

**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, 2017

or

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

For the transition period from _____ to _____

Commission File Number 000-51122

PSIVIDA CORP.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

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

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

02472
(Zip Code)

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

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

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

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

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

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

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and Emerging Growth Company in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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, 2016, the last trading day of the registrant's most recently completed second fiscal quarter, was approximately \$58,277,000.

There were 39,372,586 shares of the registrant's common stock, \$0.001 par value, outstanding as of September 8, 2017.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Annual Report on Form 10-K incorporates certain information by reference from the registrant's proxy statement for the 2017 annual meeting of stockholders to be filed no later than 120 days after the end of the registrant's fiscal year ended June 30, 2017.

PSIVIDA CORP.
Form 10-K
For the Fiscal Year Ended June 30, 2017
Table of Contents

PART I	
ITEM 1. BUSINESS	2
ITEM 1A. RISK FACTORS	29
ITEM 1B. UNRESOLVED STAFF COMMENTS	65
ITEM 2. PROPERTIES	65
ITEM 3. LEGAL PROCEEDINGS	65
ITEM 4. MINE SAFETY DISCLOSURES.	66
PART II	67
ITEM 5. MARKET FOR REGISTRANT’S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES	67
ITEM 6. SELECTED FINANCIAL DATA	68
ITEM 7. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	70
ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK	80
ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA	80
ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE	80
ITEM 9A. CONTROLS AND PROCEDURES	81
ITEM 9B. OTHER INFORMATION	84
PART III	84
ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE	84
ITEM 11. EXECUTIVE COMPENSATION	84
ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS	84
ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE	84
ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES	84
PART IV	85
ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES	85
ITEM 16. FORM 10-K SUMMARY	85

Preliminary Note Regarding Forward-Looking Statements

Various statements made in this Annual Report on Form 10-K are forward-looking and involve risks and uncertainties. All statements that address activities, events or developments that we intend, expect or believe may occur in the future are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Such statements give our current expectations or forecasts of future events and are not statements of historical or current facts. These statements include, among others, statements about:

- the sufficiency of our cash and cash equivalents to fund our operations through approximately the first quarter of calendar year 2018;
- our ability to obtain additional capital in sufficient amounts and on terms acceptable to us, and the consequences of failing to do so;
- future expenses and capital expenditures;
- our expectations regarding the timing and design of our clinical development plans;
- our ability to establish or maintain collaborations and obtain milestone, royalty or other payments from any such collaborators;
- our expectation to submit a new drug application (“NDA”) to the U.S. Food and Drug Administration (“FDA”) for Durasert™ three-year non-erodible fluocinolone acetonide (“FA”) insert for posterior segment uveitis (“Durasert three-year uveitis”) (formerly known as Medidur) in late December 2017 or early January 2018;
- the ability of Alimera Sciences, Inc. (“Alimera”) to obtain regulatory approval of and commercialize Durasert three-year uveitis in Europe, the Middle East and Africa (“EMEA”);
- the implication of results from pre-clinical and clinical trials and our other research activities;
- our ability to manufacture Durasert three-year uveitis, if approved, or any future products or product candidates, in sufficient quantities and quality;
- our ability to develop sales and marketing capabilities, whether alone or with potential future collaborators;
- our intentions regarding our research into the use and application of our Durasert technology platform;
- our expectations regarding our ability to obtain and adequately maintain sufficient intellectual property protection for Durasert three-year uveitis and our other product candidates, and to avoid infringement of third party intellectual property rights;
- our expectation that we will continue to incur significant expenses and that our operating losses and our net cash outflows to fund operations will continue for the foreseeable future;
- the potential advantages of our product candidates and technologies;
- the scope and duration of intellectual property protection; and
- the effect of legal and regulatory developments.

Forward-looking statements also include statements other than statements of current or historical fact, including, without limitation, all statements related to any expectations of revenues, expenses, cash flows, earnings or losses from operations, cash required to maintain current and planned operations, capital or other financial items; any statements of the plans, strategies and objectives of management for future operations; any plans or expectations with respect to product research, development and commercialization, including regulatory

[Table of Contents](#)

approvals; any other statements of expectations, plans, intentions or beliefs; and any statements of assumptions underlying any of the foregoing. We often, although not always, identify forward-looking statements by using words or phrases such as “likely”, “expect”, “intend”, “anticipate”, “believe”, “estimate”, “plan”, “project”, “forecast” and “outlook”.

The following are some of the factors that could cause actual results to differ materially from the anticipated results or other expectations expressed, anticipated or implied in our forward-looking statements: uncertainties with respect to: our ability to achieve profitable operations and access to needed capital; fluctuations in our operating results; successful commercialization of, and receipt of revenues from, ILUVIEN® for diabetic macular edema (“DME”), which depends on Alimera’s ability to continue as a going concern and the effect of pricing and reimbursement decisions on sales of ILUVIEN; the successful development and, if approved, commercialization of Durasert (under the ILUVIEN trademark) for posterior segment uveitis in the EMEA by Alimera, which depends on Alimera’s ability to obtain marketing approval for and successfully commercialize ILUVIEN for posterior segment uveitis; the number of clinical trials and data required for the Durasert three-year uveitis marketing approval applications in the U.S.; our ability to file and the timing of filing and acceptance of the Durasert three-year uveitis NDA in the U.S.; our ability to use data in a U.S. NDA from clinical trials outside the U.S.; our ability to successfully commercialize Durasert three-year uveitis, if approved; potential off-label sales of ILUVIEN for uveitis; consequences of FA side effects; the development of our next-generation Durasert shorter-duration treatment for posterior segment uveitis; potential declines in Retisert® royalties; efficacy and our future development of an implant to treat severe osteoarthritis (“OA”); our ability to successfully develop product candidates, initiate and complete clinical trials and receive regulatory approvals; our ability to market and sell products; the success of current and future license agreements, including our agreement with Alimera; termination or breach of current license agreements, including our agreement with Alimera; our dependence on contract research organizations (“CROs”), vendors and investigators; effects of competition and other developments affecting sales of products; market acceptance of products; effects of guidelines, recommendations and studies; protection of intellectual property and avoiding intellectual property infringement; retention of key personnel; product liability; industry consolidation; compliance with environmental laws; manufacturing risks; risks and costs of international business operations; effects of the potential United Kingdom (“U.K.”) exit from the European Union (“EU”); legislative or regulatory changes; volatility of stock price; possible dilution; and absence of dividends. Additional factors may be described in our future filings with the Securities and Exchange Commission (the “SEC”). 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 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 publicly update or revise our forward-looking statements even if experience or future changes makes it clear that any projected results expressed or implied in such statements will not be realized.

ITEM 1. BUSINESS

Introduction

Our Business

We develop sustained-release drug delivery products that deliver drugs at a controlled and steady rate for months or years. We have developed three of the four sustained-release ophthalmic products currently approved by the FDA for treatment of back-of-the-eye diseases. Our product development programs are focused primarily

[Table of Contents](#)

on utilizing our core Durasert technology platform to deliver drugs to treat chronic diseases. Durasert three-year uveitis is our most advanced development-stage product, and is designed to treat chronic non-infectious uveitis affecting the posterior segment of the eye (posterior segment uveitis) for approximately three years. Durasert three-year uveitis met its primary efficacy endpoint of prevention of recurrence of uveitis through six months with a p value of < 0.001 in two ongoing pivotal Phase 3 clinical trials. We anticipate filing an NDA with the FDA in late December 2017 or early January 2018. In July 2017, we amended our collaboration agreement (the “Prior Alimera Agreement”) with Alimera to, among other things, license distribution, regulatory and reimbursement matters for Durasert three-year uveitis (under the ILUVIEN trademark) for the EMEA to Alimera. Pursuant to the Prior Alimera Agreement, our lead licensed product, ILUVIEN® for DME, is sold by Alimera in the U.S. and multiple EU countries. Our strategy includes developing non-proprietary drugs independently in combination with our Durasert technology platform, while continuing to leverage our technology platform through collaborations and license agreements as appropriate.

Injected into the eye in an office visit, Durasert three-year uveitis is a micro-insert that delivers a micro-dose of a corticosteroid to the back of the eye on a sustained basis for approximately three years after a single administration. In Europe, we filed a marketing authorization application (“MAA”) in June 2017 and subsequently withdrew the application after out-licensing the European rights for Durasert to Alimera. Alimera plans to submit the Durasert three-year uveitis data under its existing ILUVIEN MAA and, if approved, to commercialize the uveitis indication under the ILUVIEN trademark.

We are developing Durasert three-year uveitis independently and we plan to file an NDA with the FDA in late December 2017 or early January 2018. Both of our Durasert three-year uveitis Phase 3 clinical trials met their primary efficacy endpoint of prevention of recurrence of uveitis through six months with statistical significance ($p < 0.001$; intent to treat analysis) and yielded safety profiles consistent with the known effects of ocular corticosteroid use. Similar efficacy and safety results have been observed through 12 months of follow-up in the first pivotal trial and twelve-month data from the second pivotal trial is expected in the first half of calendar year 2018. Pending NDA submission and approval by the FDA, we plan to independently commercialize Durasert three-year uveitis in the U.S. given the relatively modest market size and correspondingly limited commercial footprint required to launch on our own.

ILUVIEN, an injectable, sustained-release micro-insert delivering 0.19mg of FA to the back of the eye for the treatment of DME, was licensed to and developed with Alimera under the Prior Alimera Agreement. In July 2017, we entered into an amended and restated collaboration agreement with Alimera (the “Amended Alimera Agreement”) pursuant to which we (i) licensed the rights to our three-year uveitis indication to Alimera for the EMEA and (ii) converted our license consideration from a share of Alimera’s net profits for ILUVIEN to a royalty based on Alimera’s net sales for ILUVIEN for DME and, upon an MAA approval, for net sales of ILUVIEN for posterior segment uveitis. Sales-based royalties start at the rate of 2% effective as of July 1, 2017. Commencing January 1, 2019 (or earlier under certain circumstances), the sales-based royalty will increase to 6% (8% on total ILUVIEN net sales in excess of \$75 million on a calendar year basis). Alimera’s share of contingently recoverable accumulated ILUVIEN commercialization losses under the original net profit share arrangement (as set forth in the Prior Alimera Agreement), was capped at \$25 million. Under the Amended Alimera Agreement those recoverable losses will be reduced as follows: (i) \$10.0 million was cancelled in lieu of an upfront license fee on the effective date of the Amended Alimera Agreement; (ii) for calendar years 2019 and 2020, 50% of earned sales-based royalties in excess of 2% of net sales will be offset against the quarterly royalty payments otherwise due from Alimera; (iii) on January 1, 2020 (or earlier under certain circumstances), another \$5 million will be cancelled, provided, however, that such date of cancellation may be extended under certain circumstances related to Alimera’s regulatory approval process for ILUVIEN for posterior segment uveitis, with such extension, if any, subject to mutual agreement by the parties; and (iv) commencing in calendar year 2021, 20% of earned sales-based royalties in excess of 2% of net sales will be offset against the quarterly royalty payments due from Alimera until such time as the remaining balance of the original \$25 million of recoverable commercialization losses has been fully recouped.

[Table of Contents](#)

We believe that the terms of the Amended Alimera Agreement for ILUVIEN for DME have standardized and simplified the agreement, and improved the potential total value of the agreement for us. ILUVIEN for DME has been sold by Alimera in the U.S. since 2015, where it is indicated for the treatment of DME in patients previously treated with a course of corticosteroids without a clinically significant rise in intraocular pressure (“IOP”). Alimera has marketing approvals for ILUVIEN in 17 European countries, where it is approved for the treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies. ILUVIEN for DME has been sold by Alimera in the U.K. and Germany since 2013, in Portugal since 2015 and in Italy, Spain and certain Middle East countries (through sublicense partners) since the second quarter of calendar year 2017.

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

We are also using our Durasert technology platform to identify potential product candidates that provide sustained treatment of wet and dry age-related macular degeneration (“AMD”), glaucoma, osteoarthritis and other diseases. In collaboration with Hospital for Special Surgery (“HSS”), we are developing a sustained-release surgical implant to treat pain associated with severe knee OA. This product is currently being evaluated in an investigator-sponsored pilot clinical study that is expected to provide initial results in late calendar year 2017. We are also conducting nonclinical evaluations of various tyrosine kinase inhibitor (“TKI”) candidates for wet AMD. Finally, we are developing a next-generation Durasert shorter-acting version, initially for the treatment of posterior segment uveitis.

We have received Notices of Allowance for UVIEY™, YUTIQ™ and DELIVERING INNOVATION TO THE EYE™, and our Durasert™ mark has been published, in the United States. Retisert® and Vitrasert® are Bausch & Lomb’s trademarks. ILUVIEN® is Alimera’s trademark. This Annual Report also contains trademarks, trade names and service marks of other companies, which are the property of their respective owners.

Information with respect to ILUVIEN, including regulatory and marketing information, and Alimera’s plans and intentions, reflects information publicly disclosed by Alimera.

Fiscal 2017, fiscal 2016 and fiscal 2015 mean the twelve months ended June 30, 2017, 2016 and 2015, respectively, and fiscal 2018 means the twelve months ending June 30, 2018.

Strategy

Our strategy is to use our proprietary Durasert drug delivery technology platform to independently develop new drug delivery products that use already-approved drugs to better treat ophthalmic and other diseases, while continuing to leverage our technology platform through collaborations and licenses with leading pharmaceutical and biopharmaceutical companies, institutions and others. We believe our technologies can provide sustained, targeted delivery of therapeutic agents, resulting in improved therapeutic effectiveness, safer administration and better patient compliance and convenience, with reduced product development risk and cost. We believe that our proven track record of three approved products, all providing sustained release of previously approved drugs, reflects the benefits of this strategy.

- **Develop Sustained Delivery of Off-Patent Drugs.** Many drugs are now, or will soon be, off-patent. It is estimated that over the next several years, patent coverage will end on products with world-wide sales aggregating billions of dollars annually. We are using our technology platform to evaluate potential products that deliver off-patent and generic drugs, primarily focused on ocular diseases with significant market opportunities, where less frequent dosing through sustained delivery and/or targeted delivery at the treatment site would materially improve the effectiveness, safety or convenience of the original drug. By focusing on delivery of already-approved drugs, particularly those requiring potentially shorter clinical development programs, we believe we may be able to reduce the substantial risks and financial investment required for product approval.

[Table of Contents](#)

- **Continue Partnering with Leading Biopharmaceutical and Pharmaceutical Companies.** We intend to continue to partner with leading biopharmaceutical and pharmaceutical companies, institutions and others, where patent protection, development and regulatory costs, expertise and/or other factors make it desirable for us to have a partner. For example, drugs that might be more effectively delivered by our platform technology or may have extended patent protection could make collaborations with the patent holders attractive. We may also seek to partner the development of products that could materially benefit from sustained delivery, but would require expensive clinical trials or are in treatment areas outside of our technical expertise. We may also seek to partner with companies with drugs coming off patent where our drug delivery technology could offer an improved product and effectively extend patent protection.
- **Expand Beyond Ophthalmology.** While we continue to focus on our core ophthalmic competency, we intend to also use our technology platform for the treatment of other diseases where sustained delivery could provide a significant advantage, such as osteoarthritis.

Market Opportunity for Delivery of Drugs

We develop products to address issues inherent in the delivery of drugs. The efficacy of a therapeutic agent (small drug molecule) depends on its distribution to, and reaction with, the targeted tissue and other tissues in the body, the duration of treatment and clearance from the body. In an ideal treatment, the appropriate amount of drug is delivered to the intended tissue at an appropriate concentration and that concentration is maintained at the tissue for a sufficient period of time to provide effective treatment without causing adverse effects to other tissues. Accordingly, the delivery of a drug can be an important element of its ultimate therapeutic value.

Drugs are frequently administered systemically by oral dosing, infusion or injection and subsequently dispersed throughout the body via the circulatory system. In the case of some drugs, systemic administration does not deliver them to the intended site with an appropriate concentration for a sufficient duration or the appropriate concentration disperses too quickly or unevenly, thereby failing to achieve the maximum potential therapeutic benefit. Because systemically delivered drugs disperse throughout the body, some are administered at higher dosage levels to achieve sufficient concentrations at the intended sites. This is particularly true for the eyes, joints, brain and nervous system, which have natural barriers that impede the movement of drugs to those areas. These higher dosage levels can cause harmful side effects to the tissues beyond the intended site. To avoid these issues, drugs may be administered locally to the targeted site, typically by injection. However, maintaining a sufficient concentration at the targeted site over time typically requires timely and repeated administration of systemically and locally delivered drugs. The delivery methods themselves can have risks. Repeated administration by injection or infusion can result in serious infections and other complications.

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

Treating retinal diseases is a significant challenge for drug delivery. Due to the effectiveness of the blood-eye barrier, it is difficult for systemically administered drugs to reach the retina in sufficient quantities to have a beneficial effect without causing adverse side effects to other parts of the body. Injecting drugs in solution directly into the back of the eye can achieve effective, but often transient, dosage levels in the eye, requiring repeated injections. In addition to the issues of inconvenience, cost and noncompliance, repeated intravitreal injections have medical risks, including intraocular infection, perforated sclera and vitreous hemorrhage.

Due to the drawbacks of traditional delivery, we believe that the development of methods to deliver drugs to patients in a more precise, controlled fashion over sustained periods of time satisfies an unmet medical need. Methods for sustained drug delivery include oral and injectable controlled-release products and skin patches that seek to improve the

[Table of Contents](#)

consistency of the dosage over time and extend the duration of delivery. However, most of these methods cannot provide constant, controlled dosage or sufficient duration of delivery, particularly in diseases that are chronic or require precise dosing. Moreover, skin patches and oral products still have issues of systemic delivery.

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

Our Technology System and Products

Our core technology platform, Durasert, is designed to address the issue of sustained delivery for ophthalmic and other product candidates:

- *Extended Delivery.* Our Durasert technology platform can deliver drugs for predetermined periods of time ranging from months to years. We believe that uninterrupted, sustained delivery offers the opportunity to develop products that reduce the need for repeated applications, thereby reducing the risks of patient noncompliance and adverse effects from repeated administrations.
- *Controlled Release Rate.* Our Durasert technology platform is designed to release therapeutics at a sustained, controlled rate. We believe that this feature allows us to develop products that deliver optimal concentrations of therapeutics over time and eliminate excessive variability in dosing during treatment.
- *Localized Delivery.* Our technology platform can deliver therapeutics directly to a target site. This administration can allow the natural barriers of the body to isolate and assist in maintaining appropriate concentrations at the target site in an effort to achieve the maximum therapeutic effect while minimizing unwanted systemic effects.

Durasert Technology System

All of our commercially approved products and all our product candidates in development use our Durasert technology platform to provide sustained, localized delivery of small molecule drugs to the back of the eye or a joint. In our Durasert products and product candidates, a drug core is surrounded with one or more polymer layers, and the permeability of those layers and other design aspects of the product control the rate and duration of drug release. By changing elements of the design, we can alter both the rate and duration of release to meet different therapeutic needs. Although our earlier ophthalmic products Retisert and Vitrasert are surgically implanted, both ILUVIEN and our other ophthalmic product candidates are designed to be injected at the target site in an office visit. Our osteoarthritis product candidate is designed to be surgically implanted in the knee joint.

[Table of Contents](#)

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

<u>Product</u>	<u>Disease</u>	<u>Stage of Development</u>	<u>Partner</u>
ILUVIEN	DME	Approved in the U.S. and 17 EU countries; commercialized since 2013 in the U.K. and Germany and since 2015 in U.S. and Portugal; commenced distribution through sublicense partners in the second quarter of 2017 in Spain, Italy and various countries in the Middle East	Alimera
Retisert	Posterior segment uveitis	FDA-approved; commercialized in the U.S. since 2005	Bausch & Lomb
Vitrasert	CMV retinitis	FDA-approved; commercialized from 1996 through 2012 (patent expiration)	Bausch & Lomb
Durasert three-year Uveitis	Posterior segment uveitis	Primary efficacy endpoint achieved in two ongoing Phase 3 clinical trials	For EMEA: regulatory, reimbursement and distribution licensed to Alimera under ILUVIEN For U.S.: commercialize independently pending NDA submission and approval
Durasert shorter-acting uveitis	Posterior segment uveitis	Pre-clinical	None
Steroid implant	Severe knee OA	Investigator-sponsored study	Hospital for Special Surgery

Approved Product: ILUVIEN for DME

ILUVIEN is an injectable, sustained-release micro-insert delivering 0.19 mg of FA to the back of the eye for treatment of DME. The ILUVIEN micro-insert is substantially the same micro-insert as Durasert. ILUVIEN is injected in an office visit using a 25-gauge inserter, and delivers approximately 36 months of continuous, low-dose corticosteroid therapy with a single injection. ILUVIEN is approved in the U.S. for the treatment of DME in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in IOP. In the 17 EU countries where ILUVIEN has been approved, it is indicated for the treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies. DME is a disease suffered by diabetics where leaking capillaries cause swelling in the macula, the most sensitive part of the retina. DME is a leading cause of blindness in the working-age population in most developed countries.

We have licensed ILUVIEN to Alimera. Alimera has sold ILUVIEN in the U.K. and Germany since 2013, in Portugal and the U.S. since 2015, has commenced distribution through sublicense partners in the second quarter of 2017 in Spain, Italy and various countries in the Middle East and Alimera recently announced a new sublicense partner for France. ILUVIEN has marketing authorizations in 12 additional EU countries. Effective July 1, 2017, in connection with the Amended Alimera Agreement, we are entitled to receive royalties on net sales by Alimera of ILUVIEN for DME and all future approved indications (including for three-year uveitis in

[Table of Contents](#)

the EMEA) on a quarter-by-quarter, country-by-country basis. See “Strategic Collaborations—Alimera” below. Alimera has also sublicensed regulatory, reimbursement and distribution of ILUVIEN for DME in various other countries, including Australia, New Zealand and Canada.

Approved Product: Retisert for Posterior Segment Uveitis

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

Approved Product: Vitrasert for CMV Retinitis

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

Development Pipeline

Our internal research development is focused on using our Durasert technology platform to deliver therapeutic agents to treat uveitis, wet and dry AMD, glaucoma and osteoarthritis.

Development Product: Durasert Three-Year Uveitis

Durasert three-year uveitis, our lead development product, is an injectable, sustained-release micro-insert designed to treat chronic, noninfectious posterior uveitis, intermediate uveitis and panuveitis affecting the posterior segment of the eye. Injected in an office visit, Durasert three-year uveitis provides sustained daily release of a total of 0.18 mg of the off-patent corticosteroid FA at a controlled rate directly to the back of the eye over approximately three years, from a single administration. It is injected with our inserter using a 25-gauge needle. We are developing Durasert three-year uveitis independently and have licensed regulatory, reimbursement and distribution rights to Alimera for the EMEA under their ILUVIEN tradename. Pending NDA submission and approval by the FDA, we plan to independently commercialize Durasert three-year uveitis in the U.S. given the relatively modest market size and correspondingly limited commercial footprint required to launch on our own.

Posterior segment uveitis is a chronic, non-infectious inflammatory disease affecting the posterior segment of the eye, often involving the retina, and is a leading cause of blindness in the developed countries. It afflicts people of all ages, producing swelling and destroying eye tissues, which can lead to severe vision loss and blindness. In the U.S., posterior segment uveitis is estimated to affect approximately 80,000-120,000 people, resulting in approximately 30,000 cases of blindness and making it the third leading cause of blindness in the U.S. Patients with posterior segment uveitis are typically treated with systemic steroids, but frequently develop serious side effects over time that can limit effective dosing. Patients then often progress to steroid-sparing therapy with systemic immunosuppressants or biologics, which themselves can cause severe side effects including an increased risk of cancer.

Durasert Three-Year Uveitis Phase 3 Trials

In our two Phase 3 trials to assess the safety and efficacy of Durasert three-year uveitis, we have achieved the primary efficacy endpoint of prevention of recurrence of uveitis through six months with statistical significance (p value of < 0.001 in each study). These studies are randomized, sham injection-controlled, double-masked trials with the primary endpoint of both trials defined as recurrence of disease at six months, with patients followed for three years. Our first Phase 3 trial enrolled 129 patients in 16 centers in the U.S. and 17 centers outside the U.S, with 87 eyes treated with Durasert three-year uveitis and 42 eyes receiving sham injections. Our second Phase 3 trial enrolled 153 patients in 15 centers in India with 101 eyes treated with

Durasert three-year uveitis and 52 eyes receiving sham injections. Patient follow-up will continue for 36 months in each of the two Phase 3 trials.

Our first Phase 3 trial met its primary efficacy endpoint of prevention of recurrence of disease at 6 months with statistical significance ($p < 0.001$, intent to treat analysis; recurrence of 18.4% for Durasert versus 78.6% for control). The trial yielded similar efficacy through 12 months of follow up ($p < 0.0001$, intent to treat analysis; recurrence of 27.6% for Durasert versus 85.7% for control). Durasert three-year uveitis was generally well tolerated through 12-months of follow-up. The incremental risk of elevated IOP for Durasert-treated eyes compared to control eyes was lower through 12 months than through six months for elevation over 21 mmHg (6.1% versus 10.9%) as well as for the more serious elevation over 25 mmHg (7.6% versus 11.3%). Elevated IOP was generally well treated with eye drops. Through 12 months, the percentage of eyes requiring filtration surgery was low and similar between Durasert-treated and control eyes (3.4% versus 2.4%). Of the 63 study eyes with a natural lens at baseline, 33.3% of Durasert-treated eyes compared to 4.8% of control eyes required cataract surgery through 12 months. Cataracts are both a side effect of treatment with steroids and a natural consequence of uveitis.

Our second Phase 3 trial also met its primary efficacy endpoint of prevention of recurrence of disease at 6 months with statistical significance ($p < 0.001$, intent to treat analysis; recurrence of 21.8% for Durasert versus 53.8% for control). As in the first Phase 3 trial, Durasert three-year uveitis was generally well tolerated through 6 months. Patient follow-up beyond this latest study time point is currently underway and twelve-month data is expected in the first half of calendar year 2018.

We are also conducting a multi-center, randomized, controlled, single-masked study of the safety and utilization of two different inserters for Durasert three-year uveitis. We enrolled 26 subjects (38 eyes) in this study in 6 centers in the U.S. The utilization and safety results of this study will be included in our planned NDA filing for Durasert three-year uveitis.

Durasert Three-Year Uveitis Regulatory Strategy

In the U.S., we plan to submit an NDA to the FDA seeking approval to market Durasert three-year uveitis. We plan to support the NDA with data from our two Phase 3 trials and the inserter utilization study, as well as data referenced from Alimera's Phase 3 clinical trials of ILUVIEN for DME. We expect to file the NDA in late December 2017 or early January 2018.

We have out-licensed Durasert three-year uveitis rights to Alimera for the EMEA as an extension of the Prior Alimera Agreement that had granted worldwide license rights to ILUVIEN for DME and other potential back-of-the-eye diseases (other than uveitis) utilizing a corticosteroid in our Durasert technology. In the EU, we expect Alimera to file the Durasert three-year uveitis data as a Type II variation to its previously approved ILUVIEN MAA, and to file in the Middle East and Africa under its respective regulatory applications.

Durasert Three-Year Uveitis Marketing Strategy

We plan to commercialize Durasert three-year uveitis ourselves in the U.S. We believe that the uveitis market in the U.S. is relatively modest in size, with an estimated patient prevalence for non-infectious posterior segment uveitis of approximately 100,000 patients. Consequently, the number of retinal physicians who treat the majority of this patient population is estimated to be fewer than 500. As a result, we believe the commercial footprint and cost to market for Durasert three-year uveitis will be less than for a typical pharmaceutical product launch with a larger physician call population. Members of our leadership team have extensive commercialization experience and believe that commercializing ourselves in the U.S. will maximize the value of Durasert three-year uveitis to us. Outside of the U.S., we licensed the EMEA rights to Durasert three-year uveitis to Alimera as part of the Amended Alimera Agreement. We plan to seek out-license partner arrangements in other territories.

Development Product: Shorter Duration Durasert

We are developing a next-generation, shorter-duration treatment for posterior segment uveitis, and for use in collaborations with other drug manufacturers with their small molecules. This program is designed to provide enhanced benefits and offer a shorter delivery period with more flexibility for multiple dosing intervals. Our market research demonstrated a preference amongst those surveyed for both 6 to 9 months and three-year sustained delivery options. Although we believe many patients would likely opt for a longer-acting treatment option, some doctors may prefer to initially treat certain disease indications over shorter time periods.

Development Product: Severe Knee Osteoarthritis Implant

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

Knee OA is a degenerative joint disease that results from the breakdown of joint cartilage and underlying bone, with joint pain and stiffness the most common symptoms. More than 10 million people have knee OA. No cure exists, but pain and movement restriction associated with the disease are currently treated with oral analgesics, non-steroidal anti-inflammatory drugs, corticosteroids taken orally or injected into the knee, or hyaluronic acid injected into the knee. With degeneration, damage and pain from knee OA can become severe, making it the leading cause of total knee replacement surgery. More than 600,000 of these surgeries were performed last year in the U.S. alone, and the number is expected to grow.

Development Product: TKI Insert for Wet AMD

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

In cancer therapy, TKIs are taken orally, but their toxicity prevents their systemic use to treat AMD. Using our Durasert technology, we plan to develop an implant to deliver a TKI directly to the back of the eye with a total dose that is significantly lower than is used in a course of cancer therapy.

Our development goal is to provide sustained treatment of wet AMD for six months with a single injection of a TKI-based product, targeting VEGF while avoiding the toxic systemic side effects of TKIs and the frequent injections of current wet AMD anti-VEGF biologics. Using a model TKI (that is not patentable), we have generated pre-clinical data that demonstrate that a TKI delivered by a sustained release insert was comparably efficacious to a commercially available biologic indicated for wet AMD delivered by injection, both in preventing choroidal neovascularization and in reducing vascular leakage. On the basis of these data, we are currently evaluating other, potentially patentable TKIs for sustained release over several months and with comparable therapeutic effects.

[Table of Contents](#)

Feasibility Study Agreements

From time to time, we have entered into feasibility study agreements funded by third parties to evaluate our Durasert technology system for the treatment of ophthalmic and other diseases. We presently are engaged in one such agreement for a back of the eye disease. We intend to continue to identify other companies with compounds that could be successfully delivered with our Durasert technology and, through appropriate agreements, to generate non-dilutive operating capital for pSivida, subsequent licensing arrangements, clinical development and future royalties, should any such product candidate gain regulatory approval and achieve commercialization.

Strategic Collaborations

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

Alimera

In February 2005, as amended and restated in March 2008, we granted Alimera an exclusive worldwide license to manufacture, develop, market and sell ILUVIEN for the treatment and prevention of human eye diseases other than uveitis pursuant to the Prior Alimera Agreement. We also granted Alimera a worldwide non-exclusive license to manufacture, develop, market and sell certain additional Durasert-based products (1) to deliver a corticosteroid and no other active ingredient by a direct delivery method to the back of the eye solely for the treatment and prevention of eye diseases in humans other than uveitis and (2) to treat DME in humans by delivering a compound by a direct delivery method through an incision no smaller than that required for a 25-gauge or larger needle. The non-exclusive license is limited to those products that, among other things, (i) have a drug core within a polymer layer (with certain limitations regarding chemically bonded combinations of active agents) and (ii) are approved, or designed to be approved, to deliver a corticosteroid and no other active ingredient by a direct delivery to the posterior portion of the eye, or to treat DME by delivering a compound by a direct delivery through an incision required for a 25-gauge or larger needle. We are not permitted to use, or grant a license to any third party to use, the licensed technologies to make or sell any products that are or would be subject to the non-exclusive license granted to Alimera.

In October 2014, Alimera paid us a \$25.0 million milestone upon FDA approval of ILUVIEN as provided in the Prior Alimera Agreement.

In July 2017, we entered into the Amended Alimera Agreement to (i) license our Durasert three-year uveitis product candidate to Alimera for the EMEA under the ILUVIEN tradename and (ii) convert the previous net profit share arrangement on a country-by-country basis to sales-based royalties for DME, uveitis and any other ILUVIEN indications that obtain regulatory approval in various jurisdictions in the future, provided that certain amounts of Alimera's previous ILUVIEN net commercialization losses can be offset against earned sales-based royalties (as described below). We are entitled to receive a 2% sales-based royalty within 60 days following the end of each calendar quarter commencing with the quarter ending September 30, 2017 and through calendar year 2018. Commencing January 1, 2019 (or earlier under certain circumstances) the sales-based royalty will increase to 6% on aggregate calendar year net sales up to \$75 million and 8% on any calendar year sales in excess of \$75 million. Alimera's share of accumulated ILUVIEN commercialization losses under the original net profit share arrangement (as set forth in the Prior Alimera Agreement), is capped at \$25 million. Under the Amended Alimera Agreement those recoverable losses be reduced as follows: (i) \$10 million was cancelled in lieu of any upfront license fee on the effective date of the Amended Alimera Agreement; (ii) for calendar years 2019 and 2020, 50% of earned sales-based royalties in excess of 2% of net sales will be offset against the quarterly royalty payments due from Alimera; (iii) on January 1, 2020 (or earlier under certain circumstances), another \$5 million of the accumulated commercialization losses will be cancelled, provided, however, that such date of cancellation may be extended further under certain circumstances related to Alimera's regulatory approval process for

[Table of Contents](#)

ILUVIEN for posterior uveitis, with such extension, if any, subject to mutual agreement by the parties; and (iv) commencing in calendar year 2021, 20% of earned sales-based royalties in excess of 2% of net sales will be offset against the quarterly royalty payments due from Alimera until such time as the remaining balance of the original \$25 million of commercialization losses has been recouped by Alimera.

Bausch & Lomb

Under a 2003 amended license agreement, Bausch & Lomb has a worldwide exclusive license to make and sell Retisert and other first generation products defined in the agreement in return for royalties based on sales. This agreement also covered Vitrasert prior to patent expiration. Bausch & Lomb can terminate its agreement with us without penalty at any time upon 90 days' written notice.

Pfizer

In June 2011, we entered into an Amended and Restated Collaborative Research and License Agreement with Pfizer, Inc. ("Pfizer") (the "Restated Pfizer Agreement") to focus solely on the development of a sustained-release bioerodible micro-insert injected into the subconjunctiva designed to deliver latanoprost for human ophthalmic disease or conditions other than uveitis (the "Latanoprost Product"). Pfizer made an upfront payment of \$2.3 million and we agreed to provide Pfizer options under various circumstances for an exclusive, worldwide license to develop and commercialize the Latanoprost Product. On October 25, 2016, we notified Pfizer that we had discontinued development of the Latanoprost Product, which provided Pfizer a 60-day option to acquire a worldwide license in return for a \$10.0 million payment and potential sales-based royalties and development, regulatory and sales performance milestone payments. Pfizer did not exercise its option and the Restated Pfizer Agreement automatically terminated on December 26, 2016. Provided that we do not conduct any research and development of the Latanoprost Product through calendar 2017, we retain the right thereafter to develop and commercialize the Latanoprost Product on our own or with a partner. By letter agreement effective as of April 11, 2017, Pfizer officially waived that restriction.

Enigma Therapeutics

Our December 2012 license agreement, amended and restated in March 2013, with Enigma Therapeutics Limited (Enigma) provides Enigma with an exclusive, worldwide, royalty-bearing license for the development of BrachySil (now named OncoSil™), a product candidate for the treatment of pancreatic and other cancers. We received an upfront fee of \$100,000 and are entitled to an 8% sales-based royalty, 20% of sublicense consideration and milestones based on aggregate product sales. To date, Enigma has not received regulatory approval for OncoSil in any jurisdiction. Enigma is obligated to pay an annual license maintenance fee of \$100,000, creditable during each ensuing twelve-month period against reimbursable patent maintenance costs and sales-based royalties. Annual license maintenance fees of \$100,000 were paid in respect of each calendar year from 2013 through 2016. Enigma has the right to terminate this license upon 60 days' prior written notice.

Research and Development

Our clinical and pre-clinical research programs primarily focus on ophthalmic applications of our technology platform. Our research and development expenses totaled \$14.9 million in fiscal 2017, \$14.4 million in fiscal 2016 and \$12.1 million in fiscal 2015. Of these amounts, \$13.0 million in fiscal 2017, \$12.8 million in fiscal 2016 and \$10.6 million in fiscal 2015 were incurred for costs of research and development personnel, clinical and pre-clinical studies, contract services, testing and laboratory facilities. The remaining expense of \$1.9 million in fiscal 2017, \$1.6 million in fiscal 2016 and \$1.5 million in fiscal 2015 consisted of non-cash charges for amortization of intangible assets, depreciation of property, plant and equipment and stock-based compensation expense specifically allocated to research and development personnel.

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

Intellectual Property

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

The U.S. patent with which Retisert is marked expires in March 2019. The last expiring patent covering Retisert expires in April 2020. The latest expiring patent covering ILUVIEN and Durasert three-year uveitis expires in August 2027 in the U.S. and in October 2024 in the EU, although extensions have been obtained or applied for through May 2027 in various EU countries.

The following table provides general details relating to our owned and licensed patents (including both patents that have been issued and applications that have been accepted for issuance) and patent applications as of August 31, 2017:

<u>Technology</u>	<u>United States Patents</u>	<u>United States Applications</u>	<u>Foreign Patents</u>	<u>Foreign Applications</u>	<u>Patent Families</u>
Durasert	11	6	72	11	11
Other	15	11	39	47	15
Total	26	17	111	58	26

Employees

We had 22 employees as of August 31, 2017. None of our employees is covered by a collective bargaining agreement.

Manufacturing

We currently manufacture our product candidates for pre-clinical studies and clinical trials. We purchase raw materials and components necessary to manufacture Durasert three-year uveitis and our other product candidates in the ordinary course of business, and they are available from multiple sources. The manufacture of each of Retisert and ILUVIEN is the responsibility of our licensees. If Durasert three-year uveitis is approved, we plan to commercially manufacture the product in our current Watertown, MA facility.

Sales and Marketing

We currently have no significant marketing or sales staff, but members of our leadership team have extensive commercialization experience. We currently depend on collaborative partners to market our approved products. Should we file our Durasert three-year uveitis NDA with the FDA as planned in late December 2017 or early January 2018, we expect to invest in our sales and marketing infrastructure during calendar year 2018 in preparation for a potential U.S. product launch in the first half of calendar year 2019. Significant expenditures will be required for us to develop an independent sales and marketing organization. We intend to use an outsourced contract sales organization to promote Durasert three-year uveitis to our defined audience in the U.S., although to date we have not entered into any such agreements.

Competition

The market for products treating back-of-the-eye diseases is highly competitive and is characterized by extensive research efforts and rapid technological progress. We face substantial competition for our products and product candidates. Pharmaceutical, drug delivery and biotechnology companies, as well as research

[Table of Contents](#)

organizations, governmental entities, universities, hospitals, other nonprofit organizations and individual scientists, have developed and are seeking to develop drugs, therapies and novel delivery methods to treat diseases targeted by our products and product candidates. Most of our competitors and potential competitors are larger, better established, more experienced and have substantially more resources than we or our partners have. Competitors may reach the market earlier, may have obtained or could obtain patent protection that dominates or adversely affects our products and potential products, and may offer products with greater efficacy, lesser or fewer side effects and/or other competitive advantages. We believe that competition for treatments of back-of-the-eye diseases is based upon the effectiveness of the treatment, side effects, time to market, reimbursement and price, reliability, ease of administration, dosing or injection frequency, patent position and other factors.

Many companies have or are pursuing products to treat back-of-the-eye diseases that are or would be competitive with ILUVIEN for DME or Duraseret three-year uveitis. Some of these products and potential products include the following:

- *DME.* Genentech USA Inc.'s Lucentis (ranibizumab) and Regeneron Pharmaceutical's EYLEA (aflibercept) are approved in the U.S. and the EU for the treatment of DME. Roche's lower-cost Avastin is approved to treat various cancers, but is used off-label for treatment of diabetic retinopathy. These products are vascular endothelial growth factor ("VEGF") inhibitors which are considered first line therapy for DME due to their ability to block the VEGF protein, which at high levels can cause abnormal blood vessels to grow in the eye and leak fluid. Genentech is a wholly-owned member of the Roche Group. Novartis AG has the right to market and sell Lucentis outside of the U.S. Regeneron maintains exclusive rights to EYLEA in the U.S., and Bayer HealthCare owns the exclusive marketing rights outside the U.S. Lucentis, EYLEA and Avastin are all injected into the back of the eye on a monthly or bi-monthly basis. Allergan, Inc.'s Ozurdex® (dexamethasone intravitreal implant), a bioerodible intravitreal implant, has been approved for the treatment of DME, retinal vein occlusion ("RVO") and posterior segment uveitis, and has a therapeutic duration of several months. As with ILUVIEN, Ozurdex delivers a corticosteroid (dexamethasone) to the back of the eye through an intravitreal injection. However, it only lasts for up to several months, resulting in frequent injections compared to ILUVIEN lasting for up to three years. Other companies, including Genentech, are working on the development of product candidates and extended delivery system for the potential treatment of DME, including those that act by blocking VEGF and VEGF receptors.
- *Posterior Segment Uveitis.* Periocular steroid injections and systemic delivery of corticosteroids are routinely used to treat posterior segment uveitis, which is a chronic, inflammatory condition of the eye. It is treated both aggressively and frequently by physicians in order to minimize the disease "flares", which are the main cause of vision deterioration and potential blindness. Ozurdex is approved in the U.S. and EU for posterior segment uveitis through an intravitreal bioerodible implant that provides treatment which lasts for several months. As with DME, the several month effectiveness of Ozurdex can result in frequent intravitreal injections of the implant. AbbVie recently obtained FDA approval for Humira® (adalimumab) for the treatment of all types of non-infectious uveitis (intermediate, posterior and panuveitis) and it is administered subcutaneously every other week for systemic delivery. Humira is a biologic that blocks tumor necrosis factor (TNF) alpha, a naturally occurring cytokine that is involved in normal inflammatory and immune responses. Humira's retail price in the U.S. is approximately \$50,000 per year. Other companies have ongoing trials of posterior segment uveitis treatments, including Santen Pharmaceutical Co. Ltd., which has recently filed an NDA for sirolimus, which is administered through intravitreal injection every two months. Sirolimus is a mammalian target of rapamycin (mTOR) inhibitor and modulator of the immune system, and is being developed for non-infectious uveitis of the posterior segment. Clearside's CLS-TA (triamcinolone acetonide, a steroid) for macular edema associated with non-infectious uveitis is in Phase II trials and it is administered through a suprachoroidal injection administered every two months. Preliminary clinical data indicate that the suprachoroidal route may reduce the risk of increased intraocular pressure that is typically associated with intraocular injection of steroids.

[Table of Contents](#)

Revenues

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

	Year Ended June 30,								
	2017			2016			2015		
	U.S.	U. K.	Total	U.S.	U. K.	Total	U.S.	U. K.	Total
Revenues:	(In thousands)								
Collaborative research and development	\$ 6,469	\$ 100	\$ 6,569	\$ 298	\$ 100	\$ 398	\$ 25,311	\$ 100	\$ 25,411
Royalty income	970	—	970	1,222	—	1,222	1,154	—	1,154
	<u>\$ 7,439</u>	<u>\$ 100</u>	<u>\$ 7,539</u>	<u>\$ 1,520</u>	<u>\$ 100</u>	<u>\$ 1,620</u>	<u>\$ 26,465</u>	<u>\$ 100</u>	<u>\$ 26,565</u>

Government Regulation

We are subject to extensive regulation by the FDA and other federal, state, and local regulatory agencies. The Federal Food, Drug and Cosmetic Act, or the FD&C Act, and FDA's implementing regulations set forth, among other things, requirements for the testing, development, manufacture, quality control, safety, effectiveness, approval, labeling, storage, record-keeping, reporting, distribution, import, export, advertising and promotion of our product candidates. Although the discussion below focuses on regulation in the United States, we currently out-license certain of our products and may seek approval for, and market, other products in other countries in the future. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States, although there can be important differences. Additionally, some significant aspects of regulation in the EU are addressed in a centralized way through the European Medicines Agency, or EMA, and the European Commission but country specific regulation remains essential in many respects. The process of obtaining regulatory marketing approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources and may not be successful.

Development and Approval

Under the FD&C Act, FDA approval of an NDA is required before any new drug can be marketed in the United States. NDAs require extensive studies and submission of a large amount of data by the applicant.

Pre-clinical Testing. Before testing any compound in human patients in the United States, a company must generate extensive pre-clinical data. Pre-clinical testing generally includes laboratory evaluation of product chemistry and formulation, as well as toxicological and pharmacological studies in several animal species to assess the quality and safety of the product. Certain animal studies must be performed in compliance with the FDA's Good Laboratory Practice, or GLP, regulations and the U.S. Department of Agriculture's Animal Welfare Act.

IND Application. Human clinical trials in the United States cannot commence until an investigational new drug, or IND, application is submitted and becomes effective. A company must submit pre-clinical testing results to the FDA as part of the IND, and the FDA must evaluate whether there is an adequate basis for testing the drug in initial clinical studies in human volunteers. Unless the FDA raises concerns, the IND becomes effective 30 days following its receipt by the FDA. Once human clinical trials have commenced, the FDA may stop a clinical trial by placing it on "clinical hold" because of concerns about the safety of the product being tested, or for other reasons.

Table of Contents

Clinical Trials. Clinical trials involve the administration of a drug to healthy human volunteers or to patients, under the supervision of a qualified investigator. The conduct of clinical trials is subject to extensive regulation, including compliance with the FDA's bioresearch monitoring regulations and Good Clinical Practice, or GCP, requirements, which establish standards for conducting, recording data from, and reporting the results of, clinical trials, and are intended to assure that the data and reported results are credible and accurate, and that the rights, safety, and well-being of study participants are protected. Clinical trials must be conducted under protocols that detail the study objectives, parameters for monitoring safety, and the efficacy criteria, if any, to be evaluated. Each protocol is reviewed by the FDA as part of the IND. In addition, each clinical trial must be reviewed and approved by, and conducted under the auspices of, an Institutional Review Board, or IRB. Companies sponsoring the clinical trials, investigators, and IRBs also must comply with, as applicable, regulations and guidelines for obtaining informed consent from the study patients, following the protocol and investigational plan, adequately monitoring the clinical trial, and timely reporting of adverse events, or AEs. Foreign studies conducted under an IND must meet the same requirements that apply to studies being conducted in the United States. Data from a foreign study not conducted under an IND may be submitted in support of an NDA if the study was conducted in accordance with GCP and the FDA is able to validate the data.

A study sponsor is required to publicly post specified details about certain clinical trials and clinical trial results on government or independent websites (e.g., <http://clinicaltrials.gov>). Human clinical trials typically are conducted in three sequential phases, although the phases may overlap with one another:

- Phase 1 clinical trials involve the initial administration of the investigational drug to humans, typically to a small group of healthy human patients, but occasionally to a group of patients with the targeted disease or disorder. Phase 1 clinical trials generally are intended to determine the metabolism and pharmacologic actions of the drug, the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness.
- Phase 2 clinical trials generally are controlled studies that involve a relatively small sample of the intended patient population, and are designed to develop initial data regarding the product's effectiveness, to determine dose response and the optimal dose range, and to gather additional information relating to safety and potential AEs.
- Phase 3 clinical trials are conducted after preliminary evidence of effectiveness has been obtained, and are intended to gather the additional information about safety and effectiveness necessary to evaluate the drug's overall risk-benefit profile, and to provide a basis for physician labeling. Generally, Phase 3 clinical development programs consist of expanded, large-scale studies of patients with the target disease or disorder to obtain statistical evidence of the efficacy and safety of the drug at the proposed dosing regimen.

The sponsoring company, the FDA, or the IRB may suspend or terminate a clinical trial at any time on various grounds, including a finding that the patients are being exposed to an unacceptable health risk. Further, success in early-stage clinical trials does not assure success in later-stage clinical trials. Data obtained from clinical activities are not always conclusive and may be subject to alternative interpretations that could delay, limit or prevent regulatory approval.

NDA Submission and Review. The FD&C Act provides two pathways for the approval of new drugs through an NDA. An NDA under Section 505(b)(1) of the FD&C Act is a comprehensive application to support approval of a product candidate that includes, among other things, data and information to demonstrate that the proposed drug is safe and effective for its proposed uses, that production methods are adequate to ensure its identity, strength, quality, and purity of the drug, and that proposed labeling is appropriate and contains all necessary information. A 505(b)(1) NDA contains results of the full set of pre-clinical studies and clinical trials conducted by or on behalf of the applicant to characterize and evaluate the product candidate.

Section 505(b)(2) of the FD&C Act provides an alternate regulatory pathway to obtain FDA approval for new formulations or new uses of previously approved drug products. Specifically, Section 505(b)(2) permits the

[Table of Contents](#)

filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely to some extent upon the FDA's findings of safety and effectiveness for an approved product that acts as the reference listed drug, or RLD, and submit its own product-specific data — which may include data from pre-clinical studies or clinical trials conducted by or on behalf of the applicant — to address differences between the product candidate and the RLD.

The submission of an NDA under either Section 505(b)(1) or Section 505(b)(2) generally requires payment of a substantial user fee to the FDA. The FDA reviews applications to determine, among other things, whether a product is safe and effective for its intended use and whether the manufacturing controls are adequate to assure and preserve the product's identity, strength, quality, and purity. For some NDAs, the FDA may convene an advisory committee to seek insights and recommendations on issues relevant to approval of the application. Although the FDA is not bound by the recommendation of an advisory committee, the agency usually has followed such recommendations.

The FDA may determine that a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to ensure that the benefits of a new product outweigh its risks, and the product can therefore be approved. A REMS may include various elements, ranging from a medication guide or patient package insert to limitations on who may prescribe or dispense the drug, depending on what the FDA considers necessary for the safe use of the drug. Under the Pediatric Research Equity Act, certain applications for approval must also include an assessment, generally based on clinical study data, of the safety and effectiveness of the subject drug in relevant pediatric populations. Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with current Good Manufacturing Practice, or cGMP, requirements and adequate to assure consistent production of the product within required specifications.

Once an NDA submission has been accepted for filing—which occurs, if at all, within 60 days after submission of the NDA—the FDA's goal for a non-priority review of an NDA is ten months. The review process can be and often is significantly extended, however, by FDA requests for additional information, studies, or clarification. After review of an NDA, the FDA may decide to not approve the application or may issue a complete response letter, or CRL, outlining the deficiencies in the submission. The CRL also may request additional information, including additional pre-clinical or clinical data. Even if such additional information and data are submitted, the FDA may decide that the NDA still does not meet the standards for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than the sponsor.

Obtaining regulatory approval often takes a number of years, involves the expenditure of substantial resources, and depends on a number of factors, including the severity of the disease in question, the availability of alternative treatments, and the risks and benefits demonstrated in clinical trials. Additionally, as a condition of approval, the FDA may impose restrictions that could affect the commercial success of a drug or require post-approval commitments, including the completion within a specified time period of additional clinical studies, which often are referred to as “Phase 4” or “post-marketing” studies.

Post-approval modifications to the drug, such as changes in indications, labeling, or manufacturing processes or facilities, may require a sponsor to develop additional data or conduct additional pre-clinical studies or clinical trials, to be submitted in a new or supplemental NDA, which would require FDA approval.

Post-Approval Regulation

Once approved, products are subject to continuing regulation by the FDA. If ongoing regulatory requirements are not met, or if safety problems occur after the product reaches the market, the FDA may at any time withdraw product approval or take actions that would limit or suspend marketing. Additionally, the FDA may require post-marketing studies or clinical trials if there are new safety information developments.

[Table of Contents](#)

Good Manufacturing Practices. Companies engaged in manufacturing drug products or their components must comply with applicable cGMP requirements and product-specific regulations enforced by the FDA and other regulatory agencies. Compliance with cGMP includes adhering to requirements relating to organization and training of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, quality control and quality assurance, packaging and labeling controls, holding and distribution, laboratory controls, and records and reports. The FDA regulates and inspects equipment, facilities, and processes used in manufacturing pharmaceutical products prior to approval. If, after receiving approval, a company makes a material change in manufacturing equipment, location, or process (all of which are, to some degree, incorporated in the NDA), additional regulatory review and approval may be required. The FDA also conducts regular, periodic visits to re-inspect equipment, facilities, and processes following the initial approval of a product. Failure to comply with applicable cGMP requirements and conditions of product approval may lead the FDA to seek sanctions, including fines, civil penalties, injunctions, suspension of manufacturing operations, operating restrictions, withdrawal of FDA approval, seizure or recall of products, and criminal prosecution. Although we periodically monitor the FDA compliance of our third-party manufacturers, we cannot be certain that our present or future third-party manufacturers will consistently comply with cGMP and other applicable FDA regulatory requirements.

Advertising and Promotion. The FDA and other federal regulatory agencies closely regulate the marketing and promotion of drugs through, among other things, standards and regulations for direct-to-consumer advertising, advertising and promotion to healthcare professionals, communications regarding unapproved uses, industry-sponsored scientific and educational activities, and promotional activities involving the Internet. A product cannot be commercially promoted before it is approved. After approval, product promotion can include only those claims relating to safety and effectiveness that are consistent with the labeling approved by the FDA. Healthcare providers are permitted to prescribe drugs for “off-label” uses—that is, uses not approved by the FDA and not described in the product’s labeling—because the FDA does not regulate the practice of medicine. However, FDA regulations impose restrictions on manufacturers’ communications regarding off-label uses. Broadly speaking, a manufacturer may not promote a drug for off-label use, but under certain conditions may engage in non-promotional, balanced, scientific communication regarding off-label use. Failure to comply with applicable FDA requirements and restrictions in this area may subject a company to adverse publicity and enforcement action by the FDA, the Department of Justice, or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes a drug.

Other Requirements. NDA holders must comply with other regulatory requirements, including submitting annual reports, reporting information about adverse drug experiences, and maintaining certain records.

Hatch-Waxman Act

The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, establishes two abbreviated approval pathways for pharmaceutical products that are in some way follow-on versions of already approved products.

Generic Drugs. A generic version of an approved drug is approved by means of an abbreviated NDA, or ANDA, by which the sponsor demonstrates that the proposed product is the same as the approved, brand-name drug, which is referred to as the RLD. Generally, an ANDA must contain data and information showing that the proposed generic product and RLD (i) have the same active ingredient, in the same strength and dosage form, to be delivered via the same route of administration, (ii) are intended for the same uses, and (iii) are bioequivalent. This is instead of independently demonstrating the proposed product’s safety and effectiveness, which are inferred from the fact that the product is the same as the RLD, which the FDA previously found to be safe and effective.

505(b)(2) NDAs. As discussed above, if a product is similar, but not identical, to an already approved product, it may be submitted for approval via an NDA under section 505(b)(2) of the FD&C Act. Unlike an

[Table of Contents](#)

ANDA, this does not excuse the sponsor from demonstrating the proposed product's safety and effectiveness. Rather, the sponsor is permitted to rely to some degree on the FDA's finding that the RLD is safe and effective, and must submit its own product-specific data of safety and effectiveness to an extent necessary because of the differences between the products. An NDA approved under 505(b)(2) may in turn serve as an RLD for subsequent applications from other sponsors.

RLD Patents. In an NDA, a sponsor must identify patents that claim the drug substance or drug product or a method of using the drug. When the drug is approved, those patents are among the information about the product that is listed in the FDA publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the *Orange Book*. The sponsor of an ANDA or 505(b)(2) application seeking to rely on an approved product as the RLD must make one of several certifications regarding each listed patent. A "Paragraph III" certification is the sponsor's statement that it will wait for the patent to expire before obtaining approval for its product. A "Paragraph IV" certification is an assertion that the patent does not block approval of the later product, either because the patent is invalid or unenforceable or because the patent, even if valid, is not infringed by the new product.

Regulatory Exclusivities. The Hatch-Waxman Act provides periods of regulatory exclusivity for products that would serve as RLDs for an ANDA or 505(b)(2) application. If a product is a "new chemical entity," or NCE—generally meaning that the active moiety has never before been approved in any drug—there is a period of five years from the product's approval during which the FDA may not accept for filing any ANDA or 505(b)(2) application for a drug with the same active moiety. An ANDA or 505(b)(2) application may be submitted after four years, however, if the sponsor of the application makes a Paragraph IV certification.

A product that is not an NCE may qualify for a three-year period of exclusivity if the NDA contains new clinical data, derived from studies conducted by or for the sponsor, that were necessary for approval. In that instance, the exclusivity period does not preclude filing or review of an ANDA or 505(b)(2) application; rather, the FDA is precluded from granting final approval to the ANDA or 505(b)(2) application until three years after approval of the RLD. Additionally, the exclusivity applies only to the conditions of approval that required submission of the clinical data.

Once the FDA accepts for filing an ANDA or 505(b)(2) application containing a Paragraph IV certification, the applicant must within 20 days provide notice to the RLD NDA holder and patent owner that the application has been submitted, and provide the factual and legal basis for the applicant's assertion that the patent is invalid or not infringed. If the NDA holder or patent owner files suit against the ANDA or 505(b)(2) applicant for patent infringement within 45 days of receiving the Paragraph IV notice, the FDA is prohibited from approving the ANDA or 505(b)(2) application for a period of 30 months or the resolution of the underlying suit, whichever is earlier. If the RLD has NCE exclusivity and the notice is given and suit filed during the fifth year of exclusivity, the 30-month stay does not begin until five years after the RLD approval. The FDA may approve the proposed product before the expiration of the 30-month stay if a court finds the patent invalid or not infringed or if the court shortens the period because the parties have failed to cooperate in expediting the litigation.

Patent Term Restoration. A portion of the patent term lost during product development and FDA review of an NDA is restored if approval of the application is the first permitted commercial marketing of a drug containing the active ingredient. The patent term restoration period is generally one-half the time between the effective date of the IND or the date of patent grant (whichever is later) and the date of submission of the NDA, plus the time between the date of submission of the NDA and the date of FDA approval of the product. The maximum period of restoration is five years, and the patent cannot be extended to more than 14 years from the date of FDA approval of the product. Only one patent claiming each approved product is eligible for restoration and the patent holder must apply for restoration within 60 days of approval. The U.S. Patent and Trademark Office, or PTO, in consultation with the FDA, reviews and approves the application for patent term restoration.

European and Other International Government Regulation

In addition to regulations in the United States, we are subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Some countries outside of the United States have a similar process that requires the submission of a clinical trial application, or CTA, much like the IND prior to the commencement of human clinical trials. In the European Union, for example, a CTA must be submitted to the national health authority of each EU Member State in which the clinical trial is to be conducted and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed.

To obtain regulatory approval to commercialize a new drug under EU regulatory systems, we must submit an MAA. In the EU, marketing authorization for a medicinal product can be obtained through a centralized, mutual recognition, decentralized procedure, or the national procedure of an individual EU Member State. In accordance with the centralized procedure, the applicant can submit a single application for marketing authorization to the EMA. The agency will provide a positive opinion regarding the application if it meets certain quality, safety, and efficacy requirements. Following the opinion of the EMA, the European Commission makes a final decision to grant a centralized marketing authorization that permits the marketing of a product in all 28 EU Member States and three of the four European Free Trade Association, or EFTA, States—Iceland, Liechtenstein and Norway. The centralized procedure is mandatory for certain medicinal products, including orphan medicinal products, medicinal products derived from certain biotechnological processes, advanced therapy medicinal products and certain other medicinal products containing a new active substance for the treatment of certain diseases. This route is optional for certain other products, including medicinal products that are a significant therapeutic, scientific or technical innovation, or whose authorization would be in the interest of public or animal health.

Unlike the centralized authorization procedure, the decentralized marketing authorization procedure requires a separate application to, and leads to separate approval by, the competent authorities of each EU Member State in which the product is to be marketed. This application process is identical to the application that would be submitted to the EMA for authorization through the centralized procedure. The reference EU Member State prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the concerned EU Member States who, within 90 days of receipt, must decide whether to approve the assessment report and related materials. If a concerned EU Member State cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the European Commission, whose decision is binding on all EU Member States.

The mutual recognition procedure is similarly based on the acceptance by the competent authorities of the EU Member States of the marketing authorization of a medicinal product by the competent authorities of other EU Member States. The holder of a national marketing authorization may submit an application to the competent authority of an EU Member State requesting that this authority recognize the marketing authorization delivered by the competent authority of another EU Member State.

For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. Internationally, clinical trials are generally required to be conducted in accordance with GCP, applicable regulatory requirements of each jurisdiction and the medical ethics principles that have their origin in the Declaration of Helsinki.

[Table of Contents](#)

Accelerated Review

Under the Centralized Procedure in the European Union, the maximum timeframe for the evaluation of a MAA is 210 days (excluding “clock stops,” when additional written or oral information is to be provided by the applicant in response to questions asked by the Committee for Medicinal Products for Human Use, or CHMP). Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest. Three cumulative criteria must be fulfilled in such circumstances: the seriousness of the disease (e.g., heavy disabling or life-threatening diseases) to be treated; the absence or insufficiency of an appropriate alternative therapeutic approach; and anticipation of high therapeutic benefit. In this circumstance, EMA ensures that the opinion of the CHMP is given within 150 days.

Compliance

During all phases of development (pre- and post-marketing), failure to comply with applicable regulatory requirements may result in administrative or judicial sanctions. These sanctions could include the FDA’s imposition of a clinical hold on trials, refusal to approve pending applications, withdrawal of an approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, product detention or refusal to permit the import or export of products, injunctions, fines, civil penalties or criminal prosecution. Third country authorities can impose equivalent penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Other Exclusivities

Pediatric Exclusivity. Section 505A of the FD&C Act provides for six months of additional exclusivity or patent protection if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data does not need to show that the product is effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA’s request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or *Orange Book* listed patent protection that cover the drug are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve an ANDA or 505(b)(2) application owing to regulatory exclusivity or listed patents. When any product is approved, we will evaluate seeking pediatric exclusivity as appropriate.

Orphan Drug Exclusivity. The Orphan Drug Act provides incentives for the development of drugs intended to treat rare diseases or conditions, which generally are diseases or conditions affecting less than 200,000 individuals in the United States. If a sponsor demonstrates that a drug is intended to treat a rare disease or condition, the FDA grants orphan drug designation to the product for that use. The benefits of orphan drug designation include research and development tax credits and exemption from user fees. A drug that is approved for the orphan drug designated indication generally is granted seven years of orphan drug exclusivity. During that period, the FDA generally may not approve any other application for the same product for the same indication, although there are exceptions, most notably when the later product is shown to be clinically superior to the product with exclusivity.

In the European Union, the EMA’s Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in the European Union. Additionally, orphan drug designation is granted for products intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug. The application for orphan designation must be submitted to the EMA and approved before an application is made for marketing authorization for the product. Once authorized, orphan medicinal products are entitled to ten years of market exclusivity. During this ten-year period, with a

[Table of Contents](#)

limited number of exceptions, neither the competent authorities of the EU Member States, the EMA, or the European Commission are permitted to accept applications or grant marketing authorization for other similar medicinal products with the same therapeutic indication. However, marketing authorization may be granted to a similar medicinal product with the same orphan indication during the ten-year period with the consent of the marketing authorization holder for the original orphan medicinal product or if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities. Marketing authorization may also be granted to a similar medicinal product with the same orphan indication if this latter product is safer, more effective or otherwise clinically superior to the original orphan medicinal product. The period of market exclusivity may, in addition, be reduced to six years if it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity

Data Exclusivity. In the European Union if a marketing authorization is granted for a medicinal product containing a new active substance, that product benefits from eight years of data exclusivity, during which generic marketing authorization applications referring to the data of that product may not be accepted by the regulatory authorities, and a further two years of market exclusivity, during which such generic products may not be placed on the market. The two-year period may be extended to three years if during the first eight years a new therapeutic indication with significant clinical benefit over existing therapies is approved.

U.S. Healthcare Reform

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, which we refer to together as the Affordable Care Act, or ACA, is a sweeping measure intended to expand healthcare coverage within the United States, primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program. This law substantially changes the way healthcare is financed by both governmental and private insurers and significantly impacts the pharmaceutical industry. Changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, benefits for patients within a coverage gap in the Medicare Part D prescription drug program (commonly known as the “donut hole”), rules regarding prescription drug benefits under the health insurance exchanges, changes to the Medicaid Drug Rebate program, expansion of the Public Health Service’s 340B drug pricing discount program, or 340B program, fraud and abuse, and enforcement. These changes impact existing government healthcare programs and are resulting in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program.

Some states have elected not to expand their Medicaid programs to individuals with an income of up to 133% of the federal poverty level, as is permitted under the Affordable Care Act. For each state that does not choose to expand its Medicaid program, there may be fewer insured patients overall, which could impact our sales of products for which we receive regulatory approval, business and financial condition. Where new patients receive insurance coverage under any of the new Medicaid options made available through the Affordable Care Act, the possibility exists that manufacturers may be required to pay Medicaid rebates on drugs used under these circumstances, a decision that could impact manufacturer revenues. In addition, the federal government has announced delays in the implementation of key provisions of the Affordable Care Act.

Moreover, legislative changes to or regulatory changes under the Affordable Care Act remain possible in the 115th U.S. Congress and under the Trump Administration. The American Health Care Act of 2017, or AHCA, which would repeal and replace key portions of the Affordable Care Act, was passed by the U.S. House of Representatives but remains subject to passage by the U.S. Senate. In addition, in January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. We expect that the Affordable Care Act, as currently enacted or as it may be amended or replaced in the future, and other healthcare reform measures that may be adopted in the future

[Table of Contents](#)

could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of products for which we receive regulatory approval or to successfully commercialize our product candidates, if approved.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we may obtain regulatory approval. Sales of any of our product candidates, if approved, will depend, in part, on the extent to which the costs of the products will be covered by third-party payors, including government healthcare programs such as Medicare and Medicaid, and private payors, such as commercial health insurers and managed care organizations. Third-party payors determine which drugs they will cover and the amount of reimbursement they will provide for a covered drug. In the U.S., there is no uniform system among payors for making coverage and reimbursement decisions. In addition, the process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication.

In order to secure coverage and reimbursement for our products, if approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costly studies required to obtain FDA or other comparable regulatory approvals. Even if we conduct pharmacoeconomic studies, our product candidates may not be considered medically necessary or cost-effective by payors. Further, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved.

In the past, payors have implemented reimbursement metrics and periodically revised those metrics as well as the methodologies used as the basis for reimbursement rates, such as average sales price, or ASP, average manufacturer price, or AMP, and actual acquisition cost. The existing data for reimbursement based on these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates. The Centers for Medicare and Medicaid Services, or CMS, surveys and publishes retail pharmacy acquisition cost information in the form of National Average Drug Acquisition Cost, or NADAC files, to provide state Medicaid agencies with a basis of comparison for their own reimbursement and pricing methodologies and rates.

Participation in the Medicaid Drug Rebate program would require us to pay a rebate for each unit of drug reimbursed by Medicaid. The amount of the "basic" portion of the rebate for each product is set by law as the larger of: (i) 23.1% of quarterly AMP, or (ii) the difference between quarterly AMP and the quarterly best price available from us to any commercial or non-governmental customer, or Best Price. AMP must be reported on a monthly and quarterly basis and Best Price is reported on a quarterly basis only. In addition, the rebate also includes the "additional" portion, which adjusts the overall rebate amount upward as an "inflation penalty" when the drug's latest quarter's AMP exceeds the drug's AMP from the first full quarter of sales after launch, adjusted for increases in the Consumer Price Index-Urban. The upward adjustment in the rebate amount per unit is equal to the excess amount of the current AMP over the inflation-adjusted AMP from the first full quarter of sales. The rebate amount is recomputed each quarter based on our report to CMS of current quarterly AMP and Best Price for our drug. The terms of our participation in the program would impose a requirement for us to report revisions to AMP or Best Price within a period not to exceed 12 quarters from the quarter in which the data was originally due. Any such revisions could have the impact of increasing or decreasing our rebate liability for prior quarters, depending on the direction of the revision.

Federal law requires that any manufacturer that participates in the Medicaid Drug Rebate program also participate in the 340B program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program requires participating manufacturers to agree to charge

[Table of Contents](#)

statutorily defined covered entities no more than the 340B “ceiling price” for the manufacturer’s covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The 340B ceiling price is calculated using a statutory formula, which is based on the AMP and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate program. Any changes to the definition of AMP and the Medicaid rebate amount under the Affordable Care Act or other legislation could affect our 340B ceiling price calculations and negatively impact our results of operations.

In the U.S. Medicare program, outpatient prescription drugs may be covered under Medicare Part D. Medicare Part D is a voluntary prescription drug benefit, through which Medicare beneficiaries may enroll in prescription drug plans offered by private entities for coverage of outpatient prescription drugs. Part D plans include both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans provided for under Medicare Part C.

Coverage and reimbursement for covered outpatient drugs under Part D are not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Although Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, they have some flexibility to establish those categories and classes and are not required to cover all of the drugs in each category or class. Medicare Part D prescription drug plans may use formularies to limit the number of drugs that will be covered in any therapeutic class and/or impose differential cost sharing or other utilization management techniques.

The availability of coverage under Medicare Part D may increase demand for products for which we receive marketing approval. However, in order for the products that we market to be included on the formularies of Part D prescription drug plans, we likely will have to offer pricing that is lower than the prices we might otherwise obtain. Changes to Medicare Part D that give plans more freedom to limit coverage or manage utilization, and other cost reduction initiatives in the program, could decrease the coverage and price that we receive for any approved products and could seriously harm our business.

In order to be eligible to have our products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, we expect to participate in the U.S. Department of Veterans Affairs, or VA, Federal Supply Schedule, or FSS, pricing program. Under this program, we would be obligated to make our “innovator” drugs available for procurement on an FSS contract and charge a price to four federal agencies—the VA, U.S. Department of Defense, or DoD, Public Health Service and U.S. Coast Guard—that is no higher than the statutory Federal Ceiling Price, or FCP. The FCP is based on the non-federal average manufacturer price, or Non-FAMP, which we calculate and report to the VA on a quarterly and annual basis. We also expect to participate in the Tricare Retail Pharmacy program, under which we would pay quarterly rebates on utilization of innovator products that are dispensed through the Tricare Retail Pharmacy network to Tricare beneficiaries. The rebates are calculated as the difference between the annual Non-FAMP and FCP.

Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by manufacturers, governmental or regulatory agencies, and the courts. Civil monetary penalties can be applied if a manufacturer is found to have knowingly submitted any false price information to the government or fails to submit the required price data on a timely basis. Such conduct also could be grounds for CMS to terminate the manufacturer’s Medicaid drug rebate agreement, in which case federal payments may not be available under Medicaid or Medicare Part B for the manufacturer’s covered outpatient drugs. In addition, claims submitted to federally-funded healthcare programs, such as Medicare and Medicaid, for drugs priced based on incorrect pricing data provided by a manufacturer can implicate the federal Civil False Claims Act.

[Table of Contents](#)

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement, and requirements for substitution of generic products for branded prescription drugs. For example, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs, and reform government program reimbursement methodologies for drug products.

Beginning April 1, 2013, Medicare payments for all items and services, including drugs, were reduced by 2% under the sequestration (i.e., automatic spending reductions) required by the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012. Subsequent legislation extended the 2% reduction, on average, to 2025. If Congress does not take action in the future to modify these sequestrations, Medicare Part D plans could seek to reduce their negotiated prices for drugs. Other legislative or regulatory cost containment legislation could have a similar effect.

Further, the Affordable Care Act may reduce the profitability of drug products. It expanded manufacturers' rebate liability under the Medicaid program from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well, increased the minimum Medicaid rebate due for most innovator drugs, and capped the total rebate amount for innovator drugs at 100% of AMP. The Affordable Care Act and subsequent legislation also changed the definition of AMP. On February 1, 2016, CMS issued final regulations to implement the changes to the Medicaid drug rebate program under the Affordable Care Act. These regulations became effective on April 1, 2016.

The Affordable Care Act requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government. Each such manufacturer pays a prorated share of the branded prescription drug fee of \$4.0 billion in 2017, based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law. The Affordable Care Act also expanded the Public Health Service's 340B program to include additional types of covered entities. Substantial new provisions affecting compliance have also been enacted, which may affect our business practices with healthcare practitioners, and a significant number of provisions are not yet, or have only recently become, effective. It appears likely that the Affordable Care Act will continue the pressure on pharmaceutical pricing, especially under the Medicare and Medicaid programs, and may also increase our regulatory burdens and operating costs.

Legislative changes to and regulatory changes under the Affordable Care Act remain possible in the 115th U.S. Congress and under the Trump Administration, as discussed above under the heading "U.S. Healthcare Reform." In addition, there likely will continue to be proposals by legislators at both the federal and state levels, regulators, and third-party payors to contain healthcare costs. Thus, even if we obtain favorable coverage and reimbursement status for any products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Different pricing and reimbursement schemes exist in other countries. In the European Union, each EU Member States can restrict the range of medicinal products for which its national health insurance system provides reimbursement and can control the prices of medicinal products for human use marketed on its territory. As a result, following receipt of marketing authorization in an EU Member State, through any application route, the applicant is required to engage in pricing discussions and negotiations with the competent pricing authority in the individual EU Member State. The governments of the EU Member States influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Some EU Member States operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed upon. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently

[Table of Contents](#)

available therapies. Other EU Member States allow companies to fix their own prices for medicines, but monitor and control company profits. Others adopt a system of reference pricing, basing the price or reimbursement level in their territories either on the pricing and reimbursement levels in other countries or on the pricing and reimbursement levels of medicinal products intended for the same therapeutic indication. Further, some EU Member States approve a specific price for the medicinal product or may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. The downward pressure on healthcare costs in general, particularly prescription drugs, has become more intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, we may face competition for our product candidates from lower-priced products in foreign countries that have placed price controls on pharmaceutical products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

Health Technology Assessment, or HTA, of medicinal products, however, is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States. These EU Member States include the United Kingdom, France, Germany, Ireland, Italy and Sweden. HTA is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. HTA generally focuses on the clinical efficacy and effectiveness, safety, cost, and cost-effectiveness of individual medicinal products as well as their potential implications for the healthcare system. Those elements of medicinal products are compared with other treatment options available on the market.

The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product varies between EU Member States.

In addition, pursuant to Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, a voluntary network of national authorities or bodies responsible for HTA in the individual EU Member States was established. The purpose of the network is to facilitate and support the exchange of scientific information concerning HTAs. This may lead to harmonization of the criteria taken into account in the conduct of HTAs between EU Member States and in pricing and reimbursement decisions and may negatively affect price in at least some EU Member States.

Healthcare Fraud and Abuse Laws

In addition to FDA restrictions on marketing of pharmaceutical products, our business will be subject to healthcare fraud and abuse regulation and enforcement by both the federal government and the states in which we conduct our business, particularly once third-party reimbursement becomes available for one or more of our products. These laws include, but are not limited to, anti-kickback and false claims statutes.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any healthcare item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. A violation of the Anti-Kickback Statute may be established without proving actual knowledge of the statute or specific intent to violate it. The Affordable Care Act amended federal law to provide that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, the exceptions and safe harbors are drawn narrowly and practices that involve remuneration to those who prescribe, purchase, or

[Table of Contents](#)

recommend pharmaceuticals, including certain discounts, or engaging such individuals as consultants, speakers or advisors, may be subject to scrutiny if they do not fit squarely within the exception or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability. Moreover, there are no safe harbors for many common practices, such as educational and research grants, charitable donations, product support and patient assistance programs. Arrangements that implicate the Anti-Kickback Statute and do not fit within an exception or safe harbor are reviewed on a case-by-case basis to determine whether, based on the facts and circumstances, they violate the statute.

The federal civil False Claims Act prohibits, among other things, any person from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds, or knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly concealing or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government. Actions under the federal civil False Claims Act may be brought by private individuals known as qui tam relators in the name of the government. In recent years, several pharmaceutical and other healthcare companies have faced enforcement actions under the federal civil False Claims Act for, among other things, providing free product to customers with the expectation that the customers would bill federal programs for the product, inflating prices reported to private price publication services which are used to set drug payment rates under government healthcare programs, and other interactions with prescribers and other customers including interactions that may have affected customers' billing or coding practices on claims submitted to the federal government. Other companies have faced enforcement actions for causing false claims to be submitted because of the company's marketing the product for unapproved, and thus non-reimbursable, uses. Federal enforcement agencies also have shown increased interest in pharmaceutical companies' product and patient assistance programs, including reimbursement and co-pay support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements.

The Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which we refer to collectively as HIPAA, also created several new federal crimes, including healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services.

The majority of states also have statutes or regulations similar to the federal anti-kickback and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Several states now require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products in those states and to report gifts and payments to individual health care providers in those states. Some of these states also prohibit certain marketing-related activities including the provision of gifts, meals, or other items to certain health care providers. In addition, several states require pharmaceutical companies to implement compliance programs or marketing codes.

The Physician Payments Sunshine Act, implemented as the Open Payments program, and its implementing regulations, requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to CMS information related to certain payments made in the previous calendar year and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

Compliance with such laws and regulations will require substantial resources. Because of the breadth of these various fraud and abuse laws, it is possible that some of our business activities could be subject to

[Table of Contents](#)

challenge under one or more of such laws. Such a challenge could have material adverse effects on our business, financial condition and results of operations. In the event governmental authorities conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations, they may impose sanctions under these laws, which are potentially significant and may include civil monetary penalties, damages, exclusion of an entity or individual from participation in government health care programs, criminal fines and imprisonment, additional reporting requirements if we become subject to a corporate integrity agreement or other settlement to resolve allegations of violations of these laws, as well as the potential curtailment or restructuring of our operations. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity.

Healthcare Privacy Laws

We may be subject to laws and regulations covering data privacy and the protection of health-related and other personal information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business. Numerous federal and state laws and regulations, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use, disclosure, and protection of personal information. Failure to comply with such laws and regulations could result in government enforcement actions and create liability for us (including the imposition of significant penalties), private litigation and/or adverse publicity that could negatively affect our business. In addition, healthcare providers who prescribe our products and research institutions we collaborate with are subject to privacy and security requirements under HIPAA.

Foreign Corrupt Practices Act

In addition, the U.S. Foreign Corrupt Practices Act prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value to any official of another country, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in that capacity.

Corporate Information

pSivida Corp. was organized as a Delaware corporation in March 2008. Its predecessor, pSivida Limited, was formed in December 2000 as an Australian company incorporated in Western Australia. Our principal executive office is located at 480 Pleasant Street, Suite B300, Watertown, Massachusetts 02472 and our telephone number is (617) 926-5000.

Additional Information

Our website address is <http://www.psivida.com>. Information contained on, or connected to, our website is not incorporated by reference into this Annual Report on Form 10-K. Copies of our annual reports on Form 10-K, proxy statements, quarterly reports on Form 10-Q, current reports on Form 8-K and, if applicable, amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, are available free of charge through our website under “Investors – Financial Information – SEC Filings” as soon as reasonably practicable after we electronically file these materials with, or otherwise furnish them to, the SEC. Further, a copy of this Annual Report on Form 10-K is located at the SEC’s Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. Information on the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at www.sec.gov.

ITEM 1A. RISK FACTORS

RISKS RELATED TO OUR FINANCIAL POSITION AND OUR CAPITAL RESOURCES

We will need additional capital to fund our operations and continue as a going concern. If we are unable to obtain sufficient capital, we will need to curtail and reduce our operations and costs, and modify our business strategy.

Our principal sources of liquidity are cash and cash equivalents and the receipt of license fees, milestone payments, research and development funding and royalty income from our collaboration partners. As of June 30, 2017, our cash and cash equivalents were \$16.9 million. We believe that our existing capital resources, together with expected payments from existing collaborations, should enable us to fund our operations as currently planned through approximately the first quarter of calendar year 2018. However, changing circumstances may cause us to consume capital faster than we currently anticipate, and we may need to spend more money than currently expected because of such circumstances. Our ability to fund our planned operations beyond that time, including completing clinical development and obtaining regulatory approvals for Durasert three-year uveitis and continuing our research and development program for our other product candidates, will require additional capital. In addition, our current plan to commercialize Durasert three-year uveitis ourselves in the United States will require significant operating cost investment related to product manufacturing, marketing, sales, distribution and other commercialization costs.

To meet our capital needs, we are considering multiple alternatives, including but not limited to, equity financings, debt financings, corporate collaborations, partnerships and other strategic transactions and funding opportunities. However, there can be no assurance that we will be able to complete any one or more of such transactions on acceptable terms or otherwise. These factors raise substantial doubt about our ability to continue as a going concern. As a result, our independent registered public accounting firm has included an explanatory paragraph in its report on our financial statements for the year ended June 30, 2017 related to our ability to continue as a going concern.

If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will need to curtail and reduce our operations and costs, and modify our business strategy which may require us to, among other things:

- significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates or one or more of our other research and development initiatives;
- seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available;
- sell or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves; or
- seek to sell our company at an earlier stage than would otherwise be desirable or on terms that are less favorable than might otherwise be available.

We have incurred significant losses since our inception and anticipate that we will continue to incur losses for the foreseeable future.

We have incurred significant losses since our inception, have not generated significant revenue from commercial sales of our products and, with exception of fiscal year 2010 and fiscal year 2015, we have never been profitable. Investment in drug development is highly speculative because it entails substantial upfront operating expenses and significant risk that a product candidate will fail to successfully complete clinical trials, gain regulatory approval or become commercially viable. We continue to incur significant research, development and other expenses related to our ongoing operations, including development of our lead product candidate and other early stage and/or potential product candidates. For the year ended June 30, 2017, we had a net loss of \$18.5 million, and we had a total accumulated deficit of \$310.8 million at June 30, 2017.

[Table of Contents](#)

We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses will continue to be significant if, and as, we:

- continue the research and pre-clinical and clinical development of our product candidates;
- initiate additional pre-clinical, clinical or other studies or trials for our product candidates;
- further develop the manufacturing process for our product candidates;
- change or add additional manufacturers or suppliers;
- seek regulatory approvals for our product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain regulatory approval and for which we intend to commercialize ourselves;
- seek to identify and validate additional product candidates;
- acquire or in-license other product candidates and technologies;
- maintain, protect and expand our intellectual property portfolio;
- attract and retain skilled personnel;
- create additional infrastructure to support our product development and planned future commercialization efforts; and
- experience any delays or encounter issues with any of the above.

The net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. In any particular quarter or quarters, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline.

We may never achieve profitability from future operations.

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

[Table of Contents](#)

We will need to raise additional funds in the future, which may not be available on favorable terms and may be dilutive to stockholders or impose operational restrictions.

We will need to raise additional capital in the future to help fund our clinical trials and for the development and commercialization of our product candidates. The amount of additional capital we will require will be influenced by many factors, including, but not limited to:

- the amount of future revenues we receive with respect to the commercialization of ILUVIEN for DME and, if approved in the EMEA, ILUVIEN for posterior segment uveitis;
- the timing, cost and success of our clinical development, regulatory approval and planned direct U.S. commercialization of Durasert three-year uveitis;
- whether and to what extent we internally fund, whether and when we initiate, and how we conduct other product development programs;
- the amount of Retisert royalties and other payments we receive under collaboration agreements;
- whether and when we are able to enter into strategic arrangements for our product candidates and the nature of those arrangements;
- timely and successful development, regulatory approval and commercialization of other potential product candidates;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing any patent claims;
- changes in our operating plan, resulting in increases or decreases in our need for capital;
- our views on the availability, timing and desirability of raising capital; and
- the costs of operating as a public company.

We do not know if additional capital will be available to us when needed or on terms favorable to us or our stockholders. Collaboration, licensing or other commercial agreements may not be available on favorable terms, or at all. We do not know the extent to which we will receive funds from the commercialization of ILUVIEN or Retisert. If we seek to sell our equity securities under our at-the-market (“ATM”) program or in another offering, we do not know whether and to what extent we will be able to do so, or on what terms. Further, the rules and regulations of the Australian Securities Exchange (“ASX”) and the NASDAQ Stock Market (“NASDAQ”) require us to obtain shareholder approval for sales of our equity securities under certain circumstances, which could delay or prevent us from raising additional capital from such sales. Also, the state of the economy and financial and credit markets at the time or times we seek any additional financing may make it more difficult or more expensive to obtain. If available, additional equity financing may be dilutive to stockholders, debt financing may involve restrictive covenants or other unfavorable terms and dilute our existing stockholders’ equity, and funding through collaboration, licensing or other commercial agreements may be on unfavorable terms, including requiring us to relinquish rights to certain of our technologies or products. If adequate financing is not available if and when needed, we may delay, reduce the scope of, or eliminate research or development programs, planned independent U.S. commercialization of Durasert three-year uveitis or other new products, if any, postpone or cancel the pursuit of product candidates, including pre-clinical and clinical trials and new business opportunities, reduce staff and operating costs, or otherwise significantly curtail our operations to reduce our cash requirements and extend our capital.

Our ability to use our net operating loss carryforwards and other tax attributes may be limited.

As of June 30, 2017, we had U.S. net operating loss (“NOL”) carryforwards of approximately \$92.6 million for U.S. federal income tax and approximately \$51.6 million of state income tax purposes available to offset future taxable income and U.S. federal and state research and development tax credits of approximately \$1.2 million, prior to consideration of annual limitations that may be imposed under Section 382 of the Internal Revenue Code of 1986, as amended (“Section 382”). The U.S. NOL carryforwards begin to expire in 2023 if not utilized.

[Table of Contents](#)

Our U.S. NOL and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under Section 382, and corresponding provisions of U.S. state law, if a corporation undergoes an “ownership change,” generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation’s ability to use its pre-change U.S. NOLs and other pre-change tax attributes, such as research and development tax credits, to offset its post-change income may be limited. Our most recent analyses under Section 382 were performed in 2014 and we cannot forecast or otherwise determine our ability to derive benefit from our various federal or state tax attribute carryforwards. As a result, if we earn net taxable income, our ability to use our pre-change U.S. NOL carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of U.S. NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

In addition, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, including through completed or contemplated financings, some of which may be outside of our control. If we determine that an ownership change has occurred and our ability to use our historical net operating loss and tax credit carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

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

Our Retisert royalty income, which had ranged between \$1.2 million and \$1.4 million from fiscal 2012 through fiscal 2016, decreased to \$970,000 for fiscal 2017. We do not expect Retisert royalty income to increase materially, if at all, and it may decline further or cease. Bausch & Lomb’s obligation to pay a royalty terminates on a licensed product by licensed product basis and country by country basis upon the date that the last to expire patent expires. The patent with which Retisert is marked expires in March 2019. The latest patent covering Retisert expires in April 2020, and we will not receive any Retisert royalty income after that time. Bausch & Lomb previously ceased selling Vitrasert on its patent expiration.

Our operating results may fluctuate significantly from period to period.

Our operating results have fluctuated significantly from period to period in the past and may continue to do so in the future due to many factors, including:

- costs of internally funded research and development, including CROs and other costs related to clinical development and costs of pre-clinical studies and research;
- developments with respect to our products and product candidates, both licensed and independently developed, including pre-clinical and clinical trial data and results, regulatory developments and marketing and sales results;
- timing, receipt and amount of revenues, including receipt and recognition of collaborative research and development, licensing, milestone, royalty and other payments;
- announcement, execution, amendment and termination of collaboration and other commercial agreements;
- scope, duration and success of collaboration and other commercial agreements;
- general and industry-specific adverse economic conditions that may affect, among other things, our and our collaborators’ operations and financial results; and
- changes in accounting estimates, policies or principles and intangible asset impairments.

Due to fluctuations in our operating results, quarterly comparisons of our financial results may not necessarily be meaningful, and investors should not rely upon such results as an indication of future performance. In addition,

investors may react adversely if our reported operating results are less favorable than in a prior period or are less favorable than those anticipated by investors in the financial community, which may result in decreases in our stock price.

RISKS RELATED TO THE REGULATORY APPROVAL AND CLINICAL DEVELOPMENT OF OUR PRODUCT CANDIDATES

We are substantially dependent on the success of our lead product candidate, Durasert three-year uveitis, which is in a later stage of development than our other product candidates. To the extent regulatory approval of Durasert three-year uveitis is delayed or not granted, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline.

We are focusing a significant portion of our activities and resources on our lead product candidate, Durasert three-year uveitis, and we believe our prospects are highly dependent on, and a significant portion of the value of our company relates to, our ability to successfully develop, obtain regulatory approval for, and commercialize Durasert three-year uveitis in the U.S. The U.S. regulatory approval of Durasert three-year uveitis is subject to many risks, including the risks discussed in other risk factors set forth in this Annual Report on Form 10-K, and Durasert three-year uveitis may not receive marketing approval from the FDA. If the results or timing of regulatory filings, the regulatory process, regulatory developments, any additional clinical trials or pre-clinical studies, or other activities, actions or decisions related to Durasert three-year uveitis do not meet our or others' expectations, the market price of our common stock could decline significantly.

We plan to submit an NDA for Durasert three-year uveitis with the FDA in late December 2017 or early January 2018. Although we have discussed our clinical development plans with the FDA, the agency may ultimately determine that our Phase 3 clinical trials or other aspects of our NDA are not sufficient for regulatory approval and may issue a CRL instead of approval. If we receive a CRL, the FDA would outline deficiencies in our NDA and may request the submission of additional information, including clinical data. The FDA will also inspect our facilities, the facilities of our third-party manufacturers, and may also inspect one or more of our clinical trial sites. If any facility or site reveals anomalies or does not otherwise have a satisfactory inspection, the FDA could delay or preclude approval of our NDA. In either case, our commercialization of Durasert three-year uveitis in the U.S. may be delayed and we may incur additional costs and be required to devote additional resources to address the FDA's concerns. If the FDA requires us to conduct additional clinical trials or studies, or requires our manufacturers to improve or change their practices, our timeline for commercialization of Durasert three-year uveitis in the U.S. will be delayed and we will incur additional costs. Further, there can be no assurance that we will complete such studies or clinical trials or address manufacturing issues in a manner that is acceptable to the FDA.

In addition, one of our collaborators, Alimera, holds an exclusive license to Durasert three-year uveitis in the EMEA under the ILUVIEN trademark. Alimera plans to apply for an additional indication, ILUVIEN for posterior segment uveitis, under its existing MAA, through the MAA variation process. Obtaining regulatory approval for such a variation is uncertain and Alimera may fail to obtain the approval. The MAA variation review processes and the processes of other regulatory authorities, are extensive, lengthy, expensive, and uncertain, and such regulatory authorities may delay, limit, or deny approval of ILUVIEN for posterior segment uveitis.

Any delay or setback in the development or regulatory approval of Durasert three-year uveitis will adversely affect our business and could cause our stock price to decline. Should our recent Phase 3 clinical development program be insufficient to support regulatory approval, we may be forced to rely on our other product candidates, which are at a much earlier development stage and will require significant additional time and resources to conduct clinical development, obtain regulatory approval and proceed with commercialization.

[Table of Contents](#)

There is no assurance that data we plan to submit in support of our planned NDA for Durasert three-year uveitis will be acceptable to the FDA and accordingly that U.S. marketing authorization for Durasert three-year uveitis will be granted.

We plan to file our NDA for Durasert three-year uveitis on results from our two Phase 3 clinical trials. While each of the two trials met its primary efficacy endpoint with statistical significance and showed encouraging safety results, we conducted our first Phase 3 study in both the U.S. and five other countries (U.K., Germany, Hungary, Israel and India) and we conducted our second Phase 3 clinical trial of Durasert three-year uveitis in India. In general, the FDA accepts data from clinical trials conducted outside the United States; however, acceptance of this data is subject to, among other things, the clinical trials being conducted and performed by qualified investigators in accordance with GCP principles. The trial population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. In addition, while our Phase 3 clinical trials are subject to applicable local laws, FDA acceptance of the data from both trials will depend on its determination that they were conducted in accordance with all applicable U.S. laws and regulations.

We plan to submit data from a study of the safety and utilization of two different inserters for Durasert three-year uveitis in support of our NDA, and the FDA may require an additional study of such inserter we have proposed for U.S. commercial use.

The FDA has significant discretion in determining whether to accept an NDA for review and what data to require for review, and there is no assurance that the FDA will find the design of our clinical trials or the data we include in an NDA to be sufficient to accept the NDA for review or to approve the NDA. The refusal of the FDA to accept our marketing application for review or their requirements for additional data or trials could delay the timing, increase the expense or render impractical continued pursuit of potential marketing approval of Durasert three-year uveitis in the U.S. Delay in or inability to obtain marketing approval for Durasert three-year uveitis in the U.S. could materially and adversely affect our business and the price of our common stock.

The regulatory approval processes of the FDA or other foreign regulatory authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA or other foreign regulatory authorities is unpredictable, but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory agency. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development. It is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the regulatory authority may not accept our filing application;
- the regulatory authority may disagree with the design, scope or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the regulatory authority that a product candidate is safe and effective for its proposed indication; we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the regulatory authority may disagree with our interpretation of data from pre-clinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a drug application or marketing authorization;

Table of Contents

- the regulatory authority may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the regulatory authority may change in a manner rendering our clinical data insufficient for approval.

We cannot be certain that any of our current product candidates will receive regulatory approval. If we do not receive regulatory approval for our product candidates, we may not be able to continue our operations.

Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval and commence product sales.

Other than Durasert three-year uveitis, which is in late-stage clinical development, all of our product development is at earlier stages. Product development at all stages involves a high degree of risk, and only a small proportion of research and development programs result in product candidates that advance to pivotal clinical trials or result in approved products. There is no assurance that any feasibility study agreements we have, or enter into, with third parties, or our own research and development programs and collaborations will result in any new product candidates, or that we or any licensees will commence clinical trials for any new product candidates or continue clinical trials once commenced. If clinical trials conducted by or for us or any licensees for any product candidates do not provide the necessary evidence of safety and efficacy, those product candidates will not receive the necessary regulatory approvals, cannot be sold, and will not generate revenues for us.

We may also experience delays in clinical trials of our product candidates or the time required to complete clinical trials for our product candidates may be longer than anticipated. Our future clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients, or be completed on schedule, if at all. Our clinical trials can be delayed, or even terminated, for a variety of reasons, including, but not limited to:

- decisions not to pursue development of product candidates due to pre-clinical or clinical trial results;
- lack of sufficient funding;
- inability to attract clinical investigators for trials;
- inability to recruit patients in sufficient numbers or at the expected rate;
- decisions by licensees not to exercise options for products or not to pursue or promote products licensed to them;
- adverse side effects;
- failure of trials to demonstrate safety and efficacy;
- failure to meet FDA or other regulatory agency requirements for clinical trial design, or inadequate clinical trial design;
- inability to follow patients adequately after treatment;
- changes in the design or manufacture of a product candidate;
- failures by, changes in our (or our licensees') relationship with, or other issues at, CROs, vendors and investigators responsible for pre-clinical testing and clinical trials;
- imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or foreign regulatory authorities;
- inability to obtain supplies and/or to manufacture sufficient quantities of materials for use in clinical trials;
- stability issues with clinical materials;
- failure to comply with good laboratory practices, good clinical practices, current good manufacturing practices or similar foreign regulatory requirements that affect the conduct of pre-clinical and clinical studies and the manufacturing of product candidates;
- requests by regulatory authorities for additional data or clinical trials;

[Table of Contents](#)

- governmental or regulatory agency assessments of pre-clinical or clinical testing that differ from our (or our licensees') interpretations or conclusions;
- governmental or regulatory delays, or changes in approval policies or regulations; and
- developments, clinical trial results and other factors with respect to competitive products and treatments.

If clinical trials for our product candidates are delayed for any of the above reasons or other reasons, our development costs may increase, our approval process could be delayed and our ability to commercialize our product candidates could be materially harmed.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and product candidates for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products.

We have based our research and development efforts primarily on our Durasert technology platform to develop proprietary sustained-release pharmaceutical products for the treatment of posterior uveitis and other chronic eye diseases. As a result of pursuing the development of product candidates using our proprietary technologies, we may fail to develop product candidates or address indications based on other scientific approaches that may offer greater commercial potential or for which there is a greater likelihood of success. Research programs to identify new product candidates require substantial technical, financial and human resources. These research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development.

Initial results from a clinical trial do not ensure that the trial will be successful and success in early stage clinical trials does not ensure success in later-stage clinical trials.

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

In addition, while the clinical trials of our product candidates are designed based on the available relevant information, in view of the uncertainties inherent in drug development, such clinical trials may not be designed with focus on indications, patient populations, dosing regimens, safety or efficacy parameters or other variables that will provide the necessary safety or efficacy data to support regulatory approval to commercialize the resulting product candidates. In addition, individual patient responses to the dose administered of a product candidate may vary in a manner that is difficult to predict. Also, the methods we select to assess particular safety or efficacy parameters may not yield statistical precision in estimating our product candidates' effects on study

[Table of Contents](#)

participants. Even if we believe the data collected from clinical trials of our product candidates are promising, these data may not be sufficient to support approval by the FDA or foreign regulatory authorities. Pre-clinical and clinical data can be interpreted in different ways. Accordingly, the FDA or foreign regulatory authorities could interpret these data in different ways from us or our partners, which could delay, limit or prevent regulatory approval.

Changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols submitted to applicable regulatory authorities to reflect these changes. Amendments may require us to resubmit clinical trial protocols to institutional review boards or ethics committees for re-examination, which may impact the costs, timing or successful completion of a clinical trial.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our other product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained.

If we are required to conduct additional clinical trials or other studies with respect to our product candidates beyond those that we currently contemplate, or if we are unable to successfully complete our clinical trials or other studies, we may be delayed in obtaining regulatory approval of any of our product candidates, we may not be able to obtain regulatory approval at all or we may obtain approval of indications that are not as broad as intended. Our product development costs will also increase if we experience delays in testing or approvals, and we may not have sufficient funding to complete the testing and approval process for our product candidates. Significant clinical trial delays could allow our competitors to bring products to market before we do and impair our ability to commercialize our products if and when approved. If any of this occurs, our business would be harmed.

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

Our product candidate for severe knee OA in collaboration with HSS is the subject of an investigator-sponsored, open-label, one-dose, safety and tolerability Phase 1 clinical trial. We do not know what the final results of that clinical trial will be, whether we will be able to develop a product candidate for this indication to eventually enter into later-stage clinical trials, whether we will commence or successfully complete any such trials or whether we will obtain regulatory approvals for a product for this indication. Although we believe we will be able to do so, there is no assurance that we will be able to design a product with a longer treatment duration than six months, that we will be able to create a refillable implant or that the product, even if successful for severe knee osteoarthritis, can be extended to treat osteoarthritis of any other joint. In addition, the study for this product candidate is being conducted by an investigator, and we do not control that trial as we would if we were conducting the trial ourselves. We currently have no agreement with HSS to develop this product beyond the completion of this study, and there is no assurance that we will reach such an agreement. If we do not do so, there is a risk that the intellectual property of HSS and joint intellectual property developed in the course of our collaboration with HSS or future actions by HSS will interfere with our ability to develop and market an OA implant.

RISKS RELATED TO THE COMMERCIALIZATION OF OUR PRODUCT CANDIDATES

We have no history of commercializing drugs, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

Our operations to date have been largely focused on raising capital and developing Retisert, ILUVIEN, Durasert three-year uveitis and our other product candidates, including undertaking pre-clinical studies and

[Table of Contents](#)

conducting clinical trials. Bausch & Lomb and Alimera were responsible for completing the clinical development of, obtaining regulatory approval for, and initiating the commercial launch of Retisert and ILUVIEN, respectively under our license agreements with each of them. To date, we have not yet demonstrated our ability to successfully complete clinical development through the submission and attainment of marketing approvals for any product candidate, manufacture at commercial scale, or, with the exception of Retisert and ILUVIEN, arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer history of successfully developing and commercializing drugs.

Our current business strategy relies heavily on our ability to successfully commercialize Durasert three-year uveitis in the United States. Our product candidates, if approved, may not achieve market acceptance or be commercially successful.

Our ability to successfully commercialize Durasert three-year uveitis, if approved, in the United States is critical to the execution of our business strategy. If approved, Durasert three-year uveitis may not achieve market acceptance among physicians, patients, and third-party payors, and may not be commercially successful in the United States. The degree of market acceptance and commercial success of our products and product candidates, if approved, will depend on a number of factors, including the following:

- the acceptance of our products by patients and the medical community and the availability, perceived advantages and relative cost, safety and efficacy of alternative and competing treatments;
- our ability to obtain a J-Code for Durasert three-year uveitis and the willingness of third-party payors to reimburse Durasert three-year uveitis based on the J-Code;
- the effectiveness of our marketing, sales and distribution strategy and operations;
- our ability to manufacture commercial supplies of our products that we manufacture on our own, to remain in good standing with regulatory agencies, and to develop, validate and maintain commercially viable manufacturing processes that are, to the extent required, compliant with current good manufacturing practice, or cGMP, regulations;
- the degree to which the approved labeling supports promotional initiatives for commercial success;
- the availability of reimbursement from managed care plans and other third-party payors and the willingness and ability of patients to pay for our products;
- a continued acceptable safety profile of our products and product candidates;
- any new or unexpected results from additional clinical trials or further analysis of clinical data of completed clinical trials by us or our competitors;
- our ability to enforce our intellectual property rights;
- our ability to avoid third-party patent interference or patent infringement claims; and
- maintaining compliance with all applicable regulatory requirements.

As many of these factors are beyond our control, we cannot assure you that we will ever be able to generate meaningful revenues through product sales. Any inability on our part to successfully commercialize Durasert three-year uveitis and our other product candidates in the United States or any foreign territories where they may be approved, or any significant delay in such approvals, could have a material adverse impact on our ability to execute upon our business strategy and our future business prospects.

If we are unable to enter into agreements with third parties to market and sell Durasert three-year uveitis, if approved, we may be unable to generate any revenue from Durasert three-year uveitis.

We currently have no sales, marketing or distribution capabilities, our approved products are commercialized by others and we have no experience in commercializing products. If Durasert three-year uveitis is approved by the FDA, we intend to commercialize it in the U.S. ourselves through a contract sales organization, or CSO, although we have not yet entered into any agreements with CSOs. Direct commercialization would require us to develop sales and marketing capabilities and to make a significant financial investment. In addition, any CSO that we may use may not dedicate sufficient resources to the commercialization of Durasert three-year uveitis or may otherwise fail in its commercialization due to factors beyond our control. Additionally, any CSO that we may use may fail to comply with applicable legal or regulatory requirements, or may enter into agreements with other parties that have products and services that could compete with Durasert three-year uveitis.

In the event that we fail to successfully launch and commercialize Durasert three-year uveitis through a CSO, we may also enter into a strategic collaboration with a third party. We face significant competition in seeking appropriate strategic collaborators, and these strategic collaborations can be intricate and time-consuming to negotiate and document. We may not be able to negotiate strategic collaborations on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any strategic collaborations because of the numerous risks and uncertainties associated with establishing strategic partnerships.

We do not know if we will decide to directly commercialize any other product candidates ourselves, if approved. If we decide to commercialize a product in one or more countries, there is no assurance we will be able to hire and manage a successful sales and marketing capability or have the financial resources necessary to fund independent commercialization of any products in any country.

Even if the FDA or other foreign regulatory authority were to grant approval of Durasert three-year uveitis, the terms of the approval may limit its commercial potential.

Even if we were to successfully obtain approval from the FDA or other foreign regulatory authorities for Durasert three-year uveitis, any such approval might significantly limit the approved indications for use or patient populations, require that black box warnings, contraindications or warnings and precautions be included on the product labeling, require expensive and time-consuming post-approval clinical trials, Risk Evaluation and Mitigation Strategy, or REMS, or surveillance as conditions of approval, or, through product labeling limit the claims that we may make, any of which may impede the successful commercialization of Durasert three-year uveitis. Depending on the extent of any REMS requirements, our costs to commercialize Durasert three-year uveitis may increase significantly and distribution restrictions could limit sales. Further, if the approval of Durasert three-year uveitis contains other significant product label limitations, our ability to address our full target market will be reduced and our ability to realize the full market potential of Durasert three-year uveitis will be harmed and we may have to limit our sales and marketing efforts.

Even if we are able to commercialize our product candidates, the products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which could harm our business.

The regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenues we are able to generate from the sale of the product in that particular country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates even if our product candidates obtain marketing approval.

[Table of Contents](#)

Our ability to commercialize any products successfully will also depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Third-party payors also may seek additional clinical evidence, beyond the data required to obtain marketing approval, demonstrating clinical benefits and value in specific patient populations, before covering our products for those patients. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacturing, selling and distribution costs. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products, and our overall financial condition.

If approved, we intend to ship Durasert three-year uveitis directly to physician offices or clinics to be administered to patients. It will be shipped to physician offices or clinics primarily through specialty pharmacies and distributors and billed to doctors under a “buy and bill” model. Physicians may find it difficult to meet their payment obligations and our ability to collect payment can be highly uncertain and variable, especially given the relatively high per unit price we expect to charge for each three-year device.

If we obtain regulatory approval for Durasert three-year uveitis, our relationships with physicians, patients and payors in the U.S. will be subject to applicable anti-kickback, fraud and abuse laws and regulations. Our failure to comply with these laws could expose us to criminal, civil and administrative sanctions, reputational harm, and could harm our results of operations and financial conditions.

Although we have not obtained FDA approval for Durasert three-year uveitis and begun our commercial launch for Durasert three-year uveitis in the United States, our current and future operations with respect to the commercialization of Durasert three-year uveitis will be subject to various U.S. federal and state healthcare laws and regulations. These laws impact, among other things, our proposed sales, marketing, support and education programs and constrain our business and financial arrangements and relationships with third-party payors, healthcare professionals and others who may prescribe, recommend, purchase or provide Durasert three-year uveitis, and other parties through which we market, sell and distribute Durasert three-year uveitis, if approved. Finally, our current and future operations are subject to additional healthcare-related statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our

[Table of Contents](#)

business. The laws are described in greater detail in the section above under “Business – Government Regulation – Healthcare Fraud and Abuse Laws,” and include, but are not limited to:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order, or arranging for or recommending the purchase, lease or order of, any good or service, for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. civil False Claims Act (which can be enforced through “qui tam,” or whistleblower actions, by private citizens on behalf of the federal government), prohibits any person from, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment of government funds or knowingly making, using or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the U.S. federal government;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996, as amended, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for healthcare benefits, items or services by a healthcare benefit program, which includes both government and privately funded benefits programs; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.
- state laws and regulations, including state anti-kickback and false claims laws, that may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payer, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and
- the Physician Payments Sunshine Act, implemented as the Open Payments program, and its implementing regulations, requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children’s Health Insurance Program to report annually to Centers for Medicare & Medicaid Services information related to certain payments made in the preceding calendar year and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance or reporting requirements in multiple jurisdictions increase the possibility that a healthcare or pharmaceutical company may fail to comply fully with one or more of these requirements. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with applicable fraud and abuse or other healthcare laws and regulations or guidance. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, additional oversight and reporting requirements if we become subject to a corporate integrity agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring

[Table of Contents](#)

of our operations. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to the same criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our financial condition and divert resources and the attention of our management from operating our business.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity in addition to the aforementioned potential regulatory actions. The occurrence of any event or penalty described above may inhibit our ability to commercialize Durasert three-year uveitis in the United States, if approved, and generate revenues, which would have a material adverse effect on our business, financial condition and results of operations.

If the market opportunities for our product candidates are smaller than we believe they are, our results of operations may be adversely affected and our business may suffer.

We focus our research and product development primarily on treatments of back-of-the-eye diseases. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on estimates. These estimates may prove to be incorrect and new studies or clinical trials may change the estimated incidence or prevalence of these diseases. The number of patients in the U.S. and elsewhere may turn out to be lower than expected, may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business.

If any of our approved products were to become the subject of problems related to their efficacy, safety, or otherwise, our business would be seriously harmed.

All of our approved products will be subject to continual review by the FDA or other foreign regulatory bodies, and we cannot assure you that newly discovered or developed safety issues will not arise. Although we have seen no issues to date, we cannot rule out that issues may arise in the future. With the use of any newly marketed drug by a wider patient population, serious adverse events may occur from time to time that initially do not appear to relate to the drug itself. Any safety issues could cause us or our collaboration partners to suspend or cease marketing of our approved products, cause us or our collaboration partners to modify how we or they market our approved products, subject us to substantial liabilities, and adversely affect our financial condition and business.

The Affordable Care Act and any changes in healthcare laws may increase the difficulty and cost for us to obtain marketing approval of and commercialize Durasert three-year uveitis in the United States, if approved, and affect the prices we may obtain.

The United States has enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing of Durasert three-year uveitis in the United States, if approved, restrict or regulate post-approval activities and affect our ability to profitably sell Durasert three-year uveitis, if approved. The United States government and state legislatures also have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the Affordable Care Act was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. These intended reforms are described in greater detail in the section above under “Business – Government Regulation – U.S. Healthcare Reform.”

[Table of Contents](#)

Among the provisions of the Affordable Care Act that have been implemented since enactment and are of importance to the commercialization of Durasert three-year uveitis in the United States, if approved, are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs or biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the U.S. civil False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- requirements to report certain financial arrangements with physicians and teaching hospitals;
- a requirement to annually report certain information regarding drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Legislative changes to or regulatory changes under the Affordable Care Act remain possible in the 115th U.S. Congress and under the Trump Administration. The American Health Care Act of 2017, or AHCA, which would repeal and replace key portions of the Affordable Care Act was passed by the U.S. House of Representatives but remains subject to passage by the U.S. Senate. In addition, in January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the Affordable Care Act to waive, defer, grant exemptions from, or delay the implementation of any provision of the Affordable Care Act that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. We expect that the Affordable Care Act, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of Durasert three-year uveitis in the United States, if approved, or to successfully commercialize Durasert three-year uveitis in the United States, if approved.

We expect that the Affordable Care Act, as well as other healthcare reform measures that have and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for Durasert three-year uveitis in the United States, if approved, and could seriously harm our future revenues. Any reduction in reimbursement from Medicare, Medicaid, or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenues, attain profitability or commercialize Durasert three-year uveitis in the United States.

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

We believe that pharmaceutical, drug delivery and biotechnology companies, research organizations, governmental entities, universities, hospitals, other nonprofit organizations and individual scientists are seeking to develop drugs, therapies, products, approaches or methods to treat our targeted diseases or their underlying causes. For our targeted diseases, competitors have alternate therapies that are already commercialized or are in various stages of development, ranging from discovery to advanced clinical trials. Any of these drugs, therapies, products, approaches or methods may receive government approval or gain market acceptance more rapidly than our products and product candidates, may offer therapeutic or cost advantages, or may more effectively treat our targeted diseases or their underlying causes, which could result in our product candidates not being approved, reduce demand for our products and product candidates or render them noncompetitive or obsolete.

Many of our competitors and potential competitors have substantially greater financial, technological, research and development, marketing and personnel resources than we do. Our competitors may succeed in developing alternate technologies and products that, in comparison to the products we have and are seeking to develop:

- are more effective and easier to use;
- are more economical;
- have fewer side effects;
- offer other benefits; or
- may otherwise render our products less competitive or obsolete.

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

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

In both domestic and foreign markets, the commercial success of our products and product candidates will require not only obtaining regulatory approvals, but also obtaining market acceptance by retinal specialists and other doctors, patients, government health administration authorities and other third-party 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 and determinations of government and other third-party payors. In particular, if governments, private insurers, governmental insurers and other third-party payors do not recommend our products and product candidates, limit the indications for which they are recommended, do not provide adequate and timely coverage and reimbursement levels for our products or limit the frequency of administration, the market acceptance of our products and product candidates will be limited. Governments, governmental insurers, private insurers and other third-party payors attempt to contain healthcare costs by limiting coverage and the level of reimbursement for products and, accordingly, they may challenge the price and cost-effectiveness of our products, or refuse to provide coverage for our products. If our products and product candidates fail to achieve and maintain market acceptance, they may fail to generate significant revenues and our business may be significantly harmed.

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

Government agencies, professional societies, practice management groups, private health and science foundations and organizations focused on various diseases may publish guidelines, recommendations or studies

[Table of Contents](#)

that affect our or our competitors' products and product candidates. Any such guidelines, recommendations or studies that reflect negatively on our products or product candidates, either directly or relative to our competitive products, could result in current or potential decreased use, sales of, and revenues from one or more of our products and product candidates. Furthermore, our success depends in part on our and our partners' ability to educate healthcare providers and patients about our products and product candidates, and these education efforts could be rendered ineffective by, among other things, third-parties' guidelines, recommendations or studies.

The micro-insert for ILUVIEN and Durasert three-year uveitis delivers FA, a corticosteroid that is associated with certain adverse side effects in the eye, which may affect the success of this micro-insert for treatment of DME and posterior segment uveitis.

The micro-insert for both ILUVIEN and Durasert three-year uveitis delivers the non-proprietary corticosteroid FA, which is associated with cataract formation and elevated IOP and may increase the risk of glaucoma and related surgery to manage those side effects. These side effects shown in the Phase 3 trials for ILUVIEN resulted in limitations to the approved indications of ILUVIEN, and sales of ILUVIEN may be adversely affected by the potential side effects from FA relative to other treatments for DME. The extent of ILUVIEN's long-term side-effect profile beyond month 36 is not yet known. Alimera is conducting a five-year post-authorization, open label registry study of the safety of ILUVIEN in 800 patients treated with the European labeled indication, which was a condition of European approval. In July 2017, Alimera announced that the Medicines and Healthcare Products Regulatory Agency (MHRA) gave final approval for Alimera to cap total enrollment at 550 patients, with the last three-year patient follow-up visit anticipated in January 2020. Data from this study or other commercial experience could result in the withdrawal of ILUVIEN's marketing approval in one or more jurisdictions. Further, delay in the commercial launch of ILUVIEN could result in the withdrawal of marketing or regulatory authorization for ILUVIEN in jurisdictions where ILUVIEN has already received marketing authorization. In addition, the perception by physicians of this benefit of efficacy versus the side-effect profile could adversely affect sales of ILUVIEN.

Durasert three-year uveitis achieved encouraging safety results through the last follow-up visit in each of its two Phase 3 trials. However, there is no assurance that encouraging safety results will continue in these trials. There is also no assurance that the overall risk-benefit profile for Durasert three-year uveitis will be favorable or that it will be determined to be safe for the treatment of posterior segment uveitis in light of potential side effects from FA. These side effects may limit the population for which marketing authorization is granted or for which reimbursement is provided in one or more jurisdictions and/or adversely affect sales of Durasert three-year uveitis, if approved. In addition, because the micro-insert for ILUVIEN and Durasert three-year uveitis are substantially the same, any safety issues that arise with respect to ILUVIEN could impact Durasert three-year uveitis, which could result in delays in the approval process, prevent the FDA from approving Durasert three-year uveitis and, even if approved, cause us to suspend marketing of Durasert three-year uveitis or subject us to substantial liability, which would adversely affect our financial condition and business.

If the FDA or other applicable regulatory authorities approve generic products with claims that compete with any of our product candidates, it could reduce our sales of those product candidates.

In the United States, after an NDA is approved, the product covered thereby becomes a "listed drug" which can, in turn, be cited by potential competitors in support of approval of an ANDA. The Federal Food, Drug, and Cosmetic Act, or the FD&C Act, FDA regulations and other applicable regulations and policies provide incentives to manufacturers to create modified, non-infringing versions of a drug to facilitate the approval of an ANDA or other application for generic substitutes. These manufacturers might only be required to conduct a relatively inexpensive study to show that their product has the same active ingredients, dosage form, strength, route of administration, and conditions of use, or product labeling, as our product candidate and that the generic product is absorbed in the body at the same rate and to the same extent as, or is bioequivalent to, our product candidate. These generic equivalents would be significantly less costly than ours to bring to market and companies that produce generic equivalents are generally able to offer their products at lower prices. Thus, after the introduction of a generic

competitor, a significant percentage of the sales of any branded product are typically lost to the generic product. Accordingly, competition from generic equivalents to our product candidates would substantially limit our ability to generate revenues and therefore to obtain a return on the investments we have made in our product candidates.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

If we are unable to protect our intellectual property rights or if our intellectual property rights are inadequate to protect our product candidates, our competitors could develop and commercialize technology and products similar to ours, and our competitive position could be harmed.

Our commercial success will depend in large part on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our proprietary technology and products. We rely on trade secret, patent, copyright and trademark laws, and confidentiality and other agreements with employees and third parties, all of which offer only limited protection. We seek patent protection for many different aspects of our product candidates, including their compositions, their methods of use, processes for their manufacture, and any other aspects that we deem to be commercially important to the development of our business.

The patent prosecution process is expensive and time-consuming, and we and any licensors and licensees may not be able to apply for or prosecute patents on certain aspects of our product candidates or delivery technologies at a reasonable cost, in a timely fashion, or at all. For technology licensed to third parties, we may not have the right to control the preparation, filing and/or prosecution of the corresponding patent applications, or to maintain patent rights corresponding to such technology. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. It is also possible that we or any licensors or licensees, will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, such as with respect to proper priority claims, inventorship, claim scope or patent term adjustments. If any licensors or licensees, are not fully cooperative or disagree with us as to the prosecution, maintenance, or enforcement of any patent rights, such patent rights could be compromised and we might not be able to prevent third parties from making, using, and selling competing products. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid or unenforceable. Moreover, our competitors may independently develop equivalent knowledge, methods, and know-how. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business, financial condition, and operating results.

The patent positions of pharmaceutical companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of any patents that issue, are highly uncertain. For example, recent changes to the patent laws of the United States provide additional procedures for third parties to challenge the validity of issued patents. Under the Leahy-Smith America Invents Act (AIA), which was signed into law on September 16, 2011, patents issued from applications with an effective filing date after March 15, 2013 may be challenged by third parties using the post-grant review procedure which allows challenges for a number of reasons, including prior art, sufficiency of disclosure, and subject matter eligibility. Under the AIA, patents may also be challenged under the *inter partes* review procedure. *Inter partes* review provides a mechanism by which any third party may challenge the validity of any issued U.S. Patent in the United States Patent and Trademark Office (USPTO) on the basis of prior art. Because of a lower evidentiary standard necessary to invalidate a patent claim in USPTO proceedings as compared to the evidentiary standard relied on in U.S. federal court, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

[Table of Contents](#)

With respect to foreign jurisdictions, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States or vice versa. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Also, patents granted by the European Patent Office may be opposed by any person within nine months from the publication of their grant.

Our patents and patent applications, even if unchallenged by a third party, may not adequately protect our intellectual property or prevent others from designing around our claims. The steps we have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside the United States. Further, the examination process may require us to narrow the claims of pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. The rights that may be granted under future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. If we are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize technology and products similar or superior to ours, and our ability to successfully commercialize our technology and products may be impaired.

As of August 31, 2017, we had 137 patents and 75 pending patent applications, including patents and pending applications covering our Durasert, Tethadur and other technologies. With respect to these patent rights, we do not know whether any of our patent applications will result in issued patents or, if any of our patent applications do issue, whether such patents will protect our technology in whole or in part, or whether such patents will effectively prevent others from commercializing competitive technologies and products. There is no guarantee that any of our issued or granted patents will not later be found invalid or unenforceable. Furthermore, since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our patents or patent applications. For applications with an effective filing date before March 16, 2013, or patents issuing from such applications, an interference proceeding can be provoked by a third party, or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications and patents. As of March 16, 2013, the United States transitioned to a “first-to-file” system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. The change to “first-to-file” from “first-to-invent” is one of the changes to the patent laws of the United States resulting from the AIA.

Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or in some cases not at all, until they are issued as a patent. Therefore, we cannot be certain that we were the first to make the inventions claimed in our pending patent applications, that we were the first to file for patent protection of such inventions, or that we have found all of the potentially relevant prior art relating to our patents and patent applications that could invalidate one or more of our patents or prevent one or more of our patent applications from issuing. Even if patents do successfully issue and even if such patents cover our product candidates, third parties may initiate oppositions, interferences, re-examinations, post-grant reviews, *inter partes* reviews, nullification or derivation actions in court or before patent offices or similar proceedings challenging the validity, enforceability, or scope of such patents, which may result in the patent claims being narrowed or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates, or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties.

Furthermore, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed,

invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

We may become involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or the patents of any party from whom we may license patents from in the future. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In a patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. A court may decide that a patent of ours or of any of our future licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. In addition, to the extent that we have to file patent litigation in a federal court against a U.S. patent holder, we would be required to initiate the proceeding in the state of incorporation or residency of such entity. With respect to the validity question, for example, we cannot be certain that no invalidating prior art exists. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, found unenforceable, or interpreted narrowly, and it could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more of our products. Such a loss of patent protection could compromise our ability to pursue our business strategy.

As noted above, interference proceedings brought by the USPTO for applications with an effective filing date before March 16, 2013, or for patents issuing from such applications may be necessary to determine the priority of inventions with respect to our patents and patent applications or those of our collaborators or licensors. An unfavorable outcome could require us to cease using the technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if a prevailing party does not offer us a license on terms that are acceptable to us. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distraction of our management and other employees. We may not be able to prevent, alone or with any of our future licensors, misappropriation of our proprietary rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or other foreign patent offices, or become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could invalidate or reduce the scope of, our patent rights, allow third parties to commercialize our technology or drugs and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize drugs without infringing

[Table of Contents](#)

third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop, or commercialize current or future product candidates.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our product candidates throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States may be less extensive than those in the United States. In addition, the laws and practices of some foreign countries do not protect intellectual property rights, especially those relating to life sciences, to the same extent as federal and state laws in the United States. For example, novel formulations of drugs and manufacturing processes may not be patentable in certain jurisdictions, and the requirements for patentability may differ in certain countries, particularly developing countries. Also, some foreign countries, including European Union countries, India, Japan and China, have compulsory licensing laws under which a patent owner may be compelled under certain circumstances to grant licenses to third parties. Consequently, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, and we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions into or within the United States or other jurisdictions. This could limit our potential revenue opportunities. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products, and may export otherwise infringing products to territories where we have patent protection, but where enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing with us in these jurisdictions. Accordingly, our efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from our intellectual property. We may not prevail in any lawsuits that we initiate in these foreign countries and the damages or other remedies awarded, if any, may not be commercially meaningful.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications are required to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after a patent has issued. There are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which could be uncertain and could harm our business.

Our commercial success depends upon our ability to develop, manufacture, market and sell our product candidates, if approved, and use our proprietary technologies without infringing the proprietary rights of third parties. While many of our product candidates are in pre-clinical studies and clinical trials, we believe that the use of our product candidates in these pre-clinical studies and clinical trials falls within the scope of the exemptions provided by 35 U.S.C. Section 271(e) in the United States, which exempts from patent infringement liability activities reasonably related to the development and submission of information to the FDA. As our other product candidates progress toward commercialization, the possibility of a patent infringement claim against us increases. Accordingly, we may invest significant time and expense in the development of our product candidates only to be subject to significant delay and expensive and time-consuming patent litigation before our product

[Table of Contents](#)

candidates may be commercialized. There can be no assurance that our product candidates do not infringe other parties' patents or other proprietary rights, and competitors or other parties may assert that we infringe their proprietary rights in any event.

There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates, including interference or derivation proceedings before the USPTO. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are developing our product candidates. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue commercializing our product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if a license can be obtained on acceptable terms, the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us. If we fail to obtain a required license, we may be unable to effectively market product candidates based on our technology, which could limit our ability to generate revenues or achieve profitability and possibly prevent us from generating revenues sufficient to sustain our operations. Alternatively, we may need to redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. Under certain circumstances, we could be forced, including by court order, to cease commercializing our product candidates. In addition, in any such proceeding or litigation, we could be found liable for substantial monetary damages, potentially including treble damages and attorneys' fees, if we are found to have willfully infringed. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could harm our business. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar negative impact on our business.

The cost to us in defending or initiating any litigation or other proceeding relating to patent or other proprietary rights, even if resolved in our favor, could be substantial, and litigation would divert our management's attention. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our commercialization efforts, delay our research and development efforts and limit our ability to continue our operations. There could also be public announcements of the results of the hearing, motions, or other interim proceedings or developments. If securities analysts or investors perceive those results to be negative, it could cause the price of shares of our common stock to decline.

Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

Our competitors may seek approval to market their own products that are the same as, similar to or otherwise competitive with our product candidates. In these circumstances, we may need to defend or assert our patents by various means, including filing lawsuits alleging patent infringement requiring us to engage in complex, lengthy and costly litigation or other proceedings. In any of these types of proceedings, a court or government agency with jurisdiction may find our patents invalid, unenforceable or not infringed. We may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

Changes in either U.S. or foreign patent law or interpretation of such laws could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involve both

[Table of Contents](#)

technological and legal complexity, and it therefore is costly, time-consuming and inherently uncertain. As noted above, the AIA has significantly changed U.S. patent law. In addition to transitioning from a “first-to-invent” to “first-to-file” system, the AIA also limits where a patentee may file a patent infringement suit and provides opportunities for third parties to challenge issued patents in the USPTO via post-grant review or *inter partes* review, for example. All of our U.S. patents, even those issued before March 16, 2013, may be challenged by a third party seeking to institute *inter partes* review.

Depending on decisions by the U.S. Congress, the federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We may be subject to claims asserting that our employees, consultants, independent contractors and advisors have wrongfully used or disclosed confidential information and/or alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Although we try to ensure that our employees, consultants, independent contractors and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have inadvertently or otherwise used or disclosed confidential information and/or intellectual property, including trade secrets or other proprietary information, of the companies that any such individual currently or formerly worked for or provided services to. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our business.

In addition, while we require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property.

Intellectual property rights do not prevent all potential threats to competitive advantages we may have.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and intellectual property rights may not adequately protect our business or permit us to maintain our competitive advantage.

The following examples are illustrative:

- others may be able to make drug and device components that are the same as or similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or any of our licensors or collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or any of our licensors or collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- the prosecution of our pending patent applications may not result in granted patents;
- granted patents that we own or have licensed may not cover our products or may be held not infringed, invalid or unenforceable, as a result of legal challenges by our competitors;

Table of Contents

- with respect to granted patents that we own or have licensed, especially patents that we either acquire or in-license, if certain information was withheld from or misrepresented to the patent examiner, such patents might be held to be unenforceable;
- patent protection on our product candidates may expire before we are able to develop and commercialize the product, or before we are able to recover our investment in the product;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for such activities, as well as in countries in which we do not have patent rights, and may then use the information learned from such activities to develop competitive products for sale in markets where we intend to market our product candidates;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may have an adverse effect on our business; and
- we may choose not to file a patent application for certain technologies, trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could significantly harm our business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patent protection for certain aspects of our product candidates and technologies, we also consider trade secrets, including confidential and unpatented know-how important to the maintenance of our competitive position. We protect trade secrets and confidential and unpatented know-how, in part, by customarily entering into non-disclosure and confidentiality agreements with parties who have access to such knowledge, such as our employees, outside scientific and commercial collaborators, CROs, CMOs, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants that obligate them to maintain confidentiality and assign their inventions to us. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. In addition, our trade secrets may otherwise become known, including through a potential cybersecurity breach, or may be independently developed by competitors.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts in the United States and certain foreign jurisdictions are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

If our trademarks are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We expect to rely on trademarks as one means to distinguish any of our product candidates that are approved for marketing from the products of our competitors. We have received Notices of Allowance for UVIEY™, YUTIQ™ and DELIVERING INNOVATION TO THE EYE™, and our Durasert™ mark has been published in the United States. Retisert® and Vitrasert® are Bausch & Lomb's trademarks. ILUVIEN® is Alimera's trademark. Our and our licensees' trademarks may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. For instance, Sun Pharma has filed an extension of time to

file an opposition to our trademark application for Durasert. We are currently negotiating a co-existence agreement with Sun Pharma. If we are unable to reach an agreement and our Durasert trademark is successfully challenged, we could be forced to rebrand our Durasert technology, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing a new brand. In addition, we may not be able to protect our or our licensees' rights to these trademarks or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks, we may not be able to compete effectively.

RISKS RELATED TO OUR RELIANCE ON THIRD PARTIES

We do not control the development or commercialization of Durasert three-year uveitis for posterior segment uveitis in the EMEA, which is licensed to Alimera, and as a result we may not realize the full market potential of Durasert three-year uveitis.

Under the Amended Alimera Agreement, we granted Alimera rights to Durasert three-year uveitis in the EMEA (under the ILUVIEN trademark) and subsequently withdrew our Durasert three-year uveitis MAA and orphan drug designation for posterior segment uveitis. Alimera is now responsible for obtaining all regulatory approvals in the EMEA. Under this agreement, we have no control over Alimera's regulatory activities in the EMEA (with the exception of the completion of our ongoing Phase 3 uveitis clinical trials), including regulatory approvals, and no direct control over commercialization efforts for Durasert three-year uveitis in the EMEA. Alimera has only limited experience in filing and supporting the applications necessary to obtain marketing approvals for product candidates. Obtaining approval of an MAA by the EMA is uncertain and Alimera may fail to obtain the approval. The MAA review processes, and the processes of other regulatory authorities, are extensive, lengthy, expensive, and uncertain, and such regulatory authorities may delay, limit, or deny approval of Durasert three-year uveitis for posterior segment uveitis. Further, Alimera may abandon further development of Durasert three-year uveitis in the EMEA. Because the full market potential of Durasert three-year uveitis is contingent upon the successful development and commercialization of Durasert three-year uveitis in the EMEA, we will be dependent on Alimera to achieve the full market potential of Durasert three-year uveitis. If Alimera does not succeed in obtaining regulatory approval of Durasert three-year uveitis in the EMEA for any reason, or does not succeed in securing market acceptance of Durasert three-year uveitis in the EMEA, or elects for any reason to discontinue development of Durasert three-year uveitis, we will be unable to realize the full market potential of Durasert three-year uveitis.

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

We are dependent on CROs, vendors and investigators for pre-clinical testing and clinical trials related to our product development programs. These parties are not our employees, and we cannot control the amount or timing of resources that they devote to our programs. If they do not timely fulfill their responsibilities or if their performance is inadequate, the development and commercialization of our product candidates could be delayed. The parties with which we contract for execution of clinical trials play a significant role in the conduct of the trials and the subsequent collection and analysis of data. Their failure to meet their obligations could adversely affect clinical development of our product candidates. In addition, if we or our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving any marketing applications. Upon inspection, the FDA may determine that our clinical trials did not comply with cGCPs.

Switching or adding additional CROs involves additional cost and requires management time and focus. Identifying, qualifying and managing performance of third-party service providers can be difficult, time-consuming and cause delays in our development programs. In addition, there is a natural transition period when a new CRO commences work and the new CRO may not provide the same type or level of services as the original provider. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse

[Table of Contents](#)

impact on our business, financial condition and prospects. If any of our relationships with our CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines.

Because we have relied on third parties, our internal capacity to perform these functions is limited. Outsourcing these functions involves risks that third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor our third-party providers. To the extent we are unable to identify and successfully manage the performance of third-party service providers in the future, our ability to advance our product candidates through clinical trials will be compromised. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

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

Our business strategy includes continuing to leverage our technology platform by entering into collaborative and licensing arrangements for the development and commercialization of our product candidates, where appropriate. The success of current and future collaborative and licensing arrangements do and will depend heavily on the experience, resources, skill, efforts and activities of our licensees. Our licensees have had, and are expected to have, significant discretion in making decisions related to the development of product candidates and the commercialization of products under these collaboration agreements. Risks that we face in connection with our collaboration and licensing strategy include the following:

- our collaborative and licensing arrangements are, and are expected to be, subject to termination under various circumstances, including on short notice and without cause;
- we are required, and expect to be required, under our collaborative and licensing arrangements, not to conduct specified types of research and development in the field that is the subject of the arrangement or not to sell products in such field, limiting the areas of research, development and commercialization that we can pursue;
- our licensees may develop and commercialize, either alone or with others, products that are similar to or competitive with our products;
- our licensees may change the focus of their development and commercialization efforts or decrease or fail to increase spending related to our products or product candidates, thereby limiting the ability of these products to reach their potential;
- our licensees may lack the funding, personnel or experience to develop and commercialize our products successfully or may otherwise fail to do so; and
- our licensees may not perform their obligations, in whole or in part.

We currently have collaboration and licensing arrangements with various companies, most significantly Alimera and Bausch & Lomb. While Bausch & Lomb has significant experience in the ophthalmic field and substantial resources, there is no assurance whether, and to what extent, that experience and those resources will be devoted to Retisert, and we do not expect revenues from Retisert to increase, and they may decline further. Although we believe potential revenues from ILUVIEN are important to our future results of operations and financial condition, Alimera has limited experience and limited financial resources, and ILUVIEN for DME is currently Alimera's first and only commercial product. Alimera has reported that its negative cash flows from

[Table of Contents](#)

operations and accumulated deficit may raise substantial doubt about its ability to continue as a going concern. Further, due to the limited revenue generated by Alimera to date, Alimera may not be able to maintain compliance with covenants under its loan agreement and, in the event of a default, we do not know whether Alimera will be able to obtain amendments or waivers of those covenants. We do not know if Alimera will be able to raise additional financing if and when required.

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

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

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

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

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

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

We are entitled to royalties on a country-by-country and quarter-by-quarter basis on net sales of ILUVIEN where Alimera markets ILUVIEN directly and to a percentage of product revenues, royalties and non-royalty consideration where Alimera sublicenses the marketing of ILUVIEN. The commercialization of ILUVIEN for DME is a significant undertaking by Alimera, and ILUVIEN for DME is Alimera's first and only commercial product. Alimera's sales of ILUVIEN have not been significant to date, Alimera has continued to incur operating losses, and it has violated and in the future may violate the financial covenants of its loan agreement. We do not know if, when, or to what extent Alimera's ILUVIEN net revenues will increase significantly, which would generate royalties to us from the commercialization of ILUVIEN for DME. The amount and timing of any revenues we receive will be affected by many factors including:

- Alimera's and its distributors' and sublicensees' ability to effectively market and sell ILUVIEN in each country where sold;
- the manner of sale, whether directly by Alimera or by sublicensees or distributors, and the terms of sublicensing and distribution agreements;
- the amount and timing of sales of ILUVIEN in each country;

Table of Contents

- regulatory approvals, appropriate labeling, and desirable pricing, insurance coverage and reimbursement;
- competition;
- commencement of marketing in additional countries; and
- Alimera's ability to raise adequate capital as needed to fund its operations, to maintain compliance with its loan agreement and to achieve profitability from its operations.

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

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

Although Alimera launched ILUVIEN for DME in Germany and the U.K. in the second quarter of 2013 and in the U.S. and Portugal in the first quarter of 2015, Alimera had accumulated a deficit of \$386.6 million through June 30, 2017. Alimera has not generated revenues that cover its actual or anticipated expenses and cannot project the extent of its future losses. Alimera may continue to incur operating losses, and as a result, it is uncertain when or if it will achieve or sustain profitability. Alimera's ability to generate royalty payments to us is dependent on its ability to successfully market and sell ILUVIEN for DME.

Alimera failed to meet a revenue threshold in January 2016 and a liquidity threshold as of June 30, 2016 under the financial covenants of its loan agreement. While these failures were subsequently waived by the lender, Alimera was required to pay substantial amounts and grant concessions in connection with these waivers. In addition, through June 30, 2017, we believe that Alimera's ILUVIEN net sales were not sufficient to allow them to draw down an additional \$5 million under their existing loan facility. Alimera has an at-the-market facility in place for possible sales of its common stock. If Alimera is not successful in raising the capital it requires, and defaults on its obligations under its loan agreement, its lender may call the loan, which could require Alimera to pay back the entire amount owed and pay an early termination fee, or if the lender does not call the loan, Alimera may have to pay an increased rate of interest, pay additional monetary amounts in exchange for a waiver or modification of the loan agreement, or grant additional equity or warrant coverage and agree to further restrictions on its operations that could hinder it in the future. Alimera's failure to comply with the covenants under the loan agreement could create substantial doubt about Alimera's ability to continue as a going concern and to market and sell ILUVIEN. The termination provisions of our agreement with Alimera include various bankruptcy events.

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

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

Prices, coverage and reimbursement to consumers of ILUVIEN for DME, like other drugs, are generally regulated by third-party payors, such as government health administration authorities and plans, private health insurers and other organizations and affect ILUVIEN's sales. The timing and complexity of those reimbursements also affect sales. Prices in the EU are generally lower and coverage and access to drugs more limited than in the U.S. For example, in the U.K. and Scotland, National Health Service coverage is limited to the

[Table of Contents](#)

treatment of the eyes of chronic DME patients unresponsive to existing therapies that have undergone cataract surgery, subject to simple patient access schemes. Alimera may not achieve satisfactory agreements with statutory or other insurers. We do not know what levels of pricing will be approved or reimbursed for ILUVIEN, or what restrictions will be placed on its use or reuse in countries where ILUVIEN is not currently sold. In the U.S., Alimera has offered extended customer payment terms. Future net sales of ILUVIEN and, accordingly, the amount of royalties that we may receive from such net sales, may be adversely affected by pricing and reimbursement decisions, and such effects may be material.

RISKS RELATED TO OUR BUSINESS, INDUSTRY, STRATEGY AND OPERATIONS

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

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

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

Implementation of our development and commercialization strategies will require additional managerial, operational, sales, marketing, financial and other resources. Our current management, personnel and systems may not be adequate to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, employee turnover and reduced productivity. Future growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our existing or future product candidates. Future growth would impose significant added responsibilities on members of management, including:

- managing the commercialization of any approved product candidates;
- overseeing our pre-clinical studies and clinical trials effectively;
- identifying, recruiting, maintaining, motivating and integrating additional employees, including any sales and marketing personnel engaged in connection with the commercialization of any approved product;
- engaging and managing our relationship with any contract sales organizations; and
- managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties; and improving our managerial, development, operational and financial systems and procedures.

As our operations expand, we will need to manage additional relationships with various strategic collaborators, suppliers and other third parties. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and sales and marketing personnel. Failure to accomplish any of these activities could prevent us from successfully growing our company.

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

The testing, manufacturing, marketing and sale of the products utilizing our technologies involve risks that product liability claims may be asserted against us and/or our licensees. Our current clinical trial and product

[Table of Contents](#)

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

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

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

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

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

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

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

There are a limited number of manufacturers that operate under cGMP and other foreign regulations that are both capable of manufacturing our products and product candidates and are willing to do so. Alimera has contracted with individual third-party manufacturers for the manufacture of ILUVIEN and its components. If any of Alimera's third-party manufacturers breach their agreements or are unable or unwilling to perform for any reason or fail to comply with cGMP and comparable foreign requirements, Alimera may not be able to locate alternative acceptable manufacturers, enter into favorable agreements with them or get them approved by the applicable regulatory authorities in a timely manner. Delays in the commercial production of ILUVIEN could

[Table of Contents](#)

delay or impair Alimera's marketing of ILUVIEN, which, in turn, could adversely affect Alimera's generation of sales-based royalties to us. Failure by us, our collaborative partners, or our or their third-party manufacturers, to comply with applicable manufacturing requirements could result in sanctions being imposed on us or our collaborative partners, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product, operating restrictions and criminal prosecutions. 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 of our product candidates and our collaborative partners may not be able to conduct certain future pre-clinical and clinical testing or to supply commercial quantities of our products. We manufacture supplies in connection with pre-clinical or clinical studies conducted by us and our licensees. Our licensees have the exclusive rights to manufacture commercial quantities of products, once approved for marketing. Our licensees' reliance on third-party manufacturers entails risks, including:

- failure of third parties to comply with cGMP and other applicable U.S. and foreign regulations and to employ adequate quality assurance practices;
- inability to obtain the materials necessary to produce a product or to formulate the active pharmaceutical ingredient on commercially reasonable terms, if at all;
- supply disruption, deterioration in product quality or breach of a manufacturing or license agreement by the third party because of factors beyond our or our licensees' control;
- termination or non-renewal of a manufacturing or licensing agreement with a third party at a time that is costly or difficult; and
- inability to identify or qualify an alternative manufacturer in a timely manner, even if contractually permitted to do so.

We intend to use our own facility for the manufacturing of Durasert three-year uveitis, which will require significant resources, which could adversely affect its commercial viability.

If approved by the FDA, we plan to manufacture commercial supplies of Durasert three-year uveitis ourselves at our Watertown facility. We currently manufacture products only for clinical and testing purposes in this facility and we do not manufacture products for commercial use. We must obtain FDA approval of our manufacturing process before we can commercially manufacture Durasert three-year uveitis in the United States. In addition, we must pass a pre-approval inspection of our manufacturing facility before we can obtain marketing approval for Durasert three-year uveitis. In order to obtain approval, all of our manufacturing methods, equipment and processes must comply with the FDA's cGMP requirements. We will also need to perform extensive audits of our suppliers, vendors and contract laboratories. The cGMP requirements govern all areas of recordkeeping, production processes and controls, personnel and quality control. To ensure that we meet these requirements, we will expend significant time, money and effort. Due to the unique nature of our Durasert technology platform, we cannot predict the likelihood that the FDA will approve our facility as compliant with cGMP requirements even if we believe that we have taken the steps necessary to achieve compliance.

The FDA, in its regulatory discretion, may require us to undergo additional clinical trials with respect to any new or improved manufacturing process we develop or utilize, in the future, if any. This could delay or prevent approval of Durasert three-year uveitis or any of our other product candidates. If we fail to comply with cGMP requirements, pass an FDA pre-approval inspection or obtain FDA approval of our manufacturing process, we would not receive FDA approval and would be subject to possible regulatory action, including recall or withdrawal of the product from the market or suspension of manufacturing. The failure to successfully implement our manufacturing process may delay or prevent our ability to commercialize Durasert three-year uveitis.

If we do obtain FDA approval for Durasert three-year uveitis, including satisfying the FDA with regard to a validated manufacturing process, we may still be unable to commercially manufacture Durasert three-year

[Table of Contents](#)

uveitis. The commercial manufacture of medical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of medical products often encounter difficulties in production, particularly in scaling out and validating initial production and ensuring the absence of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. We cannot assure you that any stability or other issues relating to the manufacture of Duraser three-year uveitis, if approved, will not occur in the future.

The FDA also may, at any time following approval of a product for sale, audit our manufacturing facilities. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulation occurs independent of such an inspection or audit, we or the FDA may require remedial measures that may be costly and/or time consuming for us to implement and that may include the temporary or permanent suspension of commercial sales, recalls, market withdrawals, seizures or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us could materially harm our business.

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

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

Given the lack of comparable precedent, it is unclear what financial, trade and legal implications the withdrawal of the U.K. from the EU may have and how such withdrawal may affect us. The announcement of Brexit and the withdrawal of the U.K. from the EU may create economic uncertainty, which may reduce sales of our licensed products. A U.K. withdrawal from the EU may, among other things, increase regulatory complexities, disrupt the free movement of goods, services and people between the U.K. and the EU, undermine bilateral cooperation in key policy areas and significantly disrupt trade between the U.K. and the EU. In addition, Brexit could lead to legal uncertainty and potentially divergent national laws and regulations in Europe, as the U.K. determines which EU laws to replace or replicate. It raises uncertainty, for example, as to the regulatory path for marketing approval of ILUVIEN for posterior uveitis in the U.K.

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

Our employees, collaborators, service providers, independent contractors, principal investigators, consultants, CSOs, vendors and CROs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, collaborators, independent contractors, principal investigators, consultants, CSOs, vendors and CROs may engage in fraudulent or other illegal activity with respect to our business. Misconduct by these employees could include intentional, reckless and/or negligent conduct or unauthorized activity that violates:

- FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA;

[Table of Contents](#)

- manufacturing standards;
- federal and state healthcare fraud and abuse laws and regulations; or
- laws that require the true, complete and accurate reporting of financial information or data.

In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve individually identifiable information, including, without limitation, the improper use of information obtained in the course of clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and serious harm to our reputation. Any incidents or any other conduct that leads to an employee receiving an FDA debarment could result in a loss of business from third parties and severe reputational harm.

Although we have adopted a Code of Conduct to govern and deter such behaviors, it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations.

The security of our information technology systems may be compromised, and confidential information, including non-public personal information that we maintain, could be improperly disclosed.

Our information technology systems may be vulnerable to physical or electronic intrusions, computer viruses or other attacks. As part of our business, we and our vendors maintain large amounts of confidential information, including non-public personal information on patients and our employees. Breaches in security could result in the loss or misuse of this information, which could, in turn, result in potential regulatory actions or litigation, including material claims for damages, interruption to our operations, damage to our reputation or otherwise have a material adverse effect on our business, financial condition and operating results. We expect to have appropriate information security policies and systems in place in order to prevent unauthorized use or disclosure of confidential information, including non-public personal information, there can be no assurance that such use or disclosure will not occur.

If we fail to comply with data protection laws and regulations, we could be subject to government enforcement actions, which could include civil or criminal penalties, as well as private litigation and/or adverse publicity, any of which could negatively affect our operating results and business.

We may be subject to laws and regulations that address privacy and data security of patients who use our product candidates in the United States and in states in which we conduct our business. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act) govern the collection, use, disclosure, and protection of health-related and other personal information. For instance, HIPAA imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information and imposes notification obligations in the event of a breach of the privacy or security of individually identifiable health information on entities subject to HIPAA and their business associates that perform certain activities that

[Table of Contents](#)

involve the use or disclosure of protected health information on their behalf. Certain of these laws and regulations are described in greater detail in the section above under “Business – Government Regulation – Healthcare Privacy Laws.” Failure to comply with applicable data protection laws and regulations could result in government enforcement actions and create liability for us, which could include civil and/or criminal penalties, as well as private litigation and/or adverse publicity that could negatively affect our operating results and business.

Our business and operations would suffer in the event of computer system failures, cyberattacks or a deficiency in our cybersecurity.

Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures, cyberattacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. Such an event could cause interruption of our operations. For example, the loss of data from completed or ongoing clinical trials for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data, or inappropriate disclosure of confidential or proprietary information, we could incur material legal claims and liability and damage to our reputation and the development and commercialization of our product candidates could be delayed.

We may be exposed to liabilities under the U.S. Foreign Corrupt Practices Act and other U.S. and foreign anti-corruption anti-money laundering, export control, sanctions, and other trade laws and regulations, and any determination that we violated these laws could have a material adverse effect on our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department’s Office of Foreign Assets Control. We are also subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, the United Kingdom Bribery Act 2010, the Proceeds of Crime Act 2002, and possibly other anti-bribery and anti-money laundering laws in countries outside of the United States in which we conduct our activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees and third-party intermediaries from authorizing, promising, offering, providing, soliciting, or accepting, directly or indirectly, improper payments or benefits to or from any person whether in the public or private sector. As we commercialize Durasert three-year uveitis and any of other product candidates that we may develop, we may engage with third-party manufacturers and collaborators who operate abroad and are required to obtain certain necessary permits, licenses and other regulatory approvals with respect to our business. Our activities abroad create the risk of unauthorized payments or offers of payments by employees, consultants, sales agents or distributors, even though they may not always be subject to our control. It is our policy to implement safeguards to discourage these practices by our employees, consultants, sales agents and distributors. However, our existing safeguards and any future improvements may prove to be less than effective, and the employees, consultants, sales agents, or distributors of our company may engage in conduct for which we might be held responsible, even if we do not explicitly authorize such activities.

Noncompliance with anti-corruption, anti-money laundering, export control, sanctions, and other trade laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension and/or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage and other collateral consequences. If any subpoenas or investigations

[Table of Contents](#)

are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. Responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense and compliance costs and other professional fees. In addition, the U.S. government may seek to hold us liable for successor liability FCPA violations committed by companies in which we invest or that we acquire. As a general matter, enforcement actions and sanctions could harm our business, results of operations, and financial condition.

RISKS RELATED TO OWNERSHIP OF OUR COMMON STOCK

The trading price of the shares of our common stock has been highly volatile, and purchasers of our common stock could incur substantial losses.

The price of our common stock (including common stock represented by CHESS Depositary Interests ("CDIs")) is highly volatile and may be affected by developments directly affecting our business, as well as by developments out of our control or not specific to us. The pharmaceutical and biotechnology industries, in particular, and the stock market generally, are vulnerable to abrupt changes in investor sentiment. Prices of securities and trading volumes of companies in the pharmaceutical and biotechnology industries, including ours, can swing dramatically in ways unrelated to, or that bear a disproportionate relationship to, our performance. The price of our common stock (and CDIs) and their trading volumes may fluctuate based on a number of factors including, but not limited to:

- clinical trials and their results, and other product and technological developments and innovations;
- FDA and other domestic and international governmental regulatory actions, receipt and timing of approvals of our product candidates, and any denials and withdrawal of approvals;
- competitive factors, including the commercialization of new products in our markets by our competitors;
- advancements with respect to treatment of the diseases targeted by our product candidates;
- developments relating to, and actions by, our collaborative partners, including execution, amendment and termination of agreements, achievement of milestones and receipt of payments;
- the success of our collaborative partners in marketing any approved products and the amount and timing of payments to us;
- availability and cost of capital and our financial and operating results;
- actions with respect to pricing, reimbursement and coverage, and changes in reimbursement policies or other practices relating to our products or the pharmaceutical or biotechnology industries 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 pharmaceutical and biotechnology industries.

In addition, low trading volume in our common stock or our CDIs may increase their price volatility. Holders of our common stock and CDIs may not be able to liquidate their positions at the desired time or price. Finally, we will need to continue to meet the listing requirements of NASDAQ, including the minimum stock price, and ASX, for our stock and CDIs to continue to be traded on those exchanges, respectively.

[Table of Contents](#)

Additional shares that may be issued upon the exercise of currently outstanding options or upon the settlement of restricted or performance stock units would dilute the voting power of our currently outstanding common stock and could cause our stock price to decline.

As of August 31, 2017, we had outstanding options to acquire approximately 6.9 million shares of our common stock, outstanding restricted stock units to acquire 948,500 shares of our common stock and outstanding performance stock units to acquire 210,000 shares of our common stock, or approximately 17.0% of our shares on a fully diluted basis. The issuance of shares of our common stock upon exercise of the stock options or settlement of the restricted or performance stock units could result in dilution to the interests of other holders of our common stock and could adversely affect our stock price.

Future sales of our common stock may depress our stock price.

The market price of our common stock could decline as a result of sales of substantial amounts of our common stock in the public market, or as a result of the perception that these sales could occur, which could occur if we issue a large number of shares of common stock (or securities convertible into our common stock) in connection with a future financing, as our common stock is trading at low levels. These factors could make it more difficult for us to raise funds through future offerings of common stock or other equity securities.

Provisions in our charter documents could prevent or delay stockholders' attempts takeover our company.

Our board of directors is authorized to issue "blank check" preferred stock, with designations, rights and preferences as they may determine. Accordingly, our board of directors may in the future, without stockholder approval, issue shares of preferred stock with dividend, liquidation, conversion, voting or other rights that could adversely affect the voting power or other rights of the holders of our common stock. This type of preferred stock could also be issued to discourage, delay or prevent a change in our control. The ability to issue "blank check" preferred stock is a traditional anti-takeover measure. This provision in our charter documents makes it difficult for a majority stockholder to gain control of our company. Provisions like this may be beneficial to our management and our board of directors in a hostile tender offer and may have an adverse impact on stockholders who may want to participate in such a tender offer.

Provisions in our bylaws provide for indemnification of officers and directors, which could require us to direct funds away from our business and the development of our product candidates.

Our bylaws provide for the indemnification of our officers and directors. We may in the future be required to advance costs incurred by an officer or director and to pay judgments, fines and expenses incurred by an officer or director, including reasonable attorneys' fees, as a result of actions or proceedings in which our officers and directors are involved by reason of being or having been an officer or director of our company. Funds paid in satisfaction of judgments, fines and expenses may be funds we need for the operation of our business and the development of our product candidates, thereby affecting our ability to attain profitability.

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.

We have never declared or paid cash dividends on our capital stock, and you should not rely on an investment in our common stock to provide dividend income. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

We may be subject to securities litigation, which is expensive and could divert our management's attention.

As we operate in the pharmaceutical and biotechnology industries, we may be especially vulnerable to volatility in the market price of our common stock, especially to the extent that various factors affect the

[Table of Contents](#)

common stock of companies in our industry. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business, and could also require us to make substantial payments to satisfy judgments or to settle litigation.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We do not own any real property. We lease 1,750 square feet of laboratory space, 1,000 square feet of clean room space and 10,900 square feet of office space in Watertown, Massachusetts under a lease agreement that expires in April 2019, with a 5-year renewal option at market rates. We lease 3,000 square feet of office space in Liberty Corner, New Jersey under a lease agreement that expires in June 2022. Our lease of 1,250 square feet of laboratory space and 1,665 square feet of office space in Malvern, U.K. expired in August 2016, but was extended through November 2016 to facilitate closure of the research facility. A new lease of approximately 420 square feet in Malvern, U.K. commenced December 2016 for a 3-year term, subject to termination by the Company upon 30 days advance written notice. We believe our leased facilities are adequate for our present and anticipated needs.

ITEM 3. LEGAL PROCEEDINGS

In December 2014, we exercised our right under the Alimera Agreement to conduct an audit by an independent accounting firm of Alimera's commercialization reporting for ILUVIEN for calendar 2014. In April 2016, the independent accounting firm issued its report, which concluded that Alimera under-reported net profits payable to the Company for 2014 by \$136,000. In June 2016, Alimera remitted \$354,000 to the Company, which consisted of the under-reported net profits plus interest and reimbursement of the audit costs of \$204,000. In July 2016, Alimera filed a demand for arbitration with the American Arbitration Association in Boston, Massachusetts to dispute the audit findings and requested a full refund of the \$354,000 previously paid to us. Pending the arbitration outcome, \$136,000 of net profits participation had been recorded as deferred revenue and the remaining \$218,000 as accrued expenses at each of March 31, 2017 and June 30, 2016.

On May 3, 2017, we reached a settlement of the arbitration, which was dismissed with prejudice. As a result of the settlement, the \$136,000 of net profits became fixed and determinable, while the gain contingency resulting from reimbursement of the audit costs of \$204,000 became resolved. Accordingly, these transactions were recognized in the fourth quarter of fiscal 2017.

We are subject to various routine legal proceedings and claims incidental to our business, which management believes will not have a material effect on our financial position, results of operations or cash flows.

[Table of Contents](#)

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market Information, Holders and Dividends

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

	<u>High</u>	<u>Low</u>
Fiscal year ended June 30, 2017:		
First Quarter	\$4.25	\$2.85
Second Quarter	3.22	1.50
Third Quarter	2.16	1.63
Fourth Quarter	2.45	1.57
Fiscal year ended June 30, 2016:		
First Quarter	\$4.52	\$3.23
Second Quarter	5.81	3.46
Third Quarter	4.82	2.37
Fourth Quarter	3.87	2.64

On September 7, 2017, the last reported sale price of our common stock on the NASDAQ Global Market was \$1.30. As of that date, we had approximately 15 holders of record of our common stock and, according to our estimates, approximately 5,100 beneficial owners of our common stock. In addition, as of that date, there were approximately 1,933 beneficial owners of our CDIs.

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

Equity Compensation Plan Information

The following table provides information about the securities authorized for issuance under the Company’s equity compensation plans as of June 30, 2017:

<u>Plan category</u>	<u>Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)</u>	<u>Weighted-average exercise price of outstanding options, warrants and rights (b)</u>	<u>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in Column a) (c)</u>
Equity Compensation plans approved by security holders	6,895,685	\$ 3.38	2,962,947
Equity Compensation plans not approved by security holders	—	—	—
Total	6,895,685	\$ 3.38	2,962,947

[Table of Contents](#)**Recent Sales of Unregistered Securities**

None.

Issuer Repurchases of Equity Securities

None.

ITEM 6. SELECTED FINANCIAL DATA

The selected historical financial data set forth below as of June 30, 2017, 2016, 2015, 2014 and 2013 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, 2017 and 2016 and for the years ended June 30, 2017, 2016 and 2015 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,				
	2017	2016	2015	2014	2013
(In thousands except per share data)					
Consolidated Statements of Operations Data:					
Revenues:					
Collaborative research and development (1)	\$ 6,569	\$ 398	\$25,411	\$ 2,155	\$ 780
Royalty income	970	1,222	1,154	1,318	1,363
Total revenues	<u>7,539</u>	<u>1,620</u>	<u>26,565</u>	<u>3,473</u>	<u>2,143</u>
Operating expenses:					
Research and development	14,880	14,381	12,088	9,573	7,005
General and administrative	11,235	9,013	8,056	7,468	7,169
Gain on sale of property and equipment	—	—	—	(78)	—
Total operating expenses	<u>26,115</u>	<u>23,394</u>	<u>20,144</u>	<u>16,963</u>	<u>14,174</u>
Operating (loss) income	<u>(18,576)</u>	<u>(21,774)</u>	<u>6,421</u>	<u>(13,490)</u>	<u>(12,031)</u>
Interest and other income, net	91	72	22	5	14
(Loss) income before income taxes	<u>(18,485)</u>	<u>(21,702)</u>	<u>6,443</u>	<u>(13,485)</u>	<u>(12,017)</u>
Income tax benefit (expense)	—	155	(96)	130	117
Net (loss) income	<u><u>\$(18,485)</u></u>	<u><u>\$(21,547)</u></u>	<u><u>\$ 6,347</u></u>	<u><u>\$(13,355)</u></u>	<u><u>\$(11,900)</u></u>
Net (loss) income per share:					
Basic	<u><u>\$ (0.52)</u></u>	<u><u>\$ (0.68)</u></u>	<u><u>\$ 0.22</u></u>	<u><u>\$ (0.49)</u></u>	<u><u>\$ (0.52)</u></u>
Diluted	<u><u>\$ (0.52)</u></u>	<u><u>\$ (0.68)</u></u>	<u><u>\$ 0.21</u></u>	<u><u>\$ (0.49)</u></u>	<u><u>\$ (0.52)</u></u>
Weighted average common shares outstanding:					
Basic	<u>35,344</u>	<u>31,623</u>	<u>29,378</u>	<u>27,444</u>	<u>23,044</u>
Diluted	<u>35,344</u>	<u>31,623</u>	<u>30,584</u>	<u>27,444</u>	<u>23,044</u>

[Table of Contents](#)

	As of June 30,				
	2017	2016	2015	2014	2013
	(In thousands)				
Consolidated Balance Sheet Data:					
Cash and cash equivalents	\$16,898	\$15,313	\$19,121	\$15,334	\$ 6,899
Marketable securities	—	13,679	9,414	2,944	3,374
Total assets	18,677	31,619	32,367	22,671	16,249
Total deferred revenue—current and long-term	50	5,732	5,629	5,722	5,984
Total stockholders' equity	13,336	20,881	23,368	14,924	7,700

- (1) Includes the following: from our collaboration agreement with Alimera: \$659,000 in fiscal 2017, \$233,000 in fiscal 2016, \$25.1 million in fiscal 2015, \$114,000 in fiscal 2014 and \$67,000 in fiscal 2013; from our Restated Pfizer Agreement: \$5.6 million in fiscal 2017 and \$368,000 in fiscal 2013; from feasibility study agreements: \$211,000 in fiscal 2017, \$33,000 in fiscal 2016, \$144,000 in fiscal 2015, \$1.9 million in fiscal 2014 and \$245,000 in fiscal 2013; from our license agreement with Enigma Therapeutics: \$100,000 in fiscal 2017, \$100,000 in fiscal 2016, \$100,000 in fiscal 2015, \$102,000 in fiscal 2014 and \$100,000 in fiscal 2013. See Note 3 to the accompanying consolidated financial statements for additional information.

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

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

Overview

We develop sustained-release drug delivery products that deliver drugs at a controlled and steady rate for months or years. We have developed three of the four sustained-release ophthalmic products currently approved by the U.S. FDA for treatment of back-of-the-eye diseases. Our product development programs are focused primarily on utilizing our core Durasert technology platform to deliver drugs to treat chronic diseases. Durasert three-year uveitis is our most advanced development-stage product, and is designed to treat chronic non-infectious uveitis affecting the posterior segment of the eye (posterior segment uveitis) for a period of three years. Durasert three-year uveitis met its primary efficacy endpoint of prevention of recurrence of uveitis through six months with a p value of < 0.001 in two ongoing pivotal Phase 3 clinical trials. We anticipate filing an NDA with the FDA in late December 2017 or early January 2018. In July 2017, we amended our collaboration agreement (the "Prior Alimera Agreement") with Alimera to, among other things, license distribution, regulatory and reimbursement matters for Durasert three-year uveitis (under the ILUVIEN trademark) for the EMEA to Alimera. Pursuant to the Prior Alimera Agreement, our lead licensed product, ILUVIEN® for DME, is sold by Alimera in the U.S. and multiple EU countries. Our strategy includes developing non-proprietary drugs independently in combination with our Durasert technology platform, while continuing to leverage our technology platform through collaborations and license agreements as appropriate.

Injected into the eye in an office visit, Durasert three-year uveitis is a micro-insert that delivers a micro-dose of a corticosteroid to the back of the eye on a sustained basis for approximately three years after a single administration. In Europe, we filed a marketing authorization application ("MAA") in June 2017 and subsequently withdrew the application after out-licensing the European rights for Durasert to Alimera. Alimera plans to submit the Durasert three-year uveitis data under its existing ILUVIEN MAA and, if approved, to commercialize the uveitis indication under the ILUVIEN trademark.

We are developing Durasert three-year uveitis independently and we plan to file an NDA with the FDA by the end of calendar year 2017. Both of our Durasert three-year uveitis Phase 3 clinical trials met their primary efficacy endpoint of prevention of recurrence of uveitis through six months with statistical significance ($p < 0.001$; intent to treat analysis) and yielded safety profiles consistent with the known effects of ocular corticosteroid use. Similar efficacy and safety results have been observed through 12 months of follow-up in the first pivotal trial and twelve month data from the second pivotal trial is expected in early calendar year 2018. Pending NDA submission and approval by the FDA, we plan to independently commercialize Durasert three-year uveitis in the U.S. given the relatively modest market size and correspondingly limited commercial footprint required to launch on our own.

ILUVIEN, an injectable, sustained-release micro-insert delivering 0.19mg of FA to the back of the eye for the treatment of DME, was licensed to and developed with Alimera under the Prior Alimera Agreement. In July 2017, we entered into an amended and restated collaboration agreement with Alimera (the "Amended Alimera Agreement") pursuant to which we (i) licensed the rights to our three-year uveitis indication to Alimera for the EMEA and (ii) converted our license consideration from a share of Alimera's net profits for ILUVIEN to a royalty based on Alimera's net sales for ILUVIEN for DME and, upon an MAA approval, for net sales of ILUVIEN for posterior segment uveitis. Sales-based royalties start at the rate of 2% effective as of July 1, 2017. Commencing January 1, 2019 (or earlier under certain circumstances), the sales-based royalty

[Table of Contents](#)

will increase to 6% (8% on total ILUVIEN net sales in excess of \$75 million on a calendar year basis). Alimera's share of contingently recoverable accumulated ILUVIEN commercialization losses under the original net profit share arrangement (as set forth in the Prior Alimera Agreement), was capped at \$25 million. Under the Amended Alimera Agreement those recoverable losses will be reduced as follows: (i) \$10.0 million was cancelled in lieu of an upfront license fee on the effective date of the Amended Alimera Agreement; (ii) for calendar years 2019 and 2020, 50% of earned sales-based royalties in excess of 2% of net sales will be offset against the quarterly royalty payments otherwise due from Alimera; (iii) on January 1, 2020 (or earlier under certain circumstances), another \$5 million will be cancelled, provided, however, that such date of cancellation may be extended under certain circumstances related to Alimera's regulatory approval process for ILUVIEN for posterior segment uveitis, with such extension, if any, subject to mutual agreement by the parties; and (iv) commencing in calendar year 2021, 20% of earned sales-based royalties in excess of 2% of net sales will be offset against the quarterly royalty payments due from Alimera until such time as the remaining balance of the original \$25 million of recoverable commercialization losses has been fully recouped.

We believe that the terms of the Amended Alimera Agreement for ILUVIEN for DME have standardized and simplified the agreement, and improved the potential total value of the agreement for us. ILUVIEN for DME has been sold by Alimera in the U.S. since 2015, where it is indicated for the treatment of DME in patients previously treated with a course of corticosteroids without a clinically significant rise in intraocular pressure ("IOP"). ILUVIEN for DME has been sold by Alimera in the U.K. and Germany since 2013, in Portugal since 2015 and in Italy, Spain and certain Middle East countries (through sublicense partners) since the second quarter of calendar year 2017. ILUVIEN has marketing approvals in a total of 17 European countries, where it is indicated for the treatment of chronic DME considered insufficiently responsive to available therapies.

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

We are also using our Durasert technology platform to identify potential product candidates that provide sustained treatment of wet and dry age-related macular degeneration ("AMD"), glaucoma, osteoarthritis and other diseases. In collaboration with Hospital for Special Surgery ("HSS"), we are developing a sustained-release surgical implant to treat pain associated with severe knee OA. This product is currently being evaluated in an investigator-sponsored pilot clinical study that is expected to provide initial results in late calendar year 2017. We are also conducting nonclinical evaluations of various tyrosine kinase inhibitor ("TKI") candidates for wet AMD. Finally, we are developing a next-generation Durasert shorter-acting version, initially for the treatment of posterior segment uveitis.

Summary of Critical Accounting Policies and Estimates

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

While our significant accounting policies are more fully described in Note 2 to the accompanying consolidated financial statements, we believe that the following accounting policies are critical to understanding

[Table of Contents](#)

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

Revenue arrangements with multiple deliverables are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the collaborative partner and based on the selling price of the deliverables. When deliverables are separable, consideration received is allocated to the separate units of accounting based on the relative selling price method using management's best estimate of the standalone selling price of deliverables when vendor-specific objective evidence or third-party evidence of selling price is not available. Allocated consideration is recognized as revenue upon application of the appropriate revenue recognition principles to each unit.

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

For the years ended June 30, 2017 and 2016, we reported \$6.6 million and \$398,000, respectively, of collaborative research and development revenue. Of the total for fiscal 2017, \$5.6 million represented non-cash revenue recognized upon the termination of our Restated Pfizer Agreement (see Note 3 of Notes to Consolidated Financial Statements for more information). 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.

Recognition of Expense in Outsourced Clinical Trial Agreements

We recognize research and development expense with respect to outsourced agreements for clinical trials with contract research organizations ("CROs") as the services are provided, based on our assessment of the services performed. We make our assessments of the services performed based on various factors, including evaluation by the third-party CROs and our own internal review of the work performed during the period, measurements of progress by us or by the third-party CROs, data analysis with respect to work completed and our management's judgment. We have agreements with two CROs to conduct the Phase 3 clinical trial program for Durasert three-year uveitis. Our financial obligations under the agreements are determined by the services that we request from time to time under the agreements. The actual amounts owed under the agreements and the timing of those obligations will depend on various factors, including changes to the protocols and/or services requested, the number of patients to be enrolled and the rate of patient enrollment, achievement of pre-defined direct cost milestone events and other factors relating to the clinical trials. As of June 30, 2017, our CRO agreements provided for two Phase 3 clinical trials and a utilization and safety study of two different inserters at an aggregate remaining cost of approximately \$8.9 million, which includes several pending contract change orders. We can terminate the agreements at any time without penalty, and if terminated, we would be liable only for services through the termination date plus non-cancellable CRO obligations to third parties.

During fiscal 2017, we recognized approximately \$6.2 million of research and development expense attributable to our Durasert three-year uveitis Phase 3 clinical trial program. Changes in our estimates or differences between the actual level of services performed and our estimates may result in changes to our research and development expenses in future periods.

[Table of Contents](#)**Results of Operations***Years Ended June 30, 2017 and 2016*

	<u>Year Ended June 30,</u>		<u>Change</u>	
	<u>2017</u>	<u>2016</u>	<u>Amounts</u>	<u>%</u>
	(In thousands except percentages)			
Revenues:				
Collaborative research and development	\$ 6,569	\$ 398	\$ 6,171	1,551%
Royalty income	970	1,222	(252)	(21)%
Total revenues	<u>7,539</u>	<u>1,620</u>	<u>5,919</u>	<u>365%</u>
Operating expenses:				
Research and development	14,880	14,381	499	3%
General and administrative	11,235	9,013	2,222	25%
Total operating expenses	<u>26,115</u>	<u>23,394</u>	<u>2,721</u>	<u>12%</u>
Operating loss	(18,576)	(21,774)	3,198	15%
Interest and other income, net	91	72	19	26%
Loss before income taxes	(18,485)	(21,702)	3,217	15%
Income tax benefit	—	155	(155)	(100)%
Net loss	<u><u>\$ (18,485)</u></u>	<u><u>\$ (21,547)</u></u>	<u><u>\$ 3,062</u></u>	<u><u>14%</u></u>

Revenues

Collaborative research and development revenue totaled \$6.6 million in fiscal 2017, an increase of \$6.2 million, or 1,551%, compared to \$398,000 in fiscal 2016. This increase was attributable primarily to \$5.6 million of revenue recognized upon the termination of the Restated Pfizer Agreement in December 2016. In addition, revenues derived from our collaboration agreement with Alimera increased by \$426,000, which included \$136,000 of revenue recognized from a May 2017 arbitration settlement of Alimera's calendar year 2014 reporting of ILUVIEN net profits.

In July 2017, we restructured the Alimera collaboration agreement to (a) license Durasert three-year uveitis in the EMEA to Alimera and (b) to convert the net profit share arrangement to a sales-based royalty for all ILUVIEN licensed indications. We expect this conversion to result in increased revenues from Alimera over time, as well as better predictability and consistency of revenues to be recognized from Alimera. Based on 60-day payment terms from Alimera following the end of each calendar quarter, we expect that sales-based royalties earned from Alimera will be recognized as revenues one quarter in arrears. See Notes 3 and 14 of Notes to Consolidated Financial Statements for more information related to the Alimera collaboration agreement and to the settlement of a dispute relating to the computation of ILUVIEN net profits for calendar year 2014, respectively.

Retisert royalty income decreased by \$252,000, or 21%, to \$970,000 in fiscal 2017 compared to \$1.22 million in fiscal 2016. We expect Retisert royalty income to remain flat or decline somewhat in the next fiscal year.

Research and Development

Research and development expenses totaled \$14.9 million in fiscal 2017, an increase of \$499,000, or 3%, compared to \$14.4 million in fiscal 2016. This increase was attributable primarily to (i) a \$1.4 million increase of professional services related primarily to our Durasert three-year uveitis Phase 3 clinical development program and completed MAA filing and planned NDA filing, (ii) an \$879,000 increase in U.S. personnel and related costs, including incentive compensation and the August 2016 hire of our Chief Medical Officer and (iii) a

[Table of Contents](#)

\$596,000 increase in U.S. stock-based compensation, partially offset by decreases of (i) \$1.1 million of CRO costs for our Durasert three-year uveitis clinical development, (ii) \$1.0 million of U.K. costs primarily related to the effect of the U.K. restructuring, which included a \$147,000 foreign exchange impact of a stronger US\$ currency, and (iii) \$268,000 of U.S. pre-clinical studies and other third-party research costs related primarily to prior year studies of potential tyrosine kinase inhibitors (TKI) compounds and purchases of lab and clinical supplies for our Durasert three-year uveitis clinical development program. We expect fiscal 2018 research and development expense to increase by approximately 10- 15% compared to fiscal 2017, primarily due to pre-commercialization headcount and other costs for Durasert three-year uveitis manufacturing, quality assurance and medical affairs and increased regulatory professional services related to our planned NDA filing, partially offset by the absence of fiscal 2017 U.K. restructuring costs and reduced amortization of intangible assets.

General and Administrative

General and administrative expenses totaled \$11.2 million in fiscal 2017, an increase of \$2.2 million, or 24%, compared to \$9.0 million in fiscal 2016. This increase was attributable primarily to (i) approximately \$1.5 million of personnel and related costs, including annual incentive compensation, of which \$1.2 million represented severance compensation to our former CEO and former Vice President, Corporate Affairs and General Counsel, (ii) approximately \$1.3 million of legal fees, which included approximately \$175,000 of legal fees associated with the CEO transition and severance arrangements, \$430,000 of legal fees related to the Alimera arbitration proceedings and agreement restructuring and \$253,000 of patent legal fees, partially offset by a \$619,000 decrease in consulting services costs, which consisted primarily of prior year uveitis market assessment analyses and the \$218,000 fiscal 2017 cancellation of previously accrued audit costs in connection with the Alimera arbitration settlement.

Interest and Other Income

Interest and other income increased to \$91,000 in fiscal 2017, an increase of \$19,000, or 23%, compared to \$72,000 in fiscal 2016, due primarily to higher money market interest rates.

Income Tax Benefit

Income tax benefit was \$0 in fiscal 2017 compared to an income tax benefit of \$155,000 in fiscal 2016. We incurred \$4,000 in fiscal 2016 of federal alternative minimum tax expense based on U.S. taxable income for calendar year 2014 attributable primarily to the \$25.0 million ILUVIEN FDA-approval milestone. Refundable foreign research and development tax credits were not available for fiscal 2017 as a result of the consolidation of our research and development activities in the U.S. during the quarter ended September 30, 2016.

[Table of Contents](#)

Years Ended June 30, 2016 and 2015

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

Revenues

Collaborative research and development revenue totaled \$398,000 in fiscal 2016, a decrease of \$25.0 million, or 98%, compared to \$25.4 million in fiscal 2015. This decrease was attributable primarily to recognition of the one-time \$25.0 million FDA-approval milestone earned for ILUVIEN in September 2014.

Retisert royalty income increased by \$68,000, or 6%, to \$1.22 million in fiscal 2016 compared to \$1.15 million in fiscal 2015.

Through June 30, 2017, we were entitled to share in net profits, on a country-by-country basis, from sales of ILUVIEN by Alimera. Alimera initiated commercial sales of ILUVIEN in the U.K. and Germany in the fourth quarter of fiscal 2013 and in the U.S. and Portugal in the third quarter of fiscal 2015. We earned \$0 and \$43,000 of ILUVIEN net profits during fiscal 2016 and 2015, respectively. In addition, during fiscal 2016 we received \$157,000 from Alimera attributable to a sublicense arrangement.

Research and Development

Research and development expenses totaled \$14.4 million in fiscal 2016, an increase of \$2.3 million, or 19%, compared to \$12.1 million in fiscal 2015. This increase was attributable primarily to a \$1.4 million increase in CRO and other costs for Durasert three-year uveitis Phase 3 clinical development and regulatory submissions, \$475,000 of personnel-related costs, including incentive compensation and contractual severance obligations, and \$320,000 of pre-clinical studies and other third-party research costs.

General and Administrative

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

[Table of Contents](#)

Interest and Other Income

Interest and other income totaled \$72,000 in fiscal 2016, an increase of \$50,000, or 69%, compared to \$22,000 in fiscal 2015, due primarily to a combination of higher average balances of marketable security investments and improved yields to maturity and higher money market interest rates.

Income Tax Benefit (Expense)

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

Inflation and Seasonality

Our management believes inflation has not had a material impact on our operations or financial condition and that our operations are not currently subject to seasonal influences.

Recently Adopted and Recently Issued Accounting Pronouncements

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

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers* (Topic 606) (ASU 2014-09), which requires an entity to recognize revenue in an amount that reflects the consideration to which the entity expects to be entitled in exchange for the transfer of promised goods or services to customers. The standard will replace most existing revenue recognition guidance in U.S. GAAP. In August 2015, the FASB issued ASU 2015-14, which officially deferred the effective date of ASU 2014-09 by one year, while also permitting early adoption. As a result, ASU 2014-09 will become effective on July 1, 2018, with early adoption permitted on July 1, 2017. The standard permits the use of either the retrospective or cumulative effect transition method. We are evaluating the impact this standard will have on our consolidated financial statements.

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

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

[Table of Contents](#)

with earlier adoption permitted. We elected to early adopt ASU 2016-19 in the fourth quarter of fiscal 2017, which required any adjustments to be recorded as of the beginning of fiscal 2017. As a result, we recorded a retrospective adjustment of \$122,000 to accumulated deficit and additional paid-in capital as of July 1, 2016. Our election under ASU 2016-09 to account for forfeitures as they occur also resulted in additional stock-based compensation expense of \$23,000 for the fourth quarter of fiscal 2017.

Liquidity and Capital Resources

From fiscal 2013 through fiscal 2017, we financed our operations primarily from sales of our equity securities and the receipt of license fees, milestone payments, research and development funding and royalty income from our collaboration partners. Our principal sources of liquidity consisted of cash and cash equivalents and the receipt of license fees, milestone payments, research and development funding and royalty income from our collaboration partners. As of June 30, 2017, our cash and cash equivalents totaled \$16.9 million. Our cash equivalents are invested in an institutional money market fund.

With the exception of net income in fiscal 2015 resulting from the \$25.0 million ILUVIEN FDA-approval milestone, we have predominantly incurred operating losses since inception and, at June 30, 2017, we had a total accumulated deficit of \$310.8 million. We do not currently have any significant assured sources of future revenue, and our anticipated recurring use of cash to fund operations in combination with no probable source of additional capital raises substantial doubt about our ability to continue as a going concern for one year from the issuance of our financial statements included in this Annual Report. We believe that our cash and cash equivalents of \$16.9 million at June 30, 2017 and expected proceeds from existing collaboration agreements, will enable us to maintain our current and planned operations (including our two Durasert three-year uveitis Phase 3 clinical trials) through approximately the first quarter of calendar year 2018. In order to extend our ability to fund our operations beyond then, including our planned commercial launch of Durasert three-year uveitis in the U.S. if approved by the FDA, our plans include accessing additional equity financing from the sale of our equity securities, our ATM program or other equity or debt financing transactions and/or, as applicable, reducing or deferring operating expenses. The timing and extent of our implementation of these plans is expected to depend on the amount and timing of cash receipts from existing or any future collaboration or other agreements and/or proceeds from any financing transactions. There is no assurance that we will receive significant revenues from the commercialization of ILUVIEN or financing from any other sources.

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

- the amount of future revenues we receive with respect to the commercialization of ILUVIEN for DME and, if approved in the EMEA, of ILUVIEN for posterior uveitis;
- the timing, cost and success of our clinical development, regulatory approval and planned direct U.S. commercialization of Durasert three-year uveitis;
- whether and to what extent we internally fund, whether and when we initiate, and how we conduct other product development programs;
- the amount of Retisert royalties and other payments we receive under collaboration agreements;
- whether and when we are able to enter into strategic arrangements for our product candidates and the nature of those arrangements;
- timely and successful development, regulatory approval and commercialization of our products and product candidates;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing any patent claims;
- changes in our operating plan, resulting in increases or decreases in our need for capital; and
- our views on the availability, timing and desirability of raising capital.

[Table of Contents](#)

We do not know if additional capital will be available when needed or on terms favorable to us or our stockholders. Collaboration, licensing or other agreements may not be available on favorable terms, or at all. Although we expect that our restructured Alimera collaboration agreement will provide a more consistent flow of royalty revenues, we do not know the extent to which Alimera will achieve increasing revenues from its commercialization of ILUVIEN for DME and, if approved, for posterior segment uveitis. If we seek to sell shares under our ATM program or in another offering, we do not know whether and to what extent we will be able to do so, or on what terms. Further, the rules and regulations of the Australian Securities Exchange (ASX) and the NASDAQ Stock Market require us to obtain shareholder approval for sales of our equity securities under certain circumstances, which could delay or prevent us from raising additional capital from such sales. Also, the state of the economy and financial and credit markets at the time or times we seek any additional financing may make it more difficult or expensive to obtain. If available, additional equity financing may be dilutive to stockholders, debt financing may involve restrictive covenants or other unfavorable terms and dilute our existing stockholders' equity, and funding through collaboration agreements may be on unfavorable terms, including requiring us to relinquish rights to certain of our technologies or products. If adequate financing is not available if and when needed, we may delay, reduce the scope of, or eliminate research or development programs, potential independent commercialization of Durasert three-year uveitis or other new products, if any, and postpone or cancel the pursuit of product candidates, including pre-clinical and clinical trials and new business opportunities, reduce staff and operating costs, or otherwise significantly curtail our operations to reduce our cash requirements and extend our capital.

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

	Year Ended June 30,		
	2017	2016	2015
	(In thousands)		
Net (loss) income:	\$ (18,485)	\$ (21,547)	\$ 6,347
Changes in operating assets and liabilities	318	2,073	1,009
Other adjustments to reconcile net (loss) income to cash flows from operating activities	(2,323)	3,158	2,941
Cash flows (used in) provided by operating activities	<u>\$ (20,490)</u>	<u>\$ (16,316)</u>	<u>\$ 10,297</u>
Cash flows provided by (used in) investing activities	<u>\$ 13,577</u>	<u>\$ (4,462)</u>	<u>\$ (6,733)</u>
Cash flows provided by financing activities	<u>\$ 8,503</u>	<u>\$ 16,990</u>	<u>\$ 235</u>

Sources and uses of operating cash flows for the years ended June 30, 2017, 2016 and 2015 are summarized as follows:

	Year Ended June 30,		
	2017	2016	2015
	(In thousands)		
Operating cash inflows:			
License and collaboration agreements	\$ 891	\$ 507	\$ 25,317
Royalty income	1,008	1,298	1,086
Foreign R&D tax credits	132	163	120
Investment interest received, net	120	176	97
	<u>2,151</u>	<u>2,144</u>	<u>26,620</u>
Operating cash outflows:			
Personnel costs	(7,229)	(5,133)	(5,086)
Professional fees	(6,074)	(3,610)	(3,234)
Clinical development and third-party R&D	(7,115)	(7,615)	(5,783)
All other operating cash outflows, net	(2,223)	(2,102)	(2,220)
	<u>(22,641)</u>	<u>(18,460)</u>	<u>(16,323)</u>
Cash flows (used in) provided by operating activities	<u>\$ (20,490)</u>	<u>\$ (16,316)</u>	<u>\$ 10,297</u>

[Table of Contents](#)

Operating cash inflows for each year consisted primarily of payments received pursuant to license and collaboration agreements. As a percentage of total license and collaboration cash inflows, amounts attributable to Alimera represented 58.6% in fiscal 2017, 72.4% in fiscal 2016 and 99.3% in fiscal 2015, amounts attributable to Enigma represented 11.2% in fiscal 2017, 19.7% in fiscal 2016 and 0.4% in fiscal 2015 and amounts attributable to various feasibility study agreements represented 28.0% in fiscal 2017 and 0.2% in fiscal 2015.

Operating cash outflows increased by \$4.2 million, or 22.7%, from fiscal 2016 to fiscal 2017, as a result primarily of (a) \$2.5 million of professional fees, which consisted primarily of Durasert three-year uveitis clinical and regulatory consulting fees and general legal fees associated with the CEO transition and costs of the Alimera arbitration; (b) \$2.1 million of personnel and benefit costs, which included \$1.2 million of severance compensation and in fiscal 2017, the additions of a Chief Medical Officer and EVP of Corporate and Commercial Development and an approximate \$390,000 increase in fiscal 2016 incentive compensation awards (paid in fiscal 2017) compared to the prior year, partially offset by (c) a \$208,000 decrease in CRO costs for Durasert three-year uveitis clinical development. Operating cash outflows increased by \$2.1 million, or 13.1%, from fiscal 2015 to fiscal 2016, as a result primarily of increases of: (a) \$1.5 million in CRO costs for Durasert three-year uveitis clinical development; (b) \$376,000 of professional fees; (c) \$367,000 of pre-clinical studies and other third-party research and development costs; and (d) \$277,000 of personnel and benefit costs, partially offset by decreases of (x) \$260,000 of federal alternative minimum taxes attributable to calendar year 2014 U.S. taxable income; and (y) \$230,000 in cash incentive compensation awards.

Cash flows from investing activities were attributable primarily to maturities of marketable securities, net of purchases, of \$13.7 million for fiscal 2017 and purchases of marketable securities, net of maturities, of \$4.3 million for fiscal 2016 and \$6.6 million for fiscal 2015. Purchases of property and equipment totaled \$147,000 in fiscal 2017, \$113,000 in fiscal 2016 and \$161,000 in fiscal 2015.

Cash flows from financing activities in fiscal 2017 were related predominately to the sale of common shares under our ATM program for gross proceeds of \$8.9 million, less \$233,000 of program adoption costs and \$244,000 of share issue costs. Cash flows from financing activities in fiscal 2016 were attributable primarily to an underwritten public offering in January 2016 for gross proceeds of \$17.8 million, net of \$1.3 million of share issue costs. In addition, cash flows from financing activities included proceeds from the exercise of stock options totaling \$99,000 in fiscal 2017, \$490,000 in fiscal 2016 and \$235,000 in fiscal 2015.

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, 2017:

<u>Contractual Obligations</u>	<u>Payments Due by Period</u>				
	<u>Total</u>	<u>Less than 1 year</u>	<u>1- 3 years</u>	<u>3- 5 years</u>	<u>More than 5 years</u>
Operating Lease Obligations	\$ 1,190	\$ 510	\$ 600	\$ 80	\$ —
Purchase Obligations	233	233	—	—	—
Total	\$ 1,423	\$ 743	\$ 600	\$ 80	\$ —

Our operating lease obligations consist predominantly of office and lab space in Watertown, Massachusetts and office space in Liberty Corner, New Jersey. Our purchase obligations consist of non-cancellable purchase orders for supplies and services.

[Table of Contents](#)

We have agreements with two CROs to conduct the clinical development program for Durasert three-year uveitis. Our financial obligations under the agreements are determined by the services that we request from time to time under the agreements. The actual amounts owed under the agreements and the timing of those obligations will depend on various factors, including the number of patients and rate of patient enrollment, any protocol amendments and other factors relating to the clinical trials. We can change the services requested and thereby increase or decrease our obligations under the agreements from time to time. As of June 30, 2017, our CRO agreements provided for two Phase 3 clinical trials and an inserter safety and utilization study at an aggregate remaining cost of approximately \$8.9 million, which includes a few pending contract change orders. We can terminate the agreements at any time without penalty.

We also have employment agreements with four executive officers that would require us to make severance payments to them if we terminate their employment without cause or the executives resign for good cause. These payments are contingent upon the occurrence of various future events, and the amounts payable under these provisions depend upon the level of compensation at the time of termination of employment, which are therefore not calculable at this time, and, as a result, we have not included any such amounts in the table above.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Foreign Currency Exchange Rates

We have historically conducted operations in two principal currencies, the U.S. dollar (\$) and the Pound Sterling (£). The U.S. dollar is the functional currency for our U.S. operations, and the Pound Sterling is the functional currency for our U.K. operations.

Changes in the foreign exchange rate of the Pound Sterling to the U.S. dollar impacted the net operating expenses of our U.K. operations. The strengthening of the U.S. dollar relative to the Pound Sterling in fiscal 2017 compared to fiscal 2016 resulted in a net decrease in research and development expense of approximately \$147,000. For every incremental 5% strengthening or weakening of the weighted average exchange rate of the U.S. dollar in relation to the Pound Sterling, our research and development expense in fiscal 2016 would have decreased or increased by \$51,000, respectively. All cash and cash equivalents, and most other asset and liability balances, are denominated in each entity's functional currency and, accordingly, we do not consider our statement of comprehensive (loss) income exposure to realized and unrealized foreign currency gains and losses to be significant.

Changes in the foreign exchange rate of the Pound Sterling to the U.S. dollar also impacted total stockholders' equity. As reported in the statement of comprehensive (loss) income, the relative strengthening of the U.S. dollar in relation to the Pound Sterling at June 30, 2017 compared to June 30, 2016 resulted in \$21,000 of other comprehensive loss due to the translation of £130,000 of net assets of our U.K. operations, predominantly intangible assets, into U.S. dollars. For every incremental 5% strengthening or weakening of the U.S. dollar at June 30, 2017 in relation to the Pound Sterling, our stockholders' equity at June 30, 2017 would have decreased or increased, respectively, by approximately \$8,000.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by this item may be found on pages F-1 through F-28 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, 2017. The term “disclosure controls and procedures”, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their desired objectives, and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2017, 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, 2017. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”) in *Internal Control—Integrated Framework (2013)*. Based on this assessment, our management concluded that, as of such date, our internal control over financial reporting was effective based on those criteria.

Deloitte & Touche LLP, the independent registered public accounting firm that audited our consolidated financial statements, has issued an attestation report on our internal control over financial reporting as of June 30, 2017, which is included below in this Item 9A of our Annual Report on Form 10-K.

(b) Changes in Internal Control over Financial Reporting

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

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the internal control over financial reporting of pSivida Corp. and subsidiaries (the “Company”) as of June 30, 2017, based on the criteria established in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

The Company’s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management’s Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company’s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company’s internal control over financial reporting is a process designed by, or under the supervision of, the company’s principal executive and principal financial officers, or persons performing similar functions, and effected by the company’s board of directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company’s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company’s assets that could have a material effect on the financial statements.

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

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of June 30, 2017, based on the criteria established in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements as of and for the year ended June 30, 2017 of the Company and our report dated September 13, 2017 expressed an unqualified opinion on those financial statements.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
September 13, 2017

ITEM 9B. OTHER INFORMATION

None.

PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K and is incorporated herein by reference from our definitive proxy statement relating to our 2017 annual meeting of stockholders, pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended, also referred to in this Form 10-K as our 2017 Proxy Statement, which we expect to file with the SEC no later than October 30, 2017.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

Corporate Governance

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

We intend to disclose any future amendments to, or waivers from, the Code of Conduct that affect our directors or senior financial and executive officers within four business days of the amendment or waiver by posting such information on the website address and location specified above.

Other Information

The other information required to be disclosed in Item 10 is hereby incorporated by reference to our 2017 Proxy Statement.

ITEM 11. EXECUTIVE COMPENSATION

The information required to be disclosed in Item 11 is hereby incorporated by reference to our 2017 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 2017 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 2017 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 2017 Proxy Statement.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENTS

(a)(1) Financial Statements

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

(a)(2) Financial Statement Schedules

Schedules have been omitted because of the absence of conditions under which they are required or because the required information is included in our Consolidated Financial Statements or Notes thereto.

ITEM 16. FORM 10-K SUMMARY

Not applicable.

Table of Contents

(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(a)	Certificate of Amendment of the Certificate of Incorporation of pSivida Corp.			
3.2	By-Laws of pSivida Corp.	8-K	07/19/12	3.1
	Instruments Defining the Rights of Security Holders			
4.1	Form of Specimen Stock Certificate for Common Stock	8-K12G3	06/19/08	4.1
	Material Contracts—Management Contracts and Compensatory Plans			
10.1	Employment Agreement between pSivida Corp. and Nancy Lurker, dated September 15, 2016	10-Q	11/08/16	10.1
10.2	Amended and Restated Performance-Based Restricted Stock Unit Award Agreement, dated December 21, 2016, by and between pSivida Corp. and Nancy Lurker	8-K	12/23/16	10.1
10.3	Nonstatutory Stock Option Inducement Award granted to Nancy Lurker, subject to shareholder approval, with effect from September 15, 2016	10-Q	11/08/16	10.3
10.4	Employment Agreement between pSivida Corp. and Deb Jorn, dated November 2, 2016	10-Q	11/08/16	10.4
10.5	Amended and Restated Performance-Based Restricted Stock Unit Award Agreement, dated December 21, 2016, by and between pSivida Corp. and Deb Jorn	8-K	12/23/16	10.2
10.6	Nonstatutory Stock Option granted to Deb Jorn on November 2, 2016	10-Q	11/08/16	10.6
10.7	Employment Agreement, between pSivida Corp and Leonard S. Ross, dated December 17, 2010	8-K	12/21/10	10.1
10.8	Option Amendment Agreement, between pSivida Corp. and Leonard S. Ross, dated December 17, 2010	8-K	12/21/10	10.2
10.9	Retention Bonus Letter, dated January 5, 2017, by and between pSivida Corp. and Leonard Ross	8-K	01/10/17	10.1
10.10(a)	Employment Agreement, between pSivida Corp. and Dario Paggiarino, dated July 7, 2016			
10.11	Separation Agreement between pSivida Corp. and Paul Ashton, dated September 20, 2016	10-Q	11/08/16	10.7
10.12	Cooperation Agreement dated December 25, 2016, by and between pSivida Corp. and Lori Freedman	8-K	12/30/16	10.1

Table of Contents

Exhibit No.	Exhibit Description	Incorporated by Reference to SEC Filing		
		Form	SEC Filing Date	Exhibit No.
	Material Contracts—Management Contracts and Compensatory Plans (continued)			
10.13	2008 Equity Incentive Plan, as amended on November 19, 2009	10-K	09/10/15	10.6
10.14 +	Form of Stock Option Certificate for grants to executive officers under the pSivida Corp. 2008 Incentive Plan	8-K	09/10/08	10.1
10.15	pSivida Corp. 2016 Long Term Incentive Plan, as amended	10-Q	02/09/17	4.1
10.16 +	Form of Indemnification Agreement between pSivida Corp. and its officers and directors	10-Q	11/08/16	10.8
10.17	pSivida Short Term Incentive Plan	8-K	06/27/17	10.1
10.18(a)	Form of Restricted Stock Unit Award for grants to executive officers under the pSivida Corp. 2016 Long Term Incentive Plan, as amended			
10.19(a)	Form of Performance-Based Stock Unit Award for grants under the pSivida Corp. 2016 Long Term Incentive Plan, as amended			
	Material Contracts—Leases			
10.20	Lease Agreement between pSivida Corp. and Farley White Aetna Mills, LLC dated November 1, 2013	10-Q	11/13/13	10.1
	Material Contracts—License and Collaboration Agreements			
10.21#	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
10.22#	Second Amendment to Amended and Restated License Agreement between pSivida US, Inc. and Bausch & Lomb dated August 1, 2009	10-K	09/25/09	10.13
10.23†(a)	Second Amended and Restated Collaboration Agreement by and between pSivida US Inc. and Alimera Sciences, Inc. dated July 10, 2017			
10.24#	Amended and Restated Collaborative Research and License Agreement, dated as of June 14, 2011, by and among pSivida Corp., pSivida US, Inc., pSiMedica Limited and Pfizer, Inc.	10-K/A	12/27/11	10.13
10.25(a)	Agreement, dated April 11, 2017, by and between pSivida Corp., pSiMedica Limited and Pfizer, Inc.			
	Material Contracts—Other Agreements			
10.26	At Market Issuance Sales Agreement, dated February 8, 2017, by and between pSivida Corp. and FBR Capital Markets & Co.	8-K	02/08/17	10.1

Table of Contents

<u>Exhibit No.</u>	<u>Exhibit Description</u>	<u>Incorporated by Reference to SEC Filing</u>		
		<u>Form</u>	<u>SEC Filing Date</u>	<u>Exhibit No.</u>
	<i>Other Exhibits</i>			
21.1(a)	Subsidiaries of pSivida Corp.			
23.1(a)	Consent of Independent Registered Public Accounting Firm, Deloitte & Touche LLP			
31.1(a)	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act, as amended			
31.2(a)	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act, as amended			
32.1(a)	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002			
32.2(a)	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002			
101	The following materials from pSivida Corp.'s Annual Report on Form 10-K for the year ended June 30, 2017, formatted in eXtensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets at June 30, 2017 and 2016; (ii) Consolidated Statements of Comprehensive (Loss) Income for the years ended June 30, 2017, 2016 and 2015; (iii) Consolidated Statements of Stockholders' Equity for the years ended June 30, 2017, 2016 and 2015; (iv) Consolidated Statements of Cash Flows for the years ended June 30, 2017, 2016 and 2015; and (v) Notes to Consolidated Financial Statements.			
#	Confidential treatment has been granted for portions of this exhibit			
†	Confidential Treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the U.S. Securities and Exchange Commission.			
+	The final versions of documents denoted as "form of" have been omitted pursuant to Rule 12b-31. Such final versions are substantially identical in all material respects to the filed versions of such documents, provided that the name of the investor, and the investor's and/or the Company's signatures are included in the final versions.			
(a)	Filed herewith			

PSIVIDA CORP. AND SUBSIDIARIES
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Consolidated Financial Statements:

[Report of Independent Registered Public Accounting Firm](#)

F-2

[Consolidated Balance Sheets](#)

F-3

[Consolidated Statements of Comprehensive \(Loss\) Income](#)

F-4

[Consolidated Statements of Stockholders' Equity](#)

F-5

[Consolidated Statements of Cash Flows](#)

F-6

[Notes to Consolidated Financial Statements](#)

F-7

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, 2017 and 2016, and the related consolidated statements of comprehensive (loss) income, stockholders’ equity, and cash flows for each of the three years in the period ended June 30, 2017. These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of pSivida Corp. and subsidiaries as of June 30, 2017 and 2016, and the results of their operations and their cash flows for each of the three years in the period ended June 30, 2017, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements for the year ended June 30, 2017 have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company’s anticipated recurring use of cash to fund operations in combination with no probable source of additional capital raises substantial doubt about its ability to continue as a going concern. Management’s plans concerning these matters are also discussed in Note 1 to the consolidated financial statements. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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, 2017, based on the criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated September 13, 2017 expressed an unqualified opinion on the Company’s internal control over financial reporting.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
September 13, 2017

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

	June 30,	
	2017	2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 16,898	\$ 15,313
Marketable securities	—	13,679
Accounts and other receivables	251	488
Prepaid expenses and other current assets	591	483
Total current assets	17,740	29,963
Property and equipment, net	313	290
Intangible assets, net	364	1,102
Other assets	110	114
Restricted cash	150	150
Total assets	\$ 18,677	\$ 31,619
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,016	\$ 1,363
Accrued expenses	4,224	3,583
Deferred revenue	50	147
Total current liabilities	5,290	5,093
Deferred revenue, less current portion	—	5,585
Deferred rent	51	60
Total liabilities	5,341	10,738
Commitments and contingencies (Note 14)		
Stockholders' equity:		
Preferred stock, \$.001 par value, 5,000,000 shares authorized, no shares issued and outstanding	—	—
Common stock, \$.001 par value, 120,000,000 and 60,000,000 shares authorized, 39,356,999 and 34,172,919 shares issued and outstanding, each at June 30, 2017 and 2016, respectively	39	34
Additional paid-in capital	323,284	312,208
Accumulated deficit	(310,820)	(292,213)
Accumulated other comprehensive income	833	852
Total stockholders' equity	13,336	20,881
Total liabilities and stockholders' equity	\$ 18,677	\$ 31,619

See notes to consolidated financial statements

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

	Year Ended June 30,		
	2017	2016	2015
Revenues:			
Collaborative research and development	\$ 6,569	\$ 398	\$25,411
Royalty income	970	1,222	1,154
Total revenues	<u>7,539</u>	<u>1,620</u>	<u>26,565</u>
Operating expenses:			
Research and development	14,880	14,381	12,088
General and administrative	11,235	9,013	8,056
Total operating expenses	<u>26,115</u>	<u>23,394</u>	<u>20,144</u>
Operating (loss) income	<u>(18,576)</u>	<u>(21,774)</u>	<u>6,421</u>
Interest and other income, net	91	72	22
(Loss) income before income taxes	<u>(18,485)</u>	<u>(21,702)</u>	<u>6,443</u>
Income tax benefit (expense)	—	155	(96)
Net (loss) income	<u><u>\$(18,485)</u></u>	<u><u>\$(21,547)</u></u>	<u><u>\$ 6,347</u></u>
Net (loss) income per share:			
Basic	<u>\$ (0.52)</u>	<u>\$ (0.68)</u>	<u>\$ 0.22</u>
Diluted	<u>\$ (0.52)</u>	<u>\$ (0.68)</u>	<u>\$ 0.21</u>
Weighted average common shares outstanding:			
Basic	<u>35,344</u>	<u>31,623</u>	<u>29,378</u>
Diluted	<u>35,344</u>	<u>31,623</u>	<u>30,584</u>
Net (loss) income	<u>\$(18,485)</u>	<u>\$(21,547)</u>	<u>\$ 6,347</u>
Other comprehensive (loss) income:			
Foreign currency translation adjustments	(21)	(96)	(95)
Net unrealized gain (loss) on marketable securities	2	3	(4)
Other comprehensive loss	<u>(19)</u>	<u>(93)</u>	<u>(99)</u>
Comprehensive (loss) income	<u><u>\$(18,504)</u></u>	<u><u>\$(21,640)</u></u>	<u><u>\$ 6,248</u></u>

See notes to consolidated financial statements

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

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Number of Shares	Par Value Amount				
Balance at July 1, 2014	29,298,558	\$ 29	\$290,864	\$ (277,013)	\$ 1,044	\$ 14,924
Net income	—	—	—	6,347	—	6,347
Other comprehensive loss	—	—	—	—	(99)	(99)
Exercise of stock options	113,807	—	235	—	—	235
Stock-based compensation	—	—	1,961	—	—	1,961
Balance at June 30, 2015	29,412,365	29	293,060	(270,666)	945	23,368
Net loss	—	—	—	(21,547)	—	(21,547)
Other comprehensive loss	—	—	—	—	(93)	(93)
Issuance of stock, net of issue costs	4,440,000	5	16,495	—	—	16,500
Exercise of stock options	320,554	—	490	—	—	490
Stock-based compensation	—	—	2,163	—	—	2,163
Balance at June 30, 2016	34,172,919	34	312,208	(292,213)	852	20,881
Cumulative effect of change in accounting principle (Note 2)	—	—	122	(122)	—	—
Net loss	—	—	—	(18,485)	—	(18,485)
Other comprehensive loss	—	—	—	—	(19)	(19)
Issuance of stock, net of issue costs	5,100,000	5	8,399	—	—	8,404
Exercise of stock options	84,080	—	99	—	—	99
Stock-based compensation	—	—	2,456	—	—	2,456
Balance at June 30, 2017	<u>39,356,999</u>	<u>\$ 39</u>	<u>\$323,284</u>	<u>\$ (310,820)</u>	<u>\$ 833</u>	<u>\$ 13,336</u>

See notes to consolidated financial statements

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

	Year Ended June 30,		
	2017	2016	2015
Cash flows from operating activities:			
Net (loss) income	\$(18,485)	\$(21,547)	\$ 6,347
Adjustments to reconcile net (loss) income to cash flows (used in) provided by operating activities:			
Amortization of intangible assets	724	756	770
Depreciation of property and equipment	91	152	112
Amortization of bond (discount) premium on marketable securities	(9)	87	98
Amortization of noncurrent portion of deferred revenue	(5,585)	—	—
Stock-based compensation	2,456	2,163	1,961
Changes in operating assets and liabilities:			
Accounts and other receivables	219	116	(124)
Prepaid expenses and other current assets	(99)	187	(136)
Accounts payable	(346)	626	292
Accrued expenses	650	1,036	1,053
Deferred revenue	(97)	103	(94)
Deferred rent	(9)	5	18
Net cash (used in) provided by operating activities	<u>(20,490)</u>	<u>(16,316)</u>	<u>10,297</u>
Cash flows from investing activities:			
Purchases of marketable securities	(5,052)	(17,517)	(10,222)
Maturities of marketable securities	18,743	13,168	3,650
Purchases of property and equipment	(147)	(113)	(161)
Proceeds from sale of property and equipment	33	—	—
Net cash provided by (used in) investing activities	<u>13,577</u>	<u>(4,462)</u>	<u>(6,733)</u>
Cash flows from financing activities:			
Proceeds from issuance of stock, net of issuance costs	8,404	16,500	—
Proceeds from exercise of stock options	99	490	235
Net cash provided by financing activities	<u>8,503</u>	<u>16,990</u>	<u>235</u>
Effect of foreign exchange rate changes on cash and cash equivalents	<u>(5)</u>	<u>(20)</u>	<u>(12)</u>
Net increase (decrease) in cash and cash equivalents	1,585	(3,808)	3,787
Cash and cash equivalents at beginning of year	15,313	19,121	15,334
Cash and cash equivalents at end of year	<u>\$ 16,898</u>	<u>\$ 15,313</u>	<u>\$ 19,121</u>
Supplemental disclosure of cash flow information:			
Cash paid for income taxes	<u>\$ —</u>	<u>\$ 4</u>	<u>\$ 263</u>

See notes to consolidated financial statements

PSIVIDA CORP. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Operations

pSivida Corp. (together with its subsidiaries, the “Company”), incorporated in Delaware, develops sustained-release drug delivery products primarily for the treatment of chronic eye diseases. The Company’s approved products and product candidates deliver drugs at a controlled and steady rate for months or years. The Company has developed three of only four sustained-release products approved by the U.S. Food and Drug Administration (“FDA”) for treatment of back-of-the-eye diseases. Durasert™ three-year non-erodible fluocinolone acetonide (“FA”) insert for posterior segment uveitis (“Durasert three-year uveitis”) (formerly known as Medidur), the Company’s lead product candidate, is in pivotal Phase 3 clinical trials, and ILUVIEN® for diabetic macular edema (“DME”), the Company’s lead licensed product, is sold directly in the U.S. and three European Union (“EU”) countries. Retisert®, an earlier generation product approved in 2005 by the FDA for the treatment of posterior segment uveitis, is sold in the U.S. by Bausch & Lomb Incorporated (“Bausch & Lomb”). The Company’s development programs are focused primarily on developing sustained release products that utilize its Durasert technology platform to deliver approved drugs to treat chronic diseases. The Company’s strategy includes developing products independently while continuing to leverage its technology platforms through collaborations and license agreements.

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

Both Phase 3 clinical trials investigating Durasert three-year uveitis met their primary efficacy endpoint of prevention of recurrence of disease through six months with statistical significance ($p < 0.001$, intent to treat analysis) and with safety data consistent with the known effects of ocular corticosteroid use. The same statistical significance for efficacy and encouraging safety results was maintained through 12 months of follow-up for the first Phase 3 clinical trial and read-out at 12 months of follow-up for the second Phase 3 trial is expected in the first half of calendar 2018. The Company plans to file a new drug application (“NDA”) with the FDA in late December 2017 or early January 2018.

ILUVIEN® is an injectable, sustained-release micro-insert that provides three years of treatment of DME from a single injection. ILUVIEN is based on the same technology as the Durasert three-year uveitis insert and delivers the same corticosteroid, FA. ILUVIEN was developed in collaboration with, and is licensed to and sold by Alimera Sciences, Inc. (“Alimera”). ILUVIEN has been sold directly in the United Kingdom (“U.K.”) and Germany since 2013 and in the U.S. and Portugal since 2015, and also has marketing approvals in 14 other European countries. Alimera has sublicensed distribution, regulatory and reimbursement matters for ILUVIEN in Australia and New Zealand, Canada, Italy, Spain, France and numerous countries in the Middle East.

The Company’s development programs are focused primarily on developing sustained release drug products using its proven Durasert technology platform to deliver small molecule drugs to treat uveitis, wet age-related macular degeneration (“AMD”), glaucoma, osteoarthritis and other diseases. A sustained release, surgical implant delivering a corticosteroid to treat pain associated with severe knee osteoarthritis (“OA”) that was jointly developed by the Company and Hospital for Special Surgery is currently being evaluated in an investigator-sponsored safety and tolerability study.

The Company has financed its operations primarily from sales of equity securities and the receipt of license fees, milestone payments, research and development funding and royalty income from its collaboration partners. The Company has a history of operating losses and, to date, has not had significant recurring cash inflows from

[Table of Contents](#)

revenue. The Company's anticipated recurring use of cash to fund operations in combination with no probable source of additional capital raises substantial doubt about its ability to continue as a going concern for one year from the issuance of its financial statements. The Company believes that its cash and cash equivalents of \$16.9 million at June 30, 2017 and expected proceeds from existing collaboration agreements will enable the Company to maintain its current and planned operations (including its two Durasert three-year uveitis Phase 3 clinical trials) through approximately the first quarter of calendar year 2018. In order to extend the Company's ability to fund its operations beyond then, including its planned commercial launch of Durasert three-year uveitis in the U.S. if approved by the FDA, management's plans include accessing additional equity financing from the sale of its common stock through an underwritten public offering, its at-the-market ("ATM") program or other financing transactions and/or, as applicable, reducing or deferring operating expenses. The timing and extent of the Company's implementation of these plans is expected to depend on the amount and timing of cash receipts from existing or any future collaboration or other agreements and/or proceeds from any financing transactions. There is no assurance that the Company will receive significant revenues from the commercialization of ILUVIEN or financing from any other sources.

2. Significant Accounting Policies

Basis of Presentation

The consolidated financial statements are presented in U.S. dollars in accordance with generally accepted accounting principles in the United States ("U.S. GAAP") and include the accounts of pSivida Corp. and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated. The Company's fiscal year ends on June 30 of each year. The years ended June 30, 2017, 2016 and 2015 may be referred to herein as fiscal 2017, fiscal 2016 and fiscal 2015, respectively.

Use of Estimates

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

Foreign Currency

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

Assets and liabilities of the Company's foreign subsidiary are translated at period-end exchange rates. Amounts included in the statements of comprehensive (loss) income and cash flows are translated at the weighted average exchange rates for the period. Gains and losses from currency translation are included in accumulated other comprehensive income as a separate component of stockholders' equity in the consolidated balance sheets. The balance of accumulated other comprehensive income attributable to foreign currency translation was \$833,000 at June 30, 2017 and \$854,000 at June 30, 2016. Foreign currency gains or losses arising from transactions denominated in foreign currencies, whether realized or unrealized, are recorded in interest and other income, net in the consolidated statements of comprehensive (loss) income and were not significant for all periods presented.

Cash Equivalents

Cash equivalents represent highly liquid investments with maturities of three months or less at the date of purchase, principally consisting of institutional money market funds.

Marketable Securities

Marketable securities consist of investments with an original or remaining maturity of greater than three months at the date of purchase. The Company has classified its marketable securities as available-for-sale. Accordingly, the Company records these investments at fair value, with unrealized gains and losses excluded from earnings and reported, net of tax, in accumulated other comprehensive income, which is a component of stockholders' equity. If the Company determines that a decline of any investment is other-than-temporary, the investment is written down to fair value. As of June 30, 2017 and 2016, there were no investments in a significant unrealized loss position. The fair value of marketable securities is determined based on quoted market prices at the balance sheet date of the same or similar instruments. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts through to the earlier of sale or maturity. Such amortization and accretion amounts are included in interest and other income, net in the consolidated statements of comprehensive (loss) income. The cost of marketable securities sold is determined by the specific identification method.

Concentrations of Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash, cash equivalents and marketable securities. At June 30, 2017, a total of \$13.5 million, representing all of the Company's interest-bearing cash equivalent balances, were concentrated in one U.S. Government institutional money market fund that has investments consisting primarily of U.S. Government Agency debt, U.S. Treasury Repurchase Agreements and U.S. Government Agency Repurchase Agreements. Generally, these deposits may be redeemed upon demand and, therefore, the Company believes they have minimal risk. The Company had no marketable security investments at June 30, 2017. Marketable securities at June 30, 2016 consisted of investment-grade corporate bonds and commercial paper. The Company's investment policy, approved by the Board of Directors, includes guidelines relative to diversification and maturities designed to preserve principal and liquidity.

Revenues from Alimera accounted for \$659,000, or 9% of total revenues in fiscal 2017, \$233,000, or 14% of total revenues in fiscal 2016 and \$25.1 million, or 95% of total revenues in fiscal 2015. Revenues from Pfizer accounted for \$5.6 million, or 74% of total revenues in fiscal 2017 and were inconsequential in each of fiscal 2016 and fiscal 2015. Revenues from Bausch & Lomb accounted for \$984,000, or 13% of total revenues in fiscal 2017, \$1.3 million, or 77% of total revenues in fiscal 2016 and \$1.2 million, or 5% of total revenues in fiscal 2015. Revenues from feasibility study agreements accounted for \$211,000, or 3%, of total revenues in fiscal 2017 and were inconsequential in each of fiscal 2016 and fiscal 2015.

Accounts receivable from Bausch & Lomb accounted for \$246,000, or 98%, of total accounts receivable at June 30, 2017 and \$288,000, or 59%, of total accounts receivable at June 30, 2016.

Fair Value of Financial Instruments

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

Accounts and Other Receivables

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

Debt and Equity Instruments

Debt and equity instruments are classified as either liabilities or equity in accordance with the substance of the contractual arrangement.

Property and Equipment

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

Leases

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

Impairment of Intangible Assets

The Company's finite life intangible assets include its acquired Durasert and Tethadur patented technologies, which are being amortized on a straight-line basis over twelve years and will be fully amortized as of December 31, 2017. The intangible asset lives were determined based upon the anticipated period that the Company will derive future cash flows from the intangible assets, considering the effects of legal, regulatory, contractual, competitive and other economic factors. The Company continually monitors whether events or circumstances have occurred that indicate that the remaining estimated useful life of its intangible assets may warrant revision. The Company assesses potential impairments to its intangible assets when there is evidence that events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An impairment loss is recognized when the future undiscounted net cash flows expected to result from the use of an asset are less than its carrying value. If the Company considers an asset to be impaired, the impairment charge to be recognized is measured by the amount by which the carrying value of the asset exceeds its estimated fair value.

Revenue Recognition

Collaborative Research and Development and Multiple-Deliverable Arrangements

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

Revenue is recognized when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable, and collection is reasonably assured. Multiple-deliverable arrangements, such as license and development agreements, are analyzed to determine whether the deliverables can be separated or whether they must be accounted for as a single unit of accounting. When deliverables are separable, consideration received is allocated to the separate units of accounting based on the relative selling price method using management's best estimate of the standalone selling price of deliverables when vendor-specific objective evidence or third-party evidence of selling price is not available. Allocated consideration is recognized as revenue upon application of the appropriate revenue recognition principles to each unit. When the Company determines that an arrangement should be accounted for as a single unit of accounting, it must determine the period over which the performance obligations will be performed and revenue will be recognized.

[Table of Contents](#)

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

Royalties

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

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

Reimbursement of Costs

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

Deferred Revenue

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

Research and Development

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

Stock-Based Compensation

The Company may award stock options and other equity-based instruments to its employees, directors and consultants pursuant to stockholder-approved plans. In the fourth quarter of fiscal 2017, the Company early adopted ASU 2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*, pursuant to which it elected to account for forfeitures as they occur. Prior to the adoption of ASU 2016-09, the Company recognized compensation expense for only the portion of share-based payment awards that were expected to vest. Based on historical trends, the Company applied estimated forfeiture rates to determine the number of awards that were expected to vest. Additional expense was recorded if the actual forfeiture rate for each tranche of option grants was lower than estimated, and a recovery of prior expense was recorded if the actual forfeiture rate was higher than estimated.

[Table of Contents](#)

Compensation cost related to such share-based payment awards is based on the fair value of the instrument on the grant date and is recognized on a graded vesting basis over the requisite service period for each separately vesting tranche of the awards.

The Company may also grant share-based payment awards that are subject to objectively measurable performance and service criteria. Compensation expense for performance-based awards begins at such time as it becomes probable that the respective performance conditions will be achieved. The Company continues to recognize the grant date fair value of performance-based awards through the vesting date of the respective awards so long as it remains probable that the related performance conditions will be satisfied.

The Company estimates the fair value of stock option awards using the Black-Scholes option valuation model and the fair value of restricted stock units based on the observed grant date fair value of the underlying common stock.

Net (Loss) Income per Share

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

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

	Year Ended June 30,		
	2017	2016	2015
Number of common shares – basic	35,343,765	31,623,473	29,378,250
Effect of dilutive securities:			
Stock options	—	—	956,441
Warrants	—	—	249,449
Number of common shares – diluted	<u>35,343,765</u>	<u>31,623,473</u>	<u>30,584,140</u>

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

	Year Ended June 30,		
	2017	2016	2015
Options outstanding	6,895,685	4,981,421	2,010,793
Warrants outstanding	623,605	623,605	552,500
Restricted stock units outstanding	948,500	—	—
Performance stock units outstanding	210,000	—	—
	<u>8,677,790</u>	<u>5,605,026</u>	<u>2,563,293</u>

Comprehensive (Loss) Income

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

Income Tax

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

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

Recently Adopted and Recently Issued Accounting Pronouncements

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

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers* (Topic 606) (“ASU 2014-09”), which requires an entity to recognize revenue in an amount that reflects the consideration to which the entity expects to be entitled in exchange for the transfer of promised goods or services to customers. The standard will replace most existing revenue recognition guidance in U.S. GAAP. In August 2015, the FASB issued ASU 2015-14, which officially deferred the effective date of ASU 2014-09 by one year, while also permitting early adoption. As a result, ASU 2014-09 will become effective on July 1, 2018, with early adoption permitted on July 1, 2017. The standard permits the use of either the retrospective or cumulative effect transition method. The Company is evaluating the impact this standard will have on its consolidated financial statements.

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

In March 2016, the FASB issued ASU 2016-09, *Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*. ASU 2016-09 intends to simplify various aspects of how share-based payments are accounted for and presented in the financial statements. The main provisions include: all tax effects related to stock awards will now be recorded through the statement of operations instead of through equity, all tax-related cash flows resulting from stock awards will be reported as operating activities on the cash flow statement, and entities can make an accounting policy election to either estimate forfeitures or account for forfeitures as they occur. The amendments in ASU 2016-09 are effective for fiscal years beginning

[Table of Contents](#)

after December 15, 2016, including interim periods within those fiscal years, and may be applied prospectively with earlier adoption permitted. The Company elected to early adopt ASU 2016-19 in the fourth quarter of fiscal 2017, which required any adjustments to be recorded as of the beginning of fiscal 2017. As a result, the Company recorded an adjustment of \$122,000 to accumulated deficit and additional paid-in capital as of July 1, 2016. The election by the Company under ASU 2016-09 to account for forfeitures as they occur also resulted in additional stock-based compensation expense of \$23,000 for the fourth quarter of fiscal 2017.

3. License and Collaboration Agreements

Alimera

Under a collaboration agreement with Alimera, as amended in March 2008 (the “Prior Alimera Agreement”), the Company licensed to Alimera the rights to develop, market and sell certain product candidates, including ILUVIEN, and Alimera assumed all financial responsibility for the development of licensed products. In addition, the Company was entitled to receive 20% of any net profits (as defined) on sales of each licensed product (including ILUVIEN) by Alimera, measured on a quarter-by-quarter and country-by-country basis. Alimera could recover 20% of previously incurred and unapplied net losses (as defined) for commercialization of each product in a country, but only by an offset of up to 4% of the net profits earned in that country each quarter, reducing the Company’s net profit share to 16% in each country until those net losses are recouped. In the event that Alimera sublicensed commercialization in any country, the Company was entitled to 20% of royalties and 33% of non-royalty consideration received by Alimera, less certain permitted deductions. The Company is also entitled to reimbursement of certain patent maintenance costs with respect to the patents licensed to Alimera.

Because the Company has no remaining performance obligations under the Alimera Agreement, all amounts received from Alimera are generally recognized as revenue upon receipt or at such earlier date, if applicable, on which any such amounts are both fixed and determinable and reasonably assured of collectability. In instances when payments are received and subject to a contingency, revenue is deferred until such contingency is resolved.

Revenue under the Prior Alimera Agreement totaled \$659,000 for fiscal 2017, \$233,000 for fiscal 2016 and \$25.1 million for fiscal 2015. These revenues included (i) \$585,000 of net profit share earned in fiscal 2017, of which \$136,000 was recognized in connection with an arbitration settlement (see Note 14); (ii) \$157,000 of non-royalty sublicense consideration earned in fiscal 2016; and (iii) a \$25.0 million milestone earned as a result of the FDA approval of ILUVIEN in the first quarter of fiscal 2015. The remainder of Alimera revenues in each year consisted principally of patent fee reimbursements.

On July 10, 2017, the Company entered into a further amended and restated collaboration agreement (the “Amended Alimera Agreement”), pursuant to which the Company (i) licensed its Durasert three-year uveitis product candidate to Alimera for Europe, the Middle East and Africa (“EMEA”) and (ii) converted the net profit share arrangement for each licensed product (including ILUVIEN) to a sales-based royalty on a calendar quarter basis commencing July 1, 2017, with payments from Alimera due 60 days following the end of each quarter.

Sales-based royalties start at the rate of 2%. Commencing January 1, 2019 (or earlier under certain circumstances), the sales-based royalty will increase to 6% on aggregate calendar year net sales up to \$75 million and to 8% on any calendar years sales in excess of \$75 million. Alimera’s share of contingently recoverable accumulated ILUVIEN commercialization losses under the original net profit share arrangement, capped at \$25 million, are to be reduced as follows: (i) \$10.0 million was cancelled in lieu of an upfront license fee on the effective date of the Amended Alimera Agreement; (ii) for calendar years 2019 and 2020, 50% of earned sales-based royalties in excess of 2% will be offset against the quarterly royalty payments otherwise due from Alimera; (iii) on January 1, 2020, another \$5 million will be cancelled, provided, however, that such date of cancellation may be extended under certain circumstances related to Alimera’s regulatory approval process for ILUVIEN for posterior uveitis, with such extension, if any, subject to mutual agreement by the parties; and (iv) commencing in calendar year 2021, 20% of earned sales-based royalties in excess of 2% will be offset against the quarterly royalty payments due from Alimera until such time as the balance of the original \$25 million of recoverable commercialization losses has been fully recouped.

[Table of Contents](#)

The Company has withdrawn its previously filed EU marketing approval application (“MAA”) and its orphan drug designation for posterior uveitis, and Alimera will be responsible for filing a Type II variation for ILUVIEN for the treatment of posterior segment uveitis in the 17 countries in the EU where ILUVIEN is currently approved for the treatment of DME. Delays by Alimera in filing Type II variations in designated EU countries may, under certain circumstances, result in quarterly financial penalty payments by Alimera to the Company.

Pfizer

In June 2011, the Company and Pfizer entered into an Amended and Restated Collaborative Research and License agreement (the “Restated Pfizer Agreement”) to focus solely on the development of a sustained-release bioerodible micro-insert injected into the subconjunctiva designed to deliver latanoprost for human ophthalmic disease or conditions other than uveitis (the “Latanoprost Product”). Pfizer made an upfront payment of \$2.3 million and the Company agreed to provide Pfizer options under various circumstances for an exclusive, worldwide license to develop and commercialize the Latanoprost Product.

The estimated selling price of the combined deliverables under the Restated Pfizer Agreement of \$6.7 million was partially recognized as collaborative research and development revenue over the expected performance period using the proportional performance method with costs associated with developing the Latanoprost Product reflected in operating expenses in the period in which they were incurred. No collaborative research and development revenue was recorded during each of fiscal 2016 and fiscal 2015.

On October 25, 2016, the Company notified Pfizer that it had discontinued development of the Latanoprost Product, which provided Pfizer a 60-day option to acquire a worldwide license in return for a \$10.0 million payment and potential sales-based royalties and development, regulatory and sales performance milestone payments. Pfizer did not exercise its option and the Restated Pfizer Agreement automatically terminated on December 26, 2016. The remaining deferred revenue balance of \$5.6 million was recognized as revenue in the three-month period ended December 31, 2016. Provided that the Company did not conduct any research and development of the Latanoprost Product through calendar 2017, the Company would retain the right thereafter to develop and commercialize the Latanoprost Product on its own or with a partner. By letter agreement effective as of April 11, 2017, Pfizer officially waived that restriction.

Pfizer owned approximately 4.7% of the Company’s outstanding shares at June 30, 2017.

Bausch & Lomb

Pursuant to a licensing and development agreement, as amended, Bausch & Lomb has a worldwide exclusive license to make and sell Retisert in return for royalties based on sales. Royalty income totaled \$970,000 in fiscal 2017 and approximately \$1.2 million in each of fiscal 2016 and fiscal 2015. Accounts receivable from Bausch & Lomb totaled \$246,000 at June 30, 2017 and \$288,000 at June 30, 2016.

OncoSil Medical

The Company entered into an exclusive, worldwide royalty-bearing license agreement in December 2012, amended and restated in March 2013, with OncoSil Medical UK Limited (*f/k/a* Enigma Therapeutics Limited), a wholly-owned subsidiary of OncoSil Medical Ltd (“OncoSil”) for the development of BrachySil, the Company’s previously developed product candidate for the treatment of pancreatic and other types of cancer. The Company received an upfront fee of \$100,000 and is entitled to 8% sales-based royalties, 20% of sublicense consideration and milestone payments based on aggregate product sales. OncoSil is obligated to pay an annual license maintenance fee of \$100,000 by the end of each calendar year, the most recent of which was received in December 2016. For each calendar year commencing with 2014, the Company is entitled to receive reimbursement of any patent maintenance costs, sales-based royalties and sub-licensee sales-based royalties

[Table of Contents](#)

earned, but only to the extent such amounts, in the aggregate, exceed the \$100,000 annual license maintenance fee. The Company has no consequential performance obligations under the OncoSil license agreement, and, accordingly, any amounts to which the Company is entitled under the agreement are recognized as revenue on the earlier of receipt or when collectability is reasonably assured. Revenue related to the Enigma agreement totaled \$100,000 in each of fiscal 2017, fiscal 2016 and fiscal 2015. At June 30, 2017, no deferred revenue was recorded for this agreement.

Evaluation Agreements

The Company from time to time enters into funded agreements to evaluate the potential use of its Durasert technology system for sustained release of third party drug candidates in the treatment of various diseases. Consideration received is generally recognized as revenue over the term of the feasibility study agreement. Revenue recognition for consideration, if any, related to a license option right is assessed based on the terms of any such future license agreement or is otherwise recognized at the completion of the feasibility study agreement. Revenues under feasibility study agreements totaled \$211,000 in fiscal 2017, \$33,000 in fiscal 2016 and \$144,000 in fiscal 2015.

4. Intangible Assets

The reconciliation of intangible assets for the years ended June 30, 2017 and 2016 was as follows (in thousands):

	June 30,	
	2017	2016
Patented technologies		
Gross carrying amount at beginning of year	\$ 36,196	\$ 39,710
Foreign currency translation adjustments	(586)	(3,514)
Gross carrying amount at end of year	35,610	36,196
Accumulated amortization at beginning of year	(35,094)	(37,785)
Amortization expense	(724)	(756)
Foreign currency translation adjustments	572	3,447
Accumulated amortization at end of year	(35,246)	(35,094)
Net book value at end of year	<u>\$ 364</u>	<u>\$ 1,102</u>

The net book value of the Company's intangible assets at June 30, 2017 and 2016 is summarized as follows (in thousands):

	June 30,		Estimated Remaining Useful Life at June 30, 2017 (Years)
	2017	2016	
Patented technologies			
Durasert	\$265	\$ 795	0.5
Tethadur	99	307	0.5
	<u>\$364</u>	<u>\$1,102</u>	

The Company amortizes its intangible assets with finite lives on a straight-line basis over their respective estimated useful lives. Amortization expense for intangible assets totaled \$724,000 in fiscal 2017, \$756,000 in fiscal 2016 and \$770,000 in fiscal 2015. The carrying value of intangible assets at June 30, 2017 of \$364,000 is expected to be amortized on a straight-line basis during the six months ending December 31, 2017.

[Table of Contents](#)

5. Marketable Securities

The Company had no marketable securities at June 30, 2017. The amortized cost, unrealized loss and fair value of the Company's available-for-sale marketable securities at June 30, 2016 were as follows (in thousands):

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

During fiscal 2017, \$5.1 million of marketable securities were purchased and \$18.7 million matured.

6. Property and Equipment, Net

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

	June 30,	
	2017	2016
Property and equipment	\$ 698	\$ 1,777
Leasehold improvements	101	206
Gross property and equipment	799	1,983
Accumulated depreciation and amortization	(486)	(1,693)
	<u>\$ 313</u>	<u>\$ 290</u>

Depreciation expense was \$91,000 in fiscal 2017, \$152,000 in fiscal 2016 and \$112,000 in fiscal 2015.

7. Fair Value Measurements

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

- Level 1 – Inputs are quoted prices (unadjusted) in active markets that are accessible at the measurement date for identical assets and liabilities.
- Level 2 – Inputs are directly or indirectly observable in the marketplace, such as quoted prices for similar assets or liabilities in active markets or quoted prices for identical assets or liabilities with insufficient volume or infrequent transactions (less active markets).
- Level 3 – Inputs are unobservable estimates that are supported by little or no market activity and require the Company to develop its own assumptions about how market participants would price the assets or liabilities.

The Company's cash equivalents and marketable securities are classified within Level 1 or Level 2 on the basis of valuations using quoted market prices or alternative pricing sources and models utilizing market observable inputs, respectively. Certain of the Company's corporate debt securities were valued based on quoted prices for the specific securities in an active market and were therefore classified as Level 1. The remaining marketable securities have been valued on the basis of valuations provided by third-party pricing services, as derived from such services' pricing models. Inputs to the models may include, but are not limited to, reported

[Table of Contents](#)

trades, executable bid and ask prices, broker/dealer quotations, prices or yields of securities with similar characteristics, benchmark curves or information pertaining to the issuer, as well as industry and economic events. The pricing services may use a matrix approach, which considers information regarding securities with similar characteristics to determine the valuation for a security, and have been classified as Level 2.

The following table summarizes the Company's assets carried at fair value measured on a recurring basis at June 30, 2017 and 2016 by valuation hierarchy (in thousands):

Description	June 30, 2017			
	Total Carrying Value	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets:				
Cash equivalents	\$ 13,521	\$ 13,521	\$ —	\$ —
	<u>\$ 13,521</u>	<u>\$ 13,521</u>	<u>\$ —</u>	<u>\$ —</u>
Description	June 30, 2016			
	Total Carrying Value	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets:				
Cash equivalents	\$ 13,856	\$ 12,957	\$ 899	\$ —
Marketable securities:				
Corporate bonds	5,997	4,596	1,401	—
Commercial paper	7,682	—	7,682	—
	<u>\$ 27,535</u>	<u>\$ 17,553</u>	<u>\$ 9,982</u>	<u>\$ —</u>

8. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	June 30,	
	2017	2016
Clinical trial costs	\$1,984	\$1,678
Personnel costs	1,632	1,314
Professional fees	590	535
Other	18	56
	<u>\$4,224</u>	<u>\$3,583</u>

In January 2017, the Company entered into retention bonus agreements with five employees. Under these agreements, subject to continuing employment (a) cash payments totaling \$320,000 will be made on December 22, 2017 and (b) restricted stock units (RSUs) of an equal value will be granted at that date with a one-year vesting period. Included in personnel costs in the above table is \$160,000, representing a pro rata accrual of the cash bonus component through June 30, 2017.

9. Restructuring

In July 2016, the Company announced its plan to consolidate all research and development activities in its U.S. facility. Following employee consultations under local U.K. law, the Company determined to close its U.K. research facility and terminated the employment of its U.K. employees. The U.K. facility lease, set to expire on August 31, 2016, was extended through November 30, 2016 to facilitate an orderly transition and the required restoration of the premises. A summary reconciliation of the restructuring costs is as follows (in thousands):

	<u>Balance at June 30, 2016</u>	<u>Charged to Expense</u>	<u>Payments</u>	<u>Balance at June 30, 2017</u>
Termination benefits	\$ 118	\$ 273	\$ (391)	\$ —
Facility closure	40	73	(113)	—
Other	29	126	(155)	—
	<u>\$ 187</u>	<u>\$ 472</u>	<u>\$ (659)</u>	<u>\$ —</u>

The Company recorded approximately \$472,000 of restructuring costs during fiscal 2017 to research and development expense. These costs consisted of (i) \$273,000 of additional employee severance for discretionary termination benefits upon notification of the affected employees in accordance with ASC 420, *Exit or Disposal Cost Obligations*; and (ii) \$199,000 of professional fees, travel and lease extension costs.

In addition, for the first quarter of fiscal 2017, the Company recorded \$99,000 of non-cash stock-based compensation expense in connection with the extension, through June 30, 2017, of the exercise period for all vested stock options held by the U.K. employees at July 31, 2016 and a \$133,000 credit to stock-based compensation expense to account for forfeitures of all non-vested stock options at that date.

The Company paid all of the restructuring costs associated with the plan of consolidation as of March 31, 2017.

10. Stockholders' Equity

Sales of Common Stock

In February 2017, the Company entered into an ATM program pursuant to which, under its Form S-3 shelf registration statement, the Company may, at its option, offer and sell shares of its common stock from time to time for an aggregate offering price of up to \$20.0 million. The Company will pay the sales agent a commission of up to 3.0% of the gross proceeds from the sale of such shares. The Company incurred approximately \$223,000 of legal, accounting and other costs to establish and activate the ATM program. The Company's ability to sell shares under the ATM program is subject to Australian Securities Exchange (the "ASX") listing rules, as defined, limiting the number of shares the Company may issue in any 12-month period without stockholder approval, as well as other applicable rules and regulations of the ASX and NASDAQ Global Market.

During the period from March 2017 through May 9, 2017, the Company sold 5,100,000 shares of common stock under the ATM program ("ATM Shares Sold") at a weighted average price of \$1.74 per share for gross proceeds of approximately \$8.9 million. At a special meeting of stockholders held on June 27, 2017, the Company's stockholders ratified the ATM Shares Sold, thereby refreshing the Company's capacity to issue shares of common stock without prior stockholder approval under the ASX listing rules. In addition, the stockholders approved the adoption of an amendment to the Company's Certificate of Incorporation, as amended, to increase the number of authorized shares of common stock from 60,000,000 shares to 120,000,000 shares.

During July 2017, the Company sold an additional 15,587 shares of common stock under the ATM program at a weighted average price of \$1.40 per share for gross proceeds of \$22,000.

In January 2016, the Company sold 4,440,000 shares of its common stock in an underwritten public offering at a price of \$4.00 per share for gross proceeds of \$17.8 million. Underwriter discounts and commissions and other share issue costs totaled approximately \$1.3 million.

Warrants to Purchase Common Shares

The following table provides a reconciliation of warrants to purchase common stock for the years ended June 30, 2017 and 2016:

	Year Ended June 30,			
	2017		2016	
	Number of Warrants	Weighted Average Exercise Price	Number of Warrants	Weighted Average Exercise Price
Balance at beginning of year	623,605	\$ 2.50	1,176,105	\$ 3.67
Expired	—	—	(552,500)	5.00
Balance and exercisable at end of year	623,605	\$ 2.50	623,605	\$ 2.50

At August 7, 2017, all of these warrants expired unexercised.

11. Stock-Based Compensation**2016 Long Term Incentive Plan**

The Company's shareholders approved the adoption of the 2016 Incentive Plan on December 12, 2016 (the Adoption Date), which was previously approved by the Board of Directors on October 3, 2016 and subsequently amended by the Compensation Committee of the Board of Directors on February 3, 2017 to change the name of the plan to the 2016 Long Term Incentive Plan (the "2016 Plan"). The 2016 Plan provides for the issuance of stock options and other awards to employees and directors of, and consultants and advisors to, the Company. The 2016 Plan provides for the issuance of up to 3,000,000 shares of common stock reserved for issuance under the 2016 Plan plus (i) 336,741 shares of common stock that were previously available for grant under the pSivida Corp. 2008 Incentive Plan, as amended (the "2008 Plan") at the Adoption Date and (ii) any additional shares of common stock that would otherwise become available for grant under the 2008 Plan as a result of subsequent termination or forfeiture of awards under the 2008 Plan following the Adoption Date.

On June 27, 2017, a total of 482,000 stock options were granted to employees at an exercise price of \$1.77 per share, the closing price of the Company's common stock at that date, with ratable annual vesting over 3 years and a 10-year term. In addition, on the same date the Company issued (i) 248,500 Restricted Stock Units ("RSUs") to employees with ratable annual vesting over 3 years and (ii) 210,000 Performance Stock Units ("PSUs") to certain employees. The performance conditions associated with the PSU awards are as follows: (a) for one third of the PSUs, upon an FDA acceptance of the Company's NDA submission of Durasert three-year uveitis for review on or before March 31, 2018 and (b) for two-thirds of the PSUs, upon an FDA approval of Durasert three-year uveitis on or before March 31, 2019. For each performance criteria that is achieved, 50% of the underlying stock units that are associated with that performance condition will vest at the achievement date and 50% will vest on the first anniversary of such date. No stock-based compensation was recorded in fiscal 2017 in connection with the PSUs.

The Company measures the fair value of options on their grant date using the Black-Scholes option-pricing model. Based upon limited option exercise history, the Company has generally used the "simplified" method outlined in SEC Staff Accounting Bulletin No. 110 to estimate the expected life of stock option grants. Management believes that the historical volatility of the Company's stock price on NASDAQ best represents the expected volatility over the estimated life of the option. The risk-free interest rate is based upon published U.S. Treasury yield curve rates at the date of grant corresponding to the expected life of the stock option. An assumed dividend yield of zero reflects the fact that the Company has never paid cash dividends and has no intentions to pay dividends in the foreseeable future.

[Table of Contents](#)

The key assumptions used to apply the option pricing model for options granted under the 2016 Plan during the year ended June 30, 2017 were as follows:

	<u>2017</u>
Option life (in years)	6.0
Stock volatility	70.9%
Risk-free interest rate	1.94%
Expected dividends	0.0%

The grant date fair value of the option grants was \$1.13 per share. At June 30, 2017, all of the stock options granted were outstanding and had no intrinsic value.

At June 30, 2017, a total of 3,903,447 shares of common stock were authorized for issuance under the 2016 Plan, of which 2,962,947 shares were available for new awards.

2008 Incentive Plan

The 2008 Plan provides for the issuance of stock options and other stock awards to directors, employees and consultants. As of December 12, 2016, which was the effective date of the 2016 Plan, there were 336,741 shares available for grant of future awards under the 2008 Plan, which were carried over to the 2016 Plan. Effective as of such date, the Compensation Committee terminated the 2008 Plan in all respects, other than with respect to previously-granted awards, and no additional stock options and other stock awards will be issued under the 2008 Plan. Subsequent to December 12, 2016 and through June 30, 2017, an additional 566,706 stock options under the 2008 Plan were forfeited and became available for grant under the 2016 Plan.

Options to purchase a total of 1,535,000 shares were granted during fiscal 2017 at exercise prices equal to the closing market price of the Company's common stock on NASDAQ on the respective option grant dates. Of this total, the Company granted 1,405,300 options to employees with ratable annual vesting over 4 years, 90,000 options to non-executive directors with 1-year cliff vesting and 40,000 options to a newly appointed non-executive director with ratable vesting over 3 years. All option grants have a 10-year term.

The key assumptions used to apply the option pricing model for options granted under the 2008 Plan during the years ended June 30, 2017, 2016 and 2015 were as follows:

	<u>2017</u>	<u>2016</u>	<u>2015</u>
Option life (in years)	5.50 - 6.25	5.50 - 6.25	5.50 - 6.25
Stock volatility	70% - 72%	76% - 80%	79% - 93%
Risk-free interest rate	1.23% - 2.08%	1.47% - 1.97%	1.70% - 2.00%
Expected dividends	0.0%	0.0%	0.0%

The following table summarizes information about stock options under the 2008 Plan for the years ended June 30, 2017, 2016 and 2015 (in thousands except per share amounts):

	<u>2017</u>	<u>2016</u>	<u>2015</u>
Weighted-average grant date fair value per share	\$1.95	\$2.74	\$3.33
Total cash received from exercise of stock options	99	490	235
Total intrinsic value of stock options exercised	53	967	257

[Table of Contents](#)

The following table provides a reconciliation of stock option activity under the 2008 Plan for fiscal 2017:

	Number of options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at July 1, 2016	4,981,421	\$ 3.60		
Granted	1,535,300	3.24		
Exercised	(84,080)	1.18		
Forfeited	(868,956)	3.95		
Outstanding at June 30, 2017	<u>5,563,685</u>	<u>\$ 3.48</u>	<u>4.64</u>	<u>\$ 128</u>
Outstanding at June 30, 2017—vested or unvested and expected to vest	<u>5,442,815</u>	<u>\$ 3.47</u>	<u>4.56</u>	<u>\$ 128</u>
Exercisable at June 30, 2017	<u>3,716,651</u>	<u>\$ 3.50</u>	<u>2.62</u>	<u>\$ 128</u>

Inducement Option Grant

In connection with the September 15, 2016 hire of the Company's President and CEO, the Company granted, as an inducement award, 850,000 options to purchase common stock with ratable annual vesting over 4 years, an exercise price of \$3.63 per share and a 10-year term. Although the stock options were not awarded under the 2008 Plan, the stock options are subject to and governed by the terms and conditions of the 2008 Plan. The grant date fair value of \$0.84 per share, measured at the Adoption Date, was determined based upon assumptions of an option life of 6.25 years, historical stock volatility of 70%, a risk-free interest rate of 2.13% and expected dividends of 0%.

Restricted Stock Units

During the year ended June 30, 2017, the Company issued 700,000 market-based Restricted Stock Units ("market-based RSUs") to two employees, which included 500,000 as an inducement grant to the Company's President and CEO and 200,000 issued under the 2008 Plan. The market-based RSUs vest based upon a relative percentile rank of the 3-year change in the closing price of the Company's common stock compared to that of the companies that make up the NASDAQ Biotechnology Index ("NBI"). The Company estimated the fair value of the market-based RSUs using a Monte Carlo valuation model on the respective dates of grant, using the following key assumptions:

Grant date stock price	<u>2017</u> \$1.91 - \$3.63
Stock volatility	50% - 60%
Risk-free interest rate	0.87% - 0.98%
Expected dividends	0.0%

The weighted-average grant date fair value of the market-based RSUs was \$1.35 per share.

[Table of Contents](#)

Stock-Based Compensation Expense

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

	Year Ended June 30,		
	2017	2016	2015
Compensation expense included in:			
Research and development	\$1,109	\$ 702	\$ 676
General and administrative	1,347	1,461	1,285
	<u>\$2,456</u>	<u>\$2,163</u>	<u>\$1,961</u>

In connection with termination benefits provided to the Company's former Chief Executive Officer, the vesting of certain options was accelerated in accordance with the terms of the options, the exercise period for all vested options was extended through September 14, 2017, and all remaining non-vested options were forfeited. Additionally, in connection with the U.K. restructuring, the exercise period of all vested options held by the former U.K. employees was extended through June 30, 2017 and all non-vested options were forfeited. These option modifications and forfeitures were accounted for in the quarter ended September 30, 2016, the net effect of which resulted in an approximate \$274,000 increase of stock-based compensation expense included in general and administrative expense and an approximate \$35,000 reduction of stock-based compensation expense included in research and development expense for the year ended June 30, 2017 in the table above.

In connection with termination benefits provided to the Company's former Vice President, Corporate Affairs and General Counsel, the vesting of certain options was accelerated in accordance with the terms of the options, the exercise period for all vested options was extended through June 28, 2018 and all remaining non-vested options were forfeited. The option modification and forfeitures were accounted for in the quarter ended December 31, 2016, the net effect of which resulted in an approximate \$104,000 reduction of stock-based compensation expense included in general and administrative expense for the year ended June 30, 2017 in the table above.

At June 30, 2017, there was approximately \$4.2 million of unrecognized compensation expense related to outstanding stock options under the 2008 Plan, the inducement stock option grant to the Company's President and CEO, the market-based RSU awards and the stock options, RSU awards and PSU awards issued under the 2016 Plan, which is expected to be recognized as expense over a weighted-average period of approximately 2.04 years.

12. Retirement Plans

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

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

The Company contributed a total of \$193,000 for fiscal 2017, \$209,000 for fiscal 2016 and \$187,000 for fiscal 2015 in connection with these retirement plans.

[Table of Contents](#)

13. Income Taxes

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

	Year Ended June 30,		
	2017	2016	2015
U.S. operations:			
Current income tax expense	\$—	\$ 4	\$ 263
Deferred income tax benefit	—	—	—
	<u>—</u>	<u>4</u>	<u>263</u>
Non-U.S. operations:			
Current income tax benefit	—	(159)	(167)
Deferred income tax benefit	—	—	—
	<u>—</u>	<u>(159)</u>	<u>(167)</u>
Income tax (benefit) expense	<u>\$—</u>	<u>\$ (155)</u>	<u>\$ 96</u>

The significant components of domestic income tax expense for the fiscal year ended June 30, 2015 included a provision for current income tax expense of \$2.8 million, less a tax benefit of operating loss carry forwards of \$2.5 million, resulting in a net domestic income tax expense of \$263,000, which represented federal alternative minimum tax based on taxable income for the tax year ended December 31, 2014. During the fiscal years ended June 30, 2016 and 2015, the Company also recognized a current income tax benefit of \$159,000 and \$167,000, respectively, related to foreign research and development tax credits earned by its U.K. subsidiary.

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

	Year Ended June 30,		
	2017	2016	2015
U.S. operations	\$(17,566)	\$(19,780)	\$ 8,120
Non-U.S. operations	(919)	(1,922)	(1,677)
(Loss) income before income taxes	<u>\$(18,485)</u>	<u>\$(21,702)</u>	<u>\$ 6,443</u>

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

	Year Ended June 30,		
	2017	2016	2015
Income tax (benefit) expense at statutory rate	\$(6,284)	\$(7,379)	\$ 2,191
State income taxes, net of federal benefit	(928)	(1,044)	435
Non-U.S. income tax rate differential	(121)	778	137
Research and development tax credits	(242)	(397)	(313)
Capital loss expiration	—	—	511
Permanent items	(9)	216	236
Changes in valuation allowance	7,489	6,789	(3,572)
Other, net	95	882	471
Income tax (benefit) expense	<u>\$ —</u>	<u>\$ (155)</u>	<u>\$ 96</u>

[Table of Contents](#)

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

	June 30,	
	2017	2016
Deferred tax assets:		
Net operating loss carryforwards	\$39,439	\$31,299
Deferred revenue	20	2,198
Stock-based compensation	5,107	4,111
Tax credits	1,727	1,484
Other	186	141
Total deferred tax assets	<u>46,479</u>	<u>39,233</u>
Deferred tax liabilities:		
Intangible assets	123	367
Deferred tax assets, net	46,356	38,866
Valuation allowance	<u>46,356</u>	<u>38,866</u>
Total deferred tax liability	<u>\$ —</u>	<u>\$ —</u>

The valuation allowance generally reflects limitations on the Company's ability to use the tax attributes and reduce the value of such attributes to the more-likely-than-not realizable amount. Management assessed the available positive and negative evidence to estimate if sufficient taxable income will be generated to use the existing net deferred tax assets. Based on a weighting of the objectively verifiable negative evidence in the form of cumulative operating losses over the three-year period ended June 30, 2017, management believes that it is not more likely than not that the deferred tax assets will be realized and, accordingly, a full valuation allowance has been established. The valuation allowance increased \$7.5 million and \$6.8 million during the fiscal years ended June 30, 2017 and 2016, respectively, with such increases attributed to the re-measurement of the net deferred tax assets at the year-end dates. The valuation allowance decreased \$3.6 million during the fiscal year ended June 30, 2015, which is attributed to the consumption of \$2.5 million in tax benefits from domestic net operating loss carry forwards and a decrease of \$1.1 million attributed to re-measurement of the remaining net deferred tax assets which continue to bear a full valuation allowance.

The Company has tax net operating loss and tax credit carry forwards in its individual tax jurisdictions. At June 30, 2017, the Company had U.S. federal net operating loss carry forwards of approximately \$92.6 million, which expire at various dates between calendar years 2023 and 2037. The utilization of certain of these loss and tax credit carry forwards may be limited by Sections 382 and 383 of the Internal Revenue Code as a result of historical or future changes in the Company's ownership. At June 30, 2017, the Company had state net operating loss carry forwards of approximately \$51.6 million, which expire between 2033 and 2037, as well as U.S. federal and state research and development tax credit carry forwards of approximately \$1.2 million, which expire at various dates between calendar years 2017 and 2037. In addition, at June 30, 2017 the Company had net operating loss carry forwards in the U.K. of £21.1 million (approximately \$27.4 million), which are not subject to any expiration dates.

The Company's U.S. federal income tax returns for calendar years 2003 through 2016 remain subject to examination by the Internal Revenue Service. The Company's U.K. tax returns for fiscal years 2006 through 2016 remain subject to examination. The Australian tax returns for the Company's predecessor for fiscal years 2004 through 2008 remain subject to examination.

Through June 30, 2017, the Company had no unrecognized tax benefits in its consolidated statements of comprehensive (loss) income and no unrecognized tax benefits in its consolidated balance sheets as of June 30, 2017 or 2016.

As of June 30, 2017 and 2016, the Company had no accrued penalties or interest related to uncertain tax positions.

14. Commitments and Contingencies

Operating Leases

The Company leases approximately 13,650 square feet of combined office and laboratory space in Watertown, Massachusetts under a lease with a term from March 2014 through April 2019, with a five-year renewal option at market rates. The Company provided a cash-collateralized \$150,000 irrevocable standby letter of credit as security for the Company's obligations under the lease. In addition to base rent, the Company is obligated to pay its proportionate share of building operating expenses and real estate taxes in excess of base year amounts.

Commencing July 1, 2017, the Company leases approximately 3,000 square feet of office space in Liberty Corner, New Jersey under a lease term extending through June 2022, with two five-year renewal options at 95% of the then-prevailing market rates. In addition to base rent, the Company is obligated to pay its proportionate share of building operating expenses and real estate taxes in excess of base year amounts.

In addition, the Company occupied approximately 2,200 square feet of laboratory and office space in Malvern, U.K. under a lease with a term that expired on August 31, 2016. The lease term was extended through November 2016 to facilitate an orderly transition of the closure of the U.K. facility. The Company subsequently entered into a lease for smaller office space that commenced December 2017 for a 3-year term, subject to termination by the Company at any time upon one month's advance written notice.

At June 30, 2017, the Company's total future minimum lease payments under non-cancellable operating leases were as follows (in thousands):

<u>Fiscal Year:</u>	
2018	\$ 510
2019	445
2020	77
2021	78
2022	80
	<u>\$1,190</u>

Rent expense related to the Company's real estate and other operating leases charged to operations was approximately \$442,000 for fiscal 2017, \$485,000 for fiscal 2016 and \$494,000 for fiscal 2015.

Legal Proceedings

In December 2014, the Company exercised its right under the Prior Alimera Agreement to conduct an audit by an independent accounting firm of Alimera's commercialization reporting for ILUVIEN for calendar 2014. In April 2016, the independent accounting firm issued its report, which concluded that Alimera under-reported net profits payable to the Company for 2014 by \$136,000. In June 2016, Alimera remitted \$354,000 to the Company, which consisted of the under-reported net profits plus interest and reimbursement of the audit costs of \$204,000. In July 2016, Alimera filed a demand for arbitration with the American Arbitration Association ("AAA") in Boston, Massachusetts to dispute the audit findings and requested a full refund of the \$354,000 previously paid to the Company. Pending the arbitration outcome, \$136,000 of net profits participation had been recorded as deferred revenue and the remaining \$218,000 as accrued expenses at each of March 31, 2017 and June 30, 2016.

On May 3, 2017, the parties reached a settlement of the arbitration, which was dismissed with prejudice. As a result of the settlement, the \$136,000 of net profits became fixed and determinable, while the gain contingency resulting from reimbursement of the audit costs of \$204,000 became resolved. Accordingly, these transactions were recognized in the fourth quarter of fiscal 2017.

[Table of Contents](#)

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

15. Segment and Geographic Area Information

Business Segment

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

Geographic Area Information

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

	Revenues			Long-lived assets, net	
	2017	2016	2015	2017	2016
U.S.	\$7,439	\$1,520	\$26,465	\$ 313	\$ 277
U.K.	100	100	100	—	13
Consolidated	<u>\$7,539</u>	<u>\$1,620</u>	<u>\$26,565</u>	<u>\$ 313</u>	<u>\$ 290</u>

16. Quarterly Financial Data (unaudited)

The following table summarizes the quarterly results of operations for the years ended June 30, 2017 and 2016 (in thousands except per share amounts):

	Fiscal Year 2017				
	First Quarter Ended September 30, 2016	Second Quarter Ended December 31, 2016 (1)	Third Quarter Ended March 31, 2017	Fourth Quarter Ended June 30, 2017	Year Ended June 30, 2017
Total revenues	\$ 277	\$ 5,971	\$ 590	\$ 701	\$ 7,539
Operating loss	(7,186)	(94)	(5,160)	(6,136)	(18,576)
Net loss	(7,162)	(67)	(5,140)	(6,116)	(18,485)
Net loss per share—basic and diluted	\$ (0.21)	\$ —	\$ (0.15)	\$ (0.16)	\$ (0.52)
Weighted average common shares—basic and diluted	34,175	34,177	34,366	38,673	35,344

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

(1) Results for the second quarter of fiscal 2017 included \$5.6 million of revenue recognized as a result of the December 2016 termination of the Company's Restated Pfizer Agreement (see Note 3).

CERTIFICATE OF AMENDMENT OF THE
CERTIFICATE OF INCORPORATION
OF
PSIVIDA CORP.

pSivida Corp. (the "Corporation"), a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware (the "DGCL"), for the purpose of amending its Certificate of Incorporation, as amended (the "Certificate of Incorporation"), in accordance with the DGCL, does hereby make and execute this Certificate of Amendment to the Certificate of Incorporation, and does hereby certify that:

1. The Board of Directors of the Corporation (the "Board"), acting in accordance with the provisions of Sections 141 and 242 of the DGCL, adopted resolutions amending its Certificate of Incorporation, so that effective upon the effective time of this Certificate of Amendment to the Certificate of Incorporation with the Secretary of State of the State of Delaware, Article 4 of the Certificate of Incorporation is hereby amended by striking out Article 4 thereof and by substituting in lieu of said Article the following new Article 4:

"4. The corporation shall have two classes of stock, Common Stock, US\$.001 par value per share, and Preferred Stock, US\$.001 par value per share. The total number of shares that the corporation shall have authority to issue is 120,000,000 shares of Common Stock and 5,000,000 shares of Preferred Stock. Subject to the limitations prescribed by law and the provisions of this certificate of incorporation, the board of directors of the corporation is authorized to issue the Preferred Stock from time to time in one or more series, each of such series to have such voting powers, full or limited, or no voting powers, and such designations, preferences and relative, participating, optional or other special rights, and such qualifications, limitations or restrictions thereof, as shall be determined by the board of directors in a resolution or resolutions providing for the issue of such Preferred Stock. Subject to the powers, preferences and rights of any Preferred Stock, including any series thereof, having any preference or priority over, or rights superior to, the Common Stock and except as otherwise provided by law, the holders of the Common Stock shall have and possess all powers and voting and other rights pertaining to the stock of this corporation and each share of Common Stock shall be entitled to one vote."

2. Thereafter, pursuant to a resolution of the Board, a special meeting of the stockholders of the Corporation was duly called and held upon notice in accordance with Section 222 of the DGCL at which meeting the necessary number of shares as required by statute were voted in favor of the foregoing amendment.

3. The foregoing amendment has been duly adopted in accordance with the provisions of Section 242 of the DGCL by the vote of a majority of outstanding stock of the Corporation entitled to vote thereon.

4. This Certificate of Amendment of the Certificate of Incorporation shall be effective upon its filing with the Secretary of State of the State of Delaware.

IN WITNESS WHEREOF, I have signed this Certificate this 27th day of June, 2017.

/s/ Nancy S. Lurker

Nancy S. Lurker

President and Chief Executive Officer

July 7, 2016

Dr. Dario Paggiarino

Dear Dario:

Our management team and board have enjoyed very much our interactions over the last several months and, as a result, I am pleased to offer you the position of Chief Medical Officer at pSivida US, Inc., based in Watertown, MA.

If you accept our offer, your starting date, to be mutually agreed, will be no later than July 31, 2016 or earlier if you so desire. Your initial salary will be at the rate of \$385,000 per year, payable in accordance with the regular payroll practices of the Company. As the position is based in Watertown, MA, you will be expected ultimately to relocate to the Boston area. Until such time, in order to ensure your rapid and proper integration into our operations, you will be required to be physically present in the Watertown office each week. Also, you will be eligible to enter into an employment agreement which includes a payment equal to 100% of your annual base salary in the event, after the 3 month anniversary of your date of employment, the Company terminates your employment without cause or you terminate your employment for good cause (in each case as defined in the employment agreement provided to you by the Company).

Subject to approval of the Board of Directors, the Company will grant you an option to acquire 230,000 shares of the Company's Common Stock.

During your employment, you will be eligible to participate in all benefit plans made generally available by the Company from time to time to employees, subject to plan terms and generally applicable Company policies.

You will be expected to devote your full business time and your best professional efforts to the performance of your duties and responsibilities and to abide by all Company policies and procedures (including execution of the Company's standard Employee Confidentiality, Proprietary Rights and Noncompetition Agreement), as in effect from time to time. It is, of course, understood that all employees may be subject to promotion, transfer, or reassignment from time to time, as the Company determines appropriate.

This letter and your response are not meant to constitute a contract of employment for a specific term. Employment with the Company is at-will. This means that, if you accept this offer, both you and the Company will retain the right to terminate your employment at any time, with or without notice or cause.

The Immigration Reform and Control Act requires employers to verify employment eligibility and identity of new employees. The Company must have appropriate documents to establish your eligibility to work in the United States (e.g., Social Security Card, Drivers' License, U.S. Passport).

In accepting this offer, you give us assurance that you have not relied on any agreements or representations, express or implied, with respect to your employment that are not set forth expressly in this letter.

This offer will expire at 5:00 p.m. on July 14, 2016. Please indicate your acceptance of this offer by signing and returning to the Company the original offer letter and the Company's standard Employee Confidentiality, Proprietary Rights and Noncompetition Agreement.

Dario, I am looking forward to your joining the pSivida team!

Sincerely,

pSivida US, Inc.

By: /s/ Paul Ashton

Name: Paul Ashton

Title: President & CEO

Accepted and agreed:

By: /s/ Dario Paggiarino

Name: Dario Paggiarino, MD

Date: July 13, 2016

**PSIVIDA CORP.
2016 LONG TERM INCENTIVE PLAN**

**RESTRICTED STOCK UNIT AGREEMENT
(EXECUTIVE OFFICERS)
COVER SHEET**

pSivida Corp., a Delaware corporation (the “**Company**”), hereby grants an Award of Restricted Stock Units to the Participant named below (the “**RSUs**”). Each RSU represents the right to receive one share of common stock of the Company, par value \$0.001 per share (the “**Common Stock**”), subject to the terms and conditions set forth on this Cover Sheet and in the attached Restricted Stock Unit Agreement (together, the “**Agreement**”), as well as in the Company’s 2016 Long Term Incentive Plan (as amended from time to time, the “**Plan**”).

Participant Name:

Grant Date:

Number of Shares of Common Stock Underlying the RSUs:

Vesting Schedule: One-third (1/3) of the RSUs shall vest on each of the first, second and third anniversaries of the Grant Date, subject to the Participant’s continued Employment through the applicable vesting date, provided that if the number of RSUs is not divisible by three, then no fractional RSUs shall vest and the installments shall be as equal as possible with the smaller installments vesting first.

By the Participant’s signature below, the Participant agrees to all of the terms and conditions described in the Agreement and in the Plan, a copy of which shall be provided on request. The Participant further acknowledges that the Participant has carefully reviewed the Plan, and agrees that the Plan shall control in the event any provision of this Agreement should appear to be inconsistent with the Plan.

Participant: _____ Date: _____
[Name]

Company: _____ Date: _____
[Name]
[Title]

Attachment

This is not a share certificate or a negotiable instrument.

PSIVIDA CORP.
2016 LONG TERM INCENTIVE PLAN

RESTRICTED STOCK UNIT AGREEMENT

Restricted Stock Units	This Agreement evidences an Award of RSUs in the number set forth on the Cover Sheet of this Agreement and subject to the vesting and other terms and conditions set forth in this Agreement and in the Plan.
Vesting	The RSUs shall vest in accordance with the Vesting Schedule set forth on the Cover Sheet, subject to the Participant's continued Employment through each vesting date. The Participant may not vest in more than the number of shares of Common Stock underlying the RSUs, as set forth on the Cover Sheet of this Agreement.
Termination of Employment	<p>Unless the termination of the Participant's Employment triggers accelerated vesting or other treatment of the RSUs pursuant to the terms of this Agreement, the Participant shall immediately and automatically forfeit to the Company all of the unvested RSUs in the event the Participant's Employment terminates for any reason.</p> <p>Upon a termination of the Participant's Employment by reason of any involuntary termination without Cause (as defined in the Employment Agreement between the Company and the Participant, dated as of [Date] (the "Employment Agreement")) or a voluntary termination for Good Cause (as defined in the Employment Agreement) (such termination, a "Qualifying Termination"), any unvested RSUs that would have vested as of the first anniversary of the termination of the Participant's Employment had the Participant continued in Employment through such first anniversary shall vest immediately upon such termination of Employment. Notwithstanding the foregoing, if the Participant's Qualifying Termination occurs within twenty-four (24) months after a Change of Control (as defined below) in which the RSUs are assumed by the acquirer or surviving entity in the Change of Control transaction, then the RSUs shall automatically vest in full upon such termination of Employment.</p> <p>For purposes of this Agreement, "Employment" shall be deemed to include employment with any successor to the Company's business or assets in connection with a Change of Control.</p>
Covered Transaction	In the event of a Covered Transaction, the RSUs shall be treated in the manner so provided in Section 7 of the Plan.
Change of Control Definition	<p>For purposes of this Agreement, the term "Change of Control" shall mean:</p> <p>(A) the acquisition by any Person (defined as any individual, entity or group (within the meaning of Section 13(d)(3) or Section 14(d)(2) of the</p>

Securities Exchange Act of 1934, as amended (“**Exchange Act**”)) of beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Exchange Act) of 35% or more of the common stock of the Company; provided, however, that for purposes of this subsection (A), an acquisition shall not constitute a Change of Control if it is: (i) either by or directly from the Company, or by an entity controlled by the Company, (ii) by any employee benefit plan, including any related trust, sponsored or maintained by the Company or an entity controlled by the Company (“Benefit Plan”), or (iii) by an entity pursuant to a transaction that complies with the clauses (i), (ii) and (iii) of subsection (C) below; or

- (B) individuals who, as of the Grant Date, constitute the Board (together with the individuals identified in the proviso to this subsection (B), the “Incumbent Board”) cease for any reason to constitute at least a majority of the Board; provided, however, that any individual becoming a director subsequent to the Grant Date whose election, or nomination for election by the Company’s stockholders, was approved by at least a majority of the directors then comprising the Incumbent Board shall be treated as a member of the Incumbent Board unless he or she assumed office as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents by or on behalf of a Person other than the Board; or
- (C) consummation of a reorganization, merger or consolidation involving the Company, or a sale or other disposition of all or substantially all of the assets of the Company (a “**transaction**”), in each case unless, following such transaction, (i) all or substantially all of the Persons who were the beneficial owners of the common stock of the Company outstanding immediately prior to such transaction beneficially own, directly or indirectly, more than 50% of the combined voting power of the then outstanding voting securities of the entity resulting from such transaction (including, without limitation, an entity which as a result of such transaction owns the Company or all or substantially all of the Company’s assets either directly or through one or more subsidiaries) in substantially the same proportions as their ownership, immediately prior to such transaction, of the outstanding common stock of the Company, (ii) no Person (excluding any entity or wholly owned subsidiary of any entity resulting from such transaction or any Benefit Plan of the Company or such entity or wholly owned subsidiary of such entity resulting from such transaction) beneficially owns, directly or indirectly, 35% or more of the combined voting power of the then outstanding voting securities of such entity except to the extent that such ownership existed prior to the transaction and (iii) at least a majority of the members of the board of directors or similar board of the entity resulting from such transaction were members of the Incumbent Board at the time of the execution of the initial agreement, or of the action of the Board, providing for such transaction; or

(D) approval by the stockholders of the Company of a liquidation or dissolution of the Company.

Notwithstanding any other provision of this Agreement to the contrary, the RSUs shall not vest or become eligible to vest on any date specified above unless the Participant has continuously been, since the Grant Date until the date immediately prior to such termination of Employment, an Employee of the Company, any Affiliate, any of their respective subsidiaries, or, following a Change of Control, any successor to the Company's business or assets in connection with the Change of Control.

Leaves of Absence

For purposes of the RSUs, the Participant's Employment does not terminate when the Participant goes on a *bona fide* employee leave of absence that the Company approves in writing if the terms of the leave provided for continued service crediting or when continued service crediting is required by applicable law or contract. The Participant's Employment terminates in any event when the approved leave ends unless the Participant immediately returns to active employment. The Company, in its sole discretion, determines which leave counts for this purpose and when the Participant Employment terminates for all purposes under the Plan.

Dividend Equivalents

Should any cash dividend or other cash distribution be declared and paid with respect to the shares of Common Stock during the period between the Grant Date and the date or dates on which the RSUs are delivered as shares of Common Stock, the Company shall credit to a dividend equivalent bookkeeping account the value of such dividends or distributions that would have been paid if the outstanding RSUs at the time of the declaration of the dividend were outstanding shares of Common Stock. At the same time that the corresponding RSUs are converted to shares of Common Stock and delivered to the Participant, the Company shall pay to the Participant a lump sum cash payment equal to the value of the dividends credited to the dividend equivalent bookkeeping account that correspond to such RSUs that have become vested; provided, however, that any dividend equivalents that were credited to the Participant's dividend equivalent bookkeeping account that are attributable to RSUs that have been forfeited shall be forfeited and not be payable to the Participant. No interest shall accrue on any dividend equivalents credited to the Participant's dividend equivalent bookkeeping account.

Evidence of Issuance

The issuance of shares of Common Stock with respect to the RSUs shall be evidenced in such a manner as the Administrator, in its discretion, deems appropriate, including, without limitation, book-entry registration or delivery of stock certificates.

Delivery

Delivery of the shares of Common Stock underlying the Participant's vested RSUs shall be made as soon as practicable (but in no event later than thirty (30) days) following the applicable vesting date.

Withholding	<p>In the event that the Company determines that it is required to withhold foreign, federal, state or local tax as a result of the vesting of the RSUs, the delivery of the shares of Common Stock underlying the RSUs or the payment of dividend equivalents pursuant to this Agreement, the Participant, as a condition to such vesting, delivery of shares of Common Stock or payment of dividend equivalents, as applicable, shall make arrangements satisfactory to the Company to enable it to satisfy all withholding requirements. Satisfactory arrangements shall include share withholding and/or delivery of previously owned shares of Common Stock in an amount equal to the applicable withholding or other taxes due; provided; however, that no shares of Common Stock shall be withheld with a value in excess of the maximum statutory rates for the applicable jurisdictions or such greater amount as would not result in adverse accounting consequences to the Company under FASB ASC Topic 718 (or any successor provision)). Notwithstanding the foregoing, the Company may, in its sole discretion, elect to satisfy all applicable withholding requirements by share withholding without the Participant's consent.</p>
Transferability	<p>The RSUs may not be sold, pledged, hypothecated, assigned, margined or otherwise transferred or encumbered by the Participant in any manner, except by will or by the laws of descent and distribution. Any attempted assignment, transfer, pledge, hypothecation or other disposition of the RSUs, or levy of attachment or similar process upon the RSUs not specifically permitted herein, shall be null and void and without effect.</p>
Retention Rights	<p>This Agreement and the RSUs evidenced by this Agreement do not give the Participant the right to be retained by the Company or any Affiliate in any capacity. Unless otherwise specified in any employment or other written agreement between the Participant and the Company or any Affiliate, including the Employment Agreement, the Company and any Affiliate reserve the right to terminate the Participant's Employment at any time and for any reason.</p>
Shareholder Rights	<p>Neither the Participant nor the Participant's estate or heirs have any rights as a shareholder of the Company until the shares of Common Stock have been delivered and either a certificate evidencing the shares of Common Stock has been issued or an appropriate entry has been made on the Company's books. No adjustments are made for dividends, distributions, or other rights if the applicable record date occurs before a certificate is issued or the appropriate book entry is made, except as set forth above or as described in the Plan.</p>
Recovery of Compensation	<p>Notwithstanding anything to the contrary in this Agreement, the Participant acknowledges and agrees that the Administrator shall have the right to cause the Participant to forfeit and disgorge to the Company the RSUs (whether or not vested) and any shares of Common Stock acquired by, or dividend equivalents paid to, the Participant pursuant to the RSUs, with interest and</p>

other related earnings, as the Administrator in its discretion shall determine, (A) if the Participant violates (i) a non-competition, non-solicitation, confidentiality or other restrictive covenant by which the Participant is bound, or (ii) any Company policy applicable to the Participant that provides for forfeiture or disgorgement with respect to incentive compensation that includes Awards under the Plan, and (B) to the extent required by law or applicable stock exchange listing rules, including, without limitation, Section 10D of the Exchange Act and any related Company policy. The Participant agrees to cooperate fully with the Administrator, and to cause any and all permitted transferees of the Participant to cooperate fully with the Administrator, to effectuate any forfeiture or disgorgement required hereunder. Neither the Administrator nor the Company nor any other person, other than the Participant and the Participant's permitted transferees, if any, shall be responsible for any adverse tax or other consequences to the Participant or the Participant's permitted transferees, if any, that may arise in connection with this paragraph.

Applicable Law

The validity and construction of this Agreement shall be governed by, and construed and interpreted in accordance with, the laws of the State of Delaware, other than any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive laws of any other jurisdiction.

The Plan

The text of the Plan is incorporated into this Agreement.

Certain capitalized terms used in this Agreement are defined in the Plan, and have the meaning set forth in the Plan, unless otherwise referenced as being defined in the Employment Agreement.

This Agreement and the Plan constitute the entire understanding between the Participant and the Company regarding the RSUs. Any prior agreements, commitments, or negotiations concerning the RSUs are superseded; except that the Employment Agreement and any other written confidentiality, non-competition, non-solicitation, and/or severance agreement, or any other written agreement between the Participant and the Company or any Affiliate, as applicable, shall supersede this Agreement with respect to its subject matter.

Data Privacy

To facilitate the administration of the Plan, the Company may process personal data about the Participant. This data includes, without limitation, information provided in this Agreement and any changes to such information, other appropriate personal and financial data about the Participant, including the Participant's contact information, payroll information and any other information that the Company deems appropriate to facilitate the administration of the Plan.

By accepting the RSUs, the Participant gives explicit consent to the Company to process any such personal data.

Code Section 409A

The grant of the RSUs under this Agreement is intended to comply with Section 409A of the Code (“**Section 409A**”) to the extent subject thereto, and, accordingly, to the maximum extent permitted, this Agreement shall be interpreted and administered to be in compliance with Section 409A. Notwithstanding anything to the contrary in this Agreement, the Company is not making any representation hereunder as to the particular tax treatment of the RSUs.

To the extent that the RSUs constitute “deferred compensation” under Section 409A, a termination of Employment occurs only upon an event that would be a “separation from service” within the meaning of Section 409A. If, at the time of the Participant’s separation from service, (i) the Participant is a “specified employee” within the meaning of Section 409A, and (ii) the Company makes a good faith determination that an amount payable on account of the Participant’s separation from service constitutes deferred compensation (within the meaning of Section 409A), the payment of which is required to be delayed pursuant to the six (6)-month delay rule set forth in Section 409A to avoid taxes or penalties under Section 409A (the “**Delay Period**”), then the Company shall not pay such amount on the otherwise scheduled payment date but shall instead pay it in a lump sum on the first business day after the Delay Period (or upon the Participant’s death, if earlier), without interest. Each installment of RSUs that vest under this Agreement (if there is more than one installment) shall be considered one of a series of separate payments for purposes of Section 409A.

Disclaimer of Rights

The grant of RSUs under this Agreement shall in no way be interpreted to require the Company to transfer any amounts to a third-party trustee or otherwise hold any amounts in trust or escrow for payment to the Participant. The Participant shall have no rights under this Agreement or the Plan other than those of a general unsecured creditor of the Company. RSUs represent unfunded and unsecured obligations of the Company, subject to the terms and conditions of the Plan and this Agreement.

Notice Delivery

By accepting the RSUs, the Participant agrees that notices may be given to the Participant in writing either at the Participant’s home or mailing address as shown in the records of the Company or any Affiliate or by electronic transmission (including e-mail or reference to a website or other URL) sent to the Participant through the normal process employed by the Company or any Affiliate, as applicable, for communicating electronically with its employees.

By signing this Agreement, the Participant agrees to all of the terms and conditions described above and in the Plan.

**PSIVIDA CORP.
2016 LONG TERM INCENTIVE PLAN**

**PERFORMANCE-BASED RESTRICTED STOCK UNIT AGREEMENT
COVER SHEET**

pSivida Corp., a Delaware corporation (the “**Company**”), hereby grants an Award of performance-based Restricted Stock Units to the Participant named below (the “**PSUs**”). Each PSU represents the right to receive one share of common stock of the Company, par value \$0.001 per share (the “**Common Stock**”), subject to the terms and conditions set forth on this Cover Sheet and in the attached Performance-Based Restricted Stock Unit Agreement (together, the “**Agreement**”), as well as in the Company’s 2016 Long Term Incentive Plan (as amended from time to time, the “**Plan**”).

Participant Name:

Grant Date:

Number of Shares of Common Stock Underlying the PSUs:

Vesting Schedule: The PSUs are eligible to become earned and vested as set forth below in this Agreement.

By the Participant’s signature below, the Participant agrees to all of the terms and conditions described in the Agreement and in the Plan, a copy of which shall be provided on request. The Participant further acknowledges that the Participant has carefully reviewed the Plan, and agrees that the Plan shall control in the event any provision of this Agreement should appear to be inconsistent with the Plan.

Participant: _____
[Name]

Date: _____

Company: _____
[Name]
[Title]

Date: _____

Attachment

This is not a share certificate or a negotiable instrument.

PSIVIDA CORP.
2016 LONG TERM INCENTIVE PLAN

PERFORMANCE-BASED RESTRICTED STOCK UNIT AGREEMENT

**Performance-Based
Restricted Stock
Units**

This Agreement evidences an Award of PSUs in the number set forth on the Cover Sheet of this Agreement and subject to the vesting and other terms and conditions set forth in this Agreement and in the Plan.

Vesting

One-third (1/3) of the PSUs (the "**Acceptance PSUs**") shall become earned if the United States Food and Drug Administration (the "**FDA**") accepts the new drug application ("**NDA**") for Durasert 3-year treatment for posterior segment uveitis on or before March 31, 2018. If the Acceptance PSUs become earned as set forth in the preceding sentence, then fifty percent (50%) of the Acceptance PSUs shall vest on the date of such FDA acceptance (the "**NDA Acceptance Date**"), subject to the Participant's continued Employment through such date, and the remaining fifty percent (50%) of the Acceptance PSUs shall vest on the first anniversary of the NDA Acceptance Date, subject to the Participant's continued Employment through such date. If the Acceptance PSUs do not become earned on or before March 31, 2018, then the Participant shall immediately and automatically forfeit to the Company all of the Acceptance PSUs.

Two-thirds (2/3) of the PSUs (the "**Approval PSUs**") shall become earned if the FDA approves the NDA for Durasert 3-year treatment for posterior segment uveitis on or before March 31, 2019. If the Approval PSUs become earned as set forth in the preceding sentence, then fifty percent (50%) of the Approval PSUs shall vest on the date of such FDA approval (the "**NDA Approval Date**"), subject to the Participant's continued Employment through such date, and the remaining fifty percent (50%) of the Approval PSUs shall vest on the first anniversary of the NDA Approval Date, subject to the Participant's continued Employment through such date. If the Approval PSUs do not become earned on or before March 31, 2019, then the Participant shall immediately and automatically forfeit to the Company all of the Approval PSUs.

The Participant may not vest in more than the number of shares of Common Stock underlying the PSUs, as set forth on the Cover Sheet of this Agreement.

**Termination of
Employment**

The Participant shall immediately and automatically forfeit to the Company all of the unvested PSUs in the event the Participant's Employment terminates for any reason.

Covered Transaction

In the event of a Covered Transaction, the PSUs shall be treated in the manner so provided in Section 7 of the Plan.

Leaves of Absence	For purposes of the PSUs, the Participant's Employment does not terminate when the Participant goes on a <i>bona fide</i> employee leave of absence that the Company approves in writing if the terms of the leave provided for continued service crediting or when continued service crediting is required by applicable law or contract. The Participant's Employment terminates in any event when the approved leave ends unless the Participant immediately returns to active employment. The Company, in its sole discretion, determines which leave counts for this purpose and when the Participant Employment terminates for all purposes under the Plan.
Dividend Equivalents	Should any cash dividend or other cash distribution be declared and paid with respect to the shares of Common Stock during the period between the Grant Date and the date or dates on which the PSUs are delivered as shares of Common Stock, the Company shall credit to a dividend equivalent bookkeeping account the value of such dividends or distributions that would have been paid if the outstanding PSUs at the time of the declaration of the dividend were outstanding shares of Common Stock. At the same time that the corresponding PSUs are converted to shares of Common Stock and delivered to the Participant, the Company shall pay to the Participant a lump sum cash payment equal to the value of the dividends credited to the dividend equivalent bookkeeping account that correspond to such PSUs that have become vested; provided, however, that any dividend equivalents that were credited to the Participant's dividend equivalent bookkeeping account that are attributable to PSUs that have been forfeited shall be forfeited and not be payable to the Participant. No interest shall accrue on any dividend equivalents credited to the Participant's dividend equivalent bookkeeping account.
Evidence of Issuance	The issuance of shares of Common Stock with respect to the PSUs shall be evidenced in such a manner as the Administrator, in its discretion, deems appropriate, including, without limitation, book-entry registration or delivery of stock certificates.
Delivery	Delivery of the shares of Common Stock underlying the Participant's vested PSUs shall be made as soon as practicable (but in no event later than thirty (30) days) following the applicable vesting date.
Withholding	In the event that the Company determines that it is required to withhold foreign, federal, state or local tax as a result of the vesting of PSUs, the delivery of the shares of Common Stock underlying the PSUs or the payment of dividend equivalents pursuant to this Agreement, the Participant, as a condition to such vesting, delivery of shares of Common Stock or payment of dividend equivalents, as applicable, shall make arrangements satisfactory to the Company to enable it to satisfy all withholding requirements. Satisfactory arrangements shall include share withholding and/or delivery of previously owned shares of Common Stock in an amount equal to the

applicable withholding or other taxes due; provided; however, that no shares of Common Stock shall be withheld with a value in excess of the maximum statutory rates for the applicable jurisdictions or such greater amount as would not result in adverse accounting consequences to the Company under FASB ASC Topic 718 (or any successor provision)). Notwithstanding the foregoing, the Company may, in its sole discretion, elect to satisfy all applicable withholding requirements by share withholding without the Participant's consent.

Transferability

The PSUs may not be sold, pledged, hypothecated, assigned, margined or otherwise transferred or encumbered by the Participant in any manner, except by will or by the laws of descent and distribution. Any attempted assignment, transfer, pledge, hypothecation or other disposition of the PSUs, or levy of attachment or similar process upon the PSUs not specifically permitted herein, shall be null and void and without effect.

Retention Rights

This Agreement and the PSUs evidenced by this Agreement do not give the Participant the right to be retained by the Company or any Affiliate in any capacity. Unless otherwise specified in any employment or other written agreement between the Participant and the Company or any Affiliate, including the Employment Agreement, the Company and any Affiliate reserve the right to terminate the Participant's Employment at any time and for any reason.

Shareholder Rights

Neither the Participant nor the Participant's estate or heirs have any rights as a shareholder of the Company until the shares of Common Stock have been delivered and either a certificate evidencing the shares of Common Stock has been issued or an appropriate entry has been made on the Company's books. No adjustments are made for dividends, distributions, or other rights if the applicable record date occurs before a certificate is issued or the appropriate book entry is made, except as set forth above or as described in the Plan.

Recovery of Compensation

Notwithstanding anything to the contrary in this Agreement, the Participant acknowledges and agrees that the Administrator shall have the right to cause the Participant to forfeit and disgorge to the Company the PSUs (whether or not vested) and any shares of Common Stock acquired by, or dividend equivalents paid to the Participant pursuant to the PSUs, with interest and other related earnings, as the Administrator in its discretion shall determine, (A) if the Participant violates (i) a non-competition, non-solicitation, confidentiality or other restrictive covenant by which the Participant is bound, or (ii) any Company policy applicable to the Participant that provides for forfeiture or disgorgement with respect to incentive compensation that includes Awards under the Plan, and (B) to the extent required by law or applicable stock exchange listing rules, including, without limitation, Section 10D of the Exchange Act and any related Company policy. The Participant agrees to cooperate fully with the Administrator, and to cause any and all permitted transferees of the Participant to cooperate fully with the Administrator, to effectuate any forfeiture or disgorgement required

hereunder. Neither the Administrator nor the Company nor any other person, other than the Participant and the Participant's permitted transferees, if any, shall be responsible for any adverse tax or other consequences to the Participant or the Participant's permitted transferees, if any, that may arise in connection with this paragraph.

Applicable Law

The validity and construction of this Agreement shall be governed by, and construed and interpreted in accordance with, the laws of the State of Delaware, other than any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive laws of any other jurisdiction.

The Plan

The text of the Plan is incorporated into this Agreement.

Certain capitalized terms used in this Agreement are defined in the Plan, and have the meaning set forth in the Plan, unless otherwise referenced as being defined in the Employment Agreement.

This Agreement and the Plan constitute the entire understanding between the Participant and the Company regarding the PSUs. Any prior agreements, commitments, or negotiations concerning the PSUs are superseded; except that the Employment Agreement and any other written confidentiality, non-competition, non-solicitation, and/or severance agreement, or any other written agreement between the Participant and the Company or any Affiliate, as applicable, shall supersede this Agreement with respect to its subject matter.

Data Privacy

To facilitate the administration of the Plan, the Company may process personal data about the Participant. This data includes, without limitation, information provided in this Agreement and any changes to such information, other appropriate personal and financial data about the Participant, including the Participant's contact information, payroll information and any other information that the Company deems appropriate to facilitate the administration of the Plan.

By accepting the PSUs, the Participant gives explicit consent to the Company to process any such personal data.

Code Section 409A

The grant of the PSUs under this Agreement is intended to comply with Section 409A of the Code ("**Section 409A**") to the extent subject thereto, and, accordingly, to the maximum extent permitted, this Agreement shall be interpreted and administered to be in compliance with Section 409A. Notwithstanding anything to the contrary in this Agreement, the Company is not making any representation hereunder as to the particular tax treatment of the PSUs.

To the extent that the PSUs constitute “deferred compensation” under Section 409A, a termination of Employment occurs only upon an event that would be a “separation from service” within the meaning of Section 409A. If, at the time of the Participant’s separation from service, (i) the Participant is a “specified employee” within the meaning of Section 409A, and (ii) the Company makes a good faith determination that an amount payable on account of the Participant’s separation from service constitutes deferred compensation (within the meaning of Section 409A), the payment of which is required to be delayed pursuant to the six (6)-month delay rule set forth in Section 409A to avoid taxes or penalties under Section 409A (the “**Delay Period**”), then the Company shall not pay such amount on the otherwise scheduled payment date but shall instead pay it in a lump sum on the first business day after the Delay Period (or upon the Participant’s death, if earlier), without interest. Each installment of PSUs that vest under this Agreement (if there is more than one installment) shall be considered one of a series of separate payments for purposes of Section 409A.

Disclaimer of Rights

The grant of PSUs under this Agreement shall in no way be interpreted to require the Company to transfer any amounts to a third-party trustee or otherwise hold any amounts in trust or escrow for payment to the Participant. The Participant shall have no rights under this Agreement or the Plan other than those of a general unsecured creditor of the Company. PSUs represent unfunded and unsecured obligations of the Company, subject to the terms and conditions of the Plan and this Agreement.

Notice Delivery

By accepting the PSUs, the Participant agrees that notices may be given to the Participant in writing either at the Participant’s home or mailing address as shown in the records of the Company or any Affiliate or by electronic transmission (including e-mail or reference to a website or other URL) sent to the Participant through the normal process employed by the Company or any Affiliate, as applicable, for communicating electronically with its employees.

By signing this Agreement, the Participant agrees to all of the terms and conditions described above and in the Plan.

*** INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

SECOND AMENDED AND RESTATED

COLLABORATION AGREEMENT

BY AND BETWEEN

PSIVIDA US, INC. (f/k/a CONTROL DELIVERY SYSTEMS, INC.)

AND

ALIMERA SCIENCES, INC.

DATED AS OF JULY 10, 2017

TABLE OF CONTENTS

ARTICLE 1	DEFINITIONS	2
ARTICLE 2	DEVELOPMENT ACTIVITIES	13
2.1	Alimera Development Responsibilities	13
2.2	Regulatory Approvals	13
2.3	Performance	17
2.4	Subcontracts	17
2.5	Deliverables.	17
ARTICLE 3	COMMERCIALIZATION	18
3.1	Commercialization of Product(s) in the Collaboration Field	18
3.2	Commercialization and Projections.	18
3.3	Diligence	19
3.4	Costs of Commercialization	21
3.5	Non-Performance.	
3.6	Manufacturing for Commercial Supply Requirements	22
3.7	Product Recalls	22
ARTICLE 4	GRANT OF RIGHTS	22
4.1	Grant of License by pSivida	22
4.2	Grant of License by Alimera	23
4.3	Sublicenses and Subcontracts	23
4.4	Ownership of and Rights to Inventions	25
4.5	Limitation on Use	25
4.6	Reservation of Rights	25
4.7	No Grant of Other Technology or Patent Rights	26
4.8	Clinical IP	26
4.9	Section 365(n) of the Bankruptcy Code	26
ARTICLE 5	FINANCIALS	27
5.1	Royalty Payments	27
5.2	Royalty Offset	28
5.3	Royalty Reports	29

*****] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

5.5	Second Milestone Payment	29
5.6	Consideration from Third Party Agreements.	30
5.7	Records; Audits	30
ARTICLE 6	INTELLECTUAL PROPERTY	31
6.1	pSivida-Prosecuted Patent Rights	31
6.2	Abandonment	32
6.3	Alimera-Prosecuted Patent Rights	33
6.4	Information Disclosure; Cooperation	33
6.5	Employees and sublicensees Assignment of Inventions	34
6.6	Infringement	34
6.7	Marking	37
6.8	Trademarks	37
6.9	UKRF Licenses and B&L Agreement	37
ARTICLE 7	CONFIDENTIALITY	37
7.1	Confidentiality	37
7.2	Disclosure	38
7.3	Disclosure of Agreement	39
ARTICLE 8	REPRESENTATIONS AND WARRANTIES	39
8.1	Representations and Warranties of pSivida	39
8.2	Representations and Warranties of Alimera	41
8.4	Limited Liability	42
ARTICLE 9	INDEMNITY	42
9.1	Cross Indemnity	42
9.2	Limitation on Indemnity Obligations	43
9.3	Procedure	43
9.4	Insurance	44
ARTICLE 10	TERM AND TERMINATION	44
10.1	Term	44
10.2	Termination for Default by Either Party	44
10.4	Effect of Expiration or Termination of the Agreement	46

***** INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

10.5	Survival of Provisions Upon Expiration or Termination	46
ARTICLE 11	MISCELLANEOUS	46
11.1	Interpretation	46
11.2	Primary Contact Persons	47
11.3	Assignment	47
11.4	Severability	47
11.5	Notices	47
11.6	Governing Law and Venue	48
11.7	Compliance with Applicable Laws	49
11.8	Dispute Resolution	49
11.9	Entire Agreement	50
11.10	Headings	50
11.11	Independent Contractors	50
11.12	Waiver	50
11.13	Counterparts	50

*****] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

SECOND AMENDED AND RESTATED COLLABORATION AGREEMENT

THIS SECOND AMENDED AND RESTATED COLLABORATION AGREEMENT (the "Agreement") dated as of July 10, 2017 (the "Amendment Effective Date"), is made by and between pSivida, US, Inc. (f/k/a CONTROL DELIVERY SYSTEMS, INC.), a corporation organized and existing under the laws of the State of Delaware having its offices at 480 Pleasant St., Watertown, Massachusetts 02472 ("pSivida"), and ALIMERA SCIENCES, INC., a corporation organized and existing under the laws of the State of Delaware having its offices at 6120 Windward Parkway, Alpharetta, GA 30005 ("Alimera"). pSivida and Alimera are sometimes referred to herein individually as a "Party" and collectively as the "Parties."

R E C I T A L S

WHEREAS, pSivida designs and develops innovative ophthalmic drug delivery products; and

WHEREAS, Alimera develops and commercializes ophthalmic drug products; and

WHEREAS, the Parties were interested in collaborating with one another and jointly funding the development, and sharing net profits from the sale, of novel products for treating eye diseases in humans, including a product for the treatment of diabetic macular edema using a corticosteroid; and

WHEREAS, pSivida was willing to grant Alimera a license to certain of its proprietary technology and know-how relating to developing products for treating eye diseases; and

WHEREAS, the Parties entered into such a collaboration and licensing relationship upon the terms and conditions set forth in the Collaboration Agreement by and between Control Delivery Systems, Inc. and Alimera Sciences, Inc. (the "Original Agreement") dated as of February 11, 2005 (the "Effective Date"), as amended by Amendment No. 1 dated February 23, 2005 and Amendment No. 2 dated May 11, 2005;

WHEREAS, the Parties entered into an Amended and Restated Collaboration Agreement by and between Control Delivery Systems, Inc. and Alimera Sciences, Inc. (the "First A&R Agreement") dated as of March 14, 2008 (the "First A&R Effective Date");

WHEREAS, as part of a negotiated resolution of an arbitration proceeding and of certain disputes that had arisen between the Parties related to their performances under the First A&R Agreement, the Parties entered into an Amendment to the First A&R Agreement dated May 3, 2017 (the "Settlement Amendment"); and

WHEREAS, Alimera has obtained Approval for, and has commercially launched, ILUVIEN for DME.

*****] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

WHEREAS, pSivida and Alimera desire to enter into this Agreement to amend and restate the First A&R Agreement (as amended prior to the Amendment Effective Date) as of the Amendment Effective Date as set forth herein to, among other things, extend Alimera's rights to include uveitis in Europe, the Middle East and Africa and to replace the net profit share with royalties.

NOW THEREFORE, in consideration of the premises and of the mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto agree as follows:

ARTICLE 1 DEFINITIONS

For purposes of this Agreement, the terms defined in this Article shall have the meanings specified below, whether used in their singular or plural form:

1.1 "Affiliate" shall mean any corporation or other entity that controls, is controlled by, or is under common control with a Party to this Agreement. A corporation or other entity shall be regarded as in control of another corporation or entity if it directly or indirectly owns or controls more than fifty percent (50%) of the voting stock or other ownership interest of the other corporation or entity, or if it possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of the corporation or other entity or the power to elect or appoint more than fifty percent (50%) of the members of the governing body of the corporation or other entity.

1.2 "Africa" shall mean the countries, territories, and all land which, as of the Amendment Effective Date, comprise Algeria, Angola, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Cape Verde, Central African Republic, Chad, Comoros, Democratic Republic of the Congo, Djibouti, Egypt, Equatorial Guinea, Eritrea, Ethiopia, Gabon, Gambia, Ghana, Guinea, Guinea-Bissau, Ivory Coast, Kenya, Lesotho, Liberia, Libya, Madagascar, Malawi, Mali, Mauritania, Mauritius, Mayotte, Morocco, Mozambique, Namibia, Niger, Nigeria, Republic of the Congo, Reunion, Rwanda, Saint Helena, Ascension, and Tristan da Cunha, Senegal, Seychelles, Sierra Leone, Somalia, South Africa, South Sudan, Sudan, Swaziland, Sao Tome and Principe, Tanzania, Togo, Tunisia, Uganda, Western Sahara, Zambia, and Zimbabwe, whether or not any of the foregoing countries remain a part of Africa, and including, without limitation, their successor countries, for example, in the event that one or more parts of any of the foregoing countries secedes or splits from the remainder of such country, one or more parts of one of the foregoing countries combine with one or more parts of any other of the foregoing countries or one of the foregoing countries changes its name.

1.3 "Alimera Improvements" shall mean any and all Improvements created, conceived or reduced to practice by Alimera, or its Affiliates, agents, subcontractors or sublicensees, alone or with others, or by Third Parties acting on their behalf, that are (a) Improvements covered by or derived from practice of the pSivida Technology, and/or (b) Improvements covered by or derived from the practice of the Improvements set forth in clause

[*] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

(a); provided, however, that Alimera Improvements shall not include any Improvement that meets each of the following: (x) is related specifically to an active ingredient provided by Alimera and used in the Products, (y) can be practiced without infringing any pSivida Existing Patent Rights and any Patent Rights included within pSivida Improvements, or without utilizing any pSivida Know-How, and (z) does not fall within the definition of the pSivida Core Technology.

1.4 "Alimera Know-How" shall mean Know-How Controlled by Alimera.

1.5 "Alimera Patent Costs" shall mean fees and costs associated with filing, prosecution and maintenance of the Alimera-Prosecuted Patent Rights, as defined in Section 6.3, in the Territory.

1.6 "Alimera-Prosecuted Patent Rights" shall have the meaning set forth in Section 6.3.1.

1.7 "Amendment Effective Date" shall have the meaning set forth in the preamble.

1.8 "Annual Projections" shall have the meaning set forth in Section 3.2.

1.9 "Approval" shall mean the approvals from applicable regulatory authorities in any country or region required to lawfully market a Product in such country or region, including, but not limited to, approval of an NDA. The term "Approved" shall mean the receipt of Approval.

1.10 "Approval Royalty Date" shall mean the earliest of (a) Approval of the First Product for uveitis, (b) the date that is one year from the filing of the first Marketing Authorization Variance in Europe, and (c) January 1, 2019.

1.11 "Bankruptcy Code" shall mean Title 11 of the United States Code, as amended from time to time.

1.12 "B&L" shall mean Bausch & Lomb Incorporated.

1.13 "B&L Agreement" shall mean the Amended and Restated License Agreement between pSivida and B&L dated as of December 9, 2003 as in existence and effect on the Effective Date, a full and complete copy of which has been provided to Alimera.

1.14 "Business Day" shall mean each day of the week excluding Saturday, Sunday and U.S. federal holidays.

1.15 "Change of Control" shall mean, with respect to a Party, (a) a merger or consolidation of such Party with a Third Party which results in the voting securities of such Party 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,

*****] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

or (b) except in the case of a bona fide equity financing in which a Party issues new shares of its capital stock, 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 (c) the sale or other transfer to a Third Party of all or substantially all of such Party's assets related to the Collaboration Field.

1.16 "Clinical IP" shall mean (a) all preclinical and clinical protocols, studies, data, results, study-related forms, materials 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 any Product in the Collaboration Field that is conducted by or under the direction of Alimera or pSivida, or their Permitted Subcontractors or sublicensees, pursuant to this Agreement, and any audit of any such preclinical or clinical study or trial, and (b) 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, and other regulatory applications and Approvals regarding any Product in the Collaboration Field that are prepared or submitted by or under the direction of Alimera or pSivida, or their Permitted Subcontractors or sublicensees, pursuant to this Agreement; provided, however, that Clinical IP shall not include any Pre-Existing Clinical IP or, for clarity, any of the foregoing (a) or (b) resulting from the Phase III Clinical Trials conducted by pSivida and referenced in Section 2.2.2(b).

1.17 "CODRUG™" shall mean a compound or a pharmaceutically acceptable salt thereof comprising one constituent moiety covalently or ionically associated with at least one other constituent moiety, wherein each moiety, in its separate form (i.e., in the absence of the association), is a therapeutically or pharmacologically active agent or a prodrug or pharmaceutically acceptable salt of such an agent. The covalent association between said moieties can be either direct or indirect through a linker. Examples of covalent association include without limitation ester, amide, carbamate, carbonate, cyclic ketal, thioester, thioamide, thiocarbamate, thiocarbonate, xanthate, and phosphate ester bonds. Each constituent moiety of a CODRUG™ compound can be the same as or different from the other constituent moiety. Upon cleavage of the covalent or ionic association, the individual constituent moieties are reconstituted as the therapeutically or pharmacologically active forms of the same moieties prior to conjugation.

1.18 "Collaboration Field" shall mean (a) in Europe, the Middle East and Africa, the treatment and prevention of eye diseases in humans, and (b) in all other geographic areas of the Territory, the treatment and prevention of eye diseases in humans, provided, however, that the treatment and prevention of uveitis is excluded from the Collaboration Field for item (b).

1.19 "Collaboration Receivable Amount" shall mean, as of the Amendment Effective Date, \$25,000,000, as such amount may be reduced pursuant to Sections 5.2, 5.4 and 5.5.

[*] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

1.20 “Commercialize” or “Commercialization” shall mean any and all activities directed to marketing, promoting, Detailing, distributing, importing, offering for sale, having sold and/or selling a product including, but not limited to, sampling, and conducting Non-NDA Trials and post-approval studies.

1.21 “Commercially Reasonable Efforts” shall mean efforts and resources that parties in the pharmaceutical industry would consider normal to use for a compound or product owned by a party in that industry or to which that party has rights, which is of similar market potential at a similar stage in its Development or product life, taking into account the competitiveness of the marketplace, the proprietary position of the compound or product, the regulatory structure involved, the profitability of the applicable products, and other relevant factors, in each case, as a whole and on a country-by-country basis. In determining Commercially Reasonable Efforts with respect to a particular Product in a particular country, Alimera may consider the effects of a particular Product being Developed or Commercialized in a particular country under this Agreement by Alimera or its Affiliates (or by or through a Third Party on behalf of or under authorization from Alimera or any of its Affiliates) on any other Products being Developed or Commercialized by Alimera or its Affiliates (or by or through a Third Party on behalf of or under authorization from Alimera or any of its Affiliates) in any other countries, including, without limitation, resource allocation, pricing and re-importation concerns. To the extent that it is not in contradiction of the foregoing sentence, in determining Commercially Reasonable Efforts with respect to a particular Product, a Party may not consider any other product(s) owned or licensed by it.

1.22 “Confidential Information” shall have the meaning set forth in Section 7.1 hereof.

1.23 “Control” or “Controlled by” shall mean, in the context of a license to or ownership of intellectual property, possession of the ability on the part of a Party to grant access to or a license or sublicense as provided for herein without violating the terms of any agreement or other arrangement with any Third Party existing at the time such Party would be required hereunder to grant the other Party such access or license or sublicense.

1.24 “Detail” shall mean a face-to-face meeting (including a live video presentation) with one or more healthcare professionals with prescribing authority during which scientific and/or medical information about the Product is discussed. Detailing does not include merely a reminder or a promotional sample drop. When used as a verb, the term “Detailing” shall mean to engage in the activity of a Detail.

1.25 “Development” shall mean to discover, research or otherwise develop a product, including conducting non-clinical and clinical drug development activities related to the development and submission of information to a regulatory authority, including toxicology, pharmacology and other discovery and pre-clinical efforts, test method development and stability testing, process development, formulation development and/or modification, delivery system development and/or modification, quality assurance and quality control development, clinical studies for the purpose of obtaining Approvals, statistical analysis, regulatory affairs and pharmacovigilance. When used as a verb, “Develop” means to engage in Development.

1.26 “Disclosure Obligations” shall have the meaning set forth in Section 7.3.

1.27 “DME” shall mean diabetic macular edema.

1.28 “Durasert FA” shall mean the fluocinolone acetonide intravitreal insert that contains 0.18 mg FA and is designed to release sub-microgram quantities of FA daily over a period of thirty-six (36) months.

1.29 “Effective Date” shall have the meaning set forth in the preambles.

1.30 “Europe” shall mean the countries, territories, and all land which, as of the Amendment Effective Date, comprise Albania, Andorra, Armenia, Austria, Azerbaijan, Belarus, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Georgia, Germany, Greece, Hungary, Iceland, Ireland, Italy, Kazakhstan, Kosovo, Latvia, Liechtenstein, Lithuania, Luxembourg, Macedonia, Malta, Moldova, Monaco, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, San Marino, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine, United Kingdom, and Vatican City, whether or not any of the foregoing remain a part of Europe, and including, without limitation, their successor countries, for example, in the event that one or more parts of any of the foregoing countries secedes or splits from the remainder of such country, one or more parts of one of the foregoing countries combine with one or more parts of any other of the foregoing countries or one of the foregoing countries changes its name.

1.31 “European Filed Countries” shall mean countries in Europe in which Alimera has filed for Approval for ILUVIEN for DME.

1.32 “Excluded Product” shall mean [***] that generally conforms to the drawings and specifications (and any prior iterations thereof in whole or in part) shown in Exhibit 1.32.

1.33 “FDA” shall mean the United States Food and Drug Administration or any successor agency with responsibilities comparable to those of the United States Food and Drug Administration.

1.34 “First A&R Agreement” shall have the meaning set forth in the preambles.

1.35 “First A&R Effective Date” shall have the meaning set forth in the preambles.

1.36 “First Commercial Sale” shall mean, with respect to each Product, the first sale for use or consumption by the general public of such Product for the applicable indication in a country after required Approval has been granted by the applicable regulatory authority of such country.

1.37 “First Milestone Payment” shall have the meaning set forth in Section 5.4.

1.38 “First Product” shall have the meaning set forth in Section 1.64 hereof.

1.39 “Force Majeure Event” shall mean an act of war, flood, riot, insurrection, fire, earthquake, communication line failure, power line failure, explosion, act of God, terrorism, change in applicable law or regulation arising or resulting from the United Kingdom’s withdrawal from the European Union, or any other similar force or cause beyond the reasonable control of a Party, which causes said Party to delay or fail to perform acts in accordance with this Agreement.

1.40 “GAAP” shall mean the United States generally accepted accounting principles, consistently applied.

1.41 “GMP” shall mean then-current good manufacturing practices and standards for the production of active pharmaceutical ingredients, drugs and finished pharmaceuticals, as set forth in (a) 21 C.F.R. Parts 210, 211, 601, 610; (b) the ICH Q7 guidelines; (c) European Directive 2003/94/EC; and (d) the equivalent applicable law in any relevant country, in each case, as amended from time to time, subject to any arrangements, additions, or clarifications agreed to in writing from time to time between the parties.

1.42 “Gross Revenues” shall mean, for any period, on an accrual basis (a) for any arm’s length transaction in which Products are sold separately by Alimera or its Affiliates to a Third Party, the gross invoice price for Products in such transactions, (b) for all other transactions (i.e., other than those described in subsection (a)) in which Products are sold, used or otherwise disposed of by Alimera or its Affiliates (including in barter or similar transactions, or transactions that are not at arm’s length to a Third Party, or transactions in which Products are not sold separately, but not including the provision of Products intended for use solely as samples, including, without limitation, as free clinical trial materials), the total imputed sales price for Products in such transactions, using as the imputed sales price the weighted average gross invoice price for Products under subsection (a) during the preceding calendar quarter for the applicable indication and country or, if there have been no Gross Revenues under subsection (a) in the preceding quarter, using a reasonable imputed price to be determined at the time by the Parties and (c) all other revenue, including but not limited to royalty revenue earned and milestone consideration received, that is earned or received by Alimera or its Affiliates with regard to a Product. For purposes of this Section 1.42, “sold separately” shall mean sold, solely for monetary consideration, on a stand-alone basis (i.e., with a selling price independent of any other product) for not less than arm’s length value.

1.43 “ILUVIEN” shall mean an intravitreal implant containing 0.19 mg of fluocinolone acetonide sold by Alimera in the Territory as of the Amendment Effective Date.

1.44 “Improvements” shall mean any and all Inventions, enhancements, derivatives, new uses, developments, techniques, materials, compounds, products, designs, processes or other technology or intellectual property, whether or not patentable and all Patent Rights and other intellectual property rights in any of the foregoing.

[*] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

1.45 “IND” shall mean the Investigational New Drug Application filed with FDA or a similar application filed with an applicable regulatory authority outside of the United States.

1.46 “Invention” shall mean ideas, information, Know-How, data, research results, writings, inventions, discoveries, modifications, improvements and other technology (including, but not limited to, any proprietary biological or other materials, compounds or reagents and computer software), whether or not patentable or copyrightable.

1.47 “ISO” shall mean a worldwide federation of national standards bodies from some 100 countries, with one standards body representing each member country.

1.48 “Know-How” shall mean unpatented information, whether or not patentable, including, but not limited to, technical information, processes, formulae, trade secrets, materials, designs, drawings and data.

1.49 “Loss” shall have the meaning set forth in Section 9.1.

1.50 “Major European Market” shall mean any of Italy, Spain, the UK, Germany, Portugal or France, whether or not any of the foregoing remain a part of the European Union.

1.51 “Middle East” shall mean the countries, territories, and all land which, as of the Amendment Effective Date, comprise: Bahrain, Iran, Iraq, Israel, Jordan, Kuwait, Lebanon, Oman, the Palestinian Territories, Qatar, Saudi Arabia, Syria, United Arab Emirates, and Yemen, whether or not any of the foregoing remain a part of the Middle East, and including, without limitation, their successor countries, for example, in the event that one or more parts of any of the foregoing countries secedes or splits from the remainder of such country, one or more parts of one of the foregoing countries combine with one or more parts of any other of the foregoing countries or one of the foregoing countries changes its name.

1.52 “NDA” shall mean a new drug application or product license application or its equivalent filed with and accepted by the FDA after completion of human clinical trials to obtain marketing approval for a Product, or any comparable application filed with and accepted by the regulatory authorities of a country other than the United States, including, where applicable, any applications for governmental pricing and marketing approval.

1.53 “Net Revenues” shall mean, with regard to a Product, on an accrual basis, for any period, Gross Revenues less reasonable and customary deductions in accordance with GAAP applied on a consistent basis, however, as points of clarity, (a) the costs associated with administering any contractual and governmental rebates or co-pay assistance program shall be excluded as a deduction from Gross Revenues and (b) in all instances in which Alimera or its Affiliates invoices a sublicensee or distributor separately for the fully burdened cost of a Product

[*] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

(other than amounts specifically identified on such invoice, and invoiced at cost or less, for a Product to be used as samples or for clinical trials), such amounts are to be included as a component of Gross Revenues and Net Revenues upon which Royalties are calculated.

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

1.55 “Original Agreement” shall have the meaning set forth in the preambles.

1.56 “Party” shall mean pSivida or Alimera.

1.57 “Patent Rights” shall mean any United States or foreign patent or patent applications, any patents issuing from such patent applications, and any continuations, continuations-in-part to the extent specifically directed to subject matter specifically described in such patent applications, divisionals, renewals, reexaminations, reissues, extensions or provisional applications of any of the foregoing and any corresponding patent, patent application, utility model, inventor certificate, registration or the like in any country of the world with respect to the foregoing.

1.58 “Permitted Subcontractor” shall mean a Third Party or an Affiliate that has been awarded a subcontract with one Party in accordance with this Agreement.

1.59 “Phase III Clinical Trial” shall mean a clinical trial as defined in 21 C.F.R. 312.21(c), as may be amended from time to time, or any foreign equivalent thereto.

1.60 “Phase IV Clinical Trial” shall mean a post-marketing study of a Product designed to ascertain the efficacy or safety of such Product in certain patient populations or over an extended time period following the Approval of such Product.

1.61 “Pre-Existing Clinical IP” shall mean Clinical IP as defined in the B&L Agreement.

1.62 “Primary Contact Person” shall have the meaning set forth in Section 11.2.

1.63 “Prior Agreements” shall mean the Original Agreement (as amended) and the First A&R Agreement (as amended).

1.64 “Product” shall mean a drug delivery device that meets all of the following criteria: (A) it has a core within a polymer layer that contains a drug in a form other than a CODRUG™ and no other active ingredient, where the core does not include a CODRUG™, (B) it is Approved or designed to be Approved (1) to deliver a corticosteroid and no other active ingredient by implantation, injection, or other direct delivery method to the posterior portion of

the eye, or (2) to treat DME by delivering a compound or formulation by implantation, injection, or other direct delivery method other than through an incision smaller than that required for a 25 gauge needle, (C) it does not fall under the definition of Excluded Product, and (D) it is Approved or designed to be Approved for a particular indication in a particular country. For clarification, eye drops or other topical administration and tablets or other oral administration shall not be deemed to be direct delivery to the posterior portion of the eye. For example, "Product" shall specifically include a drug delivery device that meets all of the following criteria (such product sometimes referred to as the "First Product"): (1) [***]; (2) is Approved or designed to be Approved to be administered [***] (3) is Approved or designed to be Approved [***]; and (4) is Approved or designed to be Approved for a particular indication in a particular country. For clarification, with regard to the same drug delivery device described above, each indication in each country shall be a separate Product. By way of non-limiting examples, with regard to a particular drug delivery device X, (i) X for DME and X for age-related macular degeneration shall be two different Products, and (ii) X for DME in the United States and X for DME in Japan shall be two different Products. The Parties acknowledge that ILUVIEN for DME is a First Product.

1.65 "pSivida Core Technology" shall mean (a) any drug delivery device, or component thereof, for ophthalmic use that includes a core containing one or more drugs, and (b) any method or process for using a device described in clause (a).

1.66 "pSivida Development Activities" shall mean (a) for activities conducted prior to the First A&R Effective Date, pSivida's development activities conducted as set forth in the Development Plan (as defined in the Original Agreement), and (b) for activities conducted on and after the First A&R Effective Date through the Amendment Effective Date, pSivida's development activities conducted to the extent specifically set forth in Section 3.1.2 of the First A&R Agreement.

1.67 "pSivida Existing Patent Rights" shall mean (a) the United States and foreign patents and patent applications listed in Exhibit 1.11A, (b) any Patent Rights arising from those patents and patent applications during the Term, (c) any other patents or patent applications Controlled by pSivida as of the Effective Date, a Valid Claim of which, absent the licenses granted by pSivida to Alimera under Section 4.1, would be infringed by the making, having made, using, selling, offering to sell or importing of a Product in the Collaboration Field by Alimera or its subcontractors or sublicensees as permitted under this Agreement, and (d) any other patents or patent applications Controlled by pSivida as of the Amendment Effective Date, a Valid Claim of which, absent the licenses granted by pSivida to Alimera under Section 4.1, would be infringed by the making, having made, using, selling, offering to sell or importing of ILUVIEN for uveitis in the Collaboration Field by Alimera or its subcontractors or sublicensees as permitted under this Agreement; provided, however, that pSivida Existing Patent Rights shall in no event include the patents and patent applications listed in Exhibit 1.11B or any Patent Rights arising from those patents or patent applications.

1.68 “pSivida Improvements” shall mean any and all Improvements created, conceived or reduced to practice by pSivida, or its Affiliates, agents, or sublicensees, alone or with others or by Third Parties acting on their behalf, during the course of the performance of the pSivida Development Activities (as such term is defined in the First A&R Agreement) by pSivida, that are (a) Improvements covered by or derived from practice of the pSivida Technology, and/or (b) Improvements covered by or derived from the practice of the Improvements set forth in clause (a); provided, however, that pSivida Improvements shall not include any Improvement that is an Alimera Improvement.

1.69 “pSivida Know-How” shall mean Know-How Controlled by pSivida that is required for Development and Commercialization of a Product.

1.70 “pSivida Patent Costs” shall mean fees and costs associated with filing, prosecution and maintenance of the pSivida-Prosecuted Patent Rights, as defined in Section 6.1.1, in the countries listed on Exhibit 1.70.

1.71 “pSivida Patent Rights” shall mean pSivida Existing Patent Rights and pSivida’s interest in any Patent Rights included within Alimera Improvements and pSivida Improvements.

1.72 “pSivida-Prosecuted Patent Rights” shall have the meaning set forth in Section 6.1.1.

1.73 “pSivida Technology” shall mean pSivida Patent Rights, pSivida Know-How and pSivida’s interest in Alimera Improvements and pSivida Improvements.

1.74 “Recall” shall mean any recall of a product or any related actions (e.g., market withdrawal and stock recovery). For avoidance of doubt, Recall includes recall of product packaging.

1.75 “Right of Access to Clinical IP” shall mean the right to reference, cross-reference, review, have access to, incorporate and use Clinical IP in any regulatory applications or filings, any patent filings, or for any research or Development purpose.

1.76 “Royalties” shall have the meaning set forth in Section 5.1.

1.77 “Settlement Agreement” shall mean the Settlement Agreement, dated May 3, 2017, entered into by the Parties.

1.78 “SEC” shall have the meaning set forth in Section 7.3.

1.79 “Second Milestone Payment” shall have the meaning set forth in Section 5.5 hereof.

1.80 “Term” shall have the meaning set forth in Section 10.1.

1.81 “Territory” shall mean all countries and territories worldwide.

1.82 “Third Party” shall mean any person or entity other than pSivida, Alimera or their respective Affiliates.

1.83 “Third Party Consideration” shall mean any form of consideration to the extent that it is not included in Net Revenues (including any non-royalty consideration, milestone consideration, sales-based revenue and amounts paid for equity securities that exceed the fair market value of such securities), earned by Alimera or its Affiliates in connection with a sublicense agreement or other agreement that Alimera or its Affiliates enters into with a Third Party to sublicense, sell or otherwise transfer some or all of Alimera’s rights to a Product that are granted to it under this Agreement, including, but not limited to, marketing rights and/or distribution rights provided that (a) if listed on a national exchange, the fair market value of such securities shall equal the per share fair market value of such securities as listed on the national exchange through which such securities are publicly traded, or (b) if not listed on a national exchange, the fair market value of such securities shall be determined by mutual agreement of the Parties, and if the Parties fail to reach such mutual agreement, the matter shall be resolved by arbitration in accordance with Section 11.8.2 herein. Third Party Consideration shall not include any form of consideration earned by Alimera or its Affiliates for a Change of Control or reimbursement or payment for services or expenses to Alimera or its Affiliates. Third Party Consideration shall also not include amounts received by Alimera or its Affiliates for Product samples or Product provided for clinical trials approximately at or below cost

In the event that Alimera or its Affiliates provides Product samples or Product for clinical trials and the amounts paid or reimbursed to Alimera or its Affiliates by Third Parties for such Product samples or Product for clinical trials that is not reported in Net Revenues exceeds \$25,000 in a calendar quarter, then Alimera shall prepare a report to pSivida that details such amounts paid or reimbursed and its calculation.

1.84 “Third Party Consideration Agreement” shall have the meaning set forth in Section 4.3.

1.85 “Third Party Royalties” shall have the meaning set forth in Section 6.6.4.

1.86 “Type II Variation” shall have the definition as set forth in Commission Regulation (EC) No 1234/2008.

1.87 “UKRF” shall mean the University of Kentucky Research Foundation.

1.88 “UKRF Licenses” shall mean the licenses set forth in Exhibit 1.88, as may be amended from time to time consistent with Section 6.9, full and complete copies of which agreements in effect as of the Amendment Effective Date have been provided to Alimera.

1.89 “Valid Claim” shall mean a claim of an issued and unexpired patent, or a claim of a pending patent application, which has not been withdrawn, cancelled, abandoned, disclaimed, or held permanently revoked, unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal.

ARTICLE 2 DEVELOPMENT ACTIVITIES

2.1 Alimera Development Responsibilities. Alimera shall have sole decision-making authority with respect to the Development of Products in the Collaboration Field, consistent with its other obligations under this Agreement, provided that, if pSivida believes in good faith that a Product-related activity planned, taken or approved to be taken by Alimera in relation to uveitis in Europe, the Middle East or Africa will adversely affect the Development or Commercialization of Durasert FA by pSivida for uveitis outside of such territories, then the Parties shall meet and discuss pSivida’s concerns and Alimera shall consider in good faith pSivida’s concerns and recommendations, provided that Alimera may continue to act in its sole discretion in relation to such activities. If Alimera believes in good faith that a Durasert FA-related activity planned, taken or approved to be taken by pSivida in relation to uveitis outside of Europe, the Middle East or Africa will adversely affect the Development or commercialization of ILUVIEN by Alimera for uveitis in Europe, the Middle East or Africa, then the Parties shall meet and discuss Alimera’s concerns and pSivida shall consider in good faith Alimera’s concerns and recommendations, provided that pSivida may continue to act in its sole discretion in relation to such activities. Without limiting any of Alimera’s rights and pSivida’s obligations under this Agreement, including, without limitation, Alimera’s rights under Sections 5.2 and 5.5 and pSivida’s obligations under Section 2.2.2, Alimera shall be solely responsible for, and shall pay one hundred percent (100%) of, all Development costs for the Product(s) in the Collaboration Field, and pSivida shall have no liability whatsoever hereunder for any past, present or future Development costs.

2.2 Regulatory Approvals.

2.2.1. Regulatory Filings. Unless otherwise agreed in writing by the Parties, Alimera shall be responsible for all U.S. and non-U.S. regulatory matters, including filing an IND and NDA for the First Product in the Collaboration Field, provided that no such regulatory filings by Alimera shall include any Pre-Existing Clinical IP. Alimera shall be responsible for obtaining Approvals and for subsequent maintenance of such Approvals obtained. For all regulatory filings made with Alimera as the sponsor, Alimera shall have the sole authority and responsibility for submitting supplements, communications, annual reports, adverse event reports, manufacturing changes, supplier designations and other related filings to, and for communicating with, the FDA and other regulatory authorities. Alimera shall provide pSivida with copies of all of its submissions or filings for Approval of Products for uveitis in Europe (which are in final form) to regulatory authorities. If reasonably and specifically requested by

*****] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

pSivida, Alimera shall also provide pSivida with copies of any material submissions or filings made by Alimera thereafter in relation to such submissions or filings for Approval of Products for uveitis in Europe. The Parties hereby acknowledge and agree that on June 21, 2017, pSivida filed a Marketing Authorization Application with the European Medicines Agency seeking approval to market its Durasert FA three-year treatment for posterior segment uveitis in the European Union (the "June 2017 MAA").

(a) June 2017 MAA Withdrawal. Within three (3) Business Days following the Amendment Effective Date, pSivida shall, at its own expense, submit to its European Union legal representative a withdrawal letter for the June 2017 MAA. The Parties shall mutually agree upon the language that will be used in such withdrawal letter for explaining the reason(s) for the withdrawal. In the event that the Parties are unable to mutually agree upon such language within three (3) Business Days following the Amendment Effective Date, then such withdrawal letter shall be submitted within one (1) business day following mutual agreement by the Parties on such language. pSivida shall cause, at its own expense, such representative to take all appropriate actions, including, without limitation, submission of such letter within one business day, to (a) withdraw the June 2017 MAA and (b) confirm that such legal representative has no rights in or to any part of the June 2017 MAA. In any event, pSivida shall take all Commercially Reasonable Efforts to file such withdrawal prior to the start of the European Medicines Agency's review of the June 2017 MAA.

(b) Orphan Drug Status Withdrawal. In addition, within three (3) Business Days after pSivida's European Union legal representative has submitted the withdrawal letter for the June 2017 MAA to the European Medicines Agency, pSivida shall, at its own expense, submit to its European Union legal representative a withdrawal letter to withdraw or relinquish Orphan Drug Status in relation to Durasert FA. The Parties shall mutually agree upon the language that will be used in such withdrawal letter for explaining the reason(s) for the withdrawal. In the event that the Parties are unable to mutually agree upon such language within such three (3) Business Day period, then such withdrawal letter shall be submitted within one (1) Business Day following mutual agreement by the Parties on such language. pSivida shall cause, at its own expense, such representative to take all appropriate actions, including, without limitation, submission of such letter, to withdraw or relinquish Orphan Drug Status with the European Union in relation to Durasert FA for pSivida within five (5) Business Days following the submission of such withdrawal letter to pSivida's European Union legal representative.

(c) pSivida acknowledges and agrees that it is solely responsible for any and all amounts owed to its European Union legal representative and the European Medicines Agency in relation to the activities described in paragraphs (a) and (b) above and the June 2017 MAA and such Orphan Drug Status more generally.

2.2.2. Type II Variation Filings. Alimera (itself or through any of its Affiliates, sublicensees and subcontractors) shall file a Type II Variation for uveitis with the appropriate regulatory authorities in at least three (3) of the Major European Markets within [***] of the

[*] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

Amendment Effective Date and shall provide to pSivida validation letters evidencing such appropriate regulatory authorities' acceptances of such Type II Variation filings. In the event that Alimera fails to file Type II Variations for uveitis in at least three (3) of the Major European Markets (or Alimera does not receive validation letters evidencing such filings) in such [***] period, then for each calendar quarter of delay beyond such [***] period, Alimera shall pay to pSivida \$250,000 per calendar quarter (or a pro-rated amount for any portion of any such calendar quarter), unless otherwise provided in subsection (c) below.

(a) pSivida shall provide, in a timely manner, reasonable regulatory and clinical support to Alimera during the filing of the Type II Variations through the Approval of such applications at pSivida's cost and expense (except with respect to reasonable out-of-pocket expenses incurred by pSivida as a result of such support, including costs and expenses related to any services that pSivida must externally contract to provide such support, which shall be reimbursed by Alimera (without mark-up) within forty-five (45) days after receipt of an undisputed invoice therefor that includes reasonable documentation for such expenses), as reasonably requested by Alimera, including assistance in responding to reasonable inquiries by Alimera or any regulatory authority, provided that such support and assistance shall not exceed twenty-five (25) employee hours per month (without the possibility of carrying over any unused hours to subsequent months) without pSivida's consent. If reasonably requested by Alimera, pSivida shall provide reasonable assistance to Alimera to facilitate Alimera entering into contracts with the Third Parties set forth on Schedule 2.2.2(a) that pSivida has engaged or plans to engage for regulatory and/or clinical support in relation to obtaining Approvals for Products for uveitis, provided that any failure or delay by Alimera to enter into any such contract shall not be deemed a delay by pSivida under Section 2.2.2(c) below.

(b) pSivida shall complete, at its cost and expense, (i) its Phase III Clinical Trial conducted at sites in the United States, Europe and India (with a ClinicalTrials.gov identification number of NCT01694186), including, without limitation, completing three (3) years of follow up and producing a final clinical study report, and (ii) its ongoing Phase III Clinical Trial in India (with a ClinicalTrials.gov identification number of NCT02746991), in each case (i) and (ii), provided that there are no regulatory or legal requirements imposed on pSivida with respect to such clinical trial (e.g., receipt of a clinical hold notification) that would render continuation of such clinical trial either clinically or commercially impracticable or unreasonable. pSivida will promptly provide interim and final clinical study reports, as such reports are prepared by pSivida for each of the clinical trials identified above, to Alimera as is required to be included in the Type II Variation documentation at pSivida's cost and expense. In addition, if reasonably requested by Alimera, pSivida shall promptly deliver to Alimera any additional data and other information related to the clinical trials identified above. Alimera may review, incorporate and use such reports and data and other information in any regulatory applications or filings and for any other Development or Commercialization purpose in relation to Products in the Collaboration Field; and

[*] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

(c) Any delay in Alimera's filing of a Type II Variation for uveitis pursuant to this Section 2.2.2 that is attributable to (i) a failure by pSivida to meet its obligations set forth in the foregoing (a) or (b), (ii) a failure by pSivida to meet its obligations set forth in the second sentence of Section 2.2.5(a) or in Section 2.5, but only to the extent of documentation necessary for the filing of such Type II Variation for uveitis, (iii) a Force Majeure Event, or (iv) the requirement of any European regulatory authority as described in Section 2.2.3, shall result in the tolling of the timeframe for such filing (including the accrual of any penalties set forth in this Section 2.2.2) for the duration of such delay. If a Force Majeure Event has caused a delay in Alimera's filing of a Type II Variation for uveitis pursuant to this Section 2.2.2, then Alimera shall notify pSivida promptly of such delay and use Commercially Reasonable Efforts to overcome such Force Majeure Event.

2.2.3. Additional Clinical Trials. In the event that any European Union regulatory authority requires two (2) clinical trials for Approval in three (3) or more of the Major European Markets, then the Parties shall meet and negotiate in good faith a revised timeline for the Type II Variation filings, including a revised timeframe for the Second Milestone Payment set forth in Section 5.5.

2.2.4. Manufacture-related Activities. Alimera shall be responsible for preparing and submitting all documentation to regulatory authorities regarding the manufacture of the Product in the Collaboration Field for commercial sale necessary to obtain Approvals for such Product in the Collaboration Field. Alimera shall be responsible for all activities related to pre-Approval inspections of Alimera's (or its subcontractor's) manufacturing facility.

2.2.5. Documentation. Each Party shall maintain all records, including, but not limited to, batch records and supporting documentation required by the FDA and other applicable regulatory authorities, with respect to each Product for the periods of time required by such authorities. Upon reasonable request by the other Party, (a) pSivida shall provide Alimera promptly with reasonable access to (i) documents for Durasert FA Controlled by pSivida and reasonably necessary to file, support and maintain regulatory submissions and (ii) interim and final reports and other information Controlled by pSivida and related to any Phase IV Clinical Trial for Durasert FA for uveitis, and Alimera, its Affiliates and its and their sublicensees may reference, cross-reference, review, have access to, incorporate and use such documents and reports (and information contained therein) and other information, to the extent reasonably necessary, (A) in or to support any regulatory applications or filings or Approvals or any patent filings or (B) for any Development or Commercialization purpose, in each case, for Products in the Collaboration Field, and (b) Alimera shall provide pSivida promptly with reasonable access to (1) documents for Products Controlled by Alimera and reasonably necessary to file, support and maintain regulatory submissions and (2) interim and final reports and other information Controlled by Alimera and related to any Phase IV Clinical Trial for ILUVIEN for uveitis, and pSivida, its Affiliates and its and their sublicensees may reference, cross-reference, review, have access to, incorporate and use such documents and reports (and information contained therein) and other information, to the extent reasonably necessary, (x) in or to support any regulatory

[*] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

applications or filings or Approvals or any patent filings or (y) for any Development or Commercialization purpose, in each case, for Products outside of the Collaboration Field. Notwithstanding the foregoing, in no event shall either Party be obligated to provide the other Party with access to documents directly related to such Party's process for manufacturing Products, including, without limitation, its process for manufacturing the related inserter, if the other Party has requested such documents because it is required to disclose such documents to a regulatory authority in a country where piracy of intellectual property is of reasonable concern. For the sake of clarity, documents directly related to such Party's process for manufacturing Products does not include documents regarding a Product's chemical composition, stability data or batch release information.

2.2.6. Reporting. Each Party shall provide notice to the other Party promptly after receipt of a warning letter, any notice requiring a recall or other written letters or notices (of substantially similar importance) issued by any regulatory authorities in relation to any Products.

2.2.7. Safety Data Exchange Agreement. No later than thirty (30) days after the date on which the first Approval is received by Alimera for a Product for uveitis for one of the European Filed Countries, or such earlier date as may be required by a regulatory authority, the Parties shall enter into a mutually acceptable Safety Data Exchange Agreement, based on industry standards, to allow each Party to get safety data and other information from the other Party in relation to Products for uveitis.

2.3 Performance. Each Party shall use Commercially Reasonable Efforts to conduct all responsibilities assigned to it under this Agreement.

2.4 Subcontracts. Subject to the provisions of Article 7 and Section 6.5 hereof, either Party may subcontract portions of any activities to be performed by it under this Agreement to subcontractors. Any subcontract entered into pursuant to this Section shall be consistent with the terms of this Agreement, including providing for intellectual property ownership as set forth herein and all confidentiality obligations of the Parties.

2.5 Deliverables. Within ten (10) Business Days after the Amendment Effective Date, pSivida shall provide Alimera with all data associated with any and all clinical or preclinical information related to Durasert FA that is Controlled by pSivida and reasonably necessary to file, support or maintain any regulatory submissions for ILUVIEN for uveitis to any regulatory authority in Europe, the Middle East or Africa. This includes, to the extent Controlled by pSivida and necessary for filing, support or maintenance of such regulatory submissions, all overviews and summaries, expert clinical reports and any clinical study reports with all appendices fully populated and provided as an eCTD such that this information and data may be easily included in Alimera's electronic filing with a European Union regulatory authority. Additionally, within ten (10) Business Days after the Amendment Effective Date, pSivida shall provide Alimera with any briefing books for meetings with any European Union regulatory authority for Durasert FA for uveitis and any minutes related to such meetings. Alimera its

*****] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

Affiliates and its and their sublicensees may review, incorporate and use any such materials and information described above in any regulatory applications or filings and for any other Development or Commercialization purpose in relation to Products in the Collaboration Field. Notwithstanding the foregoing, in no event shall pSivida be obligated to provide Alimera with access to documents directly related to pSivida's process for manufacturing Products, including, without limitation, its process for manufacturing the related inserter, if Alimera has requested such documents because it is required to disclose such documents to a regulatory authority in a country where piracy of intellectual property is of reasonable concern. For the sake of clarity, documents directly related to pSivida's process for manufacturing Products does not include documents regarding a Product's chemical composition, stability data or batch release information. Each Party hereby agrees that it will not discuss the regulatory submissions or filings of the other Party with any regulatory authority unless required by applicable law, regulation or rule and except to the extent required to respond to a question or other request by a regulatory authority in connection with such Party's regulatory filings, in which case any such communication will be subject to the terms and conditions of ARTICLE 7, including, for the avoidance of doubt, Section 7.2.

ARTICLE 3 COMMERCIALIZATION

3.1 Commercialization of Product(s) in the Collaboration Field. Alimera is granted a license under this Agreement to market, distribute and/or sell any Product in the Collaboration Field in the Territory, including, but not limited to, the right to conduct marketing, reimbursement (e.g., seeking and maintaining pricing and reimbursement approvals from Third Party payors), sales and distribution activities. Alimera may subcontract with any Affiliate or Third Party to perform any of the foregoing activities in accordance with Section 4.3. Alimera shall have sole decision-making authority with respect to the Commercialization of Products in the Collaboration Field, consistent with its other obligations under this Agreement.

3.2 Commercialization and Projections.

3.2.1. Alimera shall have sole responsibility for implementing Commercialization based on Alimera's commercially reasonable expectations of the resources and expenses required to Commercialize each Product in the Collaboration Field in the Territory, taking into account industry standards, the effect that the Commercialization of one Product might have on another Product and the competitive environment in effect from time to time with regard to each Product. Alimera shall prepare schedules, on a rolling two (2) year calendar quarter-by-calendar quarter basis, to be updated semi-annually (prior to June 30 and December 31 of each year), of projected Net Revenues and Third Party Consideration amounts upon which the Royalties payable to pSivida pursuant to Section 5.1 are calculated ("Annual Projections").

3.2.2. For each country in which Alimera and its Affiliates Commercializes Products through direct sales (or reasonably expects to Commercialize directly during the applicable two (2) year projection period), Annual Projections for such country shall include, on

[*] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

a country-by-country basis, (a) unit sales, (b) the average selling price per unit in such country's applicable currency, (c) Gross Revenues, (d) Net Revenues and (e) the average foreign exchange rate for conversion from Gross Revenues and Net Revenues to U.S. Dollars.

3.2.3. For each Third Party Consideration Agreement pursuant to which a sublicensee or distributor is Commercializing a Product (or will be or is reasonably expected to be Commercializing a Product during the applicable two (2) year projection period) and for which the Gross Revenues and Net Revenues to be earned by Alimera or an Alimera Affiliate under such Agreement is based (or is expected to be based) solely on a price per unit for Product shipped to the sublicensee or distributor, the Annual Projections shall include the same information as summarized in Section 3.2.2 above. For each such Third Party Consideration Agreement for which Gross and Net Revenues to be earned by Alimera or an Alimera Affiliate is based (or is expected to be based) on Gross and Net Sales of Products by the sublicensee or distributor, the Annual Projections shall include substantially the same categories of information required for such a sublicensee or distributor in Section 5.3. To the extent that Alimera projects any increase in fully burdened cost of Product during the two (2) year projection period as it relates to each Third Party Consideration Agreement, such increase(s) shall be included in the Annual Projections. The parties acknowledge that Section 1.53(b) addresses invoices by Alimera or its Affiliates separately to a sublicensee or distributor for the fully burdened cost of a Product.

3.2.4. Within thirty (30) calendar days after the submission of Annual Projections in December of each calendar year, pSivida may request that the Parties meet in-person at Alimera's facilities (or, at pSivida's option, a meeting by telephone, videoconference or other means), during which an executive from Alimera shall present in reasonable detail its planned Commercialization activities and associated Annual Projections for the applicable time period and pSivida shall have the opportunity to ask questions and to provide comments in relation to such Annual Projections. It is understood and agreed that Alimera shall have sole decision-making authority with respect to Commercialization, consistent with its other obligations under this Agreement.

3.3 Diligence. Alimera shall use Commercially Reasonable Efforts to Commercialize a First Product (a) for uveitis in all of the Major European Markets, (b) for at least one (1) indication other than uveitis in the Collaboration Field in the United States, the European Union and Japan (collectively, the "Major Markets"), and (c) in all countries outside of the Major Markets. pSivida acknowledges and agrees that as of the Amendment Effective Date, Alimera has used Commercially Reasonable Efforts to Commercialize a First Product for at least one (1) indication other than uveitis (i.e., DME) in the Collaboration Field in the United States and the European Union. For purposes of this Section 3.3, the term "Alimera" shall include Alimera and any of its Affiliates and its and their sublicensees and subcontractors. Alimera agrees to the following specific obligations with respect to ILUVIEN for uveitis:

3.3.1. Alimera shall use Commercially Reasonable Efforts to file a Type II Variation in the Major European Markets (other than the first three (3) Major European Markets

*****] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

for which Alimera has a filing obligation pursuant to Section 2.2.2) within [***] after the Amendment Effective Date and to file a Type II Variation in the other European Filed Countries (i.e., those European Filed Countries not included in the Major European Markets) within twelve (12) months after the Amendment Effective Date. In the event that any European Union regulatory authority requires two (2) clinical trials for Approval in three (3) or more of the Major European Markets, then the Parties shall meet and negotiate in good faith a revised timeline for the Type II Variation filings.

3.3.2. Alimera shall use Commercially Reasonable Efforts to complete the preparation of and file with the appropriate reimbursement authorities reimbursement dossiers in Spain, Italy, Portugal and the United Kingdom (and Germany, to the extent a reimbursement dossier is required in Germany) within [***] following Approval of ILUVIEN for uveitis in any such country;

3.3.3. Alimera shall use Commercially Reasonable Efforts to begin promoting ILUVIEN for uveitis in the United Kingdom, Portugal and Germany within [***] following Approval of ILUVIEN for the applicable country and to use Commercially Reasonable Efforts to begin promoting ILUVIEN for uveitis in Italy and Spain within [***] following Approval of ILUVIEN for uveitis the applicable country.

3.3.4. No later than two (2) years following the First Commercial Sale of ILUVIEN in a Major European Market for uveitis, complete at least one (1) Phase IV Clinical Trial for ILUVIEN for uveitis, either independently at Alimera's sole cost and expense, or jointly with pSivida, with each Party paying its pro rata share of the costs and expenses for such joint clinical trial;

3.3.5. In the Middle East and Africa, and each European Filed Country other than the Major European Markets, allocate a commercially reasonable number of sales representatives commensurate with each country's commercial opportunity and market potential for ILUVIEN after (i) Approval and (ii) receipt of an acceptable reimbursement price and terms for ILUVIEN for uveitis in such country;

The parties shall form a Joint Reimbursement Task Force within thirty (30) days after the first Approval of ILUVIEN for uveitis in Spain, Italy, Portugal, the United Kingdom or Germany. The Joint Reimbursement Task Force shall consist of two (2) members from Alimera and one member from pSivida. The two (2) members from Alimera shall initially be [***], and [***], and the one (1) member from pSivida shall initially be [***], provided that either Party may designate a replacement for its members at any time so long as it uses good faith efforts to replace such members with its officers or employees with similar responsibilities, including, with respect to the Alimera members, with responsibility for reimbursement of ILUVIEN for uveitis. The Joint Reimbursement Task Force shall meet by remote means (*e.g.*, by phone or videoconference) at least once per calendar month for the first six (6) months following the first Approval of ILUVIEN for uveitis in Spain, Italy, Portugal, the United Kingdom or Germany and

at least once per calendar quarter thereafter until the second anniversary date of such Approval. During these meetings, Alimera would share with pSivida its strategy for reimbursement for ILUVIEN for uveitis in Europe and its plans and progress in relation thereto. With advance written notice to the other Party, either Party may invite non-member employees or independent contractors of such Party to attend meetings of the Joint Reimbursement Task Force, as applicable, subject to Section 7.2 (a) or (c), as applicable.

For clarification, Alimera may elect not to engage in Commercialization of a First Product in any country outside the Major Markets. If Alimera determines not to engage in Commercialization of First Product in any country outside the Major Markets, Alimera shall so notify pSivida. At any time after receipt of such notice, pSivida may by written notice to Alimera, effective upon the giving of such notice, terminate Alimera's license(s), and rights to Commercialize, of First Product in such country. Thereafter pSivida may, in its sole discretion, directly or through an Affiliate or Third Party, Commercialize the First Product in such country. In the event of such termination with respect to a country, pSivida shall no longer be bound by Section 4.1.2(a), 4.1.2(b), 4.1.2(c) or 4.1.2(d) with respect to such country.

If Alimera requests documents directly related to pSivida's process for manufacturing Products because Alimera is required to provide such documents to file, support and maintain regulatory submissions, as set forth in Section 2.2.5(a) above, and pSivida does not want to provide such documents (as permitted in Section 2.2.5), then in no event shall Alimera be deemed to be in breach of any diligence obligations under this Agreement that is affected by such refusal by pSivida to provide such documents.

3.4 Costs of Commercialization. Alimera shall have sole responsibility for paying all costs and expenses incurred in connection with Commercializing the Products in the Collaboration Field in the Territory, except as otherwise provided in Section 3.3.4 above.

3.5 Non-Performance. In the event that Alimera fails to achieve any of the diligence obligations set forth in Sections 3.3.1 through 3.3.5, pSivida shall provide written notice to Alimera of such failure and Alimera shall have six (6) months to cure such failure. If after such cure period Alimera fails to remedy such non-performance, then the Royalties set forth in Section 5.1 with respect to ILUVIEN (but not for any other Product) shall be increased in Europe by (a) [***] if the failure is with respect to any country in the Major European Market or by (b) [***] if the failure is with respect to any country in a Minor European Market. In no event shall such amounts of increase be cumulative, even if Alimera fails to remedy such non-performance in multiple countries, in such case the increase shall be the greater percentage in the previous sentence, if any. The Parties agree that there shall be no increase in Royalties in the event that Alimera fails to achieve any of the diligence obligations set forth in Sections 3.3.1 through 3.3.5 for any country other than a country in a Major European Market or Minor European Market. For the purposes of this Section, "Minor European Market" shall mean any of Denmark, Finland, Netherlands, Norway or Sweden.

[*] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

3.6 Manufacturing for Commercial Supply Requirements. Alimera shall use Commercially Reasonable Efforts to provide an adequate and timely supply to satisfy commercial supply requirements. Subject to the terms of this Agreement, Alimera shall have the right to manufacture, itself or through any Third Party, any Product, under the licenses granted to Alimera pursuant to Article 4 and in accordance with Section 4.3. Alimera shall be responsible for ensuring that all such manufacturing is carried out in accordance with GMP and/or ISO standards to the extent applicable for Commercialization in the relevant country.

3.7 Product Recalls. Alimera shall have the sole right and responsibility and authority to carry out any Product Recall in the Collaboration Field, whether or not such Recall is required or requested by a governmental authority. If any governmental authority having jurisdiction requires or reasonably requests either Party to Recall a Product due to a defect in the manufacture, processing, packaging or labeling of the Product or for any other reason whatsoever, the Party receiving such request shall immediately notify the other Party. Alimera shall be responsible for carrying out any Recall in the Collaboration Field as expeditiously as possible and in such a way designed to cause the least disruption to the sales of the Product and to preserve the goodwill and reputation attached to the Product and to the names of Alimera and pSivida. Each Party agrees to maintain the appropriate records and procedures to permit a Product Recall.

ARTICLE 4 GRANT OF RIGHTS

4.1 Grant of License by pSivida.

4.1.1. License to First Product. Subject to the terms and conditions of this Agreement, pSivida hereby grants to Alimera an exclusive (even as to pSivida) right and license under pSivida's interest (i.e., subject to the UKRF Licenses) in the pSivida Technology, solely to make, have made, use, offer to sell, sell, and import First Product in the Collaboration Field in the Territory.

4.1.2. License to Products Other Than First Product. Subject to the terms and conditions of this Agreement, pSivida hereby grants to Alimera a non-exclusive right and license under pSivida's interest (i.e., subject to the UKRF Licenses) in the pSivida Technology, solely to make, have made, use, offer to sell, sell, and import Products other than First Products in the Collaboration Field in the Territory, provided that during the Term of this Agreement, and subject to the terms and conditions of this Agreement and the B&L Agreement,

(a) pSivida shall not grant a license to any Affiliate or Third Party under pSivida's interest in the pSivida Technology to make, have made, use, offer to sell, sell, or import Products in the Collaboration Field in the Territory,

(b) pSivida shall not itself use the pSivida Technology to make, have made, use, offer to sell, sell, or import Products in the Collaboration Field in the Territory,

(c) pSivida shall not grant a license to any Affiliate or Third Party under pSivida's interest in the pSivida Technology to make, have made, use, offer to sell, sell, or import in the Collaboration Field in the Territory any product that otherwise meets the definition of Product under Section 1.64 except that such product is Approved or designed to be Approved to deliver [***], and

(d) pSivida shall not itself use the pSivida Technology to make, have made, use, offer to sell, sell, or import in the Collaboration Field in the Territory any product that otherwise meets the definition of Product under Section 1.64 except that such product is Approved or designed to be Approved to deliver [***].

4.1.3. License to Exhibit 1.11B Patents. Subject to the terms and conditions of this Agreement and only to the extent permitted by the B&L Agreement, pSivida hereby grants to Alimera a non-exclusive right and license under any interest pSivida may have from time to time in the United States and foreign patents and patent applications listed in Exhibit 1.11B, solely to make, have made, use, offer to sell, sell, and import Products in the Collaboration Field in the Territory, except for products that would fall under the definition of Licensed Products in the B&L Agreement.

4.1.4. Covenant. To the extent pSivida obtains or owns any rights to any Covered Patents (as defined below) during the Term, pSivida covenants that it will not sue Alimera, or its Affiliates or any of its or their subcontractors or permitted sublicensees, for infringement of any claims in the Covered Patents resulting from their making, having made, using, selling, offering to sell or importing of ILUVIEN for uveitis in the Collaboration Field. A "Covered Patent" shall mean a patent or patent application (other than any patent or patent application included in pSivida Existing Patent Rights) that is owned or Controlled by pSivida prior to any Change of Control of pSivida, a Valid Claim of which would be infringed by the making, having made, using, selling, offering to sell or importing of ILUVIEN for uveitis in the Collaboration Field. pSivida will not assign or grant any exclusive rights under a Covered Patent for ILUVIEN for uveitis in the Collaboration Field, unless the assignee or grantee agrees in writing to be bound as by all terms of this Section (as though they were pSivida).

4.2 Grant of License by Alimera. Subject to the terms of this Agreement, Alimera hereby grants to pSivida a right and license under Alimera's interest in the Alimera Know-How as necessary for pSivida to perform its obligations under this Agreement, including, but not limited to, its performance of the Development activities.

4.3 Sublicenses and Subcontracts. Subject to the terms and conditions of this Agreement, Alimera may grant sublicenses and subcontracts to its Affiliates or to Third Parties to perform Commercialization activities for Products under the licenses granted pursuant to Sections 4.1.1 and 4.1.2 of this Agreement, provided that for any sublicenses or subcontracts (and any amendments thereto) (i) to which Alimera or any Alimera Affiliate is a party and which include a sublicense of Alimera's or an Alimera Affiliate's rights to obtain Approvals for and/or

market and distribute Product(s) in the applicable region or country (each, a “Third Party Consideration Agreement”), or (ii) which include Bundling (as defined below), Alimera shall obtain pSivida’s prior written consent, which consent shall not be unreasonably withheld or delayed. For the sake of clarity, the sublicenses and subcontracts described in (i) above do not include any agreements between Alimera or any Alimera Affiliate with a wholesale distributor, such as Besse or McKesson, or any agreements between Alimera or any Alimera Affiliate with a third party logistics provider, such as arvato or ICS, which distributors and third party logistics providers are deemed to be subcontractors of Alimera or its Affiliate. For the purposes of this Section 4.3, “Bundling” is a situation in which all three (3) of the following exist: (i) the offering (whether simultaneously or not) by Alimera or its Affiliates to a Third Party, or by a Third Party to Alimera or its Affiliates, of any rights, goods or services with respect to a Product (including sale of Product itself); (ii) the offering (whether simultaneously or not) by Alimera or its Affiliates to a Third Party, or by a Third Party to Alimera or its Affiliates, of any other rights, goods or services (including any rights, goods or services relating to other products Alimera or any of its Affiliates Controls, sells or otherwise disposes of); and (iii) the consideration for the rights, goods or services with respect to any Product in such offering is less than would have been customarily accepted by Alimera, or more than would have been customarily provided by Alimera, if such rights, goods or services with respect to such Product were offered individually (i.e., separate from the bundle). In the event of a proposed sublicense or subcontract that requires pSivida’s prior written consent as described in the foregoing, Alimera shall present pSivida in writing personally or by courier or certified mail (and email to a valid email address) a complete unredacted version (including any exhibits thereto) of any such proposed sublicense or subcontract. The terms of any such proposed sublicense or subcontract shall be deemed to be Confidential Information of Alimera. Any rejection by pSivida of such proposed sublicense or subcontract must be provided in writing (or via email to a valid email address) to Alimera within two (2) business days after pSivida receives a copy of such proposed sublicense or subcontract. If pSivida rejects a proposed sublicense or subcontract, then promptly after such rejection (but in any event no later than three (3) business days thereafter), pSivida must provide to Alimera in writing (or via email to a valid email address) reasonable details of its reasons for such rejection and negotiate diligently and in good faith with Alimera regarding terms for such proposed sublicense or subcontract that would be satisfactory to pSivida. pSivida’s acceptance of a sublicense or subcontract or substitute terms for such proposed sublicense or subcontract may not be unreasonably withheld or delayed. If Alimera does not receive (a) written notice of rejection of a proposed sublicense or subcontract within two (2) business days after pSivida receives a copy of such proposed sublicense or subcontract or (b) in the event of pSivida’s rejection of a sublicense or subcontract, written notice of reasonable details of its reasons for such rejection within three (3) business days after pSivida submits the written notice of rejection to Alimera, then pSivida will be deemed to have consented to such proposed sublicense or subcontract. Each sublicense or subcontract shall be consistent with the terms and conditions of this Agreement, shall be at arm’s length, and shall include such terms as are necessary to permit Alimera to fulfill its obligations hereunder. Alimera shall be responsible for the operations of any sublicensee or subcontractor relative to this Agreement as if such operations were carried out by Alimera itself, including, but not limited to, any payment provided for hereunder, regardless of

[*] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

whether the terms of any sublicense or subcontract provide for such payment to be paid by the sublicensee or subcontractor directly to pSivida. Alimera shall provide pSivida with a copy of each of the following sublicenses or subcontracts promptly after its execution (i) those for which pSivida's consent is required by this paragraph, and (ii) those under which any rights granted by pSivida to Alimera under this Agreement are sublicensed; provided however that Alimera may redact such copies in order to protect the confidential information of the Third Party. Each sublicensee or subcontractor and its employees, contractors, consultants, clinical investigators and agents shall be required to assign all Improvements to Alimera as set forth in Section 6.5.

4.4 Ownership of and Rights to Inventions. Except as otherwise provided under this Agreement, ownership of all Inventions made by either Party shall be governed by applicable United States patent law. Alimera hereby assigns and agrees to assign to pSivida a co-ownership interest in Alimera's interest in any Alimera Improvements, excluding any rights to any trademarks. Subject to Section 4.5, each Party shall have worldwide rights to use, practice and sublicense any such Alimera Improvements, without any accounting to, reporting to, or other obligation to, or consent from, the other Party. If a Party licenses or otherwise transfers to a Third Party any Alimera Improvements, the other Party shall cooperate and give such consent to such Party to enter into such license or transfer as may be required to permit such Party to license or transfer the Alimera Improvements to the Third Party without a duty to account to such other Party.

4.5 Limitation on Use. Notwithstanding any other provisions of this Agreement, neither Alimera nor any of its Affiliates, subcontractors or sublicensees shall use Alimera Improvements for any product that falls within the definition of pSivida Core Technology, except for Products (other than any Product(s) for which Alimera's license(s) have been terminated pursuant to Sections 3.5 or 10.3 of this Agreement) during the Term of this Agreement, Alimera shall ensure that any agreement it enters into with a licensee, sublicensee, acquirer, acquiree, transferee or merger or consolidation partner of or with Alimera, or acquirer or transferee of substantially all of the assets or stock of Alimera, or of the assets or business relating to this Agreement or the Alimera Improvements, includes the same limitation of use as set forth in this Section 4.5, and any such party shall be bound by such limitation.

4.6 Reservation of Rights.

4.6.1. Reservation of Rights by pSivida. All rights and interests not expressly granted to Alimera are reserved by pSivida (the "Reserved Interests") for itself, its Affiliates and partners (other than Alimera) and other licensees and sublicensees, including, but not limited to, the rights to use and grant licenses under the pSivida Technology or any other technology owned or controlled by pSivida to make, have made, use, offer to sell, sell, have sold and import products (other than Products for so long as Alimera has a license to such Products under this Agreement). It shall not be a breach of this Agreement for pSivida, acting directly or indirectly, to exploit its Reserved Interests in any manner anywhere in the Territory, whether or not such activity is competitive with the activities of Alimera, including, but not limited to, the research,

development and Commercialization or licensing of others to research, develop and Commercialize products (other than Products for so long as Alimera has a license to such Products under this Agreement). Except as otherwise expressly provided in this Agreement, for the avoidance of doubt, pSivida shall be free to enter into an agreement with any Third Party or Third Parties under the pSivida Technology or any other technology owned or controlled by pSivida or its Affiliate or a Third Party, to research, develop and Commercialize any and all products (other than Products for so long as Alimera has a license to such Products under this Agreement), including, but not limited to, products that potentially compete in the same indication or product market as a Product.

4.6.2. Reservation of Rights by Alimera. Except as otherwise expressly provided in this Agreement, for the avoidance of doubt, Alimera shall be free to enter into an agreement with any Third Party or Third Parties under the Alimera Know-How, the Alimera-Prosecuted Patent Rights or any other technology owned or controlled by Alimera or its Affiliate or a Third Party, to research, Develop and Commercialize any and all products, including, but not limited to, products that potentially compete in the same indication or product market as a Product.

4.7 No Grant of Other Technology or Patent Rights. Except as otherwise expressly provided in this Agreement, under no circumstances shall a Party hereto, as a result of this Agreement, obtain any ownership interest or license in or other right to any technology, Know-How, patents, patent applications, products, or biological materials of the other Party, including, but not limited to, items owned, Controlled or Developed by the other Party, at any time pursuant to this Agreement. This Agreement does not create, and shall under no circumstances be construed or interpreted as creating, an obligation on the part of either Party to grant any license to the other Party other than as expressly set forth herein. Any further contract or license agreement between the Parties shall be in writing.

4.8 Clinical IP.

4.8.1. Right of Access to Clinical IP. Alimera and pSivida shall jointly own all Clinical IP and shall provide each other with a Right of Access to Clinical IP. Each Party may exercise this right of access for itself, its Affiliates and any licensees, sublicensees or any other Third Party without the consent of the other Party.

4.8.2. Cooperation. Each Party shall use Commercially Reasonable Efforts, and shall reasonably cooperate with the other Party, to provide the other Party with such waivers, irrevocable cross reference letters, assignments, and/or other reasonable documentation as may be necessary or useful for the other Party's full exercise of any Right of Access to Clinical IP granted pursuant to this Section 4.8.

4.9 Section 365(n) of the Bankruptcy Code. All rights and licenses granted under or pursuant to any section of this Agreement are rights to "intellectual property" as defined in Section 101(35A) of the Bankruptcy Code. pSivida acknowledges and agrees that in connection

[*] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

with such rights and licenses, Alimera is hereby granted a right of access and a right to obtain possession of and to benefit from (i) copies of research data, (ii) laboratory samples, (iii) product samples and inventory, (iv) formulas, (v) laboratory notes and notebooks, (vi) data and results related to clinical trials, (vii) copies of regulatory filings and Approvals, (viii) rights of reference in respect of regulatory filings and Approvals, (ix) preclinical research data and results, and (x) marketing, advertising and promotional materials, all of which constitute "embodiments" of intellectual property pursuant to Section 365(n) of the Bankruptcy Code and (xi) all other embodiments of such intellectual property, whether any of the foregoing are in pSivida's possession or control or in the possession and control of Alimera or Third Parties. pSivida agrees not to interfere with Alimera's exercise of rights and licenses to intellectual property licensed hereunder and embodiments thereof in accordance with this Agreement.

ARTICLE 5 FINANCIALS

5.1 Royalty Payments. The Parties hereto agree that notwithstanding the Amendment Effective Date: (a) Alimera shall begin paying Royalties to pSivida under Section 5.1 for Net Revenues and Third Party Consideration earned or received beginning July 1, 2017 and (b) Alimera shall not be obligated to make the Net Profit Payment under Section 6.5.1(b) of the First A&R Agreement for the period from July 1, 2017 to the Amendment Effective Date. In consideration of the licenses and rights granted to Alimera hereunder, subject to Sections 3.5 and 5.6, Alimera will pay to pSivida on a calendar quarter basis, with respect to Commercialization of Products in the Collaboration Field in the Territory during the Term, an amount equal to (such payments collectively, "Royalties"):

5.1.1. prior to the Approval Royalty Date, two percent (2%) of the sum of Net Revenues and Third Party Consideration for that calendar quarter; *plus*

5.1.2. following the Approval Royalty Date, in a given calendar year, four percent (4%) (for a total of six percent (6%)) of the sum of Net Revenues and Third Party Consideration up to \$75,000,000 in such calendar year; *plus*

5.1.3. an additional two percent (2%) (for a total of eight percent (8%)) of the sum of Net Revenues and Third Party Consideration exceeding \$75,000,000 in such calendar year, provided that the Approval Royalty Date has occurred.

All payments made under this Section 5.1 shall be made in U.S. dollars. If any currency conversion is required in connection with the calculation of Net Revenues, such conversion shall be made in accordance with GAAP. All Royalties shall be paid to pSivida within sixty (60) calendar days after the end of each calendar quarter following the Amendment Effective Date, provided however, that if Alimera amends or modifies its agreement or terms with either of its distributors in the United States (as of the Amendment Effective Date, ASD Specialty Healthcare, Inc., doing business through its Besse Medical division, or McKesson Specialty Care Distribution Corporation) so that it receives payments for Products from such distributor within ninety (90) calendar days after the invoice date, then Alimera shall pay Royalties to pSivida

[*] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

within forty-five (45) calendar days after the end of each calendar quarter following the Amendment Effective Date. Alimera shall notify pSivida of any such amendment or modification to its agreement or terms with either of its distributors in the United States.

Notwithstanding anything to the contrary in this Agreement, Alimera will pay to pSivida, on a calendar quarter basis, Royalties on the full amount of Third Party Consideration actually received by Alimera during the applicable calendar quarter, even if such Third Party Consideration is not fully recorded as Net Revenues, but only to the extent that it is not recorded, under GAAP accrual basis accounting, during such calendar quarter. To the extent that such payment on Third Party Consideration is made by Alimera to pSivida in such calendar quarter and not fully recorded as Net Revenues, then Alimera shall not pay Royalties when and to the extent that such Third Party Consideration is actually recorded as Net Revenues under GAAP accrual basis accounting in such calendar quarter or a future calendar quarter. In the event that such Third Party Consideration is subject to forfeiture and becomes forfeit, then upon such forfeit, Alimera may reduce its Royalties in the quarter of the forfeit by the amount of Royalties previously paid on such Third Party Consideration to pSivida. The Parties acknowledge and agree that Alimera has already paid to pSivida prior to the Amendment Effective Date, [***] as required under the First A&R Effective Agreement related to a [***] milestone payment that Alimera or its Affiliates received for entering into an agreement with a distributor in Canada and that notwithstanding anything herein to the contrary, Alimera shall not pay Royalties on such milestone payment if and when such milestone is actually recorded as Net Revenues under GAAP accrual basis accounting.

In consideration of all rights granted, and information provided by pSivida to Alimera, the Parties agree that the amount of Royalties set forth in this Section 5.1 reflects the value of all such rights granted, information provided and costs paid, and such Royalties shall be paid whether or not such Product is covered by a Valid Claim in the pSivida Patent Rights, and whether or not such Royalty Payments under this Section 5.1 extend beyond the term of any pSivida Patent Rights containing Valid Claims covering such Product. For the sake of clarity, the Parties have agreed not to decrease the Royalties percentage to be paid by Alimera to pSivida, even if the Product is no longer covered by a Valid Claim in the pSivida Patent Rights, in view of substantial pSivida Know-How provided in the Development of Product. Moreover, the Net Revenues value itself will at all times reflect the then-current value of the intellectual property licensed hereunder and will naturally reflect any loss of the pSivida Patent Rights.

5.2 Royalty Offset. Alimera shall be entitled to offset fifty percent (50%) of the four percent (4%) Royalty owed to pSivida pursuant to Section 5.1.2 and fifty percent (50%) of the six percent (6%) Royalty owed to pSivida pursuant to Section 5.1.3 in the first two (2) years following the Approval Royalty Date, and twenty percent (20%) thereafter until the Collaboration Receivable Amount has been fully offset. For clarity, (a) Alimera shall not be entitled to offset any amount of the two percent (2%) Royalty owed to pSivida pursuant to Section 5.1.1 and (b) pSivida shall in no event be obligated to make a cash payment for any portion of the Collaboration Receivable Amount directly to Alimera. In addition, Alimera shall be entitled to offset Royalties as provided in Section 6.6.4.

[*] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

5.3 Royalty Reports. Each quarterly Royalty payment made in accordance with Sections 5.1 and 5.2 will be accompanied by a report that reflects, in reasonable detail, the calculation of such Royalty payment (a) on a country-by-country basis where Alimera and its Affiliates Commercialize the Products directly and (b) on a sublicensee-by-sublicensee or distributor by distributor basis where Alimera or its Affiliates Commercialize the Products indirectly, including information consistent with the quarterly reporting required of each such sublicensee or distributor under the terms of each such sublicensee or distributor agreement. With regard to (a) above and for those sublicensee or distribution agreements in (b) above for which Alimera's Product revenue is based on a specified price per unit sold by it (inclusive or exclusive of fully burdened cost, as applicable), such reasonable detail shall include unit sales shipped by Alimera and Affiliates, Gross Revenues, Net Revenues (detailing all deductions by category from the gross sales invoiced price), average gross and net selling prices, foreign currency conversion to U.S. dollars, where applicable, and sublicensee or distribution milestone consideration, if any (all in sufficient detail to verify the calculations thereof). With regard to each sublicensee agreement for which Alimera's Product revenue is based on designated percentages of the sublicensee's net sales, subject in certain instances to a minimum price per unit of Product, such reasonable detail shall include unit sales shipped by Alimera and its Affiliates to the sublicensee, unit sales of the sublicensee, sublicensee gross sales, sublicensee's net sales (detailing gross-to-net deduction amounts by category), calculation of the greater of the applicable royalty percentage(s) applied to total sublicensee net sales or the stated minimum amount per unit multiplied by the total units of Product sold by the sublicensee, TM license royalty (where applicable) and, as applicable, any milestone consideration received during such quarter (for the purposes of this sentence, distributor may be substituted for sublicensee if appropriate based on Alimera or its Affiliates agreements). The aggregate of such Royalties determined in relation to (a) and (b) above, reduced by the calculation of offsets (if any) under Section 5.2, are payable to pSivida for the applicable calendar quarter. Without limiting the generality of the foregoing, Alimera will require its Affiliates to account for Net Revenues and to provide such reports with respect thereto as if such sales were made by Alimera. If no Royalties are due to pSivida for the applicable calendar quarter, then the applicable report will so state. All Royalty reports will be subject to audit rights as set forth in Section 5.7.

5.4 First Milestone Payment. Upon the execution of this Agreement by all Parties, the Collaboration Receivable Amount shall be automatically reduced by \$10,000,000 (the "First Milestone Payment").

5.5 Second Milestone Payment. Upon the earlier of (a) Approval of a Product for uveitis in any country in the European Union, or (b) January 1, 2020, unless such January 1, 2020 due date has been extended pursuant to Section 2.2.3, Alimera shall pay to pSivida \$5,000,000 (the "Second Milestone Payment"), such amount to be first allocated to reduce the Collaboration Receivable Amount remaining (if any) at the time of such Approval, and the remaining balance (if any) to be paid within thirty (30) days of such Approval to pSivida in cash.

[*] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

5.6 Consideration from Third Party Agreements. If Alimera Commercializes a Product pursuant to a Third Party Consideration Agreement in all or any part of (a) the United States of America (other than in its territories, possessions or protectorates, including but not limited to Puerto Rico), (b) the United Kingdom (other than Northern Ireland) or (c) Germany, and such Third Party Consideration Agreement through which it Commercializes such Product in that region or country results in neither Alimera nor any Alimera Affiliate having any sales personnel in such region or country, then the Royalties payable on Third Party Consideration with respect to any such agreement pursuant to Section 5.1, shall increase to twelve percent (12%).

5.7 Records; Audits.

5.7.1. Alimera shall keep, and shall cause its Affiliates, agents and sublicensees to keep, full and accurate records and books of account containing information that may be necessary for the purpose of calculating Royalties, as detailed in the Royalty Reports, including reports and supporting data detailing Net Revenues, Gross Revenues, Royalties, the number of units of Products sold or otherwise transferred and Third Party Consideration under this Agreement, including but not limited to sales ledgers and records, general ledgers, and sublicensee reporting to Alimera,. Such books of account, records and reports, with all necessary supporting data, shall be kept by Alimera at its place of business for the three (3) years following the end of the calendar year to which each shall pertain. Alimera shall permit an independent accounting firm selected by pSivida and reasonably acceptable to Alimera (the "Audit Firm"), which acceptance shall not be unreasonably withheld or delayed, to have access during normal business hours to such records as may be reasonably necessary to verify the accuracy of Alimera's reports of Net Revenues, Gross Revenues, Royalties and Third Party Consideration as provided herein. Such Audit Firm may be required by Alimera to enter into a commercially reasonable confidentiality agreement with it, and in no event shall such Audit Firm disclose to pSivida any information from the books and records of Alimera or its Affiliates to which such Audit Firm has access during the course of such audit other than such information as it relates to the accuracy of the reports and the calculation of payments made or due hereunder. All such verifications shall be conducted at the expense of pSivida and not more than once in each calendar year. The Audit Firm shall submit its final written report to both Parties. If pSivida agrees with the Audit Firm's final written report, it shall provide notice of that agreement, pursuant to Section 11.5 of this Agreement, to Alimera. Once the notice of agreement has been provided by pSivida, Alimera shall have thirty (30) days in which to provide written notice of a good faith dispute to pSivida as to the conclusions set forth in the Audit Firm's report, setting forth the nature of any disagreement with the written report. If such notice of dispute is provided, the Parties shall thereafter, for a period of sixty (60) days, attempt in good faith to resolve such dispute and if they are unable to do so, the matter will be submitted to dispute resolution in accordance with Section 11.8. If no notice of dispute is provided but an adjustment is deemed

[*] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

due, then Alimera shall, within forty-five (45) days of receiving the written report, pay any adjustment due to pSivida plus accrued interest at a rate announced by the Bank of America as its prime rate in effect on the date that such payment was first due, plus three percent (3%) for the period starting from the date the payment was first due and ending on the date the payment was made. pSivida shall be responsible for the fees, and expenses associated with the audit, provided however, that if the audit concludes that an adjustment of five percent (5%) or more of the aggregate amount paid or payable by Alimera to pSivida during the relevant period is due in pSivida's favor, then Alimera shall be responsible for the reasonable fees, costs, and expenses charged by the Audit Firm. An audit under this Section 5.7.1 shall be limited to the records and books of account for any calendar year ending not more than thirty-six (36) months before the date of the request. The Parties agree that all information subject to review under this Section 5.7 is confidential and that pSivida shall cause its accounting firm to retain all such information subject to the confidentiality restrictions of Article 7.

5.7.2. In addition to the foregoing, Alimera shall permit an independent certified public accountant retained by UKRF to inspect the records and books of account described in Section 5.7.1 during normal business hours and upon reasonable notice to the extent required by the UKRF Licenses. Such right of inspection shall last for two (2) years following the end of the calendar quarter to which such records and books of account pertain, shall be limited solely to those matters directly related to pSivida royalty obligations under the UKRF Licenses, and shall be allowed no more than once a year.

ARTICLE 6 INTELLECTUAL PROPERTY

6.1 pSivida-Prosecuted Patent Rights.

6.1.1. Filing, Prosecution and Maintenance. pSivida shall have primary responsibility for and control over the preparation, filing, prosecution and maintenance of (a) any of the pSivida Existing Patent Rights, (b) any Patent Rights included within the pSivida Improvements, and (c) any Patent Rights included within the Alimera Improvements that fall within the definition of or relate to the pSivida Core Technology (collectively, the "pSivida-Prosecuted Patent Rights"). For pSivida-Prosecuted Patent Rights, 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.

6.1.2. pSivida Patent Costs. Alimera shall be responsible for reimbursement of pSivida Patent Costs only in the jurisdictions identified in Exhibit 1.69 as follows: the pSivida Patent Costs shall be paid by pSivida, and Alimera shall reimburse pSivida fifty percent (50%) (subject to the last sentence of this paragraph) for all such costs incurred by pSivida within thirty (30) days after the date of invoice by pSivida. The list of countries identified in Exhibit 1.69 may be amended (i.e., to add or to drop one or more countries) only upon mutual agreement by the Parties. If, after the Effective Date of the Original Agreement, pSivida grants to any Third

Party a license to any of the pSivida-Prosecuted Patent Rights for which Alimera has continuing reimbursement obligations, thereafter Alimera's share of costs for those particular pSivida-Prosecuted Patent Rights shall be reduced on a per capita basis during the term of such license (by way of example, if pSivida grants a license to one Third Party to any of the pSivida-Prosecuted Patent Rights, Alimera's share of costs for those particular pSivida-Prosecuted Patent Rights shall be thirty-three percent (33%)).

6.1.3. Communication. pSivida shall provide Alimera with copies of all official correspondence (including, but not limited to, applications, office actions, responses, etc.) relating to prosecution and maintenance of pSivida-Prosecuted Patent Rights in countries identified in Exhibit 1.69. Alimera may provide comments and pSivida will give good faith consideration thereto. In order to facilitate Alimera's rights to comment, pSivida shall provide copies of all such official correspondence and any proposed responses by pSivida at least ten (10) business days prior to any filing or response deadlines. In the event that the Parties have a material disagreement relating to the prosecution or maintenance of any of the pSivida-Prosecuted Patent Rights (other than a determination by pSivida to abandon any pSivida-Prosecuted Patent Rights as described below), pSivida shall have the right to decide on the course of action. Thereafter, Alimera may choose not to pay any portion of the pSivida Patent Costs associated with the applicable pSivida-Prosecuted Patent Rights. In the event that Alimera chooses not to pay for one or more countries, then, with respect to such countries only, (a) the license for the applicable pSivida-Prosecuted Patent Rights shall automatically terminate, and (b) pSivida shall no longer be bound by Section 4.1.2(a), 4.1.2(b), 4.1.2(c), or 4.1.2(d).

6.2 Abandonment. pSivida shall not abandon prosecution or maintenance of any pSivida-Prosecuted Patent Rights already pending in any country identified in Exhibit 1.69 without notifying Alimera in a timely manner of pSivida's intention and reason therefore and providing Alimera with reasonable opportunity to comment upon such abandonment and to assume responsibility for prosecution or maintenance of such Patent Rights as set forth below. For avoidance of doubt, for pSivida-Prosecuted Patent Rights, pSivida has the sole discretion to decide whether or not to file in a country, and a decision not to file in a country shall not be deemed as abandonment of pSivida-Prosecuted Patent Rights in that country for purpose of this Article 6. In the event that pSivida abandons the prosecution or maintenance of pSivida-Prosecuted Patent Rights in any country identified in Exhibit 1.69 at any time during the Term of this Agreement, Alimera may assume prosecution responsibility therefor in the name of pSivida, and such patent costs shall be paid by Alimera and pSivida shall reimburse Alimera for [***] of such patent costs within thirty (30) days after the date of invoice from Alimera (the "pSivida Reimbursement Amount"). In the event that pSivida fails to reimburse Alimera within the time period as specified above, any future payment to pSivida shall be decreased by an amount that is calculated as follows: the amount of the non-reimbursed pSivida Reimbursement Amount is multiplied by [***], and that amount is compounded annually at the compounding rate of [***] per annum, for any period in which any portion of such costs remains non-reimbursed. pSivida may pay all or any portion of the unpaid pSivida Reimbursement Amount plus any interest accrued and due at any time.

[*] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

6.3 Alimera-Prosecuted Patent Rights.

6.3.1. Filing, Prosecution and Maintenance. Alimera shall have primary responsibility for and control over the preparation, filing, prosecution and maintenance of any Patent Rights included within Alimera Improvements that are not pSivida-Prosecuted Patent Rights (“Alimera-Prosecuted Patent Rights”). For Alimera-Prosecuted Patent Rights, Alimera 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. Alimera shall be solely responsible for Alimera Patent Costs. Alimera 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 Alimera-Prosecuted Patent Rights.

6.3.2. Abandonment. Alimera shall not abandon prosecution or maintenance of any Alimera-Prosecuted Patent Rights in the Territory without notifying pSivida in a timely manner of Alimera’s intention and reason therefore and providing pSivida with reasonable opportunity to comment upon such abandonment and to assume responsibility for prosecution or maintenance of such Alimera-Prosecuted Patent Rights. For avoidance of doubt, for Alimera-Prosecuted Patent Rights, Alimera has the sole discretion to decide whether or not to file in a country, and a decision not to file in a country shall not be deemed as abandonment of Alimera-Prosecuted Patent Rights in that country for purpose of this Article 6. In the event that Alimera abandons prosecution or maintenance of Alimera-Prosecuted Patent Rights in any country in the Territory, pSivida may assume prosecution responsibility for such Patent Rights in that country, and thereafter such Patent Rights will cease being Alimera-Prosecuted Patent Rights and will become pSivida-Prosecuted Patent Rights. Notwithstanding the foregoing, if Alimera, acting in good faith, grants a Third Party prosecution rights with respect to any Alimera-Prosecuted Patent Rights, then pSivida’s rights under this Section 6.3 shall be subject to the rights granted to such Third Party.

6.4 Information Disclosure; Cooperation. Each Party shall disclose and make available to the other Party all material information controlled by such Party that is reasonably necessary for the other Party to perform its obligations and exercise its rights under this Article 6, including the preparation, filing, prosecution and maintenance of patents and patent applications pursuant to this Article 6. All such information shall be disclosed to the other Party reasonably promptly after it is first developed or learned or its significance is first appreciated. Without limiting the foregoing, each Party agrees to disclose and make available to the other Party all Alimera Improvements and pSivida Improvements, as applicable. Neither Alimera nor pSivida shall publicly disclose any Alimera Improvements before the Party responsible for filing and prosecuting such Improvements has an opportunity to make appropriate patent filings. Each Party agrees to cooperate with the other Party with respect to the preparation, filing, prosecution and maintenance of patents and patent applications pursuant to this Article 6.

6.5 Employees and sublicensees Assignment of Inventions. Each Party shall cause all of its employees, Affiliates, contractors, sublicensees, consultants, clinical investigators and agents, acting under authority from such Party or its sublicensees, (a) to enter into written agreements pursuant to which each such person or entity assigns to such Party all Improvements and other Inventions that such individual or entity discovers, develops, creates, conceives or reduces to practice in the course of their relationship with such Party or its sublicensees; and (b) to execute such other documents and take such other actions as may be necessary to effectuate the foregoing assignments. Each Party agrees to undertake to enforce the agreements referenced in this Section 6.5 (including, where appropriate, by legal action). With respect to any university subcontractor and any of its employees, contractors, consultants, clinical investigators and agents, each Party's obligations under this Section 6.5 shall be limited to using Commercially Reasonable Efforts to obtain such assignments, and if a Party is unable to obtain such assignments, to using Commercially Reasonable Efforts to obtain a royalty-free (with the right to sublicense) exclusive license to such Improvements (or an option to obtain a royalty-free sublicensable exclusive license to such Improvements), and failing that, to using Commercially Reasonable Efforts to obtain a royalty-free (with the right to sublicense) non-exclusive license to such Improvements (or an option to obtain a royalty-free sublicensable non-exclusive license to such Improvements).

6.6 Infringement

6.6.1. Notification. Each party shall promptly report in writing to the other Party during the Term of this Agreement any known infringement or suspected infringement of any of its Patent Rights that covers a Product and shall provide the other Party with all available evidence supporting said infringement or suspected infringement.

6.6.2. Prosecution. pSivida shall have the initial right, 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 covering a Product. pSivida shall give Alimera sufficient advance notice of its intent to file said suit and the reasons therefore, and shall provide Alimera with an opportunity to make suggestions and comments regarding such filing; provided, however, that Alimera shall provide any such comments sufficiently in advance of any filing dates to allow for consideration by pSivida, and further provided that it shall be within pSivida's sole discretion whether to incorporate such suggestions or comments. pSivida shall keep Alimera reasonably informed of the status and progress of the litigation. pSivida shall have the sole and exclusive right to select counsel for any such suit and action and shall pay [***], including, but not limited to, attorneys' fees and court costs. If pSivida 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 Alimera under Section 6.6.1; (b) thirty (30) days after Alimera notifies pSivida that Alimera 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 any rights

[*] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

granted to B&L under the B&L Agreement to enforce or prosecute any Patent Rights owned or Controlled by pSivida, Alimera shall have the right to bring suit against an Infringer at Alimera's own expense. This right of Alimera to bring suit, as well as to continue an existing suit, is also conditioned on all of the following requirements:

- (i) The allegedly infringing product, device or method (collectively, the "Accused Device") falls within the definition of Product;
- (ii) If Alimera owns (or has licensed from a Third Party and has the right to enforce) any patent(s) that reads on the Accused Device practiced by the Infringer, Alimera will include in the complaint one or more claims alleging infringement of all such other patent(s);
- (iii) Alimera has provided evidence to pSivida that there is a good faith basis to believe that the Accused Device is being prepared for Commercialization or is already Commercialized;
- (iv) Alimera shall keep pSivida reasonably and timely informed of the pre-litigation and litigation issues and strategy (including, without limitation, furnishing copies of communications, pleading, and other documents and keeping pSivida informed of settlement efforts and developments), and shall obtain suggestions and strategy from pSivida, including during pre-trial motions and discovery;
- (v) In the instance of litigation issues and strategies pertaining to defenses or setting strategy for the scope of claims, Alimera shall incorporate all reasonable suggestions and strategy from pSivida as may be deemed appropriate in the reasonable business judgment of pSivida; and
- (vi) Except for joining the legal actions described in this Section 6.6.2 as a party at Alimera's request and matters discussed in the following paragraph, pSivida shall have no obligation regarding such actions unless required to participate by law or contract. However, pSivida shall have the right to participate in any such actions through its own counsel and at its expense.

Upon request of the other Party, either Party shall join as a party to the suit, at the other Party's reasonable expense, and shall offer reasonable assistance to the other Party in connection therewith at the other Party's reasonable expense. Any damages, royalties, settlement fees or other consideration for infringement resulting from such 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, any remaining compensatory damages shall be treated as Net Revenues of Products and [***] in accordance with the applicable percentages set forth in Section 5.1, and any remaining non-compensatory damages shall be allocated [***] to Alimera and [***] to pSivida. Neither Party shall settle any such action or otherwise consent to an

[*] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

adverse judgment in any such action that adversely affects the rights or interests of the other Party under this Agreement, including, without limitation, issues of validity of the pSivida Patent Rights, without the prior written consent of the other Party.

6.6.3. 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 any 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.

6.6.4. Responsibility. Subject to any rights granted to B&L under the B&L Agreement, Alimera shall have the initial right, but not the obligation, to defend any suit or action initiated by any Third Party alleging solely that a Product Developed or Commercialized hereunder has infringed, or is suspected of infringing any Third Party intellectual property rights. Upon Alimera's request, pSivida shall offer reasonable assistance to Alimera in connection therewith at Alimera's expense. Alimera 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 Alimera, and further provided that it shall be within Alimera's sole discretion whether to incorporate such suggestions or comments. Alimera shall keep pSivida reasonably informed of the status and progress of the litigation. Alimera 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. Alimera shall have the right to settle any such litigation and shall specifically have the 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 Products; provided, however, that Alimera shall not settle any such action in a manner that does not include the full release of pSivida, 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, without limitation, issues of validity of the pSivida Patent Rights, without the prior written consent of pSivida. For the avoidance of doubt, deductions in the payment of Royalties under this Section shall not be deemed to adversely affect the rights or interests of pSivida under this Agreement for the purposes of the foregoing sentence. 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 Alimera. Alimera shall provide pSivida with a copy of any such license promptly after its execution. Alimera shall bear any payments associated with any payments owed to any Third Party under such license (collectively, the "Third Party Royalties"). However, to the extent that any Third Party Royalties are paid for a license under Third Party patent rights that would otherwise be infringed by the practice of the pSivida Patent Rights hereunder, Alimera may credit up to fifty percent (50%) of the amount of any such Third Party Royalties paid by Alimera under such Third Party license against amounts payable to pSivida under Section 5.1. Alimera may take such credit during the calendar quarter for which amounts are payable hereunder;

[*] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

provided, that in no event will such credit reduce the Royalty amounts otherwise payable to pSivida for such calendar quarter by more than fifty percent (50%), and provided further, that Alimera may not take such credit during any calendar quarter in which a Royalty offset is otherwise applicable pursuant to Section 5.2. If Alimera recovers any damages or any other payments, by way of settlement or otherwise, in connection with any counterclaim made by it in any such actions, such damages shall be considered "Net Revenues" for purposes of this Agreement.

If Alimera does not defend a claim, suit or proceeding as set forth above within ninety (90) days of the date Alimera 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 6.6.4 shall apply as if the term "pSivida" were changed to "Alimera" and the term "Alimera" were changed to "pSivida."

6.7 **Marking.** Alimera and any Affiliates or sublicensees shall mark all Products with the numbers of all patents included in pSivida Technology that cover the Products. Without limiting the foregoing, all Products shall be marked in such a manner as to conform with the patent laws of the country to which such Products are shipped or in which such products are sold, including, but not limited to, the requirements of 35 U.S.C. §287.

6.8 **Trademarks.** Alimera shall be free to adopt, use and register in any trademark offices any trademarks for use with a Product in its sole discretion. Subject to Section 10.3.2, Alimera shall own all right, title and interest in and to any such trademark in its own name during and after the Term of this Agreement.

6.9 **UKRF Licenses and B&L Agreement.** pSivida shall not amend or modify any of the UKRF Licenses or the B&L Agreement, or waive any right thereunder, in any manner that would adversely affect Alimera's rights hereunder without the prior written authorization of Alimera.

ARTICLE 7 CONFIDENTIALITY

7.1 **Confidentiality.** Except as otherwise provided in this Article 7, each Party shall maintain Confidential Information of the other Party in confidence and shall not disclose Confidential Information of the other Party to any Third Party and shall not use Confidential Information of the other Party except as expressly authorized under this Agreement. "**Confidential Information**" shall mean any and all information (whether in written, electronic, visual, verbal or other form) received from the other Party or its representatives, including, but not limited to, all information relating to any technology, product, method, process or intellectual property of such disclosing Party (including, but not limited to, Patent Rights, and other owned or licensed intellectual property rights, data, Know-How, samples, technical and non-technical materials and specifications), as well as any business plan, financial information, research data or results, or other confidential commercial information of or about such disclosing Party; provided,

[*] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

however, that Confidential Information shall not include any information that: (a) is or becomes part of the public domain other than by unauthorized acts or omissions of the Party obligated not to disclose such Confidential Information or its employees, directors, officers, or agents (collectively, the “Receiving Party”); (b) can be shown by written documents to have been disclosed to the Receiving Party by a Third Party; provided, however, that such Third Party had no obligation of confidentiality or non-use to the disclosing party with respect to such Confidential Information; or (c) can be shown by written documents to have been in the possession of the Receiving Party prior to disclosure by the disclosing Party; provided, however, that such Confidential Information was not obtained directly or indirectly from the other Party to this Agreement pursuant to a confidentiality agreement. Notwithstanding any other provisions of this Article, Alimera Know-How shall be Confidential Information of Alimera and pSivida Technology shall be Confidential Information of pSivida.

7.2 Disclosure. A Party may disclose Confidential Information (a) to its employees on a need-to-know basis, provided that such employees agree in writing to non-use and non-disclosure obligations essentially the same as those set forth herein and to keep the Confidential Information confidential to the same extent as such Party is required to keep the Confidential Information confidential; (b) to its directors, Affiliates, accountants, attorneys, lenders and other financing sources, provided that the Party making such disclosure will advise the recipients that such information is confidential and of the terms of this Article 7 and that by receiving such information, the recipients are agreeing to be bound by such provisions; (c) to Third Parties on a need-to-know basis in connection with (i) a proposed financing, merger, acquisition or other comparable transaction solely for the purpose of evaluating, negotiating and, if applicable, consummating such transaction, (ii) a proposed offering of securities solely for purpose of evaluating, negotiating and, if applicable, consummating such offering, (iii) strategic consulting advice solely for the purpose of rendering such advice, and (iv) a proposed license or sublicense of the technology or intellectual property, or portion thereof, licensed hereunder as permitted under this Agreement solely for the purpose of evaluating, negotiating and, if applicable, consummating such license or sublicense; provided that the Party making such disclosure in the case of (i), (ii), (iii) and (iv) will advise the recipients that such information is confidential and of the terms of this ARTICLE 7 and will ensure that such recipients shall agree in writing to non-use and non-disclosure obligations essentially the same as those set forth herein and will be responsible for such recipients’ breach of any such obligations in relation to Confidential Information; (d) to government or other regulatory authorities to the extent that such disclosure is required by law, regulation or order (i) in connection with the filing, prosecution or maintenance of patents for which the Party disclosing the Confidential Information has responsibility or is permitted under this Agreement to file, prosecute and maintain, or (ii) to obtain authorizations to conduct clinical trials of, and to Commercialize, Product pursuant to this Agreement; and (e) as required by any applicable law, order, regulation, rule or ruling of any governmental entity, court or stock exchange, provided that the Party required to make such disclosure will provide prompt prior written notice of such request or requirement to the other Party (if legally permissible and feasible) so that the other Party may seek, at its expense, an appropriate protective order or other remedy, and in the absence of a protective order, will consult with the other Party about the

[*] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

extent and nature of such disclosure, will disclose only that portion of the Confidential Information that is required or compelled to be disclosed and will exercise commercially reasonable efforts to obtain confidential treatment (if legally permissible and practicable) with respect to such disclosure.

7.3 Disclosure of Agreement. Disclosure of the execution and terms of this Agreement shall be made by each Party in its own separate press release that is in a form acceptable to the other Party on the Amendment Effective Date (and in the case of either Party, a report on Form 8-K); and neither Party shall make any public disclosure with respect to or describing the Agreement (including the relationship of the Parties hereunder and the terms thereof) that is contrary to or inconsistent with the substance in such press release or the Agreement.

To the extent that either Party reasonably determines that it is required to file a copy of this Agreement to comply with the requirements, rules, laws or regulations of any applicable stock exchange, or any governmental or regulatory authority or body, including without limitation the U.S. Securities and Exchange Commission (the “SEC”) (collectively, the “Disclosure Obligations”), such Party shall promptly inform the other Party thereof. Prior to making any such filing of a copy of this Agreement, the Parties shall mutually agree on the provisions of this Agreement for which the Parties shall seek confidential treatment, it being understood that if one Party determines to seek confidential treatment for a provision for which the other Party does not, then the Parties will use reasonable efforts in connection with such filing to seek the confidential treatment of any such provision. The Parties shall cooperate, each at its own expense, in such filing, including without limitation such confidential treatment request, and shall execute all documents reasonably required in connection therewith. The Parties will reasonably cooperate in responding promptly to any comments received from the SEC with respect to such filing in an effort to achieve confidential treatment of such redacted form; provided, however, that a Party shall be relieved of such obligation to seek confidential treatment for a provision requested by the other Party if such treatment is not achieved after the first round of responses to comments from the SEC. Notwithstanding anything to the contrary in this Agreement, either Party may make reference to the existence of this Agreement and describe the relationship between the Parties in connection with any required securities filings or other required public disclosure without seeking the other Party’s prior consent. This paragraph shall apply with respect to the filing of a copy of this Agreement or any public disclosure relating to this Agreement to comply with the Disclosure Obligations, notwithstanding the provisions of this Section 7.

ARTICLE 8 REPRESENTATIONS AND WARRANTIES

8.1 Representations and Warranties of pSivida. pSivida represents and warrants as of the Amendment Effective Date that:

- (a) pSivida is a corporation duly organized, validly existing and in corporate good standing under the laws of Delaware;

[*] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

- (b) pSivida has the legal right, authority and power to enter into this Agreement, and to extend the rights and licenses granted to Alimera in this Agreement;
- (c) pSivida has taken all necessary action to authorize the execution, delivery and performance of this Agreement;
- (d) upon the execution and delivery of this Agreement, this Agreement shall constitute a valid and binding obligation of pSivida enforceable in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' and contracting parties' rights generally and except as enforceability may be subject to general principles of equity (regardless of whether such enforceability is considered in a proceeding in equity or at law);
- (e) the performance of its obligations under this Agreement will not conflict with its charter documents or result in a breach of any agreements, contracts or other arrangements to which it is a party;
- (f) pSivida is the sole and exclusive owner of or Controls the pSivida Existing Patent Rights;
- (g) to the best of pSivida's knowledge, no claim has been threatened or asserted that the practice of any patent or patent application listed in Exhibit 1.11A infringes patent rights of any Third Party;
- (h) pSivida has not received any complaint, demand or notice from a Third Party in writing challenging the validity or enforceability of any patent listed in Exhibit 1.11A;
- (i) pSivida has no present intention to [***] of any patent listed in Exhibit 1.11A and has not instructed its patent counsel or taken any other actions to [***] of any patent listed in Exhibit 1.11A;
- (j) pSivida is in compliance in all material respects with the UKRF Licenses and the B&L Agreement; to pSivida's knowledge, there is no noncompliance by UKRF or B&L under the UKRF Licenses and the B&L Agreement, respectively, other than noncompliance that would not adversely affect Alimera's rights hereunder;
- (k) neither pSivida nor any of its Affiliates has initiated for pSivida a filing for protection under the bankruptcy laws, an assignment for the benefit of creditors, appointment of a receiver or trustee over its property or any similar undertaking; and

[*] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

(l) to pSivida's knowledge, pSivida does not Control any patents or patent applications other than the pSivida Existing Patent Rights that would be infringed by the making, having made, using, selling, offering to sell or importing of ILUVIEN for uveitis in the Collaboration Field by Alimera or its subcontractors or sublicensees as permitted under this Agreement.

8.2 Representations and Warranties of Alimera. Alimera represents and warrants, as of the Amendment Effective Date that:

(a) Alimera is a corporation duly organized, validly existing and in corporate good standing under the laws of Delaware.

(b) Alimera has the legal right, authority and power to enter into this Agreement, and to extend the rights and licenses granted to pSivida in this Agreement;

(c) Alimera has taken all necessary action to authorize the execution, delivery and performance of this Agreement;

(d) upon the execution and delivery of this Agreement, this Agreement shall constitute a valid and binding obligation of Alimera enforceable in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or similar laws, affecting creditors' and contracting parties' rights generally and except as enforceability maybe subject to general principles of equity (regardless of whether such enforceability is considered in a proceeding in equity or at law);

(e) the performance of its obligations under this Agreement will not conflict with Alimera's charter documents or result in a breach of any agreements, contracts or other arrangements to which it is a party;

(f) to the knowledge of Alimera, Alimera is the sole and exclusive owner of the Alimera Know-How;

(g) to the best of Alimera's knowledge, no claim has been threatened or asserted that the practice of any patent or patent application listed in Exhibit 1.11A infringes patent rights of any Third Party;

(h) Alimera has not received any complaint, demand or notice from a Third Party in writing challenging the validity or enforceability of any patent listed in Exhibit 1.11A

(i) Alimera has no present intention to seek reexamination of any patent listed in Exhibit 1.11A and has not instructed its patent counsel or taken any other actions to seek reexamination of any patent listed in Exhibit 1.11A; and

[*] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

(j) Schedule 8.2(j) sets forth a true, complete and accurate list of all Third Party Consideration Agreements.

(k) other than as disclosed in Section 5.1.3 of this Agreement, no milestone has been achieved and no milestone payment has been earned under any Third Party Consideration Agreement; provided that, to the extent that the representation in this Section 8.2(k) is inaccurate, pSivida's sole remedy shall be for Alimera to pay pSivida thirty-three percent (33%) of such earned milestone due pursuant to Section 6.6 of the First A&R Agreement in the calendar quarter in which such inaccuracy is discovered.

8.3 Warranty Disclaimer. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY WARRANTY WITH RESPECT TO ANY PSIVIDA TECHNOLOGY, PSIVIDA KNOW-HOW, ALIMERA IMPROVEMENTS, ALIMERA KNOW-HOW, GOODS, SERVICES OR OTHER SUBJECT MATTER OF THIS AGREEMENT AND HEREBY DISCLAIMS WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY, SCOPE AND NON-INFRINGEMENT WITH RESPECT TO ANY AND ALL OF THE FOREGOING.

8.4 Limited Liability. EXCEPT FOR THEIR RESPECTIVE OBLIGATIONS UNDER ARTICLE 7 OR ARTICLE 9, NEITHER PSIVIDA NOR ALIMERA WILL BE LIABLE WITH RESPECT TO ANY SUBJECT MATTER OF THIS AGREEMENT UNDER ANY CONTRACT, NEGLIGENCE, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY FOR ANY PUNITIVE, EXEMPLARY, INCIDENTAL, INDIRECT OR CONSEQUENTIAL DAMAGES OR LOST PROFITS.

ARTICLE 9 INDEMNITY

9.1 Cross Indemnity. Each Party (the "Indemnifying Party") agrees to defend, indemnify and hold the other party (the "Indemnified Party"), its Affiliates and their respective directors, officers, employees and agents and their respective heirs and assigns harmless from all Third Party claims, actions, losses, damages, liabilities or expenses (including, but not limited to, reasonable attorneys' fees) (each, a "Loss") arising as a result of (a) a breach by the Indemnifying Party of any of its representations, warranties or obligations under this Agreement, (b) actual or asserted violations of any applicable law or regulation by the Indemnifying Party or any of its employees, Affiliates, sublicensees, consultants, or other agents in connection with the Development, manufacture, distribution, marketing, promotion, sale, or use of Products, or the reporting requirements for Products, including, but not limited to, any allegation or determination that a Product has been adulterated, misbranded, mislabeled or otherwise is not in compliance with any applicable law or regulation, or (c) except as provided in Section 6.6.4, bodily injury, death, property damage or other harm or damage attributable to the research, Development, manufacture, distribution, marketing, promotion, sale or use of any Products by the Indemnifying Party or its employees, Affiliates, sublicensees, consultants, or other agents.

[*] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

9.2 Limitation on Indemnity Obligations. A Party, its Affiliates and their respective directors, officers, employees and agents shall not be entitled to the indemnities set forth in Section 9.1 to the extent the Loss for which indemnification is sought was caused by the negligence, or by the reckless or intentional misconduct or omission, of such Party or its directors, officers, employees or agents.

9.3 Procedure. If an Indemnified Party intends to claim indemnification under Article 9, the Indemnified Party shall notify the Indemnifying Party of any Loss in respect of which the Indemnified Party intends to claim such indemnification, and the Indemnifying Party shall assume the defense thereof with counsel mutually satisfactory to the Parties. The failure to deliver notice to the Indemnifying Party within a reasonable time after the commencement of any such action, shall relieve such Indemnifying Party of liability to the Indemnified Party under Article 9 only to the extent that the delay adversely affects Indemnifying Party's rights or ability to defend such claim or action, but the failure so to deliver notice to the Indemnifying Party will not relieve the Indemnifying Party of any liability that it may have to any Indemnified Party otherwise than under Article 9. The Indemnified Party under Article 9 shall provide reasonable assistance to the Indemnifying Party and its legal representatives, at the Indemnifying Party's expense, in the investigation of any action, claim or liability covered by this indemnification. The Indemnifying Party shall additionally be liable to pay the reasonable legal costs and attorneys' fees incurred by the Indemnified Party in rightfully establishing its claim for indemnity. Except as provided in the next-to-last and last sentences of this Section 9.3, the indemnity agreement in this Article 9 shall not apply to amounts paid in settlement of any Loss if such settlement is effected without the consent of the Indemnifying Party, which consent shall not be withheld unreasonably or delayed. Indemnifying Party shall not, without the written consent of Indemnified Party, settle or compromise any Loss or consent to the entry of any judgment with respect to any Loss (a) that does not release Indemnified Party from all liability with respect to such Loss or (b) which may materially adversely affect Indemnified Party or under which Indemnified Party would incur any obligation or liability, other than one as to which Indemnifying Party has an indemnity obligation hereunder. If Indemnifying Party, within ten (10) days of receiving notice of a Loss or such shorter period as may be necessary for submitting or filing a response, fails to assume the defense of such Loss or fails to notify Indemnified Party that is assuming such defense, Indemnified Party shall have the right to assume the defense, compromise or settlement of such Loss at the risk and expense of Indemnifying Party. In addition, the Indemnified Party shall be entitled to participate in the defense of such Loss and to employ counsel of its choice for such purpose; *provided, however*, that such employment shall be at the Indemnified Party's sole cost and expense unless the interests of the Indemnified Party and the Indemnifying Party with respect to such Loss are sufficiently adverse to prohibit the representation by the same counsel of both Parties under applicable law, ethical rules or equitable principles (in which case, the Indemnified Party shall control its defense, compromise and settlement at the Indemnifying Party's sole expense, and to the extent applicable, the Third Party previously serving as common counsel to both the Indemnifying Party and the Indemnified Party may no longer represent either Party in connection with such Loss).

[*] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

9.4 **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 Article 9, but in no event shall a Party's insurance coverage be in an amount less than [***] per occurrence and [***] annual aggregate. The policy of insurance shall contain a provision of non-cancellation except upon the provision of thirty (30) days' notice to the other Party. The policy of insurance with respect to any Product that would, absent the licenses herein, infringe a Valid Claim under a patent licensed under one or more of the UKRF Licenses shall contain an endorsement naming UKRF and the University of Kentucky (and its Board of Trustees, agents, officers and employees) as additional insureds. 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.

ARTICLE 10 TERM AND TERMINATION

10.1 **Term.** If not earlier terminated as provided in this Article 10, the term of this Agreement (the "**Term**") shall commence on the Effective Date and expire upon the later of (i) ten (10) years after the Effective Date, or (ii) the expiration or abandonment of the last Valid Claim included in the pSivida Patent Rights, or (iii) as long as Alimera, any Affiliate of Alimera or any sublicensee is selling a Product in any part of the Territory.

10.2 **Termination for Default by Either Party.** Either Party may terminate this Agreement (i) upon the occurrence of a breach of a material term of this Agreement (other than a material breach described in clause (ii) below or in Section 10.3) if the breaching Party fails to remedy such breach within thirty (30) days after notice thereof by the non-breaching Party or, with respect to a breach (other than a failure to make a payment) that cannot be cured within such period, then such longer period (up to ninety (90) days) as may be reasonably necessary, using Commercially Reasonable Efforts, to cure the breach, or (ii) if the other Party files for protection under the bankruptcy laws, makes an assignment for the benefit of creditors, appoints or suffers appointment of a receiver or trustee over its property, files a petition under any bankruptcy or insolvency act or has any such petition filed against it and such proceeding remains undismissed or unstayed for a period of more than sixty (60) days. Upon termination, the non-breaching Party shall, subject to the dispute resolution procedures set forth in Section 11.8, have the right, in its sole discretion, to seek any other rights or remedies available to it at law or in equity.

10.3 **Termination for Abandonment.**

[*] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

10.3.1. Termination Right. For purposes of this Section 10.3, “Abandonment” by Alimera or to “Abandon” shall mean delivery of a written election by Alimera to abandon this Agreement with respect to a Product. If Alimera Abandons a Product pursuant to this Section 10.3, then pSivida’s sole remedy shall be termination with respect to such Product pursuant to this Section 10.3. Solely for purposes of this Section 10.3 the term “Product” shall have the meaning set forth in Section 1.64 except that in (D) and (4) the words “in a particular country” shall be omitted, in the next to last sentence the words “in each country” shall be omitted, and in the last sentence example (ii) shall be omitted.

10.3.2. Effect of Abandonment by Alimera. In the event that pSivida terminates this Agreement with respect to a Product in the Territory for Abandonment of that Product by Alimera under this Section 10.3, the rights and licenses granted to Alimera pursuant to ARTICLE 4 shall terminate with respect to that Product in the Territory and the Parties shall negotiate in good faith a license agreement under which Alimera shall grant to pSivida a non-exclusive license to any Alimera Know-How related to such Product. After termination with respect to such Product as set forth in this Section 10.3 and at pSivida’s request: (a) any and all Confidential Information and materials solely related to such Product provided by pSivida pursuant to this Agreement shall be promptly returned by Alimera to pSivida, (b) Alimera shall promptly deliver to pSivida copies of all Clinical IP owned or Controlled by Alimera and necessary or useful to the Development or Commercialization of such Product and Alimera shall not use any such Clinical IP thereafter for any regulatory applications or filings for such Product, provided that the foregoing shall not prevent Alimera from using such Clinical IP for other Products or from performing preclinical and clinical studies or other research of any nature, including research that reproduces data contained in the Clinical IP, or from using the results of such research in regulatory applications or filings or for any other purpose, (c) if Alimera has applied for or obtained any Approvals in any country for the Product, then Alimera shall, to the extent legally permissible, take all additional action reasonably necessary to assign all of its right, title and interest in and transfer possession and control to pSivida of such applications or Approvals, (d) any regulatory filings for the Product which have been submitted in Alimera’s name, subject to FDA approval, will be transferred to pSivida’s name, (e) Alimera will assign to pSivida all of its right, title and interest in any trademark under which Alimera shall solely have marketed the Product or registered for use solely with such Product together with the goodwill associated therewith, and (f) pSivida shall no longer be bound by Section 4.1.2(a), 4.1.2(b), 4.1.2(c), or 4.1.2(d) with respect only to the Product Abandoned by Alimera. Termination of this Agreement with respect to the Product shall be pSivida’s sole and exclusive remedy under this Agreement for Abandonment of that product by Alimera, except that Alimera shall promptly pay to pSivida all Development Payments that Alimera owes pSivida as of the date of termination (the “Alimera Abandonment Amount”), provided that, from and after the date of termination, interest on any unpaid Alimera Abandonment Amount shall accrue at [***] (rather than at [***]), compounded annually, until such costs have been paid; further provided that the accrual of such interest or payment shall not preclude pSivida from seeking full payment of amounts owed under this Section 10.3.2.

[*] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

10.4 Effect of Expiration or Termination of the Agreement. Except as expressly provided herein, the expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination and all rights and licenses granted under this Agreement shall be terminated. In the event of termination of this Agreement pursuant to Section 10.2, (a) any and all Confidential Information and materials provided by the non-breaching Party to the breaching Party pursuant to this Agreement shall be promptly returned by the breaching Party to the non-breaching Party, and (b) the breaching Party shall not use any Clinical IP arising from the activities conducted under this Agreement at any time thereafter; provided that the foregoing shall not prevent the breaching Party from performing preclinical and clinical studies or other research of any nature, including research that reproduces data contained in the Clinical IP, or from using the results of such research in regulatory applications or filings or for any other purpose.

10.5 Survival of Provisions Upon Expiration or Termination. The provisions of ARTICLE 1, Article 7, Article 9, Article 10 and ARTICLE 11 (other than Section 11.2), Sections 3.7 (with respect to Product sold by Alimera or its Affiliates prior to the effective date of the termination of this Agreement), 4.4, 4.5, 4.6, 4.8, 8.3, and 8.4 shall survive the expiration or termination of this Agreement for any reason.

ARTICLE 11 MISCELLANEOUS

11.1 Interpretation.

11.1.1. If an ambiguity or a question of intent or interpretation arises with respect to this Agreement, this Agreement shall be construed as if drafted jointly by the Parties and no presumption or burden of proof shall arise favoring or disfavoring any Party by virtue of the authorship of any provisions of this Agreement.

11.1.2. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter forms. The words “include”, “includes” and “including” shall be deemed to be followed by the phrase “but not limited to.” The word “will” shall be construed to have the same meaning and effect as the word “shall.” Unless the context requires otherwise, (A) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (B) any reference to any laws herein shall be construed as referring to such laws as from time to time enacted, repealed or amended, (C) any reference herein to any Person shall be construed to include the Person’s permitted successors and assigns, (D) the words “herein”, “hereof and “hereunder”, and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof unless specifically stated, (E) any reference herein to the words “mutually agree” or “mutual written agreement” shall not impose any obligation on either Party to agree to any terms relating thereto or to engage in discussions relating to such terms except as

[*] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

such Party may determine in such Party's sole discretion and unless otherwise stated; and (F) all references herein to Articles, Sections or Schedules shall be construed to refer to Articles, Sections and Schedules of this Agreement unless otherwise noted.

11.2 Primary Contact Persons. As of the Amendment Effective Date, pSivida has designated [***] as pSivida's primary contact person and Alimera has designated [***] as Alimera's primary contact person for Development activities hereunder and [***] as Alimera's primary contact person for Commercialization activities hereunder (each, a "Primary Contact Person"). The applicable Primary Contact Persons shall attempt to resolve any disputes that arise during the course of any Development or Commercialization activities hereunder. If the applicable Primary Contact Persons cannot resolve any such dispute within thirty (30) days (or such longer reasonable period of time as they may agree) after their initial discussion of such issue, the dispute shall be resolved in accordance with Section 11.8. Each Party may change its Primary Contact Person upon written notice to the other Party.

11.3 Assignment. This Agreement may not be assigned or otherwise transferred by either Party without the consent of the other Party; provided, however, that either Party may, without such consent, assign its rights and obligations under this Agreement in connection with a Change of Control of such Party; provided, however, that such Party's rights and obligations under this Agreement shall be assumed by its successor in interest in any such transaction. Any purported assignment in violation of the preceding sentence shall be void. Any permitted assignee shall assume all obligations of its assignor under this Agreement.

11.4 Severability. Each Party hereby agrees that it does not intend to violate any public policy, statutory or common laws, rules, regulations, treaty or decision of any government agency or executive body thereof of any country or community or association of countries. Should one or more provisions of this Agreement be or become invalid, the Parties hereto shall substitute, by mutual consent, valid provisions for such invalid provisions which valid provisions in their economic effect are sufficiently similar to the invalid provisions that it can be reasonably assumed that the Parties would have entered into this Agreement with such valid provisions. In case such valid provisions cannot be agreed upon, the invalidity of one or several provisions of this Agreement shall not affect the validity of this Agreement as a whole, unless the invalid provisions are of such essential importance to this Agreement that it is to be reasonably assumed that the Parties would not have entered into this Agreement without the invalid provisions.

11.5 Notices. Any consent, notice or report required or permitted to be given or made under this Agreement by one of the Parties hereto to the other shall be in writing, delivered personally or by facsimile (and promptly confirmed by personal delivery or courier) or courier, postage prepaid (where applicable), addressed to such other Party at its address indicated below, or to such other address as the addressee shall have last furnished in writing to the addressor and shall be effective upon receipt by the addressee.

[*] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

If to pSivida: pSivida US, Inc.
480 Pleasant Street
Watertown, MA 02472
Attention: CEO
Fax: (617)-926-5050

With a copy to: pSivida US, Inc.
480 Pleasant Street
Watertown, MA 02472
Attention: Corporate Counsel
Fax: (617) 926-5050

With a copy to: Ropes & Gray LLP
One International Place
Boston, MA 02110
Attention: Susan Galli, Esq.
Fax: (617) 951-7050

If to Alimera: Alimera Sciences, Inc.
6120 Windward Parkway, Suite 290
Alpharetta, GA 30005
Attention: CEO
Fax: (678) 990-5744

With a copy to: Alimera Sciences, Inc.
6120 Windward Parkway, Suite 290
Alpharetta, GA 30005
Attention: General Counsel
Fax: (678) 990-5744

With a copy to: Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP
One Marina Park Drive, Suite 900
Boston, MA 02210
Attention: Jay Hachigian, Esq.
Fax: (617) 648-9100

11.6 Governing Law and Venue. This Agreement shall be governed by, construed and enforced in accordance with the laws of the State of New York, without regard to any choice of law principle that would dictate the application of the laws of another jurisdiction. Any suit brought by Alimera arising under or relating to this Agreement shall be brought in a court of competent jurisdiction in the Commonwealth of Massachusetts, and Alimera hereby consents to the jurisdiction of the state and federal courts sitting in the Commonwealth of Massachusetts.

*****] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

Any suit brought by pSivida arising under or relating to this Agreement shall be brought in a court of competent jurisdiction in the state of Georgia, and pSivida hereby consents to the jurisdiction of the state and federal courts sitting in the state of Georgia. Each Party 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 specified courts, irrevocably waives any claim that such action, suit or other proceeding has been brought in any 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.

11.7 Compliance with Applicable Laws. The Parties shall use their best efforts to comply with all provisions of any applicable laws, regulations, rules and orders relating to the license granted and to the testing, production, transportation, export, packaging, labeling, sale or use of Products. The Parties shall use their best efforts to obtain written assurances regarding export and re-export of technical data (including Products made by use of technical data) as may be required by the Office of Export Administration Regulations. Notwithstanding any other provision of this Agreement, each Party (and each Affiliate and agent of the Party) may disclose the tax treatment and tax structure of the transaction and all materials of any kind (including, but not limited to, opinions and other tax analyses) that are provided to the Party relating to such tax treatment and tax structure as contemplated by section 1.6011-4(b)(3)(iii) of the Code of Federal Regulations.

11.8 Dispute Resolution. Any disputes, other than disputes regarding the construction, validity or enforcement of patents (which disputes shall be resolved by Section 11.6), arising between the Parties relating to, arising out of or in any way connected with this Agreement or any term or condition hereof, or the performance by either Party of its obligations hereunder, whether before or after termination of this Agreement, shall be resolved as follows:

11.8.1. Senior Management. If the dispute cannot be resolved by the Primary Contact Persons in accordance with Section 11.2 hereof, the Primary Contact Persons shall promptly notify the chief executive officer of each Party (or their designee), who shall meet in person at a mutually acceptable time and location or by means of telephone or video conference within sixty (60) days of such notice and attempt to negotiate a settlement.

11.8.2. Arbitration. If the chief executive officers are not able to resolve the dispute within thirty (30) days of their first meeting or within such extended period as they agree upon, either Party may submit the matter to binding arbitration in accordance with this Section 11.8.2. Except as specified below, the arbitration shall be conducted in accordance with the commercial arbitration rules of, and under the auspices of, the American Arbitration Association (the "AAA"). The arbitration will be conducted by a single, neutral arbitrator with relevant technical expertise who is jointly selected by the Parties or, if the Parties cannot mutually agree, is selected by the AAA administrator. If Alimera is the claimant, the location of the arbitration shall be in Boston, Massachusetts and if pSivida is the claimant, the location of the arbitration shall be in Atlanta, Georgia. This Agreement shall remain in effect pending completion of the

*****] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

proceedings brought under this Section 11.8.2. Within ten (10) Business Days after the deadline for filing an answering statement pursuant to the AAA rules, or such other time as the Parties and the arbitrator may mutually agree, the arbitrator shall conduct a preliminary hearing pursuant to the AAA rules. The final award by the arbitrator shall have the same force and effect as the final judgment of a court of competent jurisdiction. Nothing in this arbitration clause shall prevent either Party from seeking a pre-award attachment of assets or preliminary relief to enforce its rights in intellectual property or confidentiality obligations under this Agreement, or to enjoin any event that might cause irreparable injury, in a court of competent jurisdiction prior to the issuance of the final award by the arbitrator.

11.9 Entire Agreement. The Parties agree that this Agreement shall supersede the Prior Agreements, and any other prior agreements or understandings with respect to subject matter hereof, from and after the Amendment Effective Date; provided that the execution of this Agreement shall not be deemed to have terminated, released, extinguished or discharged any rights, claims or obligations of the Parties under (a) the Prior Agreements accrued prior to the Amendment Effective Date, except for, for clarity, rights, claims or obligations to the extent settled, resolved or released by the Parties pursuant to the Settlement Agreement or (b) the Settlement Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by both Parties hereto.

11.10 Headings. The captions to the several Articles and Sections hereof and Exhibits hereto are not a part of this Agreement, but are merely guides or labels to assist in locating and reading the several Articles and Sections hereof.

11.11 Independent Contractors. It is expressly agreed that pSivida and Alimera shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither pSivida nor Alimera shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other, without the prior consent of the other Party to do so.

11.12 Waiver. The waiver by either Party hereto of any right hereunder or the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by said other Party whether of a similar nature or otherwise.

11.13 Counterparts. This Agreement may be executed by facsimile and/or in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

<signature page to follow>

*****] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

IN WITNESS WHEREOF, the Parties have executed this Amended and Restated Collaboration Agreement as of the date first set forth above.

pSivida US, INC.

By: /s/ Nancy Lurker
Name: Nancy Lurker
Title: President and CEO

ALIMERA SCIENCES, INC.

By: /s/ Dan Myers
Name: Dan Myers
Title: Chief Executive Officer

***** INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

Amended and Restated Collaboration Agreement

EXHIBITS

EXHIBIT 1.11A:	PSIVIDA EXISTING PATENT RIGHTS
EXHIBIT 1.11B:	EXCLUDED PSIVIDA PATENTS AND PATENT APPLICATIONS
EXHIBIT 1.32:	EXCLUDED PRODUCT SPECIFICATIONS/DRAWINGS
EXHIBIT 1.69:	PSIVIDA PATENT COST-SHARING COUNTRIES
EXHIBIT 1.88:	UKRF LICENSES
SCHEDULE 2.2.2(a)	THIRD PARTY CONTRACTS REFERENCED IN SECTION 2.2.2(a)
SCHEDULE 8.2(j)	THIRD PARTY CONSIDERATION AGREEMENTS

***** INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

EXHIBIT 1.11A

PSIVIDA EXISTING PATENT RIGHTS

[*]**

ii

[*] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

EXHIBIT 1.11B

EXCLUDED PSIVIDA PATENTS AND PATENT APPLICATIONS

iii

***** INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

EXHIBIT 1.32

EXCLUDED PRODUCT SPECIFICATIONS/DRAWINGS

iv

*** INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

EXHIBIT 1.69

PSIVIDA PATENT COST-SHARING COUNTRIES

v

*** INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

EXHIBIT 1.88

UKRF LICENSES

[*]**

vi

[*] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

SCHEDULE 2.2.2(a)

THIRD PARTY CONTRACTS REFERENCED IN SECTION 2.2.2(a)

vii

*** INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

SCHEDULE 8.2(j)

THIRD PARTY CONSIDERATION AGREEMENTS

viii

*** INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

AGREEMENT

This Agreement (“**Agreement**”) is effective as of April 11, 2017 (“**Effective Date**”), by and between PSIVIDA Corp., PSIVIDA US, Inc., and pSiMedica Limited (collectively, “**PSIVIDA**”) and PFIZER Inc. (“**PFIZER**”).

Recitals:

WHEREAS, on June 14, 2011, PSIVIDA and PFIZER entered into that certain Amended and Restated Collaborative Research and License Agreement (“**Collaboration Agreement**”).

WHEREAS, pursuant to Section 3.3 of the Collaboration Agreement, Pursuant to Section 3.3 of the Restated Agreement, PSIVIDA was permitted to elect to cease development of the Product (as defined in the Collaboration Agreement) at any time after June 14, 2012 but prior to completion of Phase II clinical trials for the Product, upon providing notice to PFIZER of such election (the “**Cessation Notice**”), at which time PSIVIDA would have no further obligations with respect to the Product under the Collaboration Agreement. The Company delivered the Cessation Notice to PFIZER on October 27, 2016. Pursuant to the Restated Agreement, PFIZER had until December 26, 2016 to deliver a Funding Option Notice to the Company. PFIZER did not provide the Funding Option Notice as of December 26, 2016 and therefore, subject to the Condition (as defined below), the Restated Agreement automatically terminated as of such date.

WHEREAS, after receipt of the Cessation Notice, PFIZER had the right to elect to solely fund further development and commercialization of the Product, provided that PFIZER was required to make such election and notify the Company (the “**Funding Option Notice**”) no later than sixty days after receiving the Cessation Notice. Pursuant to the Collaboration Agreement, PFIZER had until December 26, 2016 to deliver a Funding Option Notice to PSIVIDA.

WHEREAS, Because PFIZER did not provide the Funding Option Notice by December 26, 2016, subject to the limited exception set forth below, the Collaboration Agreement automatically terminated as of such date.

WHEREAS, Pursuant to Section 3.3. of the Collaboration Agreement, if PSIVIDA provided the Cessation Notice but did not actually cease all development activities with respect to the Product for at least one year (the “**Condition**”), then the automatic termination would be null and void and the Collaboration Agreement would remain in effect.

WHEREAS PSIVIDA and PFIZER now wish ensure finality of the contract and wish to enter into this Agreement to amend and restate the Collaboration 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:

Agreement:

1. PSIVIDA hereby represents and warrants to PFIZER that from the date of the provision of the Cessation Notice to PFIZER, PSIVIDA has ceased all development activities with respect to the Product and that PSIVIDA has no current plans to restart any such development activities. PSIVIDA further hereby represents and warrants to PFIZER that PSIVIDA has, from the date of the provision of the Cessation Notice to PFIZER, had no active discussions with any third party to partner or divest the program and that PSIVIDA has no current plans to enter into any such discussions.

2. Section 3.3 of the Collaboration Agreement shall be amended so the following language:

“provided, however, that if PSIVIDA provides the notice referred to 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.”

shall be deleted in its entirety.

3. All other terms and conditions of the Collaboration Agreement will remain the same and shall continue in full force and effect.

The parties have caused this Agreement to be duly authorized, executed, and delivered as of the Effective Date.

PSIVIDA

By: /s/ Dario Paggiarino
Name: Dario A. Paggiarino, MD
Title: Chief Medical Officer

PFIZER INC.

By: /s/ Daniel J. Karp
Name: Daniel J. Karp
Title: VP, Business Development

List of Subsidiaries of pSivida Corp.

Subsidiary Name

pSivida US, Inc.

pSiMedica Limited

pSivida Securities Corporation

Jurisdiction of Incorporation

Delaware

United Kingdom

Massachusetts

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-152146, 333-163208 and 333-216166 on Form S-8 and Registration No. 333-208115 on Form S-3 of our reports dated September 13, 2017, relating to the consolidated financial statements of pSivida Corp. and subsidiaries (the “Company”) (which report expresses an unqualified opinion and includes an explanatory paragraph relating to the substantial doubt about the Company’s ability to continue as a going concern), and the effectiveness of the Company’s internal control over financial reporting, appearing in this Annual Report on Form 10-K of pSivida Corp. for the year ended June 30, 2017.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
September 13, 2017

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, Nancy Lurker, certify that:

1. I have reviewed this Annual Report on Form 10-K of **PSIVIDA CORP.**;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: September 13, 2017

/s/ **NANCY LURKER**

Name: Nancy Lurker
Title: President and Chief Executive Officer
 (Principal Executive Officer)

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

CERTIFICATIONS

I, Leonard S. Ross, certify that:

1. I have reviewed this Annual Report on Form 10-K of **PSIVIDA CORP.**;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: September 13, 2017

/s/ **LEONARD S. ROSS**

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

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

In connection with the Annual Report of pSivida Corp. (the "Company") on Form 10-K for the year ended June 30, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Nancy Lurker, 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, 2017

/s/ **NANCY LURKER**

Name: Nancy Lurker
Title: **President and Chief Executive Officer**
(Principal Executive Officer)

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

In connection with the Annual Report of pSivida Corp. (the "Company") on Form 10-K for the year ended June 30, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Leonard S. Ross, Vice President, Finance and Chief Accounting 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, 2017

/s/ **Leonard S. Ross**

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