



## RESULTS FOR ANNOUNCEMENT TO THE MARKET

For the year ended 30 June 2008

The Disclosure provided in this “Results for Announcement to the Market” meet the requirements of the ASX and are based exclusively on the material contained in the Company’s Form 10-K filed with the Securities and Exchange Commission on 26 September 2008 and in accordance with accounting principles generally accepted in the United States (U.S. GAAP).

Financial results	Year ended 30 June,		Change	
	2008	2007	Amount	%
	(In thousands of U.S. Dollars except percentages)			
Revenue from ordinary activities	3,476	1,785	1,691	95%
Loss from ordinary activities after tax attributable to members <sup>1</sup>	(75,670)	(83,525)	7,855	(9)%
Loss for the period attributable to members <sup>2</sup>	(75,670)	(81,203)	5,533	(7)%

<sup>1</sup> Loss from continuing operations

<sup>2</sup> Net loss

### Dividends

The Company does not propose to pay any dividends.

The consolidated financial statements and the accompanying notes to consolidated financial statements included in the attached Form 10-K have been subject to an audit by the Company’s independent registered public accounting firm.

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549**

**FORM 10-K**

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

For the fiscal year ended **June 30, 2008**

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)

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

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

**02472**  
(Zip Code)

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

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

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

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

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

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

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

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

The aggregate market value of the voting common stock held by non-affiliates of the registrant on December 31, 2007 was approximately \$49,980,598.

There were 18,262,345 shares of the registrant's common stock, \$0.001 par value, outstanding as of September 24, 2008.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of pSivida Corp.'s Definitive Proxy Statement, to be filed in connection with the Annual Meeting of Stockholders to be held on November 19, 2008, are incorporated by reference into Part III of this Report on Form 10-K.

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**PSIVIDA CORP.**  
**Form 10-K**  
**For the Fiscal Year Ended June 30, 2008**  
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## **Preliminary Note Regarding Forward-Looking Statements**

This Report contains forward-looking statements. All statements that address activities, events or developments that we intend, expect or believe may occur in the future and all statements that contain projections of our results of operations or financial condition are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (Exchange Act). We often, although not always, identify forward-looking statements by using words or phrases such as the following: “likely”, “expect”, “intend”, “anticipate”, “believe”, “estimate”, “plan”, “project”, “forecast” and “outlook”.

You should not unduly rely on forward-looking statements contained in this Report. Forward-looking statements involve estimates, assumptions, risks and uncertainties. Our actual results and performance may therefore differ materially from those expressed in or implied by the forward-looking statements. Various factors discussed in this Report, including, but not limited to, the risks discussed in Item 1A. “Risk Factors”, may cause actual results or outcomes to differ materially from those expressed in or implied by the forward-looking statements. You should read and interpret any forward-looking statements together with these risks.

Any forward-looking statement applies only as of the date on which that statement is made. We do not undertake to update any forward-looking statement to reflect events or circumstances that occur after the date on which such statement is made.

## **Item 1. Business**

### **Introduction**

We are a drug delivery company committed to the biomedical sector, with a primary focus on ophthalmology and oncology. We have two products approved by the Food and Drug Administration (FDA): Retisert® for the treatment of uveitis and Vitrasert® for the treatment of AIDS-related cytomegalovirus (CMV) retinitis. We have licensed both of these products and the technologies underlying them to Bausch & Lomb Incorporated (Bausch & Lomb). We have one product in fully recruited Phase III clinical trials: Iluvien™, which delivers fluocinolone acetonide (FA) for the treatment of diabetic macular edema (DME), formerly known as Medidur FA for DME. We have licensed certain of our drug delivery technology to Alimera Sciences, Inc. (Alimera) for the development of Iluvien and certain other ophthalmic products. We have a worldwide collaborative research and license agreement with Pfizer Inc. (Pfizer) under which Pfizer may develop additional ophthalmic products.

We own the rights to develop and commercialize a modified form of silicon known as BioSilicon™, which has potential therapeutic applications. Our most advanced BioSilicon product candidate, BrachySil™, delivers a therapeutic P32, a radioactive form of phosphorus used to treat cancer, directly to solid tumors. We recently completed an initial safety and efficacy clinical trial of Brachysil for the treatment of pancreatic cancer and have commenced a dose-ranging clinical trial.

Effective June 19, 2008, we reincorporated from Western Australia to the United States (the Reincorporation). Pursuant to a scheme of arrangement under Australian law, all ordinary shares, including ordinary shares represented by American Depositary Shares (ADSs), of pSivida Limited, a company incorporated in Western Australia, were transferred by court order to pSivida Corp., a company incorporated in Delaware, in exchange for shares of pSivida Corp. common stock, including common stock represented by CHES Depositary Interest (CDIs), in a ratio of 40 pSivida Limited ordinary shares to 1 share of pSivida Corp. All assets and liabilities of pSivida Limited, including outstanding options and warrants to purchase ordinary shares or ADSs of pSivida Limited, were, by court order, transferred to and assumed by pSivida Corp., following which pSivida Limited was deregistered without a winding up. All options and warrants were equitably adjusted to reflect the Reincorporation. Each CDI represents one share of common stock. The common stock of pSivida Corp. is listed on the NASDAQ Global Market. pSivida Corp. CDIs are listed on the Australian Securities Exchange (ASX) and the Frankfurt Stock Exchange.

Except as otherwise indicated, references in this Report to “pSivida”, “the Company”, “we”, “us”, “our”, or similar terms refer to pSivida Limited and its subsidiaries prior to June 19, 2008 and pSivida Corp. and its subsidiaries from such date. All share amounts and all information relating to options and warrants in this Report have been retroactively adjusted to reflect the Reincorporation share exchange ratio, unless otherwise stated. BioSilicon™, BrachySil™, Durasert™, CODRUG™, and Medidur™ are our trademarks. Retisert® and Vitrasert® are Bausch & Lomb’s trademarks. Iluvien™ is Alimera’s trademark. This Report also contains trademarks, trade names and service marks of other companies, which are the property of their respective owners.

## **Market Overview**

### ***Drug Delivery Generally***

The therapeutic value of a drug depends on its distribution throughout the body, reaction with the targeted site, reaction with other tissues and organs in the body, and clearance from the body. In an ideal treatment, the appropriate amount of drug is delivered to the intended site in the body and maintained there for an adequate period of time without adversely affecting other tissues and organs. Accordingly, the manner in which a drug is delivered can be as important to the ultimate therapeutic value of the treatment as the intrinsic properties of the drug itself.

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

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

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

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

### ***Ophthalmic Drug Delivery***

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

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

**Technologies and Products**

We have three primary technologies: Durasert, BioSilicon and CODRUG.

***The Durasert Technology System***

Our proprietary Durasert system delivers specific quantities of drugs directly to a target site in the body at controlled rates for predetermined periods of time ranging from days to years. Durasert is designed to address drawbacks of systemic drug delivery for our target diseases, which include adverse side effects characteristic of high dosing levels and reduced treatment benefits due to variations in drug levels at the target site.

Durasert is designed to offer three principal advantages:

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

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

***Durasert Products and Product Candidates***

Our Durasert portfolio of products and product candidates is as follows:

<u>Product</u>	<u>Disease</u>	<u>Stage of Development</u>
Retisert	Posterior uveitis . . . . .	FDA-approved; commercialized since 2005
Vitrasert	CMV retinitis . . . . .	FDA-approved; commercialized since 1996
Iluvien	Diabetic macular edema (DME) . . . . .	Phase III clinical trials
Iluvien	Age-related macular degeneration (AMD) . . .	Investigator-sponsored pilot clinical trial
Medidur	Retinitis Pigmentosa . . . . .	Pre-clinical trials

*Retisert.* Retisert treats posterior uveitis and is the only drug approved by the FDA to treat this disease. Posterior uveitis is an autoimmune condition characterized by inflammation of the inside of the eye that can cause sudden or gradual vision loss. The disease has been estimated to affect 175,000 people in the United States and to have resulted in blindness in approximately 30,000 people in the U.S. Retisert, which is surgically implanted through a 3-4 mm incision, delivers sustained levels of the anti-inflammatory corticosteroid FA for 30



months. Although there are off-label treatments for posterior uveitis, these treatments generally only slow the progression of the disease and can have more serious side effects than Retisert. Clinical trials have shown that many patients treated with Retisert experience improved vision. Retisert was approved as an orphan drug, which provided for seven-year exclusive marketing rights. Retisert is marketed and sold in the United States by Bausch & Lomb.

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

*Iluvien.* The Iluvien product candidate (formerly known as Medidur FA for DME) is designed to treat DME, a disease that causes swelling in the macula, the most sensitive part of the retina. DME is a major cause of vision loss in diabetics and a leading cause of vision loss for Americans under 65. Iluvien, which is injected via a 25 gauge transconjunctival delivery system to the back of the eye in an in-office procedure, is designed to deliver FA on a sustained basis for up to 36 months and is based upon certain of our proprietary drug delivery technology. We are not aware of any approved drug treatment for DME. Current treatments of DME have serious limitations, which include repeat treatments or invasive surgical procedures, and in general only temporarily reverse vision loss and slow the progression of the disease.

We licensed Alimera to develop, market and sell Iluvien, which is currently in fully enrolled Phase III trials for DME. Under the Alimera agreement, Iluvien is also in an investigator-sponsored pilot clinical trial for treatment of exudative age-related macular degeneration (wet AMD) in conjunction with Lucentis®.

*Medidur.* We have a worldwide collaborative research and license agreement with Pfizer under which Pfizer may develop certain additional ophthalmic applications of Medidur-based products. In addition, we have conducted pre-clinical studies for retinitis pigmentosa.

### ***The BioSilicon Technology System***

Our proprietary BioSilicon technology system is based on a nano-porous form of elemental silicon. We believe it has the potential to deliver a wide variety of drugs, including small chemical entities, peptides, proteins and other therapeutics such as P32. The BioSilicon technology involves processing the silicon to create a “honeycomb” structure of pores. BioSilicon has two significant characteristics:

- *Biocompatibility.* BioSilicon is biocompatible, meaning that it is not injurious and does not cause immunological rejection within the body when it degrades into silicic acid (the non-toxic, dietary form of silicon found in food).
- *Biodegradability.* BioSilicon is biodegradable both in vivo (in animals and humans) and in vitro (in solution). BioSilicon’s biodegradability can be finely tuned so that it dissolves in suitable environments in days, weeks or months.

As a result, we believe that BioSilicon, like Durasert, can be designed to locally deliver therapeutics to a target site at a controlled release rate for an extended period of time.

The following properties make BioSilicon a potentially effective drug delivery platform:

- high level drug loading (up to 95%) and up to 50% weight/weight;
- ability to improve the dissolution and bioavailability of poorly water soluble drugs and the ability to control drug release;

- ability to accommodate different molecular sizes of drugs; and
- ability to serve as a conductor of electrical charge which can be altered to regulate drug delivery rate (in potential future advanced drug delivery systems).

#### *BioSilicon Product Candidate and Potential Applications.*

*BrachySil for Pancreatic Cancer.* Our BrachySil product candidate is designed to treat pancreatic cancer. BrachySil is injected through a needle directly to the tumor site in an in-office procedure. BrachySil delivers phosphorus-32, or P32, a beta-emitting radioactive isotope that has been shown to shrink tumors. Because this radiation is also harmful to healthy tissue, BrachySil is designed to reduce radiation dispersed beyond the area of the tumor. Existing P32-based products allow the isotope to dissolve, disperse throughout the body and harm healthy tissue in other parts of the body.

We believe BrachySil has a number of potential advantages:

- *Short range.* P32 isotope has a short active range resulting in less damage to healthy tissue;
- *Range of tumors.* Fine gauge needle delivery allows potential application to a range of solid tumors;
- *Direct delivery.* Injection via fine gauge needle minimizes side effects and tissue trauma;
- *Distribution.* P32 half-life of 14 days allows more logistically convenient distribution to hospitals and application in the patient;
- *Immobilization.* P32 particles are generally localized in the tumor, significantly reducing risk of leakage or systemic side effects.

We have completed an initial clinical trial, designed as a safety study, of BrachySil for the treatment of pancreatic cancer and have commenced a dose-ranging trial. We are seeking to clarify the regulation of BrachySil as a medical device in the U.S. and the European Union (EU). Generally, obtaining regulatory approval to market a medical device is less expensive and time consuming than the process required for approval of a new drug. Our strategic plan is to secure a development and marketing partner in advance of commencing a pivotal Phase III clinical trial of BrachySil.

#### *Other Potential BioSilicon Applications*

We believe BrachySil has the potential to be used to treat other solid tumors, and we intend to investigate other tumor indications, such as liver metastases.

#### ***The CODRUG Technology System***

Our proprietary CODRUG system allows for the simultaneous release of two or more drugs from the same product at the same controlled rate over a predetermined period of time. Using this technology, we chemically link two or more identical or different drugs. Codrugs can be administered by virtually any delivery method and dissolve into the body at a predetermined rate, and then separate into the original active drug(s) when the chemical bond breaks apart. We believe that many drugs can be chemically linked with our CODRUG technology and have synthesized a library of several hundred CODRUG compounds.

#### **Acquisition of Control Delivery Systems**

On December 30, 2005, we completed the acquisition of Control Delivery Systems, Inc., since renamed pSivida US, Inc. We refer to Control Delivery Systems as “CDS” prior to the acquisition and as “pSivida US” after the acquisition. In this acquisition, we acquired the Durasert technology system, including the Vitrasert and Retisert products and the Iluvien product candidate, and the CODRUG technology system.



## **Strategic Collaborations**

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

### ***Chiron Vision Corporation***

Our first collaboration was with Chiron Vision Corporation (“Chiron”), a subsidiary of Chiron Corporation. Under a 1992 licensing and development agreement with CDS, Chiron financed the development of Vitrasert, and was granted a worldwide, exclusive license to make and sell products based on the Durasert technology used in Vitrasert for the treatment of conditions of the eye. Chiron commenced commercial sales of Vitrasert following FDA approval in 1996. Bausch & Lomb acquired Chiron in 1997, assumed this agreement and currently markets Vitrasert and pays us royalties on sales.

### ***Bausch & Lomb Incorporated***

In 1999, CDS entered into a licensing and development agreement with Bausch & Lomb for additional products for the treatment of eye diseases. CDS granted Bausch & Lomb a worldwide, exclusive license for the life of the relevant patents to use certain of its technologies for the treatment, prevention or diagnosis of any disease, disorder or condition of the eye in humans or in animals.

In December 2003, under an amended and restated license agreement that significantly revised the 1992 and 1999 agreements, CDS granted Bausch & Lomb a worldwide, exclusive license to certain of its technologies to make and sell Vitrasert and CDS’s first generation products (as defined in the agreement), including the Retisert device, for the treatment, prevention and diagnosis of any disease, disorder or condition of the human eye. Bausch & Lomb agreed to pay CDS royalties based on sales of any products that meet the definition of first generation products. Bausch & Lomb can terminate its agreement with us without penalty at any time upon 90 days’ written notice.

### ***Alimera Sciences Inc.***

In February 2005, CDS granted Alimera a worldwide exclusive license to use certain of its technologies to make and sell certain Medidur-based products for the treatment and prevention of eye diseases other than uveitis. CDS also granted Alimera a worldwide non-exclusive license to use certain of its technologies to make and sell certain additional Medidur-based products for the treatment and prevention of eye diseases other than uveitis that are not exclusively licensed to Bausch & Lomb, have a drug core within a polymer layer and are either approved or designed to be approved either to deliver a corticosteroid by a direct delivery method to the posterior portion of the eye or to treat DME by delivering a compound through a direct delivery method other than through incisions smaller than a specified size. Other than the licenses to Bausch & Lomb, we are not permitted to use, or grant a license to any third party to use, such technologies to make or sell any products subject to the non-exclusive license granted to Alimera. Under the terms of this original license and collaboration agreement, we agreed to jointly fund the development of Iluvien and share in net profits.

On March 14, 2008, we amended and restated this license and collaboration agreement. In exchange for current and future consideration of up to approximately \$78 million, we agreed to receive a 20% share in the future profits of Iluvien and any other licensed products developed under this amended collaboration agreement.

Current consideration consisted of \$12.0 million in cash received upon the execution of the amended collaboration agreement and cancellation of \$5.7 million of accrued development cost liabilities, including related penalties and accrued interest, owed by us to Alimera as of March 14, 2008. Other consideration, exclusive of our 20% profit share, includes (i) conditional principal and interest payments of up to approximately

\$21.0 million through September 2012 under a note issued by Alimera; (ii) a \$25.0 million milestone payment upon FDA approval of Iluvien for DME; (iii) reimbursement of approved development costs we incur in support of the ongoing clinical studies of Iluvien for the treatment of DME and anticipated regulatory submissions; and (iv) assumption by Alimera of all financial responsibility for the development of licensed products under the collaboration agreement, which will result in the elimination of an estimated \$14.0 million of development cost obligations that would otherwise have been payable by us to Alimera in connection with the development of Iluvien during the period from April 2008 through the completion of the development process under the original collaboration agreement.

Either party may terminate the agreement for the other party's uncured material breach. pSivida may terminate the agreement with respect to a particular product if Alimera abandons such product, in which case the agreement provides for specific, exclusive remedies.

### ***Pfizer***

On April 3, 2007, we entered into an exclusive worldwide Collaborative Research and License Agreement with Pfizer for certain of our technologies, including the technology underlying the Medidur drug delivery device, in certain ophthalmic applications.

Under the terms of the agreement, we are eligible to receive up to \$153.5 million in development and sales related milestones. We are working together on a joint research program aimed at developing ophthalmic products using our sustained drug delivery technology. Beginning with the first calendar quarter of 2008, Pfizer has paid us \$500,000 per quarter and is required to continue to make quarterly payments of at least \$500,000 until a Phase III clinical trial commences. Pfizer will have an exclusive license to market all products developed under this collaboration agreement and will pay us a royalty on net sales of those products. Pfizer may terminate the agreement without penalty on 60 days notice without cause.

In addition, Pfizer made a \$5.0 million equity investment in the Company upon entering into the license agreement. Pursuant to the terms of the license agreement, Pfizer made an additional \$6.5 million investment in the Company in connection with our July 2007 share issue transaction. As a result of these equity investments, Pfizer is currently the Company's largest shareholder, owning approximately 10.2% of total shares outstanding as of August 31, 2008.

### ***Evaluation Agreements***

We have entered into agreements with potential collaborative partners to evaluate our technologies for the delivery of drug molecules utilizing our Durasert, BioSilicon or CODRUG technologies. If the work being conducted under these evaluation agreements is successful, we believe there is the potential to license the relevant technology for a specific drug molecule and/or application.

### **Research and Development**

Our primary activity is the development of products based on our Durasert, BioSilicon and other technologies. Our research and development expenses, including acquired in-process research and development (IPR&D) and impairment of intangible assets, were \$14.4 million, \$66.3 million and \$45.6 million during fiscal 2008, 2007 and 2006, respectively. Of these amounts, approximately \$10.2 million, \$9.7 million and \$11.1 million for fiscal 2008, 2007 and 2006, respectively, were incurred for costs of research and development personnel, clinical trials, contract services, testing and laboratory facilities. Such costs are charged to operations as incurred. The remaining expense of \$4.2 million, \$56.6 million and \$34.5 million for fiscal 2008, 2007 and 2006, respectively, consisted of non-cash charges for an impairment write-down of our Retisert intangible asset, acquired IPR&D, amortization of intangible assets, depreciation of property, plant and equipment and stock-based compensation expense specifically allocated to research and development personnel.

## Intellectual property

Our intellectual property rights are crucial to our business. We hold or are licensed patents relating to our core technologies in the United States and European markets. The following table provides general details relating to our owned and licensed patents (including both patents that have been issued and applications that have been accepted for issuance) and patent applications, and is based on information available as of August 31, 2008.

<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>
<b>Durasert</b> .....	10	19	43	111	18
<b>BioSilicon</b> .....	10	20	46	72	24
<b>CODRUG</b> .....	3	19	10	34	19
<b>Other</b> .....	—	3	—	4	3
<b>Total</b> .....	<u>23</u>	<u>61</u>	<u>99</u>	<u>221</u>	<u>64</u>

*Durasert Technology.* Our patent portfolio comprises patents and patent applications relating to the use of a drug-containing core and one or more polymer layers, membranes or coatings, that deliver drugs locally or systemically at a controlled rate for a predetermined period of time ranging from days to years.

*BioSilicon Technology.* Our patent portfolio comprises patents and patent applications relating to the use of BioSilicon on or in the body in various healthcare applications, including drug delivery, targeted internal cancer therapy and the use of silicon in pharmaceuticals.

*CODRUG Technology.* Our patent portfolio comprises patents and patent applications relating to the use and delivery of codrugs for various pharmaceutical and healthcare-related applications.

*Other Technology.* We have patents and patent applications relating to various other technologies, including methods for controlling elevated intraocular pressure.

## Employees

The Company had 21 employees as of August 31, 2008.

## Sales and Marketing

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

## Reimbursement

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

## Competition

We are engaged in healthcare product development, an industry that is characterized by extensive research efforts and rapid technological progress. Our principal competitors in this market are the numerous drug delivery

and pharmaceutical companies that are attempting to improve the safety and efficiency of pharmaceuticals by developing and introducing novel delivery methods. In addition, 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 therapies for our targeted diseases.

Retisert is the only FDA-approved treatment for posterior uveitis, although steroids and other existing drugs approved for other uses are commonly administered systemically or by local injection to treat this condition in off-label use. Vitrasert primarily competes with treatments involving the systemic delivery of ganciclovir, a Roche Holdings AG product, and other drugs.

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

- Genentech, Inc. has developed an FDA-approved treatment for wet AMD, Lucentis, which is injected directly into the eye approximately every month to six weeks. Clinical trials are underway investigating the use of this drug for treatment of DME.
- Allergan, Inc. is in Phase III clinical trials of its product, Posurdex®, for the treatment of persistent macular edema. If approved by the FDA, this product may be used off-label for the treatment of DME.
- Merck & Co., Inc (Merck) has licensed from SurModics Inc. a device composed of a helical coil coated with drug releasing polymer which is implanted in the back of the eye to treat DME. Recently, Merck announced that it suspended recruitment of a Phase II clinical trial.
- Neurotech SA has begun Phase II clinical trials of its NT-501, a cell-based implant that releases ciliary neurotrophic factor for the treatment of retinitis pigmentosa.

BrachySil competes with a number of treatments of pancreatic cancer, including surgery, radiation and chemotherapy.

## Revenues

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

	Year Ended June 30,								
	2008			2007			2006		
	United States	United Kingdom	Total	United States	United Kingdom	Total	United States	United Kingdom	Total
	(In thousands)								
Revenue:									
Collaborative research and development . . . . .	\$3,328	\$—	\$3,328	\$ 652	\$—	\$ 652	\$642	\$—	\$ 642
Royalties . . . . .	148	—	148	1,052	—	1,052	343	—	343
Other . . . . .	—	—	—	—	81	81	—	51	51
	<u>\$3,476</u>	<u>\$—</u>	<u>\$3,476</u>	<u>\$1,704</u>	<u>\$ 81</u>	<u>\$1,785</u>	<u>\$985</u>	<u>\$ 51</u>	<u>\$1,036</u>

## Long-Lived Assets

The following table summarizes our long-lived assets by geographical location:

	Long-lived assets		
	2008	2007	2006
		(In thousands)	
United States . . . . .	\$10,072	\$11,281	\$62,197
United Kingdom . . . . .	27,203	30,024	32,145
Other . . . . .	—	9	61
Consolidated . . . . .	<u>\$37,275</u>	<u>\$41,314</u>	<u>\$94,403</u>

## Government Regulation

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

- pre-clinical laboratory and animal tests;
- submission to the FDA of an investigational new drug application (IND), which must become effective before clinical trials may begin in the United States;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed pharmaceutical for its intended use;
- submission to the FDA of a new drug application; and
- FDA review and approval of the new drug application.

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

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

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified principal investigators. Clinical trials are conducted in accordance with protocols that detail the objectives of the study, the parameters to be used to monitor safety and any efficacy criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND. Further, each clinical study must be conducted under the auspices of an independent institutional review board at the institution where the study will be conducted. The institutional review board will consider, among other things, ethical factors, safety of human subjects and possible liability of the institution. Some clinical trials, called “investigator-sponsored” clinical trials, are conducted by third-party investigators. The results of these trials may be used as supporting data by a company in its application for FDA approval, provided that the company has contractual rights to use the results.

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

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

In the case of products for life-threatening diseases such as cancer, or severe conditions such as blinding eye disease, or for products that require invasive delivery, the initial human testing is often conducted in patients with the disease rather than in healthy volunteers. Since these patients already have the targeted disease or condition, these studies may provide initial evidence of efficacy traditionally obtained in Phase II trials and so these trials are frequently referred to as Phase I/II or IIa trials. We cannot be certain that we will successfully complete Phase I, Phase II or Phase III testing of our product candidates within any specific time period, if at all. Furthermore, we, the FDA, the institutional review board or the sponsor, if any, may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

The Food and Drug Administration Amendments Act of 2007 (FDAAA) is designed to provide the public with more easily accessible information about the safety and efficacy of marketed drugs and the FDA with increased authority to ensure drug safety. The FDAAA requires that we register each controlled clinical trial, aside from a Phase I trial, on a website administered by National Institutes of Health (NIH), including descriptive information (e.g., a summary in lay terms of the study design, type and desired outcome), recruitment information (e.g., target number of participants and whether healthy volunteers are accepted), location and contact information and administrative data (e.g., FDA identification numbers). Effective September 2008, within one year of a trial's completion, information about the trial including characteristics of the patient sample, primary and secondary outcomes, trial results written in lay and technical terms and the full trial protocol must be submitted to the FDA. The information is then posted to the website unless the drug has not yet been approved, in which case the FDA posts the information shortly after approval. A new drug application, supplement, and certain other submissions to the FDA require certification of compliance with the FDAAA clinical trials database requirements.

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

If a drug is intended for the treatment of a serious or life-threatening condition and has the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA "fast track" designation. The fast track designation applies only for the specific indications for which the product satisfies these two requirements. Under fast track provisions, the FDA is committed to working with the sponsor for the purpose of expediting the clinical development and evaluation of the drug's safety and efficacy for the fast track indication.

Marketing applications filed by sponsors of products in fast track development often will qualify for expedited review under policies or procedures offered by the FDA, but fast track designation does not assure this qualification.



If a drug treats a disease or condition that affects fewer than 200,000 people in the United States, the drug sponsor may apply to the FDA for “orphan drug” designation under the Orphan Drug Act. More than one drug may be given an orphan drug designation by the FDA for a given disease or condition. However, the first drug with an orphan drug designation to receive marketing approval for the treatment of that disease or condition is granted a period of marketing exclusivity. Sponsors are granted seven years of exclusive rights to market the first approved orphan drug for treatment of that disease or condition, independent of any additional patent protection that may apply to the product. This marketing exclusivity does not prevent a competitor from obtaining approval to market a different drug that treats the same disease or condition or the same drug to treat a different disease or condition. Sponsors also are granted tax incentives for clinical research undertaken to support an application for an orphan drug, and grants to defray some of these clinical costs may also be available. In addition, the FDA will typically coordinate with the sponsor on research study design for an orphan drug and may exercise its discretion to grant marketing approval on the basis of more limited product safety and efficacy data than would ordinarily be required. If the FDA withdraws a product’s orphan drug designation, however, these various benefits no longer apply.

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

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

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

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

We are also subject to foreign regulatory requirements governing human clinical trials and marketing approval for pharmaceutical products which we may sell outside the U.S. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary widely by country. Whether or not we obtain FDA approval, we must obtain approval of a product by the comparable regulatory authorities of

foreign countries before manufacturing or marketing the product in those countries. The approval process varies from country to country, and the time required for these approvals may differ substantially from that required for FDA approval. There is no assurance that clinical trials conducted in one country will be accepted by other countries or that approval in one country will result in approval in any other country. For clinical trials conducted outside the U.S., the clinical stages generally are comparable to the phases of clinical development established by the FDA.

In the event that we seek approval of Brachysyl as a device in the United States, we would need to satisfy the following regulatory requirements. Products that are classified as devices also require some form of FDA approval prior to marketing. Devices are classified as Class I, II or III, depending upon the information available to assure their safety and effectiveness. In general, Class I and Class II devices are devices whose safety and effectiveness can reasonably be assured through general or specific controls, respectively. Class III devices are life sustaining, life supporting, are of substantial importance in preventing impairment to health or pose an unreasonable risk of adverse effect. They are implantable devices or new devices which have been found not to be substantially equivalent to legally marketed devices. The steps required for approval of a Class III device include:

- preclinical laboratory tests and in vitro and in vivo preclinical studies;
- the submission to the FDA and approval of an Investigational Device Exemption (IDE) application to allow initiation of clinical testing;
- human clinical studies to prove safety and effectiveness of the device;
- the submission of a Pre-Marketing Approval application (PMA); and
- the approval by the FDA of the PMA.

Typically, clinical testing of devices involves initial testing to evaluate safety and feasibility and expanded trials to collect sufficient data to prove safety and effectiveness. In addition, the procedures and the facilities used to manufacture the device are subject to review and approval by the FDA.

A device (other than a Class III device) that is proven to be substantially equivalent to a device marketed prior to May 28, 1976, when government regulations for devices were first introduced, can be marketed after clearance of a 510(k) application rather than the filing of an IDE application and a PMA. The 510(k) application must contain a description of the device, its methods of manufacture and quality control procedures and the results of testing to demonstrate that the device is substantially equivalent to the device already marketed.

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

### **Available Information**

Our principal executive office is located at 400 Pleasant Street, Watertown, Massachusetts 02472 and our telephone number is 617-926-5000. We maintain a website at [www.psvida.com](http://www.psvida.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 amendments to those filings pursuant to Section 13(a) or 15(d) of the Exchange Act are available free of charge through our website under "SEC Filings", as soon as reasonably practicable after we electronically file these materials with, or otherwise furnish them to, the Securities and Exchange Commission (SEC).

## Item 1A. Risk Factors.

### Risks related to our company and our business

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

Our cash and cash equivalents totaled approximately \$15.6 million at June 30, 2008. We believe we can fund our operations as currently conducted through at least June 30, 2010. This expectation is based on the assumptions that we continue to receive the Pfizer quarterly \$500,000 research and development funding, Alimera continues to fund the development of Iluvien, we resume receiving Retisert royalties from Bausch & Lomb during the fiscal year ending June 30, 2010 and we receive the scheduled conditional note payments from Alimera. However, whether and when we will require additional capital will depend upon many other factors, including, but not limited to:

- the continuation of our existing collaborations with Pfizer and Alimera, including their continued funding of our programs and our receipt of milestone, royalty, note and other payments;
- the timely development, regulatory approval and commercialization of Iluvien, which is our primary product candidate currently in development;
- the amount and timing of sales of Retisert, which affect the timing of the resumption of Retisert royalty payments and the amount of such royalty payments;
- the scope and extent of our internally funded operations, including our programs for BrachySil (including any Phase III trials for BrachySil for pancreatic cancer), any new product candidates, or any new business opportunities;
- our ability to establish and maintain strategic arrangements for Brachysil or any other product candidates for research, development, clinical testing, manufacturing and marketing;
- the success of our products and product candidates, including the timing and costs of regulatory approvals and the commercial success of approved products;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims; and
- changes in our operating plan, including the pursuit of any new business opportunities, which may affect our need for capital.

In particular, our future cash position depends significantly on the approval and marketing of Iluvien and the occurrence of certain liquidity events under the terms of our amended collaboration agreement with Alimera. Alimera has agreed to pay us a \$25 million payment upon FDA approval of Iluvien and a 20% share in the future profits of Iluvien. In addition, the \$15 million note issued by Alimera becomes due and payable upon the occurrence of certain defined liquidity events (such as an initial public offering) that result in aggregate proceeds to Alimera in excess of \$75 million. There is no assurance that the FDA will approve Iluvien or that Iluvien will achieve market acceptance even if it is approved by the FDA. There is similarly no guarantee of the occurrence of a liquidity event resulting in aggregate gross proceeds to Alimera in excess of \$75 million.

If we require additional capital in the future, we do not know if it will be available when needed or on terms favorable to us or our stockholders. If available, additional equity financing may be dilutive to stockholders, debt financing may involve restrictive covenants or other unfavorable terms and potentially dilutive equity, and collaboration agreements may be on unfavorable terms, including a requirement that we relinquish rights to certain of our technologies or products. If adequate financing is not available if and when needed, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs, postpone the pursuit of product candidates and new business opportunities, or otherwise reduce our cash requirements.

***We have a history of losses; we expect to continue to incur losses, and we may never become profitable.***

pSivida was formed in 2000. As primarily a research and development company, we have incurred operating losses in every year of our existence. We incurred a net loss of \$47.0 million for the year ended June 30, 2006, a net loss of \$81.2 million for the year ended June 30, 2007 and a net loss of \$75.7 million for the year ended June 30, 2008. As of June 30, 2008, we had an accumulated deficit of \$224.5 million. We have not achieved profitability and expect to continue to incur net losses through at least the fiscal year ending June 30, 2010, and we may incur losses beyond that time if our Iluvien product candidate is not approved and widely marketed. Even if Iluvien is approved and marketed at some point after June 30, 2010, our profit share on sales of Iluvien, combined with royalty income from our current products and product candidates, and any other sources of revenue, may not be sufficient to result in profitability at that time or at any other time.

***We do not currently derive revenue from Retisert, and there is no assurance that Retisert will ever be a material source of revenue.***

In consideration of a June 2005 royalty advance of \$3.0 million, we agreed that Bausch & Lomb would retain \$6.25 million of future Retisert royalties that otherwise would be payable to us under the license agreement. As of June 30, 2008, an additional \$2.8 million of future royalties otherwise payable to us from the sales of Retisert will be retained by Bausch & Lomb before we are entitled to receive any further royalty payments. At June 30, 2007, we decreased our assessment of the probable level of future sales of Retisert as a result of historical sales trends and Bausch & Lomb's decision to withdraw its European application for authorization to market Retisert, resulting in a \$45.3 million impairment write-down of the value assigned to the Retisert patents at the time of the CDS acquisition. In addition, the use of the corticosteroid FA in Retisert has been associated with undesirable side effects, including increased incidence of cataract formation and increased intraocular pressure, which side effects we believe have negatively affected sales of Retisert. We cannot predict when, if ever, we will begin receiving full royalty payments from Bausch & Lomb or the amount of any future royalty payments that we will receive.

***Certain of our current licensees may terminate their agreements with us at any time, and if they do, we may not be able to effectively develop and sell our products.***

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

We have exclusively licensed certain of our controlled drug delivery technologies to Pfizer for certain ophthalmic applications. Pfizer is funding research and further development and commercialization of products licensed under our agreement with them. Pfizer may terminate the agreement without penalty at any time and for any reason upon 60 days written notice. We have exclusively licensed our technology underlying Vitrasert, Retisert and other ophthalmic applications to Bausch & Lomb, and have licensed the technology underlying Iluvien and certain ophthalmic applications to Alimera. Bausch & Lomb is responsible for funding and managing the development and commercialization of all licensed products and can terminate its agreement with us without penalty at any time upon 90 days' written notice. Pursuant to the amended collaboration agreement with Alimera, Alimera has assumed financial responsibility for the development of licensed products, along with sole responsibility for the commercialization of such licensed products. Alimera may abandon the development and commercialization of any licensed product at any time.

Alimera was incorporated in June 2003 and has limited resources. Any of Pfizer, Alimera or Bausch & Lomb may decide not to continue with or commercialize any or all of the licensed products, change strategic

focus, pursue alternative technologies or develop competing products. While Pfizer and Bausch & Lomb have significant experience in the ophthalmic field and have substantial resources, there is no assurance as to whether, and to what extent, that experience and those resources will be devoted to our technologies. Because we do not currently have sufficient funding or internal capabilities to develop and commercialize our products and product candidates, decisions, actions, breach or termination of these agreements by Pfizer, Bausch & Lomb or Alimera could delay or stop the development or commercialization of Retisert, Iluvien or other potential future product candidates licensed to such entities.

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

We have registration rights agreements that require us to file and maintain the effectiveness of registration statements for the resale of our common stock, which provide for monetary penalties in the event of our failure to do so. During the year ended June 30, 2007, we paid registration delay penalties of approximately \$2.3 million in connection with our then outstanding Sandell subordinated convertible promissory note and Absolute subordinated convertible notes. Our failure or inability to maintain the effectiveness of any of our required registration statements or to adequately update information in the related prospectuses may subject us to additional penalties under our current registration rights agreements. Payment of additional penalties may have a material adverse effect on our financial condition and may require us to suspend, curtail or terminate our operations or delay, reduce the scope of or eliminate one or more of our research and development programs, any of which could have a material adverse effect on our business.

***If we do not receive the necessary regulatory approvals, we will be unable to commercialize our product candidates.***

Our current and future activities are and will be subject to stringent regulation by governmental authorities both in the United States and in any other country in which our products are marketed. Before we or our collaborative partners can manufacture, market and sell any of our product candidates, approval from the FDA and/or foreign regulatory authorities is first required. Generally, in order to obtain these approvals, pre-clinical studies and clinical trials must demonstrate that each of our product candidates is safe for human use and effective for its targeted disease or condition. Our product candidates are in various stages of pre-clinical and clinical testing. In particular, Iluvien is in Phase III clinical trials and Brachysil is in a dose ranging clinical trial. Product development involves a high degree of risk, and only a small number of research and development programs result in an approved product. If clinical trials for any of our product candidates do not provide the necessary evidence of safety and effectiveness, those product candidates cannot be manufactured and sold and will not generate revenue from sales. Clinical trials for our product candidates may fail or be delayed by many factors, including the following:

- our lack of sufficient funding to pursue trials rapidly or at all;
- our inability to attract clinical investigators for trials;
- our inability to recruit patients in sufficient numbers or at the expected rate;
- our inability to reach agreement with a collaborative partner to undertake the clinical trials;
- adverse side effects;
- failure of the trials to demonstrate a product's safety or efficacy;
- our failure to meet FDA or other regulatory agency requirements for clinical trial design;
- our inability to follow patients adequately after treatment;
- changes in the design or manufacture of a product;
- failures by, or changes in the relationship of our collaboration partners with, contract research organizations, third-party vendors and investigators responsible for preclinical testing and clinical trials;



- our inability to manufacture sufficient quantities of materials for use in clinical trials; and
- governmental or regulatory delays.

Results from pre-clinical testing and early clinical trials often do not accurately predict results of later clinical trials. Data obtained from pre-clinical and clinical activities are susceptible to varying interpretations which may delay, limit or prevent regulatory approval. Data from pre-clinical studies, early clinical trials and interim periods in multi-year trials are preliminary and may change, and final data from pivotal trials for such products may differ significantly. Adverse side effects may develop that delay, limit or prevent the regulatory approval of products, or cause their regulatory approvals to be limited or even rescinded. For example, Iluvien utilizes the corticosteroid FA as its active ingredient, which has been associated with undesirable side effects in Retisert. Our collaborative partner must demonstrate that Iluvien presents an acceptable risk/benefit profile in order to achieve FDA approval.

Additional trials necessary for approval may not be undertaken or may ultimately fail to establish the safety and efficacy of proposed products. The FDA or other relevant regulatory agencies may not approve proposed products for manufacture and sale. Any product approvals we achieve could also be withdrawn for failure to comply with regulatory standards or due to unforeseen problems after the products' marketing approval. In either case, we would be required to cease marketing the affected product. In addition, the FDA or other regulatory agencies may impose limitations on the indicated uses for which a product may be marketed.

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

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

Our success is dependent on whether we can obtain patents, defend our existing patents and operate without infringing on the proprietary rights of third parties. As of August 31, 2008, we had 122 patents and 282 pending patent applications, including patents and pending applications covering our Durasert, BioSilicon and CODRUG technologies. Intellectual property protection of our technologies is uncertain. We expect to seek to patent and protect our proprietary technologies. However, there is no assurance that any additional patents will be issued to us as a result of our pending or future patent applications or that any of our patents will withstand challenges by others. In addition, we may not have sufficient funds to patent and protect our proprietary technologies to the extent that we would desire or at all. If we were determined to be infringing any third party patent, we could be required to pay damages, alter our products or processes, obtain licenses, pay royalties or cease certain operations. We may not be able to obtain any required licenses on commercially favorable terms, if at all. In addition, many foreign country laws may treat the protection of proprietary rights differently from, and may not protect our proprietary rights to the same extent as, laws in the United States and Patent Co-operation Treaty countries.

Prior art may reduce the scope or protection of, or invalidate, patents. Previously conducted research or published discoveries may prevent patents from being granted, invalidate issued patents or narrow the scope of any protection obtained. Reduction in scope of protection or invalidation of our licensed or owned patents, or our inability to obtain patents, may enable other companies to develop products that compete with our products and product candidates on the basis of the same or similar technology. As a result, our patents and those of our licensors may not provide any or sufficient protection against competitors.



While we have not been and are not currently involved in any litigation over intellectual property, such litigation may be necessary to enforce any patents issued or licensed to us or to determine the scope and validity of third party proprietary rights. We may also be sued by one or more third parties alleging that we infringe their intellectual property rights. Any intellectual property litigation would be likely to result in substantial costs to us and diversion of our efforts. If our competitors claim technology also claimed by us and if they prepare and file patent applications in the U.S. or other jurisdictions, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark office or appropriate foreign patent office to determine priority of invention, which could result in substantial cost to us and diversion of our efforts. Any such litigation or interference proceedings, regardless of the outcome, could be expensive and time consuming. Litigation could subject us to significant liabilities to third parties, requiring disputed rights to be licensed from third parties and/or require us to cease using certain technologies.

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

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

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

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

The success of these and future collaborative arrangements will depend heavily on the experience, resources, efforts and activities of our collaborators. Our collaborators have, and are expected to have, significant discretion in making these decisions. Risks that we face in connection with our collaboration strategy include the following:

- our collaborative 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 arrangements not to conduct specified types of research and development in the field that is the subject of the collaboration, limiting the areas of research and development that we can pursue;
- our collaborators may develop and commercialize, either alone or with others, products that are similar to or competitive with our products;
- our collaborators, consistent with other pharmaceutical and biotechnology companies that have historically acted similarly, may for a variety of reasons change the focus of their development and commercialization efforts or decrease or fail to increase spending related to our products, limiting the ability of our products to reach their potential;

- our collaborators may lack the funding or experience to develop and commercialize our products successfully or may otherwise fail to do so; and
- our collaborators may not perform their obligations, in whole or in part.

To the extent that we choose not to, or we are unable to, enter into future license agreements with marketing and sales partners and seek to market and sell products ourselves, we would experience increased capital requirements to develop the ability to manufacture, market and sell future products. We may not be able to manufacture, market or sell our technology or future products independently in the absence of such agreements.

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

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

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

- are more effective and easier to use;
- are more economical;
- have fewer side effects; or
- 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, and have more significant resources.

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

We currently maintain offices in the U.S. and the U.K. BrachySil is produced for us in Germany and the U.K., and BioSilicon is produced in-house and by third party contractors in the U.K. We have research and development facilities in the U.S. and the U.K., and we intend to license products for sale and/or sell products in most major world healthcare markets. A number of risks are inherent in our international strategy. In order for us to license and manufacture our products, we must obtain country and jurisdiction-specific regulatory approvals or clearances to comply with regulations regarding safety and quality. We may not be able to obtain or maintain regulatory approvals or clearances in such countries, and we may be required to incur significant costs in

obtaining or maintaining foreign regulatory approvals or clearances. In addition, our operations and revenues may be subject to a number of risks associated with foreign commerce, including the following:

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

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

Our ability to conduct timely preclinical and clinical research and development programs, obtain regulatory approvals, commercialize our product candidates and fulfill our contract manufacturing obligations to others will depend, in part, upon our and our collaborative partners' ability to manufacture our products, either directly or through third parties, in accordance with FDA and other regulatory requirements. The manufacture and packaging of our products and product candidates are regulated by the FDA and similar foreign regulatory entities and must be conducted in accordance with applicable current good manufacturing practices, or cGMP. There are a limited number of manufacturers that operate under these cGMP regulations which are both capable of manufacturing our products and product candidates and are willing to do so. Failure by us, our collaborative partners or our or their third-party manufacturers to comply with applicable manufacturing requirements could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product, operating restrictions and criminal prosecutions.

We currently have BioSilicon production capability at our facility and under contract in the U.K. for use in internal and collaborative research. BrachySil is currently manufactured by a third party under contract, in accordance with cGMP. We currently manufacture clinical supplies of Iluvien pursuant to our agreement with Alimera. We are also obligated to manufacture all clinical supplies pursuant to our agreement with Pfizer, but only to the extent required in the research plan.

We could experience delays in the development or commercialization of our product candidates if we or our partners are unable to manufacture by ourselves, or to source third parties to manufacture, Iluvien, BioSilicon, BrachySil or other product candidates. We or our collaborative partners may not be able to manufacture our proposed products successfully or have a third party manufacture them in a cost-effective manner. If we or our collaborative partners are unable to develop our own manufacturing facilities or to obtain or retain third-party manufacturing on acceptable terms, we may not be able to conduct certain future pre-clinical and clinical testing or to supply commercial quantities of our products.

We have licensed to Pfizer the exclusive rights to manufacture commercial quantities of ophthalmic products covered by its license agreement with us. We have licensed to Bausch & Lomb the exclusive rights to manufacture commercial quantities of Vitrasert, Retisert and other products covered by its license agreement with us. We have licensed to Alimera the rights to manufacture commercial quantities of Iluvien, if approved for marketing, and other products covered by its license agreement with us. Our current reliance on third party manufacturers entails risks, including:

- the possibility that third parties may not comply with the FDA's cGMP regulations, other regulatory requirements, and those of similar foreign regulatory bodies, and may not employ adequate quality assurance practices;

- supply disruption, deterioration in product quality or breach of a manufacturing or license agreement by the third party because of factors beyond our control;
- the possible termination or non-renewal of a manufacturing or licensing agreement with a third party at a time that is costly or inconvenient to us; and
- our inability to identify or qualify an alternative manufacturer in a timely manner, even if contractually permitted to do so.

For example, we believe that Alimera currently intends to rely on a single manufacturer of Iluvien and a single active pharmaceutical ingredient formulator. Our business could be significantly harmed if these third parties are not able to satisfy demand and alternative sources are not available. In addition, the materials necessary to produce Iluvien or formulate the active pharmaceutical ingredient may not be available on commercially reasonable terms, which could affect the development and commercialization of Iluvien.

***Reimbursement of our products by government health administration authorities and other third-party payors could affect market acceptance.***

In both domestic and foreign markets, our ability to commercialize our products successfully depends, in part, upon the availability and extent of reimbursement from third-party payors, such as government health administration authorities, private health insurers and other organizations. Governments and other third-party payors attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for products. Third-party payors may challenge the price and cost-effectiveness of our products. If our products are not considered cost-effective, third-party payors may deny or limit reimbursement. Governments and other third-party payors may refuse to provide coverage for uses of approved products for disease indications for which they have not been granted regulatory approval. If government and third-party payors do not provide adequate coverage and reimbursement levels for uses of our products, the market acceptance of our products would be limited.

There have been a number of U.S. federal and state proposals during the last few years to subject the pricing of pharmaceuticals to government control and to make other changes to the health care system in the U.S. It is uncertain what legislative proposals will be adopted or what actions federal, state or private payors for health care goods and services may take in response to any health care reform proposals or legislation. Similar health care reforms may also be implemented outside of the U.S. We cannot predict the effect health care reforms may have on our business.

***If we fail to retain some or all of our key personnel, our business could suffer.***

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

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

The testing, manufacturing, and marketing and sale of the products utilizing our technologies involves risks that product liability claims may be asserted against us or our licensees. Our current clinical trial and product liability insurance may not be adequate to cover damages resulting from product liability claims. 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.

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

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

***We have identified a material weakness in our internal control over financial reporting. If we fail to achieve and maintain effective internal control over financial reporting, we may be unable to accurately report our financial results on a timely basis or prevent or detect errors in our financial statements, and investor confidence and the market price of our shares may be adversely affected.***

Our management assessed the effectiveness of our internal control over financial reporting as of June 30, 2008 pursuant to section 404 of the Sarbanes-Oxley Act of 2002 and related SEC rules and concluded that our internal control over financial reporting was not effective as of June 30, 2008. Specifically, management identified a material weakness in our internal control over financial reporting. The material weakness that management identified relates to our controls over the application of U.S. GAAP to complex transactions. This material weakness in our internal control over financial reporting also resulted in a conclusion by our management that disclosure controls and procedures were not effective as of June 30, 2008.

In June 2008, we restated our unaudited condensed consolidated financial statements as of and for the quarters ended March 31, 2008, December 31, 2007 and September 30, 2007. Subsequent to March 31, 2008, we identified an error requiring an adjustment of \$4.7 million to Goodwill and Additional paid-in capital at March 31, 2008, December 31, 2007 and September 30, 2007. The error originally occurred in December 2005 and was the result of incorrectly translating the A\$ value of shares issued as purchase consideration for the acquisition of CDS back to US\$ as a result of using the exchange rate at the measurement date determined under the Australian equivalents of International Financial Reporting Standards (A-IFRS) instead of under U.S. GAAP. This error relates to the control deficiency identified above.

We are in the process of addressing our material weakness and will seek to maintain effective internal control over financial reporting and disclosure controls and procedures. If we are not able to effectively address the identified material weakness or otherwise fail to maintain effective internal control over financial reporting or effective disclosure controls and procedures, we may be unable to accurately report our financial results in a timely manner or prevent errors or fraud, and investor confidence and the market price of our shares may be adversely affected.

***Our results could be adversely affected as a result of the impact of impairment of our intangible assets, which could adversely affect the price of your securities.***

In connection with our acquisitions of CDS and pSiMedica, we recorded significant amounts of goodwill, patents and licenses, as well as deferred tax liabilities. Goodwill is subject to at least annual impairment analysis, and the recorded value of patents and licenses must also be evaluated for impairment in certain circumstances. Impairment charges may be material and may adversely affect the price of our shares.

At June 30, 2008, we conducted our annual impairment analysis of goodwill as required under generally accepted accounting principles in the United States (U.S. GAAP). The goodwill impairment charge of \$60.1 million was determined by comparing the carrying value of goodwill of the reporting unit with the implied fair value of goodwill of the reporting unit, and was primarily due to the decline in the Company's share price during the fourth quarter that was deemed to be other than temporary.

Further, in July 2007, we received formal confirmation of our prior understanding from industry sources that Bausch & Lomb had withdrawn its application for authorization to market Retisert in Europe. As required under U.S. GAAP, we evaluated the recoverable amounts of the Retisert intangible assets at June 30, 2007 and recorded an impairment charge of \$45.3 million related to these assets. We have \$36.8 million of intangible assets on our balance sheet at June 30, 2008. We will conduct impairment analyses of our intangible assets as required. Our results of operations may be materially adversely affected by impairment charges that may result from such analyses.

### **Risks related to our stock**

#### ***The price of our common stock may be volatile.***

The price of our common stock (and CDIs) may be affected by developments directly affecting our business and by developments out of our control or unrelated to us. The biotechnology sector, in particular, and the stock market generally, are vulnerable to abrupt changes in investor sentiment. Prices of securities and trading volume of companies in the biotechnology industry, including ours, can swing dramatically in ways unrelated to, or that bear a disproportionate relationship to, operating performance. The price of our stock (and CDIs) and their trading volumes may fluctuate based on a number of factors including, but not limited to:

- clinical trial results and other product and technological developments and innovations;
- FDA and other governmental regulatory actions, receipt and timing of approvals of our product candidates, and any denials and withdrawals of approvals;
- competitive factors, including the commercialization of new products in our markets by our competitors;
- advancements with respect to treatment of the diseases targeted by our product candidates;
- developments relating to collaborative partners, including execution and termination of agreements, achievement of milestones and receipt of payments;
- the success of our collaborative partners in marketing any approved products and the amount and timing of the royalties payable to us;
- availability and cost of capital and our financial and operating results;
- changes in reimbursement policies or other practices relating to our product candidates or the pharmaceutical industry generally;
- meeting, exceeding or failing to meet analysts' or investors' expectations, and changes in evaluations and recommendations by securities analysts;
- economic, industry and market conditions, changes or trends; and
- other factors unrelated to us or the biotechnology industry.

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

#### ***If the holders of our outstanding warrants and stock options exercise their warrants and options, your ownership may be diluted and our stock price may decline.***

The issuance of shares of our common stock upon exercise of our outstanding warrants and stock options would result in dilution to the interests of other holders of our common stock and could adversely affect our



stock price. As of September 15, 2008, we had outstanding warrants and options to acquire 12,171,773 shares of our common stock, or approximately 66.6% of our total outstanding shares. Although the exercise prices of the vast majority of these warrants and options are substantially above the current price, the overhang of such warrants and options may adversely affect our stock price. The warrant exercise prices may be adjusted under certain circumstances, including, among others, in the event we issue securities in a rights offering at a lower price than the exercise price.

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

Pfizer owned approximately 10.2% of our outstanding shares as of August 31, 2008 and is a collaborative partner. As a result, Pfizer may be able to exert significant influence over our board of directors and how we operate our business. The concentration of ownership may also have the effect of delaying or preventing a change in control of our company.

**Item 1B. Unresolved Staff Comments**

Not applicable.

**Item 2. Properties**

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

- 3,940 square feet of laboratory space, 1,582 square feet of clean room space and 7,890 square feet of office space in Watertown, Massachusetts under a lease agreement that expires in April 2011; and
- 1,500 square feet of laboratory space and 3,600 square feet of office space in Malvern, United Kingdom under a lease agreement that expires in December 2008.

**Item 3. Legal Proceedings**

None.

**Item 4. Submission of Matters to a Vote of Security Holders.**

On June 6, 2008, we held a special meeting of shareholders in connection with the Reincorporation (the Scheme Meeting). Under Australian law, a majority of the shareholders present and voting and 75% of the total number of shares voted had to approve the Reincorporation in order for the resolution to pass. Our shareholders passed the resolution as follows:

<u>Resolution</u>	<u>For</u>	<u>Against</u>	<u>Abstain</u>
Approval of the Reincorporation . . . . .	247 shareholders 4,186,849 shares	12 shareholders 174,829 shares	2 shareholders 49,978 shares

Immediately following the Scheme Meeting, we held a special meeting of shareholders (the EGM) to approve the pSivida Corp. 2008 Incentive Plan. Under Australian law, a majority of the total number of shares voted had to approve the pSivida Corp. 2008 Incentive Plan in order for the resolution to pass. Our shareholders passed the resolution as follows:

<u>Resolution</u>	<u>For</u>	<u>Against</u>	<u>Abstain</u>
Approval of the pSivida Corp. 2008 Incentive Plan . . . . .	4,010,781 shares	201,131 shares	58,478 shares

For purposes of reporting the voting results of both the Scheme Meeting and the EGM, the share numbers have been adjusted to give effect to the Reincorporation, including the Reincorporation's share exchange ratio.

## Part II

### Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

#### Market Information, Holders and Dividends

Commencing June 20, 2008, our common stock has been listed on the NASDAQ Global Market. Prior to that date, our predecessor's ADSs, each of which represented 10 ordinary shares in our predecessor, were listed on the NASDAQ Global Market. The quarterly high and low prices for our predecessor's ADSs and our common stock for the fiscal years ended June 30, 2008 and 2007 are set forth in the table below. The prices of our predecessor's ADSs have been adjusted to give effect to the Reincorporation's share exchange ratio.

	Quarter Ended			
	Sep 2007	Dec 2007	Mar 2008	Jun 2008
High .....	\$5.20	\$4.92	\$4.00	\$5.00
Low .....	2.80	3.00	1.56	2.05

  

	Quarter Ended			
	Sep 2006	Dec 2006	Mar 2007	Jun 2007
High .....	\$18.56	\$11.20	\$8.40	\$11.96
Low .....	8.24	5.44	6.16	5.48

Commencing June 20, 2008, our CDIs, each representing one share of our common stock, have been listed on ASX. Prior to that date, our predecessor's ordinary shares were listed on ASX. The quarterly high and low prices for our predecessor's ordinary shares and our CDIs for the fiscal years ended June 30, 2008 and 2007 are set forth in the table below. The prices of our predecessor's ordinary share have been adjusted to give effect to the Reincorporation's share exchange ratio.

	Quarter Ended			
	Sep 2007	Dec 2007	Mar 2008	Jun 2008
	(In Australian dollars)			
High .....	6.60	5.40	4.40	6.00
Low .....	3.60	3.24	2.64	2.40

  

	Quarter Ended			
	Sep 2006	Dec 2006	Mar 2007	Jun 2007
	(In Australian dollars)			
High .....	22.80	13.20	11.80	13.40
Low .....	10.40	9.00	8.00	6.20

As of August 31, 2008, we had approximately 1,850 shareholders. In addition, as of August 31, 2008, there were approximately 3,500 registered owners of our CDIs.

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

## Equity Compensation Plan Information

The following table provides equity compensation plan information as of June 30, 2008. All of the information relates to options granted under our Employee Stock Option Plan (the "Plan"). Shareholders first approved the Plan at our predecessor's annual general meeting on November 30, 2001. Shareholders re-approved the Plan at each of our predecessor's annual general meetings held on November 17, 2004 and November 27, 2007.

<u>Plan categories</u>	<u>Number of securities to be issued upon exercise of outstanding options</u> (a)	<u>Weighted-average exercise price of outstanding options</u> (b)	<u>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in Column a)</u> (c)
Equity Compensation plans approved by security holders .....	455,478	A\$29.57	(*)
Equity Compensation plans not approved by security holders .....	—	—	—
<b>Total</b> .....	<u>455,478</u>	<u>A\$29.57</u>	<u>(*)</u>

\* Following the Reincorporation, no additional grants will be made under the Plan. On June 6, 2008, our shareholders approved the pSivida Corp 2008 Incentive Plan, under which we may issue awards for up to 1,750,000 shares over the life of the incentive plan. As of June 30, 2008, we had not issued any awards under this incentive plan. We have subsequently issued 601,000 options to executive officers and other employees under the pSivida Corp. 2008 Incentive Plan.

## Use of Proceeds

On March 9, 2007, the SEC declared our registration statement (No. 333-141091) on Form F-3 effective with respect to \$60.0 million of our common stock, warrants, preference shares and units. In July 2007, we concluded an offering under this shelf registration statement and a related, but separate, unregistered offering to an Australian institutional investor. The aggregate net offering proceeds to us from these offerings were \$18.4 million, all which were invested in bank accounts for eventual application to working capital. As of June 30, 2008, the entire net offering proceeds had been applied to working capital. The proceeds applied to working capital include payments of salary, director fees and other compensation to current and former executive officers and directors. The proceeds applied to working capital have otherwise been paid to unaffiliated third parties.

## Issuer Purchases of Securities

Holders of our predecessor's ordinary shares who would otherwise have received fractional shares of our common stock pursuant to the Reincorporation as a result of the Reincorporation's 1:40 share exchange ratio instead received from us the cash value of such fractional shares.

<u>Period</u>	<u>(a)</u> <u>Total</u> <u>Number</u> <u>of Shares</u> <u>Purchased</u>	<u>(b)</u> <u>Average</u> <u>Price</u> <u>Paid Per</u> <u>Share (1)</u>	<u>(c)</u> <u>Total Number of</u> <u>Shares Purchase as</u> <u>Part of Publicly</u> <u>Announced</u> <u>Reincorporation (2)</u>	<u>(d)</u> <u>Maximum</u> <u>Number of</u> <u>Shares that May</u> <u>Yet Be</u> <u>Purchased</u> <u>under the</u> <u>Reincorporation</u>
June 2008 .....	624	A\$4.40	624	0

- (1) The closing price per share of the our predecessor's ordinary shares on ASX on June 10, 2008.
- (2) We announced our intention to reincorporate in the United States on April 18, 2008. There was no explicit dollar or share amount approved for repurchase; we agreed to pay our predecessor's shareholders the cash value of any fractional shares of common stock that they otherwise would have received as a result of the Reincorporation's share exchange ratio. No other shares of our common stock have been or will be repurchased by us pursuant to the Reincorporation.

## Item 6. Selected Financial Data

The following table presents our selected historical consolidated financial data as of the dates and for each of the periods indicated. The information set forth below is not necessarily indicative of future results and should be read in conjunction with Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our audited consolidated financial statements and the notes thereto appearing elsewhere in this Report. The selected consolidated balance sheet data as of June 30, 2008 and 2007 and the selected consolidated statement of operations data for each of the three years in the period ended June 30, 2008 have been derived from our audited consolidated financial statements and the notes thereto appearing elsewhere in this Annual Report on Form 10-K. The selected consolidated balance sheet data as of June 30, 2006 and the selected consolidated statement of operations data for the year ended June 30, 2005 have been derived from our audited consolidated financial statements contained in our Form 8-K filed with the SEC on June 20, 2008. The selected consolidated balance sheet data as of June 30, 2005 and 2004 and the selected consolidated statement of operations data for the year ended June 30, 2004 have been derived from our audited consolidated financial statements (including the U.S. GAAP reconciliation contained therein) contained in our predecessor’s 2007 Form 20-F, which are not included herein.

	Year Ended June 30,				
	2008 (1)	2007 (2,3)	2006 (4)	2005	2004
	(Amounts in thousands, except per share amounts)				
<b>STATEMENT OF OPERATIONS DATA:</b>					
Revenues	\$ 3,476	\$ 1,785	\$ 1,036	\$ 122	\$ 40
Loss from continuing operations	(75,670)	(83,525)	(45,312)	(11,738)	(7,503)
Net loss	(75,670)	(81,203)	(46,957)	(12,322)	(3,584)
Loss per share—basic and diluted					
Loss from continuing operations	\$ (4.17)	\$ (7.57)	\$ (6.02)	\$ (2.26)	\$ (2.36)
Net loss	\$ (4.17)	\$ (7.36)	\$ (6.24)	\$ (2.37)	\$ (1.13)
Weighted average shares outstanding—basic and diluted	18,166	11,038	7,521	5,195	3,175
	As of June 30,				
	2008	2007	2006	2005	2004
	(Amounts in thousands)				
<b>BALANCE SHEET DATA:</b>					
Total assets	\$ 55,784	\$107,220	\$165,504	\$ 70,254	\$ 28,506
Long-term debt	—	—	2,912	—	—
Total stockholders’ equity	30,078	88,265	130,747	61,821	25,680

- (1) At June 30, 2008, in connection with our annual review of goodwill pursuant to SFAS 142, “*Goodwill and Other Intangibles*”, we incurred a \$60.1 million goodwill impairment charge. See Note 5 to the accompanying audited consolidated financial statements for additional information.
- (2) At June 30, 2007, we recorded a \$45.3 million impairment charge related to our Retisert intangible assets. See Note 5 to the accompanying audited consolidated financial statements for additional information.
- (3) In April 2007, we sold the stock of our AION Diagnostics, Inc. subsidiary for a pre-tax and after-tax gain of \$3.6 million. See Note 14 to the accompanying audited consolidated financial statements for additional information.
- (4) In December 2005, we completed the acquisition of CDS for aggregate consideration of \$108.2 million, including \$3.0 million in cash. For the years ended June 30, 2008, 2007 and 2006, 100% of our collaborative research and development revenues and royalty income have been attributable to the operations of CDS (renamed pSivida US, Inc.). Approximately \$25.0 million of the purchase price was allocated to our Iluvien product candidate and was charged to acquired in-process research and development expense for the year ended June 30, 2006. See Note 3 to the accompanying audited 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 should be read in conjunction with our audited consolidated financial statements and notes there to appearing elsewhere in this Annual Report on Form 10-K.

### **Overview**

We are a drug delivery company committed to the biomedical sector, with a primary focus on ophthalmology and oncology. We have two products approved by the FDA: Retisert for the treatment of uveitis and Vitrasert for the treatment of AIDS-related CMV retinitis. We have licensed both of these products and the technologies underlying them to Bausch & Lomb. We have one product in fully recruited Phase III clinical trials: Iluvien™, which delivers FA for the treatment of diabetic macular edema (DME), formerly known as Medidur FA for DME. We have licensed certain of our drug delivery technology to Alimera for the development of Iluvien and certain other ophthalmic products. We have a worldwide collaborative research and license agreement with Pfizer under which Pfizer may develop additional ophthalmic products.

We own the rights to develop and commercialize a modified form of silicon known as BioSilicon™, which has potential therapeutic applications. Our most advanced BioSilicon product candidate, BrachySil™, delivers a therapeutic P32, a radioactive form of phosphorus used to treat cancer, directly to solid tumors. We recently completed an initial safety and efficacy clinical trial of Brachysil for the treatment of pancreatic cancer and have commenced a dose-ranging clinical trial.

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

In January 2008 we announced the results of our initial clinical study of BrachySil for the treatment of advanced, inoperable pancreatic cancer. The trial, designed as a safety study, indicated that BrachySil, in combination with standard chemotherapy, was well tolerated with no clinically significant adverse events related to BrachySil. In July 2008, we commenced a dose-ranging trial.

On March 14, 2008, we amended and restated our license and collaboration agreement with Alimera. In exchange for current and future consideration of up to approximately \$78 million, we agreed to a 20% share in the future profits of Iluvien and any other licensed products developed under the amended collaboration agreement.

Current consideration consisted of (i) \$12.0 million in cash received upon the execution of the amended collaboration agreement and (ii) cancellation of \$5.7 million of accrued development cost liabilities, including related penalties and accrued interest, owed by us to Alimera as of March 14, 2008. Other consideration, exclusive of our 20% profit share, includes (i) conditional principal and interest payments of up to approximately \$21.0 million through September 2012 under a note issued by Alimera; (ii) a \$25.0 million milestone payment upon FDA approval of Iluvien for the treatment of DME; (iii) reimbursement of approved development costs we incur in support of the ongoing clinical studies of Iluvien for the treatment of DME and anticipated regulatory submissions; and (iv) assumption by Alimera of all financial responsibility for the development of licensed products under the collaboration agreement, which will result in the elimination of an estimated \$14.0 million of development cost obligations that would otherwise have been payable by us to Alimera during the period from April 2008 through the completion of the development process under the original collaboration agreement.

Effective June 19, 2008, we reincorporated from Western Australia to the United States (the Reincorporation). Pursuant to a scheme of arrangement under Australian law, all ordinary shares, including ordinary shares represented by ADSs, of pSivida Limited, a company incorporated in Western Australia, were transferred by court order to pSivida Corp., a company incorporated in Delaware, in exchange for shares of pSivida Corp. common stock, including common stock represented by CDIs, in a ratio of 40 pSivida Limited ordinary shares to 1 share of pSivida Corp. All of the assets and liabilities of pSivida Limited, including outstanding options and warrants to purchase ordinary shares or ADSs of pSivida Limited, were, by court order, transferred to pSivida Corp., following which pSivida Limited was deregistered without a winding up. All options and warrants were equitably adjusted to reflect the Reincorporation. Each CDI represents one share of common stock. The common stock of pSivida Corp. is listed on the NASDAQ Global Market. pSivida Corp. CDIs are listed on the ASX and the Frankfurt Stock Exchange.

### **Summary of Critical Accounting Policies**

We prepare our consolidated financial statements in accordance with U.S. GAAP. In preparing these financial statements, 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 periods presented. These estimates, judgments and assumptions, which management believes are reasonable under the circumstances and are based upon the information available at the time, cannot be made with certainty. These estimates, judgments and assumptions may change as new events occur or as additional information is obtained, and actual results may differ from these estimates under different assumptions or conditions. While there are a number of accounting policies, methods and estimates affecting our financial statements as described in Note 2 to the accompanying audited consolidated financial statements, management has identified certain of these accounting policies to be critical to aid in a full understanding and evaluation of our financial condition and results of operations. A critical accounting policy is one that is both material to the presentation of our financial statements and requires us to make subjective or complex judgments that could have a material effect on our financial condition and results of operations. We believe the following critical accounting policies, and our procedures relating to these policies, require more significant judgments and estimates in the preparation of our consolidated financial statements.

### **Revenue Recognition for License Agreements**

We have entered into collaborative license and development arrangements with strategic partners for the development and commercialization of products utilizing our technologies. The terms of these agreements typically include multiple deliverables by us (for example, license rights, providing research and development services and manufacturing of clinical materials) in exchange for consideration to us of some combination of non-refundable license fees, funding of research and development activities, payments based upon achievement of clinical development milestones and royalties in the form of a designated percentage of product sales or profits. We follow the provisions of the SEC Staff Accounting Bulletin (“SAB”) No. 101 (“SAB 101”), “*Revenue Recognition in Financial Statements*”, as amended by SAB No. 104 (“SAB 104”), “*Revenue Recognition*”, and Emerging Issues Task Force (“EITF”) Issue No. 00-21 (“EITF 00-21”), “*Accounting for Revenue Arrangements with Multiple Deliverables*”. With the exception of royalties, these types of consideration are classified as collaborative research and development revenue in our statements of operations when revenue recognition is appropriate.

Non-refundable license fees are recognized as revenue when we have a contractual right to receive such payment, the contract price is fixed or determinable, the collection of the resulting receivable is reasonably assured and we have no further performance obligations under the license agreement. Multiple element arrangements, such as license and development arrangements, are analyzed to determine whether the deliverables can be separated or whether they must be accounted for as a single unit of accounting in accordance with EITF 00-21. We recognize up-front license payments as revenue upon delivery of the license only if the license has stand-alone value and the fair value of the undelivered performance obligations can be determined. If the fair



value of the undelivered performance obligations can be determined, such obligations would then be accounted for separately as performed. If the license is considered to either (i) not have stand-alone value or (ii) have stand-alone value but the fair value of any of the undelivered performance obligations cannot be determined, the arrangement would then be accounted for as a single unit of accounting.

For arrangements that are accounted for as a single unit of accounting, total payments under the arrangement are recognized as revenue on a straight-line basis over the period we expect to complete our performance obligations. The cumulative amount of revenue earned is limited to the cumulative amount of payments received as of the period ending date.

If we cannot reasonably estimate when our performance obligation either ceases or becomes inconsequential, then revenue is deferred until we can reasonably estimate when the performance obligation ceases or becomes inconsequential. Revenue is then recognized over the remaining estimated period of performance. Deferred revenue amounts are classified as current liabilities to the extent that revenue is expected to be recognized within one year.

Significant management judgment is required in determining the level of effort required under an arrangement and the period over which we are expected to complete our performance obligations under an arrangement.

#### *Amended and Restated Collaboration Agreement with Alimera*

As discussed in Note 4 to the accompanying audited consolidated financial statements, we entered into an amended collaboration agreement with Alimera on March 14, 2008. The terms and conditions of this amendment required an assessment of the expected term of the agreement and our obligations thereunder. Pursuant to EITF 00-21, we evaluated our obligations under the amended agreement and concluded that, since each deliverable did not have a determinable fair value to the licensee on a standalone basis, such deliverables represented a single unit of accounting. We further determined that all of our consequential development obligations under the amended agreement would cease no later than December 31, 2009. Accordingly, commencing on the effective date of the amended agreement, we will amortize the aggregate \$18.3 million deferred revenue balance that existed at that date on a straight-line basis over the 21.5 month performance period. The \$18.3 million deferred revenue balance consisted of (i) a \$12.0 million payment received upon the execution of the amended agreement; (ii) cancellation of approximately \$5.7 million of accrued development costs, including related penalties and accrued interest, owed by us to Alimera as of March 14, 2008; and (iii) \$650,000 of previously received but unamortized milestone payments.

All future payments received from Alimera during the designated performance period will be recognized as revenue using the cumulative catch-up method. Under this method, the portion of any such payment represented by the time elapsed from the amendment effective date to the payment date as a percentage of the 21.5 month performance period will be recognized immediately as revenue, with the remainder amortized on a straight-line basis over the remaining performance period. All payments received from Alimera following the end of the performance period will be recognized as revenue when earned.

#### *Pfizer Collaborative Research and License Agreement*

On April 3, 2007, we and Pfizer entered into a Collaborative Research and License Agreement (the "Pfizer Agreement") which superseded a prior research agreement dated December 22, 2006. Under the Pfizer Agreement, the parties have implemented a joint research program aimed at developing certain ophthalmic products using our Durasert drug delivery technology. In addition to potential development and sales related milestone payments, Pfizer pays us a minimum of \$500,000 per quarter, which commenced in calendar year 2008, in consideration of our costs in performing the research program, and continues until the commencement of a Phase III clinical trial for the first licensed product candidate or until the agreement is earlier terminated.

The two Pfizer agreements have been combined for accounting purposes and, following an evaluation of the multiple deliverables in accordance with the provisions of EITF 00-21, we concluded that there was a single unit of accounting. We are evaluating the timing of the deliverables and other obligations under the Pfizer Agreement and, as a result, all payments received through June 30, 2008 from Pfizer totaling \$2.25 million have been recorded as deferred revenue.

### ***Intangible Assets and Goodwill***

#### ***Impairment of Intangible Assets***

We review our intangible assets that are being amortized for impairment whenever events or other changes in circumstances indicate that the carrying value of an asset may no longer be recoverable. At December 31, 2006 and at June 30, 2007, we identified triggering events that required in-depth assessment of the recoverability of the carrying value of our Retisert and BrachySil intangible assets. The valuation assessment required detailed analysis of projected future cash inflows and cash outflows associated with each intangible asset. These projections required the application of numerous judgments. In the case of Retisert, a commercialized product with two years of sales history, these judgments and estimates included market penetration rates, estimated market growth, potential impact of new technologies under development, penetration rate for re-implants and appropriate weighted average cost of capital rate to discount the future cash flows. In the case of BrachySil, a product candidate then in Phase IIa clinical trials, other estimates included the cost and duration of later stage clinical trials, timing of regulatory approval and the probability of a collaboration agreement with a third party.

At June 30, 2007, we recorded an impairment write-down of \$45.3 million in connection with our Retisert patents. No impairment write-downs were required at December 31, 2006. In connection with the goodwill impairment analysis at June 30, 2008, we determined that the forecasted undiscounted cash flows associated with each of the Company's intangible assets exceeded its carrying value, and therefore no impairment of intangible assets was recorded at June 30, 2008. These projections required the application of numerous judgments, including future growth rates.

If there are future triggering events, we may be required to record additional impairment write-downs against the \$36.8 million carrying value (at June 30, 2008) of our intangible assets

#### ***Goodwill Impairment.***

In performing the goodwill impairment testing, management relies on a number of factors including operating results, business plans, economic projections, anticipated future cash flows, and transactions and market place data. There are inherent uncertainties related to these factors and judgment in applying them to the analysis of goodwill impairment. Since judgment is involved in performing goodwill valuation analyses, there is risk that the carrying value of our goodwill may be overstated or understated. We calculate our goodwill valuation using a combination of the income and market approaches. These methods incorporate many assumptions including future growth rates, discount factors and income tax rates. Changes in economic and operating conditions impacting these assumptions could result in goodwill impairment in future periods.

We test goodwill as of June 30 each year for impairment, or more frequently if certain indicators are present or changes in circumstances suggest that impairment may exist. When conducting an annual goodwill impairment test, we utilize a two-step approach. The first step requires a comparison of the carrying value of the reporting unit to its fair value. If the carrying value of the reporting unit exceeds its fair value, we will perform the second step of the goodwill impairment to measure the amount of impairment loss, if any. The second step of the goodwill impairment test compares the implied fair value of a reporting unit's goodwill with its carrying value. The implied fair value of goodwill is determined in the same manner that the amount of goodwill recognized in a business combination is determined. We allocate the fair value of a reporting unit to all of the assets and liabilities, including intangible assets, as if the reporting unit had been acquired in a business combination. Any excess of the value of a reporting unit over the amounts assigned to its assets and liabilities is the implied fair value of goodwill.

During fiscal 2008, we recorded a goodwill impairment charge of \$60.1 million. There were no goodwill impairment charges during fiscal 2007 and 2006.

### *Accounting for Convertible Notes*

We financed our activities partially through the issuance of convertible notes with detachable warrants in November 2005 and September 2006 to institutional investors. These compound instruments require analysis of their component parts and appropriate classification as liabilities and equity. We concluded that the note holder conversion option was an embedded derivative that required bifurcation and classification as a derivative liability subject to fair value adjustment through the consolidated statements of operations. The fair value of the embedded derivative was estimated using the Binomial Tree Model, taking into account assumptions as to share price volatility, dividend yield and market interest rates for a comparable non-convertible debt instrument.

The initial carrying value of a convertible note liability is determined by first subtracting from the gross proceeds the relative fair value of any equity component and then subtracting the fair value of any compound embedded derivatives. The effective interest method is used to amortize to finance costs the debt discount over the expected life of the financial liability, or such shorter period as may be deemed appropriate. Debt issue costs are recorded as an asset and similarly amortized to finance costs over the life of the financial liability.

During the year ended June 30, 2007, we entered into multiple amendments of the terms of the Sandell convertible note. For each amendment, we estimated the present value of the future cash flows of the amended note, including cash and non-cash consideration, against that of the pre-amendment note. If the resulting present values reflected a change of greater than 10%, the pre-amendment note was accounted for as an extinguishment of debt and the amended note as the issuance of a new compound debt instrument. Alternatively, if the resulting present values reflected a change of less than 10%, the amendment was treated as a modification of the original debt instrument. As more fully described in Note 8 to the accompanying audited consolidated financial statements, during the year ended June 30, 2007, we entered into three amendments of our Sandell convertible note, two of which were recorded as an extinguishment of the prior debt instrument and one of which was treated as a debt modification.

## Results of Operations for the Year Ended June 30, 2008 Compared to the Year Ended June 30, 2007

	Year ended June 30,		Change	
	2008	2007	Amounts	%
	(In thousands except percentages)			
Revenues .....	\$ 3,476	\$ 1,785	\$ 1,691	95%
Operating expenses:				
Impairment of goodwill .....	60,106	—	60,106	na
Impairment of intangible assets .....	—	45,278	(45,278)	na
Research and development .....	14,426	21,065	(6,639)	(32)%
General and administrative .....	13,951	11,204	2,747	25%
Total operating expenses .....	88,483	77,547	10,936	14%
Operating loss from continuing operations .....	(85,007)	(75,762)	(9,245)	12%
Other income (expense):				
Change in fair value of derivative .....	8,357	11,434	(3,077)	(27)%
Interest income .....	648	277	371	134%
Interest and finance costs .....	(507)	(9,491)	8,984	(95)%
Loss on extinguishment of debt .....	—	(23,361)	23,361	na
Other income, net .....	356	153	203	133%
Total other income (expense) .....	8,854	(20,988)	29,842	(142)%
Loss from continuing operations before income taxes .....	(76,153)	(96,750)	20,597	(21)%
Income tax benefit .....	483	13,225	(12,742)	(96)%
Loss from continuing operations .....	(75,670)	(83,525)	7,855	(9)%
Loss from discontinued operations .....	—	(1,318)	1,318	na
Gain on sale of discontinued operations .....	—	3,640	(3,640)	na
Income from discontinued operations .....	—	2,322	(2,322)	—
Net loss .....	<u>\$(75,670)</u>	<u>\$(81,203)</u>	<u>\$ 5,533</u>	<u>(7)%</u>

na = not applicable

### Revenue

Revenue increased by approximately \$1.7 million, or 95%, to approximately \$3.5 million for the year ended June 30, 2008 from approximately \$1.8 million for the year ended June 30, 2007. Collaborative research and development revenues increased by \$2.6 million, principally due to revenue recognized in connection with the March 2008 amended collaboration agreement with Alimera. This increase was partially offset by a \$900,000 decrease in Retisert royalties payable to us.

On March 14, 2008, we amended and restated our collaboration agreement with Alimera dated February 2005. Pursuant to the amended collaboration agreement, a total of \$18.3 million of deferred revenue at that date is being recognized ratably over a period of 21.5 months from the effective date of the amendment through December 31, 2009, which represents the period of our performance obligations. Additional cash consideration received by us from Alimera during the period from the amendment effective date through December 31, 2009 will also be recognized ratably over the performance period, including immediate revenue recognition catch-up for the pro rata period from the amendment effective date to the date of receipt. For the year ending June 30, 2009, the Company expects to record collaborative development revenue of at least \$10.5 million related to the amended collaboration agreement.

Pursuant to an advance royalty agreement dated June 2005, CDS received \$3.0 million from Bausch & Lomb as an advance payment in lieu of \$6.25 million of future Retisert royalties that otherwise would be payable

under our license agreement with Bausch & Lomb. Bausch & Lomb was entitled to retain 50% of the first \$3.0 million of royalties otherwise payable, or \$1.5 million, and 100% of the next \$4.75 million of royalties otherwise payable. Thereafter, we are entitled to receive 100% of the royalties to which we are otherwise entitled under the license agreement. The following table summarizes the applicable royalty amounts for the period from inception (July 1, 2005) through June 30, 2008 and the future effect of this agreement prospectively from that date:

	<b>Royalties Otherwise Payable Under the License Agreement</b>	<b>Net Royalty Amounts Payable Under the Amended License Agreement</b>
	(In thousands)	
For the six months ended December 31, 2005 (1) . . . . .	\$ 555	\$ 278
For the six months ended June 30, 2006 . . . . .	589	294(2)
For the year ended June 30, 2007 . . . . .	1,921	928(3)
For the year ended June 30, 2008 . . . . .	<u>1,849</u>	<u>—</u>
From inception through June 30, 2008 . . . . .	4,914	1,500
For the period from July 1, 2008 until such time as cumulative royalties otherwise payable under the License Agreement total \$7.75 million . . . . .	<u>2,836</u>	<u>—</u>
Total . . . . .	<u><u>\$7,750</u></u>	<u><u>\$1,500</u></u>

- (1) Represents the period prior to our acquisition of CDS, which closed on December 30, 2005
- (2) Represents the Retisert royalties included as revenue in our audited consolidated financial statements for the fiscal year ended June 30, 2006
- (3) Represents 50% of \$1,856,000 of royalties otherwise payable and 0% of \$65,000 of royalties otherwise payable

As of June 30, 2008, Bausch & Lomb is entitled to retain an additional \$2.8 million of future Retisert royalties otherwise payable to the Company. Accordingly, we currently do not expect to receive any Retisert royalty income from Bausch & Lomb until at least the fiscal year ending June 30, 2010.

### ***Impairment of Goodwill***

As a result of our annual evaluation of goodwill under the terms and provisions of Statement of Financial Accounting Standards (“SFAS”) No. 142, “*Goodwill and Other Intangible Assets*” (“SFAS 142”), the Company recognized an impairment charge equal to the total carrying value of goodwill of \$60.1 million for the year ended June 30, 2008. The goodwill impairment charge was determined by comparing the carrying value of goodwill of the reporting unit with the implied fair value of goodwill of the reporting unit (see Note 5 to the accompanying audited consolidated financial statements for further information).

### ***Impairment of Intangible Assets***

Impairment of intangible assets totaled \$45.3 million for the year ended June 30, 2007. In July 2007, we received formal confirmation of our prior understanding from industry sources that Bausch & Lomb had withdrawn its European application for authorization to market Retisert. As a result, we assessed the recoverability of the carrying value of the Retisert patents at June 30, 2007 (see Note 5 of the accompanying audited consolidated financial statements) and determined that the value of such patents was \$11.1 million.

### ***Research and Development***

Research and development decreased by approximately \$6.6 million, or 32%, to \$14.4 million for the year ended June 30, 2008 from \$21.1 million for the year ended June 30, 2007. This decrease was primarily attributable to the following factors:

- a net decrease of approximately \$5.4 million in amortization of intangibles, primarily resulting from the \$45.3 million impairment of our Retisert patents at June 30, 2007 and, to a lesser extent, the effect of an increase in the estimated useful life of the BrachySil patents as of December 31, 2006; and
- a decrease of approximately \$2.3 million in U.K.- and Singapore-based operating expenses as a result of (i) significant head count reductions in the U.K in fiscal year 2007; (ii) reduced levels of clinical trial program activities; and (iii) reduced depreciation expense principally related to a clean room facility that was fully depreciated as of March 2007; partially offset by
- an increase of approximately \$1.2 million in co-development costs related to the Phase III clinical trial of the Iluvien product candidate through the March 14, 2008 effective date of our amended collaboration agreement with Alimera.

Pursuant to the terms of the amended collaboration agreement, Alimera assumed complete financial responsibility for the ongoing Phase III clinical trial and other regulatory activities related to Iluvien. As a result, in future periods we do not expect to incur co-development costs for Iluvien, which totaled approximately \$4.7 million for the year ended June 30, 2008.

### ***General and Administrative***

General and administrative costs increased by approximately \$2.7 million, or 25%, to approximately \$14.0 million for the year ended June 30, 2008 from \$11.2 million for the year ended June 30, 2007, primarily as the result of an increase of approximately \$1.9 million of legal, audit and professional fees and other transactional costs incurred during the year ended June 30, 2008 due to the Reincorporation.

### ***Change in Fair Value of Derivative***

Change in fair value of derivative decreased by approximately \$3.1 million, or 27%, to income of \$8.4 million for the year ended June 30, 2008 from income of \$11.4 million for the year ended June 30, 2007.

During the years ended June 30, 2008 and 2007, we recorded the value of detachable warrants issued in share offerings denominated in Australian dollars (A\$) as a derivative liability, subject to revaluation at subsequent reporting dates. The change in fair value of derivative related to these warrants resulted in income of \$8.4 million and \$6.8 million for the years ended June 30, 2008 and 2007, respectively, primarily attributable to a net decrease in the market price of our shares during the periods.

We recorded derivative liabilities in connection with the conversion option feature of our convertible note issued in November 2005, as amended, and our convertible notes issued in September 2006. These derivative liabilities were revalued at market from inception until the notes were redeemed. The change in fair value of these derivative liabilities through the redemption of the convertible notes in May 2007 and June 2007 resulted in income of \$4.6 million for the year ended June 30, 2007.

### ***Interest Income***

Interest income increased by \$371,000, or 134%, to \$648,000 for the year ended June 30, 2008 from \$277,000 for the year ended June 30, 2007, primarily due to increased levels of interest-bearing cash balances resulting from a July 2007 share offering and the initial \$12.0 million cash consideration received in March 2008 in connection with the amended collaboration agreement with Alimera and an increase of approximately \$100,000 of interest accrued on a note receivable.



### ***Interest and Finance Costs***

Interest and finance costs decreased by approximately \$9.0 million, or 95%, to \$507,000 for the year ended June 30, 2008 from \$9.5 million for the year ended June 30, 2007. This decrease was attributable to:

- a decrease of \$1.3 million in interest expense primarily as the result of the redemption of our convertible notes that were redeemed in May 2007 and June 2007;
- the absence of \$5.4 million of amortization of debt discount and issue costs in connection with our convertible notes; and
- the absence of \$2.3 million of registration rights penalties incurred in fiscal year 2007 in connection with our convertible note agreements.

Pursuant to the March 14, 2008 amendment to our collaboration agreement with Alimera, Alimera agreed to assume sole financial responsibility for the development of Iluvien, and all previously deferred co-development cost amounts, related penalties and compound annual interest charged on the foregoing, that we owed to Alimera were deemed to have been paid. We therefore do not expect to incur any future interest charges on Iluvien development costs.

### ***Loss on Extinguishment of Debt***

Loss on extinguishment of debt totaled \$23.4 million for the year ended June 30, 2007. In each of September 2006 and December 2006, we amended the terms of the convertible promissory note originally issued to Sandell in November 2005. The terms of each such amendment required us to account for the amendment as an extinguishment of the original note and the issuance of a new debt instrument. In May 2007, we redeemed the Sandell note by a single payment of \$13.7 million, and in June 2007, we redeemed the Absolute notes by aggregate payments of \$885,000. In connection with each of the Sandell amendments and the final Sandell redemption, we issued warrants that were treated as additional consideration paid by us to Sandell in the extinguishment transactions. These warrants, valued using the Binomial Tree Method, accounted for \$20.7 million of the total loss on extinguishment of debt during the year ended June 30, 2007.

### ***Other Income, net***

Other income, net increased by \$203,000, or 133%, to \$356,000 for the year ended June 30, 2008 from \$153,000 for the year ended June 30, 2007. This increase consisted primarily of \$412,000 of income in 2008 attributable to a revenue sharing arrangement with the provider of our predecessor's ADR program, partially offset by a \$305,000 net unfavorable change in foreign exchange gains and losses.

### ***Income Tax Benefit***

Income tax benefit decreased by approximately \$12.7 million, or 96%, to \$483,000 for the year ended June 30, 2008 from \$13.2 million for the year ended June 30, 2007. The decrease was primarily attributable to the fact that in fiscal 2008 our ability to record tax benefits associated with losses incurred was limited by the amount of deferred tax liabilities recorded.

Since June 30, 2007, we have been required to establish valuation allowances to offset the tax benefit of all net operating loss carryforwards due to uncertainty that we will be able to use these carryforwards.

### ***Loss From Discontinued Operations***

In April 2007, we recorded a gain on sale of discontinued operations of \$3.6 million in connection with the sale of the stock of our AION Diagnostics subsidiary. Proceeds consisted of approximately \$1.9 million in cash and a \$1.5 million unsecured promissory note, bearing 8% interest compounded monthly. The promissory note was due April 12, 2008 but has not yet been paid and is overdue (see Note 14 to the accompanying audited consolidated financial statements). Loss from discontinued operations in fiscal 2007 through the date of sale was \$1.3 million.

## Results of Operations for the Year Ended June 30, 2007 Compared to the Year Ended June 30, 2006

	Year ended June 30,		Change	
	2007	2006	Amounts	%
	(In thousands except percentages)			
Revenues .....	\$ 1,785	\$ 1,036	\$ 749	72%
Operating expenses:				
Impairment of intangible assets .....	45,278	—	45,278	na
Acquired in-process research and development .....	—	24,957	(24,957)	na
Research and development .....	21,065	20,612	453	2%
General and administrative .....	11,204	7,903	3,301	42%
Total operating expenses .....	77,547	53,472	24,075	45%
Loss from operations .....	(75,762)	(52,436)	(23,326)	44%
Other income (expense):				
Change in fair value of derivative .....	11,434	2,533	8,901	351%
Interest income .....	277	420	(143)	(34)%
Interest and finance costs .....	(9,491)	(3,376)	(6,115)	181%
Loss on extinguishment of debt .....	(23,361)	—	(23,361)	na
Other income, net .....	153	628	(475)	(76)%
Total other income (expense) .....	(20,988)	205	(21,193)	(10338)%
Loss from continuing operations before income taxes .....	(96,750)	(52,231)	(44,519)	85%
Income tax benefit .....	13,225	6,919	6,306	91%
Loss from continuing operations .....	(83,525)	(45,312)	(38,213)	84%
Loss from discontinued operations .....	(1,318)	(1,645)	327	(20)%
Gain on sale of discontinued operations .....	3,640	—	3,640	na
Income (loss) from discontinued operations .....	2,322	(1,645)	3,967	(241)%
Net loss .....	<u>\$(81,203)</u>	<u>\$(46,957)</u>	<u>\$(34,246)</u>	<u>73%</u>

### Revenue

Revenue increased by \$749,000, or 72%, to approximately \$1.8 million for the year ended June 30, 2007 from approximately \$1.0 million for the year ended June 30, 2006. The revenues in both periods were predominantly related to the operations of pSivida US (formerly CDS), which was acquired on December 30, 2005, the mid-point of the earlier fiscal year. The increase was primarily attributable to a \$634,000 increase in Retisert royalty income from Bausch & Lomb.

### Impairment of Intangible Assets

Impairment of intangible assets totaled approximately \$45.3 million for the year ended June 30, 2007. The impairment was attributable to a write-down of the carrying value of our Retisert patents as a result of a triggering event that required us to assess the recoverability of such carrying value at June 30, 2007 (see Note 5 of the accompanying audited consolidated financial statements). At June 30, 2007, the remaining carrying values of the Company's intangible assets were \$11.1 million for Retisert and \$29.7 million for BrachySil.

### IPR&D

In connection with the acquisition of CDS on December 30, 2005, approximately \$25.0 million of the purchase price was allocated to the Iluvien product candidate in Phase III clinical trials and was immediately charged to operations in the year ended June 30, 2006.

### ***Research and Development***

Research and development increased by \$453,000, or 2%, to \$21.1 million for the year ended June 30, 2007 from \$20.6 million for the year ended June 30, 2006. This increase was primarily attributable to the following factors:

- a net increase of approximately \$2.0 million in amortization of intangibles, primarily due to the effect of a full year of amortization of the Retisert patents (which were amortized during the prior year only from the December 30, 2005 acquisition date of CDS); and
- an increase of approximately \$2.0 million due to the effect of a full year of the research operations of pSivida US (formerly CDS); which were partially offset by
- a decrease of approximately \$2.7 million in U.K.- and Singapore-based operating expenses as a result of (i) significant head count reductions in the U.K.; (ii) reduced levels of clinical trial program activities; and (iii) reduced depreciation expense related to a clean room facility that was fully depreciated as of March 2007; and
- a net decrease of approximately \$150,000 in share-based payments expense, primarily related to options that fully vested in 2006.

### ***General and Administrative***

General and administrative costs increased by approximately \$3.3 million, or 42%, to \$11.2 million for the year ended June 30, 2007 from \$7.9 million for the year ended June 30, 2006. This increase was primarily attributable to the following factors:

- an increase of approximately \$2.3 million of personnel, occupancy and operating costs for pSivida US, primarily because the current period costs reflect a full year of operations compared to six months of operations for the prior year; and
- an increase of approximately \$1.9 million of professional fees in connection with U.S. statutory filings, registration statement filings in connection with convertible note transactions and amendments thereto, the negotiation of license agreements and evaluation of potential financing sources; which were partially offset by
- a decrease of approximately \$500,000 of share-based payments expense primarily attributable to options that fully vested during the year ended June 30, 2006.

### ***Change in Fair Value of Derivative***

Change in fair value of derivative increased by approximately \$8.9 million, or 351%, to income of \$11.4 million for the year ended June 30, 2007 from income of \$2.5 million for the year ended June 30, 2006.

We recorded derivative liabilities in connection with the embedded conversion option feature of our convertible note issued to Sandell in November 2005, as amended, and of our convertible notes issued to Absolute in September 2006. These derivative liabilities were revalued at market from inception until the notes were redeemed in May 2007 and June 2007, respectively. The change in fair value of derivative related to the convertible note transactions resulted in income of \$4.6 million and \$2.5 million in the years ended June 30, 2007 and 2006, respectively.

In connection with several capital raising transactions during the year ended June 30, 2007, we issued shares together with detachable warrants to purchase additional shares over a specified time period. To the extent that the warrants were denominated in A\$, which is different than our US\$ functional currency, the value of the options were recorded as a derivative liability, subject to revaluation at subsequent reporting dates. The change in fair value of derivative related to these investor options resulted in income during the period of \$6.8 million, primarily attributable to a net decrease in the market price of the Company's shares during the period.

### ***Interest Income***

Interest income decreased by \$143,000, or 34%, to \$277,000 for the year ended June 30, 2007 from \$420,000 for the year ended June 30, 2006. The decrease was primarily due to reduced levels of interest-bearing cash balances.

### ***Interest and Finance Costs***

Interest and finance costs increased by approximately \$6.1 million, or 181%, to \$9.5 million for the year ended June 30, 2007 from \$3.4 million for the year ended June 30, 2006. This increase was attributable to:

- an increase of \$1.0 million in interest expense, of which \$500,000 was related to interest on our convertible note transactions and \$500,000 was related to interest accrued on the portion of Iluvien development costs for which we deferred payment under the terms of the original February 2005 collaboration agreement with Alimera;
- an increase of \$3.2 million in the amortization of debt discount and issue costs in connection with our convertible note transactions; and
- an increase of \$1.9 million of registration rights penalties predominantly related to delayed compliance with the registration rights obligations that we incurred in connection with our convertible note agreements.

As of June 30, 2007, we redeemed all of the outstanding convertible note balances.

### ***Loss on Extinguishment of Debt***

Loss on extinguishment of debt totaled \$23.4 million for the year ended June 30, 2007. In each of September 2006 and December 2006, we amended the terms of the convertible promissory note originally issued to Sandell in November 2005. The terms of each of those amendments required us to account for the transaction as an extinguishment of the original note and the issuance of a new debt instrument. In May 2007 we redeemed the Sandell note by a single payment of \$13.7 million, and in June 2007, we redeemed the Absolute notes by payments of \$885,000. In connection with each of the Sandell amendments and the final Sandell redemption, we issued warrants that were treated as additional consideration paid by us to Sandell in the extinguishment transactions. These warrants, valued using the Binomial Tree Method, accounted for \$20.7 million of the total loss on extinguishment of debt during the year ended June 30, 2007.

### ***Other Income, net***

Other income, net decreased by \$475,000, or 76%, to \$153,000 for the year ended June 30, 2007 from \$628,000 for the year ended June 30, 2006. This decrease was primarily due to lower unrealized foreign exchange gains on cash balances held in currencies other than our US\$ functional currency, partially offset by the strengthening of the A\$ against the US\$. During the year ended June 30, 2007, as we began the process of centralizing our accounting and finance functions in the U.S., excess cash balances were primarily maintained in the U.S. denominated in US\$. In addition, during the year ended June 30, 2007, we recorded an expense of \$75,000 to reverse income recorded in the prior year related to amortization of deferred gain resulting from a sale and leaseback transaction entered into by CDS in 2005 in relation to its premises. During fiscal 2007, we concluded that the deferred gain attributable to the sale and leaseback should not have been included in the US GAAP purchase price allocation for the acquisition of CDS (see Note 5 to the accompanying audited consolidated financial statements).

### ***Income Tax Benefit***

Deferred income tax benefit increased by approximately \$6.3 million, or 91%, to \$13.2 million for the year ended June 30, 2007 from \$6.9 million for the year ended June 30, 2006. The increase was primarily attributable to the larger pre-tax loss in fiscal 2007.

### ***Loss From Discontinued Operations***

In April 2007, we recorded a gain on sale of discontinued operations of \$3.6 million in connection with the sale of our stock in our AION Diagnostics subsidiary.

Loss from discontinued operations decreased by approximately \$327,000, or 20%, to \$1.3 million for the year ended June 30, 2007 from \$1.6 million for the year ended June 30, 2006. The decrease was primarily due to approximately nine months of AION operations during fiscal 2007 compared to a full year in fiscal 2006.

### **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.

### **Recent Accounting Pronouncements**

In September 2006, the FASB issued SFAS No. 157, "Fair Value Measurements" ("SFAS 157"). SFAS 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, for purposes such as derivative valuation and impairment analysis, and expands disclosures about fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007. Pursuant to FASB Staff Position ("FSP") No. FAS 157-2, issued in February 2008, the application of SFAS 157 for nonfinancial assets and liabilities that are not recognized or disclosed at fair value in financial statements on a recurring basis may be deferred until fiscal years beginning after November 15, 2008. We are evaluating the implications of SFAS 157, but do not believe that it will have a material effect on our consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159: "*The Fair Value Option for Financial Assets and Financial Liabilities—Including an Amendment of FASB Statement No. 115*" ("SFAS 159"), which becomes effective for fiscal periods beginning after November 15, 2007. Under SFAS 159, companies may elect to measure selected financial assets and liabilities at fair value, with changes in fair value recognized in earnings each reporting period. This election, called the "fair value option", will enable some companies to reduce volatility in reported earnings caused by measuring related assets and liabilities differently. We will be required to adopt SFAS 159 for the fiscal year beginning July 1, 2008. The adoption of SFAS 159 on July 1, 2008 did not have a material impact on the consolidated financial statements.

In June 2007, the FASB issued EITF 07-03, "*Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*" ("EITF 07-03"), which requires nonrefundable advance payments for future research and development activities to be capitalized and recognized as an expense as the goods are delivered or services are performed. The effects of applying EITF 07-03 will be reported as a change in accounting principle through a cumulative-effect adjustment to retained earnings in the statement of financial position as of the beginning of the year of adoption. EITF 07-03 is effective for our fiscal year beginning July 1, 2008. We are evaluating the potential impact of adopting EITF 07-03, but do not believe that it will have a material effect on our consolidated financial statements.

In November 2007, the FASB issued EITF 07-01, "*Accounting for Collaborative Arrangements*" ("EITF 07-01"). EITF 07-01 defines a collaborative arrangement as a contractual arrangement in which the parties are (i) active participants to the arrangement; and (ii) exposed to significant risks and rewards that depend upon the commercial success of the endeavor. It also addresses the appropriate statement of operations presentation for activities and payments between the participants in a collaborative arrangement as well as for costs incurred and revenue generated from transactions with third parties. EITF 07-01 will be effective for our fiscal year beginning July 1, 2009. We are evaluating the potential impact of adopting EITF 07-01 on our consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141 (revised), “*Business Combinations*” (“SFAS 141 (revised)”). SFAS 141 (revised) relates to business combinations and requires the acquirer to recognize the assets acquired, the liabilities assumed and any noncontrolling interest in the acquiree at the acquisition date, measured at their fair values as of that date. SFAS 141 (revised) applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. An entity may not apply it before that date. We must adopt this standard on a prospective basis for any business combinations entered into after June 30, 2009.

In March 2008, the FASB issued SFAS No. 161, “*Disclosures about Derivative Instruments and Hedging Activities—an amendment of FASB Statement No. 133*” (“SFAS 161”). SFAS 161 changes the disclosure requirements for derivative instruments and hedging activities. Entities are required to provide enhanced disclosures about (a) how and why an entity uses derivative instruments, (b) how derivative instruments and related hedged items are accounted for under FASB Statement No. 133 and its related interpretations, and (c) how derivative instruments and related hedged items affect an entity’s financial position, financial performance, and cash flows. The guidance in SFAS 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008, with early application encouraged. SFAS 161 encourages, but does not require, comparative disclosures for earlier periods at initial adoption. We are assessing the potential impact of SFAS 161.

In April 2008, the FASB issued FSP No. 142-3, “*Determination of the Useful Life of Intangible Assets*” (“FSP 142-3”). FSP 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS 142. The objective of FSP 142-3 is to improve the consistency between the useful life of a recognized intangible asset under SFAS 142 and the period of expected cash flows used to measure the fair value of the asset under SFAS 141 (revised) and other accounting principles. FSP 142-3 applies to all intangible assets, whether acquired in a business combination or otherwise, and early adoption is prohibited. We will be required to adopt FSP 142-3 for our fiscal year beginning July 1, 2009. We are evaluating the potential impact of adopting FSP 142-3 on our consolidated financial statements

### **Liquidity And Capital Resources**

We have incurred operating losses since inception, and, at June 30, 2008, we had a total accumulated deficit of \$224.5 million. Our research and development and general and administrative costs, in the aggregate, have exceeded our revenues, including revenues related to our two commercialized products, and, accordingly, our operations have historically generated negative cash flows. We generally expect negative cash flows from operations on a quarterly basis at least until such time as one or more of our product candidates achieves regulatory approval and commences commercial sales. Since our inception, we have relied primarily on sales of our equity and debt securities and the proceeds from license fees and collaboration payments to fund our operations.

Cash and cash equivalents totaled approximately \$15.6 million at June 30, 2008 compared to \$2.7 million at June 30, 2007. In addition to our amended collaboration agreement with Alimera, which generated \$12.4 million in cash during fiscal year 2008 (see Note 4 to the accompanying audited consolidated financial statements), in July 2007 we completed a share offering pursuant to which we issued 4,114,199 common shares for net cash proceeds of approximately \$18.4 million.



We believe we can fund our operations as currently conducted through at least June 30, 2010. This expectation is based on the assumptions that we continue to receive the Pfizer quarterly \$500,000 research and development funding, Alimera continues to fund the development of Iluvien, we resume receiving Retisert royalties from Bausch & Lomb during the fiscal year ending June 30, 2010 and we receive the scheduled conditional note payments from Alimera. However, whether and when we will require additional capital will depend upon many other factors, including, but not limited to:

- the continuation of our existing collaborations with Pfizer and Alimera, including their continued funding of our programs and our receipt of milestone, royalty, note and other payments;
- the development, regulatory approval and commercialization of Iluvien, which is our primary product candidate currently in development;
- the amount and timing of sales of Retisert, which affect the timing of the resumption of Retisert royalty payments and the amount of such royalty payments;
- the scope and extent of our internally funded operations, including our programs for BrachySil (including any Phase III clinical trials for BrachySil for pancreatic cancer), any new product candidates, or any new business opportunities;
- our ability to establish and maintain strategic arrangements for Brachysil or any other product candidates for research, development, clinical testing, manufacturing and marketing;
- the success of our products and product candidates, including the timing and costs of regulatory approvals and the commercial success of approved products;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims; and
- changes in our operating plan, including the pursuit of new business opportunities, which may affect our need for capital.

In particular, our future cash position depends significantly on the approval and marketing of Iluvien and the occurrence of certain liquidity events under the terms of our amended collaboration agreement with Alimera. Alimera has agreed to pay us a \$25 million payment upon FDA approval of Iluvien and a 20% share in the future profits of Iluvien. In addition, the \$15 million note issued by Alimera becomes due and payable upon the occurrence of certain defined liquidity events (such as an initial public offering) that result in aggregate proceeds to Alimera in excess of \$75 million. There is no assurance that the FDA will approve Iluvien or that Iluvien will achieve market acceptance even if it is approved by the FDA. There is similarly no guarantee of the occurrence of a liquidity event resulting in aggregate gross proceeds to Alimera in excess of \$75 million.

If we require additional capital in the future, we do not know if it will be available when needed or on terms favorable to us or our stockholders. If available, additional equity financing may be dilutive to stockholders, debt financing may involve restrictive covenants or other unfavorable terms and potential dilutive equity, and funding through collaboration agreements may be on unfavorable terms including requiring us to relinquish rights to our technologies or products. If adequate financing is not available if and when needed, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs, postpone the pursuit of product candidates and new business opportunities, or otherwise reduce our cash requirements.

Cash to fund working capital requirements is managed centrally, with most cash deposits maintained in U.S. dollars.

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

	<u>Year Ended June 30,</u>		
	<u>2008</u>	<u>2007</u>	<u>2006</u>
	(In thousands)		
Loss from continuing operations: . . . . .	\$(75,670)	\$(83,525)	\$(45,312)
Changes in operating assets and liabilities . . . . .	13,455	1,164	2,488
Other adjustments to reconcile net loss to cash flows from operating activities . . . . .	<u>57,072</u>	<u>61,992</u>	<u>28,099</u>
Cash flows used in operating activities of continuing operations . . . . .	<u>\$ (5,143)</u>	<u>\$ (20,369)</u>	<u>\$ (14,725)</u>
Cash flows used in operating activities of discontinued operations . . . . .	<u>\$ —</u>	<u>\$ (977)</u>	<u>\$ (1,486)</u>
Cash flows (used in) provided by investing activities of continuing operations . . . . .	<u>\$ (259)</u>	<u>\$ 4,423</u>	<u>\$ (8,384)</u>
Cash flows provided by (used in) investing activities of discontinued operations . . . . .	<u>\$ —</u>	<u>\$ 1,792</u>	<u>\$ (217)</u>
Cash flows provided by financing activities . . . . .	<u>\$ 18,385</u>	<u>\$ 11,193</u>	<u>\$ 21,939</u>

Net cash used in operating activities of continuing operations for the year ended June 30, 2008 decreased by approximately \$15.2 million as compared to the prior year. This decrease was primarily attributable to (a) \$12.4 million cash received in connection with our amended collaboration agreement with Alimera, (b) the absence in fiscal 2008 of \$3.2 million of interest expense and registration rights penalties paid in connection with our convertible notes, which were redeemed in full prior to June 30, 2007; and (c) approximately \$2.3 million of cost reductions implemented in our UK and Singapore operations, partially offset by (x) \$1.6 million paid through June 30, 2008 in connection with our reincorporation transaction and (y) an increase of \$1.8 million of co-development payments to Alimera. As a result of the sale of our AION Diagnostics subsidiary in April 2007, there was no cash used in operating activities of discontinued operations during the year ended June 30, 2008, as compared to \$977,000 in the prior year.

Net cash used in operating activities of continuing operations for the year ended June 30, 2007 increased by approximately \$5.6 million as compared to the prior year. This increase was primarily attributable to (i) a full year of operating costs for pSivida US; (ii) increased legal and audit fees; and (iii) increased interest expense and registration rights penalties paid in connection with our convertible note borrowings, partially offset by cost reductions implemented in our UK and Singapore operations. Net cash used in operating activities of discontinued operations decreased by \$509,000 as a result of the sale of our AION Diagnostics subsidiary in April 2007.

Net cash used in investing activities of continuing operations for the year ended June 30, 2008 totaled \$259,000 compared to net cash provided by investing activities of continuing operations of \$4.4 million for the year ended June 30, 2007. This change was attributable to the elimination of \$4.5 million of restricted cash balances in fiscal year 2007 related to our Sandell convertible note and an approximate \$200,000 increase in capital expenditures from 2007 to 2008, which were primarily related to the ongoing expansion of our BioSilicon manufacturing capacity.

Net cash provided by investing activities of continuing operations totaled \$4.4 million for the year ended June 30, 2007 compared to \$8.4 million of cash used in investing activities for the year ended June 30, 2006. Cash provided by investing activities for the year ended June 30, 2007 consisted of a \$4.5 million decrease in restricted cash balances resulting from the May 2007 redemption of the Sandell convertible note. Cash used in investing activities of continuing operations for the year ended June 30, 2006 consisted of (i) approximately \$3.0 million of cash paid for the December 2005 acquisition of CDS, net of cash acquired; and (ii) a \$4.5 million increase in restricted cash pursuant to the terms of the Sandell convertible note, which required the Company to

maintain a minimum cash balance equal to 30% of the note principal. Purchases of property and equipment decreased from \$940,000 in fiscal 2006 to \$78,000 in fiscal 2007, primarily due to the completion during fiscal 2006 of construction of a clean room facility in Germany for use in the production of BrachySil. Cash provided by investing activities of discontinued operations consisted of approximately \$1.8 million in cash proceeds from the April 2007 sale of the stock of our AION Diagnostics subsidiary, net of cash balances sold, and, for the year ended June 30, 2006, represented purchases of property and equipment by AION Diagnostics.

Net cash flows from financing activities totaled \$18.4 million, \$11.2 million and \$21.9 million for the years ended June 30, 2008, 2007 and 2006 respectively. Cash flows from financing activities during the year ended June 30, 2008 resulted from a July 2007 issuance of 4,114,199 units at \$5.00 per unit net of \$2.2 million of share issue costs. Each unit consisted of one common share and one warrant to purchase 0.4 common share, with a warrant exercise price of \$6.60 per share.

Cash flows from financing activities during the year ended June 30, 2007 reflected the following transactions:

- (a) Share issues (in each case giving effect to the Reincorporation's share exchange ratio)

<u>Date</u>	<u>Transaction</u>	<u>Number of Common Shares</u>	<u>Price Per Share</u>	<u>Gross Proceeds</u>	<u>Share Issue Costs</u>
(In thousands)					
Dec-06	Private placement . . . . .	358,269	A\$ 10.40	\$ 2,933	\$ (135)
Feb-07	Private placement . . . . .	1,251,103	A\$ 9.20	9,083	(593)
Apr-07	Private placement . . . . .	1,584,512	A\$ 10.80	13,975	(611)
	Various Note conversions . . . . .	1,040,494	US\$ 8.00	n/a	(122)
		<u>4,234,378</u>		<u>\$25,991</u>	<u>\$(1,461)</u>

- (b) Proceeds from borrowings:

In September 2006, we issued subordinated convertible notes to Absolute in the amount of \$6.5 million less borrowing costs of \$1.1 million. In connection with various Sandell note amendments and a letter agreement treated as a debt modification, we incurred borrowing costs of approximately \$700,000.

- (c) Premiums paid on extinguishment of debt:

- In connection with the September 14, 2006 amendment of the Sandell note we made an additional payment to Sandell of \$1.0 million; and
- In connection with the optional redemptions of the Sandell and Absolute notes in May 2007 and June 2007, respectively, we were required to pay an 8% premium to the principal and accrued interest amounts being redeemed, or approximately \$1.0 million. In addition, in order for us to redeem the Sandell note at a date earlier than that specified under the terms of the note agreement, we agreed to pay an additional fee of approximately \$1.0 million.

- (d) Repayment of borrowings:

- In connection with the September 14, 2006 amendment of the Sandell note, we repaid \$2.5 million of the note principal;
- In connection with the May 15, 2007 redemption of the Sandell note, we repaid the remaining approximately \$11.7 million principal balance of the note; and
- In connection with the June 14, 2007 redemption of the Absolute notes, we repaid the remaining \$806,000 principal balance of the notes.

pSivida had no borrowings as of June 30, 2007 and June 30, 2008.

Cash flows from financing activities during the year ended June 30, 2006 consisted primarily of the proceeds from a rights offering, a private placement of shares and the issuance of a subordinated convertible note.

### 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 is material to investors.

### Tabular Disclosure Of Contractual Obligations

The following table summarizes our minimum contractual obligations as of June 30, 2008:

<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>
			(In thousands)		
Operating Lease Obligations . . . . .	\$1,055	\$418	\$637	\$—	\$—
Purchase Obligations . . . . .	581	581	—	—	—
Total . . . . .	<u>\$1,636</u>	<u>\$999</u>	<u>\$637</u>	<u>\$—</u>	<u>\$—</u>

Our purchase obligations primarily consist of purchase orders for clinical trial materials, supplies and other operating needs.

We also have contractual obligations that are variable in nature and, as such, are not included in the above table. These include the following:

*Executive contracts.* At June 30, 2008, we had agreements with three executive officers that would require us to make severance payments to them if we terminate their employment without cause or the executives resign for good cause. Such severance agreements would require us to make aggregate payments of up to \$900,000. The amounts payable pursuant to severance arrangements change over time depending upon the date of termination and then current salaries.

### Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

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

#### Derivative Liabilities

The change in fair value of derivatives related to liabilities for investor warrants denominated in A\$ resulted in income of approximately \$8.4 million and \$6.8 million during the years ended June 30, 2008 and 2007, respectively, and was determined using the Black-Scholes valuation model.

Our financial position and results of operations will be sensitive to future revaluations of these derivative liabilities. The primary factor that impacts the change in fair value of these derivatives is fluctuations in our share price. Reduction of the remaining useful life of the warrants, assuming that share price remains constant, will result in a modest decrease of the derivative liability value. Changes in risk-free interest rates have a de minimis effect.

At June 30, 2008, the closing price of our common shares traded on NASDAQ was \$2.90 per share. The following table summarizes the sensitivity of our consolidated statements of operations for the year ended June 30, 2008 to assumed increases or decreases of our share price at June 30, 2008:

	Decrease in Share Price			Current Price	Increase in Share Price		
	-15%	-10%	-5%		+5%	+10%	+15%
				(In thousands)			
Change in fair value of derivatives—income (expense) .....	\$573	\$392	\$201	\$—	\$(210)	\$(429)	\$(656)

### Foreign Currency Exchange Rates

We conduct operations in two principal currencies, the U.S. dollar and the Pound Sterling. The U.S. dollar operates as the functional currency for our U.S. operations and the Pound Sterling as the functional currency for our U.K. operations. Cash to fund working capital requirements is managed centrally in U.S. dollars. We do not consider our exposure to foreign currency exchange rates to be significant.

### Interest Rates

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

### Item 8. Financial Statements and Supplementary Data.

The information required by this item may be found on pages F-1 through F-33 of this annual report.

### Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

Not applicable.

### Item 9A.(T) Controls and Procedures

#### 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, 2008. Based upon that evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were not effective as of such date. The basis for this determination was that, as discussed below, management has identified a material weaknesses in our internal control over financial reporting, which management views as an integral part of our disclosure controls and procedures.

#### Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting for the Company. Our management, with the participation of our principal executive officer and principal financial officer, assessed the effectiveness of our internal control over financial reporting as of June 30, 2008. In making this assessment, management used the criteria set forth in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management has concluded that our internal control over financial reporting was not effective as of June 30, 2008.

In connection with our management's assessment of our internal control over financial reporting, the following material weakness has been identified as of June 30, 2008:

- Subsequent to March 31, 2008, an error was identified requiring an adjustment to both Goodwill and Additional paid-in capital at March 31, 2008, December 31, 2007, September 30, 2007 and June 30, 2007 of approximately \$4.7 million. The error was the result of incorrectly translating the A\$ value of shares issued as purchase consideration for the acquisition of CDS back to US\$ by using the exchange rate at the measurement date determined under A-IFRS instead of under U.S. GAAP. Management has determined that these restatements resulted from the control deficiency that there are inadequate controls over the application of U.S. GAAP to complex transactions and this control deficiency constitutes a material weakness.

This annual report does not include an attestation report of the Company's independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's independent registered public accounting firm pursuant to temporary rules of the Security and Exchange Commission that permit the Company to provide only management's report in this annual report.

**(c) Management's Plan for Remediation of Material Weakness**

In light of the conclusion that our Company's internal control over financial reporting was not effective, our management developed a plan intended to remediate such ineffectiveness and to strengthen our internal control over financial reporting through the implementation of certain remedial measures, which include the development of additional procedures intended to improve controls over the application of U.S. GAAP to complex transactions.

**(d) Changes in Internal Control over Financial Reporting**

During the quarter ended June 30, 2008, we implemented the following actions for purpose of complying with Section 404 of the Sarbanes-Oxley Act of 2002:

- In June 2008, we reincorporated in the United States. Reincorporation in the United States will simplify our regulatory compliance obligations and make available to us more resources for resolving U.S. GAAP accounting issues, as we will no longer be required to prepare financial statements in accordance with A-IFRS.

Other than those changes referenced above, there were no other changes in our internal control over financial reporting during the quarter ended June 30, 2008 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. Other Information**

Not applicable.



## **Item 10. Directors, Executive Officers, and Corporate Governance**

### **Executive Officers**

#### **Paul Ashton, 47**

Managing Director

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

#### **Lori Freedman, 41**

Vice President of Corporate Affairs, General Counsel and Company Secretary

Ms. Freedman was appointed Vice President of Corporate Affairs, General Counsel and Company Secretary of pSivida Limited, predecessor of the Company, on May 23, 2006. Prior to Ms. Freedman’s appointment with pSivida Limited, she served as Vice President of Corporate Affairs, General Counsel and Secretary of CDS, a drug delivery company, from 2001 to May 23 2006. Prior to that, Ms. Freedman served as Vice President, Business Development, and Counsel of Macromedia, Inc., a provider of software for creating Internet content and business applications, from March 2001 through September 2001. Ms. Freedman has also served as Vice President, General Counsel, and Secretary of Allaire Corporation, a provider of Internet infrastructure for building business applications, from 1999 until Allaire’s acquisition by Macromedia in 2001, as Corporate Counsel of Polaroid Corporation from May 1998 to December 1998 and with the law firm of McDermott, Will & Emery.

#### **Michael J. Soja, 59**

Vice President of Finance, Chief Financial Officer and Treasurer

Mr. Soja was appointed Vice President of Finance, Chief Financial Officer and Treasurer of pSivida Limited, predecessor issuer of the Company, on May 23, 2006. Prior to Mr. Soja’s appointment with pSivida Limited, he served as Vice President of Finance and Chief Financial Officer of CDS, a drug delivery company, from 2001 until May 23 2006. Mr. Soja was employed by XTRA Corporation, a transportation equipment leasing company, from 1974 to 2001, serving as Vice President and Chief Financial Officer from 1980 to 2001.

Each officer shall hold office until the first meeting of the board of directors following the next annual meeting of the stockholders and until such officer’s respective successor is chosen and qualified, unless a shorter period shall have been specified by the terms of such officer’s election or appointment.

### **Corporate Governance**

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

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

The other information required to be disclosed in Item 10 is hereby incorporated by reference to our definitive Proxy Statement to be filed with the SEC in connection with our Annual Meeting of Stockholders to be held on November 19, 2008.

**Item 11. Executive Compensation**

The information required to be disclosed in Item 11 is hereby incorporated by reference to our definitive Proxy Statement to be filed with the SEC in connection with our Annual Meeting of Stockholders to be held on November 19, 2008.

**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 definitive Proxy Statement to be filed with the SEC in connection with our Annual Meeting of Stockholders to be held on November 19, 2008.

**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 definitive Proxy Statement to be filed with the SEC in connection with our Annual Meeting of Stockholders to be held on November 19, 2008.

**Item 14. Principal Accounting Fees and Services**

The information required to be disclosed in Item 14 is hereby incorporated by reference to our definitive Proxy Statement to be filed with the SEC in connection with our Annual Meeting of Stockholders to be held on November 19, 2008.

## Item 15. Exhibits and Financial Statements

### (a) Financial Statements

For a list of the consolidated financial information included herein, see Index to the Consolidated Financial Statements on page F-1.

### (b) Exhibits.

<u>Exhibit No.</u>	<u>Exhibit Title</u>
3(i).1	Certificate of Incorporation of pSivida Corp. and Certificates of Amendment of Certificate of Incorporation of pSivida Corp. (u)
3(ii).1	By-Laws of pSivida Corp. (u)
4.1	Form of Specimen Stock Certificate for Common Stock (t)
4.2	Form of Warrant, dated as of November 15, 2005 (d)**
4.3	Form of Series A Warrant (g)**
4.4	Form of Series B Warrant (g)**
4.5	Registration Rights Agreement, dated as of September 26, 2006 by and among pSivida Limited, Australian IT Investments Limited, Absolute Octane Fund and European Catalyst Fund (h)
4.6	Form of pSivida Limited Warrants to Purchase ADRs, dated September 26, 2006 (h)**
4.7	pSivida Limited Series C Warrants to Purchase ADRs (k)
4.8	Series D Warrants (n)
4.9	Series E Warrants (n)
4.10	Series F Warrants (n)
4.11	Series G Warrants (n)
4.12	Second Amended and Restated Registration Rights Agreement dated May 15, 2007 by and among pSivida Limited and Castlerigg Master Investments Ltd. (n)
4.13	Form of Investor Warrant (o)**
4.14	Form of Placement Agent Warrant (o)**
4.15	Form of Application for Shares and Options (u)**
4.16	Securities Purchase Agreement, dated February 16, 2007, by and among pSivida Limited and the investors set forth on the signature pages thereto (u)
9.1	Deed Poll, dated October 26, 2004, executed by Qinetiq (c)
10.1	License Agreement, dated as of October 20, 1991, by and between the University of Kentucky Research Foundation and Control Delivery Systems, Inc., including amendment (b)*
10.2	License Agreement, dated as of October 31, 1995, by and between the University of Kentucky Research Foundation and Control Delivery Systems, Inc. (b)*
10.3	License Agreement, dated as of September 9, 1997, by and between the University of Kentucky Research Foundation and Control Delivery Systems, Inc. (b)*
10.4	License Agreement, dated as of September 9, 1997, by and between the University of Kentucky Research Foundation and Control Delivery Systems, Inc. (b)*
10.5	License Agreement, dated as of September 9, 1997, by and between the University of Kentucky Research Foundation and Control Delivery Systems, Inc. (b)*
10.6	Process Development and Manufacturing Agreement between pSiMedica Limited and AEA Technology QSA GmbH, dated March 4, 2004 (c)*
10.7	Employment Agreement, between pSivida Limited and Aaron Finlay, dated April 19, 2004 (p)
10.8	Commercial Sublease, between Exergen Corporation, and Control Delivery Systems, Inc., dated as of April 6, 2005 (e)
10.9	Amended and Restated License Agreement, between Control Delivery Systems, Inc. and Bausch & Lomb Incorporated dated December 9, 2003, as amended on June 28, 2005 (e)*

<u>Exhibit No.</u>	<u>Exhibit Title</u>
10.10	Non-Competition Agreement, between pSivida Limited and Paul Ashton, dated October 3, 2005 (e)***
10.11	Securities Purchase Agreement, dated October 5, 2005, between pSivida Limited and the investor listed on the Schedule of Buyers attached thereto (d)
10.12	Employment Agreement, between pSivida Limited and Paul Ashton, dated January 1, 2006 (j)***
10.13	Amendment to Employment Agreement, between pSivida Limited and Aaron Finlay, dated January 25, 2006. (p)
10.14	Employment Agreement, between pSivida Limited and Lori Freedman, dated as of May 16, 2006 (f)***
10.15	Employment Agreement, between pSivida Limited and Michael Soja, dated as of May 16, 2006 (f)***
10.16	Amendment Agreement between pSivida Limited and Castlerigg Master Investments Ltd., dated July 28, 2006 (g)
10.17	Securities Purchase Agreement, dated as of September 18, 2006 by and among pSivida Limited, Australian IT Investments Limited, Absolute Octane Fund and European Catalyst Fund (h)
10.18	Form of pSivida Limited Subordinated Convertible Note, dated September 26, 2006 (h)**
10.19	Letter Agreement, dated October 17, 2006, between pSivida Limited and Castlerigg Master Investments Ltd. (i)
10.20	Employment Agreement, between pSivida Limited and Roger Brimblecombe dated December 5, 2006 (j)***
10.21	Form of Second Amended and Restated Convertible Note (k)**
10.22	Form of Common Stock Purchase Agreement between pSivida Ltd. and GEM Global Yield Fund dated February 2007 (p)**
10.23	Form of Amendment No. 1 to the Common Stock Purchase Agreement between pSivida Ltd. and GEM Global Yield Fund dated March 20, 2007 (p)**
10.24	Collaborative Research and License Agreement, dated as of April 3, 2007, by and among pSivida Limited, pSivida Inc. and Pfizer Inc. (m)*
10.25	Binding Letter of Intent by and between pSivida Limited and Castlerigg Master Investments Ltd. (l)
10.26	Memorandum of Understanding by and between pSivida Limited and Castlerigg Master Investments Ltd. (l)
10.27	Amended and Restated Second Amendment Agreement dated May 15, 2007 by and among pSivida Limited and Castlerigg Master Investments Ltd. (n)
10.28	Lease Renewal Agreement between pSivida Inc. and Exergen Corporation dated October 18, 2007 (q)
10.29	Deed of Release between pSivida Limited and Aaron Finlay dated February 29, 2008 (s)***
10.30	Contractor Agreement between pSivida Limited and Sol Capital Pty Ltd dated February 29, 2008 (s)***
10.31	Amended and Restated Collaboration Agreement by and between pSivida Inc. and Alimera Sciences, Inc. dated March 14, 2008 (s)*
10.32	Implementation Agreement by and between pSivida Limited and pSivida Corp. dated as of April 28, 2008 (r)
10.33	Rules of the pSivida Corp. Employee Share Option Plan (u)***
10.34	pSivida Corp. 2008 Incentive Plan (u)***
10.35	Form of Stock Option Certificate for grants to executive officers under the pSivida Corp. 2008 Incentive Plan (v)(**)(***)
10.36	Form of pSivida Corp. Nonstatutory Stock Options granted to Michael J. Soja and Lori Freedman on September 4, 2008 and September 10, 2008 (a)(**)(***)
21.1	List of subsidiaries (a)
23.1	Consent of Independent Registered Public Accounting Firm, Deloitte & Touche LLP (a)
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act, as amended (a)

<u>Exhibit No.</u>	<u>Exhibit Title</u>
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act, as amended (a)
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (a)
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (a)

\* Confidential treatment has been granted for portions of this exhibit.

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

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

(a) Filed herewith.

(b) Incorporated herein by reference to Control Delivery Systems, Inc.’s Form S-1 filed on December 15, 2000.

(c) Incorporated herein by reference to pSivida Limited’s Form 20-F filed on January 20, 2005.

(d) Incorporated herein by reference to pSivida Limited’s Form 6-K filed on November 15, 2005.

(e) Incorporated herein by reference to pSivida Limited’s Form 20-F filed on January 18, 2006.

(f) Incorporated herein by reference to pSivida Limited’s Form 6-K filed on May 23, 2006.

(g) Incorporated herein by reference to pSivida Limited’s Form 6-K/A filed on July 31, 2006.

(h) Incorporated herein by reference to pSivida Limited’s Form 6-K filed on September 26, 2006.

(i) Incorporated herein by reference to pSivida Limited’s Form 6-K filed on October 18, 2006.

(j) Incorporated herein by reference to pSivida Limited’s Form 20-F filed on December 8, 2006.

(k) Incorporated herein by reference to pSivida Limited’s Form 6-K filed on January 3, 2007.

(l) Incorporated herein by reference to pSivida Limited’s Form 6-K dated April 4, 2007.

(m) Incorporated herein by reference to pSivida Limited’s Form 6-K filed on April 26, 2007.

(n) Incorporated herein by reference to pSivida Limited’s Form 6-K filed on May 16, 2007.

(o) Incorporated herein by reference to pSivida Limited’s Form 6-K filed on July 2, 2007.

(p) Incorporated herein by reference to pSivida Limited’s Form 20-F filed on October 1, 2007.

(q) Incorporated herein by reference to pSivida Limited’s Form 10-Q filed on February 11, 2008.

(r) Incorporated herein by reference to pSivida Limited’s Form 8-K dated May 2, 2008.

(s) Incorporated herein by reference to pSivida Limited’s Form 10-Q filed May 12, 2008.

(t) Incorporated herein by reference to pSivida Corp.’s Form 8-K12G3 dated June 19, 2008.

(u) Incorporated herein by reference to pSivida Corp.’s Form 8-K dated June 19, 2008.

(v) Incorporated herein by reference to pSivida Corp.’s Form 8-K dated September 10, 2008.





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

By:           /s/ DAVID J. MAZZO                                

David J. Mazzo,  
Non-Executive Chairman

Date: September 26, 2008

By:           /s/ PAUL ASHTON                                

Paul Ashton,  
Managing Director  
(Principal Executive Officer)

Date: September 26, 2008

By:           /s/ MICHAEL J. SOJA                                

Michael J. Soja,  
Vice President, Finance and CFO  
(Principal Financial and Accounting Officer)

Date: September 26, 2008

By:           /s/ PAUL A. HOPPER                                

Paul A. Hopper,  
Non-Executive Director

Date: September 26, 2008

By:           /s/ MICHAEL ROGERS                                

Michael Rogers,  
Non-Executive Director

Date: September 26, 2008

By:           /s/ PETER SAVAS                                

Peter Savas,  
Non-Executive Director

Date: September 26, 2008

By:   

Katherine Woodthorpe,  
Non-Executive Director

Date:

**PSIVIDA CORP. AND SUBSIDIARIES**  
**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of pSivida Corp. and subsidiaries (the “Company”) as of June 30, 2008 and 2007, and the related consolidated statements of operations, stockholders’ equity and cash flows for each of the three years in the period ended June 30, 2008. These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, 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, 2008 and 2007, and the results of their operations and their cash flows for each of the three years in the period ended June 30, 2008, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 2, the Company adopted Financial Accounting Standards Board (“FASB”) Interpretation No. 48, “*Accounting for Uncertainty in Income Taxes—an Interpretation of FASB Statement No. 109*”, effective July 1, 2007.

/s/ DELOITTE & TOUCHE LLP

Boston, Massachusetts  
September 26, 2008

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

	June 30,	
	2008	2007
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents .....	\$ 15,609	\$ 2,670
Note receivable, net of allowance .....	481	1,500
Accounts and other receivables .....	986	1,008
Prepaid expenses and other current assets .....	614	516
Total current assets .....	17,690	5,694
Note receivable, net of allowance .....	819	—
Property and equipment, net .....	473	512
Other intangibles, net .....	36,802	40,802
Goodwill .....	—	60,212
<b>Total assets</b> .....	<b>\$ 55,784</b>	<b>\$ 107,220</b>
<b>Liabilities and stockholders' equity</b>		
<b>Current liabilities:</b>		
Accounts payable .....	\$ 2,634	\$ 1,472
Accrued expenses .....	2,236	6,064
Deferred revenue .....	10,476	356
Derivative liabilities .....	1,930	8,865
Total current liabilities .....	17,276	16,757
Deferred revenue and other .....	8,114	1,346
Deferred tax liabilities .....	316	852
<b>Total liabilities</b> .....	<b>25,706</b>	<b>18,955</b>
<b>Commitments and contingencies (Note 15)</b>		
<b>Stockholders' equity:</b>		
Preferred stock, \$.001 par value, 5,000,000 shares authorized, none issued and outstanding .....	—	—
Common stock, \$.001 par value, 60,000,000 shares authorized, 18,262,345 and 14,140,184 shares issued and outstanding at June 30, 2008 and 2007, respectively .....	18	14
Additional paid-in capital .....	247,628	229,913
Accumulated deficit .....	(224,537)	(148,867)
Accumulated other comprehensive income .....	6,969	7,205
Total stockholders' equity .....	30,078	88,265
<b>Total liabilities and stockholders' equity</b> .....	<b>\$ 55,784</b>	<b>\$ 107,220</b>

See notes to consolidated financial statements

**PSIVIDA CORP. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
(In thousands except per share data)

	<u>Year Ended June 30,</u>		
	<u>2008</u>	<u>2007</u>	<u>2006</u>
Revenues:			
Collaborative research and development .....	\$ 3,328	\$ 733	\$ 693
Royalty income .....	148	1,052	343
Total revenues .....	<u>3,476</u>	<u>1,785</u>	<u>1,036</u>
Operating expenses:			
Impairment of goodwill .....	60,106	—	—
Impairment of intangible assets .....	—	45,278	—
Acquired in-process research and development .....	—	—	24,957
Research and development .....	14,426	21,065	20,612
General and administrative .....	13,951	11,204	7,903
Total operating expenses .....	<u>88,483</u>	<u>77,547</u>	<u>53,472</u>
Operating loss from continuing operations .....	<u>(85,007)</u>	<u>(75,762)</u>	<u>(52,436)</u>
Other income (expense):			
Change in fair value of derivatives .....	8,357	11,434	2,533
Interest income .....	648	277	420
Interest and finance costs .....	(507)	(9,491)	(3,376)
Loss on extinguishment of debt .....	—	(23,361)	—
Other income, net .....	356	153	628
Total other income (expense) .....	<u>8,854</u>	<u>(20,988)</u>	<u>205</u>
Loss from continuing operations before income taxes .....	<u>(76,153)</u>	<u>(96,750)</u>	<u>(52,231)</u>
Income tax benefit .....	483	13,225	6,919
Loss from continuing operations .....	<u>(75,670)</u>	<u>(83,525)</u>	<u>(45,312)</u>
Discontinued operations:			
Loss from discontinued operations .....	—	(1,318)	(1,645)
Gain on sale of discontinued operations .....	—	3,640	—
Income (loss) from discontinued operations .....	<u>—</u>	<u>2,322</u>	<u>(1,645)</u>
Net loss .....	<u>\$(75,670)</u>	<u>\$(81,203)</u>	<u>\$(46,957)</u>
Basic and diluted net loss per share:			
Loss from continuing operations .....	\$ (4.17)	\$ (7.57)	\$ (6.02)
Income (loss) from discontinued operations .....	—	0.21	(0.22)
Net loss .....	<u>\$ (4.17)</u>	<u>\$ (7.36)</u>	<u>\$ (6.24)</u>
Weighted average common shares outstanding:			
Basic and diluted .....	<u>18,166</u>	<u>11,038</u>	<u>7,521</u>

See notes to consolidated financial statements

**PSIVIDA CORP. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENT 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, 2005	5,482,804	\$ 5	\$ 81,311	\$ (20,707)	\$ 1,212	\$ 61,821
Comprehensive loss:						
Net loss	—	—	—	(46,957)	—	(46,957)
Change in functional currency of parent company					3,450	3,450
Foreign currency translation adjustments	—	—	—	—	(2,825)	(2,825)
Total comprehensive loss						(46,332)
Stock issued, net of issue costs	429,145	1	7,494	—	—	7,495
Stock and options issued as consideration for acquisition, net of issue costs	3,771,117	4	105,050	—	—	105,054
Stock-based compensation	—	—	1,458	—	—	1,458
Equity portion of convertible note	—	—	1,251	—	—	1,251
Exercise of stock options	969	—	—	—	—	—
Balance at June 30, 2006	9,684,035	10	196,564	(67,664)	1,837	130,747
Comprehensive loss:						
Net loss	—	—	—	(81,203)	—	(81,203)
Foreign currency translation adjustments	—	—	—	—	5,368	5,368
Total comprehensive loss						(75,835)
Stock issued, net of issue costs	3,193,884	3	24,649	—	—	24,652
Stock-based compensation	—	—	497	—	—	497
Vesting of nonvested shares	221,771	—	—	—	—	—
Equity portion of convertible note	—	—	1,373	—	—	1,373
Conversion of convertible notes, net of issue costs	1,040,494	1	993	—	—	994
Fair value of warrants issued in connection with convertible note amendments	—	—	21,469	—	—	21,469
Proceeds allocated to derivative liabilities in connection with warrants issued to investors	—	—	(15,632)	—	—	(15,632)
Balance at June 30, 2007	14,140,184	14	229,913	(148,867)	7,205	88,265
Comprehensive loss:						
Net loss	—	—	—	(75,670)	—	(75,670)
Foreign currency translation adjustments	—	—	—	—	(236)	(236)
Total comprehensive loss						(75,906)
Stock issued, net of issue costs	4,114,199	4	18,383	—	—	18,387
Stock-based compensation	—	—	756	—	—	756
Vesting of nonvested shares	8,587	—	—	—	—	—
Proceeds allocated to derivative liabilities in connection with warrants issued to investors	—	—	(1,422)	—	—	(1,422)
Cash in lieu of fractional shares in connection with reincorporation	(625)	—	(2)	—	—	(2)
Balance at June 30, 2008	18,262,345	\$ 18	\$247,628	\$(224,537)	\$ 6,969	\$ 30,078

See notes to consolidated financial statements



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

	Year Ended June 30,		
	2008	2007	2006
<b>Cash flows from operating activities:</b>			
Net loss	\$(75,670)	\$(81,203)	\$(46,957)
Loss from discontinued operations	—	1,318	1,645
Gain on sale of discontinued operations	—	(3,640)	—
Loss from continuing operations	(75,670)	(83,525)	(45,312)
Adjustments to reconcile net loss to cash flows from operating activities:			
Impairment of goodwill	60,106	—	—
Impairment of intangible assets	—	45,278	—
Amortization of intangible assets	3,886	9,247	7,229
In-process research and development	—	—	24,957
Depreciation of property and equipment	397	1,767	1,776
Loss on extinguishment of debt	—	23,361	—
Amortization of convertible note debt discount and issue costs	—	5,416	2,209
Change in fair value of derivatives	(8,357)	(11,434)	(2,533)
Non-cash interest expense	507	875	49
Stock-based compensation expense	756	707	1,337
Gain on sale of fixed assets	(13)	—	(6)
Provision for losses on note receivable	325	—	—
Deferred income tax benefit	(535)	(13,225)	(6,919)
Changes in operating assets and liabilities:			
Accounts, note and other receivables	(105)	(213)	176
Prepaid expenses and other current assets	(97)	(57)	8
Accounts payable	1,400	158	(804)
Accrued expenses	(4,676)	1,228	2,501
Deferred revenue	16,933	48	607
Net cash used in operating activities of continuing operations	(5,143)	(20,369)	(14,725)
Net cash used in operating activities of discontinued operations	—	(977)	(1,486)
Net cash used in operating activities	(5,143)	(21,346)	(16,211)
<b>Cash flows from investing activities:</b>			
Purchases of property and equipment	(272)	(77)	(941)
Decrease (increase) in restricted cash	—	4,500	(4,500)
Net cash paid for acquisition of businesses, net of cash acquired	—	—	(2,962)
Proceeds from sale of property and equipment	13	—	19
Net cash provided by (used in) investing activities of continuing operations	(259)	4,423	(8,384)
Net cash provided by (used in) investing activities of discontinued operations	—	1,792	(217)
Net cash provided by (used in) investing activities	(259)	6,215	(8,601)
<b>Cash flows from financing activities:</b>			
Proceeds from issuance of stock	20,622	25,991	9,017
Stock issuance costs	(2,237)	(1,461)	(1,522)
Proceeds from issuance of convertible notes	—	6,500	15,000
Debt issuance costs	—	(1,830)	(556)
Repayment of convertible notes	—	(14,973)	—
Premium paid on extinguishment of debt	—	(3,034)	—
Net cash provided by financing activities	18,385	11,193	21,939
Effect of foreign exchange rate changes on cash and cash equivalents	(44)	(84)	(259)
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>12,939</b>	<b>(4,022)</b>	<b>(3,132)</b>
<b>Cash and cash equivalents at beginning of year</b>	<b>2,670</b>	<b>6,692</b>	<b>9,824</b>
<b>Cash and cash equivalents at end of year</b>	<b>\$ 15,609</b>	<b>\$ 2,670</b>	<b>\$ 6,692</b>

See notes to consolidated financial statements

**PSIVIDA CORP. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**(tabular amounts in thousands except share, per share and percentage amounts)**

**1. Nature of the Business**

pSivida Corp. (together with its subsidiaries, “pSivida” or the “Company”), incorporated in Delaware, is a drug delivery company committed to the biomedical sector, with a primary focus on ophthalmology and oncology.

The Company has two products approved by the Food and Drug Administration (“FDA”): Retisert® for the treatment of uveitis and Vitrasert® for the treatment of AIDS-related cytomegalovirus (“CMV”) retinitis. The Company has licensed both of these products and the technologies underlying them to Bausch & Lomb Incorporated (“Bausch & Lomb”). The Company has one product candidate in fully recruited Phase III clinical trials: Iluvien™, which delivers fluocinolone acetonide (“FA”) for the treatment of diabetic macular edema (“DME”), formerly known as Medidur FA for DME. The Company has licensed certain of its drug delivery technology to Alimera Sciences (“Alimera”) for the development of Iluvien and certain other ophthalmic products. The Company has a worldwide collaborative research and license agreement with Pfizer, Inc. (“Pfizer”) under which Pfizer may develop additional ophthalmic products.

The Company owns the rights to develop and commercialize a modified form of silicon known as BioSilicon™, which has potential therapeutic applications. The Company’s most advanced BioSilicon product candidate, BrachySil™, delivers a therapeutic P32, a radioactive form of phosphorus used to treat cancer, directly to solid tumors. The Company recently completed an initial safety and efficacy clinical trial of BrachySil for the treatment of pancreatic cancer and has commenced a dose-ranging clinical trial.

**Basis of Presentation**

These audited consolidated financial statements at June 30, 2008 and 2007 and for each of the three years in the period ended June 30, 2008 are presented in U.S. dollars in accordance with generally accepted accounting principles in the United States (“U.S. GAAP”). Throughout these financial statements, references to “US\$” and “\$” are to U.S. dollars and references to “A\$” are to Australian dollars.

Effective June 19, 2008, the Company reincorporated from Western Australia to the United States. Pursuant to a scheme of arrangement under Australian law, all ordinary shares, including ordinary shares represented by American Depositary Shares (“ADSs”), of pSivida Limited, a company incorporated in Western Australia, were transferred by court order to pSivida Corp., a company incorporated in Delaware, in exchange for shares of pSivida Corp. common stock, including common stock represented by CHES Depositary Interests (“CDIs”), in a ratio of 40 pSivida Limited ordinary shares to 1 share of pSivida Corp. common stock. All assets and liabilities of pSivida Limited, including outstanding options and warrants to purchase ordinary shares or ADSs of pSivida Limited, were, by court order, transferred to and assumed by pSivida Corp., following which pSivida Limited was deregistered without a winding up. All options and warrants were equitably adjusted to reflect the reincorporation. Each CDI represents one share of common stock. Throughout these financial statements, all share, option and warrant information, including related per share data, have been adjusted to give effect to the reincorporation for all periods presented.

**Business Risks and Uncertainties**

The Company’s prospects are subject to the risks and uncertainties typical of companies that have achieved limited commercialization of their products and technologies. These risks include, but are not limited to, uncertainties regarding the achievement of milestones and other contingent contractual payment events; failure to prove safety and efficacy of Iluvien or BrachySil; inability to raise capital; continued losses and lack of

profitability; uncertainty regarding the timing and amount of revenues from Retisert; registration rights agreement penalties; termination of license agreements; inability to develop or obtain regulatory approval for new products; inability to protect intellectual property or infringement of others' intellectual property; inability to obtain partners to develop and market products; competition; problems with international business operations; manufacturing problems; insufficient third-party reimbursement for products; failure to retain key personnel; product liability; failure to comply with laws; failure to achieve and maintain effective internal control over financial reporting; potential impairment of intangible assets; stock price volatility; possible dilution through exercise of outstanding warrants and stock options or future stock issuances; and possible influence by Pfizer. As a result, the Company's operating results may fluctuate significantly in the future.

The success of the Company's technology and business development programs and, ultimately, the attainment of profitable operations, is dependent on future events, including the Company's ability to continue its development activities and to ultimately achieve revenues in excess of its expenses. The Company is exposed to substantial concentration of its key collaboration agreements — Alimera and Pfizer. The Company cannot be certain that it will be able to maintain its existing collaboration agreements, achieve additional collaboration arrangements or obtain other sources of funding, if and when needed, on acceptable terms, or at all, or that the Company will be able to achieve revenues sufficient for profitable operations. If the Company is unable to do any of the foregoing, it could be required to reduce the scope of its development plans and operations.

## **2. Significant Accounting Policies**

### **Principles of Consolidation**

These consolidated financial statements include the accounts of pSivida Corp. and its wholly owned subsidiaries. Intercompany balances and transactions have been eliminated in consolidation.

### **Use of Estimates**

The preparation of the Company's consolidated financial statements in conformity with U.S. GAAP requires the Company to make judgments, assumptions and estimates that affect the reported amounts of assets, liabilities, revenues and expenses, and the related disclosure of contingent assets and liabilities at the date of the financial statements. On an ongoing basis, the Company evaluates its estimates. The Company bases its estimates on historical experience and various other assumptions that it believes 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 apparent from other sources. Actual results could differ from these estimates.

### **Foreign Currency**

Upon the acquisition of Control Delivery Systems, Inc. ("CDS") in December 2005, the Company determined that the U.S. was the primary economic environment in which the then Australian parent entity operated. Accordingly, effective January 1, 2006, the Company changed its functional currency from A\$ to US\$ and recorded approximately \$3.5 million in other comprehensive income. The functional currency of each other entity is the currency of the primary economic environment in which that entity operates, primarily the U.S. dollar or the Pound Sterling.

The translation of the applicable foreign currency into U.S. dollars is performed for balance sheet accounts using current exchange rates in effect at the balance sheet date, and for revenue and expense accounts using the exchange rates throughout the year. Adjustments from such translation are included as a separate component of comprehensive income. Foreign currency transaction gains or losses, whether realized or unrealized, are recorded in "Other income, net".

### **Cash and Cash Equivalents**

Cash consists of demand deposits. Cash equivalents are highly liquid investments with maturities of less than three months at the date of acquisition that are readily convertible to known amounts of cash. The Company maintains its cash and cash equivalents with what the Company believes are high credit quality financial institutions. At June 30, 2008, substantially all of the Company's interest-bearing cash equivalent balances were concentrated with a single banking institution.

### **Fair Value of Financial Instruments**

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

### **Note, Accounts and Other Receivables**

Receivables are recorded net of allowance for doubtful accounts and consist primarily of (i) a note receivable in connection with the 2007 sale of the Company's AION Diagnostics subsidiary; (ii) goods and services and valued added tax reimbursements in certain foreign jurisdictions; and (iii) quarterly royalties earned. At June 30, 2008, an allowance for doubtful accounts of \$325,000 was recorded to reduce the carrying value of a note receivable and related accrued interest to estimated net realizable value (see Note 14). There was no allowance for doubtful accounts at June 30, 2007.

### **Debt and Equity Instruments**

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

### **Embedded Derivatives**

The proceeds received upon the issuance of a convertible note with detachable warrants are allocated into liability and equity components on a relative fair value basis. Management reviews the terms of a compound instrument to determine whether there are embedded derivatives that may be required to be bifurcated and accounted for separately as a derivative financial instrument. In connection with the Company's issuance of convertible notes during the years ended June 30, 2007 and 2006, management determined that the note holder conversion options were required to be bifurcated and accounted for separately as derivative financial instruments. Bifurcated embedded derivatives are initially recorded at fair value as a reduction of the liability component of the convertible debt instrument. Changes in the fair value of the embedded derivative are recorded in the consolidated statement of operations in each subsequent reporting period. Fair value is determined using a Binomial Tree Model.

### **Property and Equipment**

Property and equipment is recorded at cost. The Company uses the straight-line method to record depreciation expense over an estimated useful life of the asset, which is generally three years. Leasehold improvements are amortized over the shorter of the remaining lease term or the useful life of the asset. Repairs and maintenance costs are expensed as incurred.

When impairment indicators are present, the Company evaluates the recoverability of its long-lived assets. Should the assessment indicate an impairment the affected assets are written down to fair value.

## **Leases**

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

## **Goodwill and Acquired Intangible Assets**

The Company tests goodwill for impairment using a fair value approach on an annual basis, or when events indicate that the carrying value of the asset may be impaired. The Company has elected the last day of each fiscal year as its measurement date.

The goodwill impairment test is a two-step process. In the first step, the Company compares the fair value of the reporting unit to its carrying value. The Company determines the fair value of its reporting unit using a combination of a discounted cash flow and a market value approach. If the fair value of the reporting unit exceeds the carrying value of the net assets assigned to that reporting unit, goodwill is not impaired and the Company is not required to perform further testing.

If the carrying value of the net assets assigned to the reporting unit exceeds the fair value of the reporting unit, then the Company must perform the second step in order to determine the implied fair value of the reporting unit's goodwill and compare it to the carrying value of the reporting unit's goodwill. The activities in the second step include valuing the tangible and intangible assets and liabilities of the impaired reporting unit based on their fair value and determining the fair value of the impaired reporting unit's goodwill based upon the residual of the summed identifiable tangible and intangible assets and liabilities.

At June 30, 2008, the carrying value of the Company's reporting unit exceeded the fair value and therefore the second step was required. As a result, the Company recorded a \$60.1 million impairment charge related to goodwill (see Note 5).

The Company's intangible assets that are subject to amortization include patents and licenses. The intangible assets are being amortized on a straight-line method over twelve years. The intangible asset lives have been determined based upon the anticipated period over which the Company will derive future cash flow benefits from the intangible assets. The Company has considered the effects of legal, regulatory, contractual, competitive and other economic factors in determining these useful lives. Recoverability of these assets is assessed when triggering events have occurred that may give rise to an impairment loss and is determined by a comparison of the carrying amount of the asset to the future undiscounted net cash flows expected to be generated by the asset. When it is determined that the carrying value of the asset is not recoverable, the asset is written down to its estimated fair value based on a discounted cash flow analysis.

At June 30, 2007, the Company recorded a \$45.3 million impairment write-down of its Retisert intangible asset (see Note 5). In connection with the goodwill impairment analysis at June 30, 2008, the forecasted undiscounted cash flows associated with each of the Company's intangible assets exceeded its carrying value, therefore no impairment of intangible assets was recorded at June 30, 2008.

## **Revenue Recognition**

The Company recognizes revenues when they are realized or realizable and earned. Revenues are realized or realizable and earned when the Company has persuasive evidence that an arrangement exists, the goods have been delivered or the services have been rendered to the customer, the sales price is fixed or determinable and collectability is reasonably assured. In addition to this general policy, the following are specific revenue recognition policies:

### *Royalties*

Royalty revenues are recognized on an accrual basis and consist of amounts earned from licensees as a designated percentage of their sales of products utilizing the Company's licensed technologies. Non-refundable

royalties received in advance for which the Company has no obligation to perform future services are recognized when received. In connection with the Retisert product, CDS and Bausch & Lomb entered into an advance royalty agreement in June 2005 pursuant to which CDS received a cash payment of \$3.0 million in exchange for which Bausch & Lomb was entitled to retain (i) 50% of the first \$3.0 million of royalties otherwise payable and (ii) 100% of the next \$4.75 million of royalties otherwise payable under their license agreement. As of June 30, 2008, Bausch & Lomb was entitled to retain the next \$2.8 million of Retisert royalties otherwise payable to the Company.

#### *Collaborative research and development*

The Company's business strategy involves entering into collaborative research and development arrangements with strategic partners for the development and commercialization of products utilizing the Company's technologies. The terms of these agreements typically include multiple deliverables by the Company (for example, license rights, providing research and development services and manufacturing of clinical materials) in exchange for consideration to the Company of some combination of non-refundable license fees, funding of research and development activities, payments based upon achievement of clinical development milestones and royalties in the form of a designated percentage of product sales or profits. The Company follows the provisions of Securities and Exchange Commission ("SEC") Staff Accounting Bulletin ("SAB") No. 101, "Revenue Recognition in Financial Statements", as amended by SAB No. 104, "Revenue Recognition", and Emerging Issues Task Force ("EITF") Issue No. 00-21, "Accounting for Revenue Arrangements with Multiple Deliverables" ("EITF 00-21"). With the exception of royalties, these types of consideration are recorded in the statements of operations as collaborative research and development revenues when revenue recognition is appropriate.

Non-refundable license fees are recognized as revenue when the Company has a contractual right to receive such payment, the contract price is fixed or determinable, the collection of the resulting receivable is reasonably assured and the Company has no further performance obligations under the license agreement. Multiple element arrangements, such as license and development arrangements, are analyzed to determine whether the deliverables can be separated or whether they must be accounted for as a single unit of accounting in accordance with EITF 00-21. The Company recognizes up-front license payments as revenue upon delivery of the license only if the license has stand-alone value and the fair value of the undelivered performance obligations can be determined. If the fair value of the undelivered performance obligations can be determined, such obligations would then be accounted for separately as performed. If the license is considered not to have stand-alone value or if the fair value of any of the undelivered performance obligations cannot be determined, the arrangement would then be accounted for as a single unit of accounting.

For arrangements that are accounted for as a single unit of accounting, total payments under the arrangement, excluding royalties and payments contingent upon achievement of substantive milestones, are recognized as revenue on a straight-line basis over the period the Company expects to complete its performance obligations. The cumulative amount of revenue earned is limited to the cumulative amount of payments received as of the period ending date.

If the Company cannot reasonably estimate when its performance obligation either ceases or becomes inconsequential, then revenue recognition is deferred until the Company can reasonably estimate when the performance obligation ceases or becomes inconsequential. Revenue is then recognized over the remaining estimated period of performance. Deferred revenue amounts are classified as current liabilities to the extent that revenue is expected to be recognized within one year.

Significant management judgment is 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 an arrangement.



## Research and Development

Research and development costs are recognized as an expense in the period in which they are incurred. Research and development costs include wages, benefits and other operational costs related to the Company's research and development departments, clinical trial activities and supplies and amortization of intangible assets. The fair value of acquired in-process research and development costs is expensed as of the acquisition date if the related projects have not reached technological feasibility and are determined to have no alternative future use.

## Stock-based Compensation

Effective July 1, 2005, the Company adopted SFAS No. 123(R), "*Share-Based Payment*", ("SFAS 123(R)") which requires a company to measure the grant date fair value of equity awards given to employees in exchange for services and to recognize that cost over the requisite service period. SFAS 123(R) is a revision of SFAS No. 123, "*Accounting for Stock-Based Compensation*" ("SFAS 123") and supersedes Accounting Principles Board Opinion No. 25, "*Accounting for Stock Issued to Employees*", and its related implementation guidance. The Company elected the "modified prospective" method of applying SFAS 123(R) pursuant to which restatement of prior period results was not required. Under this method, compensation expense is recognized beginning with the adoption date (i) based on the requirements of SFAS 123(R) for all share-based payments granted after the adoption date and (ii) based on the requirements of SFAS 123 for all awards granted to employees prior to the adoption date of SFAS 123(R) that were unvested at the adoption date. The Company recognizes stock-based compensation for awards that have graded vesting on a straight-line basis over the requisite service period of each separately vesting portion of the award as if the award was, in substance, multiple awards. The Company estimates the fair value of stock option awards on the date of grant using the Black-Scholes option valuation model. See Note 11 for additional information regarding the impact of SFAS 123(R) on the Company's consolidated financial statements.

In connection with the December 2005 acquisition of CDS, the Company issued nonvested stock to CDS employees in exchange for their nonvested CDS stock. Deferred compensation related to these non-vested shares was charged to compensation expense over the remaining requisite service period.

## Net Loss per Share

Basic net loss per share is computed by dividing the net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing the net loss by the sum of (i) the weighted average number of common shares outstanding and (ii) the weighted average number of common shares that would be issued on the conversion of all dilutive securities outstanding. Potentially dilutive securities were not included in the calculation of diluted net loss per share for the years ended June 30, 2008, 2007 and 2006, as their inclusion would be anti-dilutive.

Potentially dilutive securities at the end of each year in the three year period ended June 30, 2008 are summarized as follows:

	<b>June 30,</b>		
	<b>2008</b>	<b>2007</b>	<b>2006</b>
Options .....	473,092	505,281	530,536
Warrants .....	11,182,181	9,464,492	242,951
Non-vested stock issued in connection with CDS acquisition .....	—	8,587	241,868
Convertible note .....	—	—	528,169
	<u>11,655,273</u>	<u>9,978,360</u>	<u>1,543,524</u>

## Comprehensive Loss

Comprehensive loss is comprised of net loss and foreign currency translation adjustments and is reported in the consolidated statement of stockholders' equity.

## Income Tax

The Company recognizes deferred income tax assets and liabilities for the expected future tax consequences of events that have been included in the Company's financial statements or tax returns. Deferred tax assets and liabilities are based on the difference between the financial statement and tax bases of assets and liabilities using tax rates expected to be in effect in the years in which these differences are expected to reverse. A valuation allowance is provided to reduce the deferred tax assets to the amount that will more likely than not be realized.

As of July 1, 2007, the Company adopted Financial Accounting Standards Board ("FASB") Interpretation ("FIN") No. 48, "*Accounting for Uncertainty in Income Taxes—an interpretation of FASB Statement No. 109*" ("FIN 48"). FIN 48 prescribes a recognition threshold and measurement attributes for financial statement disclosure of tax positions taken, or expected to be taken, on a tax return. Under FIN 48, the amount of tax benefits recognized must be the largest amount of tax benefit that has a greater than 50% likelihood of being sustained upon audit by the relevant tax authority. In addition, FIN 48 provides guidance on derecognition, classification, interest and penalties, and accounting for interim periods and requires expanded disclosure with respect to the uncertainty in income taxes. Potential interest and penalties associated with such uncertain tax positions are recorded as a component of income tax expense. See Note 13 for additional information on income taxes.

## Recently Issued Accounting Pronouncements

In September 2006, the FASB issued SFAS No. 157, "*Fair Value Measurements*" ("SFAS 157"). SFAS 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, for purposes such as derivative valuation and impairment analysis, and expands disclosures about fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007. Pursuant to FASB Staff Position ("FSP") No. FAS 157-2, issued in February 2008, the application of SFAS 157 for nonfinancial assets and liabilities that are not recognized or disclosed at fair value in financial statements on a recurring basis may be deferred until fiscal years beginning after November 15, 2008. The Company is evaluating the implications of SFAS 157, but does not believe that it will have a material effect on its consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159: "*The Fair Value Option for Financial Assets and Financial Liabilities—Including an Amendment of FASB Statement No. 115*" ("SFAS 159"), which becomes effective for fiscal periods beginning after November 15, 2007. Under SFAS 159, companies may elect to measure selected financial assets and liabilities at fair value, with changes in fair value recognized in earnings each reporting period. This election, called the "fair value option", will enable some companies to reduce volatility in reported earnings caused by measuring related assets and liabilities differently. The Company will be required to adopt SFAS 159 for the fiscal year beginning July 1, 2008. The adoption of SFAS 159 on July 1, 2008 did not have a material impact on the consolidated financial statements.

In June 2007, the FASB issued EITF 07-03, "*Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*" ("EITF 07-03"), which requires nonrefundable advance payments for future research and development activities to be capitalized and recognized as an expense as the goods are delivered or services are performed. The effects of applying EITF 07-03 will be reported as a change in accounting principle through a cumulative-effect adjustment to retained earnings in the statement of financial position as of the beginning of the year of adoption. EITF 07-03 is effective for the Company's fiscal year beginning July 1, 2008. The Company is evaluating the potential impact of adopting EITF 07-03, but does not believe that it will have a material effect on its consolidated financial statements.

In November 2007, the FASB issued EITF 07-01, "*Accounting for Collaborative Arrangements*" ("EITF 07-01"). EITF 07-01 defines a collaborative arrangement as a contractual arrangement in which the parties are (i) active participants to the arrangement; and (ii) exposed to significant risks and rewards that depend upon the

commercial success of the endeavor. It also addresses the appropriate statement of operations presentation for activities and payments between the participants in a collaborative arrangement as well as for costs incurred and revenue generated from transactions with third parties. EITF 07-01 will be effective for the Company's fiscal year beginning July 1, 2009. The Company is evaluating the potential impact of adopting EITF 07-01 on its consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141 (revised), "*Business Combinations*" ("SFAS 141 (revised)"). SFAS 141 (revised) relates to business combinations and requires the acquirer to recognize the assets acquired, the liabilities assumed and any noncontrolling interest in the acquiree at the acquisition date, measured at their fair values as of that date. SFAS 141 (revised) applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. An entity may not apply it before that date. The Company must adopt this standard on a prospective basis for any business combinations entered into after June 30, 2009.

In March 2008, the FASB issued SFAS No. 161, "*Disclosures about Derivative Instruments and Hedging Activities—an amendment of FASB Statement No. 133*" ("SFAS 161"). SFAS 161 changes the disclosure requirements for derivative instruments and hedging activities. Entities are required to provide enhanced disclosures about (a) how and why an entity uses derivative instruments, (b) how derivative instruments and related hedged items are accounted for under FASB Statement No. 133 and its related interpretations, and (c) how derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. The guidance in SFAS 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008, with early application encouraged. SFAS 161 encourages, but does not require, comparative disclosures for earlier periods at initial adoption. The Company is assessing the potential impact of SFAS 161.

In April 2008, the FASB issued FSP No. 142-3, "*Determination of the Useful Life of Intangible Assets*" ("FSP 142-3"). FSP 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS 142. The objective of FSP 142-3 is to improve the consistency between the useful life of a recognized intangible asset under SFAS 142 and the period of expected cash flows used to measure the fair value of the asset under SFAS 141 (revised) and other accounting principles. FSP 142-3 applies to all intangible assets, whether acquired in a business combination or otherwise, and early adoption is prohibited. The Company will be required to adopt FSP 142-3 for its fiscal year beginning July 1, 2009. The Company is evaluating the potential impact of adopting FSP 142-3 on its consolidated financial statements.

### **3. Business Combinations**

#### **Control Delivery Systems, Inc.**

On December 30, 2005, the Company completed the acquisition of 100% of the outstanding stock of CDS pursuant to a definitive agreement dated October 3, 2005. The acquisition was an integral part of the Company's U.S. growth strategy, creating a company specializing in drug delivery. CDS' portfolio of products and product candidates included two approved and marketed products (Retisert and Vitrasert), one Phase III product candidate (Iluvien) and other early-stage product candidates. This acquisition also provided the Company with an operating base in the Boston biotech hub, enhanced its overall visibility, provided access to the U.S. scientific and investment communities and brought additional development and regulatory expertise to the Company's management team. These factors contributed to the purchase price that resulted in recognition of a significant amount of goodwill, as further noted below. The goodwill amount is not deductible for tax purposes.

The CDS acquisition was accounted for under the purchase method of accounting and the results of operations of CDS have been included in the consolidated statements of operations of the Company from the December 30, 2005 acquisition date. On completion of the acquisition, the CDS name was changed to pSivida Inc. and was more recently changed to pSivida US, Inc.

The acquisition consideration was valued at \$108.2 million and consisted of the following:

Cash .....	\$ 83
3,771,117 shares of pSivida common stock at \$26.40 per share .....	99,550
224,798 nonvested shares of pSivida common stock at \$26.40 per share .....	5,935
Less: unearned compensation related to the future service period of nonvested shares .....	(1,099)
43,112 vested options at Black-Scholes fair value of \$15.48 per share .....	668
Direct acquisition costs .....	3,045
	<u>\$108,182</u>

The fair value of the shares issued as consideration was based upon the weighted average closing price of the Company's common stock on NASDAQ for the period including two days before and after the date that the terms of the acquisition were agreed to and announced. The fair value of the nonvested shares was reduced by the portion of the fair value attributable to the requisite future service period. The fair value of the options was determined using the Black-Scholes model.

The following table summarizes the allocation of the purchase price for the acquisition of CDS:

Current assets .....	\$ 770
Property and equipment .....	454
Intangible assets:	
Patents (Retisert) .....	64,399
Acquired in-process research and development (Iluvien) .....	24,957
Total intangible assets .....	<u>89,356</u>
Goodwill .....	35,585
Accounts payable and accrued expenses .....	(2,634)
Deferred revenue .....	(1,667)
Deferred income tax liabilities, net .....	(13,682)
	<u>\$108,182</u>

The Company estimated the fair values of identified intangibles of CDS (Vitrasert, Retisert and Iluvien) utilizing the discounted value of projected cash flows for periods that reflected management's assessment of expected patent protection. The patents related to Vitrasert were given no value based upon the judgment that the incidence of the disease to which the application of this technology related had been significantly reduced as a result of advancements in the treatment of AIDS. The value ascribed to patents was associated with the Retisert product, which was licensed to Bausch & Lomb and received FDA regulatory approval in April 2005. Projected cash flows for Iluvien were adjusted downwards after applying an estimated probability of successful commercialization in light of that product candidate's then current stage of development. The \$25.0 million allocated to acquired in-process research and development ("IPR&D") was reflected as an expense in the fiscal year ended June 30, 2006 because the Iluvien product candidate to which it related had not received regulatory approval prior to the acquisition date.

#### 4. License and Collaboration Agreements

##### Alimera

On March 14, 2008, the Company and Alimera amended and restated their license and collaboration agreement dated February 11, 2005 relating to Iluvien (formerly Medidur FA for DME), the companies' Phase III investigative treatment for DME, and certain other products. In exchange for current and future consideration to the Company, the Company decreased its share in the future profits of Iluvien from 50% to 20%.

Current consideration consisted of (i) \$12.0 million in cash paid upon the execution of the amended collaboration agreement and (ii) cancellation of approximately \$5.7 million of accrued development cost liabilities, including related penalties and accrued interest, owed by the Company to Alimera as of March 14, 2008. The Company's performance period under the amended collaboration agreement ends December 31, 2009. Accordingly, an aggregate \$18.3 million of deferred revenue, consisting of the aforementioned current consideration and \$650,000 of previously received but unamortized milestone payments, will be recognized as revenue on a straight-line basis over the 21.5 month performance period from the effective date of the amended collaboration agreement through December 31, 2009. For the year ended June 30, 2008, revenue related to the Alimera collaboration agreement, as amended, totaled \$3,258,000, which represented 98% of collaborative research and development revenue.

Other consideration, exclusive of the Company's 20% profit share, includes (i) conditional principal and interest payments of up to approximately \$21.0 million through September 2012 under a note issued by Alimera; (ii) a \$25.0 million milestone payment due upon FDA approval of Iluvien and (iii) reimbursement of approved development costs actually incurred by the Company in support of the ongoing clinical studies of Iluvien and anticipated regulatory submissions. All future payments received from Alimera during the performance period will be recognized as revenue during the performance period using the cumulative catch-up method. All payments received after December 31, 2009 will be recognized as revenue when earned.

### **Pfizer**

On April 3, 2007, the Company and Pfizer entered into a Collaborative Research and License Agreement which superseded a prior research agreement dated December 22, 2006. Under the Pfizer Agreement, the parties have implemented a joint research program aimed at developing certain ophthalmic products using the Company's Durasert drug delivery technology. In addition to potential development and sales related milestone payments, Pfizer pays the Company a minimum of \$500,000 quarter in consideration of the Company's costs in performing the research program. These payments commenced in calendar year 2008 and continue until the commencement of a Phase III clinical trial for the first licensed product candidate or until the Agreement is earlier terminated.

The two Pfizer agreements have been combined for accounting purposes and, following an evaluation of the multiple deliverables in accordance with the provisions of EITF 00-21, the Company concluded that there was a single unit of accounting. The Company is evaluating the timing of the deliverables and other obligations under the Pfizer Agreement and, as a result, all payments received from Pfizer through June 30, 2008 totaling \$2.25 million have been classified in deferred revenue as a non-current liability.

### **Intrinsiq**

On January 17, 2008, the Company and Intrinsiq Materials Cayman Limited ("Intrinsiq") entered into an agreement pursuant to which Intrinsiq acquired an exclusive license to develop and commercialize nutraceutical and food science applications of BioSilicon, and certain related assets, for \$1,230,000. Intrinsiq paid \$500,000 at closing and has agreed to make additional payments totaling \$730,000 through January 2009. In addition, subject to Intrinsiq's unilateral right to terminate the license upon 90 days prior written notice, Intrinsiq will be obligated to pay the Company minimum royalties of \$3.95 million over six years, of which the first \$500,000 payment is due in July 2009.

The Company is required to spend approximately \$460,000 (of which approximately \$306,000 has been incurred and recorded as construction in progress at June 30, 2008 (see note 6)) to expand the Company's BioSilicon manufacturing capacity and is obligated to enter into a manufacture and supply agreement with Intrinsiq. The parties have not yet consummated a supply agreement and, accordingly, the Company is unable to determine the period of its performance obligations in accordance with EITF 00-21. The total amount received of \$500,000 has been classified as a non-current liability at June 30, 2008.

## 5. Goodwill and Acquired Intangible Assets

The reconciliation of goodwill and acquired intangible assets for the years ended June 30, 2008 and 2007 are as follows:

	June 30,	
	2008	2007
<b>Goodwill</b>		
Balance at beginning of year	\$ 60,212	\$ 58,212
Impairment write-down	(60,106)	—
Sale and leaseback adjustment (i)	—	(337)
Foreign currency translation adjustments	(106)	2,337
Balance at end of year	<u>\$ —</u>	<u>\$ 60,212</u>
<b>Patents and licences</b>		
Gross carrying amount at beginning of year	64,534	105,561
Asset impairment write-down	—	(45,278)
Foreign currency translation adjustments	(192)	4,251
Gross carrying amount at end of year	<u>64,342</u>	<u>64,534</u>
Accumulated amortization at beginning of year	(23,732)	(13,251)
Amortization expense	(3,886)	(9,247)
Foreign currency translation adjustments	78	(1,234)
Accumulated amortization at end of year	<u>(27,540)</u>	<u>(23,732)</u>
Net book value at end of year	<u>\$ 36,802</u>	<u>\$ 40,802</u>

- (i) Prior to the date of its acquisition by the Company, CDS entered into a sale and leaseback transaction for its premises. The gain on sale was initially deferred and amortized on a straight-line basis over the initial lease period of three years. In connection with the Company's acquisition of CDS in fiscal 2006, the deferred gain was included in the purchase price allocation. However, during fiscal 2007, the Company concluded that the deferred gain should not have been included in the purchase price allocation for the acquisition of CDS. The Company has adjusted goodwill for this misstatement in the year ended June 30, 2007. Prior period amounts have not been restated as the adjustment was not deemed to be material under SAB No. 99, "Materiality" and SAB No. 108 "Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements".

The net book value of the Company's intangible assets (other than goodwill) by product and/or product candidate at June 30, 2008 and 2007 is summarized as follows:

	June 30,		Estimated Remaining Useful Life at June 30, 2008 (Years)
	2008	2007	
<b>Patents and licences</b>			
Retisert	\$10,004	\$11,057	9.5
BrachySil	26,798	29,745	9.5
	<u>\$36,802</u>	<u>\$40,802</u>	

The Company amortizes its acquired intangible assets that have finite lives on a straight-line basis over their respective estimated useful lives. The aggregate amortization expense for intangible assets with finite lives was \$3.9 million, \$9.2 million and \$7.2 million for the years ended June 30, 2008, 2007 and 2006, respectively.



Based upon intangible assets in service as of June 30, 2008, amortization expense for each of the next five years is estimated to be approximately \$3.9 million per year.

In connection with an exclusive worldwide collaborative research and license agreement entered into with Pfizer in April 2007, the Company granted Pfizer a security interest (i) in certain patents owned by the Company and (ii) in certain other patents owned by third parties and licensed exclusively to the Company. Pursuant to the terms and conditions of the security agreement, the security interest was released as of March 31, 2008.

The ultimate recoupment of the carrying value of patents and licenses is dependent on the Company's successful development and commercial exploitation of its technology.

### **Impairment of Goodwill**

At June 30, 2008, the Company performed its annual impairment assessment of the carrying value of goodwill as required under SFAS 142. In accordance with SFAS 142, the Company compared the carrying value of its single reporting unit to its estimated fair value.

The Company assessed fair value as of June 30, 2008 through a combination of a discounted future cash flows analysis (an income approach) and a review of the market capitalization of its outstanding shares, adjusted for an estimated control premium. The income approach consisted of management's best estimates of future cash flows associated with its current products, product candidates, other business operations and existing tax loss carry-forwards, including estimated asset terminal values, with varying discount rates applied based upon perceived risk premiums. As a result of this step one analysis, the Company concluded that the carrying value of its net assets at June 30, 2008, including goodwill, exceeded fair value. This result was primarily due to a decline in the Company's share price during the fourth quarter that was deemed to be other than temporary. In the required step two analysis, the Company determined the fair value of its total assets and liabilities as if the step one fair value was the purchase price paid for the Company in a business combination. The individual product and product candidate intangible assets (Retisert, Iluvien and BrachySil) were valued by applying appropriate discount rates to present value the estimated cash flows, excluding any terminal value. The implied fair value of goodwill in the step two analysis was zero, resulting in a fourth quarter impairment charge of \$60.1 million, which represented the entire carrying value of the Company's goodwill at June 30, 2008. This impairment charge is not tax deductible because the acquisitions that gave rise to the goodwill were structured as stock transactions.

At each of June 30, 2007 and 2006, the Company's market capitalization, adjusted for an estimated control premium, exceeded the carrying value of its net assets. As the step one analysis did not indicate any potential goodwill impairment, a step two analysis was not required and there was no impairment of goodwill for the years ended June 30, 2007 and 2006.

## Impairment of Intangible Assets

At June 30, 2007, the Company evaluated the recoverability of its Retisert intangible assets based upon revised sales trend information and the receipt of formal confirmation in July 2007 of its prior understanding from industry sources that Bausch & Lomb had withdrawn its European application for authorization to market Retisert. Projections of future pre-tax undiscounted cash flows for Retisert were determined to be less than its asset carrying value at June 30, 2007. The Company estimated the net after-tax cash flows for Retisert, less direct costs, over its expected economic useful life from the June 30, 2007 measurement date. Management then determined what it believed to be an appropriate nominal after-tax discount rate to present value the estimated after-tax net cash flows. The results of management's impairment analysis at June 30, 2007 are summarized as follows:

<u>Intangible Asset</u>	<u>Asset Classification</u>	<u>Fair Value</u>	<u>Asset Carrying Value at June 30, 2007</u>	<u>Impairment Write-down</u>
Retisert .....	Patents	<u>\$11,057</u>	<u>\$56,335</u>	<u>\$(45,278)</u>

## 6. Property and Equipment, Net

	<u>June 30,</u>	
	<u>2008</u>	<u>2007</u>
Property and equipment .....	\$ 4,386	\$ 4,869
Construction in Progress .....	306	—
Leasehold improvements .....	<u>195</u>	<u>274</u>
Gross property and equipment .....	4,887	5,143
Accumulated depreciation and amortization .....	<u>(4,414)</u>	<u>(4,631)</u>
	<u>\$ 473</u>	<u>\$ 512</u>

Depreciation expense was \$397,000, \$1,767,000 and \$1,776,000 for the years ended June 30, 2008, 2007 and 2006, respectively.

## 7. Accrued Expenses

	<u>June 30,</u>	
	<u>2008</u>	<u>2007</u>
Professional fees .....	\$ 873	\$1,027
Personnel costs .....	794	330
Income taxes .....	52	—
Clinical trials .....	39	290
Amounts payable to development partner .....	—	3,742
Other .....	<u>478</u>	<u>675</u>
	<u>\$2,236</u>	<u>\$6,064</u>

## 8. Loss on Extinguishments of Debt

During the year ended June 30, 2007, the Company incurred a loss on extinguishments of debt in connection with (i) the subordinated convertible note issued in November 2005 to Sandell, as amended, and (ii) the subordinated convertible notes issued in September 2006 to other institutional investors (“Absolute”). The debt extinguishments consisted of the transactions summarized in the following table and are more fully described below:

	<u>Year ended June 30, 2007</u>
Sandell Note:	
September 14, 2006 amendment .....	\$ 8,871
December 29, 2006 amendment .....	3,276
May 15, 2007 note redemption .....	<u>10,867</u>
	23,014
Absolute Notes:	
June 14, 2007 note redemption .....	<u>347</u>
	<u>\$23,361</u>

### Sandell Convertible Note

In November 2005, the Company issued a \$15.0 million subordinated convertible note to Sandell with a term of three years and interest at 8% payable quarterly. The note was convertible into common shares at an initial conversion price of \$28.40 per share, subject to adjustments as defined. Warrants to purchase 158,451 shares at an exercise price of \$28.80 per share were issued in connection with the transaction. The facility was determined to be a hybrid financial instrument consisting of a loan host contract and a compound embedded derivative. The convertible note was valued using a Binomial Tree Model, with the initial carrying value of the note equal to the gross proceeds reduced by the values assigned to the conversion option derivative, the issued warrants and debt issue costs. The terms of the note agreement also required the Company to maintain minimum cash balances equal to 30% of the outstanding principal balance (\$4.5 million at June 30, 2006).

On September 14, 2006, the Company closed an agreement revising the terms of the Sandell note (the “Amended Note”). The Amended Note continued to have a three-year term and to bear 8% interest payable quarterly in arrears in cash or, under certain conditions, at the Company’s option, in the form of common shares. The terms of the Amended Note included an adjusted conversion price of \$8.00 per share, subject to further adjustment based upon certain events or circumstances. The investor’s conditional redemption rights under the original note were replaced by unilateral redemption rights for up to 50% of the Amended Note principal at July 31, 2007 and January 31, 2008. In connection with the amendment, the Company repaid \$2.5 million of the outstanding note principal and agreed to pay \$1.0 million in related penalties, which were paid on September 14, 2006. Sandell retained its existing warrants to purchase 158,451 shares, exercisable for six years at an adjusted exercise price of \$28.68 per share. Sandell extended the deadline for the registration statement required by a registration rights agreement to be declared effective by the SEC through October 15, 2006, with increased penalties if that deadline was missed. The Company’s registration statement was declared effective on September 29, 2006. The Company was also released from restrictions on future fundraising transactions contained in the original note documentation. The Company also granted to Sandell (i) Series A warrants to purchase 1,425,000 common shares exercisable for five years with an exercise price of \$7.20 per share; (ii) a security interest in the Company’s current royalties, subject to release of that security upon any disposition by the Company of the royalty stream; and (iii) a guarantee by the Company’s US subsidiary, pSivida US Inc.

The present value of the future cash flows of the Amended Note, including the \$1.0 million of cash fees paid and the value of the Series A warrants granted, was determined to be substantially different compared to the

future cash flows under the original note terms, both discounted using the effective interest rate determined under the original note. The Company recorded a loss on extinguishment of debt of approximately \$8.9 million, which represented the difference between the carrying amount of the original debt instrument and the consideration paid, including the value of the Series A warrants. The Amended Note, embedded derivative and the Series A warrants were valued using a Binomial Tree Model.

On October 17, 2006, the Company signed a letter agreement with Sandell further revising the terms of the Amended Note. Pursuant to the letter agreement, the Company was released until March 30, 2007 from the requirement to maintain a net cash balance in excess of 30% of the outstanding principal amount of the Amended Note and instead was required to maintain a net cash balance through that date of \$1.5 million. Sandell further waived any default that would otherwise have resulted from the unavailability of a resale registration statement until the Company filed with the SEC the 2006 audited financial statements reconciled to US GAAP. The Company filed those financial statements on October 31, 2006, thus satisfying the condition in the agreement. In exchange for the foregoing, the Company agreed to make (i) a one-time payment to the investor of \$800,000 on December 28, 2006 in satisfaction of registration rights penalties through the date of the letter agreement; and (ii) three payments of \$150,000 on January 31, 2007, February 28, 2007 and March 30, 2007.

The present value of the future cash flows of the Amended Note, as further modified, was determined not to be substantially different compared to the future cash flows of the original Amended Note, both discounted using the effective interest rate as determined under the Amended Note dated September 14, 2006. Accordingly, the \$450,000 of cash fees and the transaction costs directly related to the letter agreement reduced the carrying amount of the Amended Note, subject to amortization over the remaining term at an adjusted effective interest rate.

In November 2006, Sandell exercised its right to convert \$245,000 of the note principal and associated unpaid interest into 30,625 common shares.

On December 29, 2006, the Company entered into a second amendment agreement with Sandell revising the Amended Note (the "Second Amended Note"), pursuant to which Sandell agreed, subject to closing, to a general forbearance with respect to any defaults through March 31, 2007 or such earlier date as defined in the amendment agreement, including the following:

- Sandell agreed to allow the Company to transfer or grant security interests in certain of the Company's assets which would be necessary if the Company were to complete a pending transaction;
- Sandell agreed to forego the cash interest payment due on January 2, 2007 in favor of adding approximately \$306,000 to the outstanding principal amount of the convertible note, which amount represented the value of the common shares which the Company would have issued to satisfy the payment had the Company met certain conditions allowing the Company to pay the interest with shares;
- Sandell agreed to defer the Company's scheduled payment of \$800,000;
- Sandell agreed to forgive \$770,000 of pending registration delay penalties;
- Sandell agreed to amend the debt covenants to release the Company from the obligation to satisfy a minimum cash balance test of 30% of the outstanding note principal; and
- Sandell agreed that the Company would have until ten days after March 31, 2007 or an earlier defined date to file a registration statement with respect to securities issuable on exercise of Sandell's Series A warrants.

In return for the foregoing, the Company issued to Sandell Series C warrants to purchase 375,000 shares exercisable for five years with an exercise price of \$8.00 per share and agreed, upon receipt of required approvals, including shareholder approval, and satisfaction of other closing conditions, as defined, to issue additional Series D warrants to purchase 1.0 million shares exercisable for five years with an exercise price of \$8.00.

The present value of the future cash flows of the Second Amended Note, including the value of the Series C warrants issued, were determined to be substantially different compared to the future cash flows of the Amended Note, both discounted using the effective interest rate as determined under the original Amended Note. The Company recorded a loss on extinguishment of debt of approximately \$3.3 million, which represented the difference between the carrying amount of the Amended Note instrument and the consideration paid, including the value of the Series C warrants.

On February 22, 2007, as a result of the terms of a fund raise transaction (see Note 10), the note conversion price was adjusted from \$8.00 per share to \$6.48 per share. In March and April 2007, Sandell exercised their right to convert \$900,000 of the note principal and associated unpaid interest into 138,889 common shares.

On March 30, 2007, the Company paid the \$800,000 penalty payment that had been previously deferred pursuant to the December 29, 2006 second amendment agreement.

On May 15, 2007, the Company and Sandell amended the second amendment agreement and completed the transactions contemplated thereby pursuant to which the Company: (i) redeemed the remaining principal balance and accrued interest of the convertible note by a single payment of \$13.7 million which also included an excess payment made in consideration of the Company's ability to redeem earlier than the terms of the Second Amended Note otherwise permitted; (ii) issued the previously agreed Series D warrants to purchase 1.0 million common shares with an exercise price of \$8.00 per share; and (iii) issued additional warrants to purchase 1.0 million common shares with an exercise price of \$6.28 per share, 250,000 common shares with an exercise price of \$7.80 per share and 585,337 common shares with an exercise price of \$4.84 per share, in each case with a term of five years. In connection with the final redemption of the Second Amended Note, the Company recorded a loss on extinguishment of debt of approximately \$10.9 million, which represented the difference between the carrying amount of the Second Amended Note and the consideration paid, including the value of the additional warrants issued, reduced by (i) the portion of the consideration allocated to the equity component of the convertible note instrument at the date of the transaction and (ii) the value of the conversion option derivative re-measured immediately prior to the redemption. On May 24, 2007, the Company filed a registration statement to register the 4,635,337 common shares issuable upon exercise by Sandell of the warrants that were issued in connection with the various Sandell amendment agreements. The SEC declared the registration statement effective on June 11, 2007 and, under the terms of the registration rights agreement, as amended, all pending registration delay penalties were permanently waived.

### **Absolute Convertible Notes**

On September 26, 2006, the Company issued new subordinated convertible promissory notes to Absolute in the principal amount of \$6.5 million with a term of three years and interest at 8% per annum payable quarterly. The notes were initially convertible into common shares at a conversion price of \$8.00 per share, subject to adjustment based on certain events or circumstances. The Company also issued warrants to Absolute with a term of five years which entitled the investors to purchase 731,250 common shares at \$8.00 per share. The Company also entered into a registration rights agreement pursuant to which the Company agreed to file a registration statement covering the resale of the shares underlying the notes and the warrants as soon as practicable and to have the registration statement declared effective on or before January 1, 2007. The convertible notes were valued using a Binomial Tree Model, with the initial carrying value equal to the gross proceeds reduced by the value assigned to the conversion option derivative, the issued warrants and debt issue costs.

In November 2006, one of the note holders exercised its right to convert \$290,000 of note principal and associated unpaid interest into 36,250 common shares. As a result of the price at which common shares and warrants were issued in a private placement transaction on February 22, 2007 (see Note 10), the note conversion price was adjusted to \$6.48 per share. In April 2007, certain note holders exercised their rights to convert \$5,409,000 of note principal and associated unpaid interest into 834,730 common shares. As a result of the exercise price of certain warrants issued to Sandell on May 15, 2007, the note conversion price was further adjusted to \$4.84 per share.

The Company filed the required registration statement on March 6, 2007 and it was declared effective by the SEC on March 9, 2007. The Company paid \$147,000 of registration delay penalties to the investors through the effective date.

The Company could redeem the notes at any time by payment of 108% of the face value and could force conversion if the price of the Company's shares remained above two times the conversion price for a period of 25 days. On May 15, 2007, the Company issued to the note holders notice of its irrevocable election to redeem the remaining principal balance of the notes, pursuant to which the Company paid the holders \$885,000 on June 14, 2007, which consisted of \$806,000 of note principal, accrued and unpaid interest and the 8% redemption premium. In connection with the final redemption of the notes, the Company recorded a loss on extinguishment of debt of \$347,000, which represented the difference between the carrying amount of the notes and the consideration paid, less the value of the conversion option derivative re-measured immediately prior to the redemption.

## **9. Derivative Liabilities**

### **Convertible Note Transactions**

Conversion option derivatives arose in connection with the subordinated convertible promissory note issued to Sandell in November 2005, as subsequently amended, and in connection with the Absolute subordinated convertible notes issued in September 2006. The facility agreements contained a number of options such that they created hybrid financial instruments that consisted of a loan host contract and a compound embedded derivative. This embedded derivative was recognized separately from the host debt instrument. The value of the derivative embedded in the loan changed over time and was re-valued on a marked-to-market basis through profit and loss. The derivatives were valued using the Binomial Tree Method. The net change in the value of the conversion option derivatives from the dates of issuance of the convertible notes until immediately prior to the final redemptions of the convertible notes resulted in income recognized of approximately \$4.7 million and \$2.5 million during the years ended June 30, 2007 and 2006, respectively. The fair value of the conversion option derivatives immediately prior to the redemption of each of the Sandell and Absolute notes was written off in 2007 as part of the loss on extinguishment of debt (see Note 8).

### **Warrants Issued to Investors**

In connection with several capital raising transactions during the years ended June 30, 2008 and 2007, the Company issued units consisting of common shares together with detachable warrants to purchase additional common shares over a specified time period. These warrants were denominated in A\$, which is different than the Company's US\$ functional currency. To the extent that the potential exercise of such warrants would result in a variable amount of proceeds in the Company's functional currency, the fair value of the warrants was recorded as a derivative liability, with a corresponding reduction in additional paid-in capital, subject to revaluation of the liability on a marked-to-market basis through profit and loss. The fair value of the warrants was determined using a Black-Scholes Model. The grant date valuations of the A\$-denominated warrants issued in the capital raising transactions totalled approximately \$17.1 million. The net reduction in the fair values of these derivative liabilities for the years ended June 30, 2008 and 2007 resulted in income recognized of approximately \$8.4 million and \$6.8 million, respectively.

## **10. Stockholders' Equity**

The Company has historically financed a significant portion of its operations through the sale of equity and debt securities.

### **Stock Offerings**

In August 2005, the Company issued 166,250 common shares at \$26.00 per share to predominantly U.S. investors in a private placement transaction for gross proceeds of \$4.3 million, less issue costs of approximately



\$600,000. In connection with the offering, a total of 33,250 warrants to purchase common shares were issued to the investors and placement agents, exercisable for three years at \$50.00 per share, and have expired unexercised.

In December 2005, in connection with shares issued as consideration for the acquisition of CDS, the Company incurred approximately \$850,000 of share issue and registration costs.

In June 2006, the Company issued 262,895 common shares at A\$24.00 per share to Australian investors pursuant to a rights issue for gross proceeds of \$4.7 million, less issue costs of approximately \$120,000.

In December 2006, the Company issued 358,269 units at A\$10.40 per share in a private placement transaction for gross proceeds of \$2.9 million, less issue costs of approximately \$130,000. Each purchased unit consisted of one common share and a warrant to purchase two common shares exercisable for four years at A\$10.40 per share.

In February 2007, the Company issued 1,251,103 units at A\$9.20 per share in a private placement transaction for gross proceeds of \$9.1 million, less issue costs of approximately \$600,000. Each purchased unit consisted of one common share and a warrant to purchase two common shares exercisable for four years at A\$9.20 per share.

In April 2007, the Company issued 1,022,418 units at A\$10.78 per share in a private placement transaction for gross proceeds of \$9.0 million, less issue costs of approximately \$600,000. Each purchased unit consisted of one common share and a warrant to purchase 0.5 common share exercisable for four years at A\$10.78 per share.

In April 2007, pursuant to the terms of a Collaborative Research and License Agreement dated April 3, 2007 between the Company and Pfizer, Pfizer invested \$5.0 million for the purchase of 562,094 common shares at A\$10.94 per share.

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

### **Convertible Notes**

In connection with the November 2005 issuance of the subordinated convertible note to Sandell, the Company issued warrants to purchase 158,451 common shares at an initial exercise price of \$28.80 per share. In connection with the September 2006 issuance of the subordinated convertible notes to Absolute, the Company issued warrants to purchase 731,250 common shares at an initial exercise price of \$8.00 per share. In applying the relative fair value method to the allocation of the proceeds from these convertible notes, the equity portion of the Sandell and Absolute convertible notes was valued at \$1,252,000 and \$1,373,000, respectively.

During the year ended June 30, 2007, holders of the Sandell and Absolute convertible notes converted a total of \$6,844,000 of note principal and associated accrued and unpaid interest into 1,040,494 common shares at the applicable note conversion prices (see Note 8). For each conversion, an amount of unearned discount and issue costs was charged to additional paid-in capital such that the effective interest rate used to amortize the respective notes remained constant.

## Nonvested Stock

Nonvested stock was issued to employees of CDS as part of the Company's acquisition of CDS in December 2005 (see Note 3). The amortization of the unearned compensation amounts was recorded on a straight-line basis over the requisite service periods, which ranged from January 2007 through May 2008 (see Note 11). At June 30, 2008, these shares were fully vested.

## Investor Warrants to Purchase Common Shares

During the years ended June 30, 2008 and 2007, the Company issued warrants to purchase common shares (denominated in US\$), predominantly in connection with (i) its July 2007 share offering and (ii) its convertible note transactions and various amendments thereto (see Note 8).

At June 30, 2008, the Company had outstanding warrants to purchase common shares that are denominated in US\$ with a weighted average remaining life at June 30, 2008 of 3.65 years, as follows:

	Year Ended June 30,			
	2008		2007	
	Number of Warrants	Weighted Average Exercise Price US\$	Number of Warrants	Weighted Average Exercise Price US\$
Balance at beginning of year . . . . .	5,683,288	8.00	191,701	32.38
Granted . . . . .	1,512,210	6.60	5,491,587	7.13
Balance and exercisable at end of year . . . . .	<u>7,195,498</u>	<u>7.69</u>	<u>5,683,288</u>	<u>8.00</u>

During the years ended June 30, 2008 and 2007, the Company issued warrants to purchase common shares (denominated in A\$) to investors in connection with various stock offering transactions describe above.

At June 30, 2008, the Company had outstanding warrants to purchase common shares that are denominated in A\$ with a weighted average remaining life at June 30, 2008 of 2.68 years, as follows:

	Year Ended June 30,			
	2008		2007	
	Number of Warrants	Weighted Average Exercise Price A\$	Number of Warrants	Weighted Average Exercise Price A\$
Balance at beginning of year . . . . .	3,781,204	10.11	51,250	43.60
Granted . . . . .	205,479	7.68	3,729,954	9.65
Balance and exercisable at end of year . . . . .	<u>3,986,683</u>	<u>9.98</u>	<u>3,781,204</u>	<u>10.11</u>

At June 30, 2008 and 2007, the weighted exercise price of these warrants translated to US\$ is \$9.60 and \$8.58, respectively.

## Registration Rights Agreements

During each of the years ended June 30, 2007 and 2006, the Company entered into registration rights agreements with purchasers of certain of its equity and debt securities. These registration rights agreements required the Company to register with the SEC the resale of shares issued or issuable to such persons. The

Company's obligations to register shares in such transactions were subject to various deadlines, and the Company's failure to meet certain of these deadlines resulted in financial penalties against the Company. Predominantly related to the Company's convertible note financing transactions, the Company incurred registration rights penalties totaling \$2,274,000 and \$370,000 for the years ended June 30, 2007 and 2006, respectively, all of which had been paid prior to June 30, 2007. These amounts were included in interest and finance costs in the consolidated statements of operations. In connection with the convertible note transactions, all required registration statements were filed and declared effective by the SEC during the year ended June 30, 2007.

## 11. Stock-Based Compensation

### Employee Share Option Plan

The Company's Employee Share Option Plan (the "Plan") was initially approved by shareholders at the Company's annual general meeting on November 30, 2001 and, as required under Australian law, was re-approved by shareholders at each of the Company's annual general meetings held on November 17, 2004 and November 27, 2007. The Plan provides for the issuance of non-qualified stock options to eligible employees and directors subject to the terms and conditions determined by the administrator. During the three year period ended June 30, 2007, option grants under the Plan had requisite service periods ranging from immediate vesting to 3-year graded vesting and a contractual life of five years. Common shares issuable upon the exercise of stock options under the Plan will be newly issued shares.

The Company uses the Black-Scholes option pricing model to calculate the fair value of stock option grants. The table below indicates the key weighted average assumptions used in the option valuation calculations for options granted under the Plan during the years ended June 30, 2008, 2007 and 2006.

	<u>2008</u>	<u>2007</u>	<u>2006</u>
Option life (in years) .....	4.61	4.49	4.66
Stock volatility .....	70.0%	65.0%	55.0%
Risk-free interest rate .....	6.39%	5.89%	5.26%
Expected dividends .....	0.0%	0.0%	0.0%

The key assumptions for this valuation method include the expected life of the option, stock price volatility, risk-free interest rate and dividend yield. Many of these assumptions are judgmental and highly sensitive to the determination of fair value. Stock-based awards pursuant to the Plan have historically been granted in the form of options to acquire common shares priced in A\$, generally at a 10% premium to the grant date closing share price on the Australian Securities Exchange. The expected life is based upon limited historical exercise behavior adjusted for subjective factors that may influence future exercise patterns, including the shift in operational focus during the past two years to the U.S. The Company uses an expected stock-price volatility assumption that is a combination of historical and current implied volatilities of the underlying stock which is obtained from public data sources. The risk-free interest rate is based upon published Australian government bond rates over a term equivalent to the expected option term. 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.

For any option grants to non-executives during the years ended June 30, 2008 and 2007, an estimated forfeiture rate of 10% was used in calculating stock-based compensation. No forfeiture rate has been assumed for option grants to executives and directors. Additional expense will be recorded if the actual forfeiture rate is lower than estimated, and a recovery of prior year expense will be recorded if the actual forfeiture rate is higher than estimated.

Estimates of fair value may not represent actual future events or the value to be ultimately realized by persons who receive stock option awards.

The weighted average grant date fair value of stock options granted pursuant to the Plan during the years ended June 30, 2008, 2007 and 2006 was A\$2.47, A\$6.40 and A\$10.40 per share, respectively. The exercise prices of all outstanding options under the Plan at June 30, 2008 were in excess of the market price of the Company's common shares at that date and, accordingly, the options had no intrinsic value. The exercise prices of all options vested during each of the years ended June 30, 2008, 2007 and 2006 were in excess of the market price of the Company's common shares at those respective dates and, accordingly, the vested options had no intrinsic value. At June 30, 2008, there were 454,394 options vested and expected to vest, in the future, with an aggregate intrinsic value of \$0 and a weighted-average remaining contractual term of 2.36 years.

The following table summarizes the stock-based compensation expense related to the Plan by expense category charged to operations for the years ended June 30, 2008, 2007 and 2006:

	<b>Year ended June 30,</b>		
	<b>2008</b>	<b>2007</b>	<b>2006</b>
Research and development .....	\$—	\$(63)	\$272
General and administrative .....	540	35	569
	<u>\$540</u>	<u>\$(28)</u>	<u>\$841</u>

At June 30, 2008, there was \$225,000 of unrecognized compensation expense related to non-vested share-based payment awards that is expected to be recognized over a weighted average period of 1.47 years.

The following table provides a reconciliation of stock option activity under the Plan for the year ended June 30, 2008:

	<b>Number of options</b>	<b>Weighted average exercise price</b>
		A\$
Balance at beginning of year .....	466,838	36.41
Granted .....	136,250	5.50
Forfeited .....	(147,610)	28.98
Balance at end of year .....	<u>455,478</u>	<u>29.57</u>
Exercisable at end of year .....	<u>282,873</u>	<u>41.78</u>

Outstanding and exercisable stock options under the Plan as of June 30, 2008 are summarized below:

<b>Options Outstanding</b>				<b>Options Exercisable</b>	
<b>Range of Exercise Prices</b>	<b>Number Outstanding</b>	<b>Weighted Average Remaining Contractual Life</b>	<b>Weighted Average Exercise Price</b>	<b>Number Exercisable</b>	<b>Weighted Average Exercise Price</b>
A\$		(in years)	A\$		A\$
5.50	136,250	4.25	5.50	—	n/a
13.00	28,750	3.25	13.00	9,583	13.00
32.00 - 36.80	105,338	1.93	34.56	93,150	34.27
40.80	5,000	1.81	40.80	—	n/a
47.20	<u>180,140</u>	<u>1.04</u>	<u>47.20</u>	<u>180,140</u>	<u>47.20</u>
<u>13.00 - 47.20</u>	<u>455,478</u>	<u>2.36</u>	<u>29.57</u>	<u>282,873</u>	<u>41.78</u>

At June 30, 2008 the weighted average exercise price of outstanding and exercisable options translated into US\$ is \$28.43 and \$40.17, respectively. The weighted-average remaining contractual life of exercisable options under the Plan at June 30, 2008 was 1.40 years.

The Plan was assumed by pSivida Corp. in the reincorporation, but no further options will be granted under the Plan. At an Extraordinary General Meeting on June 6, 2008, shareholders approved and adopted the pSivida Corp. 2008 Incentive Plan pursuant to which a maximum of 1,750,000 common shares were authorized for issuance in satisfaction of stock-based awards to management, key employees, consultants and directors. No options under the 2008 Incentive Plan had been granted as of June 30, 2008.

### Nonvested Stock Issued to CDS Employees

On December 30, 2005, the Company issued 224,798 nonvested common shares with a fair value of \$26.40 per common share to CDS employees in exchange for their non-vested CDS stock. The portion of the fair value attributable to the employees' pre-acquisition service period was included as part of the CDS acquisition cost and the value attributable to the post-acquisition service period was expensed over the vesting period (see Note 3).

On December 30, 2005, the Company also granted 30,280 nonvested common shares with a fair value of \$20.68 per share to CDS employees in connection with employee retention agreements for which employee services subsequent to the consummation date of the acquisition were required in order for the shares to vest. The grant date fair value was expensed over the vesting period, which was completed in March 2007.

The following table presents a reconciliation of the activity related to the issuance of these nonvested common shares:

	Year Ended June 30,	
	2008	2007
Balance at beginning of year	8,587	241,868
Vested	(8,587)	(221,771)
Forfeited	—	(11,510)
Balance at end of year	<u>—</u>	<u>8,587</u>

The total fair value of shares vested during the year ended June 30, 2008 was approximately \$32,000.

The following table summarizes the stock-based compensation expense related to the nonvested common shares by expense category charged to operations for the years ended June 30, 2008, 2007 and 2006:

	Year ended June 30,		
	2008	2007	2006
Research and development	\$ 28	\$588	\$406
General and administrative	188	147	90
	<u>\$216</u>	<u>\$735</u>	<u>\$496</u>

### Options Issued in Exchange for CDS Options

On December 30, 2005, as part of the consideration for the acquisition of CDS, the Company issued 43,112 fully vested stock options with a fair value of \$15.48 per share in exchange for outstanding CDS options (see Note 3). The following table presents a reconciliation of the activity related to the issuance of these options:

	Year Ended June 30,			
	2008		2007	
	Number of Options	Weighted Average Exercise Price US\$	Number of Options	Weighted Average Exercise Price US\$
Balance at beginning of year	38,443	18.44	40,381	23.44
Options cancelled	(20,829)	24.44	(1,938)	122.16
Balance outstanding and exercisable at end of year	<u>17,614</u>	<u>11.35</u>	<u>38,443</u>	<u>18.44</u>

The weighted average remaining contractual life of these exercisable options at June 30, 2008 was 1.26 years.

## 12. Retirement Plans

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

The Company's UK subsidiary operates a defined contribution pension plan pursuant to which the Company makes contributions on behalf of employees plus a matching percentage of elective employee contributions.

Under government regulations in Australia, the Company was required to contribute 9% of Australian employees' gross wages, as defined, to an approved superannuation fund selected by each employee. Employees are entitled to contribute additional amounts to the fund at their own discretion.

The Company contributed a total of \$210,000, \$316,000 and \$277,000 for the years ended June 30, 2008, 2007 and 2006, respectively, in connection with these retirement plans.

## 13. Income Taxes

The components of income tax benefit are as follows:

	Year Ended June 30,		
	2008	2007	2006
Current income tax provision .....	\$ 52	\$ —	\$ —
Deferred income tax benefit .....	(535)	(13,225)	(6,919)
Income tax benefit .....	<u>\$(483)</u>	<u>\$(13,225)</u>	<u>\$(6,919)</u>

The components of loss from operations before income taxes are as follows:

	Year Ended June 30,		
	2008	2007	2006
U.S. operations .....	\$(47,969)	\$(61,697)	\$(32,046)
Non-U.S. operations .....	(28,184)	(35,053)	(20,185)
Loss from operations before income taxes .....	<u>\$(76,153)</u>	<u>\$(96,750)</u>	<u>\$(52,231)</u>

Our income tax benefit differed from that using the statutory U.S. federal tax rate of 34% as follows:

	Year Ended June 30,		
	2008	2007	2006
Statutory U.S. federal tax rate applied to loss before income taxes .....	\$(25,892)	\$(32,896)	\$(17,759)
State taxes .....	(2,878)	(3,701)	(1,922)
Non-U.S. tax rate differential .....	312	8,942	2,748
Goodwill impairment .....	21,556	—	—
In-process research and development .....	—	—	9,982
Other, net .....	80	(354)	(199)
Unused tax losses not recognized .....	6,339	14,784	231
Income tax benefit .....	<u>\$ (483)</u>	<u>\$(13,225)</u>	<u>\$ (6,919)</u>



The Company does not provide for taxes on the undistributed earnings of its foreign subsidiaries as it considers these earnings to be permanently re-invested outside the U.S.

The components of deferred income taxes are as follows:

	<u>June 30,</u>	
	<u>2008</u>	<u>2007</u>
Deferred tax assets comprise:		
NOL carryforwards .....	\$26,616	\$28,210
Temporary differences:		
Research and development accruals .....	—	1,436
Revenue recognition .....	6,641	369
Other .....	177	125
	<u>\$33,434</u>	<u>\$30,140</u>
Deferred tax liabilities comprise:		
Patents .....	\$11,505	\$13,342
Other .....	—	38
	<u>\$11,505</u>	<u>\$13,380</u>
Net deferred tax assets before valuation allowances .....	21,929	16,760
Valuation allowances .....	22,245	17,612
Net deferred tax liability .....	<u>\$ 316</u>	<u>\$ 852</u>

The valuation allowances generally reflect limitations on the Company's ability to use the tax attributes and reduce the value of such attributes to the likely net realizable amount. The increase in the valuation allowance of approximately \$4.6 million during 2008 is primarily related to an increase in the deferred tax asset related to deferred revenue and the reduction in the deferred tax liability related to patent intangibles.

The Company and various operating subsidiaries have tax loss carry forwards in their individual tax jurisdictions. At June 30, 2008, the Company had U.S. federal net operating loss carry forwards of approximately \$44.0 million which expire at various dates between calendar years 2022 and 2027. The utilization of these loss carry forwards may be limited by Section 382 of the Internal Revenue Code as a result of future changes in the Company's ownership. At June 30, 2008, the Company had state net operating loss carry forwards in the U.S. of approximately \$31.9 million which expire at various dates between calendar years 2008 and 2012. Additionally, at June 30, 2008 the Company had loss carry forwards in the UK of £17.4 million (approximately \$34.8 million).

The Company's U.S. federal income tax returns for calendar years 2004 through 2008 remain subject to examination by the Internal Revenue Service. The Company's U.K. tax returns for the years ended June 30, 2006 to June 30, 2008 remain subject to examination. The Australian tax returns for the former parent company for the years ended June 30, 2004 through June 30, 2008 remain subject to examination.

In June 2006, the FASB issued FIN 48, which prescribes detailed guidance for the financial statement recognition, measurement and disclosure of uncertain tax positions recognized in an enterprise's financial statements in accordance with FASB Statement No. 109, "Accounting for Income Taxes". Tax positions must meet a more-likely-than-not recognition threshold at the effective date to be recognized upon the adoption of FIN 48 and in subsequent periods. The Company adopted FIN 48 as of July 1, 2007. The adoption of FIN 48 did not have any impact on the Company's consolidated financial statements for the year ended June 30, 2008.

As of July 1, 2007, the Company recorded no liability for unrecognized tax benefits related to various federal, state and foreign income tax matters. The Company continues to record no liability as of June 30, 2008.

The Company does not expect that the amounts of unrecognized tax benefits will change significantly within the next 12 months. Future changes in unrecognized tax benefit will have no impact on the effective tax rate due to the existence of a valuation allowance.

#### 14. Discontinued Operations

On April 12, 2007, the Company sold its interest in AION Diagnostics Inc. (“AION”) to GEM Global Yield Fund (“GEM”), a portfolio management company. Total consideration included cash payments totaling \$1.85 million and a \$1.5 million promissory note due on April 12, 2008. Interest on the note was accrued at an annual rate of 8% compounded monthly and was due at maturity. The Company recorded a gain on sale of discontinued operations of \$3.7 million for the year ended June 30, 2007. In addition, the Company granted an exclusive license for non-electronic imaging diagnostic applications of its BioSilicon technology to AION and the Company is entitled to sales-based royalties on any commercialized products.

The promissory note was due April 12, 2008, but has not yet been paid. As of June 30, 2008, the carrying value of the note and related accrued interest was approximately \$1.6 million. The Company has demanded payment of the note and is in negotiations with GEM. The Company has reduced the carrying value of the note and accrued interest to its estimated net realizable value of \$1.3 million. The \$325,000 charge to bad debt expense is included in general and administrative expense in the consolidated statement of operations.

The operating results of AION for each of the two years in the period ended June 30, 2007 were included as discontinued operations in the accompanying consolidated financial statements. During those periods, AION generated no revenues and there was no income tax benefit associated with its operating loss.

#### 15. Commitments and Contingencies

##### Operating Leases

In October 2007, the Company extended the lease of its office and research laboratory space in Watertown, Massachusetts for a period of three years through April 6, 2011. The base rent for the extended lease term totals approximately \$1,040,000. The lease agreement requires the Company to pay for utilities, taxes, insurance, maintenance and other operating expenses in addition to base rent. The Company leases laboratory and office space in Malvern, UK through December 2008. The Company also leases certain office equipment under operating lease agreements that expire through 2010.

At June 30, 2008, the Company’s total future minimum lease payments under non-cancellable operating leases were as follows:

<b><u>Fiscal Year:</u></b>	
2009 .....	\$ 418
2010 .....	362
2011 .....	275
2012 .....	—
2013 .....	—
Thereafter .....	—
	<u>\$1,055</u>

Rent expense related to operating leases charged to operations was approximately \$529,000, \$610,000 and \$433,000 for the years ended June 30, 2008, 2007 and 2006, respectively.

## 16. Segment and Geographic Area Information

### (a) Business Segment

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

### (b) Geographic Area Information

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

	Revenues			Long-lived assets		
	2008	2007	2006	2008	2007	2006
United States .....	\$3,476	\$1,704	\$ 985	\$10,072	\$11,281	\$62,197
United Kingdom .....	—	81	51	27,203	30,024	32,145
Other .....	—	—	—	—	9	61
Consolidated .....	<u>\$3,476</u>	<u>\$1,785</u>	<u>\$1,036</u>	<u>\$37,275</u>	<u>\$41,314</u>	<u>\$94,403</u>

## 17. Supplemental Cash Flow Information

Supplemental cash flow information and non-cash investing and financing activities are as follows:

	Year Ended June 30,		
	2008	2007	2006
Supplemental cash flow information:			
Cash paid for interest on convertible notes .....	\$—	\$ 925	\$ 746
Cash paid for income taxes .....	—	—	—
Non-cash investing and financing activities:			
Purchases of property and equipment .....	101	—	—
Conversion of convertible notes, net of unearned discount and issue costs . . . .	—	1,116	—
Issuance of warrants in connection with convertible note amendments .....	—	21,469	—
Stock and options issued as consideration for the acquisition of CDS .....	—	—	105,054

**18. Quarterly Financial Data (unaudited)**

The following table summarizes the quarterly results of operations for the years ended June 30, 2008 and 2007:

	<u>First Quarter</u>	<u>Second Quarter</u>	<u>Third Quarter</u>	<u>Fourth Quarter</u>	<u>Year Ended June 30,</u>
<b><u>2008</u></b>				(1)	(1)
Total revenues	\$ 103	\$ 128	\$ 542	\$ 2,703	\$ 3,476
Operating loss from continuing operations	(5,213)	(8,036)	(6,609)	(65,149)	(85,007)
Loss from continuing operations	(795)	(5,795)	(5,501)	(63,579)	(75,670)
Net loss	<u>(795)</u>	<u>(5,795)</u>	<u>(5,501)</u>	<u>(63,579)</u>	<u>(75,670)</u>
Basic and diluted loss per common share:					
Loss from continuing operations	<u>\$ (0.04)</u>	<u>\$ (0.32)</u>	<u>\$ (0.30)</u>	<u>\$ (3.48)</u>	<u>\$ (4.17)</u>
Net loss	<u>\$ (0.04)</u>	<u>\$ (0.32)</u>	<u>\$ (0.30)</u>	<u>\$ (3.48)</u>	<u>\$ (4.17)</u>
Weighted average common shares:					
Basic and diluted	<u>17,890</u>	<u>18,254</u>	<u>18,260</u>	<u>18,261</u>	<u>18,166</u>
<b><u>2007</u></b>				(2)	(2)
Total revenues	\$ 606	\$ 508	\$ 369	\$ 302	\$ 1,785
Operating loss from continuing operations	(8,318)	(8,500)	(6,848)	(52,096)	(75,762)
Loss from continuing operations	(19,998)	(10,125)	(11,838)	(41,564)	(83,525)
Net loss	<u>(20,452)</u>	<u>(10,607)</u>	<u>(12,197)</u>	<u>(37,947)</u>	<u>(81,203)</u>
Basic and diluted loss per common share:					
Loss from continuing operations	<u>\$ (2.07)</u>	<u>\$ (1.04)</u>	<u>\$ (1.10)</u>	<u>\$ (2.96)</u>	<u>\$ (7.57)</u>
Net loss	<u>\$ (2.11)</u>	<u>\$ (1.09)</u>	<u>\$ (1.14)</u>	<u>\$ (2.70)</u>	<u>\$ (7.36)</u>
Weighted average common shares:					
Basic and diluted	<u>9,684</u>	<u>9,736</u>	<u>10,727</u>	<u>14,032</u>	<u>11,038</u>

(1) In 2008, results for the fourth quarter were adversely affected by a goodwill impairment write-down of \$60.1 million in connection with the Company's annual impairment testing at June 30, 2008 (see Note 5).

(2) In 2007, results for the fourth quarter were adversely affected by an asset impairment write-down of \$45.3 million related to the Company's Retisert patents (see Note 5).

Nonstatutory Stock Option  
Granted Under pSivida Corp. 2008 Incentive Plan

**1. Grant of Option.**

This certificate evidences a nonstatutory stock option (this "Stock Option") granted by pSivida Corp., a Delaware corporation (the "Company"), on \_\_\_\_\_ (the "Date of Grant") to \_\_\_\_\_ (the "Participant") pursuant to the Company's 2008 Incentive Plan (as from time to time in effect, the "Plan"). Under this Stock Option, the Participant may purchase, in whole or in part, on the terms herein provided, a total of \_\_\_\_\_ shares of common stock of the Company (the "Shares") at \_\_\_\_\_ per Share, which is not less than the fair market value of a Share on the Date of Grant. The latest date on which this Stock Option, or any part thereof, may be exercised is 5:00 P.M. Eastern Time on \_\_\_\_\_ (the "Final Exercise Date"). The Stock Option evidenced by this certificate is intended to be, and is hereby designated, a nonstatutory option, meaning an option that does *not* qualify as an incentive stock option as defined in section 422 of the Internal Revenue Code of 1986, as amended from time to time (the "Code").

**2. Vesting.**

(a) During Employment. This Stock Option will vest and become exercisable with respect to 25% of the Shares on each of the first, second, third and fourth anniversaries of the Grant Date; provided that, and subject to Section 2(c) below, upon a cessation of the Participant's Employment by reason of an involuntary termination without Cause (as defined in the Employment Agreement between the Company and the Participant dated \_\_\_\_\_ ("Employment Agreement") ("Cause")) or a voluntary termination for Good Cause (as defined in the Employment Agreement ("Good Cause")) any unvested portion of this Stock Option that would have vested as of the first anniversary of the cessation of the Participant's Employment had the Participant continued in Employment through such first anniversary will vest immediately prior to such cessation of Employment.

(b) Termination of Employment. Notwithstanding the foregoing, and subject to Section 2(c) below, the following rules will apply if a Participant's Employment ceases regardless of the circumstances: automatically and immediately upon the cessation of Employment, this Stock Option will cease to be exercisable and will terminate, except that:

(I) such portion, if any, of this Stock Option as is held by the Participant immediately prior to the cessation of the Participant's Employment for any reason other than for Cause or as a result of Participant's death and as is then exercisable (after giving effect to any accelerated vesting owing to a cessation of Employment by reason of an involuntary termination without Cause or a voluntary termination for Good Cause pursuant to Section 2(a) above), will remain exercisable until (i) 5:00 P.M. Eastern Time on the last day of the three-month period commencing on the date of such cessation of Employment or (ii) the Final Exercise Date, if earlier, and will thereupon terminate;

(II) such portion, if any, of this Stock Option as is held by the Participant immediately prior to the Participant's death and as is then exercisable, will remain exercisable until (i) 5:00 P.M. Eastern Time on the first anniversary of the Participant's death or (ii) the Final Exercise Date, if earlier, and will thereupon terminate; and

(III) such portion, if any, of this Stock Option as is held by the Participant immediately prior to the cessation of the Participant's Employment for Cause will immediately terminate.

(c) Change of Control. Notwithstanding any other provision of this Section 2 to the contrary, if a Change of Control occurs, whether or not the Change of Control also constitutes a Covered Transaction, and within the 24 months thereafter there is a cessation of the Participant's Employment by reason of an involuntary termination without Cause or a voluntary termination for Good Cause, the provisions of this Section 2(c) shall apply:

(I) This Stock Option, if it survives the Change of Control, including any stock option granted in substitution for this Stock Option in connection with the Change of Control, shall automatically vest and become

exercisable immediately prior to such cessation of Employment and will remain exercisable until (i) 5:00 P.M. Eastern Time on the first anniversary of the date of such cessation of Employment or (ii) the Final Exercise Date, if earlier, and will thereupon terminate; provided that, in the event of the Participant's death during such extended exercise period following a Change of Control, any portion of this Stock Option as is held by the Participant immediately prior to the Participant's death will remain exercisable until (i) 5:00 P.M. Eastern Time on the first anniversary of the Participant's death or (ii) the Final Exercise Date, if earlier, and will thereupon terminate.

(II) Any and all performance or other vesting conditions imposed pursuant to Section 7(a)(5) of the Plan with respect to any stock, cash or other property delivered in exchange for this Stock Option in connection with the Change of Control shall automatically be deemed to have been satisfied immediately prior to such cessation of Employment.

(III) For purposes of this Section 2(c), "Employment" shall be deemed to include employment with any successor to the Company's business or assets in connection with a Change of Control.

(IV) For purposes of this Stock Option, "Change of Control" shall mean:

(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 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 Date of Grant, constitute the Board (together with the individuals identified in the proviso to this Section 2(c)(IV)(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 Date of Grant 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.

(d) Notwithstanding the foregoing provisions of this Section 2, this Stock Option 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, Employed by the Company, its Affiliates, its subsidiaries, or, following a Change of Control, any successor to the Company's business or assets in connection with the Change of Control.

### **3. Exercise of Stock Option.**

Each election to exercise this Stock Option shall be in writing, signed by the Participant or the Participant's executor, administrator, or legally appointed representative (in the event of the Participant's incapacity) or the person or persons to whom this Stock Option is transferred by will or the applicable laws of descent and distribution (collectively, the "Option Holder"), and received by the Company at its principal office, accompanied by this certificate and payment in full as provided in the Plan. Subject to the further terms and conditions provided in the Plan, the purchase price may be paid as follows: (i) by delivery of cash or check acceptable to the Administrator; or (ii) through a broker-assisted exercise program acceptable to the Administrator; or (iii) by any other means acceptable to the Administrator, or (iv) by any combination of the foregoing means of exercise. In the event that this Stock Option is exercised by an Option Holder other than the Participant, the Company will be under no obligation to deliver Shares hereunder unless and until it is satisfied as to the authority of the Option Holder to exercise this Stock Option.

### **4. Withholding.**

Except as otherwise determined by the Administrator, this Stock Option may not be exercised unless the person exercising this Stock Option timely remits to the Company, in cash, all amounts required to be withheld upon exercise (all as determined by the Administrator) or makes other arrangements satisfactory to the Administrator for the payment of such taxes.

### **5. Nontransferability of Stock Option.**

This Stock Option is not transferable by the Participant otherwise than by will or the laws of descent and distribution, and is exercisable during the Participant's lifetime only by the Participant (or in the event of the Participant's incapacity, the person or persons legally appointed to act on the Participant's behalf).

### **6. Provisions of the Plan.**

This Stock Option is subject to the provisions of the Plan, which are incorporated herein by reference. A copy of the Plan as in effect on the date of the grant of this Stock Option has been furnished to the Participant. By accepting this Stock Option, the Participant agrees to be bound by the terms of the Plan and this certificate. All initially capitalized terms used herein will have the meaning specified in the Plan, unless another meaning is specified herein.

### **7. Other Agreements.**

The Company and Participant agree, in consideration of the grant of this Stock Option, and other good and valuable consideration, the receipt of which is mutually acknowledged, that the provisions of Section 2 shall supersede section of the Employment Agreement or the provisions of any other agreement between the Company and Participant regarding the vesting and exercise of this Stock Option following a cessation of the Participant's Employment by reason of an involuntary termination without Cause or a voluntary termination for Good Cause.

IN WITNESS WHEREOF, the Company has caused this instrument to be executed by its duly authorized officer.

pSivida Corp.

By \_\_\_\_\_

Dated:

Acknowledged and agreed:

\_\_\_\_\_

Dated:

**List of Subsidiaries of pSivida Corp.**

pSivida US, Inc. (Delaware)  
pSiMedica Limited (United Kingdom)

In addition, pSivida Corp. also has two directly held dormant or inactive subsidiaries named pSiNutria Limited (Australia) and pSivida UK Limited (United Kingdom), and two indirectly held dormant or inactive subsidiaries named pSiOncology Pte Limited (Singapore) and pSiNutria UK Limited (United Kingdom).

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in Registration Statement No. 333-152146 on Form S-8 and Registration Statement Nos. 333-141083, 333-132777, 333-143225 and 333-141091 on Form S-3 of our report dated September 26, 2008 (which report expresses an unqualified opinion and includes an explanatory paragraph relating to the adoption of FASB Interpretation No. 48, “*Accounting for Uncertainty in Income Taxes – an interpretation of FASB Statement No. 109*”, effective July 1, 2007), relating to the financial statements of pSivida Corp. appearing in this Annual Report on Form 10-K of pSivida Corp. for the year ended June 30, 2008.

/s/ DELOITTE & TOUCHE LLP

Boston, Massachusetts  
September 26, 2008

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

**CERTIFICATIONS**

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

1. I have reviewed this Annual Report on Form 10-K of **PSIVIDA CORP.**;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: September 26, 2008

/s/ **PAUL ASHTON**

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Name: **Paul Ashton**  
Title: **Managing Director**

**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, **Michael J. Soja**, certify that:

1. I have reviewed this Annual Report on Form 10-K of **PSIVIDA CORP.**;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: September 26, 2008

/s/ **MICHAEL J. SOJA**

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Name: **Michael J. Soja**  
Title: **Vice President, Finance and CFO**



**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, 2008, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Paul Ashton, Managing Director 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 26, 2008

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*/s/* **PAUL ASHTON**

**Name:** Paul Ashton  
**Title:** Managing Director

**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, 2008, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael J. Soja, Vice President, Finance and CFO 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 26, 2008

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/s/ MICHAEL J. SOJA  
Name: Michael J. Soja  
Title: Vice President, Finance and CFO