

**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, 2009

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

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

**02472**  
(Zip Code)

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

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

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

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

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

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

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405) 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   
Non-accelerated filer

Accelerated filer   
Smaller reporting company

(Do not check if a smaller reporting company)

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

The aggregate market value of the common stock held by non-affiliates of the registrant, computed by reference to the closing sales price of the stock on NASDAQ on December 31, 2008, the last trading day of the registrant's most recently completed second fiscal quarter, was approximately \$14,886,000.

There were 18,293,961 shares of the registrant's common stock, \$0.001 par value, outstanding as of September 23, 2009.

**DOCUMENTS INCORPORATED BY REFERENCE**

Specified portions of the registrant's definitive proxy statement, to be filed in connection with the Annual Meeting of Stockholders to be held on November 19, 2009, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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**Form 10-K**  
**For the Fiscal Year Ended June 30, 2009**  
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## **PART I**

### **Preliminary Note Regarding Forward-Looking Statements**

This Form 10-K and our 2009 Annual Report contain forward-looking statements, within the meaning of Section 27A of the Securities Act of 1933, as amended (Securities Act) and Section 21E of the Securities Exchange Act of 1934, as amended (Exchange Act). Forward-looking statements are inherently subject to risks, uncertainties and potentially inaccurate assumptions. Such statements give our current expectations or forecasts of future events; they do not relate strictly to historical or current facts. All statements other than statements of historical fact could be deemed forward-looking statements, including, without limitation, any expectations of revenue, expenses, cash flows, earnings or losses from operations, capital or other financial items; any statements of the plans, strategies and objectives of management for future operations; any statements concerning product research, development and commercialization timelines; any statements of expectations or belief; and any statements of assumptions underlying any of the foregoing. We often, although not always, identify forward-looking statements by using words or phrases such as the following: “likely”, “expect”, “intend”, “anticipate”, “believe”, “estimate”, “plan”, “project”, “forecast” and “outlook”.

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

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

## **ITEM 1. BUSINESS**

### **Introduction**

We develop tiny, sustained release, drug delivery products that are administered by implantation, injection or insertion. Once administered, the drug is released on a controlled and level basis for months or years. We have developed with partners two of the only three products approved by the U.S. Food and Drug Administration (FDA) for the long-term, sustained release delivery of drug to treat chronic eye disease, and a third partnered product is currently in late-stage Phase III clinical trials with a New Drug Application (NDA) filing anticipated in early 2010.

Our Phase III partnered product, which utilizes the third-generation of our Durasert™ technology system, delivers fluocinolone acetonide (FA) for the treatment of diabetic macular edema (DME). DME is a leading cause of vision loss for people under the age of 65 and has been estimated to affect over 1,000,000 people in the United States. Currently there is no FDA-approved drug therapy for the treatment of DME, and the only FDA-approved method for treating DME is laser photocoagulation therapy, which can leave irreversible blind spots. This product candidate, formerly known as Medidur™ FA for DME, is licensed to Alimera, which is conducting fully-recruited Phase III clinical trials. Alimera expects that 24-month interim data from these clinical trials will be available in late 2009 and plans to file an NDA with the FDA in early 2010. Alimera intends to commercialize the product under the name Iluvien®. Under our collaboration agreement with Alimera, investigator-sponsored pilot clinical trials are being conducted that are designed to assess the safety and efficacy of Iluvien in both wet and dry Age-Related Macular Degeneration (AMD) and retinal vein occlusion.

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Our two FDA-approved sustained release products to treat chronic back of the eye diseases are our second-generation Retisert® for the treatment of posterior uveitis and our first-generation Vitrasert® for the treatment of AIDS-related cytomegalovirus (CMV) retinitis. We have licensed both of these products and the technologies underlying them to Bausch & Lomb Incorporated (Bausch & Lomb). Retisert provides sustained release for approximately two and a half years, and Vitrasert provides sustained release for six to nine months.

We also have a worldwide collaborative research and license agreement with Pfizer, Inc. (Pfizer) under which Pfizer may develop additional ophthalmic products based on certain of our technologies.

BioSilicon™, our other principal technology system, is a fully-erodible, nanostructured, porous silicon designed to provide sustained delivery of various therapeutics, including small drug molecules, proteins and peptides. Based on our pre-clinical data, we currently are targeting BioSilicon as a key second prong of our drug delivery platform.

Our lead BioSilicon product candidate, BrachySil™, delivers therapeutic phosphorus-32, or P32, a radioactive form of phosphorus used to treat cancer, directly to solid tumors. We completed an initial safety and efficacy clinical trial of BrachySil for the treatment of pancreatic cancer and are nearing completion of a follow-on, dose-ranging clinical trial for this developmental product.

Medidur™, Durasert™, BioSilicon™, BrachySil™ and CODRUG™ 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 is often necessary to maintain therapeutic drug levels over an extended period of time. Patients, however, often fail to take drugs as prescribed or fail to attend follow-up visits 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.

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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 intraocular infection, perforated sclera, vitreous hemorrhage and cataract formation.

### **Technologies and Products**

We have three technology systems: Durasert, BioSilicon and CODRUG.

#### ***Durasert Technology System***

The Retisert and Vitrasert products, the Iluvien product candidate and other product candidates based on our Medidur technology, all use our proprietary Durasert system, which delivers specific quantities of drugs directly to a target site in the body at controlled rates for predetermined periods of time ranging from days to years. The Durasert system is designed to provide the benefits of direct delivery of appropriate quantities of drug over an extended period, while addressing the drawbacks of systemic drug delivery, including adverse side effects characteristic of high dosing levels and reduced treatment benefits due to variations in drug levels at the target site. The Durasert system has three principal attributes designed to deliver these 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 release is controlled by the permeability of the polymer layers. 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.

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Our portfolio of products and product candidates includes:

<u>Product</u>	<u>Disease</u>	<u>Stage of Development</u>	<u>Licensee</u>
Retisert	Posterior uveitis	FDA-approved; commercialized since 2005	Bausch & Lomb
Vitrasert	CMV retinitis	FDA-approved; commercialized since 1996	Bausch & Lomb
Iluvien	Diabetic macular edema (DME)	Phase III clinical trials; NDA filing planned early 2010	Alimera
Iluvien	Wet age-related macular degeneration (Wet AMD)	Investigator-sponsored pilot clinical trial	Alimera
Iluvien	Dry age-related macular degeneration (Dry AMD)	Investigator-sponsored pilot clinical trial	Alimera
Iluvien	Retinal vein occlusion	Investigator-sponsored pilot clinical trial	Alimera
BrachySil	Pancreatic cancer	Phase II clinical trials	
Durasert	Glaucoma	Pre-clinical trials	
Durasert	Retinitis pigmentosa	Pre-clinical trials	
BioSilicon	Retinal vein occlusion	Pre-clinical trials	

### *Durasert Products and Product Candidates*

*Retisert.* Retisert is the only product approved by the FDA for the treatment of posterior uveitis, an autoimmune condition characterized by inflammation of the inside of the eye that can cause sudden or gradual vision loss. This disease has been estimated to affect 175,000 people in the U.S. and to have resulted in blindness in approximately 30,000 people in the U.S. Retisert, which is about the size of a grain of rice, is surgically implanted through a 3-4 mm incision and delivers sustained levels of the anti-inflammatory corticosteroid 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.

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

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We licensed Alimera the rights to develop, market and sell Medidur FA, which Alimera intends to commercialize under the name Iluvien. Alimera is conducting fully enrolled Phase III trials for Iluvien. Alimera expects that 24-month data from these clinical trials will be available in late 2009, and plans to file an NDA with the FDA in early 2010. Under our collaboration agreement, Alimera is also studying Iluvien in three investigator-sponsored pilot clinical trials. One trial is designed to assess the safety and efficacy of Iluvien in conjunction with Lucentis in patients with exudative age-related macular degeneration (wet AMD) to provide information on the potential of Iluvien to maintain the efficacy of Lucentis while reducing the overall number of Lucentis treatments. A second trial is designed to assess the safety and efficacy of Iluvien in patients with bilateral geographic atrophy secondary to dry-AMD. The third trial is designed to assess the safety and efficacy of Iluvien in patients with macular edema secondary to retinal vein occlusion.

*Other Technology Applications.* We have a worldwide collaborative research and license agreement with Pfizer under which Pfizer may develop certain ophthalmic applications of Medidur-based products that are not licensed to Alimera. In addition, we are conducting pre-clinical studies utilizing our Durasert technology designed to treat glaucoma and retinitis pigmentosa.

### **BioSilicon Technology System**

Our proprietary BioSilicon technology system utilizes a “honeycomb” structure of nano-porous, elemental silicon to deliver therapeutics. 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 drugs and therapeutics to a target site at a controlled release rate for an extended period of time. We believe BioSilicon can be used to deliver a wide variety of drugs, including small chemical entities, peptides, proteins and other therapeutics such as P32.

Based on our pre-clinical data, we currently are targeting BioSilicon as a key second prong of our drug delivery platform.

*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 P32, a beta-emitting radioactive isotope that has been shown to shrink tumors. Because this radiation is also harmful to healthy tissue, use of BrachySil is designed to reduce radiation dispersed beyond the area of the tumor, as compared to existing P32-based products that 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 potentially advantageous attributes:

- *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.

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We have completed an initial safety and efficacy clinical trial of BrachySil for the treatment of inoperable pancreatic cancer, which indicated that BrachySil, in combination with standard chemotherapy, was well tolerated with no clinically significant adverse events related to BrachySil. We are nearing the completion of a follow-on dose-ranging clinical trial for BrachySil. BrachySil is being regulated as a medical device in the European Union (EU), and we currently anticipate that the same designation will apply in the U.S. 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 BioSilicon Applications.* We are conducting pre-clinical studies using BioSilcon technology designed to treat retinal vein occlusion. We have out-licensed certain non-core field of use applications of BioSilicon in the areas of nutraceuticals and food science and diagnostics.

### ***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.

### **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***

Vitrasert was developed and commercialized under a 1992 licensing and development agreement with Chiron Vision Corporation (Chiron), a subsidiary of Chiron Corporation. When Bausch & Lomb acquired Chiron, Bausch & Lomb assumed this agreement, and currently sells Vitrasert under a worldwide exclusive license and pays us royalties on sales.

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

Retisert was developed and commercialized under a 1992 licensing and development agreement with Bausch & Lomb. Pursuant to a subsequent collaboration agreement, Bausch & Lomb has a worldwide exclusive license to make and sell Vitrasert and our first-generation products (as defined in the agreement, including the Retisert device) in return for royalties based on sales. Bausch & Lomb can terminate its agreement with us without penalty at any time upon 90 days' written notice.

#### ***Alimera***

Under a 2005 collaboration agreement, Alimera has a worldwide exclusive license to use certain of our technologies to make and sell certain Medidur-based products that deliver a corticosteroid for the treatment and prevention of eye diseases other than uveitis. Alimera also has a worldwide non-exclusive license to use certain of our technologies to make and sell certain additional Medidur-based products for the treatment and prevention of eye diseases other than uveitis that (i) are not exclusively licensed to Bausch & Lomb, (ii) have a drug core within a polymer layer and (iii) are approved or designed to be approved (a) to deliver a corticosteroid and no



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other active ingredient by implantation, injection or other direct delivery method to the posterior portion of the eye or (b) to treat DME by delivering a compound or formulation through implantation, injection or other direct delivery method other than through an incision smaller than that required for a 25 gauge needle. 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.

On March 14, 2008, we amended and restated our collaboration agreement with Alimera. In exchange for aggregate 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 this amended agreement. Aggregate consideration consisted of (i) \$12.0 million in cash received upon the execution of the amended agreement; (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; (iii) conditional principal and interest payments of up to approximately \$21.3 million through September 2012 under a note issued by Alimera; (iv) a \$25.0 million milestone payment upon FDA approval of Iluvien for DME; (v) 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 (vi) assumption by Alimera of all financial responsibility for the development of licensed products under the amended agreement, the result of which is 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 2005 collaboration agreement.

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

### ***Pfizer***

In April 2007, we entered into an exclusive worldwide collaborative research and license agreement with Pfizer for certain of our technologies, including the technology underlying the Medidur drug delivery device, in certain ophthalmic applications that are not licensed to Alimera.

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 first Phase III clinical trial commences. Pfizer will have an exclusive license to market any products developed under the agreement, and will pay us a royalty on net sales of those products. Pfizer may terminate the agreement without penalty on 90 days notice without cause.

Pfizer has made equity investments totaling \$11.5 million in pSivida, making Pfizer our largest shareholder, owning approximately 10.2% of total shares outstanding as of August 31, 2009.

### ***Intrinsiq***

In January 2008, we entered into an exclusive field of use license with Intrinsiq Materials Cayman Limited (Intrinsiq) for nutraceutical and food science applications of BioSilicon. In connection with the license, we received license fee payments of \$730,000 and \$500,000 during the years ended June 30, 2009 and 2008, respectively. In addition, subject to Intrinsiq's unilateral right to terminate the license upon 90 days prior written notice, we are entitled to receive scheduled minimum royalties of \$3.55 million through April 2014, of which the first \$450,000 payment was received in July 2009. For the year ending June 30, 2010, we are entitled to the receipt of quarterly royalties earned, if any. The next scheduled minimum royalty payment of \$630,000 is due in January 2012.

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### **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 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 technology systems. Our research and development expenses were \$8.0 million, \$14.4 million and \$21.1 million during fiscal 2009, 2008 and 2007, respectively. Of these amounts, approximately \$4.4 million, \$10.2 million and \$9.7 million for fiscal 2009, 2008 and 2007, respectively, were incurred for costs of research and development personnel, clinical trials, contract services, testing and laboratory facilities and included approximately \$4.7 million and \$3.5 million for the years ended June 30, 2008 and 2007, respectively, of Medidur FA co-development costs incurred prior to the amendment and restatement of the 2005 collaboration agreement with Alimera. Such costs were charged to operations as incurred. The remaining expense of \$3.6 million, \$4.2 million and \$11.4 million for fiscal 2009, 2008 and 2007, respectively, consisted of non-cash charges for amortization of intangible assets, depreciation of property, plant and equipment and stock-based compensation expense specifically allocated to research and development personnel.

### **Intellectual property**

Our intellectual property rights are crucial to our business. We hold or are licensed patents relating to our core technology systems in the United States and 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 as of August 31, 2009.

<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	18	62	96	21
<b>BioSilicon</b>	10	20	51	68	24
<b>CODRUG</b>	3	10	11	24	14
<b>Other</b>	—	2	—	4	3
<b>Total</b>	<u>23</u>	<u>50</u>	<u>124</u>	<u>192</u>	<u>62</u>

### **Employees**

We had 22 employees as of August 31, 2009. None of our employees are covered by a collective bargaining agreement.

### **Sales and Marketing**

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

### **Reimbursement**

The successful commercialization of our current products depends, and of any future products will depend, in significant part on the extent to which reimbursement of the cost of the products and the related administration

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procedures will be available from government health administration authorities, private health insurers and other organizations. Medicaid and Medicare, most major health maintenance organizations and most health insurance carriers reimburse \$4,240 for the cost of the Vitrasert implant, with associated surgical fees reimbursed separately. The Centers for Medicare and Medicaid Services designated Retisert as eligible for Medicare reimbursement at the rate of \$19,345, with associated surgical fees reimbursed separately.

### Competition

We are engaged in healthcare product development, an industry that is characterized by extensive research efforts and rapid technological progress. We believe that pharmaceutical, drug delivery and biotechnology companies, research organizations, governmental entities, universities, hospitals, other nonprofit organizations and individual scientists are seeking to develop drugs, therapies and novel delivery methods to treat our targeted diseases.

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. has developed Ozurdex®, which was recently approved by the FDA for the treatment of persistent macular edema associated with retinal vein occlusion. Phase III clinical trials are underway investigating this product for the treatment of DME. This product may be used off-label for the treatment of DME.
- 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 and dry-AMD.

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,								
	2009			2008			2007		
	United States	United Kingdom	Total	United States	United Kingdom	Total	United States	United Kingdom	Total
Revenue:									
Collaborative research and development	\$11,925	\$ 77	\$12,002	\$3,328	\$ —	\$3,328	\$ 652	\$ 81	\$ 733
Royalties	160	—	160	148	—	148	1,052	—	1,052
	<u>\$12,085</u>	<u>\$ 77</u>	<u>\$12,162</u>	<u>\$3,476</u>	<u>\$ —</u>	<u>\$3,476</u>	<u>\$ 1,704</u>	<u>\$ 81</u>	<u>\$ 1,785</u>

## Government Regulation

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

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

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

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

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators. Clinical trials are conducted in accordance with protocols that detail the objectives of the study, the parameters to be used to monitor safety and any efficacy criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND. Further, each clinical study must be conducted under the auspices of an independent institutional review board 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 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.

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- *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. An NDA, supplement and certain other submissions to the FDA require certification of compliance with the FDAAA clinical trials reporting requirements.

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

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 may also qualify for priority review under policies or procedures offered by the FDA.

Satisfaction of FDA requirements or similar requirements of foreign regulatory agencies typically takes several years, and the actual time required may vary substantially based upon factors including the type, complexity and novelty of the pharmaceutical product. Such government regulation may delay or prevent marketing of potential products for a considerable period of time, and may impose costly procedures upon our

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activities. Success in pre-clinical or early stage clinical trials does not assure success in later stage clinical trials. Data from pre-clinical and clinical activities is not always conclusive, and may be susceptible to varying interpretations which could delay or prevent regulatory approval. Even if a product receives regulatory approval, the approval may be subject to significant limitations based on data from pre-clinical and clinical activities. Further, discovery of previously unknown problems in connection with a product's use may result in restrictions on the product, or even complete withdrawal of the product from the market.

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

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

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

We 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 BrachySil as a device in the United States, we would need to satisfy different regulatory requirements. Products that are classified as devices also require some form of FDA clearance or 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 include 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:

- pre-clinical laboratory tests and in vitro and in vivo pre-clinical studies;

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- 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;
- submission to the FDA of a Pre-Marketing Approval application (PMA); and
- 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 after 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 an already-marketed device.

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

### **Corporate Information**

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

### **Additional Information**

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

**ITEM 1A. RISK FACTORS**

**RISKS RELATED TO OUR COMPANY AND OUR BUSINESS**

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

Our cash and cash equivalents totaled approximately \$6.9 million at June 30, 2009. We believe we can fund our operations as currently conducted through at least December 31, 2010. This expectation is based on certain key assumptions that include (i) continued receipt from Pfizer of quarterly \$500,000 research and development funding; (ii) Alimera's continued funding of the development of Iluvien; and (iii) the continued receipt of 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;
- 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 and programs (including any Phase III trials for BrachySil for pancreatic cancer), any new product candidates and any new business opportunities;
- our ability to establish and maintain strategic arrangements for BrachySil and 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 timing of FDA approval and the initiation and success of marketing of Iluvien, and the occurrence of certain milestone events under the terms of our collaboration agreement with Alimera. Alimera has agreed to pay us \$25 million upon FDA approval of Iluvien for DME 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 of Alimera) 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.

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



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

We have incurred operating losses since our inception in 2000. For the years ended June 30, 2009, 2008 and 2007, we incurred net losses of \$2.5 million, \$75.7 million and \$81.2 million, respectively. As of June 30, 2009, we had an accumulated deficit of \$227.0 million. We 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 timely approved and successfully commercialized. Even if Iluvien is approved and marketed, our profit share on sales of Iluvien, combined with royalty income from our current products, and any other sources of revenue, may not be sufficient to result in profitability.

***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. As of June 30, 2009, an additional \$1.2 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 charge on the recorded value that had been assigned to the Retisert patents. In addition, the amount of corticosteroid FA delivered by Retisert has been associated with increased incidence of cataract formation and increased intraocular pressure, which side effects we believe may have also negatively affected sales of Retisert. We currently do not expect to record royalty income on sales of Retisert by Bausch & Lomb until at least the fourth quarter of our fiscal year ending June 30, 2010. There is no assurance, however, if we will commence receiving full royalty amounts at that time or at any other time. We also cannot predict the amount of any future royalty payments that we will receive.

***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 our securities.***

Impairment charges on our intangible assets could have a material effect on our results of operations, which could in turn adversely affect the price of our securities. We have recorded significant amounts of intangible assets in connection with acquisitions. We took a \$60.1 million impairment charge on goodwill as of June 30, 2008 (which reduced the carrying value of our goodwill to zero), and a \$45.3 million impairment charge on the recorded value of our Retisert intangible asset as of June 30, 2007. We still have \$28.8 million of intangible assets on our balance sheet as of June 30, 2009, of which approximately \$19.8 million relates to our BioSilicon technology and approximately \$9.0 million relates to Retisert. We will continue to conduct impairment analyses of our intangible assets as required, and may be required to take significant impairment charges in the future.

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

In connection with certain capital raising transactions during the years ended June 30, 2008 and 2007, we issued detachable warrants denominated in A\$. The fair values of the warrants have been recorded as derivative liabilities on our balance sheet. We are required to assess the fair value of these warrants at each subsequent balance sheet date, and changes in their fair values will result in adjustments to our recorded derivative liabilities, and a corresponding gain or loss on our statement of operations. The fair values of these warrants are sensitive to changes in our share price, among other factors, and are measured using the Black-Scholes valuation model. Fluctuations in the fair values of these warrants could be substantial and could continue to affect our operating results until the last-to-expire of these warrants in July 2012.

***Our operating results may fluctuate significantly from period to period.***

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

- the timing, receipt and amount of payments, if any, from current and potential future collaboration partners and the revenue recognition policies related thereto;
- changes in accounting estimates, policies or principles;
- the entry into, or termination of, collaboration agreements;
- the scope, duration and effectiveness of our collaboration arrangements;
- the quarterly income or expense amounts recorded from the revaluation of our derivative liabilities;
- the amount of research and development costs, including pre-clinical studies and clinical trials, that are funded internally;
- general and industry-specific adverse economic conditions that may affect, among other things, our and our collaborators' operations and financial results; and
- impairment write-downs of one or more of our intangible assets.

Due to fluctuations in our operating results, quarterly comparisons of our financial results may not necessarily be meaningful, and investors should not rely upon such results as an indication of future performance. In addition, investors may react adversely if our reported operating results are less favorable than in a prior period or are less favorable than those anticipated by investors in the financial community, which may result in a decrease in our stock price.

**RISKS RELATED TO THE DEVELOPMENT AND COMMERCIALIZATION OF OUR PRODUCTS**

***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 one or more of our licensees may leave us, at least temporarily, 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 currently funding early stage research and pre-clinical development of potential product candidates under our worldwide collaborative research and license agreement with it. Pfizer may terminate the agreement without penalty at any time and for any reason upon 90 days written notice. We have exclusively licensed our technology underlying Vitrasert and Retisert to Bausch & Lomb, which can terminate its agreement with us without penalty at any time upon 90 days' written notice. We have licensed the technology underlying Iluvien and certain ophthalmic applications to Alimera. Alimera has the financial responsibility for the development of Iluvien and any other licensed products developed under our collaboration agreement, along with sole responsibility for the commercialization of such licensed products. Alimera may abandon the development and commercialization of any licensed product at any time.

Any of Pfizer, Alimera or Bausch & Lomb may decide not to continue with or commercialize any or all of the licensed products, change strategic focus, pursue alternative technologies or develop competing products. Alimera was incorporated in June 2003 and may have limited resources. While Pfizer and Bausch & Lomb have significant experience in the ophthalmic field and have substantial resources, there is no assurance whether, and

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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.

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

Our current and future activities are and will be subject to stringent regulation by governmental authorities both in the United States and in any other country in which our products are marketed. Before we or our licensees can manufacture, market and sell any of our product candidates, approval from the FDA and/or foreign regulatory authorities is first required. Generally, in order to obtain these approvals, pre-clinical studies and clinical trials must demonstrate that each of these product candidates is safe for human use and effective for its targeted disease or condition. Our product candidates are in various stages of pre-clinical and clinical testing. In particular, Iluvien is in fully-enrolled Phase III clinical trials being conducted by Alimera and BrachySil is nearing the completion of a Phase II 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 (or our licensees') lack of sufficient funding to pursue trials rapidly or at all;
- our (or our licensees') inability to attract clinical investigators for trials;
- our (or our licensees') inability to recruit patients in sufficient numbers or at the expected rate;
- our inability to reach agreement with a licensee to undertake the clinical trials;
- adverse side effects;
- failure of the trials to demonstrate a product's safety or efficacy;
- our (or our licensees') failure to meet FDA or other regulatory agency requirements for clinical trial design;
- our (or our licensees') inability to follow patients adequately after treatment;
- changes in the design or manufacture of a product;
- failures by, or changes in our relationship, or that of our licensees, with contract research organizations, third-party vendors and investigators responsible for pre-clinical 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 such regulatory approvals to be limited or even rescinded. For example, Iluvien utilizes the corticosteroid FA as its active ingredient, which has been associated with certain undesirable side effects in Retisert. Alimera must demonstrate that Iluvien presents an acceptable risk/benefit profile in order to achieve FDA approval.

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

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

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

We have limited product development capability and no marketing or sales staff. Developing products and achieving market acceptance for them 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 and licensing arrangements for the development and commercialization of our product candidates, and we currently have collaboration and licensing arrangements with Alimera, Pfizer, Bausch & Lomb and Intrinsiq. The curtailment or termination of any of these arrangements could adversely affect our business, the ability to develop and commercialize our products and proposed products and our ability to fund operations.

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

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

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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 technologies 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 Vitraser 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
- may otherwise render our products less competitive or obsolete.

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

***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

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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.

### **RISKS RELATED TO OUR INTELLECTUAL PROPERTY**

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

Our success is dependent on whether we can obtain patents, defend our existing patents and operate without infringing on the proprietary rights of third parties. As of August 31, 2009, we had 147 patents and 242 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.

## **RISKS RELATED TO OUR BUSINESS, INDUSTRY, STRATEGY AND OPERATIONS**

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

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

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

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

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

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

Our ability to conduct timely pre-clinical and clinical research and development programs, obtain regulatory approvals, develop and commercialize our product candidates and fulfill our contract manufacturing obligations

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to others will depend, in part, upon our and our collaborative partners' ability to manufacture our products and product candidates, either directly or through third parties, in accordance with FDA and other regulatory requirements. The manufacture 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.

In addition, we or our collaborative partners may not be able to manufacture our product candidates successfully or have a third party manufacture them in a cost-effective manner. If we or our collaborative partners are unable to develop our own manufacturing facilities or to obtain or retain third-party manufacturing on acceptable terms, we may not be able to conduct certain future pre-clinical and clinical testing or to supply commercial quantities of our products.

We manufacture clinical supplies of Iluvien and certain clinical supplies for Pfizer. BrachySil clinical supplies are manufactured by third parties under contract. We have licensed to Pfizer the exclusive rights to manufacture commercial quantities of ophthalmic products, if approved for marketing, covered by its worldwide collaborative research and license agreement with us. We have licensed to Bausch & Lomb the exclusive rights to manufacture commercial quantities of Vitrasert and Retisert. We have licensed to Alimera the rights to develop, manufacture and commercialize Medidur FA, which Alimera intends to commercialize under the name Iluvien, if approved for marketing, and have licensed to Alimera rights to other products covered by its collaboration 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.

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 for Iluvien 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.

***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



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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.

### **RISKS RELATED TO OUR COMMON STOCK**

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

The price of our common stock (including common stock represented by CHES Depositary Interests (CDIs)) may be affected by developments directly affecting our business and by developments out of our control or unrelated to us. The biotechnology sector, in particular, and the stock market generally, are vulnerable to abrupt changes in investor sentiment. Prices of securities and trading volume of companies in the biotechnology industry, including ours, can swing dramatically in ways unrelated to, or that bear a disproportionate relationship to, operating performance. The price of our 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.

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In addition, low trading volume in our common stock or our CDIs may increase their price volatility. As of August 31, 2009, we had approximately 18.3 million shares of common stock outstanding. The average combined daily trading volume in the common stock (and CDIs) on the exchanges in which our common stock are listed was approximately 26,000 shares during the period May to August 2009. 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, 2009, we had outstanding warrants and options to acquire 13,005,613 shares of our common stock, or approximately 41.6% of our shares on a fully diluted basis. Although the exercise prices of the 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, 2009 and is a collaborative partner. As a result, Pfizer may be able to exert significant influence over our board of directors and how we operate our business. The concentration of ownership may also have the effect of delaying or preventing a change in control of our company.

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

We have registration rights agreements that require us to file and maintain the effectiveness of registration statements for the resale of our common stock, which provide for monetary penalties in the event of our failure to do so. During the year ended June 30, 2007, we paid registration delay penalties of approximately \$2.3 million in connection with our then outstanding Sandell 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.

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

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

### **ITEM 1B. UNRESOLVED STAFF COMMENTS**

Not applicable.

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### **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 1,800 square feet of office space in Malvern, United Kingdom under lease agreements that expire in December 2009.

### **ITEM 3. LEGAL PROCEEDINGS**

None.

### **ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

No matters were submitted to a vote of our security holders during the last quarter of the fiscal year ended June 30, 2009.

### **ITEM 4A. EXECUTIVE OFFICERS OF THE REGISTRANT**

Each of our officers holds office until the first meeting of the board of directors following the next annual meeting of 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. Our current officers are listed below.

#### **Paul Ashton, 48**

President and Chief Executive Officer

Dr. Ashton has served as President and Chief Executive Officer since January 2009 and was previously the Managing Director of the Company from January 2007 and 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-LaRoche.

#### **Lori Freedman, 42**

Vice President of Corporate Affairs, General Counsel and Company Secretary

Ms. Freedman has served as Vice President of Corporate Affairs, General Counsel and Company Secretary of pSivida Limited, predecessor of the Company, since May 2006, and of Control Delivery Systems, Inc. (CDS) from 2001 to May 2006. Prior to that, Ms. Freedman served as Vice President, Business Development, and Counsel of Macromedia, Inc., a provider of software for creating Internet content and business applications, from March 2001 through September 2001. Ms. Freedman has also served as Vice President, General Counsel, and Secretary of Allaire Corporation, a provider of Internet infrastructure for building business applications, from 1999 until Allaire's acquisition by Macromedia in 2001, as Corporate Counsel of Polaroid Corporation from May 1998 to December 1998 and with the law firm of McDermott, Will & Emery.

#### **Leonard S. Ross, 59**

Corporate Controller

Mr. Ross has served as Corporate Controller since October 2006 and was designated as the Company's principal financial officer in March 2009. From 2001 through April 2006 Mr. Ross served as Corporate Controller for NMT Medical, Inc., a medical device company. From 1990 to 1999, Mr. Ross was employed by JetForm Corporation, a developer of workflow software solutions, where he served in various capacities, including Vice President, Finance and Vice President, International Operations.

**PART II**

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

**Market Information, Holders and Dividends**

Commencing June 20, 2008, our common stock has traded on the NASDAQ Global Market under the symbol “PSDV”. 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 common stock and our predecessor’s ADSs for the fiscal years ended June 30, 2009 and 2008 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.

	<u>High</u>	<u>Low</u>
Fiscal year ended June 30, 2009:		
First Quarter	\$3.65	\$1.35
Second Quarter	2.49	0.51
Third Quarter	1.20	0.60
Fourth Quarter	2.22	0.81
Fiscal year ended June 30, 2008:		
First Quarter	\$5.20	\$2.80
Second Quarter	4.92	3.00
Third Quarter	4.00	1.56
Fourth Quarter	5.00	2.05

On September 24, 2009, the last reported sale price of our common stock on the NASDAQ Global Market was \$4.66. As of that date, we had approximately 32 holders of record of our common stock and, according to our estimates, approximately 1,500 beneficial owners of our common stock. In addition, as of that date, there were approximately 2,970 registered owners of our CDIs.

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

**Equity Compensation Plan Information**

The following table provides information about the securities authorized for issuance under the Company’s equity compensation plans as of June 30, 2009:

<u>Plan category</u>	<u>Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)</u>	<u>Weighted-average exercise price of outstanding options, warrants and rights (*) (b)</u>	<u>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in Column a) (c)</u>
Equity Compensation plans approved by security holders	2,060,783	\$ 6.36	82,384
Equity Compensation plans not approved by security holders	—	—	—
<b>Total</b>	<b>2,060,783</b>	<b>\$ 6.36</b>	<b>82,384</b>

(\*) Of the total outstanding options, 424,783 are denominated in A\$ and were translated at the June 30, 2009 exchange rate of A\$1.00 = US\$0.8048.

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

None

**ITEM 6. SELECTED FINANCIAL DATA**

The following selected financial data as of and for each of the five years in the period ended June 30, 2009 should be read in conjunction with Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations”, and the audited consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. The selected consolidated balance sheet data as of June 30, 2009 and 2008, and the selected consolidated statement of operations data for each of the three years in the period ended June 30, 2009 have been derived from our audited consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. The selected consolidated balance sheet data as of June 30, 2007 and 2006 and the selected consolidated statement of operations data for the years ended June 30, 2006 and 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 has been derived from our audited consolidated financial statements (including the U.S. GAAP reconciliation contained therein) contained in our predecessor’s 2006 Form 20-F filed December 8, 2006.

	Year Ended June 30,				
	2009 (1)	2008 (1,2)	2007 (3,4)	2006 (5)	2005
(Amounts in thousands, except per share amounts)					
<b>Consolidated Statement of Operations Data:</b>					
Revenues	\$12,162	\$ 3,476	\$ 1,785	\$ 1,036	\$ 122
Loss from continuing operations	(2,511)	(75,670)	(83,525)	(45,312)	(11,738)
Net loss	(2,511)	(75,670)	(81,203)	(46,957)	(12,322)
<b>Loss per share—basic and diluted</b>					
Loss from continuing operations	\$ (0.14)	\$ (4.17)	\$ (7.57)	\$ (6.02)	\$ (2.26)
Net loss	\$ (0.14)	\$ (4.17)	\$ (7.36)	\$ (6.24)	\$ (2.37)
Weighted average shares outstanding—basic and diluted	18,263	18,166	11,038	7,521	5,195

	As of June 30,				
	2009	2008	2007	2006	2005
(Amounts in thousands)					
<b>Consolidated Balance Sheet Data:</b>					
Cash and cash equivalents	\$ 6,899	\$ 15,609	\$ 2,670	\$ 6,692	\$ 9,824
Total assets	37,104	55,784	107,220	165,504	70,254
Total deferred revenue	10,534	18,590	1,702	1,948	—
Long-term debt	—	—	—	2,912	—
Total stockholders’ equity	23,541	30,078	88,265	130,747	61,821

- (1) During the years ended June 30, 2009 and 2008, we recognized \$11.8 million and \$3.3 million, respectively, of collaborative research and development revenue under our collaboration agreement with Alimera. See Note 3 to the accompanying audited consolidated financial statements for additional information.
- (2) At June 30, 2008, in connection with our annual review of goodwill pursuant to SFAS 142, “Goodwill and Other Intangibles”, we incurred a \$60.1 million goodwill impairment charge. See Note 4 to the accompanying audited consolidated financial statements for additional information.
- (3) At June 30, 2007, we recorded a \$45.3 million impairment charge related to our Retisert intangible asset. See Note 4 to the accompanying audited consolidated financial statements for additional information.

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- (4) In April 2007, we sold the stock of our AION Diagnostics, Inc. subsidiary for a pre-tax and after-tax gain of \$3.6 million. See Note 14 to the accompanying audited consolidated financial statements for additional information.
- (5) In December 2005, we completed the acquisition of Control Delivery Systems, Inc. (CDS) for aggregate consideration of \$108.2 million. For the years ended June 30, 2009, 2008, 2007 and 2006, substantially all of our collaborative research and development revenues and royalty income were 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.

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

*The following discussion and analysis of financial condition and results of operations should be read in conjunction with "Selected Financial Data" and our audited consolidated financial statements and accompanying notes appearing elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements, based on current expectations and related to future events and our future financial performance, that involve risks and uncertainties. Our actual results may differ materially from those anticipated or implied in these forward-looking statements as a result of many important factors, including those set forth under Item 1A, "Risk Factors", and elsewhere in this report.*

### Overview

We develop tiny, sustained release, drug delivery products that are administered by implantation, injection or insertion. Once administered, the drug is released on a controlled and level basis for months or years.

Our Phase III partnered product, which utilizes the third-generation of our Durasert technology system, delivers FA for the treatment of DME. This product candidate, formerly known as Medidur FA for DME, is licensed to Alimera, which is conducting fully-recruited Phase III clinical trials. Alimera expects that 24-month interim data from these clinical trials will be available in late 2009 and plans to file an NDA with the FDA in early 2010. Alimera intends to commercialize the product under the name Iluvien. We have a collaboration agreement with Alimera, pursuant to which we have licensed certain of our drug delivery technologies to Alimera for the development of Iluvien and certain other ophthalmic products.

Our two FDA-approved sustained release products to treat chronic back of the eye diseases are our second-generation Retisert for the treatment of posterior uveitis and our first-generation Vitrasert for the treatment of AIDS-related CMV retinitis. We have licensed both of these products and the technologies underlying them to Bausch & Lomb.

BioSilicon, our other principal technology system, is a fully-erodible, nanostructured, porous silicon designed to provide sustained delivery of various therapeutics, including small drug molecules, proteins and peptides. Our lead BioSilicon product candidate, BrachySil, delivers therapeutic P32, a radioactive form of phosphorus used to treat cancer, directly to solid tumors. We have completed an initial safety and efficacy clinical trial of BrachySil for the treatment of pancreatic cancer, which indicated that BrachySil, in combination with standard chemotherapy, was well tolerated with no clinically significant adverse events related to BrachySil. We are nearing completion of a follow-on dose-ranging clinical trial for BrachySil. Our strategic plan is to seek a development partner in advance of commencing a pivotal Phase III clinical trial. Based on our early pre-clinical phase, we are currently targeting BioSilicon as a key second prong of our drug delivery platform.

We also have a worldwide collaborative research and license agreement with Pfizer under which Pfizer may develop additional ophthalmic products based on certain of our technologies.

Effective June 19, 2008, we reincorporated from Western Australia to the United States (the Reincorporation).

### Equity Financing

In July 2007, we sold 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 share of common stock; and (ii) one warrant to purchase 0.4 share of common stock at \$6.60 per share. In addition, we simultaneously completed a sale of 513,699 units for gross proceeds of approximately \$2.6 million.

## License and Collaboration Agreements

### *Alimera*

On March 14, 2008, we amended and restated our collaboration agreement with Alimera. In exchange for aggregate 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 agreement. Aggregate consideration consisted of (i) \$12.0 million in cash received upon the execution of the amended agreement; (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; (iii) conditional principal and interest payments of up to approximately \$21.3 million through September 2012 under a note issued by Alimera; (iv) a \$25.0 million milestone payment upon FDA approval of Iluvien for the treatment of DME; (v) 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 (vi) the assumption by Alimera of all financial responsibility for the development of licensed products under the amended agreement, the result of which is 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 2005 collaboration agreement.

Pursuant to the amended agreement, a total of \$18.3 million of deferred revenue is being recognized ratably over a period of 21.5 months from the amendment effective date through December 31, 2009, which represents the period of our performance obligations. Following consummation of the amended agreement, we received conditional note payments and reimbursements of approved development costs totaling approximately \$1.9 million and \$437,000 during the years ended June 30, 2009 and 2008, respectively. This cash consideration, and future cash consideration received by us from Alimera during the remainder of the performance period, is being 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 each receipt.

### *Pfizer*

Under our worldwide collaborative research and license agreement with Pfizer, beginning in calendar year 2008 and continuing until commencement of the first Phase III clinical trial, Pfizer has agreed to provide us with a minimum of \$500,000 per quarter in research funding. To date, the joint research program has been limited to pre-clinical studies. Under the agreement, we are also entitled to receive clinical development milestone payments and, following commercialization of any products, sales-based milestones and royalties.

### *Bausch & Lomb*

Bausch & Lomb sells Vitrasert and Retisert. Although our collaboration agreement with Bausch & Lomb provides for royalties on such sales, in June 2005 CDS received a \$3.0 million advance from Bausch & Lomb in lieu of \$6.25 million of future Retisert royalties that otherwise would be payable. Bausch & Lomb became 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. During the years ended June 30, 2009 and 2008, we received \$0 and \$247,000 in Retisert royalty payments. Subsequent to June 30, 2009, Bausch & Lomb will be entitled to retain the next \$1.2 million of royalties otherwise payable, following which we will resume receiving 100% of the Retisert royalties. Based on historical Retisert sales volumes, we currently expect that the resumption of the receipt of Retisert royalties will not occur until at least the fourth quarter of our fiscal year ending June 30, 2010.

### *Intrinsiq*

In connection with a January 2008 exclusive field of use license with Intrinsiq for nutraceutical and food science applications of BioSilicon, we received license fee payments of \$730,000 and \$500,000 during the years ended June 30, 2009 and 2008, respectively. In addition, subject to Intrinsiq's unilateral right to terminate the



license upon 90 days prior written notice, we are entitled to receive scheduled minimum royalties of \$3.55 million through April 2014, of which the first \$450,000 payment was received in July 2009. For the year ending June 30, 2010, we are entitled to the receipt of quarterly royalties earned, if any. The next scheduled minimum royalty payment of \$630,000 is due in January 2012.

### **Summary of Critical Accounting Policies and Estimates**

The preparation of our consolidated financial statements in conformity with U.S. GAAP requires that we make certain estimates, judgments and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses. These estimates and judgments include revenue recognition and the carrying value of our intangible assets. We base our estimates, judgments and assumptions on historical experience, anticipated results and trends and on various other factors that we believe are reasonable under the circumstances at the time. By their nature, these estimates, judgments and assumptions are subject to an inherent degree of uncertainty. Actual results may differ from our estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to the accompanying audited consolidated financial statements, we believe that the following accounting policies are most critical to an understanding of the judgments and estimates used in the preparation of these financial statements.

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

The terms of our collaborative license and development arrangements 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.

We recognize non-refundable license fees 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. We analyze multiple element arrangements, such as license and development arrangements, 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 we determine the license either (i) does not have stand-alone value or (ii) has stand-alone value but the fair value of any of the undelivered performance obligations cannot be determined, the arrangement is accounted for as a single unit of accounting.

For arrangements that are accounted for as a single unit of accounting, we recognize total payments under the arrangement as revenue on a straight-line basis over the period we expect to complete our performance obligations using the cumulative catch-up method. Under this method, the portion of any such payment represented by the time elapsed from the commencement of the performance period to the payment date as a percentage of the total 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 following the end of the performance period will be recognized as revenue when earned.

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We limit the cumulative amount of revenue earned 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. We then recognize revenue 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.

For the years ended June 30, 2009 and 2008, we reported collaborative research and development revenue of \$12.0 million and \$3.3 million, respectively. As discussed in Note 3 of the accompanying audited consolidated financial statements, substantially all of these revenues were attributable to our March 2008 amended and restated collaboration agreement with Alimera.

### **Valuation of Intangible Assets**

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

- Significant change relative to historical or projected future operating results;
- Significant changes in the use of the assets or the strategy for the overall business; and
- Significant industry or economic trends and developments.

If an impairment trigger is identified, an impairment test is performed based on a comparison of the estimated undiscounted future cash flows to the recorded carrying value of the asset. When it is determined that the carrying value of intangibles may not be recoverable based upon the existence of one or more of the above indicators of impairment, the asset is written down to its estimated fair value on a discounted cash flow basis.

At June 30, 2007, we evaluated the recoverability of our Retisert intangible asset based upon revised sales trend information and the receipt of formal confirmation in July 2007 of our prior understanding from industry sources that Bausch & Lomb had withdrawn its European application for authorization to market Retisert. The valuation assessment required detailed analysis of projected future cash flows associated with the intangible asset. For Retisert, a commercialized product with two years of sales history, these projections required the application of judgments and estimates that included market penetration rates, estimated market growth, potential impact of new technologies under development, penetration rate for re-implants and an appropriate weighted average cost of capital rate to discount the future cash flows. As a result of this analysis, we recorded an impairment write-down of \$45.3 million in connection with our Retisert patents.

We evaluate the recoverability of our intangible assets based on estimated undiscounted cashflows related to existing contractual agreements as well as projected cashflows from potential future research and development collaboration agreements. In the event that actual cashflows are less than those projected, we may be required in the future to take impairment charges with respect to some or all of the \$28.8 million of intangible assets that appear on our balance sheet as of June 30, 2009.

[Table of Contents](#)**Results of Operations***Years Ended June 30, 2009 and 2008*

	Year ended June 30,		Change	
	2009	2008	Amounts	%
	(In thousands except percentages)			
Revenues	\$ 12,162	\$ 3,476	\$ 8,686	250%
Operating expenses:				
Impairment of goodwill	—	60,106	(60,106)	na
Research and development	8,007	14,426	(6,419)	(44)%
General and administrative	8,791	13,951	(5,160)	(37)%
Total operating expenses	16,798	88,483	(71,685)	(81)%
Operating loss from continuing operations	(4,636)	(85,007)	80,371	(95)%
Other income (expense):				
Change in fair value of derivatives	959	8,357	(7,398)	(89)%
Interest income	162	648	(486)	(75)%
Interest and finance costs	—	(507)	507	(100)%
Other income, net	53	356	(303)	(85)%
Total other income (expense)	1,174	8,854	(7,680)	(87)%
Loss before income taxes	(3,462)	(76,153)	72,691	(95)%
Income tax benefit	951	483	468	97%
Net loss	\$ (2,511)	\$ (75,670)	\$ 73,159	(97)%

na = not applicable

**Revenues**

Revenues increased by approximately \$8.7 million, or 250%, to approximately \$12.2 million for the year ended June 30, 2009 (fiscal 2009) from approximately \$3.5 million for the year ended June 30, 2008 (fiscal 2008). In each fiscal year, revenues were almost entirely attributable to our collaboration agreement with Alimera, consisting of (i) the portion of the upfront license consideration that we recognized in the given fiscal year; and (ii) the aggregate of conditional note payments and reimbursement of our development costs received from Alimera that we recognized in the given fiscal year.

For the year ending June 30, 2010, assuming continued payment of scheduled conditional note payments from Alimera and the reimbursement of remaining development costs during the performance period, we currently expect to record collaborative research and development revenue attributable to the Alimera collaboration agreement of approximately \$9.1 million.

Pursuant to a June 2005 side letter to the collaboration agreement with Bausch & Lomb, 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 have been payable under our collaboration agreement with Bausch & Lomb. Bausch & Lomb became 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 collaboration agreement. During fiscal 2009, Bausch & Lomb retained approximately \$1.6 million of Retisert royalties that otherwise would have been payable to us, as compared to approximately \$1.8 million during fiscal 2008. As of June 30, 2009, Bausch & Lomb is entitled to retain an additional \$1.2 million of future Retisert royalties otherwise payable to us. Accordingly, we currently do not expect to record royalty income on sales of Retisert by Bausch & Lomb until at least the fourth quarter of our fiscal year ending June 30, 2010.

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

In fiscal 2008 we recorded an impairment charge of \$60.1 million equal to the total carrying value of goodwill. See Note 4 to the accompanying audited consolidated financial statements.

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

Research and development decreased by approximately \$6.4 million, or 44%, to \$8.0 million for fiscal 2009 from \$14.4 million for fiscal 2008. This decrease was primarily attributable to the following factors:

- the absence in fiscal 2009 of \$4.7 million of Iluvien co-development costs incurred in fiscal 2008 as a result of the assumption by Alimera of all financial responsibility for the development of licensed products pursuant to the amendment and restatement of our collaboration agreement with Alimera; and
- a decrease in fiscal 2009 of approximately \$1.6 million in U.K.-based research and development costs, of which approximately \$1.1 million was attributable to the relative strengthening of the U.S. dollar against the Pound Sterling and approximately \$470,000 was primarily attributable to reduced levels of personnel, legal, facilities and depreciation expenses.

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

General and administrative costs decreased by approximately \$5.2 million, or 37%, to approximately \$8.8 million for fiscal 2009 from \$14.0 million for fiscal 2008. This net decrease was primarily attributable to the following factors:

- the absence of approximately \$3.0 million of costs incurred in fiscal 2008 directly attributable to the Reincorporation;
- a decrease of approximately \$1.9 million of audit, tax, financial reporting consulting services and legal fees primarily as a result of the Reincorporation and the absence in fiscal 2009 of costs incurred in fiscal 2008 in connection with the amendment and restatement of the collaboration agreement with Alimera;
- the absence of approximately \$700,000 of personnel, facility and travel costs associated with the fiscal 2008 closing of our Perth, Australia office;

partially offset by:

- an approximate \$1.0 million increase in provision for losses on the note receivable from GEM; and
- an approximate \$300,000 increase in U.S. personnel and benefit costs related to the March 2009 severance agreement with our former Vice President, Finance and Chief Financial Officer.

### ***Change in Fair Value of Derivatives***

Change in fair value of derivatives decreased by approximately \$7.4 million, or 89%, to income of \$959,000 for fiscal 2009 from income of \$8.4 million for fiscal 2008.

During fiscal 2008 and the year ended June 30, 2007 (fiscal 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 for each year, determined using the Black-Scholes valuation model, was impacted primarily by a net decrease in the market price of our shares in each period.

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We will be required to assess the fair value of these warrants at each subsequent balance sheet date, and changes in their fair values will result in adjustments to our recorded derivative liabilities, and a corresponding gain or loss in our statement of operations. Fluctuations in the fair values of these warrants could be substantial and could continue to affect our operating results until the last-to-expire of these warrants in July 2012.

### ***Interest Income***

Interest income decreased by \$486,000, or 75%, to \$162,000 for fiscal 2009 from \$648,000 for fiscal 2008, primarily due to (i) a combination of decreased levels of interest-bearing cash balances and sharply lower weighted average interest rates; and (ii) the absence in the current year of approximately \$100,000 of interest accrued in fiscal 2008 on the \$1.5 million note receivable due from GEM.

### ***Interest Expense***

Interest expense of \$507,000 was accrued during fiscal 2008 on the portion of shared Iluvien product candidate co-development costs that we elected not to pay under the original Alimera collaboration agreement. In connection with the March 2008 amendment and restatement of that agreement, the total co-development costs, including associated penalties and accrued interest, which we then owed to Alimera were cancelled and, accordingly, no interest expense was incurred during fiscal 2009.

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

Other income, net decreased by \$303,000, or 85%, to \$53,000 for fiscal 2009 from \$356,000 for fiscal 2008. This decrease was primarily attributable to the absence in fiscal 2009 of \$412,000 of income in fiscal 2008 attributable to a revenue sharing arrangement under the ADR program, which was terminated as a result of the Reincorporation, partially offset by net unrealized foreign exchange gains of \$69,000 in fiscal 2009 resulting from the write-off of foreign currency translation reserve balances in connection with the dissolution of subsidiaries.

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

Income tax benefit increased by approximately \$468,000, or 97%, to \$951,000 for fiscal 2009 from \$483,000 for fiscal 2008. The increase was primarily attributable to approximately \$840,000 of foreign research and development tax credits earned by our U.K. subsidiary, partially offset by a \$427,000 reduction in U.S. deferred tax benefits.

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### Year Ended June 30, 2008 and 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 derivatives	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	(100)%
Gain on sale of discontinued operations	—	3,640	(3,640)	na
Income from discontinued operations	—	2,322	(2,322)	(100)%
Net loss	<u>\$ (75,670)</u>	<u>\$ (81,203)</u>	<u>\$ 5,533</u>	<u>(7)%</u>

na = not applicable

### Revenue

Revenues increased by approximately \$1.7 million, or 95%, to approximately \$3.5 million for fiscal 2008 from approximately \$1.8 million for fiscal 2007. Collaborative research and development revenues increased by \$2.6 million, principally due to revenue recognized in connection with the March 2008 amendment and restatement of the collaboration agreement with Alimera. This increase was partially offset by the absence in fiscal 2008 of \$928,000 of Retisert royalties earned in fiscal 2007 as a result of the terms of the side letter to the collaboration agreement with Bausch & Lomb.

### Impairment of Goodwill

Fiscal 2008 included a \$60.1 million goodwill impairment charge as compared to fiscal 2007, which had no impairment charges.

### Impairment of Intangible Assets

Impairment of intangible assets totaled \$45.3 million for fiscal 2007 as a result of a reduction in our assessment of the recoverability of the carrying value of the Retisert patents. There was no such impairment charge in fiscal 2008.

### **Research and Development**

Research and development decreased by approximately \$6.6 million, or 32%, to \$14.4 million for fiscal 2008 from \$21.1 million for fiscal 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 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 BioSilicon technology 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 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 March 14, 2008 as a result of the amendment and restatement of our collaboration agreement with Alimera.

### **General and Administrative**

General and administrative costs increased by approximately \$2.7 million, or 25%, to approximately \$14.0 million for fiscal 2008 from \$11.2 million for fiscal 2007, primarily as a result of an increase of approximately \$1.9 million of professional fees and other transactional costs incurred in fiscal 2008 in connection with the Reincorporation.

### **Change in Fair Value of Derivatives**

Change in fair value of derivatives decreased by approximately \$3.1 million, or 27%, to income of \$8.4 million for fiscal 2008 from income of \$11.4 million for fiscal 2007.

During fiscal 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 fiscal 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 fiscal 2007.

### **Interest Income**

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

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

Interest and finance costs decreased by approximately \$9.0 million, or 95%, to \$507,000 for fiscal 2008 from \$9.5 million for fiscal 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.

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

Loss on extinguishment of debt totaled \$23.4 million for fiscal 2007, which consisted primarily of (i) \$20.7 million for the value of warrants issued as additional consideration for amendments to our convertible notes that were accounted for as extinguishments of debt; and (ii) approximately \$3.0 million of cash premiums paid in connection with redemptions of the convertible notes.

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

Other income, net increased by \$203,000, or 133%, to \$356,000 for fiscal 2008 from \$153,000 for fiscal 2007. This increase consisted primarily of \$412,000 of income in fiscal 2008 attributable to the 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 fiscal 2008 from \$13.2 million for fiscal 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. Loss from discontinued operations in fiscal 2007 through the date of sale was \$1.3 million.

### ***Inflation and Seasonality***

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

### ***Recently Adopted 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. Under the standard, fair value measurements are to be separately disclosed by level within a fair



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value hierarchy. SFAS 157 applies under other accounting pronouncements that require or permit fair value measurements. 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 recognized or disclosed at fair value in financial statements on a non-recurring basis may be deferred until fiscal years beginning after November 15, 2008. We adopted SFAS 157 as of July 1, 2008, with the exception of the application of the statement to non-recurring nonfinancial assets and nonfinancial liabilities. See Note 13 of the accompanying audited consolidated financial statements for additional disclosure.

In July 2008, we adopted SFAS No. 159, “*The Fair Value Option for Financial Assets and Financial Liabilities—Including an Amendment of FASB Statement No. 115*” (“SFAS 159”). SFAS 159 permits companies to choose to measure selected financial assets and liabilities at fair value, with changes in fair value recognized in earnings each reporting period. Prior to July 2008, we recorded derivative liabilities at fair value in accordance with SFAS No. 133, “*Accounting for Derivative Instruments and Hedging Activities*”, as amended. The adoption of SFAS 159 had no impact on our consolidated financial position and results of operations as management has not elected the fair value option for any other financial assets and liabilities.

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 the related services are performed. We adopted EITF 07-03 as of July 1, 2008 and the adoption did not have any impact on our consolidated financial statements.

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 statements. We adopted SFAS 161 on January 1, 2009. See Notes 8 and 13 of the accompanying audited consolidated financial statements for the Company’s disclosures about our derivative liabilities.

In May 2009, the FASB issued SFAS No. 165, “*Subsequent Events*” (“SFAS 165”). SFAS 165 defines the subsequent events or transaction period, circumstances under which such events or transactions should be recognized, and disclosures regarding subsequent events or transactions. SFAS 165 is effective for interim or annual periods ending after June 15, 2009. We have adopted the provisions of SFAS 165 as of June 30, 2009. Although the adoption of SFAS 165 did not materially impact our financial condition, results of operations, or cash flow, we are now required to provide additional disclosures, which are included in Note 20 of the accompanying audited consolidated financial statements.

### **Recently Issued Accounting Pronouncements**

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 141R”), which provides revised guidance for recognition and measurement of identifiable assets and goodwill acquired,

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liabilities assumed, and any noncontrolling interest in the acquiree at fair value. SFAS 141R 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 141R also establishes disclosure requirements to enable the evaluation of the nature and financial effects of the business combination. SFAS 141R is required to be applied 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 as well as the subsequent recognition of acquired deferred tax benefits of previous acquisitions. We will be required to adopt SFAS 141R in connection with business combination transactions, if any, after June 30, 2009.

### **Liquidity and Capital Resources**

We have incurred operating losses since inception, and, at June 30, 2009, we had a total accumulated deficit of \$227.0 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 achieves sufficient 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 \$6.9 million at June 30, 2009 compared to \$15.6 million at June 30, 2008. We believe we can fund our operations as currently conducted through at least December 31, 2010. This expectation is based on certain key assumptions that include (i) continued receipt from Pfizer of quarterly \$500,000 research and development funding; (ii) Alimera's continued funding of the development of Iluvien; and (iii) the continued receipt of the scheduled conditional note payments from Alimera. Management has identified contingency plans in the event of a significant shortfall in payments, focused primarily on reduced spending for non-critical activities. Whether and when we will require, or desire to raise, 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;
- 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 existing operations and programs (including any Phase III trials for BrachySil for pancreatic cancer), any new product candidates and 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.

Absent adequate levels of funding from new collaboration agreements and/or financing transactions, management currently believes that our cash position beyond December 31, 2010 will be substantially dependent upon the timing of FDA approval and the initiation and success of marketing of Iluvien, and the resulting

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occurrence of certain milestone events under the terms of our collaboration agreement with Alimera. Alimera has agreed to pay us \$25.0 million upon FDA approval of Iluvien for DME and a 20% share in the future profits of Iluvien. In addition, the \$15.0 million note issued by Alimera becomes due and payable upon the occurrence of certain defined liquidity events (such as an initial public offering of Alimera) 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 assurance that a liquidity event resulting in aggregate proceeds to Alimera in excess of \$75 million will occur.

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

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:

	Year Ended June 30,		
	2009	2008	2007
	(In thousands)		
Loss from continuing operations:	\$ (2,511)	\$ (75,670)	\$ (83,525)
Changes in operating assets and liabilities	(10,452)	13,455	1,164
Other adjustments to reconcile net loss to cash flows from operating activities	4,527	57,072	61,992
Cash flows used in operating activities of continuing operations	\$ (8,436)	\$ (5,143)	\$ (20,369)
Cash flows used in operating activities of discontinued operations	\$ —	\$ —	\$ (977)
Cash flows (used in) provided by investing activities of continuing operations	\$ (195)	\$ (259)	\$ 4,423
Cash flows provided by investing activities of discontinued operations	\$ —	\$ —	\$ 1,792
Cash flows provided by financing activities	\$ —	\$ 18,385	\$ 11,193

Net cash used in operating activities for the year ended June 30, 2009 increased by approximately \$3.3 million compared to the prior year. The largest contributing factor was the impact of the March 2008 amendment and restatement of our collaboration agreement with Alimera. It accounted for an increase of approximately \$6.7 million of cash used in operating activities, which consisted of the absence in fiscal 2009 of \$12.0 million of upfront cash consideration received in March 2008, partially offset by the absence in fiscal 2009 of approximately \$3.9 million of Iluvien co-development costs paid to Alimera in fiscal 2008 under the terms of the original 2005 collaboration agreement and a \$1.4 million increase in conditional note interest and development cost reimbursements received from Alimera. The net decrease in fiscal 2009 of approximately \$3.4 million in operating cash activities unrelated to the amended collaboration agreement with Alimera consisted primarily of: (i) a reduction of approximately \$1.7 million of professional fees, primarily as a result of the Reincorporation; (ii) a decrease of approximately \$500,000 in personnel and occupancy costs attributable to the closing of the

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Perth, Australia office; (iii) the receipt of approximately \$600,000 of U.K. research and development tax credits related to the current and prior years; (iv) a decrease of approximately \$950,000 in U.K. personnel and operating costs, of which approximately \$600,000 was due to the relative strengthening of the US\$ during fiscal 2009; and (v) a net decrease of approximately \$300,000 of professional fees and other costs directly related to the Reincorporation, which decreases were partially offset by \$600,000 of fiscal 2008 bonuses paid in fiscal 2009.

Net cash used in operating activities of continuing operations for fiscal 2008 decreased by approximately \$15.2 million as compared to fiscal 2007. This decrease was primarily attributable to (a) \$12.4 million cash received in connection with the amendment and restatement of our 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 fiscal 2007; and (c) approximately \$2.3 million of cost reductions implemented in our U.K. and Singapore operations, partially offset by (x) \$1.6 million paid through June 30, 2008 in connection with the Reincorporation 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 fiscal 2008, as compared to \$977,000 in fiscal 2007.

Cash used in investing activities of continuing operations included purchases of property and equipment totaling \$195,000, \$272,000 and \$77,000 for fiscal 2009, 2008 and 2007, respectively. For fiscal 2007, cash provided by investing activities was attributable to the elimination of \$4.5 million of restricted cash balances resulting from the May 2007 redemption of a convertible note.

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.

Net cash flows from financing activities totaled \$0, \$18.4 million and \$11.2 million for fiscal 2009, 2008 and 2007, respectively. Cash flows from financing activities during fiscal 2008 resulted from July 2007 issuances of 4,114,199 units at a price per unit of \$5.00, 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 fiscal 2007 reflected the following transactions:

(a) Share issues:

<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

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- 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.
- We had no borrowings during fiscal 2008 and 2009.

## Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that would be material to investors.

## Tabular Disclosure Of Contractual Obligations

The following table summarizes our minimum contractual obligations as of June 30, 2009:

<u>Contractual Obligations</u>	<u>Total</u>	<u>Payments Due by Period</u>			
		<u>Less than 1 year</u>	<u>1-3 years (In thousands)</u>	<u>3-5 years</u>	<u>More than 5 years</u>
Operating Lease Obligations	\$675	\$ 400	\$ 275	\$ —	\$ —
Purchase Obligations	311	311	—	—	—
<b>Total</b>	<b>\$986</b>	<b>\$ 711</b>	<b>\$ 275</b>	<b>\$ —</b>	<b>\$ —</b>

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

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

*Executive contracts.* At June 30, 2009, we had agreements with two 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 approximately \$980,000. 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**

At June 30, 2009, the balance of our derivative liabilities, which are related to warrants denominated in A\$, totaled \$971,000 and was determined using the Black-Scholes valuation model. The change in fair value of derivatives resulted in income of \$959,000 and \$8.4 million for fiscal 2009 and 2008, respectively.

Our financial position and results of operations will continue to be sensitive to future revaluations of these derivative liabilities. At June 30, 2009, these warrants had a weighted average remaining contractual life of 1.7 years and a weighted average exercise price of \$7.68 per share compared to the \$1.79 NASDAQ closing price of our common shares. 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, would result in a significant decrease of the derivative liability value during the fiscal year ending June 30, 2010 based on the relatively short remaining life of the underlying warrants. Changes in risk-free interest rates have a de minimis effect.

The following table summarizes the sensitivity of our consolidated statements of operations for fiscal 2009 to assumed increases or decreases of our share price at June 30, 2009:

	<u>Decrease in Share Price</u>			<u>Current</u>	<u>Increase in Share Price</u>		
	<u>-15%</u>	<u>-10%</u>	<u>-5%</u>	<u>Price</u>	<u>+5%</u>	<u>+10%</u>	<u>+15%</u>
				(In thousands)			
Change in fair value of derivatives—income (expense)	\$ 287	\$ 197	\$ 101	\$ —	\$(106)	\$(216)	\$(331)

**Foreign Currency Exchange Rates**

We conduct operations in two principal currencies, the U.S. dollar and the Pound Sterling (£). The U.S. dollar is the functional currency for our U.S. operations and the Pound Sterling is the functional currency for our U.K. operations. Changes in the foreign exchange rate of the U.S. dollar and Pound Sterling impact the net operating expenses of our U.K. operations. For fiscal 2009, the strengthening of the U.S. dollar compared to fiscal 2008 resulted in a net decrease in research and development expense of approximately \$1.1 million. All cash and cash equivalents, and most other asset and liability balances, are denominated in each entity's functional currency and, accordingly, we do not consider our statement of operation exposure to realized and unrealized foreign currency gains and losses to be significant.

Changes in the foreign exchange rate of the U.S. dollar and Pound Sterling also impact total stockholders' equity. During fiscal 2009, the relative strengthening of the U.S. dollar in relation to the Pound Sterling resulted in a net decrease of \$4.8 million in stockholders' equity due to the translation of approximately £11.6 million of net assets of our U.K. operations, predominantly the BioSilicon technology intangible asset, into U.S. dollars. For every incremental 5% strengthening or weakening of the U.S. dollar at June 30, 2009 in relation to the Pound Sterling, our stockholders' equity at June 30, 2009 would have decreased or increased, respectively, by approximately \$960,000.

**Interest Rates**

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

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### **ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

The information required by this item may be found on pages F-1 through F-30 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**

#### **Evaluation of Disclosure Controls and Procedures**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their desired objectives, and management necessarily applies its judgment in evaluating the risk related to controls and procedures.

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2009. Based on that evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were effective as of such date.

#### **(a) Management's Annual Report on Internal Control Over Financial Reporting**

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

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

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

Our management, 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, 2009. 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, or COSO. Based on this assessment, management has concluded that our internal control over financial reporting was effective as of June 30, 2009.

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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 Securities and Exchange Commission that permit the Company to provide only management's report in this annual report.

### **(b) Changes in Internal Control over Financial Reporting**

#### *Remediation of Prior Year Material Weakness*

In Item 9A.(T) of our Annual Report on Form 10-K for the fiscal year ended June 30, 2008, management reported the following material weakness in our internal control over financial reporting:

*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.*

Remedial measures undertaken during fiscal 2009 included (i) utilization of third party consulting expertise for research and documentation of complex transactions; (ii) enhancing the review of account reconciliation and consolidation schedules involving foreign currency translations; and (iii) completion of financial reporting checklists with respect to the appropriate application of U.S. GAAP. During the quarter ended June 30, 2009, we completed the testing of these enhanced controls to demonstrate their operating effectiveness over a period of time sufficient to support our conclusion that, as of June 30, 2009, we had remediated the previously reported material weakness in our internal control over financial reporting.

#### *Other Changes in Internal Control*

Other than the control improvements referenced above, there have been no changes in our internal control over financial reporting during the quarter ended June 30, 2009 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

### **ITEM 9B. OTHER INFORMATION**

Not applicable.



**PART III**

**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE**

**Corporate Governance**

We have adopted a written code of ethics that applies to all of our employees, officers and directors. The Code of Conduct is designed to ensure that our business is conducted with integrity, and to comply with SEC regulations and NASDAQ and 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.

**Other Information**

The other information required to be disclosed in Item 10 is hereby incorporated by reference to our 2009 Proxy Statement.

**ITEM 11. EXECUTIVE COMPENSATION**

The information required to be disclosed in Item 11 is hereby incorporated by reference to our 2009 Proxy Statement.

**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

The information required to be disclosed in Item 12 is hereby incorporated by reference to our 2009 Proxy Statement.

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

The information required to be disclosed in Item 13 is hereby incorporated by reference to our 2009 Proxy Statement.

**ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES**

The information required to be disclosed in Item 14 is hereby incorporated by reference to our 2009 Proxy Statement.

**PART IV**

**ITEM 15. EXHIBITS AND FINANCIAL STATEMENTS**

**(a)(1) Financial Statements**

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

**(a)(2) Financial Statement Schedules**

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

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### (a)(3) Exhibits.

Exhibit No.	Exhibit Description	Incorporated by Reference to SEC Filing		
		Form	SEC Filing Date	Exhibit No.
<b>Articles of Incorporation and By-Laws</b>				
3.1	Certificate of Incorporation of pSivida Corp.	8-K12G3	06/19/08	3.1
3.2	By-Laws of pSivida Corp.	8-K12G3	06/19/08	3.2
<b>Instruments Defining the Rights of Security Holders</b>				
4.1	Form of Specimen Stock Certificate for Common Stock	8-K12G3	06/19/08	4.1
4.2 +	Form of Warrant, dated as of November 15, 2005	6-K	11/15/05	99.3
4.3 +	Form of Series A Warrant	6-K/A	07/31/06	99.4
4.4	Registration Rights Agreement, dated as of September 26, 2006, by and among pSivida Limited, Australian IT Investments Limited, Absolute Octane Fund and European Catalyst Fund	6-K	09/26/06	99.5
4.5 +	Form of pSivida Limited Warrants to Purchase ADRs, dated September 26, 2006	6-K	09/26/06	99.4
4.6	pSivida Limited Series C Warrants to Purchase ADRs	6-K	01/03/07	99.2
4.7	Series D Warrants	6-K	05/16/07	99.4
4.8	Series E Warrants	6-K	05/16/07	99.5
4.9	Series F Warrants	6-K	05/16/07	99.6
4.10	Series G Warrants	6-K	05/16/07	99.7
4.11	Second Amended and Restated Registration Rights Agreement dated May 15, 2007 by and among pSivida Limited and Castlerigg Master Investments Ltd	6-K	05/16/07	99.3
4.12 +	Form of Investor Warrant	6-K	07/02/07	99.4
4.13 +	Form of Placement Agents Warrant	6-K	07/02/07	99.5
4.14 +	Form of Application for Shares and Options	8-K	06/19/08	4.16
4.15	Securities Purchase Agreement, dated February 16, 2007, by and among pSivida Limited and the investors set forth on the signature pages thereto	8-K	06/19/08	4.17
<b>Material Contracts—Management Contracts and Compensatory Plans (*)</b>				
10.1	Employment Agreement, between pSivida Limited and Paul Ashton, dated January 1, 2006	20-F	12/08/06	4.35
10.2	Non-Competition Agreement, between pSivida Limited and Paul Ashton, dated October 3, 2005	20-F	01/18/06	4.35
10.3	Employment Agreement, between pSivida Limited and Lori Freedman, dated as of May 16, 2006	6-K	05/23/06	99.3
10.4	Employment Agreement, between pSivida Limited and Michael Soja, dated as of May 16, 2006	6-K	05/23/06	99.2
10.5	Resignation Letter of Michael J. Soja, Vice President, Finance and Chief Financial Officer, dated March 11, 2009	10-Q	05/13/09	10.1
10.6	Rules of the pSivida Corp. Employee Share Option Plan	8-K	06/19/08	10.40
10.7	pSivida Corp. 2008 Incentive Plan	8-K	06/19/08	10.41
10.8 +	Form of Stock Option Certificate for grants to executive officers under the pSivida Corp. 2008 Incentive Plan	8-K	09/10/08	10.1

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Exhibit No.	Exhibit Description	Incorporated by Reference to SEC Filing		
		Form	SEC Filing Date	Exhibit No.
10.9 +	Form of pSivida Corp. Nonstatutory Stock Options granted to Michael J. Soja and Lori Freedman on September 4, 2008 and September 10, 2008	10-K	09/26/08	10.36
	<b>Material Contracts—Leases</b>			
10.10	Commercial Sublease, between Exergen Corporation and Control Delivery Systems, Inc., dated as of April 6, 2005	20-F	01/18/06	4.19
10.11	Lease Renewal Agreement between pSivida Inc. and Exergen Corporation dated October 18, 2007	10-Q	02/11/08	10.1
	<b>Material Contracts—License and Collaboration Agreements</b>			
10.12 #	Amended and Restated License Agreement between Control Delivery Systems, Inc. and Bausch & Lomb Incorporated dated December 9, 2003, as amended on June 28, 2005	20-F	01/18/06	4.12
10.13 (a) #	Second Amendment to Amended and Restated License Agreement between pSivida US, Inc. and Bausch & Lomb dated August 1, 2009			
10.14 #	Collaborative Research and License Agreement, dated as of April 3, 2007, by and among pSivida Limited, pSivida Inc. and Pfizer, Inc.	6-K	04/26/07	99.1
10.15 #	Amended and Restated Collaboration Agreement by and between pSivida Inc. and Alimera Sciences, Inc. dated March 14, 2008	10-Q	05/12/08	10.1
	<b>Material Contracts—Other</b>			
10.16 #	Process Development and Manufacturing Agreement between pSiMedica Limited and AEA Technology QSA GmbH, dated March 4, 2004	20-F	01/18/06	4.3
	<b>Other Exhibits</b>			
21.1 (a)	Subsidiaries of pSivida Corp.			
23.1 (a)	Consent of Independent Registered Public Accounting Firm, Deloitte & Touche LLP			
31.1 (a)	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act, as amended			
31.2 (a)	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act, as amended			
32.1 (a)	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002			
32.2 (a)	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002			

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- # 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

**SIGNATURES**

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

**PSIVIDA CORP.**

By: \_\_\_\_\_ /s/ **PAUL ASHTON**  
**Paul Ashton,**  
**President and Chief Executive Officer**

Date: September 25, 2009

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

<u>Name</u>	<u>Title</u>	<u>Date</u>
_____ /s/ <b>DAVID J. MAZZO</b> David J. Mazzo	Chairman of the Board of Directors	September 25, 2009
_____ /s/ <b>PAUL ASHTON</b> Paul Ashton	President, Chief Executive Officer and Director (Principal Executive Officer)	September 25, 2009
_____ /s/ <b>LEONARD S. ROSS</b> Leonard S. Ross	Corporate Controller (Principal Financial and Accounting Officer)	September 25, 2009
_____ /s/ <b>PAUL A. HOPPER</b> Paul Hopper	Director	September 25, 2009
_____ /s/ <b>MICHAEL ROGERS</b> Michael Rogers	Director	September 25, 2009
_____ /s/ <b>PETER SAVAS</b> Peter Savas	Director	September 25, 2009

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PSIVIDA CORP. AND SUBSIDIARIES  
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**Consolidated Financial Statements:**

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[Consolidated Balance Sheets](#)  
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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, 2009 and 2008, and the related consolidated statements of operations, stockholders’ equity and cash flows for each of the three years in the period ended June 30, 2009. 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, 2009 and 2008, and the results of their operations and their cash flows for each of the three years in the period ended June 30, 2009, 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 24, 2009

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

	June 30,	
	2009	2008
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 6,899	\$ 15,609
Note receivable, net of allowance	—	481
Accounts and other receivables, net of allowance	815	986
Prepaid expenses and other current assets	413	614
Total current assets	8,127	17,690
Note receivable and other, net of allowance	109	819
Property and equipment, net	66	473
Intangibles, net	28,802	36,802
<b>Total assets</b>	<b>\$ 37,104</b>	<b>\$ 55,784</b>
<b>Liabilities and stockholders' equity</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 284	\$ 2,634
Accrued expenses	1,552	2,236
Deferred revenue	5,912	10,476
Derivative liabilities	971	1,930
Total current liabilities	8,719	17,276
Deferred revenue	4,622	8,114
Deferred tax liabilities	222	316
<b>Total liabilities</b>	<b>13,563</b>	<b>25,706</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, 18,293,961 and 18,262,345 shares issued and outstanding at June 30, 2009 and 2008, respectively	18	18
Additional paid-in capital	248,500	247,628
Accumulated deficit	(227,048)	(224,537)
Accumulated other comprehensive income	2,071	6,969
Total stockholders' equity	23,541	30,078
<b>Total liabilities and stockholders' equity</b>	<b>\$ 37,104</b>	<b>\$ 55,784</b>

See notes to consolidated financial statements



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

	Year Ended June 30,		
	2009	2008	2007
Revenues:			
Collaborative research and development	\$12,002	\$ 3,328	\$ 733
Royalty income	160	148	1,052
Total revenues	<u>12,162</u>	<u>3,476</u>	<u>1,785</u>
Operating expenses:			
Impairment of goodwill	—	60,106	—
Impairment of intangible assets	—	—	45,278
Research and development	8,007	14,426	21,065
General and administrative	8,791	13,951	11,204
Total operating expenses	<u>16,798</u>	<u>88,483</u>	<u>77,547</u>
Operating loss from continuing operations	<u>(4,636)</u>	<u>(85,007)</u>	<u>(75,762)</u>
Other income (expense):			
Change in fair value of derivatives	959	8,357	11,434
Interest income	162	648	277
Interest and finance costs	—	(507)	(9,491)
Loss on extinguishment of debt	—	—	(23,361)
Other income, net	53	356	153
Total other income (expense)	<u>1,174</u>	<u>8,854</u>	<u>(20,988)</u>
Loss from continuing operations before income taxes	<u>(3,462)</u>	<u>(76,153)</u>	<u>(96,750)</u>
Income tax benefit	951	483	13,225
Loss from continuing operations	<u>(2,511)</u>	<u>(75,670)</u>	<u>(83,525)</u>
Discontinued operations:			
Loss from discontinued operations	—	—	(1,318)
Gain on sale of discontinued operations	—	—	3,640
Income from discontinued operations	<u>—</u>	<u>—</u>	<u>2,322</u>
Net loss	<u>\$ (2,511)</u>	<u>\$ (75,670)</u>	<u>\$ (81,203)</u>
Basic and diluted net loss per share:			
Loss from continuing operations	\$ (0.14)	\$ (4.17)	\$ (7.57)
Income from discontinued operations	—	—	0.21
Net loss	<u>\$ (0.14)</u>	<u>\$ (4.17)</u>	<u>\$ (7.36)</u>
Weighted average common shares outstanding:			
Basic and diluted	<u>18,263</u>	<u>18,166</u>	<u>11,038</u>

See notes to consolidated financial statements

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

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Number of Shares	Par Value Amount				
Balance at July 1, 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						<u>\$ (75,835)</u>
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						<u>\$ (75,906)</u>
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
Comprehensive loss:						
Net loss	—	—	—	(2,511)	—	(2,511)
Reclassification of foreign currency translation gains to earnings upon dissolution of subsidiaries					(69)	(69)
Foreign currency translation adjustments	—	—	—	—	(4,829)	(4,829)
Total comprehensive loss						<u>\$ (7,409)</u>
Stock-based compensation	—	—	815	—	—	815
Issuance of fully vested shares	31,616	—	57	—	—	57
Balance at June 30, 2009	<u>18,293,961</u>	<u>\$ 18</u>	<u>\$ 248,500</u>	<u>\$ (227,048)</u>	<u>\$ 2,071</u>	<u>\$ 23,541</u>

See notes to consolidated financial statements

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

	Year Ended June 30,		
	2009	2008	2007
<b>Cash flows from operating activities:</b>			
Net loss	\$ (2,511)	\$ (75,670)	\$ (81,203)
Loss from discontinued operations	—	—	1,318
Gain on sale of discontinued operations	—	—	(3,640)
Loss from continuing operations	(2,511)	(75,670)	(83,525)
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	3,336	3,886	9,247
Depreciation of property and equipment	102	397	1,767
Loss on extinguishment of debt	—	—	23,361
Amortization of convertible note debt discount and issue costs	—	—	5,416
Change in fair value of derivatives	(959)	(8,357)	(11,434)
Non-cash interest expense	—	507	875
Stock-based compensation	872	756	707
Loss (gain) on sale of equipment	39	(13)	—
Provision for losses on note receivable	1,300	325	—
Deferred income tax benefit	(94)	(535)	(13,225)
Foreign currency translation gains upon dissolution of subsidiaries	(69)	—	—
Changes in operating assets and liabilities:			
Accounts, note and other receivables	124	(105)	(213)
Prepaid expenses and other current assets	117	(97)	(57)
Accounts payable	(2,156)	1,400	158
Accrued expenses	(649)	(4,676)	1,228
Deferred revenue	(7,888)	16,933	48
Net cash used in operating activities of continuing operations	(8,436)	(5,143)	(20,369)
Net cash used in operating activities of discontinued operations	—	—	(977)
Net cash used in operating activities	(8,436)	(5,143)	(21,346)
<b>Cash flows from investing activities:</b>			
Purchases of property and equipment	(195)	(272)	(77)
Decrease (increase) in restricted cash	—	—	4,500
Proceeds from sale of property and equipment	—	13	—
Net cash (used in) provided by investing activities of continuing operations	(195)	(259)	4,423
Net cash provided by investing activities of discontinued operations	—	—	1,792
Net cash (used in) provided by investing activities	(195)	(259)	6,215
<b>Cash flows from financing activities:</b>			
Proceeds from issuance of stock	—	20,622	25,991
Stock issuance costs	—	(2,237)	(1,461)
Proceeds from issuance of convertible notes	—	—	6,500
Debt issuance costs	—	—	(1,830)
Repayment of convertible notes	—	—	(14,973)
Premium paid on extinguishment of debt	—	—	(3,034)
Net cash provided by financing activities	—	18,385	11,193
Effect of foreign exchange rate changes on cash and cash equivalents	(79)	(44)	(84)
<b>Net (decrease) increase in cash and cash equivalents</b>	<b>(8,710)</b>	<b>12,939</b>	<b>(4,022)</b>
<b>Cash and cash equivalents at beginning of year</b>	<b>15,609</b>	<b>2,670</b>	<b>6,692</b>
<b>Cash and cash equivalents at end of year</b>	<b>\$ 6,899</b>	<b>\$ 15,609</b>	<b>\$ 2,670</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, the “Company”), incorporated in Delaware, develops tiny, sustained release, drug delivery products that are administered by implantation, injection or insertion. The Company’s Phase III partnered product, which utilizes the third generation of the Company’s Durasert™ technology systems, delivers fluocinolone acetonide (“FA”) for the treatment of diabetic macular edema (“DME”). This product candidate, formerly known as Medidur™ FA for DME, is licensed to Alimera Sciences, Inc. (“Alimera”), which is conducting fully-recruited Phase III clinical trials. Alimera expects that 24-month interim data from these clinical trials will be available in late 2009 and plans to file a New Drug Application (“NDA”) with the Food and Drug Administration (“FDA”) in early 2010. Alimera intends to commercialize the product under the name Iluvien®. The Company’s two FDA-approved sustained release products to treat chronic back of the eye diseases are Retisert® for the treatment of posterior 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 also has a worldwide collaborative research and license agreement with Pfizer, Inc. (“Pfizer”) under which Pfizer may develop additional ophthalmic products using certain of the Company’s technologies.

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 lead BioSilicon product candidate, BrachySil™, delivers a therapeutic phosphorus-32, or 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 is nearing completion of a follow-on dose-ranging clinical trial.

**Basis of Presentation**

These audited consolidated financial statements at June 30, 2009 and 2008 and for each of the three years in the period ended June 30, 2009 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 CHESS 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.

**Management’s Plans**

Since its inception, the Company has incurred operating losses related to its research and development programs and supporting activities, and has consistently run a deficit in operating cash flows. Cash and cash equivalents totaled approximately \$6.9 million at June 30, 2009 compared to \$15.6 million at June 30, 2008.

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Management believes that it can fund its operations for at least the next 12 months. This expectation is based on certain key assumptions that include (i) continued receipt from Pfizer of quarterly research and development funding of \$500,000; (ii) Alimera's continued funding of the development of Iluvien; and (iii) the continued receipt of the scheduled conditional note payments from Alimera. Management has identified contingency plans in the event of a significant shortfall in payments, focused primarily on reduced spending for non-critical activities. Whether and when the Company will require, or desire to raise, additional capital will depend upon many factors, including, but not limited to:

- the continuation of the Company's collaborations with Pfizer and Alimera, including their continued funding of the Company's programs and the Company's receipt of applicable milestone, royalty, note and other payments;
- the timely development, regulatory approval and commercialization of Iluvien;
- the amount and timing of sales of Retisert, which affect the timing of the resumption of Retisert royalty payments and the amounts of such royalty payments;
- the scope and extent of the Company's internally funded existing operations and programs (including any Phase III trials for BrachySil for pancreatic cancer), any new product candidates and any new business opportunities;
- the Company's 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 the Company's 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 the Company's operating plan, including the pursuit of new business opportunities, which may affect its need for capital.

## **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 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. On an ongoing basis, the Company evaluates its estimates. The Company bases its estimates on historical experience and various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates.

### **Foreign Currency**

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

Assets and liabilities of the Company's foreign subsidiaries are translated at period end exchange rates. Amounts included in the statements of operations are translated at the average exchange rate for the period. The

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resulting currency translation adjustments are recorded in Accumulated other comprehensive income as a separate component of stockholders' equity in the consolidated balance sheet. Foreign currency gains or losses arising from transactions denominated in foreign currencies, whether realized or unrealized, are recorded in Other income, net in the consolidated statements of operations.

During the year ended June 30, 2009, the Company dissolved its subsidiaries in Singapore and Australia. The accumulated translation adjustment component of equity related to the investments in these subsidiaries of \$69,000 has been accounted for as a foreign currency gain and included in Other income, net in the consolidated statement of operations.

### **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, 2009, 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 at June 30, 2009 consisted primarily of (i) value added tax reimbursements in certain foreign jurisdictions; (ii) refundable U.K. research and development tax credits and (iii) quarterly royalties earned. At June 30, 2009 and 2008, an allowance for doubtful accounts of \$1,625,000 and \$325,000, respectively, was recorded to reduce the carrying value of a note receivable and related accrued interest to estimated net realizable value (see Note 14).

### **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 derivative liabilities, reflecting the variable amount of functional currency to be received upon potential exercise. After initial recognition, subsequent changes in the fair value of the derivative liabilities are recorded in the consolidated statements of operations in each reporting period. Fair value is determined using a Black-Scholes valuation model.

### **Property and Equipment**

Property and equipment is recorded at cost. The Company uses the straight-line method to record depreciation expense over an asset's estimated useful life, 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. If the assessment indicates an impairment, the affected assets are written down to fair value.

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### **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.

At June 30, 2008, the carrying value of the Company's reporting unit exceeded its fair value. As a result, the Company recorded a \$60.1 million impairment charge related to goodwill, which reduced goodwill to zero (see Note 4).

The Company's intangible assets that are subject to amortization include patents and licenses. The intangible assets are being amortized on a straight-line basis over twelve years. The intangible asset lives have been determined based upon the anticipated period over which the Company will derive future cash flows 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 charge of its Retisert intangible asset (see Note 4).

### **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.

#### *Collaborative research and development*

The Company's business strategy includes entering into collaborative arrangements with strategic partners for the development and commercialization of product candidates utilizing the Company's technologies. The terms of these agreements typically include multiple deliverables by the Company (for example, license rights, 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

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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”).

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.

### **Stock-Based Compensation**

The Company awards stock options and other equity-based instruments to its employees, directors and consultants pursuant to stockholder-approved plans. The Company recognizes compensation expense for awards on a straight-line basis over the requisite service period, which generally equals the vesting period. The Company estimates the fair value of stock option awards on the date of grant using the Black-Scholes option valuation model.

### **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



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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, 2009, 2008 and 2007, as their inclusion would be anti-dilutive.

Potentially dilutive securities at the end of each year in the three year period ended June 30, 2009 are summarized as follows:

	June 30,		
	2009	2008	2007
Options	2,078,397	473,092	505,281
Warrants	11,097,681	11,182,181	9,464,492
Restricted stock issued in connection with CDS acquisition	—	—	8,587
	<u>13,176,078</u>	<u>11,655,273</u>	<u>9,978,360</u>

### **Comprehensive Loss**

Comprehensive loss is comprised of net loss and foreign currency translation adjustments and is reported in the consolidated statements 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.

In June 2006, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation ("FIN") No. 48, "*Accounting for Uncertainty in Income Taxes—an interpretation of FASB Statement No. 109*" ("FIN 48"), which clarifies the accounting for uncertainty in income taxes recognized in a company's financial statements in accordance with SFAS No. 109, "*Accounting for Income Taxes*". FIN 48 prescribes a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The Company adopted FIN 48 on July 1, 2007. The Company accounts for interest and penalties related to uncertain tax positions as part of its provision for income taxes. See Note 12 for additional information on income taxes.

### **Recently Adopted Accounting Pronouncements**

In September 2006, the FASB issued Statement of Financial Accounting Standards ("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. Under the standard, fair value measurements are to be separately disclosed by level within a fair value hierarchy. SFAS 157 applies under other accounting pronouncements that require or permit fair value measurements. Pursuant to FASB Staff Position ("FSP") No. 157-2, issued in February 2008, the application of SFAS 157 for nonfinancial assets and nonfinancial liabilities that are recognized or disclosed at fair value in financial statements on a non-recurring basis may be

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deferred until fiscal years beginning after November 15, 2008. The Company adopted SFAS 157 as of July 1, 2008, with the exception of the application of the statement to non-recurring nonfinancial assets and nonfinancial liabilities. See Note 13 for additional disclosure.

In July 2008, the Company adopted SFAS No. 159, “*The Fair Value Option for Financial Assets and Financial Liabilities—Including an Amendment of FASB Statement No. 115*” (“SFAS 159”). SFAS 159 permits companies to choose to measure selected financial assets and liabilities at fair value, with changes in fair value recognized in earnings each reporting period. Prior to July 2008, the Company recorded derivative liabilities at fair value in accordance with SFAS No. 133, “*Accounting for Derivative Instruments and Hedging Activities*”, as amended. The adoption of SFAS 159 had no impact on the Company’s consolidated financial position and results of operations as management has not elected the fair value option for any other financial assets and liabilities.

In June 2007, the FASB issued EITF Issue No. 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 the related services are performed. The Company adopted EITF 07-03 as of July 1, 2008, and the adoption did not have any impact on its consolidated financial statements.

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 amends and expands the disclosure requirements for derivative instruments and hedging activities, with the intent to provide users of financial statements with an enhanced understanding of (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 statements. The Company adopted SFAS 161 on January 1, 2009. See Notes 8 and 13 for the Company’s disclosures about its derivative liabilities.

In May 2009, the FASB issued SFAS No. 165, “*Subsequent Events*” (“SFAS 165”). SFAS 165 defines the subsequent events or transaction period, circumstances under which such events or transactions should be recognized, and disclosures regarding subsequent events or transactions. SFAS 165 is effective for interim or annual periods ending after June 15, 2009. The Company has adopted the provisions of SFAS 165 as of June 30, 2009. Although the adoption of SFAS 165 did not materially impact its financial condition, results of operations, or cash flow, the Company is now required to provide additional disclosures, which are included in Note 20.

### **Recently Issued Accounting Pronouncements**

In November 2007, the FASB issued EITF Issue No. 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 141R”), which provides revised guidance for recognition and measurement of identifiable assets and goodwill acquired, liabilities assumed, and any noncontrolling interest in the acquiree at fair value. SFAS 141R 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 141R also establishes disclosure requirements to enable the evaluation of the nature and financial effects of the business combination. SFAS 141R is required to

be applied 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 as well as the subsequent recognition of acquired deferred tax benefits of previous acquisitions. The Company will be required to adopt SFAS 141R in connection with business combination transactions, if any, after June 30, 2009.

### **3. License and Collaboration Agreements**

#### **Alimera**

On March 14, 2008, the Company amended and restated its collaboration agreement with Alimera (the "Alimera Agreement"). Under the Alimera Agreement, the Company has licensed Alimera the rights to develop, market and sell certain product candidates, including Medidur FA, which Alimera intends to commercialize under the name Iluvien. Alimera is conducting fully-enrolled Phase III trials for Iluvien. 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%.

Consideration received upon execution of the Alimera Agreement consisted of (i) \$12.0 million in cash 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 Alimera Agreement ends December 31, 2009. Accordingly, from the effective date, the aggregate \$18.3 million of deferred revenue, consisting of the aforementioned current consideration and \$650,000 of previously received but unamortized milestone payments, is being recognized as revenue on a straight-line basis over the 21.5 month performance period through December 31, 2009. For the years ended June 30, 2009 and 2008, revenue related to the Alimera Agreement totaled approximately \$11.8 million and \$3.3 million.

Other consideration, exclusive of the Company's 20% profit share, includes (i) conditional principal and interest payments of up to approximately \$21.3 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) the assumption by Alimera of all financial responsibility for the development of licensed products under the Alimera Agreement, including reimbursement of approved development costs incurred by the Company in support of the ongoing clinical studies of Iluvien and anticipated regulatory submissions. All payments received from Alimera during the performance period are being recognized as revenue during the performance period using the cumulative catch-up method.

#### **Pfizer**

In April 2007, the Company and Pfizer entered into a worldwide collaborative research and license agreement (the "Pfizer Agreement"), which superseded a December 2006 research agreement. 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 quarterly in consideration of the Company's costs in performing the research program. These payments commenced in calendar year 2008 and will continue until the earlier of the commencement of the first Phase III clinical trial for a licensed product candidate or the termination of the Pfizer Agreement.

The Pfizer Agreement and the preceding Pfizer research agreement 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 unable to define the time period of its overall deliverables and other obligations under the Pfizer Agreement and, as a result, all payments received from Pfizer through June 30, 2009 totaling \$3.75 million have been classified in deferred revenue as a non-current liability.

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### **Intrinsiq**

In January 2008, the Company and Intrinsiq Materials Cayman Limited (“Intrinsiq”) entered into an agreement pursuant to which Intrinsiq acquired an exclusive field-of-use license to develop and commercialize nutraceutical and food science applications of BioSilicon, and certain related assets, for \$1.2 million. In addition, subject to Intrinsiq’s unilateral right to terminate the license upon 90 days prior written notice, Intrinsiq is obligated to pay the Company aggregate minimum royalties of \$3.55 million through April 2014, of which the first \$450,000 was paid in July 2009.

Under the original agreement, the parties were obligated to enter into a manufacture and supply agreement, which was consummated effective as of February 1, 2009. Pursuant to the supply agreement, the Company leased to Intrinsiq certain equipment for its use in manufacturing BioSilicon material. Subject to its right to terminate the lease, Intrinsiq will acquire title to the equipment upon the remittance of lease payments totaling \$122,000 over the 2-year lease term, of which the first payment of \$24,000 was received in June 2009.

The Company has determined that the equipment lease component represents a separate element of this arrangement to be accounted for in accordance with SFAS No. 13, “Accounting for Leases”. Using the relative fair value method prescribed under EITF 00-21, the Company allocated the arrangement consideration between the lease and license deliverables. The Company has determined the performance period of the license arrangement to be 17 years, coinciding with the last to expire of the patents licensed to Intrinsiq, and is recognizing consideration allocated to the license arrangement on a straight-line basis over this period. During the year ended June 30, 2009, the Company recognized \$77,000 of collaborative research and development revenue, and the remaining balance of payments received of approximately \$932,000 has been recorded as deferred revenue at June 30, 2009.

#### **4. Goodwill and Acquired Intangible Assets**

The reconciliation of goodwill and acquired intangible assets for the years ended June 30, 2009 and 2008 is as follows:

	June 30,	
	2009	2008
<b>Goodwill</b>		
Balance at beginning of year	\$ —	\$ 60,212
Impairment write-down	—	(60,106)
Foreign currency translation adjustments	—	(106)
Balance at end of year	<u>\$ —</u>	<u>\$ —</u>
<b>Patents and licenses</b>		
Gross carrying amount at beginning of year	\$ 64,342	\$ 64,534
Foreign currency translation adjustments	(7,783)	(192)
Gross carrying amount at end of year	<u>56,559</u>	<u>64,342</u>
Accumulated amortization at beginning of year	(27,540)	(23,732)
Amortization expense	(3,336)	(3,886)
Foreign currency translation adjustments	3,119	78
Accumulated amortization at end of year	<u>(27,757)</u>	<u>(27,540)</u>
Net book value at end of year	<u>\$ 28,802</u>	<u>\$ 36,802</u>

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The net book value of the Company's acquired intangible assets by product and technology at June 30, 2009 and 2008 is summarized as follows:

	June 30,		Estimated Remaining Useful Life at June 30, 2009 (Years)
	2009	2008	
<b>Patents and licences</b>			
Retisert	\$ 8,951	\$10,004	8.5
BioSilicon	19,851	26,798	8.5
	<u>\$28,802</u>	<u>\$36,802</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 \$3.3 million, \$3.9 million and \$9.2 million for the years ended June 30, 2009, 2008 and 2007, respectively. Based upon intangible assets in service as of June 30, 2009, amortization expense for each of the next five years is estimated to be approximately \$3.4 million per year.

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 market approach. The income approach consisted of management's estimates of future cash flows associated with its current products, product candidates and other business operations, 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. In the required step two of the 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 BioSilicon) were valued by applying appropriate discount rates to present value the estimated cash flows. 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.

**Impairment of Intangible Assets**

At June 30, 2007, the Company evaluated the recoverability of its Retisert intangible asset 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 as of 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 Charge</u>
Retisert	Patents	<u>\$11,057</u>	<u>\$56,335</u>	<u>\$ (45,278)</u>

**5. Property and Equipment, Net**

	<u>June 30,</u>	
	<u>2009</u>	<u>2008</u>
Property and equipment	\$ 3,740	\$ 4,386
Construction in progress	—	306
Leasehold improvements	188	195
Gross property and equipment	3,928	4,887
Accumulated depreciation and amortization	(3,862)	(4,414)
	<u>\$ 66</u>	<u>\$ 473</u>

Depreciation expense was \$102,000, \$397,000 and \$1,767,000 for the years ended June 30, 2009, 2008 and 2007, respectively.

**6. Accrued Expenses**

	<u>June 30,</u>	
	<u>2009</u>	<u>2008</u>
Professional fees	\$ 264	\$ 873
Personnel costs	911	794
Clinical trials	182	39
Other	159	478
Income taxes	36	52
	<u>\$ 1,552</u>	<u>\$ 2,236</u>

## **7. Loss on Extinguishments of Debt**

During the year ended June 30, 2007, the Company incurred a \$23.4 million loss on extinguishments of debt in connection with (i) the subordinated convertible note issued in November 2005 (“Sandell note”) to Sandell Asset Management (“Sandell”), as amended, and (ii) the subordinated convertible notes issued in September 2006 (“Absolute notes”) to other institutional investors (collectively, “Absolute”). In connection with the modification of the Sandell note terms in September 2006 and December 2006, the Company accounted for each amendment as an extinguishment of the then existing note and the issuance of a new debt instrument. In May 2007, the Company redeemed the Sandell note by a single payment of \$13.7 million and, in June 2007, the Company redeemed the Absolute notes by aggregate payments of \$885,000. In connection with each of the Sandell amendments and the final Sandell redemption, the Company recorded a loss on extinguishment of debt, which represented the difference between the carrying amount of the debt instrument and the fair value of the cash and warrants issued.

## **8. Derivative Liabilities**

### **Convertible Note Transactions**

Conversion option derivatives arose in connection with the Sandell note, as subsequently amended, and in connection with the Absolute notes. The convertible note 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 the statements of operations. 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 Sandell and Absolute notes until immediately prior to their final redemptions resulted in income recognized of approximately \$4.7 million during the year ended June 30, 2007. 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 7).

### **Warrants Issued to Investors**

During the years ended June 30, 2008 and 2007, the Company sold units consisting of common shares together with detachable warrants to purchase additional common shares within specified time periods. In several transactions, the warrants were denominated in A\$, which is different than the Company’s functional currency. Because 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 the statements of operations. The fair value of the warrants was determined using a Black-Scholes Model. The grant date valuations of the A\$-denominated warrants issued totalled approximately \$17.1 million. The net reduction in the fair values of these derivative liabilities for the years ended June 30, 2009, 2008 and 2007 resulted in income recognized of approximately \$1.0 million, \$8.4 million and \$6.8 million, respectively. The change in the fair value of these derivative liabilities is primarily attributable to changes in the Company’s share price, and secondarily to changes in assumed volatility rates and the remaining contractual life of the warrants.

## **9. Stockholders’ Equity**

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

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### **Stock Offerings**

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 \$9.1 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 the Pfizer Agreement, 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 Pfizer Agreement. A total of 72,010 warrants, with a warrant exercise price of \$6.60 per share, were issued to the placement agents in connection with the offering. In addition, the Company simultaneously completed a sale of 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 issuance of the Sandell note, the Company issued warrants to purchase 158,451 common shares at an initial exercise price of \$28.80 per share. In connection with the issuance of the Absolute notes, 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 warrants issued with the Sandell and Absolute notes were valued at approximately \$1.3 million and \$1.4 million, respectively.

During the year ended June 30, 2007, holders of the Sandell and Absolute notes converted a total of approximately \$6.8 million of note principal and associated accrued and unpaid interest into 1,040,494 common shares at the applicable note conversion prices (see Note 7).

### **Restricted Stock**

Employees of Control Delivery Systems, Inc. ("CDS") who held restricted stock of CDS received restricted shares of pSivida as part of the Company's acquisition of CDS in December 2005. 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 10). At June 30, 2008, these shares were fully vested.



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### 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 Sandell and Absolute note transactions and various amendments thereto (see Note 7). The following table provides a reconciliation of these warrants for the years ended June 30, 2009 and 2008:

	Year Ended June 30,			
	2009		2008	
	Number of Warrants	Weighted Average Exercise Price	Number of Warrants	Weighted Average Exercise Price
Balance at beginning of year	7,195,498	\$ 7.69	5,683,288	\$ 8.00
Granted	—	—	1,512,210	6.60
Expired	(33,250)	50.00	—	—
Balance and exercisable at end of year	<u>7,162,248</u>	<u>\$ 7.50</u>	<u>7,195,498</u>	<u>\$ 7.69</u>

At June 30, 2009, these outstanding warrants had a weighted average remaining life of 2.67 years.

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 described above. The following table provides a reconciliation of these warrants for the years ended June 30, 2009 and 2008:

	Year Ended June 30,			
	2009		2008	
	Number of Warrants	Weighted Average Exercise Price A\$	Number of Warrants	Weighted Average Exercise Price A\$
Balance at beginning of year	3,986,683	9.98	3,781,204	10.11
Granted	—	—	205,479	7.68
Expired	(51,250)	43.60	—	—
Balance and exercisable at end of year	<u>3,935,433</u>	<u>9.54</u>	<u>3,986,683</u>	<u>9.98</u>

At June 30, 2009 and 2008, the weighted exercise price of these warrants translated to US\$ was \$7.68 and \$9.60, respectively. At June 30, 2009, these outstanding warrants had a weighted average remaining life of 1.71 years.

### Registration Rights Agreements

The Company has entered into registration rights agreements with purchasers of certain of its equity and debt securities. These registration rights agreements required the Company to register with the Securities and Exchange Commission ("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 Sandell and Absolute notes, the Company incurred registration rights penalties totaling approximately \$2.3 million for the year ended June 30, 2007, all of which had been paid prior to June 30, 2007. These amounts were included in interest and finance costs in the consolidated statement of operations. All required registration statements related to these notes were filed and declared effective by the SEC during the year ended June 30, 2007.

## 10. Stock-Based Compensation

### 2008 Incentive Plan

The pSivida Corp. 2008 Incentive Plan (the “2008 Plan”) provides for the issuance of a maximum of 1,750,000 shares of common stock in satisfaction of stock-based awards to directors, executives, employees and consultants. Awards may include stock options, stock appreciation rights, restricted and unrestricted stock, deferred stock, performance awards, convertible securities and cash grants. A total of 1,641,000 options were granted during the year ended June 30, 2009 at exercise prices equal to the closing market price of the Company’s common stock on the NASDAQ Global Market (“NASDAQ”) on the respective option grant dates. Of this total, 1,301,000 options were issued to employees with ratable annual vesting over 4 years and 340,000 options were issued to non-employee directors with ratable annual vesting ranging from 1 to 3 years. All option grants have a 10-year life. During the year ended June 30, 2009 the Company awarded 31,616 shares of unrestricted stock. The fair value of the award was \$57,000 and was recognized as stock-based compensation in the consolidated statement of operations. No awards were granted under the 2008 Plan during the year ended June 30, 2008.

The Company measures the fair value of options on their grant date using the Black-Scholes option-pricing model. Based upon limited option exercise history, the Company has used the “simplified” method outlined in SEC Staff Accounting Bulletin No. 107 to estimate the expected life of stock option grants. Management believes that the historical volatility of the Company’s stock price on NASDAQ, for which there has been trading history for approximately 4.5 years, best represents the estimated volatility over the expected life of the option. The risk-free interest rate is based upon published U.S. Treasury yield curve rates at the date of grant corresponding to the expected life of the stock option. An assumed dividend yield of zero reflects the fact that the Company has never paid cash dividends and has no intentions to pay dividends in the foreseeable future.

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

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

The Company recognizes compensation expense for only the portion of options that are expected to vest. An estimated annual forfeiture rate of 5% was used to determine awards expected to vest and to calculate stock-based compensation during the year ended June 30, 2009, except that no forfeiture rate was assumed for option grants to executive officers 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 values to be ultimately realized by persons who receive stock options.

The weighted average grant date fair value of stock options granted pursuant to the 2008 Plan for the year ended June 30, 2009 was \$1.43 per share. A total of 110,000 options vested during the year ended June 30, 2009. These options vested pursuant to the terms of a March 2009 severance agreement with the Company’s former Vice President, Finance and Chief Financial Officer, and expire in March 2010.

At June 30, 2009, there was approximately \$1.4 million of unrecognized compensation expense related to non-vested share-based payment awards that is expected to be recognized over a weighted average period of 2.17 years.

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The following table provides a reconciliation of stock option activity under the 2008 Plan for the year ended June 30, 2009:

	<u>Number of options</u>	<u>Weighted average exercise price</u>	<u>Weighted average Remaining Contractual Life (in years)</u>	<u>Aggregate Intrinsic Value</u>
Outstanding at June 30, 2008	—	\$ —		
Granted	1,641,000	1.94		
Forfeited	(5,000)	2.85		
Outstanding at June 30, 2009	<u>1,636,000</u>	<u>\$ 1.94</u>	<u>8.91</u>	<u>\$ 410</u>
Outstanding at June 30, 2009—vested or unvested and expected to vest	<u>1,552,589</u>	<u>\$ 1.91</u>	<u>8.87</u>	<u>\$ 410</u>
Exercisable at June 30, 2009	<u>110,000</u>	<u>\$ 2.89</u>	<u>0.72</u>	<u>\$ —</u>

### Employee Share Option Plan

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

The Company used the Black-Scholes option pricing model to calculate the fair value of these stock options. 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 and 2007:

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

The weighted average grant date fair value of stock options granted pursuant to the Plan during the years ended June 30, 2008 and 2007 was A\$2.47 and A\$6.40 per share, respectively. The exercise prices of all outstanding options under the Plan at June 30, 2009, converted to US\$ at the rate of exchange at that date, were in excess of the market price of the Company's common shares at that date and, accordingly, the options had no intrinsic value. No options were exercised under the Plan during the years ended June 30, 2009, 2008 and 2007.

At June 30, 2009, there was \$50,000 of unrecognized compensation expense related to non-vested share-based payment awards that is expected to be recognized over a weighted average period of 0.93 years.

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The following table provides a reconciliation of stock option activity under the Plan for the year ended June 30, 2009:

	<u>Number of options</u>	<u>Weighted average exercise price</u> A\$	<u>Weighted average Remaining Contractual Life</u> (in years)	<u>Aggregate Intrinsic Value</u> A\$
Outstanding at June 30, 2008	455,478	29.57		
Granted	—	—		
Forfeited	(3,334)	5.50		
Cancelled	(27,361)	40.65		
Outstanding at June 30, 2009	<u>424,783</u>	<u>29.05</u>	<u>1.30</u>	<u>—</u>
Outstanding at June 30, 2009—vested or unvested and expected to vest	<u>419,241</u>	<u>28.93</u>	<u>1.31</u>	<u>—</u>
Exercisable at end of year	<u>328,064</u>	<u>34.40</u>	<u>0.84</u>	<u>—</u>

At June 30, 2009 the weighted average exercise price of outstanding and exercisable options translated into US\$ was \$23.38 and \$27.69, respectively.

**Restricted Stock Issued to CDS Employees**

On December 30, 2005, in the CDS merger, the Company issued 224,798 restricted common shares, with a fair value of \$26.40 per common share, to CDS employees in consideration of their restricted CDS stock. The portion of the fair value attributable to the post-acquisition service period was expensed over the vesting period.

On December 30, 2005, the Company also granted 30,280 restricted 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 restricted common shares:

	<u>Year Ended June 30,</u>	
	<u>2008</u>	<u>2007</u>
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>

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### Stock-Based Compensation Expense

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

	Year ended June 30,		
	2009	2008	2007
Compensation expense from:			
Stock options	\$815	\$540	\$(28)
Restricted stock	—	216	735
Issuance of fully vested shares	57	—	—
	<u>\$872</u>	<u>\$756</u>	<u>\$707</u>
Compensation expense included in:			
Research and development	\$216	\$28	\$525
General and administrative	656	728	182
	<u>\$872</u>	<u>\$756</u>	<u>\$707</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 consideration of outstanding CDS options which were fully vested at the merger. The following table presents a reconciliation of the activity related to the issuance of these options:

	Year Ended June 30,			
	2009		2008	
	Number of Options	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price
Outstanding at June 30, 2008	17,614	\$ 11.35	38,443	\$ 18.44
Options cancelled	—	—	(20,829)	24.44
Outstanding and exercisable at June 30, 2009	<u>17,614</u>	<u>\$ 11.35</u>	<u>17,614</u>	<u>\$ 11.35</u>

The weighted average remaining contractual life of these exercisable options at June 30, 2009 was 0.26 years.

### 11. Retirement Plans

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

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

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.

The Company contributed a total of \$155,000, \$210,000 and \$316,000 for the years ended June 30, 2009, 2008 and 2007, respectively, in connection with these retirement plans.

[Table of Contents](#)**12. Income Taxes**

The components of income tax benefit are as follows:

	Year Ended June 30,		
	2009	2008	2007
<b>U.S. operations:</b>			
Current income tax (benefit) provision	\$ (19)	\$ 52	\$ —
Deferred income tax benefit	(94)	(535)	(10,300)
	<u>(113)</u>	<u>(483)</u>	<u>(10,300)</u>
<b>Non-U.S. operations:</b>			
Current income tax benefit	(838)	—	—
Deferred income tax benefit	—	—	(2,925)
	<u>(838)</u>	<u>—</u>	<u>(2,925)</u>
<b>Income tax benefit</b>	<u><u>\$ (951)</u></u>	<u><u>\$ (483)</u></u>	<u><u>\$ (13,225)</u></u>

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

	Year Ended June 30,		
	2009	2008	2007
<b>U.S. operations</b>	<u>\$ 1,183</u>	<u>\$ (47,969)</u>	<u>\$ (61,697)</u>
<b>Non-U.S. operations</b>	<u>(4,645)</u>	<u>(28,184)</u>	<u>(35,053)</u>
<b>Loss before income taxes</b>	<u><u>\$ (3,462)</u></u>	<u><u>\$ (76,153)</u></u>	<u><u>\$ (96,750)</u></u>

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

	Year Ended June 30,		
	2009	2008	2007
<b>Income tax benefit at statutory rate</b>	<u>\$ (1,177)</u>	<u>\$ (25,892)</u>	<u>\$ (32,896)</u>
<b>State income taxes, net of federal benefit</b>	<u>20</u>	<u>(2,878)</u>	<u>(3,701)</u>
<b>Non-U.S. income tax rate differential</b>	<u>218</u>	<u>312</u>	<u>8,942</u>
<b>Research and development tax credits</b>	<u>(838)</u>	<u>—</u>	<u>—</u>
<b>Goodwill impairment</b>	<u>—</u>	<u>21,556</u>	<u>—</u>
<b>Changes in valuation allowance, including revisions of prior year estimates</b>	<u>771</u>	<u>6,339</u>	<u>14,784</u>
<b>Other, net</b>	<u>55</u>	<u>80</u>	<u>(354)</u>
<b>Income tax benefit</b>	<u><u>\$ (951)</u></u>	<u><u>\$ (483)</u></u>	<u><u>\$ (13,225)</u></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.

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The components of deferred income taxes were as follows:

	June 30,	
	2009	2008
<b>Deferred tax assets:</b>		
Net operating loss carryforwards	\$ 28,073	\$ 26,616
Deferred revenue	1,007	6,641
Provision for losses on note receivable	520	—
Other	1,028	177
Total deferred tax assets	30,628	33,434
<b>Deferred tax liabilities:</b>		
Intangible assets	9,086	11,505
Deferred tax assets, net	21,542	21,929
Valuation allowance	21,764	22,245
Net deferred tax liability	<u>\$ 222</u>	<u>\$ 316</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 more likely than not realizable amount. The valuation allowance decreased by \$481,000 and increased by approximately \$4.6 million during the years ended June 30, 2009 and 2008, respectively.

The Company has tax loss carry forwards in their individual tax jurisdictions. At June 30, 2009, the Company had U.S. federal net operating loss carry forwards of approximately \$54.4 million which expire at various dates between calendar years 2022 and 2028. 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, 2009, the Company had state net operating loss carryforwards of approximately \$30.5 million which expire at various dates between calendar years 2009 and 2013. During the year ended June 30, 2009, approximately \$11.8 million of state net operating loss carryforwards expired unutilized. Additionally, at June 30, 2009 the Company had loss carryforwards in the U.K. of £16.8 million (approximately \$27.7 million). During the year ended June 30, 2009, the Company recognized a current income tax benefit of \$838,000 related to foreign research and development tax credits earned by its U.K. subsidiary.

The Company's U.S. federal income tax returns for calendar years 2002 through 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.

The Company adopted FIN 48 as of July 1, 2007. The implementation of FIN 48 did not have any impact on the Company's consolidated financial position or results of operations. From adoption through June 30, 2009, the Company had no significant unrecognized tax benefits in its consolidated statements of operations and no material unrecognized tax benefits in its consolidated balance sheets as of June 30, 2009 or 2008.

The Company recognizes interest and penalties related to uncertain tax positions in income tax expense. As of June 30, 2009, the Company had no accrued penalties or interest related to uncertain tax positions.

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### 13. Fair Value Measurements

In September 2006, the FASB issued SFAS 157, which defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. The Company adopted SFAS 157 on July 1, 2008. SFAS 157 establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs, where available. The three levels of the fair value hierarchy are described as follows:

- Level 1—Inputs are quoted prices in active markets that are accessible at the measurement date for identical assets and liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.
- Level 2—Inputs are observable prices that are based on inputs not quoted on active markets, but corroborated by market data.
- Level 3—Inputs are unobservable inputs that are supported by little or no market activity and require the Company to develop its own assumptions about how market participants would price the assets or liabilities. The fair value hierarchy gives the lowest priority to Level 3 inputs.

The Company classified cash equivalents, which are held in money market funds with purchased maturities of less than 90 days, at fair value determined by quoted prices in an active market as Level 1.

The Company's derivative liabilities were classified as Level 3 and valued using the Black-Scholes model.

The following table summarizes the Company's assets and liabilities carried at fair value measured on a recurring basis at June 30, 2009 by valuation hierarchy:

Description	Total Carrying Value at June 30, 2009	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
<b>Assets:</b>				
Cash equivalents	\$ 6,124	\$ 6,124	\$ —	\$ —
<b>Liabilities:</b>				
Derivative liabilities	\$ 971	\$ —	\$ —	\$ 971

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

	June 30,	
	2009	2008
Balance at beginning of year	\$1,930	\$8,865
Proceeds allocated to derivative liabilities in connection with warrants issued to investors	—	1,422
Change in fair value of derivatives—other income	959	8,357
Balance at end of year	\$ 971	\$1,930

### 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.



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The promissory note was due April 12, 2008, but has not yet been paid. During the fourth quarter of the year ended June 30, 2008, the Company demanded payment of the note and, based upon initial negotiations, the Company reduced the carrying value of the note and accrued interest by \$325,000 to its estimated net realizable value of \$1.3 million at June 30, 2008. Based upon the Company's inability to reach agreement with GEM after further discussions, during the year ended June 30, 2009 the Company recorded an aggregate charge to operations for the remaining carrying value of the note. The provision for losses on the note receivable of \$1.3 million and \$325,000 for the years ended June 30, 2009 and 2008 were included in general and administrative expense in the consolidated statements of operations.

The operating results of AION for the year ended June 30, 2007 were included as discontinued operations in the accompanying consolidated financial statements. During that period, 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 lease agreement requires the Company to pay for utilities, taxes, insurance, maintenance and other operating expenses in addition to base rent. The Company has a lease for laboratory and office space in Malvern, U.K. that extends through December 2009. The Company also leases certain office equipment under operating lease agreements that expire through calendar year 2010.

At June 30, 2009, the Company's total future minimum lease payments under non-cancellable operating leases were as follows:

<u>Fiscal Year:</u>	
2010	\$400
2011	275
2012	—
2013	—
2014	—
Thereafter	—
	<u>\$675</u>

Rent expense related to operating leases charged to operations was approximately \$463,000, \$529,000 and \$610,000 for the years ended June 30, 2009, 2008 and 2007, respectively.

### Litigation

In the opinion of the Company's management, the outcome of pending or threatened litigation will not have a material effect on the Company's financial position or results of operations.

## 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.

[Table of Contents](#)**(b) Geographic Area Information**

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

	Revenues			Long-lived assets		
	2009	2008	2007	2009	2008	2007
United States	\$ 12,085	\$ 3,476	\$ 1,704	\$ 36	\$ 68	\$ 224
United Kingdom	77	—	81	30	405	279
Other	—	—	—	—	—	9
Consolidated	<u>\$ 12,162</u>	<u>\$ 3,476</u>	<u>\$ 1,785</u>	<u>\$ 66</u>	<u>\$ 473</u>	<u>\$ 512</u>

**17. Supplemental Cash Flow Information**

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

	Year Ended June 30,		
	2009	2008	2007
Supplemental cash flow information:			
Cash paid for interest on convertible notes	\$—	\$—	\$ 925
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

**18. Related Party Transactions**

As of June 30, 2009, Pfizer owns approximately 10.2% of the Company's outstanding shares, making it the Company's largest shareholder. During the years ended June 30, 2009, 2008 and 2007, the Company received \$1.5 million, \$1.5 million and \$750,000, respectively, from Pfizer under the Pfizer Agreement and the preceding Pfizer research agreement (see Notes 3 and 9). All payments received from Pfizer through June 30, 2009, totaling \$3.75 million, have been classified in deferred revenue as a non-current liability.

[Table of Contents](#)**19. Quarterly Financial Data (unaudited)**

The following table summarizes the quarterly results of operations for the years ended June 30, 2009 and 2008:

	<u>First Quarter</u>	<u>Second Quarter</u>	<u>Third Quarter</u>	<u>Fourth Quarter</u>	<u>Year Ended June 30,</u>
<b>2009</b>					
Total revenues	\$ 2,806	\$ 2,970	\$ 3,163	\$ 3,223	\$ 12,162
Loss from operations	(2,379)	(1,421)	(781)	(55)	(4,636)
Net loss	<u>(471)</u>	<u>(870)</u>	<u>(636)</u>	<u>(534)</u>	<u>(2,511)</u>
Basic and diluted loss per common share:					
Net loss	<u>\$ (0.03)</u>	<u>\$ (0.05)</u>	<u>\$ (0.03)</u>	<u>\$ (0.03)</u>	<u>\$ (0.14)</u>
Weighted average common shares:					
Basic and diluted	<u>18,262</u>	<u>18,262</u>	<u>18,262</u>	<u>18,264</u>	<u>18,263</u>
<b>2008</b>					
Total revenues	\$ 103	\$ 128	\$ 542	(1) \$ 2,703	(1) \$ 3,476
Loss from operations	(5,213)	(8,036)	(6,609)	(65,149)	(85,007)
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:					
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>

(1) In 2008, results for the fourth quarter included a charge for goodwill impairment of \$60.1 million in connection with the Company's annual impairment testing at June 30, 2008 (see Note 4).

**20. Subsequent Events**

The Company has evaluated all events or transactions that occurred after June 30, 2009 up through September 24, 2009 and determined that there were no subsequent events that required adjustments or additional disclosure to these financial statements.



**List of Subsidiaries of pSivida Corp.**

pSivida US, Inc. (Delaware)  
pSiMedica 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 24, 2009 (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, 2009.

/s/ Deloitte & Touche LLP

Boston, Massachusetts  
September 24, 2009

**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 25, 2009

	<b>/s/ PAUL ASHTON</b>
<b>Name:</b>	<b>Paul Ashton</b>
<b>Title:</b>	<b>President and Chief Executive Officer (Principal Executive Officer)</b>

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

**CERTIFICATIONS**

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

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

Date: September 25, 2009

	/s/ <b>LEONARD S. ROSS</b>
Name:	Leonard S. Ross
Title:	Corporate Controller (Principal Financial and Accounting Officer)



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

In connection with the Annual Report of pSivida Corp. (the "Company") on Form 10-K for the year ended June 30, 2009, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Paul Ashton, President and Chief Executive Officer of the Company, certify that to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: September 25, 2009

/s/ **PAUL ASHTON**

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

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

In connection with the Annual Report of pSivida Corp. (the "Company") on Form 10-K for the year ended June 30, 2009, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Leonard S. Ross, Corporate Controller 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 25, 2009

/s/ **LEONARD S. ROSS**

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Name: **Leonard S. Ross**  
Title: **Corporate Controller**  
**(Principal Financial and Accounting Officer)**