UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 OR 15(d) of
The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) January 18, 2011

PSIVIDA CORP.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**000-51122**	**26-2774444**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

400 Pleasant Street
Watertown, MA 02472
(Address of Principal Executive Offices) (Zip Code)

(617) 926-5000
(Registrant's Telephone Number, Including Area Code)

Not applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events

pSivida Corp. (the "Company" or "we") is filing the following information for the purpose of updating the Company's risk factors:

RISK FACTORS

RISKS RELATED TO OUR COMPANY AND OUR BUSINESS

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

Our cash, cash equivalents and marketable securities totaled approximately $15.3 million at September 30, 2010. We believe we can fund our operations as currently conducted into at least calendar year 2012. Receipt of the net proceeds from this offering will extend that date. Whether we will require additional capital will be influenced by many factors, including, but not limited to:

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

In particular, our future cash position depends significantly on approval of Iluvien by the U.S. Food and Drug Administration ("FDA") and foreign regulatory authorities and the initiation and success of marketing of Iluvien. Alimera Sciences, Inc. ("Alimera") has agreed to pay us $25 million upon FDA approval of Iluvien for DME. In addition, we will be entitled to 20% of any future profits, as defined, on sales of Iluvien by Alimera, subject to an offset of 20% of defined pre-profitability commercialization costs incurred by Alimera. In the event Alimera sublicenses commercialization, we would receive 20% of royalties and 33% of non-royalty consideration received by Alimera, less certain permitted deductions. However, there is no assurance that the FDA or other regulatory authorities will approve Iluvien or that Iluvien will achieve market acceptance even if it is approved.

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 and may incur losses in the future.

With the exception of the fiscal year ended June 30, 2010 ("fiscal 2010"), we have incurred operating losses since our inception in 2000. For fiscal 2010, we recorded net income of $8.8 million, primarily due to the accelerated payment in full by Alimera of a $15.0 million conditional note. For fiscal 2009 and fiscal 2008 we

incurred net losses of $2.5 million and $75.7 million, respectively. We incurred a loss of $3.1 million in the quarter ended September 30, 2010 and expect to incur losses in the fiscal year ending June 30, 2011 ("fiscal 2011") and for the foreseeable future if Iluvien is not approved and successfully commercialized. Even if Iluvien is approved and marketed, our profit share on sales of Iluvien, combined with any royalty income from our current products, and any other sources of revenue, may not be sufficient to result in profitability on an ongoing basis.

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 recorded significant amounts of intangible assets in connection with earlier acquisitions. We took a $60.1 million impairment charge on goodwill as of June 30, 2008 (which reduced the carrying value of our goodwill to zero), and a $45.3 million impairment charge on the recorded value of our Durasert™ intangible asset as of June 30, 2007. We still had $23.8 million of intangible assets on our balance sheet as of September 30, 2010, of which approximately $16.2 million related to our BioSilicon™ technology and approximately $7.6 million related to our Durasert technology. We do not believe that there has been any change in circumstance that would require us to conduct an impairment analysis of our intangible assets at December 31, 2010 under U.S. generally accepted accounting principles, but we have not completed our financial statements for the quarter and six months then ended, and there can be no assurance that there will not be an impairment in the value of our intangible assets at that date. 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 the fiscal years ended June 30, 2008 and 2007, we issued warrants denominated in Australian dollars (A$). The fair values of these warrants have been recorded as derivative liabilities on our balance sheet. We are required to assess the fair value of these warrants at each balance sheet date, and changes in their fair values result in adjustments to our recorded derivative liabilities, and corresponding gains or losses in our statements of operations. The fair values of these warrants are sensitive to changes in our share price, among other factors, and are measured using the Black-Scholes valuation model. Fluctuations in the fair values of these warrants could be substantial and will 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, including, without limitation, collaborative research, milestone and royalty payments, and the revenue recognition policies related thereto;
- changes in accounting estimates, policies or principles;
- the entry into, or termination of, collaboration agreements;
- the scope, duration and effectiveness of our collaboration arrangements;
- the quarterly income or expense amounts recorded from the revaluation of our derivative liabilities;
- the amount of research and development costs, including pre-clinical studies and clinical trials, that we fund internally;
- general and industry-specific adverse economic conditions that may affect, among other things, our and our collaborators' operations and financial results; and
- impairment write-downs of one or more of our intangible assets.

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

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

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

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

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

Alimera will not be able to market Iluvien for DME in the U.S. unless and until it receives FDA approval. Our ability to generate significant revenues from this product depends on the ability of Alimera to obtain regulatory approval for and successfully commercialize Iluvien. Alimera has completed 36 month Phase III clinical trials for the use of Iluvien in the treatment of DME (collectively, the "FAME Study") and has reported that it is in the process of analyzing the data through month 36. Based on Alimera's analysis of the month 24 clinical readout of data from the FAME Study ("24 Month Data"), Alimera filed a New Drug Application ("NDA") for approval of the low dose of Iluvien in the United States in June 2010, followed by registration filings in Austria, France, Germany, Italy, Portugal and Spain in July 2010. The FDA accepted Alimera's submission and granted a Priority Review. The FDA issued a Complete Response Letter ("CRL") to Alimera in December 2010, which communicated the FDA's decision that the NDA for Iluvien for DME could not be approved in its present form.

In the CRL, the FDA asked for analyses of safety and efficacy of the clinical readout of data from the FAME Study through month 36 ("36 Month Data"), including certain exploratory analyses in addition to analyses previously submitted in the NDA, to further assess the relative benefits and risks of Iluvien. Alimera reported that it is preparing analyses of the 36 Month Data and that it has requested a meeting with the FDA with respect to the CRL. In the CRL, the FDA requested additional information regarding controls and specifications concerning the manufacturing, packaging and sterilization of Iluvien, which Alimera reports it is in the process of compiling. Additionally, the FDA indicated in the CRL that it had observed deficiencies in current good manufacturing practices ("cGMP") during facility inspections of two of Alimera's third-party manufacturers, which were completed in August and September of 2010, and that all facilities and controls will need to comply with cGMP. Alimera reports that its third-party manufacturers are in the process of resolving these deficiencies.

In the NDA, Alimera included analyses of the 24 Month Data utilizing the full data set of all 956 patients randomized into Alimera's FAME Study, with data imputation employed using "last observation carried forward" ("LOCF") for data missing because of patients who discontinued the trial or were unavailable for follow-up (the "Full Analysis Set") as well as other data sets including one that excludes from the Full Analysis Set three patients who were enrolled but never treated, excludes data collected for patients subsequent to their use of treatments prohibited by Alimera's FAME Study protocol and imputes the last observation prior to the protocol violation forward to month 24 using the LOCF method (the "Modified ART Data Set"). Both Alimera and we believed that the FDA would consider the Full Analysis Set the most relevant population for determining the safety and efficacy of Iluvien based on the month 24 data. The primary efficacy endpoint at month 24 was met with statistical significance for both the low dose and the high dose of Iluvien in both trials using the Full Analysis Set. However, Alimera's FAME Study protocol did not include the Full Analysis Set. The FAME Study protocol provides that the primary assessment of efficacy will be based on the Modified ART Data Set. Statistical significance was not achieved at month 24 for either the low dose or the high dose of Iluvien in one trial using the Modified ART Data Set. Although the CRL requested certain exploratory analyses with respect to the 36 Month Data, it did not specify what data set or sets Alimera should utilize to analyze the 36 Month Data. There is no assurance that the FDA will utilize the Full Analysis Set and not the Modified ART Data Set or another data set in determining whether Iluvien is safe and effective. We do not know whether any analyses of the 36 Month Data will demonstrate to the FDA that Iluvien is safe and efficacious.

In order to obtain approval to market Iluvien for DME in the U.S., Alimera will need to demonstrate to the FDA that Iluvien for DME is safe and efficacious and satisfy the FDA on each of the issues raised in the CRL. There is no assurance that the 36 Month Data or other responses provided by Alimera and its third-party manufacturers will be sufficient to satisfy the FDA. The FDA may not grant marketing approval or it may request additional information from Alimera, including requesting data from additional clinical trials, and ultimately may not grant marketing approval for Iluvien. In addition, Alimera will also require regulatory approvals to sell Iluvien for DME in other countries, and there is no assurance that it will receive those approvals.

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

- receive marketing approval from the FDA and similar foreign regulatory authorities;
- maintain commercial manufacturing arrangements with third-party manufacturers;
- produce, or have its third-party manufacturers produce, sufficient quantities of Iluvien in a validated process to permit successful commercialization;
- launch commercial sales of Iluvien; and
- secure acceptance of Iluvien in the medical community and with third-party payors.

Alimera reports that it expects to obtain a regulatory agency waiver from the requirement to perform carcinogenicity studies of Iluvien in animals. Alimera's month 18 readouts from its open-label Phase II human pharmacokinetic clinical trial (the "PK Study") indicated to Alimera that there is negligible systemic absorption of fluocinolone acetonide ("FA") in patients being treated with Iluvien. However, Alimera may be unable to demonstrate negligible systemic absorption of FA in its PK Study beyond month 18, or may not obtain a regulatory agency waiver from the requirement to perform carcinogenicity studies of Iluvien in animals regardless. Alimera reports that if it is required to perform carcinogenicity studies of Iluvien in animals, the approval of Iluvien could be delayed by up to 36 months.

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

Iluvien utilizes FA, a corticosteroid whose use in the eye has been associated with undesirable side effects such as increased incidence of intraocular pressure (IOP), which may increase the risk of glaucoma and cataract formation. Alimera has performed a full analysis of only the month 24 clinical data from its FAME Study, and the extent of Iluvien's long-term side-effect profile is not yet known. Upon review of Alimera's NDA for the low dose of Iluvien in the treatment of DME as well as the analysis of the 36 Month Data, the FDA may conclude that Alimera's FAME Study did not demonstrate that Iluvien has sufficient levels of efficacy to outweigh the risks associated with its side-effect profile. Conversely, the FDA may conclude that Iluvien's side-effect profile does not demonstrate an acceptable risk/benefit relationship in line with Iluvien's demonstrated efficacy. In the event of such conclusions, Alimera may not receive regulatory approval from the FDA or from similar regulatory agencies in other countries.

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

Regulatory agencies generally approve products for particular indications. If any regulatory agency approves Iluvien for a limited indication, the size of the potential market for Iluvien will be reduced. For example, the potential market for Iluvien would be reduced if the FDA limited the indications of use to only those patients who had previously undergone cataract surgery or to those patients diagnosed with particularly severe DME as opposed to all those diagnosed with clinically significant DME.

Additionally, product approvals, once granted, may be withdrawn if problems occur after initial marketing. If and when Iluvien does receive regulatory approval or clearance, the marketing, distribution and manufacture of Iluvien will be subject to regulation by the FDA in the United States and by similar entities in other countries. Alimera will need to comply with facility registration and product listing requirements of the FDA and similar entities in other countries, and will need to adhere to the FDA's Quality System Regulations. Noncompliance with

applicable FDA and similar entities' requirements could result in warning letters, fines, injunctions, civil penalties, recall or seizure of Iluvien, total or partial suspension of production, refusal of regulatory agencies to grant approvals, withdrawal of approvals by regulatory agencies or criminal prosecution. Alimera also will need to maintain compliance with federal, state and foreign laws regarding sales incentives, referrals and other programs.

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

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

Our product candidates, other than Iluvien for DME, are in early stages of development. Product development involves a high degree of risk, and only a small proportion of research and development programs result in an approved product. If clinical trials that may be conducted by us or our licensees for any of our product candidates do not provide the necessary evidence of safety and effectiveness, those product candidates could not be manufactured and sold, and would not generate revenues. Clinical trials initiated by us or our licensees for 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 (or our licensees') relationship with, contract research organizations, third-party vendors and investigators responsible for pre-clinical testing and clinical trials;
- our (or our licensees') inability to manufacture sufficient quantities of materials for use in clinical trials;
- governmental or regulatory agency assessments of pre-clinical or clinical testing that differs from our (or our licensees') interpretations or conclusions that product candidates meet quality standards for stability, quality, purity and potency; and
- governmental or regulatory delays, or changes in approval policies or regulations.

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

The FDA or other relevant regulatory agencies may not approve our product candidates for manufacture and sale, and any approval by the FDA does not ensure approval by other regulatory agencies or vice versa (which could require us to comply with numerous and varying regulatory requirements, possibly including additional clinical testing). Any product approvals we or our licensees achieve could also be withdrawn for failure to comply with regulatory standards or due to unforeseen problems after the products' marketing approval. In either case, marketing efforts with respect to the affected product would have to cease. In addition, the FDA or other regulatory agencies may impose limitations on the indicated uses for which a product may be marketed.

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

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

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

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

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

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

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

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

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

We have exclusively licensed certain of our controlled drug delivery technologies to Pfizer for certain ophthalmic applications. We have negotiated and continue to negotiate with Pfizer about potential amendments to the agreement, but we cannot predict whether or how that agreement will be amended. Pfizer may terminate the agreement without penalty at any time and for any reason upon 60 days' written notice. We have exclusively licensed our technology underlying Vitrasert and Retisert to Bausch & Lomb, which can terminate its agreement with us without penalty at any time upon 90 days' written notice. We have licensed the technology underlying Iluvien for DME and certain ophthalmic applications to Alimera. Alimera has 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 to develop or to commercialize any or all of the licensed products under their respective agreements, change strategic focus, pursue alternative technologies or develop competing products. While Pfizer and Bausch & Lomb have significant experience in the ophthalmic field and have substantial resources, there is no assurance whether, and to what extent, that experience and those resources will be devoted to our technologies. Alimera has limited experience, and if approved, Iluvien would be its first product. Because we do not currently have sufficient funding or internal capabilities to develop and commercialize our products and product candidates, decisions, actions, breach or termination of these agreements by Pfizer, Bausch & Lomb or Alimera could delay or stop the development or commercialization of any of the products or product candidates licensed to such entities.

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

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

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

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

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

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

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

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

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

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

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

Our success is dependent on whether we can obtain patents, defend our existing patents and operate without infringing on the proprietary rights of third parties. As of December 31, 2010, we had 168 patents and 164 pending patent applications, including patents and pending applications covering our Durasert, BioSilicon and CODRUG™ technologies. Intellectual property protection of our technologies is uncertain. We expect to seek to patent and protect our proprietary technologies. However, there is no assurance that any additional patents will be issued to us as a result of our pending or future patent applications or that any of our patents will withstand challenges by others. In addition, we may not have sufficient funds to patent and protect our proprietary technologies to the extent that we would desire, or at all. If we were determined to be infringing any third party patent, we could be required to pay damages, alter our products or processes, obtain licenses, pay royalties or cease certain operations. We may not be able to obtain any required licenses on commercially favorable terms, if at all. In addition, many foreign country laws may treat the protection of proprietary rights differently from, and may not protect our proprietary rights to the same extent as, laws in the United States and Patent Co-operation Treaty countries.

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

or licensed to us or to determine the scope and validity of third party proprietary rights. We may also be sued by one or more third parties alleging that we infringe their intellectual property rights. Any intellectual property litigation would be likely to result in substantial costs to us and diversion of our efforts, and could prevent or delay our discovery or development of product candidates. If our competitors claim technology also claimed by us, and if they prepare and file patent applications in the U.S. or other jurisdictions, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office or the appropriate foreign patent office to determine priority of invention, which could result in substantial cost to us and diversion of our efforts. Any such litigation or interference proceedings, regardless of the outcome, could be expensive and time consuming. Litigation could subject us to significant liabilities to third parties, requiring disputed rights to be licensed from third parties and/or requiring us to cease using certain technologies.

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

RISKS RELATED TO OUR BUSINESS, INDUSTRY, STRATEGY AND OPERATIONS

If we fail to retain 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 have a small number of employees and our products are unique and highly specialized, the loss of the services of one or more of the senior management or scientific staff, or the inability to attract and retain additional personnel and develop expertise as needed, could have a material adverse effect on our results of operations and financial condition.

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

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

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

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

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

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

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

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

There are a limited number of manufacturers that operate under cGMP regulations that are both capable of manufacturing our products and product candidates and are willing to do so. Failure by us, our collaborative partners, or our or their third-party manufacturers, to comply with applicable manufacturing requirements could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product, operating restrictions and criminal prosecutions. In addition, we or our collaborative partners may not be able to manufacture our product candidates successfully or have a third party manufacture them in a cost-effective manner. If we or our collaborative partners are unable to develop our own manufacturing facilities or to obtain or retain third-party manufacturing on acceptable terms, we may not be able to conduct certain future pre-clinical and clinical testing or to supply commercial quantities of our products.

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

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

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

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

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

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

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

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

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

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

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

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

The U.S. Food and Drug Administration Amendment Act of 2007 granted the FDA enhanced authority over products already approved for sale, including authority to require post-marketing studies and clinical trials, labeling changes based on new safety information and compliance with risk evaluations and mitigation strategies approved by the FDA. The FDA's exercise of this relatively new authority could result in delays and increased costs during product development, clinical trials and regulatory review and approval, increased costs following regulatory approval to assure compliance with new post-approval regulatory requirements, and potential restrictions on the sale or distribution of approved products following regulatory approval.

RISKS RELATED TO OUR COMMON STOCK

The price of our common stock may be volatile.

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

- clinical trial results and other product and technological developments and innovations;
- FDA and other governmental regulatory actions, receipt and timing of approvals of our (and our licensees') 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, amendment and termination of agreements, achievement of milestones and receipt of payments;
- the success of our collaborative partners in marketing any approved products and the amount and timing of the royalties payable to us;
- availability and cost of capital and our financial and operating results;
- changes in reimbursement policies or other practices relating to our product candidates or the pharmaceutical industry generally;
- meeting, exceeding or failing to meet analysts' or investors' expectations, and changes in evaluations and recommendations by securities analysts;
- economic, industry and market conditions, changes or trends; and
- other factors unrelated to us or the biotechnology industry.

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

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

As of December 31, 2010, we had outstanding approximately 10.3 million warrants and 2.9 million options to acquire shares of our common stock, or approximately 41.5% of our shares on a fully diluted basis. Certain of the options are subject to performance conditions, and the exercise prices of substantially all of these warrants and a small portion of the stock options were substantially above the market price at that date. 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. The overhang of outstanding 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 10.0% of our outstanding shares as of December 31, 2010 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.

Signature

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

PSIVIDA CORP.

Date: January 19, 2011

By: /s/ Lori Freedman
Name: Lori Freedman
Title: Vice President, Corporate Affairs, General Counsel and Secretary