect and shall not affect the validity of the remainder of this Agreement or any of its provisions; provided, however, the Parties shall use their respective

Commercially Reasonable Efforts to replace the invalid provisions in a manner that best accomplishes the original intentions of the Parties.

16.5. Waivers. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party or Parties waiving such term or condition. Neither the waiver by any Party of any term or condition of this Agreement nor the failure on the part of any Party, in one or more instances, to enforce any of the provisions of this Agreement or to exercise any right or privilege, shall be deemed or construed to be a waiver of such term or condition for any similar instance in the future or of any subsequent breach hereof. All rights, remedies, undertakings, obligations and agreements contained in this Agreement shall be cumulative and none of them shall be a limitation of any other remedy, right, undertaking, obligation or agreement.

16.6. Entire Agreements; Amendments. This Agreement sets forth the entire agreement and understanding between the Parties as to the subject matter hereof and supersedes all agreements or understandings, verbal or written, made between PSIVIDA and PFIZER before the date hereof with respect to the subject matter hereof, including the Confidentiality Agreement between the Parties, dated February 2, 2007, the Feasibility Study Agreement dated December 22, 2006 and the Collaborative Research and License Agreement dated April 3, 2007. All Confidential Information disclosed prior to the Effective Date will be deemed to have been disclosed pursuant to this Agreement. None of the terms of this Agreement shall be amended, supplemented or modified except in writing signed by the Parties.

16.7. Survival. The provisions of Section 1 (Definitions), 4.2(b), 5.2 (Regulatory Affairs), 7.5 (Inspection of Records), 8.1 (Disclosure and Ownership of Program Technology and Program Patent Rights), 9.1 (Confidential Information), 9.2 (Disclosure of Agreement Terms), 9.4 (Filing, Registration or Notification of the Agreement), 13 (Termination), 14 (Indemnification and Insurance), 15 (Governing Law and Jurisdiction) and 16 (Miscellaneous), as well as any other Sections or defined terms referred to in such Sections or necessary to give them effect shall survive termination or expiration of this Agreement and remain in force until discharged in full. Furthermore, any other provisions required to interpret and enforce the Parties' rights and obligations or to wind up their outstanding obligations under this Agreement shall survive to the extent required.

16.8. Assignment. Neither this Agreement nor any rights or obligations of

either Party to this Agreement may be assigned or otherwise transferred by either Party without the consent of the other Party; provided, however, either Party may, without such consent, assign this Agreement, in whole or in part: (i) to any of its respective Affiliates; (ii) to any transferee of all or substantially all of such Party's assets or business or all or substantially all of such Party's ophthalmic assets or business, or (iii) in connection with a Change of Control of such Party; provided that such assigning Party shall remain jointly and severally liable with such assignee or transferee in respect of all obligations so assigned. Any purported assignment in violation of this Section 16.8 shall be void. Any permitted assignee shall assume all obligations of its assignor under this Agreement.

16.9. Independent Contractor. The relationship between PSIVIDA and PFIZER is that of independent contractors. PSIVIDA and PFIZER are not joint venturers, partners, principal and agent, employer and employee, and have no other relationship other than independent contracting parties.

16.10. Notices. Each communication and document made or delivered by one Party to another under this Agreement shall be made in the English language. All notices, consents, approvals, requests or other communications required hereunder given by one Party to the other hereunder shall be in writing and made by registered or certified air mail, facsimile, express overnight courier or delivered personally to the following addresses of the respective Parties:

If to PSIVIDA:
PSIVIDA Inc.
400 Pleasant Street
Watertown, MA 02472
Attention: President
Fax: (617) 926-5050

with a copy to:
PSIVIDA Inc.
400 Pleasant Street
Watertown, MA 02472
Attention: General Counsel
Fax: (617) 926-5050

with a copy to:
Ropes & Gray LLP
800 Boylston Street
Boston, MA 02199
Attention: Susan Galli, Esq.

Invoices should be sent to PSIVIDA as directed by PSIVIDA.

If to PFIZER: Pfizer Inc.
235 East 42nd Street
New York, New York 10017-5755
U.S.A.
Attention: Senior Vice President Worldwide Business Development

with a copy to: Pfizer Inc.
235 East 42nd Street
New York, New York 10017-5755
U.S.A.
Attention: General Counsel

Invoices should be sent to PFIZER as directed by PFIZER.

Notices hereunder shall be deemed to be effective (a) upon receipt if personally delivered, (b) on the tenth (10th) Business Day following the date of mailing if sent by registered or certified air mail; (c) on the second (2nd) Business Day following the date of transmission or delivery to the overnight courier if sent by facsimile or overnight courier. A Party may change its address listed above by sending notice to the other Party in accordance with this Section 16.10.

16.11. Third Party Beneficiaries. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including any creditor of either Party. No Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against either Party.

16.12. Binding Effect. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective heirs, successors and permitted assigns.

16.13. Counterparts. This Agreement may be executed in any two or more counterparts, including by facsimile or by electronic scan copies delivered by email, each of which, when executed, shall be deemed to be an original and all of which together shall constitute one and the same document.

16.14. Headings. Headings in this Agreement are included herein for ease of reference only and shall have no legal effect. References to the parties, Sections, Schedules, and Exhibits are to the parties, Sections, Schedules and Exhibits to and of this Agreement unless otherwise specified.

[Signature page follows.]

IN WITNESS WHEREOF the Parties hereto have caused this Agreement to be executed by their duly authorized officers upon the date set out above.

PSIVIDA CORP.

For itself and as successor to pSivida Limited

By: /s/ Paul Ashton
Name: Paul Ashton
Title: President and CEO

PSIVIDA US, INC.

Formerly known as pSivida, Inc.

By: /s/ Paul Ashton
Name: Paul Ashton
Title: President and CEO

PSIMEDICA LIMITED

By: /s/ Paul Ashton
Name: Paul Ashton
Title: Director

PFIZER INC.

By: /s/ Adam Woodrow
Name: Adam Woodrow
Title: VP Commercial Development

CONFIDENTIAL TREATMENT REQUESTED

Schedule 1.65

PFIZER Patent Rights

[*]

* Confidential information has been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request.

CONFIDENTIAL TREATMENT REQUESTED

Schedule 1.66

PFIZER Program Patent Rights

All right, title and interest to [*].

* Confidential information has been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request.

CONFIDENTIAL TREATMENT REQUESTED

Schedule 1.74

Phase II Activities

[*]

* Confidential information has been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request.

CONFIDENTIAL TREATMENT REQUESTED

Schedule 1.82

PSIVIDA Patent Rights

[*]

* Confidential information has been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request.

CONFIDENTIAL TREATMENT REQUESTED

Schedule 1.83

PSIVIDA Program Patent Rights

All right, title and interest to [*].

* Confidential information has been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request.

CONFIDENTIAL TREATMENT REQUESTED

Schedule 10.1.5

Scheduled PSIVIDA Patent Rights

[*]

pSivida US, Inc., owns all right, title and interest to [*].

* Confidential information has been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request.

CONFIDENTIAL TREATMENT REQUESTED

Exhibit A

FCPA

PFIZER ANTI-BRIBERY AND ANTI-CORRUPTION PRINCIPLES

Pfizer Corporate Policy # 201 (Lawful and Ethical Behavior) provides that Pfizer colleagues must conduct all Pfizer business in a lawful and ethical manner, in accordance with applicable laws and regulations, including the U.S. Foreign Corrupt Practices Act of 1977 (the "FCPA"). The FCPA prohibits making, promising, or authorizing the making of a corrupt payment or providing anything of value to a government official to induce that official to make any governmental act or decision to assist a company in obtaining or retaining business. The FCPA also prohibits a company or person from using another company or individual to engage in any of the foregoing activities. As a U.S. company, Pfizer must comply with the FCPA and could be held liable as a result of acts committed anywhere in the world by a Pfizer consultant, agent, or representative, or even by a company acting on behalf of Pfizer ("Business Associates"). Therefore, Pfizer requires all of its Business Associates to conduct their Pfizer-related work in accordance with these principles.

Definition of a Government Official

Under Pfizer's policies, "government official" is broadly interpreted and includes: (i) any elected or appointed government official (e.g., a member of a ministry of health); (ii) any employee or person acting for or on behalf of a government official, agency, or enterprise performing a governmental function; (iii) any political party, officer, employee, or person acting for or on behalf of a political party or candidate for public office; or (iv) an employee or person acting for or on behalf of a public international organization (e.g., the United Nations). "Government" is meant to include all levels and subdivisions of governments (i.e., local, regional, or national and administrative, legislative, or executive). Because this definition of "government official" is so broad, it is likely that Business Associates will interact with a government official in the ordinary course of their business on behalf of Pfizer. For example, doctors employed by state-owned hospitals could be considered "government officials" under Pfizer's policies.

FCPA, Anti-Corruption and Anti-Bribery Principles

Business Associates may not directly or indirectly make, promise, or authorize the making of a corrupt payment or provide anything of value to any government official to induce that government official to make any governmental act or decision to help Pfizer obtain or retain business. Business Associates may never make a payment to or offer a government official any item or benefit, regardless of value, as an improper inducement for such government official to

approve, reimburse, prescribe, or purchase a Pfizer product, to influence the outcome of a clinical trial, or otherwise improperly to benefit Pfizer's business activities.

Understand and Follow Local Laws

Business Associates need to understand whether local laws, regulations, or operating procedures (including requirements imposed by government entities such as state-owned hospitals or research institutions) impose any limits, restrictions, or disclosure requirements on compensation, financial support, donations, or gifts that may be provided to government officials. Business Associates must take into account and comply with any applicable restrictions in conducting their Pfizer-related activities. If a Business Associate is uncertain as to the meaning or applicability of any identified limits, restrictions, or disclosure requirements with respect to interactions with government officials, that Business Associate should consult with his or her primary Pfizer contact before undertaking their activities.

Exhibit 21.1

List of Subsidiaries of pSivida Corp.

pSivida US, Inc. (Delaware)
pSiMedica Limited (United Kingdom)

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 Nos. 333-132777, 333-141083, 333-143225, 333-163347 and 333-163349 on Form S-3 of our reports dated September 13, 2011, relating to the financial statements of pSivida Corp. (which report expresses an unqualified opinion and includes an explanatory paragraph relating to the adoption of Accounting Standards Update No. 2009-13, *Multiple-Deliverable Revenue Arrangements*, effective July 1, 2010), 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, 2011.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
September 13, 2011

Exhibit 31.1

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

CERTIFICATIONS

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

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

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

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

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

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

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

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

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

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

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

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

Date: September 13, 2011

/s/ PAUL ASHTON

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

Exhibit 31.2

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

CERTIFICATIONS

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

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

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

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

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

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

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

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

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

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

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

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

Date: September 13, 2011

/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, 2011, 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, 2011

/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, 2011, 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, 2011

/s/ LEONARD S. ROSS

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