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): December 23, 2009

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:

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

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

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

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

Section 8 — Other Events

Item 8.01. Other Events.

On December 23, 2009, pSivida's collaborative partner, Alimera Sciences, Inc. ("Alimera"), filed a Form S-1/A with the Securities & Exchange Commission which reported the 24 month results of the two Phase 3 pivotal clinical trials (FAME™ Study) for Iluvien® in the treatment of Diabetic Macular Edema. Alimera reported that based on these results, it plans to submit a New Drug Application (NDA) to the Food and Drug Administration (FDA) for approval of the low dose of Iluvien in the second quarter of 2010, followed by registration filings in various European countries and Canada; that it intends to request Priority Review of the NDA from the FDA; and that if Priority Review is granted, it can expect a response to its NDA from the FDA in the fourth quarter of 2010. The section of Alimera's Form S-1/A entitled "Business—Iluvien Clinical Development Program" and certain risk factors relating to the Iluvien clinical development program under "Risk Factors" are filed as Exhibit 99.1 to this report and incorporated herein by reference.

Section 9 — Financial Statements and Exhibits

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

The following Exhibit is filed with this report on Form 8-K:

No.	Description
99.1	"Business—Iluvien Clinical Development Program" and certain risk factors relating to the Iluvien clinical development program under "Risk Factors" from Form S-1/A of Alimera, Registration No. 333-162782, filed December 23, 2009.

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: December 23, 2009

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

Iluvien Clinical Development Program and certain risk factors relating to the Iluvien Clinical Development program from Form S-1/A of Alimera, Registration No. 333-162782, filed December 23, 2009

Iluvien Clinical Development Program

The following table summarizes current and planned clinical trials for Iluvien.

Population	Trial Name	Phase	Objectives	Geography	Number of Patients	Enrollment Status
DME	FAME Study (Trial A)	Phase 3	Safety Dosage Efficacy	Northern Regions of the U.S., Europe and India and all of Canada	481	Completed
DME	FAME Study (Trial B)	Phase 3	Safety Dosage Efficacy	Southern Regions of the U.S., Europe and India	475	Completed
DME	PK Study	Phase 2	Pharmaco-kinetics	U.S.	37	Completed
Dry AMD	MAP GA	Phase 2	Safety Dosage Proof of Concept	U.S.	40	On-going
Wet AMD	MAP	Phase 2	Safety Dosage Proof of Concept	U.S.	30	On-going
RVO	FAVOR	Phase 2	Safety Dosage Proof of Concept	U.S.	20	On-going

Development Program for the Treatment of DME

We are currently conducting two Phase 3 pivotal clinical trials (individually referred to as Trial A and Trial B, and collectively as our FAME Study) for Iluvien involving 956 patients in sites across the United States, Canada, Europe and India to assess the efficacy and safety of Iluvien in the treatment of DME. Combined enrollment was completed in October 2007, and the month 24 clinical readout from our FAME Study was received in December 2009. We believe that the month 24 data supports approval of the low dose of Iluvien for the treatment of DME. Therefore, we plan to proceed with the preparation of a registration dossier and to submit an NDA in the United States for the low dose of Iluvien to the FDA in the second quarter of 2010 with the month 24 clinical data, followed by registration filings in certain European countries and Canada.

Consistent with the FDA requirement for registration and approval of drugs being developed for diabetic retinopathy, including DME, the primary efficacy endpoint for our FAME Study is the difference in the percentage of patients whose best corrected visual acuity (BCVA) improved from baseline by 15 or more letters on the Early Treatment Diabetic Retinopathy Study (ETDRS) eye chart between the treatment and control groups at month 24. The ETDRS eye chart is the standard used in clinical trials for measuring sharpness of sight as established by the National Eye Institute's Early Treatment Diabetic Retinopathy Study. In addition, the FDA requires a numerical comparison of the percentage of patients with BCVA improvement of 15 or more letters between the month 24 and month 18 data to determine if the month 24 results are equal to or greater than the month 18 results. Patients enrolled in our FAME Study will be followed for 36 months. Although we will submit the additional 12 months of clinical data to applicable regulatory authorities, the approval of Iluvien by regulatory authorities, including the FDA, will be based on the month 24 clinical data from our FAME Study.

We believe that Iluvien meets the requirements for Priority Review in the United States and we intend to make a formal request for this review classification when we file our NDA with the FDA. Upon receipt, the FDA will notify us within 60 days of Iluvien's final review classification. In the European Union, we will be utilizing the

decentralized registration procedure. The Iluvien insertion system will not require a separate device application, but it must meet the safety and regulatory requirements of the applicable regulatory authorities when evaluated as part of the drug product marketing application.

FAME Study

We initiated our FAME Study in September 2005. Trial A and Trial B have identical protocols and completed enrollment in October 2007 with a total of 956 patients across 101 academic and private practice centers. Trial A drew patients from sites located in the northern regions of the United States, Europe and India and all sites in Canada, while sites in the southern regions of the United States, India and Europe comprise Trial B.

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

The following table describes the baseline characteristics of the patients randomized into our FAME Study.

	Trial A			Trial B		
	Control	Low Dose	High Dose	Control	Low Dose	High Dose
Number of Patients	95	190	196	90	186	199
Mean Age (years)	62.7	64.0	62.3	61.1	61.8	62.2
Mean Baseline Vision (letters)	54.8	53.4	52.5	54.7	53.3	53.3
Male/Female (percent)	50.5/49.5	57.9/42.1	60.2/39.8	66.7/33.3	56.5/43.5	63.8/36.2
Mean Time Since Diagnosis (years)						
Diabetes	16.5	17.4	16.5	16.3	16.8	15.9
DME	4.4	3.9	3.9	3.5	3.3	3.3

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

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

As part of our FAME Study, investigators were able to re-treat each patient with Iluvien following their month 12 follow up visit. Through month 24, 24.5% of patients had been treated with more than one Iluvien insert and 2.5% of patients had been treated with three or more Iluvien inserts.

Primary Efficacy Endpoint. The primary efficacy endpoint for our FAME Study is the difference in the percentage of patients with improved BCVA from baseline of 15 or more letters on the ETDRS eye chart at month 24 between the treatment and control groups. In December 2009, we received the month 24 clinical readout for our FAME Study and have analyzed the full data set consistent with the recommendations regarding the appropriate

population for primary analysis as described in the FDA-adopted International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Guidance E9, “Statistical Principles for Clinical Trials.” ICH is a joint initiative involving regulatory authorities and pharmaceutical industry representatives from Europe, Japan and the United States who discuss scientific and technical aspects of product registration.

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

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

Patients Gaining At Least 15 Letters At Month 24

	Trial A			Trial B		
Study Group	**Individuals**	**%**	**p-value**	**Individuals**	**%**	**p-value**
Control	14/95	14.7%	—	16/90	17.8%	—
Low Dose	51/190	26.8%	0.029	57/186	30.6%	0.030
High Dose	51/196	26.0%	0.034	62/199	31.2%	0.027

	Combined		
Study Group	**Individuals**	**%**	**p-value**
Control	30/185	16.2%	—
Low Dose	108/376	28.7%	0.002
High Dose	113/395	28.6%	0.002

Additionally, as required by the FDA, a numerical comparison of the responder rates at month 18 and month 24 in the Full Analysis Set demonstrated that the responder rates for both the low dose and high dose of Iluvien at month 24 were numerically greater than the month 18 responder rates in both Trial A and Trial B.

Based on these results, we plan to submit an NDA in the United States for the low dose of Iluvien in the second quarter of 2010, followed by registration filings in various European countries and Canada. We intend to request Priority Review of our NDA from the FDA. If Priority Review is granted, we can expect a response to our NDA from the FDA in the fourth quarter of 2010.

Our FAME Study protocol provides for analyses of additional data sets. The all-randomized and treated data set includes 953 patients randomized into our FAME Study and treated, with data imputation employed, using the LOCF method, for data missing because of patients who discontinued the trial or are unavailable for follow-up (the ART Data Set). Three patients who were randomized, but not treated, are included in the Full Data Set and excluded from the ART Data Set. In the ART Data Set, the primary efficacy endpoint was met with statistical significance for both doses of Iluvien in both Trial A and Trial B. The percentage of patients in the ART Data Set achieving improved BCVA of 15 or more letters at month 24 for Trial A is 14.7% for the control group, 26.8% for the low dose

(p-value 0.029) and 26.2% for the high dose (p-value 0.032). The percentage of patients in the ART Data Set achieving improved BCVA of 15 or more letters at month 24 for Trial B is 17.8% for the control group, 30.8% for the low dose (p-value 0.028) and 31.3% for the high dose (p-value 0.026).

The modified ART Data Set includes all 953 patients included in our ART Data Set and excludes data collected subsequent to the use of treatments prohibited by the protocol, such as Avastin, Lucentis, triamcinolone acetonide or vitrectomy (the Modified ART Data Set). In instances when a treatment prohibited by our FAME study protocol was used, the last observation prior to the protocol violation was imputed forward to month 24 using the LOCF method. The percentage of patients in the Modified ART Data Set achieving improved BCVA of 15 or more letters for Trial A is 12.6% for the control group, 22.6% for the low dose (p-value 0.057) and 24.1% for the high dose (p-value 0.026). Neither dose of Iluvien for Trial A was statistically significant based on the H-B procedure. The percentage of patients in the Modified ART Data Set achieving improved BCVA of 15 or more letters at month 24 for Trial B is 13.3% for the control group, 29.7% for the low dose (p-value 0.004) and 29.3% for the high dose (p-value 0.005). Both doses of Iluvien for Trial B were statistically significant.

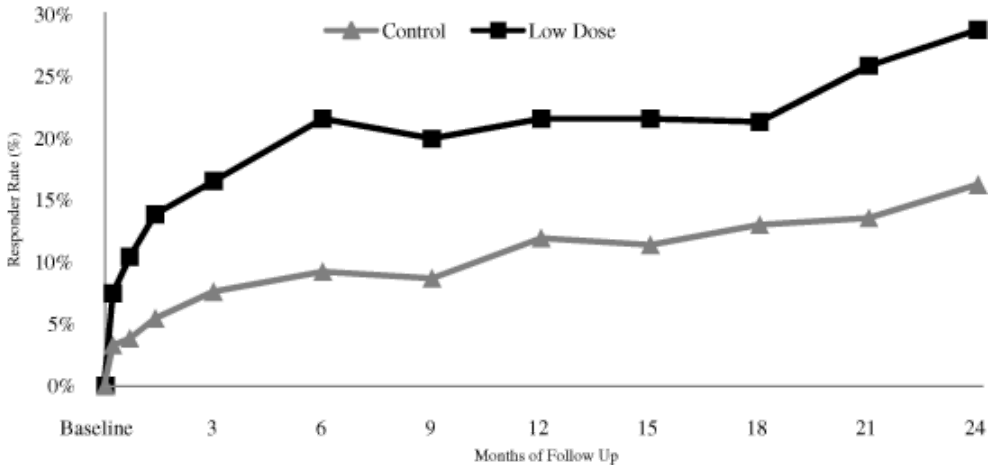
Our FAME Study protocol provides that the primary assessment of efficacy is based on the Modified ART Data Set and that other data sets are considered secondary. The protocol did not specify the Full Analysis Set as a data set for analyzing the study; however, consistent with the recommendations regarding the appropriate population for primary analysis as described in the FDA-adopted ICH Guidance E9, we believe that the FDA will consider the Full Analysis Set to be the most relevant data set for determining the safety and efficacy of Iluvien in Trials A and B.

Additional Clinical Observations. In addition to the primary efficacy variable, we also observed a number of other clinically relevant results in the month 24 clinical data from our FAME Study. These observations included, among others, the following:

- patients with improved BCVA of 15 or more letters at each follow up visit;
- patients with improved BCVA of 15 or more letters at any time point;
- other levels of BCVA improvement at month 24;
- BCVA improvement of 15 or more letters relative to baseline BCVA; and
- decrease in excess foveal thickness.

The analyses of these Full Analysis Set observations set forth below are presented for Trial A and Trial B on a combined basis for patients who received the low dose of Iluvien in comparison to the control group.

Patients With Improved BCVA of 15 Letters or More at Each Follow Up Visit. Our analysis of the results of the FAME Study through month 24 indicates that the low dose of Iluvien provides an improvement in BCVA as early as three weeks after insertion. The low dose of Iluvien was statistically significantly better than the control group in our FAME Study by week 3 of patient follow up, and maintained a statistically significant advantage over the control through month 24. The chart below demonstrates the treatment effect of the low dose of Iluvien versus the control group, as measured by an improvement in BCVA of 15 letters or more, at each scheduled follow up visit during the FAME Study.



Patients With Improved BCVA of 15 or More Letters at Any Time Point. Our analysis of the results of the FAME Study through month 24 indicates that a significantly greater percentage of patients receiving the low dose of Iluvien versus the control group had an improvement in BCVA of 15 letters or more when assessed at any follow up visit. During the first 24 months of the FAME Study, 177 out of 376 patients randomized to receive the low dose of Iluvien, or 47.1%, demonstrated improved BCVA of 15 letters or more at any time point compared to 51 out of 185 patients, or 27.6%, randomized to the control group.

Other Levels of BCVA Improvement at Month 24. While the FDA's requirement for the registration and approval of drugs being developed for DME is that the primary efficacy variable be based on an improvement in BCVA of 15 letters or more, lesser degrees of improvement in BCVA are considered clinically significant. The table below demonstrates the low dose of Iluvien's statistically significant improvements in BCVA versus the control group at month 24 of our FAME Study.

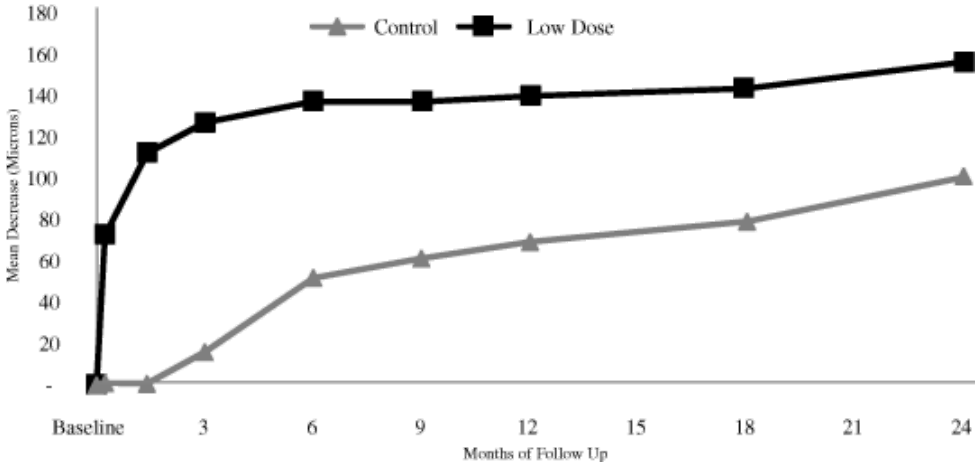
	Trial A & Trial B Combined		
BCVA Improvement	**Control**	**Low Dose**	**p-value**
[3] **1 letter**	54.1%	66.8%	0.005
[3] **5 letters**	40.0%	52.1%	0.010
[3] **10 letters**	26.5%	38.3%	0.009

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

	Trial A & Trial B Combined		
Baseline BCVA	**Control**	**Low Dose**	**p-value**
Greater Than 49 Letters	11.8%	21.1%	0.027
49 Letters or Less	28.6%	46.1%	0.039

Decrease In Excess Foveal Thickness. In addition to the functional measures of BCVA, we assessed the effect of Iluvien using an anatomic measure, namely the decrease in excess foveal thickness as determined by optical coherence tomography. Excess foveal thickness is a measurement of the swelling of the macula at its center point (known as the fovea). We consider any measurement above 180 microns to represent excess foveal thickness. Based on a review of the month 24 clinical readout as summarized in the chart below, patients receiving the low dose

of Iluvien demonstrated a statistically significant difference versus the control group in decreasing excess foveal thickness by week 1 of patient follow up of our FAME Study, and maintain a statistically significant advantage through month 24. At month 24, patients receiving the low dose of Iluvien demonstrated a mean decrease in excess foveal thickness of 156.1 microns versus 100.5 microns for the control group.



Safety. Iluvien was well tolerated through month 24 of our FAME Study in both the low and high dose patient populations. Our preliminary assessment of adverse event data indicates that there is no apparent risk of systemic adverse events to patients as a result of the use of Iluvien. The use of corticosteroids in the eye is primarily associated with two undesirable side effects: increased IOP, which may increase the risk of glaucoma and require additional procedures to manage, and cataract formation. Excluding IOP related side effects and cataracts, we observed no significant eye related adverse events when comparing both the low dose and high dose patient populations to control. Thus, based on the month 24 clinical readout from our FAME Study, we believe that the adverse events associated with the use of Iluvien are within the acceptable limits of a drug for the treatment of DME.

The table below summarizes the IOP related adverse events occurring in all patients randomized and treated in our FAME Study.

	Trial A & Trial B Combined		
	Control N=185	**Low Dose N=375**	**High Dose N=393**
IOP > 30 mmHg(1)	2.7%	16.3%	21.6%
Trabeculoplasty	0.0%	1.3%	2.5%
IOP-Lowering Surgeries			
Trabeculectomy (filtration)	0.0%	2.1%	5.1%
Vitrectomy	0.0%	0.3%	0.5%
Other Surgery Performed	0.5%	1.3%	2.5%
Percentage of Patients Requiring One or More IOP-Lowering Surgeries	0.5%	3.5%	7.4%

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

According to the CDC, diabetic individuals aged 50 or older are 1.5 times more likely to develop cataracts than non-diabetic individuals. A review of the baseline characteristics of our patient population reflects this increased risk of cataracts for diabetic patients, with 34.3% of the patients randomized into our FAME Study having previously undergone a cataract surgery in the study eye. The month 24 clinical readout from our FAME Study

demonstrated that of the patients who had a natural lens (no prior cataract surgery) at baseline, 43.6% of the control group, 80.0% of the low dose and 87.5% of the high dose had cataract formation reported as an adverse event. Additionally, of the patients who had a natural lens at baseline, 23.1% of the control group, 74.9% of the low dose and 84.5% of the high dose underwent cataract surgery.

PK Study

We initiated an open-label Phase 2 human pharmacokinetic clinical study (PK Study) in August 2007 to assess the systemic exposure of FA by measuring plasma levels of FA. Analysis of plasma levels through month 18 in September 2009 demonstrated no systemic exposure of FA (plasma levels were below the limit of detection of 100 picograms per milliliter). Based on these results, we intend to file a carcinogenicity waiver with the applicable regulatory authorities, including with the FDA in connection with our NDA submission.

A total of 37 patients were enrolled in the PK Study, 17 patients on the high dose of Iluvien and 20 patients on the low dose of Iluvien. The last patient was enrolled in the study at the end of February 2008. Data from the PK Study are being evaluated on an ongoing basis with interim evaluations at months 3, 6, 12, 18, 24, 30 and 36.

Risks Related to Our Business and Industry

We are heavily dependent on the success of our lead product candidate, Iluvien, which is still under development. If we are unable to commercialize Iluvien, or experience significant delays in doing so, our business will be materially harmed.

We have invested a significant portion of our time and financial resources in the development of Iluvien, our only product candidate in clinical development. We anticipate that in the near term our ability to generate revenues will depend solely on the successful development and commercialization of Iluvien. Based on our analysis of the month 24 clinical readout from our Phase 3 pivotal clinical trials for the use of Iluvien in the treatment of diabetic macular edema, or DME (collectively, our FAME Study), we plan to file a New Drug Application (NDA) for the low dose of Iluvien in the United States in the second quarter of 2010, followed by registration filings in certain European countries and Canada. However, we may not complete our registration filings in our anticipated time frame. Even after we complete our NDA filing, the U.S. Food and Drug Administration (FDA) may not accept our submission, may request additional information from us, including data from additional clinical trials, and, ultimately, may not grant marketing approval for Iluvien. In addition, although we believe the month 24 clinical readout from our FAME Study demonstrates that Iluvien is effective in the treatment of DME, clinical data often is susceptible to varying interpretations and many companies that have believed that their products performed satisfactorily in clinical trials have nonetheless failed to obtain FDA approval for their products.

If we are not successful in commercializing Iluvien, or are significantly delayed in doing so, our business will be materially harmed and we may need to curtail or cease operations. Our ability to successfully commercialize Iluvien will depend, among other things, on our ability to:

- successfully complete our clinical trials;
- produce, through a validated process, batches of Iluvien in quantities sufficiently large to permit successful commercialization;
- receive marketing approvals from the FDA and similar foreign regulatory authorities;
- establish commercial manufacturing arrangements with third-party manufacturers;
- launch commercial sales of Iluvien; and
- secure acceptance of Iluvien in the medical community and with third-party payors.

We face heavy government regulation, and approval of Iluvien and our other product candidates from the FDA and from similar entities in other countries is uncertain.

The research, testing, manufacturing and marketing of drug products are subject to extensive regulation by U.S. federal, state and local government authorities, including the FDA, and similar entities in other countries. To

obtain regulatory approval of a product, we must demonstrate to the satisfaction of the regulatory agencies that, among other things, the product is safe and effective for its intended use. In addition, we must show that the manufacturing facilities used to produce the products are in compliance with current Good Manufacturing Practice (cGMP) regulations.

The process of obtaining regulatory approvals and clearances will require us to expend substantial time and capital. Despite the time and expense incurred, regulatory approval is never guaranteed. The number of preclinical and clinical tests that will be required for regulatory approval varies depending on the drug candidate, the disease or condition for which the drug candidate is in development and the regulations applicable to that particular drug candidate. Regulatory agencies, including those in the United States, Canada, the European Union and other countries where drugs are regulated, can delay, limit or deny approval of a drug candidate for many reasons, including that:

- a drug candidate may not be safe or effective;
- regulatory agencies may interpret data from preclinical and clinical testing in different ways from those which we do;
- they may not approve of our manufacturing process;
- they may conclude that the drug candidate does not meet quality standards for stability, quality, purity and potency; and
- they may change their approval policies or adopt new regulations.

The FDA may make requests or suggestions regarding conduct of our clinical trials, resulting in an increased risk of difficulties or delays in obtaining regulatory approval in the United States. For example, the FDA may object to the use of a sham injection in our control arm or may not approve of certain of our methods for analyzing our trial data, including how we evaluate the risk/benefit relationship. Further, we intend to market Iluvien, and may market other product candidates, outside the United States and specifically in the European Union and Canada. Regulatory agencies within these countries will require that we obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedures within these countries can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Additionally, the foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. For all of these reasons, we may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or jurisdictions or by the FDA.

We plan to submit an NDA in the United States for the low dose of Iluvien in the second quarter of 2010 with 24 months of clinical data from our FAME study, followed by registration filings in certain European countries and Canada. Consistent with recommendations regarding the appropriate population for primary analysis as described in the FDA-adopted International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Guidance E9, “Statistical Principals for Clinical Trials,” we believe that the FDA will consider the most relevant population for determining safety and efficacy to be the full data set of all 956 patients randomized into our FAME Study, with data imputation employed using “last observation carried forward,” for data missing because of patients who discontinued the trial or are unavailable for follow-up (the Full Analysis Set). The primary efficacy endpoint was met with statistical significance for both the low dose and the high dose of Iluvien in both trials using the Full Analysis Set and we intend to submit an analysis based on this data set for the low dose to the FDA. However, our FAME Study protocol did not include the Full Analysis Set and provides that the primary assessment of efficacy will be based on another data set that excludes from the Full Analysis Set three patients who were enrolled but never treated as well as data collected for patients subsequent to their use of treatments prohibited by our FAME Study protocol (the Modified ART Data Set). Statistical significance was not achieved for either the low dose or the high dose in one trial using the Modified ART Data Set. There is no assurance that 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, which could result in the FDA not granting marketing approval for Iluvien.

In addition, although we expect to obtain a waiver from regulatory agencies for the requirement to perform a carcinogenicity study in animals, this waiver is dependent upon our demonstration of negligible systemic absorption exposure of the active fluocinolone acetonide (FA) in our open-label Phase 2 human pharmacokinetic clinical study (PK Study) which we may not be able to demonstrate beyond month 18. Carcinogenicity studies identify a tumorigenic potential in animals and are used to assess the relevant risk in humans.

Any delay or failure by us to obtain regulatory approvals for our product candidates could diminish competitive advantages that we may attain and would adversely affect the marketing of our products. We have not yet received regulatory approval to market any of our product candidates in any jurisdiction.

Iluvien utilizes FA, a corticosteroid that has demonstrated undesirable side effects in the eye; therefore, the success of Iluvien will be dependent upon the achievement of an appropriate relationship between the benefits of its efficacy and the risks of its side-effect profile.

The use of corticosteroids in the eye has been associated with undesirable side effects, including increased incidence of intraocular pressure (IOP), which may increase the risk of glaucoma, and cataract formation. We have received only the month 24 clinical readout from our FAME Study and the extent of Iluvien's long-term side effect profile is not yet known. Upon review of our NDA for the low dose of Iluvien in the treatment of DME, the FDA may conclude that our 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, we may not receive regulatory approval from the FDA or from similar regulatory agencies in other countries.

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

Regulatory agencies generally approve products for particular indications. If any such regulatory agency approves Iluvien for a limited indication, the size of our potential market for Iluvien will be reduced. For example, our potential market for Iluvien would be reduced if the FDA limited the indications of use to patients diagnosed with only clinically significant DME as opposed to DME or restricted the use to patients exhibiting IOP below a certain level at the time of treatment. 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 in the United States by the FDA and by similar entities in other countries. We will need to comply with facility registration and product listing requirements of the FDA and similar entities in other countries and adhere to the FDA's Quality System Regulations. Noncompliance with applicable FDA and similar entities' requirements can 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. We would also need to maintain compliance with federal, state and foreign laws regarding sales incentives, referrals and other programs.

Iluvien may not be granted Priority Review by the FDA and, even if Iluvien receives Priority Review, Iluvien may not receive approval within the six-month review/approval cycle.

We believe that Iluvien may be eligible for Priority Review under FDA procedures. We will request Priority Review for Iluvien at the time we submit our NDA. Although the FDA has granted Priority Review to other products that treat retinal disease (including Visudyne, Retisert, Macugen, Lucentis and Ozurdex), Iluvien may not receive similar consideration. However, even in the event that Iluvien is designated for Priority Review, such a designation does not necessarily mean a faster regulatory review process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving Priority Review from the FDA does not guarantee approval within the six-month review/approval cycle.