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

Form 10-K

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

For the Fiscal Year Ended December 31, 2008

OR

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

For the Transition period from _____ to _____
Commission file number: 001-32836

Medivation, Inc.

(Exact name of Registrant as specified in its charter)

SEC
Mail Processing
Section

MAY 12 2009



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Delaware

(State or other jurisdiction of incorporation or organization)

13-3863260

(I.R.S. Employer Identification No.)

Washington, DC
100

201 Spear Street, 3rd Floor

San Francisco, California 94105

(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (415) 543-3470

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

Title of Each Class

Name of Each Exchange on Which Registered

Common Stock, par value \$0.01 per share

Nasdaq Global Market

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

(Title of Class)

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

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

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

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

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

Large accelerated filer Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company

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

The aggregate market value of the voting stock held by non-affiliates of the Registrant was approximately \$188,796,047 as of June 30, 2008, based upon the closing sale price on the Nasdaq Global Market reported on June 30, 2008.

There were 30,106,723 shares of Registrant's Common Stock issued and outstanding as of February 28, 2009.

DOCUMENTS INCORPORATED BY REFERENCE

Items 10, 11, 12, 13 and 14 of Part III of this Annual Report on Form 10-K incorporate information by reference from the definitive proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A, no later than 120 day after the end of the fiscal year covered by this Annual Report on Form 10-K, for the Registrant's 2009 Annual Meeting of Stockholders. Except with respect to the information specifically incorporated by reference in this Annual Report on Form 10-K, the Registrant's proxy statement is not deemed to be filed as part hereof.

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MEDIVATION, INC.
2008 ANNUAL REPORT ON FORM 10-K

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K includes forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, or the Exchange Act. All statements other than statements of historical facts contained in this Annual Report on Form 10-K, including statements regarding our anticipated future clinical and regulatory milestone events, future financial position, business strategy and plans and objectives of management for future operations, are forward-looking statements. The words “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “expect” and similar expressions, as they relate to us, are intended to identify forward-looking statements. Such forward-looking statements include, without limitation, statements regarding the anticipated start dates, durations and completion dates of our ongoing and future clinical studies, statements regarding the anticipated designs of our future clinical studies, statements regarding our anticipated future regulatory submissions and statements regarding our anticipated future cash position. We have based these forward-looking statements largely on our current expectations and projections about future events, including the responses we expect from the U.S. Food and Drug Administration, or FDA, and other regulatory authorities and financial trends that we believe may affect our financial condition, results of operations, business strategy, preclinical and clinical trials and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions including without limitation the risks described in “Risk Factors” in Part I, Item 1A of this Annual Report on Form 10-K. These risks are not exhaustive. Other sections of this Annual Report on Form 10-K include additional factors which could adversely impact our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. You should not rely upon forward-looking statements as predictions of future events. We cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. We assume no obligation to update or supplement forward-looking statements.

PART I

Item 1. Description of Business.

The Company

We are a biopharmaceutical company focused on the rapid development of novel small molecule drugs to treat serious diseases for which there are limited treatment options. Our current lead clinical candidates are directed at treating Alzheimer's disease, Huntington's disease and castration-resistant prostate cancer. Our Alzheimer's and Huntington's disease programs are partnered with Pfizer Inc, or Pfizer, and our prostate cancer program remains unpartnered. With Pfizer, we are conducting a broad Dimebon clinical development program, including a pivotal and confirmatory Phase 3 trial in patients with mild-to-moderate Alzheimer's disease. The program also includes additional Phase 3 trials beginning this year in both Alzheimer's disease and Huntington's disease. In addition, we are conducting a Phase 1-2 clinical trial of MDV3100 in patients with castration-resistant (also known as hormone-refractory) prostate cancer, and plan to seek FDA approval to begin a Phase 3 trial this year.

In September 2008, we announced a Collaboration Agreement with Pfizer, which became effective on October 21, 2008. Under the terms of the agreement, we and Pfizer will develop and commercialize Dimebon, our investigational drug for treatment of Alzheimer's disease and Huntington's disease. We and Pfizer will share the costs and expenses of developing and commercializing Dimebon for the United States market on a 60% Pfizer/40% Medivation basis, and will share profits (or losses) resulting from commercialization of Dimebon in the United States in the same proportions. Outside the United States, Pfizer will bear all development and commercialization costs, and will pay us tiered royalties on aggregate net sales of Dimebon. In October 2008, we received a non-refundable, up-front cash payment of \$225.0 million pursuant to our Collaboration Agreement with Pfizer.

In the fourth quarter of 2008, we recognized \$12.6 million in collaboration revenue attributable to our up-front payment from Pfizer. Previously we had not recognized any revenue. We have funded our operations primarily through private and public offerings of our common stock, and from the up-front payment and cost-sharing payments from our Collaboration Agreement with Pfizer. As of December 31, 2008, we had an accumulated deficit of \$122.7 million and expect to incur substantial and increasing additional losses in the future as we expand our research and development activities.

Our Pipeline

Dimebon in Alzheimer's Disease and Huntington's Disease. Our lead product candidate, Dimebon, has successfully completed the first of two pivotal trials required to seek marketing approval in the United States for mild-to-moderate Alzheimer's disease. In January 2008, the U.S. Food and Drug Administration, or FDA, informed us that this study can be used as one of the pivotal studies required to support the approval of Dimebon to treat mild-to-moderate Alzheimer's disease, as long as a significant proportion of the sites in the confirmatory Phase 3 trial are located in the United States. However, as is typically the case at this stage of the regulatory review process, the FDA has not yet performed an in-depth review of our preclinical and clinical data, so its views remain subject to change. In June 2008, we commenced a second confirmatory Phase 3 clinical trial in patients with mild-to-moderate Alzheimer's disease, which we refer to as the CONNECTION trial. We expect to complete enrollment of this trial in 2009.

We are also studying Dimebon to treat patients with mild-to-moderate Huntington's disease. In July 2008, we announced top-line results of a Phase 2 study showing that Dimebon was well tolerated and significantly improved cognitive function in patients with mild-to-moderate Huntington's disease compared to those treated with a placebo. The study met its primary endpoint of safety and tolerability; in addition, Dimebon showed statistically significant benefit versus placebo in cognition as measured by the Mini-Mental State Examination, or MMSE, a secondary endpoint in the study. Huntington's disease is a progressive neurodegenerative disease

characterized by the gradual development of involuntary muscle movement, progressive deterioration of cognitive processes and memory and severe behavioral disturbances. There are currently no approved drugs in the United States to treat the cognitive impairment of this uniformly fatal genetic disorder. In January 2009, we held an end-of-Phase 2 meeting at which the FDA informed us that we could begin a Phase 3 trial of Dimebon in patients with Huntington's disease using the MMSE and the Clinician's Interview-based Impression of Change, plus caregiver input, or CIBIC-plus, as co-primary endpoints. Medivation intends to begin a Phase 3 Huntington's disease study in 2009.

MDV3100 in Castration-Resistant Prostate Cancer. Our proprietary compound MDV3100, a novel androgen receptor antagonist, is currently being evaluated in a Phase 1-2 clinical trial in 140 patients with castration-resistant prostate cancer. We intend to seek approval from the FDA to advance MDV3100 into Phase 3 clinical trials in 2009. In February 2009, we announced the presentation of new efficacy and safety data from this trial covering all 114 patients who had been followed for 12 weeks or longer as of January 2009. In these patients, MDV3100 consistently demonstrated encouraging anti-tumor activity across dose levels and endpoints. MDV3100 is the lead clinical development candidate from a library of approximately 170 small molecules licensed by us. These molecules were rationally designed to treat castration-resistant prostate cancer by modulating the androgen receptor, or AR, in a different manner from currently approved AR antagonist drugs, which generally are ineffective in treating prostate cancers that have become castration-resistant.

New Product Candidates. We remain actively engaged in identifying new product candidates to further expand our pipeline. Our internal pipeline expansion efforts are focused on the development of novel second generation Dimebon analogs.

Our Corporate Structure

We have formed separate subsidiaries to hold the product candidates we are developing. Our subsidiary Medivation Neurology, Inc. holds our Dimebon technology, and our subsidiary Medivation Prostate Therapeutics, Inc. holds our MDV300 series technology. Our subsidiary Medivation Technologies, Inc. holds our technologies that have not yet entered clinical development.

Our History

We are a corporation formed in Delaware in October 1995, under our former name Orion Acquisition Corp. II, to identify and consummate a business combination. Medivation Neurology, Inc. was formed in Delaware in September 2003 to acquire and develop Dimebon. On December 17, 2004, Medivation Neurology, Inc. became our subsidiary pursuant to a merger. Medivation Prostate Therapeutics, Inc. was formed in Delaware as our subsidiary to acquire and develop our MDV300 series technology.

Our Dimebon Program

Potential Neuroprotective Activity

In preclinical experiments, Dimebon demonstrated neuroprotective activity in models relevant to Alzheimer's disease and Huntington's disease. The β -amyloid protein is a known neurotoxin that is widely believed to contribute to the neurofibrillary tangles and plaques that characterize Alzheimer's disease. When neurons are exposed to the β -amyloid protein in vitro, a significant portion of them die. Dimebon has been shown to inhibit this β -amyloid induced neuron death in vitro. In addition, in a transgenic *Drosophila* (fruit fly) model of Huntington's disease, Dimebon has been shown to protect photoreceptor neurons against death induced by the human gene encoding the huntingtin protein, an abnormal protein widely believed to cause Huntington's disease.

Mechanism of Action

We believe that Dimebon is exerting its activity through a novel mechanism of action involving enhancement of mitochondrial function. Mitochondria are intracellular structures that are responsible for

generating energy within all cells and play important roles in mediating brain cell function and survival. Mitochondrial dysfunction has been linked in the published literature to both Alzheimer's and Huntington's diseases. In addition, autopsy studies of brains from patients with Alzheimer's disease suggest that mitochondrial damage and synapse dysfunction are early cellular events in Alzheimer's disease development and progression.

In July 2008, we presented new preclinical data on Dimebon's novel mitochondrial mechanism of action. These data showed that Dimebon improves mitochondrial function in the setting of cellular stress with very high potency. For example, Dimebon treatment improved mitochondrial function and increased the number of surviving cells in a dose-dependent fashion after treatment with a cell toxin known as ionomycin.

In December 2008, we announced preclinical data that demonstrated that Dimebon impacted two key aspects of brain cell function: promotion of neurite outgrowth and preservation of mitochondrial function after brain cells were challenged with beta amyloid, a toxic substance often associated with Alzheimer's disease and the loss of brain cells. Results of the study showed that Dimebon induced a statistically significant increase in neurite outgrowth from cortical, hippocampal and spinal cord neurons. Dimebon's potent effect on neurite outgrowth was seen at low concentrations and was comparable to that achieved with maximally effective concentrations of a potent naturally occurring protein that is known to enhance brain cell function (Brain Derived Neurotrophic Factor). Study results also showed that Dimebon reduced mitochondrial impairment in the setting of cellular stress. Specifically, Dimebon treatment mitigated mitochondrial impairment induced by beta amyloid.

In addition, we believe based on preclinical data that Dimebon works through a different mechanism of action than other drugs that focus on targets implicated in cognition and memory loss, such as cholinesterase inhibition. In these preclinical experiments, Dimebon was shown to be a weak cholinesterase inhibitor, and additional data from binding assays showed that Dimebon did not have strong affinity to other standard targets. This suggests that Dimebon's potential novel mitochondrial mechanism of action may account for the clinical benefit observed in the Dimebon Alzheimer's and Huntington's disease clinical trials completed to date.

First Clinical Indication—Alzheimer's Disease

Alzheimer's Disease

Alzheimer's disease, the leading cause of dementia, is characterized by the progressive loss of memory, thinking and ability to perform activities of daily living (bathing, feeding, self-care, etc.), as well as significant behavioral disturbances (agitation, aggression, delusions, hallucinations, etc). There is currently no cure. According to the Alzheimer's Association and the American Health Assistance Foundation:

- Alzheimer's disease currently affects approximately 5.2 million people in the U.S., including as many as 13% of people aged 65 and older and approximately 50% of those aged 85 and older.
- Worldwide, Alzheimer's disease affects 26 million people, and that number is expected to reach 106 million by 2050.
- There are approximately 400,000 new diagnoses of Alzheimer's disease, and approximately 72,000 Alzheimer's disease deaths, per year in the U.S.
- Following initial diagnosis, patients live four to six years on average, but may live up to 20 years with the disease.
- Total annual expenditures on Alzheimer's disease in the U.S. exceed \$148 billion annually, and the average lifetime cost per Alzheimer's disease patient is \$174,000.

There are only four commonly-used drugs that the FDA has approved for the treatment of Alzheimer's disease. Although the precise mechanism of action of these four drugs is unknown, three of them are believed to inhibit cholinesterase, and one is believed to inhibit the NMDA-receptor. These four drugs and their respective

marketers, FDA approval dates (as listed in the FDA's on-line edition of its Orange Book) and postulated mechanisms of action (as appearing in the package inserts for these drugs) are set forth in the following table.

<u>Drug (Trade Name/Generic)</u>	<u>Marketed by</u>	<u>FDA Approval Date</u>	<u>Postulated Mechanism</u>
Aricept® (donepezil)	Pfizer Inc./Eisai Co., Ltd.	November 25, 1996	Cholinesterase inhibition
Exelon® (rivastigmine)	Novartis AG	April 21, 2000	Cholinesterase inhibition
Razadyne® (galantamine)	Johnson & Johnson	February 28, 2001	Cholinesterase inhibition
Namenda® (memantine)	Forest Laboratories, Inc.	October 16, 2003	NMDA-receptor inhibition

According to IMS Health, the worldwide market for Alzheimer's disease therapies currently exceeds \$5 billion, with the largest selling cholinesterase inhibitor, Aricept, generating more than half of those sales, followed by Forest Laboratories, Inc.'s NMDA-receptor antagonist Namenda. In 2008, the first generic equivalent, galantamine, entered the market. Further generic entrants are expected as the remaining branded drugs lose patent protection in the United States and Europe between 2010 and 2015.

First Pivotal Clinical Trial

We completed our first pivotal Alzheimer's disease trial in 2007. This randomized, double-blinded, placebo-controlled clinical trial enrolled 183 patients with mild-to-moderate Alzheimer's disease at 11 sites in Russia. Patients were randomized to two treatment groups—one of which received Dimebon three times per day and the other of which received placebo—and were not permitted to take any other Alzheimer's disease drugs during the trial. We used five widely-accepted clinical endpoints in this trial to assess Dimebon's effects on all of the primary aspects of Alzheimer's disease—memory, thinking, activities of daily living (bathing, feeding, self-care, etc), behavior (agitation, aggression, delusions, hallucinations, etc.) and overall clinical function. Patients were treated for six months, and those who completed the initial six months of treatment were offered the opportunity to continue treatment for an additional six months on a blinded basis in the same treatment group to which they originally were randomized.

Dimebon caused statistically significant improvement over placebo on all five clinical endpoints after six months and a full year of treatment. Particularly high levels of statistical significance were achieved after both six months and a full year of treatment on both of the two endpoints used by the FDA to approve drugs for mild-to-moderate Alzheimer's disease—the Alzheimer's Disease Assessment Scale-cognitive subscale, or ADAS-cog, ($p < 0.0001$ at both six months and one year) and the Clinician's Interview-based Impression of Change-plus caregiver input, or CIBIC-plus, ($p < 0.0001$ at six months and $p = 0.006$ at one year). These levels of significance are many times better than that required to obtain marketing approval ($p < 0.05$). Dimebon's benefits over placebo were seen very quickly after treatment began, reaching statistical significance on four of the five clinical endpoints, including both the ADAS-cog and the CIBIC-plus, after only twelve weeks of therapy. Compared to their starting scores at the beginning of the trial, Dimebon-treated patients were significantly better on all five endpoints after six months of treatment and remained stabilized on all five clinical endpoints after a full year of treatment. By contrast, scores of the placebo-treated patients declined from their starting levels on all five endpoints after both six months and a full year of treatment. The overall benefit seen in Dimebon-treated patients compared to placebo-treated patients continued to increase in magnitude over the course of the trial. The mean drug-placebo difference on the ADAS-cog increased from 4.0 points at six months to 6.9 points at one year, while that on the CIBIC-plus increased from 0.6 points at six months to 0.8 points at one year. The clinical relevance of these data was evaluated by independent assessment, including caregiver input, which confirmed improvement or stabilization in 81% and 70% of Dimebon-treated patients after six months and a full year of treatment, respectively.

Dimebon was well tolerated throughout the entire one year treatment period. There were fewer serious adverse events in Dimebon-treated patients than in placebo-treated patients after both six months and a full year of treatment, and this difference reached statistical significance after one year of treatment ($p = 0.03$). The most

frequently occurring adverse events in the Dimebon-treated patients were dry mouth (13.5% and 18.0% incidence after six months and one year of treatment, respectively) and depression/depressed mood (13.5% and 14.6% incidence after six months and one year of treatment, respectively). Depression/depressed mood reflected reports from patients and their caregivers, not clinical diagnoses of depression. The reported depression/depressed mood was generally mild and did not cause any of the affected patients to discontinue participation in the trial. Nausea, vomiting and diarrhea, the most prevalent side effects associated with the currently marketed Alzheimer's disease drugs, occurred in fewer than 3% of the Dimebon-treated patients after both six months and one year of treatment.

We are not aware of any other published Alzheimer's disease study in which a drug has achieved statistically significant benefits of the breadth, size and duration of those seen in our first pivotal clinical trial of Dimebon. The data from this trial were published in the July 19, 2008 issue of *The Lancet*.

In January 2008, the FDA informed us that this trial can be used as one of the two pivotal studies required to support the approval of Dimebon to treat mild-to-moderate Alzheimer's disease, as long as a significant portion of the sites in our confirmatory pivotal Phase 3 trial are located in the United States. However, as is typically the case at this stage of the regulatory review process, the FDA has not yet performed an in-depth review of our preclinical and clinical data, so its views remain subject to change.

We offered all patients in this trial who completed a full year of treatment, including placebo patients, the opportunity to receive Dimebon on an open-label basis for at least an additional six months (for a total duration of treatment of at least 18 months). In July 2008, we announced data from this six-month open-label extension, which demonstrated that Dimebon continued to improve the clinical course of patients' disease. After 18 months of treatment, Dimebon preserved function in patients at or near their original levels upon entering the trial across all key aspects of Alzheimer's disease, specifically memory and thinking, behavior, activities of daily living and overall function. These results are noteworthy as untreated Alzheimer's patients progressively deteriorate over time in these areas. Dimebon remained well tolerated throughout the 18-month treatment period. We also announced new data from subgroup analyses by disease severity of the Dimebon double-blind placebo-controlled trial showing that Dimebon benefited both mild and moderate patients. In both mild and moderate patients, Dimebon treatment resulted in significant benefit on the study's primary endpoint, the ADAS-cog. The benefit in the moderate subpopulation was particularly robust, with a 9.7 point drug-placebo difference on the ADAS-cog ($p < 0.0001$) after 12 months of treatment.

Patients originally on placebo for 12 months who were then crossed over to Dimebon in the open-label extension phase stabilized across all key measures tested. Since these patients had declined over the previous 12 months while on placebo, they generally stabilized at a lower level of function than those treated with Dimebon for the full 18 months, suggesting a benefit of earlier treatment. Because there was no placebo-control in the open-label extension, direct comparisons versus placebo cannot be made.

Confirmatory Pivotal Phase 3 Clinical Trial – The CONNECTION Trial

We have commenced a second pivotal Phase 3 Alzheimer's disease clinical trial, known as the CONNECTION trial, to confirm the results seen in our first pivotal trial. The CONNECTION trial will enroll approximately 525 patients with mild-to-moderate Alzheimer's disease at approximately 60 sites in the United States, Europe and South America. Patients will be randomized to one of three treatment groups: Dimebon 20 mg three times per day (the same dose of Dimebon studied in our first pivotal trial), Dimebon 5 mg three times per day or placebo. Patients will be treated for six months and may not be taking any other Alzheimer's disease drugs during the trial. After completing six months of treatment, all patients—including placebo patients—will be offered the opportunity to receive Dimebon in an open-label extension of at least six months. The primary endpoints in the CONNECTION trial are the ADAS-cog and the CIBIC-plus. These are the two endpoints that have been accepted by the FDA to support registration of all approved drugs for mild-to-moderate Alzheimer's disease. We expect to complete enrollment in the CONNECTION trial in 2009. However, we caution you that

this is a forward-looking statement, and is subject to significant risk and uncertainty, including the risk that we may not be able to enroll patients into a monotherapy trial as quickly as we anticipate or in the numbers that we require.

Additional Phase 3 Clinical Trials

In November 2008, we announced that we and Pfizer are working together on an expanded clinical development program designed to support a broad, differentiated label for Dimebon in Alzheimer's disease, and to achieve expeditious regulatory submissions and market acceptance. This expanded development program includes four additional Phase 3 trials in Alzheimer's disease. We plan to begin all of these trials in 2009, and to use them to support a marketing application in 2011 for a label broader than mild-to-moderate Alzheimer's disease. However, we caution you that these are forward looking statements and are subject to significant risk and uncertainty. The four additional Phase 3 trials that we have initiated or plan to initiate in 2009 are as follows:

The CONCERT Trial. The CONCERT trial is a twelve-month randomized, double-blind, placebo-controlled Phase 3 trial of Dimebon in approximately 1,000 patients with mild-to-moderate Alzheimer's disease who are also taking Aricept, the leading approved Alzheimer's disease medication. We have completed a Phase 1 randomized, double-blind, placebo-controlled safety and tolerability study of Dimebon plus Aricept combination therapy in patients with Alzheimer's disease, which found the combination to be well tolerated with no serious adverse events. The CONCERT trial is designed to evaluate the potential benefits of Dimebon over a one-year treatment period when added to treatment with Aricept, as compared to treatment with Aricept alone. We expect to enroll the first patient in the CONCERT trial in April 2009.

Safety Study. In March 2009, we dosed the first patient in a randomized, double-blind, placebo-controlled Phase 3 safety study of Dimebon in approximately 750 patients with mild-to-moderate Alzheimer's disease. This safety study is designed to fully populate the safety database required to support the initial marketing application for Dimebon. The purpose of the safety study is to give us the option for an earlier-than-planned filing of our initial marketing application should we and Pfizer elect to pursue that option.

Moderate-to-Severe Studies. We plan to initiate two Phase 3 studies in moderate-to-severe Alzheimer's disease patients in 2009. They will be randomized, double-blind, placebo-controlled studies designed to support labeling of Dimebon to treat moderate-to-severe Alzheimer's disease. We expect that approximately 1,100 patients will be enrolled between the two trials. Enrolled patients will be permitted to take one background Alzheimer's disease medication, either Namenda or Aricept.

Second Clinical Indication—Huntington's Disease

Huntington's Disease

Huntington's disease is a fatal neurological disorder characterized clinically by involuntary movements, loss of cognitive function and a wide spectrum of behavioral disorders. Common motor symptoms include chorea (involuntary writhing and spasming), clumsiness and progressive loss of the abilities to walk, speak and swallow. Cognitive symptoms include loss of intellectual speed, attention and short-term memory. Behavioral symptoms span the range of changes in personality, depression, irritability, emotional outbursts and apathy. Huntington's disease is known to be caused by a specific genetic mutation, which results in degeneration of neurons in many different regions of the brain. This degeneration is particularly focused in neurons located in the basal ganglia, structures deep within the brain that control many important functions, including coordinating movement, and also in neurons on the outer surface of the brain or cortex, which controls thought, perception and memory.

There are no FDA-approved therapies to treat the cognitive impairment associated with Huntington's disease. Everyone who carries at least one copy of the Huntington's disease mutation and lives long enough will develop the disease. Symptoms generally begin between the ages of 30 and 45, but have been reported to appear

as early as two years of age. The disease is invariably fatal and death usually occurs between 10 and 20 years after the onset of symptoms, making Huntington's disease not only a devastating but also a protracted illness. According to the Hereditary Disease Foundation (www.hdfoundation.org), in the United States alone approximately 30,000 patients currently suffer from Huntington's disease, and an additional 150,000 are genetically at risk for developing it. The Huntington's Disease Society of America estimates that the prevalence of Huntington's disease in the U.S. population is approximately 1 in 10,000 persons (www.hdsa.org).

Phase 2 Clinical Trial

In 2008, we completed a randomized, double-blinded, placebo-controlled Phase 2 clinical trial of Dimebon in Huntington's disease patients. The trial was conducted at 16 centers in the United States and the United Kingdom in collaboration with the Huntington Study Group, or HSG, a network of more than 250 experienced clinical trial investigators, coordinators and consultants from more than 60 academic and research institutions throughout the United States, Canada, Europe and Australia dedicated to clinical research of Huntington's disease. The trial enrolled 90 patients with Huntington's disease, with half randomized to Dimebon and the other half to placebo for a three-month dosing period. The primary endpoint of the trial was safety and tolerability. The secondary endpoint was efficacy, as measured by the Mini-Mental State Examination, or MMSE, the cognition scale most widely used by clinicians to assess patients with neurodegenerative diseases, the Unified Huntington's Disease Rating Scale, or UHDRS, a composite assessment tool that evaluates the impact of Huntington's disease on cognition, motor function, behavior, overall function and level of independence and the ADAS-cog, a cognition scale generally used in Alzheimer's disease clinical trials.

In July 2008, we announced top-line results of the Phase 2 trial which demonstrated that Dimebon significantly improved cognitive function in patients with mild-to-moderate Huntington's disease. Cognitive function was significantly improved over placebo ($p=0.03$) as measured by the MMSE. Dimebon-treated patients also demonstrated favorable results on the behavioral component of the UHDRS, but these results did not reach statistical significance.

Dimebon was well tolerated in this trial. There were fewer patients reporting adverse events in the Dimebon group than in the placebo group (70% vs. 80%). Huntington's disease patients treated with Dimebon had fewer falls (9%), a common problem in this patient population that often results in injury and associated health care costs, than did patients on placebo (16%). The most common adverse event in the Dimebon group was headache, which occurred in 19% of treated patients compared to 7% of placebo patients. Headaches were generally mild in severity. Dry mouth and depressed mood were similar in both treated and placebo groups (4% and 7%, respectively).

The full data from this trial were presented in March 2009 at the 9th International Conference on Alzheimer's and Parkinson's diseases ("AD/PD") in Prague, Czech Republic. Also at the AD/PD meeting, we presented subgroup analysis data from the Phase 2 trial showing that Dimebon's positive effect on cognition, as measured by the MMSE, was 60% greater in the more cognitively impaired patients with MMSE scores below 27. The highest possible MMSE score is 30, which reflects the absence of any cognitive impairment. Because Dimebon treatment resulted in improvement over baseline at the start of the trial and because patients with normal or near normal MMSE scores at baseline have little opportunity to improve, this analysis focused on the subgroup of patients with clear cognitive impairment (baseline MMSE scores <27) and found an almost 1.6 point improvement in the MMSE scores in the Dimebon-treated group as compared to the placebo group ($p=0.008$).

Phase 3 Clinical Trial

In January 2009, we held our end-of-phase 2 meeting with the FDA, and received permission to begin a Phase 3 clinical trial of Dimebon in patients with mild-to-moderate Huntington's disease. This will be a randomized, double-blinded, placebo-controlled trial in approximately 350 patients. The primary endpoints in the trial will be the MMSE and the CIBIC-plus. We expect to begin this Phase 3 trial in 2009. Based on the subgroup analysis from our Phase 2 trial, we intend to enroll only patients with MMSE scores of 26 or lower in our Phase 3 trial in order to maximize the chances of a positive outcome.

Potential Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. Huntington's disease is specifically mentioned in the Orphan Drug Act as an example of an orphan indication, and the FDA previously has granted orphan drug designation to other drugs in development to treat Huntington's disease. We therefore believe that Dimebon will qualify for orphan drug designation for treating Huntington's disease. If a product that has orphan drug designation subsequently receives FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, i.e., the FDA may not approve any other applications to market the same drug for the same disease, except in very limited circumstances, for seven years. Orphan drug designation does not shorten the duration of the regulatory review or approval process.

Potential Fast Track Status and Priority New Drug Application (NDA) Review

The FDA provides several options to facilitate development of drugs for serious, life-threatening diseases—fast track status and priority NDA review—that we believe may be available for our Huntington's disease program.

The FDA's fast-track program is intended to facilitate the development and expedite the review of drugs that are intended for the treatment of a serious or life-threatening condition for which there is no effective treatment and demonstrate the potential to address unmet medical needs for the condition. We believe Huntington's disease meets the conditions for fast-track designation. If fast-track designation is obtained, the FDA may initiate review of sections of an NDA before the application is complete. This rolling review is available if the applicant provides a schedule for the submission of the remaining information and pays applicable user fees. Fast-track designation may be withdrawn by the FDA if it believes the designation is no longer supported by data emerging in the clinical trial process.

In some cases, a fast-track designated product may also qualify for priority review under FDA policies. A product is eligible for priority review, or review within a six month timeframe from the time an NDA is accepted for filing, if the product provides a significant improvement compared to marketed products in the treatment, diagnosis or prevention of a disease. A fast-track designated product would ordinarily meet the FDA's criteria for priority review. We cannot guarantee that any of our product candidates will receive a priority review designation, or if a priority designation is received, that review or approval, if any, will be faster than conventional FDA procedures.

Potential Second Generation Molecules

We are actively engaged in research to identify second generation molecules that can potentially improve upon the properties of Dimebon. This ongoing research is directed primarily to rational design and synthesis of novel Dimebon analogs. We have filed for patent protection on numerous novel compounds. The ultimate objective of this research is to identify the most promising second generation molecule to advance to formal preclinical and clinical development.

Pfizer Inc. Collaboration Agreement

In September 2008, we announced a Collaboration Agreement with Pfizer. Under this agreement, we and Pfizer will collaborate on development of Dimebon for Alzheimer's disease and Huntington's disease for the United States market, including associated regulatory filings with the FDA. In addition, following FDA approval and launch of Dimebon in the United States, we, at our option, and Pfizer will co-promote Dimebon to specialty physicians in the United States, and Pfizer will promote Dimebon to primary care physicians in the United States. Pfizer will be responsible for development and seeking regulatory approval for, and commercialization of, Dimebon outside the United States. After a period of transition from our contract manufacturers to Pfizer, Pfizer

will be responsible for all manufacture of product for both clinical and commercial purposes. Both we and Pfizer have agreed not to commercialize for the treatment of specified indications any other products directed to the same primary molecular target as Dimebon for a specified time period, subject to certain exceptions.

The agreement establishes several joint committees consisting of an equal number of representatives from both parties that will operate by consensus to oversee the collaboration. In the event that a joint committee is unable to reach consensus on a particular issue, then, depending on the issue, a dispute may be decided at the joint committee level by the party with the final decision on the issue or escalated to senior management of the parties. If a dispute is escalated to senior management and no consensus is reached, then the dispute may be decided by the party to whom the contract grants final decision on such issue. Other issues can only be decided by consensus of the parties, and unless and until the parties' representatives reach agreement on such issue, no decision on such issue will be made, and the status quo will be maintained.

Under the Collaboration Agreement, Pfizer paid us an up-front cash payment of \$225 million in the fourth quarter of 2008. We are also eligible to receive payments of up to \$500 million upon the attainment of development and regulatory milestones plus additional milestone payments upon the achievement of certain net sales levels for the product. We and Pfizer will share the costs and expenses of developing and commercializing Dimebon for the United States market on a 60%/40% basis, with Pfizer assuming the larger share, and we and Pfizer will share profits (or losses) resulting from the commercialization of Dimebon in the United States in such proportions. Outside the United States, Pfizer will bear all development and commercialization costs and will pay us tiered royalties on the aggregate net sales of Dimebon.

If one of the parties merges with, or acquires or is acquired by, a third party and as a result such party must divest its interest in the Dimebon collaboration due to a governmental requirement, then the other party has the first right to purchase the divesting party's interest in the collaboration, on terms to be negotiated by the parties. In the event that the parties are unable to agree on the terms of this purchase after following the negotiation procedure outlined in the Collaboration Agreement, the divesting party will have a time-limited right to sell its interest in the collaboration to a third party. However, the terms of this sale must be more favorable than any terms offered by the non-divesting party and the third party will remain bound by the terms of the Collaboration Agreement. In the event the non-divesting party declines to purchase the divesting party's interest, the divesting party may sell its interest in the collaboration to a third party on any terms but such third party will remain bound by the terms of the Collaboration Agreement.

We are permitted to terminate the Collaboration Agreement for an uncured material breach by Pfizer. Pfizer has a right to terminate the Collaboration Agreement unilaterally, after 18 months following Dimebon's first commercial sale, but can earlier terminate at its discretion with advance written notice to us if clinical data for Dimebon generated after the effective date do not meet certain specified criteria or if regulatory approval is conditioned or delayed. In the event of our uncured material breach of the Collaboration Agreement, Pfizer may elect either to terminate the Collaboration Agreement or to keep the Collaboration Agreement in place, but terminate our right to participate in development, commercialization (other than co-promoting Dimebon) and other activities for Dimebon, including the joint committees and decision making for Dimebon. However, such termination would not affect our financial return or, unless we commit an uncured material breach of our co-promotion obligations, our co-promotion rights. Following any termination of the Collaboration Agreement, all rights to develop and commercialize Dimebon will revert to us, and Pfizer will grant a license to us to enable us to continue such development and commercialization, and will supply product to us during a specified transition period.

Our MDV300 Series Prostate Cancer Program

Our subsidiary, Medivation Prostate Therapeutics, Inc. owns an exclusive, worldwide commercial license to a series of novel small molecules, referred to as the MDV300 series compounds. Our lead development candidate from the MDV300 series is a molecule we refer to as MDV3100.

Prostate Cancer Statistics

According to the American Cancer Society, prostate cancer is the most commonly diagnosed cancer among men in the United States, other than skin cancer. The American Cancer Society estimates that approximately 186,000 new cases of prostate cancer were diagnosed, and approximately 29,000 men died of prostate cancer, in the United States alone during 2008. Prostate cancer is thus the second-leading cause of cancer death in men in the United States, after lung cancer.

Metastatic Prostate Cancer—The Hormone-Sensitive and Castration-Resistant States

Metastatic prostate cancer is cancer that has spread beyond the prostate and surrounding tissues into distant organs and tissues. The majority of men who die from prostate cancer die from the consequences of metastatic disease. According to the National Cancer Institute, the median survival of patients with prostate cancer that has metastasized to distant organs is usually one to three years, and most such patients will die of prostate cancer. Metastatic prostate cancer is generally divided into two states: the hormone-sensitive state and the castration-resistant state (also referred to as the hormone-refractory state).

The Hormone-Sensitive State. Testosterone and other male sex hormones, known collectively as “androgens,” can fuel the growth of prostate cancer cells. Androgens exert their effects on prostate cancer cells by binding to and activating the androgen receptor, which is expressed in prostate cancer cells. When they first metastasize to distant sites, most prostate cancers depend on androgens for growth. These prostate cancers are known as “hormone-sensitive” cancers.

Accordingly, the leading therapies currently used for the treatment of metastatic prostate cancer are focused on diminishing, or “antagonizing,” the effects of androgens on prostate cancer cells. This effect is achieved through two separate approaches. The first approach uses drugs known as “anti-androgens,” which directly block the interaction of androgens with the androgen receptor. Casodex® (bicalutamide), sold by AstraZeneca PLC, is the largest selling of these drugs, with global annual sales of more than \$1.2 billion in 2008 according to the public disclosures of AstraZeneca PLC. The second approach is to reduce the amount of androgens produced in the body, primarily in the testes. This can be achieved surgically by removal of both testicles (orchiectomy) or through use of drugs known as luteinizing hormone-releasing hormone, or LHRH, agonist drugs, which lower the native production of testosterone in the testicles (sometimes called “chemical castration”). Anti-androgens and LHRH agonists often are given in combination therapy, an approach known as a “combined androgen blockade.” However, because these therapies operate by reducing the ability of androgens to fuel the growth of prostate cancer cells, they generally are effective only on prostate cancers that remain hormone-sensitive—i.e., those that still depend on androgens for growth.

The Castration-Resistant State. Most metastatic prostate cancer initially is hormone-sensitive and thus responds to hormonal therapies. However, according to a study published in the October 7, 2004 issue of *The New England Journal of Medicine*, virtually all hormone-sensitive metastatic prostate cancer undergoes changes that convert it to the castration-resistant state in a median of 18-24 months after initiation of hormonal therapy. Once in this state, prostate cancers generally continue to grow in an androgen-dependent manner despite the reduction of testosterone production to very low (i.e., post-castration) levels. Prostate cancer in this state is known as “castration-resistant” prostate cancer, or CRPC. The switch from the hormone-sensitive to the castration-resistant state following initiation of hormonal therapy is generally determined based on either rising levels of prostate-specific antigen, or PSA, or documented disease progression as evidenced by imaging tests or clinical symptoms. Metastatic prostate cancer that has become castration-resistant is extremely aggressive; these patients have a median survival of only 10 to 16 months.

A primary reason that CRPC is so deadly is that it is difficult to treat. CRPC no longer responds to hormonal therapies that are effective in the hormone-sensitive state. To further complicate the situation, due to biological changes in prostate cancer that has entered the castration-resistant state, drugs that initially block the androgen receptor and inhibit growth of hormone-sensitive prostate cancer may have precisely the opposite effect and start to fuel the growth of CRPC. Agents are clearly needed to improve the treatment options for patients with CRPC.

Switch from the Hormone-Sensitive to the Castration-Resistant State

One of the factors that historically hindered the development of drugs to treat CRPC was that the cause of the switch from the hormone-sensitive to the castration-resistant state was not known. This problem was addressed by Dr. Charles Sawyers and his colleagues, who discovered that one of the important mechanisms by which prostate cancer cells switch from the hormone-sensitive to the castration-resistant state appears to be through overexpression of the androgen receptor. In experiments comparing gene expression in hormone-sensitive and castration-resistant prostate cancer cells, the results of which were published in the January 1, 2004 issue of *Nature Medicine*, Dr. Sawyers and his colleagues reported that an increase in androgen receptor expression was the only gene change consistently associated with castration-resistant disease. In a series of experiments, scientists showed (as expected) that activation of the androgen receptor in hormone-sensitive human prostate cancer cell lines was inhibited by current androgen receptor blockers, including Casodex. However, when the prostate cancer cell lines were genetically engineered to overexpress the androgen receptor (converting them from the hormone-sensitive to the castration-resistant state), not only did Casodex fail effectively to inhibit the androgen receptor in these cells, but in some cases it became a stimulant of the androgen receptor. Androgen receptor activation is correlated with the growth of prostate cancer. This finding is consistent with the published human clinical experience with Casodex in CRPC.

The MDV300 Series Compounds

The MDV300 series compounds, a series of approximately 170 small molecules, were synthesized based on the discovery of a mechanism by which prostate cancer shifts from the hormone-sensitive to the castration-resistant state. These molecules bind the androgen receptor, the same target bound by Casodex and other marketed drugs for metastatic prostate cancer, but do so in a manner designed to render them effective in treating cancers that have become refractory to currently used drugs. For example, our lead development candidate from the MDV300 series compounds, MDV3100, is a novel small-molecule androgen receptor antagonist that inhibits androgen receptor function by blocking nuclear translocation of the androgen receptor and DNA binding.

Preclinical Data

Experiments Using Human CRPC Cells. In these experiments, human CRPC cell lines were created by engineering cultured human prostate cancer cells to overexpress the androgen receptor. Both MDV300 series compounds and Casodex were then tested in these human CRPC cells. The impact of these drugs on four endpoints of potential interest in treating CRPC was measured—the degree to which they activated the androgen receptor, affected the expression of prostate-specific antigen, or PSA, inhibited the growth of human CRPC cells, and inhibited the growth of tumors due to human CRPC cells that had been implanted into mice. MDV300 series compounds showed promising effects in these experiments while Casodex, as would be expected based on its known limited efficacy in treating CRPC, did not. The results of these experiments provided the basis for our decision to advance MDV3100 into clinical development for the treatment of CRPC.

Experiments Using Human Hormone-Sensitive Prostate Cancer Cells. These experiments used human prostate cancer cell lines that had not been engineered to overexpress the androgen receptor, and thus remained in the hormone-sensitive state. Both MDV300 series compounds and Casodex were tested in these human hormone-sensitive prostate cancer cells for their ability to inhibit cell growth. As expected based on its demonstrated efficacy in treating hormone-sensitive prostate cancer, Casodex inhibited cell growth in these experiments. Significantly, however, MDV300 series compounds also inhibited the growth of these hormone-sensitive prostate cancer cells—comparably to, and in certain cases better than, Casodex. In our opinion, the results of these experiments provide a scientific rationale for considering MDV300 series compounds as potential therapeutic agents for hormone-sensitive prostate cancer as well as for CRPC.

Phase 1-2 Clinical Trial and Subsequent Development Plans

We are conducting an open-label Phase 1-2 clinical trial of MDV3100, the lead development candidate from our MDV300 series compounds, in patients with CRPC. The trial is being conducted at several clinical sites in

the United States, including Memorial Sloan-Kettering Cancer Center in New York. The study enrolled 140 patients in seven dose groups, and enrollment was completed in December 2008. Patients are permitted to remain on study drug until their disease progresses (by biochemical, radiographic or clinical criteria) or until they cease tolerating the drug. Patients enrolled in the trial were heavily pretreated, with 77% having failed two or more lines of prior hormonal therapy and 43% having also failed prior chemotherapy. All patients had progressive disease upon enrollment into the trial. The study endpoints include safety, tolerability, pharmacokinetics, circulating tumor cell, or CTC, counts, serum PSA levels, radiographic change in soft tissue and bony metastases, and time on treatment.

In February 2009, we announced efficacy and safety data covering all 114 patients who had been followed for 12 weeks or longer as of January 2009. In the trial, MDV3100 consistently demonstrated encouraging anti-tumor activity across dose levels and endpoints. Almost all patients with favorable CTC counts of four or less at the start of treatment maintained favorable counts at week 12 (89% of chemotherapy naïve patients and 100% of post-chemotherapy patients). Importantly, a significant number of patients with unfavorable CTC counts of five or higher at baseline converted to favorable counts of less than five at week 12 (73% of chemotherapy naïve patients and 40% of post-chemotherapy patients). This CTC conversion rate is important in light of a recently published study in the October 2008 issue of *Clinical Cancer Research*, in which post-treatment conversion to a CTC count below five was associated with a 15-month survival benefit in CRPC patients.

MDV3100 also produced significant PSA declines (50% or more from baseline) and radiographic control (partial response or stable disease) in both chemotherapy naïve and post-chemotherapy patients at week 12, as follows (data as of January 2009):

	<u>PSA response > 50%</u>	<u>Radiographic control: soft tissue lesions</u>	<u>Radiographic control: bony lesions</u>
<i>Chemotherapy naïve</i>	57%	80%	61%
<i>Post-chemotherapy</i>	45%	70%	64%

As of the announcement, the median time on treatment for chemotherapy-naïve patients and post-chemotherapy patients was 276 and 145 days, respectively.

MDV3100 has been generally well tolerated at doses of up to and including 240 mg/day. The most frequently reported adverse event was fatigue. Seizures were observed in two patients, one each at doses of 600 and 360 mg/day. Both patients were taking concomitant medications that can cause seizures. A possible but unwitnessed seizure was reported in a patient taking a dose of 480 mg/day.

We intend to seek FDA approval to begin this year a pivotal Phase 3 registration study in CRPC patients who have failed chemotherapy. We also believe that MDV3100 has potential utility in both CRPC patients who have not yet had chemotherapy, as well as in hormone-sensitive prostate cancer patients. We are evaluating whether clinical development in those additional patient populations is warranted.

Intellectual Property

As of December 31, 2008, we owned issued patents in the United States and Europe claiming the use of Dimebon and certain related compounds to treat neurodegenerative diseases, an issued patent in the United States claiming the use of Dimebon to treat Alzheimer's disease, and issued foreign counterpart patents in Canada and Hong Kong. The U.S. and European patents expire in October 2016. However, if we succeed in receiving regulatory approval to sell Dimebon, under current laws our U.S. and European patent protection for Dimebon for the first approved indication may be eligible for extension for up to five additional years. We also own multiple pending patent applications claiming, among other things, the use of Dimebon to treat Huntington's disease and other indications, and numerous novel second generation Dimebon analogs. We own all of the above Dimebon intellectual property and have full control over prosecution and enforcement against potential infringers, subject to the terms of our Collaboration Agreement with Pfizer in the case of intellectual property we have sublicensed to Pfizer. In addition, we have an exclusive license to multiple pending patent applications

covering the MDV300 series compounds, including our lead development candidate MDV3100, and their uses in the treatment and prevention of disease. We intend to prosecute all of our owned intellectual property, and request that our licensors prosecute all of our licensed intellectual property, in the United States, Europe and other jurisdictions that we deem appropriate.

We require our employees and consultants to execute non-disclosure and proprietary rights agreements at the beginning of employment or consulting arrangements with us. These agreements generally acknowledge our exclusive ownership of all inventions and intellectual property, including, but not limited to patents, developed by the individual during the course of his or her work with us and require that all proprietary information disclosed to the individual remain confidential. We intend to enforce vigorously our intellectual property rights if infringement or misappropriation occurs.

Government Regulation and Product Approvals

The clinical development, manufacturing and marketing of our products are subject to regulation by various authorities in the U.S., the E.U. and other countries, including, in the U.S., the FDA, and, in the E.U., the European Agency for the Evaluation of Medical Products, or EMEA. The Federal Food, Drug, and Cosmetic Act and the Public Health Service Act in the U.S., and numerous directives, regulations, local laws, and guidelines in the E.U. govern testing, manufacture, safety, efficacy, labeling, storage, record keeping, approval, advertising and promotion of our products. Product development and approval within these regulatory frameworks takes a number of years, and involves the expenditure of substantial resources.

Regulatory approval will be required in all markets in which we, or our partners, including Pfizer, seek to test and market our drug candidates. At a minimum, approval requires evaluation of data relating to quality, safety and efficacy of a product for its proposed use. The specific types of data required and the regulations relating to these data differ depending on the territory, the drug involved, the proposed indication and the stage of development.

In the U.S., specific preclinical data, chemical data and a proposed clinical study protocol must be submitted to the FDA as part of an Investigational New Drug application, or IND, which, unless the FDA objects, will become effective 30 days following receipt by the FDA. Phase 1 trials may commence only after the IND application becomes effective. Prior regulatory approval for human healthy volunteer studies is also required in member states of the European Union, or E.U. Currently, in each member state of the E.U., following successful completion of Phase 1 trials, data are submitted in summarized format to the applicable regulatory authority in the member state in respect of applications for the conduct of later Phase 2 trials. The regulatory authorities in the E.U. typically have between one and three months in which to raise any objections to the proposed clinical trial, and they often have the right to extend this review period at their discretion. In the U.S., following completion of Phase 1 trials, further submissions to regulatory authorities are necessary in relation to Phase 2 and 3 trials. Authorities may require additional data before allowing the trials to commence and could demand discontinuation of studies at any time if there are significant safety issues.

In addition to regulatory review, a clinical trial involving human subjects has to be approved by an independent body. The exact composition and responsibilities of this body differ from country to country. In the U.S., for example, each clinical trial is conducted under the auspices of an Institutional Review Board at the institution at which the clinical trial is conducted. This board considers among other things, the design of the clinical trial, ethical factors, the safety of the human subjects and the possible liability risk for the institution. Equivalent rules apply in each member state of the E.U., where one or more independent ethics committees that typically operate similarly to an Institutional Review Board, will review the ethics of conducting the proposed research. Other authorities elsewhere in the world have slightly differing requirements involving both execution of clinical trials and import or export of pharmaceutical products. It is our responsibility to ensure that we conduct our business in accordance with the regulations of each relevant territory.

Information generated in this process is susceptible to varying interpretations that could delay, limit, or prevent regulatory approval at any stage of the approval process. Failure to demonstrate adequately the quality,

safety and efficacy of a therapeutic drug under development would delay or prevent regulatory approval of the product. There can be no assurance that if clinical trials are completed, either we or our collaborative partners will submit applications for required authorizations to manufacture or market potential products or that any such application will be reviewed and approved by appropriate regulatory authorities in a timely manner, if at all.

In order to gain marketing approval, we must submit an application to the relevant authority for review, which is known in the U.S. as an NDA and in the E.U. as a marketing authorization application or MAA. The format is usually specified by each authority, although in general it will include information on the quality of the chemistry, manufacturing and pharmaceutical aspects of the product and non-clinical and clinical data. The FDA undertakes such reviews for the U.S. In the E.U., there is, for many products, a choice of two different authorization routes: centralized and decentralized. Under the centralized route, one marketing authorization is granted for the entire E.U., while under the decentralized route a series of national marketing authorizations are granted. In the centralized system, applications are reviewed by members of the Committee for Medicinal Products for Human Use, on behalf of the EMEA. The EMEA will, based upon the review of the Committee for Medicinal Products for Human Use, provide an opinion to the European Commission on the safety, quality and efficacy of the product. The decision to grant or refuse an authorization is made by the European Commission. In circumstances where use of the centralized route is not mandatory, we can choose to use the decentralized route, in which case the application will be reviewed by each member state's regulatory agency. If the regulatory agency grants the authorization, other member states' regulatory authorities are asked to "mutually recognize" the authorization granted by the first member state's regulatory agency.

Approval by regulatory authorities can take several months to several years or be denied. The approval process can be affected by a number of factors. Additional studies or clinical trials may be requested during the review and may delay marketing approval and involve unbudgeted costs. Regulatory authorities may conduct inspections of relevant facilities and review manufacturing procedures, operating systems and personnel qualifications. In addition to obtaining approval for each product, in many cases each drug manufacturing facility must be approved. Further, inspections may occur over the life of the product. An inspection of the clinical investigation sites by a competent authority may be required as part of the regulatory approval procedure. As a condition of marketing approval, the regulatory agency may require post-marketing surveillance to monitor adverse effects, or other additional studies as deemed appropriate. After approval for the initial indication, further clinical studies are usually necessary to gain approval for additional indications. The terms of any approval, including labeling content, may be more restrictive than expected and could affect product marketability.

Competition

The biopharmaceutical industry is intensely competitive in general. Furthermore, our business strategy is to target large unmet medical needs, and those markets are even more highly competitive. For example, there are four branded drugs and one generic drug currently marketed to treat Alzheimer's disease. These drugs are all dosed once or twice per day, while Dimebon was dosed three times per day in our first pivotal clinical trial and is being dosed three times per day in all of our ongoing and planned Phase 3 trials. This difference in dosing regimen may make Dimebon less competitive than alternative Alzheimer's disease drugs if Dimebon receives marketing approval based on a thrice per day dosing regimen. In addition, one of the four branded Alzheimer's disease drugs has already lost patent protection, and the other three branded drugs are expected to lose patent protection between 2010 and 2015. Such loss of patent protection typically results in the entry of generic competition for, and significant reductions in the commercial pricing of, those approved drugs. A generic version of one Alzheimer's disease drug received FDA marketing approval in 2008. This development would put significant competitive pressure on the prices we or our potential partners could charge for Dimebon should it ever be approved. Companies marketing currently approved Alzheimer's disease therapeutics include some of the world's largest and most experienced pharmaceutical companies, such as Novartis AG and Johnson & Johnson. Pfizer also already markets a currently approved Alzheimer's disease drug. In addition, in January 2009, Pfizer signed an agreement to merge with Wyeth, Inc., which is co-developing a Alzheimer's disease product candidate that, like Dimebon, is currently in Phase 3 development. There are also dozens of additional small molecule and recombinant protein candidates in development targeting the clinical indications we are

pursuing, particularly Alzheimer's disease and CRPC, including compounds already in Phase 3 clinical trials. One or more such compounds may be approved in each of our target indications before any of our product candidates could potentially be approved. Most, if not all, of these competing drug development programs are being conducted by pharmaceutical and biotechnology companies with considerably greater financial resources, human resources and experience than ours. Any of our product candidates that receives regulatory approval will face significant competition from both approved drugs and from any of the drugs currently under development that may subsequently be approved. Bases upon which our product candidates would have to compete successfully include efficacy, safety, price and cost-effectiveness. In addition, our product candidates would have to compete against these other drugs with several different categories of decision makers, including physicians, patients, government and private third-party payors, technology assessment groups and patient advocacy organizations. Even if one of our product candidates is approved, we cannot guarantee that we, Pfizer or any of our potential future partners will be able to compete successfully on any of these bases. Any future product candidates that we may subsequently acquire will face similar competitive pressures. If we or our partners cannot compete successfully on any of the bases described above, our business will not succeed.

Research and Development Expenses

A significant portion of our operating expenses is related to research and development, and we intend to maintain our strong commitment to research and development. See Item 15a "Financial Statements" of this Annual Report on Form 10-K for costs and expenses related to research and development, and other financial information for fiscal years 2008, 2007, and 2006.

Manufacturing

Our business strategy is to use cGMP-compliant contract manufacturers for manufacture of clinical supplies as well as for commercial supplies if required by our commercialization plans, and to transfer manufacturing responsibility to our corporate partners when possible.

The Dimebon tablets and matching placebos we used in our first pivotal Alzheimer's disease clinical trial were produced by a Russian company that is licensed by the Russian government to manufacture Dimebon tablets for human use in Russia and that engaged in such manufacture for several years. The Dimebon tablets and matching placebos used in all of our other clinical trials in both Alzheimer's disease and Huntington's disease were manufactured by cGMP compliant contract manufacturers in the U.S. and Western Europe. Pursuant to our Collaboration Agreement, Pfizer is assuming manufacturing responsibility for Dimebon, including clinical and commercial manufacturing capacity, after we complete transfer of those responsibilities to Pfizer, which we expect to do in 2009.

The MDV3100 being used in our ongoing Phase 1-2 clinical trial in CRPC was manufactured by cGMP-compliant contract manufacturers. We have not yet manufactured MDV3100 at commercial scale. Based on currently available information, we believe that MDV3100 drug product can be manufactured at commercial scale on a cost-effective basis. However, we caution you that this is a forward-looking statement and that we cannot guarantee that we will be able to complete this work on a timely basis or at all.

Scientific and Clinical Advisory Board

We maintain a Scientific and Clinical Advisory Board comprised of scientists and physicians with experience relevant to our company and our product candidates. Members of our Scientific and Clinical Advisory Board have agreed to consult and advise us in their respective areas of expertise. We have placed special emphasis on identifying members of our Scientific and Clinical Advisory Board with expertise in the treatment of the clinical indications targeted by our programs. Our Scientific and Clinical Advisory Board consists of the following members:

Paul Aisen, M.D. Dr. Aisen is a Professor in the Department of Neurosciences at the University of California, San Diego, and the National Institute on Aging-appointed director of the Alzheimer's Disease

Cooperative Study. Dr. Aisen was one of the first Alzheimer's disease clinical trialists in the United States, and was an investigator in the pivotal FDA registration studies for Namenda. Dr. Aisen received his M.D. from Columbia University, College of Physicians and Surgeons.

Sergey Bachurin, Ph.D., D.Sc., Prof. Dr. Bachurin is the Director of the Institute of Physiologically Active Compounds in Chernogolovka, Russia, and a member of the Russian Academy of Sciences. Dr. Bachurin has served as a visiting scholar at several U.S. academic research centers, including the University of California, San Francisco, Tufts University and St. Elizabeth's Medical Center. Dr. Bachurin holds a Ph.D. in Chemical Catalysis and a D.Sc. in Biochemistry from Moscow State University. In addition, Dr. Bachurin holds a Professor degree in Bioorganic Chemistry from the Institute of Physiologically Active Compounds.

Rachelle Doody, M.D., Ph.D. Dr. Doody is a Professor of Neurology, the Effie Marie Cain Chair in Alzheimer's Disease Research, and the Director of the Alzheimer's Disease and Memory Disorder Center at Baylor College of Medicine. Dr. Doody participated in the development of CIBIC-plus, one of the primary cognitive assessment endpoints that the FDA has used for the currently approved Alzheimer's disease drugs. Dr. Doody has worked on clinical studies for all of the FDA-approved cholinesterase inhibitors for Alzheimer's disease. Dr. Doody received her M.D. from Baylor College of Medicine and holds a M.A. and Ph.D. in Cognitive Anthropology from Rice University.

Michael E. Jung, Ph.D. Dr. Jung is a Distinguished Professor of Chemistry at the University of California, Los Angeles, where his research focuses on the development of new synthetic methods and the total synthesis of biologically interesting natural products. Dr. Jung has authored more than 240 scientific publications, and is a named inventor on multiple issued patents and pending patent applications. He holds a B.A. from Rice University and a Ph.D. in Chemistry from Columbia University.

Benjamin Lewin, Ph.D. Dr. Lewin is the founding editor of *Cell*, a leading international journal in the field of biology and, until 1999, also served as the Chief Executive Officer of Cell Press, the publisher of *Cell*. Dr. Lewin holds a M.Sc. from the University of London, and a M.A. and a Ph.D. from the University of Cambridge. Dr. Lewin also has authored multiple books and scientific publications in the field of genetics.

Charles Sawyers, M.D. Dr. Sawyers is Chair of the Human Oncology and Pathogenesis Program, and holds the Marie-Josee and Henry R. Kravis Chair at Memorial Sloan-Kettering Cancer Center in New York. Dr. Sawyers' work focuses on how signaling pathway abnormalities in cancer cells can be exploited as targets for new cancer drugs. Dr. Sawyers played a key role in the clinical development of Gleevec® (imatinib), which targets the molecular cause of chronic myeloid leukemia with minimal side effects, as well as in the invention of our MDV300 series compounds. Dr. Sawyers holds an M.D. from The Johns Hopkins University and is a Howard Hughes Medical Investigator.

Marc A. Shuman, M.D. Dr. Shuman is Professor of Medicine and Urology at the University of California, San Francisco, and Co-Leader of the Prostate Cancer Program at the UCSF Helen Diller Family Comprehensive Cancer Center. Dr. Shuman also serves as Clinical Director of the California Institute for Quantitative Biosciences. Dr. Shuman is a member of the American Society of Clinical Investigation and the Association of American Physicians, and has published extensively in the field of prostate cancer. Dr. Shuman received his M.D. from the Thomas Jefferson Medical College and clinical training at the University of Pennsylvania and Washington University in St. Louis.

Roger Tung, Ph.D. Dr. Tung is the president and chief executive officer of Concert Pharmaceuticals. He has more than twenty years of experience in scientific and scientific management positions at the Squibb Institute for Medical Research, Merck Research Laboratories and Vertex Pharmaceuticals Incorporated. Prior to joining Concert, he served as vice president, drug discovery, of Vertex Pharmaceuticals Incorporated. He discovered two of Vertex's currently marketed products, and is an inventor on multiple issued U.S. patents. Dr. Tung holds a Ph.D. in Pharmaceutical Chemistry from the University of Wisconsin-Madison.

Pablo Valenzuela, Ph.D. Dr. Valenzuela is a Professor of Biochemistry at the Universidad Andres Bello in Santiago, Chile. Dr. Valenzuela has founded several companies, including Chiron Corporation, a major biotechnology company that was acquired by Novartis AG, and Chilean biotechnology companies Bios-Chile Ingenieria Genetica SA, Austral Biologicals and Algisa SA. He also founded, and serves as the Director of, Fundacion Ciencia para la Vida, a private, non-profit foundation promoting the adoption and use of science-based innovation by Chilean companies. Dr. Valenzuela holds a Ph.D. in Biochemistry from Northwestern University.

Employees

As of December 31, 2008, we had 59 employees.

Available Information

Our website address is www.medivation.com; however, information found on, or that can be accessed through, our website is not incorporated by reference into this Annual Report on Form 10-K. We file or furnish electronically with the SEC our Annual Report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. We make available free of charge on or through our website copies of these reports as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The SEC maintains an internet site that contains reports, proxy and information statements and other information regarding our filings at www.sec.gov. You may also read and copy any of our materials filed with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. Information regarding the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330.

Item 1A. Risk Factors.

Our business faces significant risks, some of which are set forth below to enable readers to assess, and be appropriately apprised of, many of the risks and uncertainties applicable to the forward-looking statements made in this Annual Report on Form 10-K. You should carefully consider these risk factors as each of these risks could adversely affect our business, operating results and financial condition. If any of the events or circumstances described in the following risks actually occurs, our business may suffer, the trading price of our common stock could decline and our financial condition or results of operations could be harmed. Given these risks and uncertainties, you are cautioned not to place undue reliance on forward-looking statements. These risks should be read in conjunction with the other information set forth in this Annual Report on Form 10-K. There may be additional risks faced by our business, though we do believe that the risks set forth below reflect the more important ones.

Risks Related to Our Business

We have incurred net losses since inception, expect to incur increasingly large losses in the future as we expand our development activities and may never achieve sustained revenues or profitability. Our only revenue to date has been collaboration revenue under our Collaboration Agreement with Pfizer. We have not completed development of any of our product candidates and do not expect that any of our present or future product candidates will be commercially available for a number of years, if at all. We have incurred losses since inception and expect to continue to incur substantial and increasing losses for the foreseeable future as we increase our spending to finance clinical and preclinical studies of our existing product candidates, the evaluation, acquisition and development of additional product candidates, additional headcount and the costs associated with operating as a public company. Our operating losses have had, and will continue to have, an adverse impact on our working capital, total assets and stockholders' equity. We do not know when or if we will ever generate any additional revenue, including any additional collaboration revenue under our Collaboration Agreement with Pfizer, or become profitable because of the significant uncertainties with respect to our ability to generate product revenue from and obtain approval from the FDA for any of our current or future product candidates.

Because we depend on financing from third parties for our operations, our business may fail if such financing becomes unavailable or is offered on commercially unreasonable terms. To date, we have financed our operations primarily through the sale of our debt and equity securities and from the \$225 million up-front payment we received pursuant to our collaboration agreement with Pfizer. We believe that our existing capital resources and interest thereon, including the \$225 million up-front payment we received from Pfizer in October 2008, will be sufficient to meet our current operating requirements beyond 2009. However, if we change our development plans, acquire rights to new product candidates or cannot find third party collaborators for our other product candidates, we may need additional capital sooner than we expect. Our future capital requirements will depend on many factors, including without limitation:

- the scope and results of our preclinical and clinical trials;
- whether we experience delays in our preclinical and clinical development programs, or slower than anticipated product development;
- whether opportunities to acquire additional product candidates arise and the costs of acquiring and developing those product candidates;
- whether we are able to enter into additional third party collaborative partnerships to develop and/or commercialize any of our product candidates on terms that are acceptable to us;
- the timing and requirements of, and the costs involved in, conducting studies required to obtain regulatory approvals for our product candidates from the FDA and comparable foreign regulatory agencies;
- the availability of third parties to perform the key development tasks for our product candidates, including conducting preclinical and clinical studies and manufacturing our product candidates to be tested in those studies and the associated costs of those services;
- the costs involved in preparing, filing, prosecuting, maintaining, defending the validity of and enforcing, patent claims and other costs related to patent rights and other intellectual property rights, including litigation costs and the results of such litigation.

We may not be able to obtain additional financing when we need it on acceptable terms or at all. If we cannot raise funds on acceptable terms, we may not be able to continue developing our product candidates, acquire or develop additional product candidates or respond to competitive pressures or unanticipated requirements. For these reasons, any inability to raise additional capital when we require it would seriously harm our business.

Our business strategy depends on our ability to identify and acquire additional product candidates which we may never acquire or identify for reasons that may not be in our control, or are otherwise unforeseen or unforeseeable to us. A key component of our business strategy is to diversify our product development risk by identifying and acquiring new product opportunities for development. However, we may not be able to identify promising new technologies. In addition, the competition to acquire promising biomedical technologies is fierce and many of our competitors are large, multinational pharmaceutical, biotechnology and medical device companies with considerably more financial, development and commercialization resources and experience than we have. Thus, even if we succeed in identifying promising technologies, we may not be able to acquire rights to them on acceptable terms or at all. If we are unable to identify and acquire new technologies, we will be unable to diversify our product risk. We believe that any such failure would have a significant negative impact on our prospects because the risk of failure of any particular development program in the pharmaceutical field is high.

Because we depend on our management to oversee the execution of development plans for our existing product candidates and to identify and acquire promising new product candidates, the loss of any of our managers would harm our business. Our future success depends upon the continued services of our executive officers. We are particularly dependent on the continued services of David Hung, M.D., our president and chief executive officer and a member of our board of directors. Dr. Hung identified all of our existing product

candidates for acquisition and has primary responsibility for identifying and evaluating other potential product candidates. We believe that Dr. Hung's services in this capacity would be difficult to replace. None of our executive officers is bound by an employment agreement for any specific term and they may terminate their employment at any time. In addition, we do not have "key person" life insurance policies covering any of our executive officers. The loss of the services of any of our executive officers could delay the development of our existing product candidates and delay or preclude the identification and acquisition of new product candidates, either of which events could harm our business.

Our reliance on third parties for the operation of our business may result in material delays, cost overruns and/or quality deficiencies in our development programs. We rely on outside vendors to perform key product development tasks, such as conducting preclinical and clinical studies and manufacturing our product candidates at appropriate scale for preclinical and clinical trials and, in situations where we are unable to transfer those responsibilities to a corporate partner, for commercial use as well. In order to manage our business successfully, we will need to identify, engage and properly manage qualified external vendors who will perform these development activities. For example, we need to monitor the activities of our vendors closely to ensure that they are performing their tasks correctly, on time, on budget and in compliance with strictly enforced regulatory standards. Our ability to identify and retain key vendors with the requisite knowledge is critical to our business and the failure to do so could negatively impact our business. Because all of our key vendors perform services for other clients in addition to us, we also need to ensure that they are appropriately prioritizing our projects. If we fail to manage our key vendors well, we could incur material delays, cost overruns or quality deficiencies in our development programs, as well as other material disruptions to our business.

Future interest income and value of our investments may be impacted by further declines in interest rates and broader effect of the recent disruption of credit markets. While we are conservative in our investment policies and have invested the \$225 million payment from Pfizer in short-term U.S. Treasury securities and in money market funds consisting solely of short-term U.S. Treasury securities, the interest paid on this type of investment and the value of certain securities may decline in the future as credit markets continue to adjust to the current global financial crisis.

Risks Related to Our Product Development Candidates

Our product candidates require extensive, time consuming and expensive preclinical and clinical testing to establish safety and efficacy. We may never attract additional partners for our technologies or receive marketing approval in any jurisdiction. The research and development of pharmaceuticals is an extremely risky industry. Only a small percentage of product candidates that enter the development process ever receive marketing approval. Except for Dimebon's approval in Russia as an antihistamine, which is not a commercially attractive opportunity for us, none of our product candidates is currently approved for sale anywhere in the world and none of them may ever receive such approval. The process of conducting the preclinical and clinical testing required to establish safety and efficacy and obtain marketing approval is expensive, uncertain and takes many years. If we are unable to complete preclinical or clinical trials of any of our current or future product candidates, or if the results of these trials are not satisfactory to convince regulatory authorities or partners of their safety or efficacy, we will not be able to attract additional partners or obtain marketing approval for any product candidates. Furthermore, even if we or our partners are able to obtain marketing approvals for any of our product candidates, those approvals may be for indications that are not as broad as desired, or may contain other limitations that would adversely affect our ability to generate revenue from sales of those products. If this occurs, our business will be materially harmed and our ability to generate revenue will be severely impaired.

Positive results in any of our clinical trials, including our first pivotal clinical trial of Dimebon in Alzheimer's disease, may not be predictive of future clinical trial results. Even where we achieve positive results in clinical trials, including our first pivotal clinical trial of Dimebon in Alzheimer's disease conducted in Russia, we do not know whether subsequent clinical trials, including the confirmatory Phase 3 pivotal Alzheimer's disease clinical trial currently underway in the U.S., Europe and South America will also generate positive

results. Product candidates in clinical trials, including Phase 3 clinical trials, often fail to show the desired safety and efficacy traits despite having progressed successfully through prior stages of preclinical and clinical testing. In addition, we do not know whether interim results from any of our ongoing clinical trials, including the interim results of our Phase 1-2 clinical trial of MDV3100 in castration-resistant prostate cancer, will be predictive of final results of any such trial.

We are dependent upon our collaborative relationship with Pfizer to further develop, manufacture and commercialize Dimebon. There may be circumstances that delay or prevent Pfizer's ability to develop, manufacture and commercialize Dimebon. In September 2008, we announced that we had entered into a collaboration agreement with Pfizer for the development, manufacture and commercialization of Dimebon to treat Alzheimer's disease and Huntington's disease. We are dependent on Pfizer for developing, manufacturing and commercializing Dimebon. Under the agreement, Pfizer will be responsible for development and seeking regulatory approval for, and commercialization of, Dimebon outside the United States, and it will be responsible for all manufacture of product for both clinical and commercial purposes. In the United States, we and Pfizer will jointly develop and commercialize Dimebon, and share costs, profits and losses on a 60%/40% basis, with Pfizer assuming the larger share.

We are subject to a number of risks associated with our dependence on our collaborative relationship with Pfizer, including:

- adverse decisions by Pfizer regarding the amount and timing of resource expenditures for the development and commercialization of Dimebon;
- possible disagreements as to the timing, nature and extent of our development plans, including clinical trials or regulatory approval strategy;
- the right of Pfizer to terminate its collaboration agreement with us on limited notice for its convenience;
- loss of significant rights if we fail to meet our obligations under the collaboration agreement;
- withdrawal of support by Pfizer following the development or acquisition by it of competing products, including competing Alzheimer's disease development candidates that Pfizer already has in its portfolio, or change of Pfizer corporate strategy;
- changes in key management personnel at Pfizer that are members of the collaboration's various operating committees; and
- possible disagreements with Pfizer regarding the collaboration agreement or ownership of proprietary rights.

Due to these factors and other possible disagreements with Pfizer, we may be delayed or prevented from further developing, manufacturing or commercializing Dimebon, or we may become involved in litigation or arbitration, which would be time consuming and expensive.

The term of our collaboration agreement with Pfizer extends, on a country by country basis, until Pfizer no longer is obligated to pay us royalties for countries outside the United States, or no longer sells the product in the United States. If Pfizer were to unilaterally terminate our collaborative relationship, we would need to undertake development, manufacturing and marketing activities for Dimebon solely at our own expense and/or seek another partner for some or all of these activities, worldwide. If we pursued these activities on our own, it would significantly increase our capital and infrastructure requirements and might limit the indications we are able to pursue and could prevent us from effectively developing and commercializing Dimebon. If we sought to find another pharmaceutical company partner for some or all of these activities, we may not be successful in such efforts, or they may result in a collaboration that has us expending greater funds and efforts than our current relationship with Pfizer.

We are dependent on the efforts of and funding by Pfizer for the development of Dimebon. Under the terms of the collaboration agreement, we and Pfizer must agree on any changes to the development plan for Dimebon that is set forth in the collaboration agreement. If we and Pfizer cannot agree, clinical trial progress could be significantly delayed or halted. Subject to certain limitations set forth in the collaboration agreement, Pfizer is generally free to terminate our agreement at its discretion on limited notice to us. If Pfizer terminates its co-funding of Dimebon development, we may be unable to fund the development costs on our own and may be unable to find a new collaborator, which could cause our business to fail. In the event of an uncured material breach of the agreement by us, Pfizer may elect either to terminate the agreement or to keep the agreement in place, but terminate our right to participate in development, commercialization (other than co-promoting Dimebon, which right Pfizer may terminate only if our uncured material breach pertains to our exercise of that right) and other activities for Dimebon, including the joint committees and decision making for Dimebon. If Pfizer terminates our right to participate in such activities, we would be entirely dependent on Pfizer's actions with respect to the development and commercialization of Dimebon. In addition, under our agreement Pfizer is solely responsible for the development and regulatory approval of Dimebon outside the United States, so we are entirely dependent on Pfizer for the successful completion of those activities.

The financial returns to us, if any, under our collaboration agreement with Pfizer depend in large part on the achievement of development and commercialization milestones, plus a share of any profits from sales in the United States and royalties from sales outside the United States. Therefore, our success, and any associated financial returns to us and our investors, will depend in large part on the performance of Pfizer under the agreement. If Pfizer fails to perform or satisfy its obligations to us, the development, regulatory approval or commercialization of Dimebon would be delayed or may not occur and our business and prospects could be materially and adversely affected for that reason.

We are dependent on the efforts of Pfizer to market and promote Dimebon. Under our collaboration with Pfizer, we and Pfizer will co-promote Dimebon to specialty physicians in the United States and Pfizer will promote Dimebon to primary care physicians in the United States. Outside the United States, Pfizer will solely promote Dimebon. We are thus solely dependent on Pfizer to successfully promote Dimebon to primary care physicians in the United States and to all customers outside of the United States and are partially dependent on Pfizer to successfully promote Dimebon to specialty physicians in the United States. We have limited ability to direct Pfizer in its commercialization of Dimebon in any country, including the United States. If Pfizer fails to adequately market and promote Dimebon, whether inside or outside of the United States, we may be unable to obtain any remedy against Pfizer. If this were to happen, sales of Dimebon may be harmed, which would negatively impact our business, results of operations, cash flows and liquidity.

We will need to hire additional employees in order to complete development of, and co-promote, Dimebon. Any inability to manage future growth could harm our ability to develop and commercialize Dimebon, comply with our obligations under our Collaboration Agreement with Pfizer, increase our costs and adversely impact our ability to compete effectively. In order to complete development of and co-promote Dimebon with Pfizer, we will need to expand the number of our clinical, commercial and administrative personnel. We will need to hire additional clinical development personnel in order to perform our share of the expanded Phase 3 development program for Dimebon that we and Pfizer announced in November 2008. In addition, should Dimebon receive marketing approval in the United States and should we exercise our co-promotion option, we would need to hire a substantial number of commercial and medical affairs personnel, including field based sales and medical affairs representatives. We would also need to increase our finance and other administrative headcount to support these expanded development and commercialization operations. The competition for qualified personnel in the biotechnology field is intense. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Our future financial performance and our ability to develop and commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. Should we be unable to do this, we may not be able to comply with our contractual obligations to Pfizer under our Collaboration Agreement, or to successfully develop or commercialize Dimebon.

We are dependent on Pfizer to manufacture clinical and commercial requirements of Dimebon, which could result in the delay of clinical trials or regulatory approval or lost sales. Under our Collaboration Agreement with Pfizer, after a transition period Pfizer will have the primary right and responsibility to supply Dimebon for clinical trials and all commercial requirements pursuant to a joint manufacturing plan. Consequently, we are, and expect to remain, dependent on Pfizer to manufacture Dimebon. Pfizer may encounter difficulties in production scale-up, including problems involving production yields, quality control and quality assurance, and shortage of qualified personnel. Pfizer may not perform as agreed or may default in its obligations to supply clinical trial supplies and/or commercial product. Pfizer may fail to deliver the required quantities of our products or product candidates on a timely basis. Any such failure by Pfizer could delay our future clinical trials and our applications for regulatory approval, or could impair our ability to meet the market demand for Dimebon and therefore result in decreased sales. If Pfizer does not adequately perform, we may be forced to incur additional expenses, delays, or both, to arrange for other third parties to manufacture products on our behalf, as we do not have any internal manufacturing capabilities.

If Pfizer's business strategy changes, it may adversely affect our collaborative relationship. Pfizer may change its business strategy. Decisions by Pfizer to either reduce or eliminate its participation in the Alzheimer's field, to emphasize other competitive agents currently in its portfolio at the expense of Dimebon, or to add additional competitive agents to its portfolio, could reduce its financial incentive to continue to develop, seek regulatory approval for, or commercialize Dimebon. A change in Pfizer's business strategy may adversely affect activities under its collaboration agreement with us, which could cause significant delays and funding shortfalls impacting the activities under the collaboration and seriously harming our business.

Our industry is highly regulated by the FDA, and comparable foreign regulatory agencies. We must comply with extensive, strictly enforced regulatory requirements in order to develop and obtain marketing approval for any of our product candidates. Before we, Pfizer or our potential future partners can obtain regulatory approval for the sale of our product candidates, our product candidates must be subjected to extensive preclinical and clinical testing to demonstrate their safety and efficacy for humans. The preclinical and clinical trials of any product candidates that we develop must comply with regulation by numerous federal, state and local government authorities in the U.S., principally the FDA, and by similar agencies in other countries. We will be required to obtain and maintain an effective investigational new drug application to commence human clinical trials in the U.S. and must obtain and maintain additional regulatory approvals before proceeding to successive phases of our clinical trials. Securing FDA approval requires the submission of extensive preclinical and clinical data and supporting information for each therapeutic indication to establish the product candidate's safety and efficacy for its intended use. It takes years to complete the testing of a new drug or medical device and development delays and/or failure can occur at any stage of testing. Any of our present and future clinical trials may be delayed or halted due to any of the following:

- any preclinical test or clinical trial may fail to produce safety and efficacy results satisfactory to the FDA or foreign regulatory authorities;
- preclinical and clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval;
- negative or inconclusive results from a preclinical test or clinical trial or adverse medical events during a clinical trial could cause a preclinical study or clinical trial to be repeated or a program to be terminated, even if other studies or trials relating to the program are successful;
- the FDA or foreign regulatory authorities can place a clinical hold on a trial if, among other reasons, it finds that patients enrolled in the trial are or would be exposed to an unreasonable and significant risk of illness or injury;
- the FDA might not approve the clinical processes or facilities that we utilize, or the processes or facilities of our consultants, including without limitation the vendors who will be manufacturing drug substance and drug product for us or any potential collaborators;

- any regulatory approval we, Pfizer or any potential future collaborators ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the product not commercially viable; and
- we may encounter delays or rejections based on changes in FDA policies or the policies of foreign regulatory authorities during the period in which we develop a product candidate or the period required for review of any final regulatory approval before we are able to market our product candidates.

Furthermore, as is typically the case at this stage of the regulatory review process, the FDA has not yet performed an in-depth review of our preclinical and clinical data. Any views the FDA has expressed to us thus remain subject to change, including the view that our previously completed trial conducted in Russia can be used as one of the two pivotal studies required to support the approval of Dimebon to treat mild-to-moderate Alzheimer's disease, as long as a significant proportion of the sites in the confirmatory Phase 3 trial are located in the U.S.

Enrollment of patients in clinical trials is often an expensive and time-consuming process, and could result in significant delays, cost overruns, or both, in our product development activities. We may encounter delays in enrolling a sufficient number of patients to complete our clinical trials. Patient enrollment depends on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites and the eligibility criteria for the study. In particular, our confirmatory pivotal Phase 3 trial of Dimebon in Alzheimer's disease is evaluating Dimebon as a "monotherapy" in Alzheimer's disease patients—meaning that patients in the placebo group do not receive treatment with any approved Alzheimer's disease drugs. Because approved Alzheimer's disease drugs are widely available in the U.S. and Europe, we believe that patient accrual in Dimebon monotherapy studies, including our confirmatory pivotal Phase 3 trial of Dimebon in Alzheimer's disease, may be particularly time-consuming. Delays in planned patient enrollment may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop Dimebon or any other product candidates.

Although we have entered into a collaboration agreement with Pfizer for Dimebon, we have not yet partnered any of our other product development candidates with third party collaborators, and we cannot control whether we will be able to do so on favorable terms or at all. Our business strategy relies in part on potentially partnering successful product development candidates with larger companies to complement our internal development and commercialization efforts. We may also be required to enter into collaborative relationships to complement our internal efforts, whether in research and development, manufacturing or commercialization and/or to generate necessary financing. It may be difficult for us to find third parties that are willing to enter into such transactions on acceptable economic terms or at all. We also will be competing with many other companies as we seek partners for our product candidates and we may not be able to compete successfully against those other firms. If we are not able to enter into collaboration transactions for our other product development candidates, we would be required to undertake and fund further development, clinical trials, manufacturing and commercialization activities solely at our own expense and risk. If we are unable to finance and/or successfully execute those expensive activities, our business and prospects would be materially and adversely harmed for that reason.

We expect that the financial returns to us in any collaboration agreement would depend in large part on the achievement of development and/or commercialization milestones for, and royalties, co-promotion fees or other payments based upon sales of, our product candidates. Therefore, our success, and any associated financial returns to us and our investors, will depend on the ability of Pfizer and any of our future collaborators to obtain and maintain regulatory approvals from the FDA and other foreign regulatory agencies and successfully commercialize our product candidates. We may also be dependent on our collaborators for the commercial scale manufacture, distribution, sales, marketing and reimbursement of our product candidates. These collaborators may not be successful. If Pfizer or any future collaborator terminates its collaboration with us or fails to perform or satisfy its obligations to us, the development, regulatory approval or commercialization of our product candidates would be delayed or may not occur and our business and prospects could be materially and adversely affected for that reason.

If our product candidates cannot be manufactured in a cost-effective manner and in compliance with current good manufacturing practices and other applicable regulatory standards, they will not be commercially successful. All pharmaceutical and medical device products in the U.S., Europe and other countries must be manufactured in strict compliance with current good manufacturing practices, or cGMP, and other applicable regulatory standards. Establishing a cGMP-compliant process to manufacture pharmaceutical and medical device products involves significant time, cost and uncertainty. Furthermore, in order to be commercially viable, any such process would have to yield product on a cost-effective basis, using raw materials that are commercially available on acceptable terms. We face the risk that our contract manufacturers may have interruptions in raw material supplies, be unable to comply with strictly enforced regulatory requirements, or for other reasons beyond their or our control, be unable to complete their manufacturing responsibilities on time, on budget, or at all. Under our collaboration agreement with Pfizer, Pfizer is responsible for all manufacture of Dimebon for both clinical and commercial purposes, but we cannot guarantee that Pfizer will be able to manufacture Dimebon in a timely manner or at all. Furthermore, neither Dimebon nor MDV3100 has been manufactured at commercial-scale under cGMP-compliant conditions. We thus cannot guarantee that commercial-scale cGMP manufacture of Dimebon and/or MDV3100 will be possible, on a cost-effective basis or at all, which would materially and adversely affect the value of these programs.

Any of our product development candidates that receive marketing approval will face significant competition from other approved products, including generic products and products with more convenient dosing regimens, and other products in development. The biopharmaceutical industry is intensely competitive in general. Furthermore, our business strategy is to target large unmet medical needs, and those markets are even more highly competitive. For example, there are four branded drugs and one generic drug currently marketed to treat Alzheimer's disease. These drugs are all dosed once or twice per day, while Dimebon was dosed three times per day in our first pivotal clinical trial and is being dosed three times per day in all of our ongoing and planned Phase 3 trials. This difference in dosing regimen may make Dimebon less competitive than alternative Alzheimer's disease drugs if Dimebon receives marketing approval based on a thrice per day dosing regimen. In addition, one of the four branded Alzheimer's disease drugs has already lost patent protection, and the other three branded drugs are expected to lose patent protection between 2010 and 2015. Such loss of patent protection typically results in the entry of generic competition for, and significant reductions in the commercial pricing of, those approved drugs. A generic version of one Alzheimer's disease drug received FDA marketing approval in 2008. This development would put significant competitive pressure on the prices we or our potential partners could charge for Dimebon should it ever be approved. Companies marketing currently approved Alzheimer's disease therapeutics include some of the world's largest and most experienced pharmaceutical companies, such as Novartis AG and Johnson & Johnson. Pfizer also already markets a currently approved Alzheimer's disease drug. In addition, in January 2009, Pfizer signed an agreement to merge with Wyeth, Inc., which is co-developing a Alzheimer's disease product candidate that, like Dimebon, is currently in Phase 3 development. There are also dozens of additional small molecule and recombinant protein candidates in development targeting the clinical indications we are pursuing, particularly Alzheimer's disease and CRPC, including compounds already in Phase 3 clinical trials. One or more such compounds may be approved in each of our target indications before any of our product candidates could potentially be approved. Most, if not all, of these competing drug development programs are being conducted by pharmaceutical and biotechnology companies with considerably greater financial resources, human resources and experience than ours. Any of our product candidates that receives regulatory approval will face significant competition from both approved drugs and from any of the drugs currently under development that may subsequently be approved. Bases upon which our product candidates would have to compete successfully include efficacy, safety, price and cost-effectiveness. In addition, our product candidates would have to compete against these other drugs with several different categories of decision makers, including physicians, patients, government and private third-party payors, technology assessment groups and patient advocacy organizations. Even if one of our product candidates is approved, we cannot guarantee that we, Pfizer or any of our potential future partners will be able to compete successfully on any of these bases. Any future product candidates that we may subsequently acquire will face similar competitive pressures. If we or our partners cannot compete successfully on any of the bases described above, our business will not succeed.

Any of our product candidates that is eventually approved for sale may not be commercially successful if not widely-covered and appropriately reimbursed by third-party payors. Third-party payors, including public insurers such as Medicare and Medicaid and private insurers, pay for a large share of health care products and services consumed in the U.S. In Europe, Canada and other major international markets, third-party payors also pay for a significant portion of health care products and services and many of those countries have nationalized health care systems in which the government pays for all such products and services and must approve product pricing. Even if approved by the FDA and foreign regulatory agencies, our product candidates are unlikely to achieve commercial success unless they are covered widely by third-party payors and reimbursed at a rate which generates an acceptable commercial return for us and any collaborative partner. It is increasingly difficult to obtain coverage and acceptable reimbursement levels from third-party payors and we may be unable to achieve these objectives. Achieving coverage and acceptable reimbursement levels typically involves negotiating with individual payors and is a time-consuming and costly process. In addition, we would face competition in such negotiations from other approved drugs against which we compete, which may include other approved drugs marketed by Pfizer, and the marketers of such other drugs are likely to be significantly larger than us and therefore enjoy significantly more negotiating leverage with respect to the individual payors than we may have. The competition for coverage and reimbursement level with individual payors will be particularly intense for Dimebon, if approved to treat Alzheimer's disease, because all four currently marketed Alzheimer's disease drugs are expected to lose patent protection prior to, or shortly following, Dimebon's potential commercial launch, and thus are likely to be available at generic price levels that are more attractive to individual payors. One such drug already has lost patent protection and a generic version is on the market. Our commercial prospects would be further weakened if payors approved coverage for our product candidates only as second- or later-line treatments, or if they placed any of our product candidates in tiers requiring unacceptably high patient co-payments. Failure to achieve acceptable coverage and reimbursement levels could materially harm our or our partner's ability to successfully market our product candidates.

We may be subject to product liability or other litigation, which could result in an inefficient allocation of our critical resources, delay the implementation of our business strategy and, if successful, materially and adversely harm our business and financial condition as a result of the costs of liabilities that may be imposed thereby. Our business exposes us to the risk of product liability claims that is inherent in the development of pharmaceutical products. If any of our product candidates harms people, or is alleged to be harmful, we may be subject to costly and damaging product liability claims brought against us by clinical trial participants, consumers, health care providers, corporate partners or others. We have product liability insurance covering our ongoing clinical trials, but do not have insurance for any of our other development activities. If we are unable to obtain insurance at an acceptable cost or otherwise protect against potential product liability claims, we may be exposed to significant litigation costs and liabilities, which may materially and adversely affect our business and financial position. If we are sued for injuries allegedly caused by any of our product candidates, our litigation costs and liability could exceed our total assets and our ability to pay. In addition, we may from time to time become involved in various lawsuits and legal proceedings which arise in the ordinary course of our business. Any litigation to which we are subject could require significant involvement of our senior management and may divert management's attention from our business and operations. Litigation costs or an adverse result in any litigation that may arise from time to time may adversely impact our operating results or financial condition.

Risks Related to Intellectual Property

Intellectual property protection for our product candidates is crucial to our business, and is subject to a significant degree of legal risk—particularly in the life sciences industry. The success of our business will depend in part on our ability to obtain and maintain intellectual property protection—primarily patent protection—of our technologies and product candidates, as well as successfully defending these patents against third-party challenges. We and our collaborators will only be able to protect our technologies and product candidates from unauthorized use by third parties to the extent that valid and enforceable patents or trade secrets cover them. Furthermore, the degree of future protection of our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us or our potential future collaborators to gain or keep our competitive advantage.

The patent positions of life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Further, changes in either the patent laws or in interpretations of patent laws in the U.S. or other countries may diminish the value of our intellectual property rights. Accordingly, we cannot predict the breadth of claims that may be granted or enforced for our patents or for third-party patents that we have licensed. For example:

- we or our licensors might not have been the first to make the inventions covered by each of our pending patent applications and issued patents;
- we or our licensors might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that none of our pending patent applications or the pending patent applications of our licensors will result in issued patents;
- our issued patents and future issued patents, or those of our licensors, may not provide a basis for protecting commercially viable products, may not provide us with any competitive advantages, or may be challenged by third parties and invalidated or rendered unenforceable; and
- we may not develop additional proprietary technologies or product candidates that are patentable.

Our existing and any future patent rights may not adequately protect any of our product candidates, which could prevent us from ever generating any revenues or profits. We cannot guarantee that any of our pending or future patent applications will mature into issued patents, or that any of our current or future issued patents will adequately protect our product candidates from competitors. For example, there is a large body of prior art, including multiple issued patents and published patent applications, disclosing molecules in the same chemical class as our MDV300 series compounds. Since our MDV300 series compounds include approximately 170 specific molecules, we expect that some members of this series may not be patentable in light of this prior art, or may infringe the claims of patents presently issued or issued in the future. Furthermore, we also cannot guarantee that any of our present or future issued patents will not be challenged by third parties, or that they will withstand any such challenge. If we are not able to obtain adequate protection for, or defend, the intellectual property position of our technologies and product candidates, then we may not be able to attract collaborators to acquire or partner our development programs. Further, even if we can obtain protection for and defend the intellectual property position of our technologies and product candidates, we or any of our potential future collaborators still may not be able to exclude competitors from developing or marketing competing drugs. Should this occur, we and our potential future collaborators may not generate any revenues or profits from our product candidates or our revenue or profits would be significantly decreased.

We could become subject to litigation or other challenges regarding intellectual property rights, which could divert management attention, cause us to incur significant costs, prevent us from selling or using the challenged technology and/or subject us to competition by lower priced generic products. In recent years, there has been significant litigation in the U.S. and elsewhere involving pharmaceutical patents and other intellectual property rights. In particular, generic pharmaceutical manufacturers have been very aggressive in challenging the validity of patents held by proprietary pharmaceutical companies, especially if these patents are commercially significant. If any of our present or future product candidates succeed, we may face similar challenges to our existing or future patents. For example, in the prosecution of our issued U.S. patents claiming the use of Dimebon and certain related compounds to treat neurodegenerative diseases, including Alzheimer's disease, the prior owners missed a filing deadline with the U.S. Patent & Trademark Office, or PTO, which resulted in the patent application being deemed abandoned. The prior owners petitioned the PTO to revive the patent application alleging that missing the deadline was unintentional and the PTO approved the petition and issued the patent. However, as with any other decision the PTO makes, this decision could be challenged in subsequent litigation in an attempt to invalidate this issued U.S. patent and any other U.S. patent that may issue based on the same patent application. If a generic pharmaceutical company or other third party were able to successfully invalidate any of

our present or future patents, any of our product candidates that may ultimately receive marketing approval could face additional competition from lower priced generic products that would result in significant price and revenue erosion and have a significantly negative impact on the commercial viability of the affected product candidate(s).

In the future, we may be a party to litigation to protect our intellectual property or to defend our activities in response to alleged infringement of a third party's intellectual property. These claims and any resulting lawsuit, if successful, could subject us to significant liability for damages and invalidation, or a narrowing of the scope, of our proprietary rights. These lawsuits, regardless of their success, would likely be time-consuming and expensive to litigate and resolve and would divert management time and attention. Any potential intellectual property litigation also could force us to do one or more of the following:

- discontinue our products that use the challenged intellectual property; or
- obtain from the owner of the infringed intellectual property right a license to sell or use the relevant technology, which license may not be available on reasonable terms, or at all.

If we are forced to take any of these actions, our business may be seriously harmed. Although we carry general liability insurance, our insurance does not cover potential claims of this type.

In addition, our patents and patent applications, or those of our licensors, could face other challenges, such as interference proceedings, opposition proceedings and re-examination proceedings. Any such challenge, if successful, could result in the invalidation of, or in a narrowing of the scope of, any of our patents and patent applications subject to the challenge. Any such challenges, regardless of their success, would likely be time-consuming and expensive to defend and resolve and would divert our management's time and attention.

We may in the future initiate claims or litigation against third parties for infringement in order to protect our proprietary rights or to determine the scope and validity of our proprietary rights or the proprietary rights of competitors. These claims could result in costly litigation and the diversion of our technical and management personnel and we may not prevail in making these claims.

We may need to obtain licenses of third-party technology that may not be available to us or are available only on commercially unreasonable terms, and which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated. From time to time we may be required to license technology from third parties to develop our existing and future product candidates. For example, in our industry there are a large number of issued patents and published patent applications with claims to treating diseases generically through use of any product that produces one or more biological activities—such as inhibiting a specific biological target. We are aware of several such issued patents relating to Alzheimer's disease and expect to continue to encounter such patents relating to other diseases targeted by our present and future product candidates. We have not conducted experiments to analyze whether, and we have no evidence that, any of our product candidates produce the specific biological activities covered in any of the issued patents or published patent applications of which we are presently aware. We have not sought to acquire licenses to any such patents. In addition, the commercial scale manufacturing processes that we are developing for our product candidates may require licenses to third party technology. Should we be required to obtain licenses to any third-party technology, including any such patents based on biological activities or required to manufacture our product candidates, such licenses may not be available to us on commercially reasonable terms, or at all. The inability to obtain any third-party license required to develop any of our product candidates could cause us to abandon any related development efforts, which could seriously harm our business and operations.

We may become involved in disputes with Pfizer or potential future collaborators over intellectual property ownership, and publications by our research collaborators and scientific advisors could impair our ability to obtain patent protection or protect our proprietary information, which, in either case, could have a significant impact on our business. Inventions discovered under research, material transfer or other such collaborative agreements, including our collaboration agreement with Pfizer, may become jointly owned by us and the other

party to such agreements in some cases and the exclusive property of either party in other cases. Under some circumstances, it may be difficult to determine who owns a particular invention, or whether it is jointly owned, and disputes could arise regarding ownership of those inventions. These disputes could be costly and time consuming and an unfavorable outcome could have a significant adverse effect on our business if we were not able to protect or license rights to these inventions. In addition, our research collaborators and scientific advisors generally have contractual rights to publish our data and other proprietary information, subject to our prior review. Publications by our research collaborators and scientific advisors containing such information, either with our permission or in contravention of the terms of their agreements with us, may impair our ability to obtain patent protection or protect our proprietary information, which could significantly harm our business.

Trade secrets may not provide adequate protection for our business and technology. We also rely on trade secrets to protect our technology, especially where we believe patent protection is not appropriate or obtainable. However, trade secrets are difficult to protect. While we use reasonable efforts to protect our trade secrets, our or our potential collaborators' employees, consultants, contractors or scientific and other advisors may unintentionally or willfully disclose our information to competitors. If we were to enforce a claim that a third party had illegally obtained and was using our trade secrets, our enforcement efforts would be expensive and time consuming, and the outcome would be unpredictable. In addition, courts outside the U.S. are sometimes less willing to protect trade secrets. Moreover, if our competitors independently develop equivalent knowledge, methods or know-how, it will be more difficult or impossible for us to enforce our rights and our business could be harmed.

Risks Related to Ownership of Our Common Stock

Our stock price may be volatile, and our stockholders' investment in our stock could decline in value. The market prices for our securities and those of other life sciences companies have been highly volatile and may continue to be highly volatile in the future. The following factors, in addition to other risk factors described in this Annual Report on Form 10-K, may have a significant impact on the market price of our common stock:

- the receipt or failure to receive the additional funding necessary to conduct our business;
- the progress and success of preclinical studies and clinical trials of our product candidates conducted by us, Pfizer or our future collaborative partners or licensees, if any;
- selling by existing stockholders and short-sellers;
- announcements of technological innovations or new commercial products by our competitors or us;
- developments concerning proprietary rights, including patents;
- developments concerning our collaboration with Pfizer or any future collaborations;
- publicity regarding us, our product candidates or those of our competitors, including research reports published by securities analysts;
- regulatory developments in the U.S. and foreign countries;
- litigation;
- economic and other external factors or other disaster or crisis; and
- period-to-period fluctuations in financial results.

We do not intend to pay dividends on our common stock for the foreseeable future. We do not expect for the foreseeable future to pay dividends on our common stock. Any future determination to pay dividends on or repurchase shares of our common stock will be at the discretion of our board of directors and will depend upon, among other factors, our success in completing sales or partnerships of our programs, our results of operations, financial condition, capital requirements, contractual restrictions and applicable law.

Our principal stockholders exert substantial influence over us and may exercise their control in a manner adverse to your interests. Certain stockholders and their affiliates own a substantial amount of our outstanding common stock. These stockholders may have the power to direct our affairs and be able to determine the

outcome of certain matters submitted to stockholders for approval. Because a limited number of persons controls us, transactions could be difficult or impossible to complete without the support of those persons. Subject to applicable law, it is possible that these persons will exercise control over us in a manner adverse to your interests.

Provisions of our charter documents, our stockholder rights plan and Delaware law could make it more difficult for a third party to acquire us, even if the offer may be considered beneficial by our stockholders. Provisions of the Delaware General Corporation Law could discourage potential acquisition proposals and could delay, deter or prevent a change in control. The anti-takeover provisions of the Delaware General Corporation Law impose various impediments to the ability of a third party to acquire control of us, even if a change in control would be beneficial to our existing stockholders. In addition, Section 203 of the Delaware General Corporation Law, unless its application has been waived, provides certain default anti-takeover protections in connection with transactions between the company and an "interested stockholder" of the company. Generally, Section 203 prohibits stockholders who, alone or together with their affiliates and associates, own more than 15% of the subject company from engaging in certain business combinations for a period of three years following the date that the stockholder became an interested stockholder of such subject company without approval of the board or the vote of two-thirds of the shares held by the independent stockholders. Our board of directors has also adopted a stockholder rights plan, or "poison pill," which would significantly dilute the ownership of a hostile acquirer. Additionally, provisions of our amended and restated certificate of incorporation and bylaws could deter, delay or prevent a third party from acquiring us, even if doing so would benefit our stockholders, including without limitation, the authority of the board of directors to issue, without stockholder approval, preferred stock with such terms as the board of directors may determine.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

We currently lease approximately 30,300 square feet of office space located on the 3rd and 12th floors at 201 Spear Street, San Francisco, California 94105 for all of our operations. We also lease 5,700 square feet of office space located at 55 Hawthorne Street, Suite 610, San Francisco, California 94105, our former office location. We have sub-leased the Hawthorne Street space to a third party. The telephone number at our office is (415) 543-3470.

Item 3. Legal Proceedings.

None.

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

No matters were submitted to a vote of our stockholders during the fiscal quarter ended December 31, 2008.

PART II

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

Market for Our Common Stock

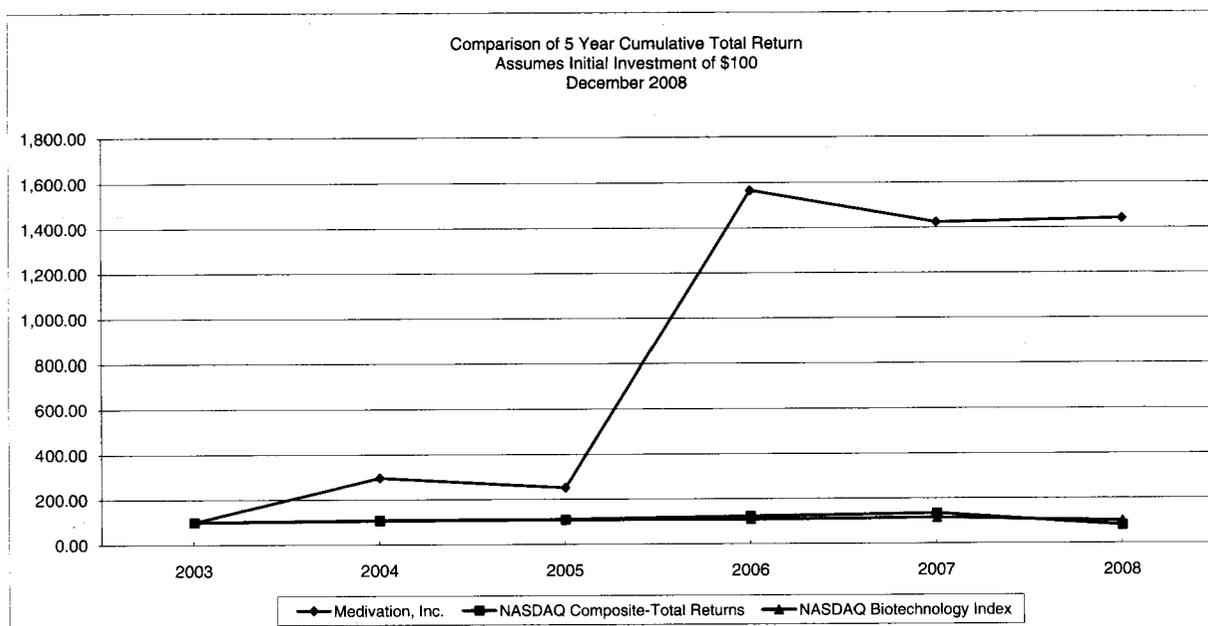
Our common stock began trading on the Nasdaq Global Market under the symbol "MDVN" on March 20, 2007. Our common stock was traded on the American Stock Exchange under the symbol "MDV" from March 15, 2006 until March 19, 2007. The following table sets forth on a per share basis the high and low sales prices of our common stock as reported on the Nasdaq Global Market from March 20, 2007 through December 31, 2008 and on the American Stock Exchange from January 1, 2007 through March 19, 2007:

	<u>High</u>	<u>Low</u>
2008		
Quarter ended March 31, 2008	\$18.85	\$12.07
Quarter ended June 30, 2008	\$17.47	\$11.75
Quarter ended September 30, 2008	\$34.40	\$11.53
Quarter ended December 31, 2008	\$27.34	\$11.27
2007		
January 1, 2007 to March 19, 2007	\$20.50	\$12.50
March 20, 2007 to March 31, 2007	\$19.75	\$17.28
Quarter ended June 30, 2007	\$21.85	\$15.84
Quarter ended September 30, 2007	\$22.08	\$16.26
Quarter ended December 31, 2007	\$25.06	\$12.78

As of March 2, 2009, there were 36 stockholders of record of our common stock. We have never paid our stockholders cash dividends and we do not anticipate paying any cash dividends in the foreseeable future as we intend to retain any earnings for use in our business. Any future determination to pay dividends will be at the discretion of our board of directors.

Performance Graph

The following graph shows the total stockholder return of an investment of \$100 in cash on December 31, 2003 for: (i) the Company's Common Stock; (ii) the Nasdaq U.S. Index; and (iii) the Nasdaq Pharmaceutical Stocks Index. All values assume reinvestment of the full amount of all dividends and are calculated as of the last stock trading day of each year:



	December 31, 2003	December 31, 2004	December 30, 2005	December 29, 2006	December 31, 2007	December 31, 2008
Medivation, Inc.	100.00	297.03	251.49	1,566.34	1,425.74	1,442.57
Nasdaq Composite Index . .	100.00	109.15	111.47	123.04	136.15	81.72
Nasdaq Biotechnology Index	100.00	106.16	109.21	110.37	115.49	101.27

Source: Nasdaq.net. The information under "Performance Graph" is not deemed to be "soliciting material" or "filed" with the Securities and Exchange Commission or subject to Regulation 14A or 14C, or to the liabilities of Section 18 of the Exchange Act of 1934, as amended and is not to be incorporated by reference in any filing of Medivation under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this annual report on Form 10-K and irrespective of any general incorporation language in those filings.

Medivation, Inc. was formed in Delaware in October 1995, under our former name Orion Acquisition Corp. II, to identify and consummate a business combination. Medivation Neurology, Inc. was formed in Delaware in September 2003 to acquire and develop Dimebon. On December 17, 2004, Medivation Neurology, Inc. became our subsidiary pursuant to a merger. Medivation Prostate Therapeutics, Inc. was formed in Delaware as our subsidiary to acquire and develop our MDV300 series technology.

Recent Sales of Unregistered Securities

On September 9, 2008, the Company issued 5,496 shares of common stock in connection with a cashless exercise of a warrant. The warrant was exercisable for 5,806 shares of common stock and had an exercise price of \$1.55 per share. In connection with the exercise, the number of shares issuable pursuant to the warrant was reduced by 310 shares pursuant to the operation of the cashless exercise provisions in the warrant. The Company relied on the exemption provided by Section 4(2) of the Securities Act of 1933, as amended.

Item 6. Selected Financial Data.

The statement of operations data for the years ended December 31, 2008, 2007 and 2006, and the balance sheet data as of December 31, 2008 and 2007, are derived from our audited consolidated statements included in Item 8 of this Report. The statement of operations data for the years ended December 31, 2005 and 2004, and the balance sheet data as of December 31, 2006, 2005 and 2004, are derived from our financial statements not included in this Report. The information below is not necessarily indicative of results of future operations, and should be read in conjunction with Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" of this Annual Report on Form 10-K and the financial statements and related notes thereto, included in Item 8 of this Report to fully understand factors that may affect the comparability of the information presented below.

	Year Ended December 31,				
	2008	2007	2006	2005	2004
	(in thousands, except per share data)				
Consolidated Statements of Operations Data					
Collaboration revenue	\$ 12,578	\$ —	\$ —	\$ —	\$ —
Operating expenses:					
Research and development	54,895	23,399	11,825	5,272	1,723
Selling, general and administrative	21,865	10,364	4,321	3,143	1,062
Total operating expenses	<u>76,760</u>	<u>33,763</u>	<u>16,146</u>	<u>8,415</u>	<u>2,785</u>
Loss from operations	(64,182)	(33,763)	(16,146)	(8,415)	(2,785)
Interest and other income and (expense), net	1,722	2,020	783	(1,403)	(89)
Net loss	<u>(62,460)</u>	<u>(31,743)</u>	<u>(15,363)</u>	<u>(9,818)</u>	<u>(2,874)</u>
Basic and diluted net loss per share	<u>\$ (2.12)</u>	<u>\$ (1.14)</u>	<u>\$ (0.63)</u>	<u>\$ (0.70)</u>	<u>\$ (7.81)</u>
Shares used in computing basic and diluted net loss per share	<u>29,478</u>	<u>27,932</u>	<u>24,248</u>	<u>13,937</u>	<u>368</u>
	December 31,				
	2008	2007	2006	2005	2004
	(in thousands)				
Consolidated Balance Sheet Data:					
Cash and cash equivalents	\$ 71,454	\$ 43,258	\$ 4,649	\$ 12,843	\$10,672
Short-term investments	149,968	—	42,534	—	—
Working capital	149,584	40,214	45,777	11,681	9,957
Total assets	229,272	45,596	47,612	13,281	11,117
Long-term obligations, excluding current portion	399	492	—	—	—
Deferred revenue	212,423	—	—	—	—
Accumulated deficit	(122,660)	(60,200)	(28,457)	(13,093)	(3,276)
Total stockholders' equity	\$ 3,408	\$ 41,058	\$ 45,873	\$ 11,815	\$10,090

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion should be read in conjunction with our audited consolidated financial statements and notes thereto for the fiscal year ended December 31, 2008, included elsewhere in this Report. The following Management's Discussion and Analysis of Financial Condition and Results of Operations contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. We intend that these forward-looking statements be subject to the safe harbors created by those provisions. Forward-looking statements are generally written in the future tense and/or are preceded by words such as "may," "should," "forecast," "could," "expect," "suggest," "believe," "anticipate," "intend," "plan," or other similar words. The forward-looking statements contained in this Report involve a number of risks and uncertainties, many of which are outside of our control. Factors that could cause actual results to differ materially from projected results include, but are not limited to, those discussed in "Risk Factors" elsewhere in this Report. Readers are expressly advised to review and consider those Risk Factors, which include risks associated with (1) our ability to successfully conduct clinical and preclinical trials for our product candidates, (2) our ability to obtain required regulatory approvals to develop and market our product candidates, (3) our ability to raise additional capital on favorable terms, (4) our ability to execute our development plan on time and on budget, (5) our ability to obtain commercial partners, (6) our ability, whether alone or with commercial partners, to successfully commercialize any of our product candidates that may be approved for sale, and (7) our ability to identify and obtain additional product candidates. Although we believe that the assumptions underlying the forward-looking statements contained in this Report are reasonable, any of the assumptions could be inaccurate, and therefore there can be no assurance that such statements will be accurate. In light of the significant uncertainties inherent in the forward-looking statements included herein, the inclusion of such information should not be regarded as a representation by us or any other person that the results or conditions described in such statements or our objectives and plans will be achieved. Furthermore, past performance in operations and share price is not necessarily indicative of future performance. We disclaim any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

The Company

We are a biopharmaceutical company focused on the rapid development of novel small molecule drugs to treat serious diseases for which there are limited treatment options. Our current lead clinical candidates are directed at treating Alzheimer's disease, Huntington's disease and castration-resistant prostate cancer. Our Alzheimer's and Huntington's disease programs are partnered with Pfizer Inc, or Pfizer, and our prostate cancer program remains unpartnered. With Pfizer, we are conducting a broad Dimebon clinical development program, including a pivotal and confirmatory Phase 3 trial in patients with mild-to-moderate Alzheimer's disease. The program also includes additional Phase 3 trials beginning this year in both Alzheimer's disease and Huntington's disease. In addition, we are conducting Phase 1-2 clinical trial of MDV3100 in patients with castration-resistant (also known as hormone-refractory) prostate cancer, and plan to seek FDA approval to begin a Phase 3 trial this year.

In September 2008, we announced a Collaboration Agreement with Pfizer, which became effective on October 21, 2008. Under the terms of the agreement, we and Pfizer will develop and commercialize Dimebon, our investigational drug for treatment of Alzheimer's disease and Huntington's disease. We and Pfizer will share the costs and expenses of developing and commercializing Dimebon for the United States market on a 60% Pfizer/40% Medivation basis, and will share profits (or losses) resulting from commercialization of Dimebon in the United States in the same proportions. Outside the United States, Pfizer will bear all development and commercialization costs, and will pay us tiered royalties on aggregate net sales of Dimebon. In October 2008, we received a non-refundable, up-front cash payment of \$225.0 million pursuant to our Collaboration Agreement with Pfizer.

In the fourth quarter of 2008, we recognized \$12.6 million in collaboration revenue attributable to our up-front payment from Pfizer. Previously we had not recognized any revenue. We have funded our operations

primarily through private and public offerings of our common stock, and from the up-front payment and cost-sharing payments from our Collaboration Agreement with Pfizer. As of December 31, 2008, we had an accumulated deficit of \$122.7 million and expect to incur substantial and increasing additional losses in the future as we expand our research and development activities.

Our Pipeline

Dimebon in Alzheimer's Disease and Huntington's Disease

Our lead product candidate, Dimebon, has successfully completed the first of two pivotal clinical trials required to seek marketing approval from the U.S. Food and Drug Administration, or FDA, in the U.S. for mild-to-moderate Alzheimer's disease. We began our confirmatory pivotal Phase 3 Alzheimer's disease trial in the second quarter of 2008, and expect to complete enrollment in that trial in 2009. Dimebon also has successfully completed a Phase 2 clinical trial in patients with mild-to-moderate Huntington's disease, the top-line results of which we reported in July 2008. Dimebon has been shown to inhibit the death of brain cells, or neurons, in preclinical models of Alzheimer's disease and Huntington's disease, making it a potential novel treatment for these neurodegenerative diseases. Based on data generated in independent third party laboratories, we believe that Dimebon operates through a novel mitochondrial mechanism of action.

MDV3100 in Castration-Resistant Prostate Cancer

Our proprietary compound MDV3100 is currently in a Phase 1-2 clinical trial in patients with castration-resistant prostate cancer, or CRPC. We completed enrollment in that trial in December 2008. MDV3100 is the lead clinical development candidate from a library of approximately 170 small molecules licensed by our subsidiary, Medivation Prostate Therapeutics, Inc. These molecules were rationally designed to treat castration-resistant prostate cancer by modulating the androgen receptor, or AR, in a different manner from currently approved AR antagonist drugs, which generally are ineffective in treating prostate cancers that have become castration-resistant. We intend to seek FDA approval to begin a Phase 3 clinical trial of MDV3100 in CRPC in 2009.

New Product Candidates

We remain actively engaged in identifying new product candidates, both internally and externally, to further expand our pipeline of product candidates.

Critical Accounting Policies and the Use of Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S., or U.S. GAAP. The preparation of our financial statements requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. Actual results could differ materially from those estimates.

The items in our financial statements requiring significant estimates and judgments are as follows:

Revenue Recognition

Revenue recognized to date is attributable solely to the non-refundable up-front payment of \$225.0 million we received in the fourth quarter of 2008 pursuant to our Collaboration Agreement with Pfizer. For a description of the Collaboration Agreement, see Note 3.

The Collaboration Agreement contains multiple elements and deliverables, and requires evaluation pursuant to EITF Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables* ("EITF 00-21"). We evaluated the facts and circumstances of the Collaboration Agreement to determine whether it had obligations

constituting deliverables under EITF 00-21. We concluded that it had multiple deliverables, including deliverables relating to the grant of a technology license, and performance of manufacturing, regulatory and clinical development services in the U.S. We estimated that the period in which we would perform those deliverables began in the fourth quarter of 2008 and will be completed in the first quarter of 2012. We also concluded that these deliverables should be accounted for as a single unit of accounting under EITF 00-21. Accordingly, we will recognize the non-refundable, up-front payment of \$225.0 million as revenue on a straight-line basis over the estimated performance period, using the proportional performance model. Estimation of the performance period of our deliverables requires the use of management's judgment. Significant factors considered in management's evaluation of the estimated performance period include, but are not limited to, its experience, along with Pfizer's experience, in conducting clinical development activities. We will review the estimated duration of our performance period on a quarterly basis and make any appropriate adjustments on a prospective basis. Future changes in our estimate of the performance period may materially impact the timing of future revenue recognized under the Collaboration Agreement.

Under the Collaboration Agreement, we are entitled to receive up to \$500 million in development and regulatory milestone payments. Management evaluated the nature of the events triggering these contingent payments, and concluded that these events – except for those relating solely to development and commercialization in Japan, where we have no contractual responsibilities – constituted milestones under proposed EITF Issue No. 08-9, *Milestone Method of Revenue Recognition* ("EITF 08-9"). This conclusion was based primarily on the facts that each triggering event represents a specific outcome that can be achieved only through successful performance by us of one or more of our deliverables, and that achievement of each triggering event was subject to inherent risk and uncertainty and would result in additional payments becoming due to us. Management then concluded that each of these milestones was substantive, based primarily on the facts that the payments they trigger are non-refundable, that achievement of the milestone entails risk and was not reasonably assured at inception of the Collaboration Agreement, that substantial effort is required to complete each milestone, that the amount of each milestone payment is reasonable in relation to the value created in achieving the milestone, that a substantial amount of time is expected to pass between the up-front payment and the potential milestone payments, and that the milestone payments relate solely to past performance. Based on the foregoing, we will recognize any revenue from these milestone payments under the substantive milestone method in the period in which the underlying triggering event occurs.

Under the Collaboration Agreement, we are entitled to receive milestone payments based on development and regulatory events in Japan, milestone payments based on commercial events globally, profit sharing payments on sales of Dimebon products in the U.S., and royalties on sales of Dimebon products outside the U.S. We will recognize any revenue from these events based on the revenue recognition criteria set forth in FASB Concept Statements 5. Based on those criteria, we consider these potential payments to be contingent revenues, and will recognize them as revenue in the period in which the applicable contingency is resolved.

Under the Collaboration Agreement, we and Pfizer share certain Dimebon-related development and commercialization costs in the U.S. on a 60% Pfizer, 40% Medivation basis. The parties make quarterly true-up payments between themselves to ensure that each has borne its applicable percentage of the shared commercialization costs. We account for cost-sharing true-up payments that we receive from Pfizer as reductions of expense rather than as revenue.

Stock-based Compensation

We apply Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment*, or SFAS No. 123R, to stock-based compensation awards. SFAS No. 123R requires the measurement and recognition of non-cash compensation expense for all share-based payment awards made to employees and directors, including employee stock options and employee stock purchases related to our Restated 2004 Equity Incentive Award Plan, based on estimated fair values. We have applied the provisions of Staff Accounting Bulletin No. 107, or SAB 107, and Staff Accounting Bulletin No. 110, or SAB 110, in our adoption of SFAS No. 123R.

Stock compensation arrangements with non-employee service providers are accounted for in accordance with SFAS No. 123 and EITF No. 96-18, *Accounting for Equity Instruments that Are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, using a fair value approach. The compensation costs of these arrangements are subject to remeasurement over the vesting terms as earned.

We recognized stock-based compensation expense of \$8.5 million, \$5.9 million and \$2.5 million during the years ended December 31, 2008, 2007 and 2006, respectively, which increased our reported research and development expenses, and selling, general and administrative expenses during those periods. These expenses break out as follows (in millions):

	<u>Year Ended December 31,</u>		
	<u>2008</u>	<u>2007</u>	<u>2006</u>
Selling, general and administrative expense	\$4.3	\$3.9	\$1.5
Research and development expense	\$4.2	\$2.0	\$1.0

We calculated these expenses based on the fair values of the stock-based compensation awards as estimated using the Black-Scholes model. Use of this model requires us to make assumptions about expected future volatility of our stock price and the expected term of the options that we grant. Calculating stock-based compensation expense under SFAS No. 123R also requires us to make assumptions about expected future forfeiture rates for our option awards. As of December 31, 2008, total unrecognized compensation expense related to unvested share-based compensation arrangements previously granted was \$27.0 million, which we expect to recognize over a weighted-average period of 2.96 years.

The Black-Scholes option valuation model requires the use of several subjective assumptions, including assumptions of expected stock price volatility, expected stock option term and forfeiture rates, and expected risk-free rates of return. If any of the assumptions used change significantly, stock-based compensation expense could differ materially in the future from that recorded in the current and past periods.

Research and Development Expenses and Accruals

Research and development expenses include personnel expenses, outside contracted services including clinical trial costs, manufacturing and process development costs, research costs and other consulting services. Research and development costs are expensed as incurred. In instances where we enter into agreements with third parties to provide research and development services to us, costs are expensed as services are performed. Amounts due under such arrangements may be either fixed fee or fee for service, and may include upfront payments, monthly payments, and payments upon the completion of milestones or receipt of deliverables.

Our cost accruals for clinical trials and other research and development activities are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical trial centers and contract research organizations. In the normal course of business we contract with third parties to perform various research and development activities in the on-going development of our product candidates, including without limitation, third party clinical trial centers and contract research organizations that perform and administer our clinical trials on our behalf. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Payments under these agreements depend on factors such as the achievement of certain events, the successful enrollment of patients, and the completion of portions of the clinical trial or similar conditions. The objective of our accrual policy is to match the recording of expenses in our financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical trials and other research and development activities are recognized based on our estimate of the degree of completion of the event or events specified in the specific agreement.

Our estimates are dependent upon the timelines and accuracy of data provided by third parties regarding the status and cost of studies, and may not match the actual services performed by the organizations. This could result in adjustment to our research and development expense in future periods. To date, we have had no significant adjustments.

Accounting for Income Taxes

On January 1, 2007, we adopted FASB Interpretation 48, *Accounting for Uncertainty in Income Taxes*, which clarifies the accounting for uncertainty in income taxes recognized in accordance with SFAS No. 109, *Accounting for Income Taxes*. Our policy is to recognize interest and/or penalties related to income tax matters in income tax expense. There were no accrued interest or penalties associated with uncertain tax positions as of December 31, 2008. We had \$0.4 million of unrecognized tax benefits as of December 31, 2008 and we do not expect our unrecognized tax benefits to change significantly over the next twelve months.

We maintained a full valuation allowance on our net deferred tax assets as of December 31, 2008. The valuation allowance was determined in accordance with the provisions of Statement of Financial Accounting Standards No. 109, or SFAS No. 109, *Accounting for Income Taxes*, which requires an assessment of both positive and negative evidence when determining whether it is more likely than not that deferred tax assets are recoverable; such assessment is required on a jurisdiction by jurisdiction basis. Cumulative historic losses represented sufficient negative evidence under SFAS No. 109 and accordingly, a full valuation allowance was recorded against U.S. deferred tax assets. We intend to maintain a full valuation allowance on the U.S. deferred tax assets until sufficient positive evidence exists to support reversal of the valuation allowance.

Recent Accounting Pronouncements

In October 2008, the Financial Accounting Standards Board, or FASB, issued FASB Staff Position, or FSP, FAS 157-3, *Determining the Fair Value of a Financial Asset When the Market for that Asset is not Active*, or FSP 157-3. FSP 157-3 clarified the application of FAS 157. FSP 157-3 demonstrated how the fair value of a financial asset is determined when the market for that financial asset is inactive. FSP 157-3 was effective upon issuance, including prior periods for which financial statements had not been issued. The implementation of this standard did not have an impact on our consolidated financial statements.

In June 2008, the FASB ratified EITF Issue 07-5, *Determining Whether an Instrument (or Embedded Feature) is Indexed to an Entity's Own Stock*, effective for us as of January 1, 2009. This standard establishes criteria for determining whether freestanding instruments or embedded features are considered "indexed to an entity's own stock." This guidance must be applied in assessing the equity conversion features in our outstanding warrants. These conversion features have been exempted from derivative accounting because they are indexed to our own stock and would be classified in stockholders' equity. We will have to assess whether they are still considered indexed to our own stock under this new guidance. The standard applies to all outstanding instruments at January 1, 2009, with any transition impacts recognized as a cumulative effect adjustment to the opening balance of retained earnings. We are evaluating the impact, if any, this standard will have on our consolidated financial statements.

In February 2008, the FASB issued FASB Staff Position FAS 157-2, *Effective Date of FASB Statement No. 157*, which deferred the effective date of SFAS No. 157 for one year, effective for fiscal years beginning after November 15, 2008, as it relates to non-financial assets and liabilities. The Company does not expect that the adoption of FAS 157-2 will have a significant impact on the consolidated results of operations or financial position of the Company.

Results of Operations

Years Ended December 31, 2008, 2007 and 2006

Collaboration Revenue

	<u>Year Ended December 31,</u>		
	<u>2008</u>	<u>2007</u>	<u>2006</u>
	<u>(In thousands)</u>		
Collaboration revenue	\$12,578	\$—	\$—

We recorded \$12.6 million of amortized collaboration revenue in connection with our Dimebon collaboration agreement with Pfizer in the year ended December 31, 2008. In October 2008, we received an upfront payment of \$225.0 million, which we are amortizing over a period of approximately 3.5 years based on the expected performance period of our deliverables under this agreement. Further, we are eligible to receive payments of up to \$500.0 million upon the attainment of certain development and regulatory milestones plus certain additional undisclosed commercial milestone payments. At present, we are unable to predict the timing or likelihood of such milestone payments, although we do not expect to receive any milestone payments from Pfizer in the year ended December 31, 2009. (See Note 3 in the Notes to Financial Statements for further details on our collaboration with Pfizer). There were no revenues in 2007 or 2006.

Research and Development Expense

	Year Ended December 31,		
	2008	2007	2006
	(In thousands)		
Research and development expense	\$54,895	\$23,399	\$11,825
Percentage increase	135%	98%	

The increase in research and development expense of 135% or \$31.5 million in 2008 as compared to 2007 was primarily due to an increase in clinical and preclinical study expense of \$26.2 million. Additionally, we had an increase in payroll related costs of \$6.6 million as we increased research and development headcount by 17 employees during 2008, offset by a decrease in other department costs of \$1.3 million. The increases in clinical and preclinical study costs, including associated payroll costs, were driven primarily by significant expansions in our clinical development work for both Dimebon and MDV3100, including initiation of our ongoing confirmatory Phase 3 clinical trial of Dimebon in Alzheimer’s disease and continuation of our ongoing Phase 1-2 clinical trial of MDV3100 in castration-resistant prostate cancer.

The increase in research and development expense of 98% or \$11.6 million in 2007 as compared to 2006 was primarily due to an increase in clinical and preclinical study expense of \$5.7 million driven primarily by a significant expansion in our clinical development work for Dimebon as we extended our first pivotal clinical study in Alzheimer’s disease and realized a full year of clinical expenses for the Phase 1-2 clinical trial of Dimebon in Huntington’s disease which began in October 2006. Additionally, we had an increase in payroll related costs of \$4.1 million as we increased headcount by 15 employees, and an increase in other associated departmental costs of \$1.8 million.

Under our Collaboration Agreement with Pfizer, we share certain Dimebon-related development costs in the U.S. on a 60% Pfizer, 40% Medivation basis. The parties make quarterly true-up payments between themselves to ensure that each has borne its applicable percentage of the shared development costs. We account for development cost true-up payments as additions to research and development expense, when such payments are made by us, and as reductions to research and development expense, when such payments are made to us. For the year ended December 31, 2008, total development cost true-up payments to us were \$3.2 million, reflecting costs incurred following October 21, 2008, the effective date of the Collaboration Agreement. There were no such payments in prior periods.

To date, we have been engaged in two major research and development programs: the development of Dimebon for the treatment of Alzheimer’s disease and Huntington’s disease, and the development of MDV3100 for the treatment of castration-resistant prostate cancer. Other research and development programs consist of preclinical stage programs, primarily our Dimebon analog program. Research and development costs are identified as either directly allocable to one of our research and development programs or as an indirect cost, with only direct costs being tracked by specific program. Direct costs consist primarily of clinical and preclinical study costs, cost of supplying drug substance and drug product for use in clinical and preclinical studies, contract research organization fees, and other contracted services pertaining to specific clinical and preclinical studies. Indirect costs consist of personnel costs (including both cash costs and non-cash stock-based compensation

costs), corporate overhead costs, and other administrative and support costs. The following table summarizes the direct costs attributable to each program and the total indirect costs for each respective period.

	Year Ended December 31,			
	2008	2007	2006	2005
	(In thousands)			
Direct Costs:				
Dimebon	\$27,910	\$10,721	\$ 5,186	\$3,077
MDV3100	8,845	2,619	3,021	261
Other	3,481	748	198	—
Total direct costs	40,236	14,088	8,405	3,338
Indirect costs	14,659	9,311	3,420	1,934
Total research and development expenses	<u>\$54,895</u>	<u>\$23,399</u>	<u>\$11,825</u>	<u>\$5,272</u>

The Company did not track research and development expense by project prior to 2005.

We expect our research and development expenses to increase in 2009 as we further expand development of Dimebon for the treatment of Alzheimer's disease and Huntington's disease, and MDV3100 for the treatment of castration-resistant prostate cancer, and other programs. Our projects or intended projects may be subject to change from time to time as we evaluate our research and development priorities and available resources.

Selling, General and Administrative Expense

	Year Ended December 31,		
	2008	2007	2006
	(In thousands)		
Selling, general and administrative expense	\$21,865	\$10,364	\$4,321
Percentage increase	111%	140%	

Selling, general and administrative expenses consisted of primarily payroll and related costs associated with corporate administration and executive management, facilities, marketing and medical science personnel, professional services including legal and accounting services, medical education and other administrative costs.

The increase in selling, general and administrative expenses of 111% or \$11.5 million in 2008 as compared to 2007 was due primarily to payroll and related costs of \$4.6 million, a fee of \$3.5 million paid to our financial advisor in connection with our Collaboration Agreement with Pfizer, and increases in patent fees of \$1.3 million. These increases in selling, general and administrative costs were incurred primarily in support of our expanded research and development work, and our Collaboration Agreement with Pfizer. Selling, general and administrative headcount increased by 14 employees during 2008.

The increase in selling, general and administrative expenses of 140% or \$6.0 million in 2007 as compared to 2006 was due primarily to increased patent and other professional fees of \$2.6 million, payroll and related costs of \$2.1 million, other department costs of \$1.3 million incurred primarily in support of our expanded research and development work. Selling, general and administrative headcount increased by 4 employees during 2007.

Under our Collaboration Agreement with Pfizer, we share certain Dimebon-related commercialization costs in the U.S., including pre-launch commercialization costs, on a 60% Pfizer, 40% Medivation basis. The parties make quarterly true-up payments between themselves to ensure that each has borne its applicable percentage of the shared commercialization costs. We account for commercialization cost true-up payments as additions to selling, general and administrative expense, when such payments are made by us, and as reductions to selling, general and administrative expense, when such payments are made to us. For the year ended December 31, 2008, total commercialization cost true-up payments to us were \$0.3 million, reflecting costs incurred following October 21, 2008, the effective date of the Collaboration Agreement. There were no such collaboration payments in prior periods.

We expect total selling, general and administrative expenses to increase in 2009, as those costs tend to move in parallel with our research and development expenses.

Interest Income, net

	<u>Year Ended December 31,</u>		
	<u>2008</u>	<u>2007</u>	<u>2006</u>
	(In thousands)		
Interest income, net	\$1,206	\$2,020	\$785
Percentage increase (decrease)	(40%)	158%	

The decrease in net interest income of 40% or \$0.8 million in the year ended December 31, 2008 as compared 2007 was primarily attributable to interest income on lower average cash balances and lower prevailing interest rates. We received our \$225.0 million up-front license fee from Pfizer on October 27, 2008, so its impact on our average cash balance for the full year was limited.

The increase in net interest income of 158% in 2007 compared to 2006 was primarily attributable to interest income on higher average cash balances and higher prevailing interest rates.

Other Income (Expense), net

	<u>Year Ended December 31,</u>		
	<u>2008</u>	<u>2007</u>	<u>2006</u>
	(In thousands)		
Other income (expense), net	\$516	\$—	\$(2)

The increase in other income (expense), net of \$0.5 million in 2008 as compared to 2007 was due to a payment of \$0.6 million we received for a securities law violation by one of our unaffiliated stockholders resulting in short swing trading profits that were remitted back to us, offset by realized losses on foreign exchange payables of \$0.1 million. There were no such realized losses in 2007 and 2006. As currency rates change and our international clinical activities increase, we may record income or expense to other income (expense), net related to our clinical vendor payable balances.

Based on current tax law, \$12.6 million of the \$225.0 million up-front payment we received from Pfizer in the fourth quarter of 2008 was recognized as revenue for federal and state income tax purposes in the year ended December 31, 2008, which is equal to the amount recognized for financial statement purposes. The remaining amount of \$212.4 million will be recognized as revenue for both federal and state tax purposes in the year ended December 31, 2009, regardless of financial statement revenue recognition. We therefore expect to have taxable income for that year. In response to budgetary pressures, the State of California has temporarily suspended the use of net operating loss carryforwards for the 2009 tax year as well as imposed limitations on the amount of credits that can offset California tax. Consequently, we expect to incur state income tax liabilities in 2009. Based on current forecasts and due to certain exemptions granted to companies regarding the alternative minimum tax, we do not expect to incur federal income tax liabilities in 2009. If earnings increase from our forecasts in excess of our federal net operating losses and other tax assets, the Company may incur a federal tax liability.

Liquidity and Capital Resources

Sources of Liquidity

We have incurred cumulative net losses of \$122.7 million through December 31, 2008, and we expect to incur substantial and increasing additional losses in the future as we expand our research and development activities. We have not generated any revenue from product sales to date, and we and do not expect to generate

product revenue for several years, if ever. In the year ended December 31, 2008, we generated \$12.6 million in collaboration revenue from the Pfizer Collaboration Agreement. All of our operations to date have been funded through the sale of our debt and equity securities, the \$225.0 million up-front payment we received from Pfizer on October 27, 2008, and cost-sharing true-up payments from Pfizer. As of December 31, 2008 we had cash, cash equivalents and short-term investments of \$221.4 million available to fund operations. In addition, at December 31, 2008, the remaining capacity under our committed equity line of credit with Azimuth Opportunity, Ltd. was \$78.8 million. The Azimuth facility expires on April 1, 2009, and we do not anticipate drawing any additional amounts under that facility prior to its expiration. Based upon our current expectations, we believe our capital resources at December 31, 2008 will be sufficient to fund our currently planned operations for at least the next twelve months.

Pfizer Collaboration Agreement

In September 2008, we announced a Collaboration Agreement with Pfizer. Under this agreement, we and Pfizer will collaborate on development of Dimebon for Alzheimer's disease and Huntington's disease for the United States market, including associated regulatory filings with the FDA. In addition, following FDA approval and launch of Dimebon in the United States, we, at our option, and Pfizer will co-promote Dimebon to specialty physicians in the United States, and Pfizer will promote Dimebon to primary care physicians in the United States. Pfizer will be responsible for development and seeking regulatory approval for, and commercialization of, Dimebon outside the United States. After a period of transition from our contract manufacturers to Pfizer, Pfizer will be responsible for all manufacture of product for both clinical and commercial purposes. Both we and Pfizer have agreed not to commercialize for the treatment of specified indications any other products directed to the same primary molecular target as Dimebon for a specified time period, subject to certain exceptions.

The agreement establishes several joint committees consisting of an equal number of representatives from both parties that will operate by consensus to oversee the collaboration. In the event that a joint committee is unable to reach consensus on a particular issue, then, depending on the issue, a dispute may be decided at the joint committee level by the party to whom the contract grants final decision on the issue or escalated to senior management of the parties. If a dispute is escalated to senior management and no consensus is reached, then the dispute may be decided by the party with the final decision on such issue. Other issues can only be decided by consensus of the parties, and unless and until the parties' representatives reach agreement on such issue, no decision on such issue will be made, and the status quo will be maintained.

Under the Collaboration Agreement, Pfizer paid us an up-front cash payment of \$225 million in the fourth quarter of 2008. We are also eligible to receive payments of up to \$500 million upon the attainment of development and regulatory milestones plus additional milestone payments upon the achievement of certain net sales levels for the product. We and Pfizer will share the costs and expenses of developing and commercializing Dimebon for the United States market on a 60%/40% basis, with Pfizer assuming the larger share, and we and Pfizer will share profits (or losses) resulting from the commercialization of Dimebon in the United States in such proportions. Outside the United States, Pfizer will bear all development and commercialization costs and will pay us tiered royalties on the aggregate net sales of Dimebon.

If one of the parties merges with, or acquires or is acquired by, a third party and as a result such party must divest its interest in the Dimebon collaboration due to a governmental requirement, then the other party has the first right to purchase the divesting party's interest in the collaboration, on terms to be negotiated by the parties. In the event that the parties are unable to agree on the terms of this purchase after following the negotiation procedure outlined in the Collaboration Agreement, the divesting party will have a time-limited right to sell its interest in the collaboration to a third party. However, the terms of this sale must be more favorable than any terms offered by the non-divesting party and the third party will remain bound by the terms of the Collaboration Agreement. In the event the non-divesting party declines to purchase the divesting party's interest, the divesting party may sell its interest in the collaboration to a third party on any terms but such third party will remain bound by the terms of the Collaboration Agreement.

We are permitted to terminate the Collaboration Agreement for an uncured material breach by Pfizer. Pfizer has a right to terminate the Collaboration Agreement unilaterally, after 18 months following Dimebon's first commercial sale, but can earlier terminate at its discretion with advance written notice to us if clinical data for Dimebon generated after the effective date do not meet certain specified criteria or if regulatory approval is conditioned or delayed. In the event of our uncured material breach of the Collaboration Agreement, Pfizer may elect either to terminate the Collaboration Agreement or to keep the Collaboration Agreement in place, but terminate our right to participate in development, commercialization (other than co-promoting Dimebon) and other activities for Dimebon, including the joint committees and decision making for Dimebon. However, such termination would not affect our financial return or, unless we commit an uncured material breach of our co-promotion obligations, our co-promotion rights. Following any termination of the Collaboration Agreement, all rights to develop and commercialize Dimebon will revert to us, and Pfizer will grant a license to us to enable us to continue such development and commercialization, and will supply product to us during a specified transition period.

Cash Flow

	Year ended December 31,		
	2008	2007	2006
	(In thousands)		
Net cash provided by (used in):			
Operating activities	\$ 162,172	\$(23,358)	\$(12,972)
Investing activities	(149,546)	40,931	(33,935)
Financing activities	15,570	21,036	46,972
Net change in cash and cash equivalents	<u>\$ 28,196</u>	<u>\$ 38,609</u>	<u>\$ 65</u>

Cash, cash equivalents and short-term investments totaled \$221.4 million at December 31, 2008, compared to \$43.3 million at December 31, 2007 and \$47.2 million at December 31, 2006. The net increase in cash, cash equivalents and short-term investments of \$178.1 million in 2008 as compared to 2007 was due primarily to cash proceeds from an up-front license payment received from Pfizer of \$225.0 million and the issuance of \$15.0 million of common stock, partially offset by operating losses of \$62.5 million incurred in 2008. The net decrease in cash, cash equivalents and short-term investments of \$3.9 million in 2007 as compared to 2006 was due primarily to our operating losses of \$31.7 million partially offset by issuance of \$20.8 million of common stock net of issuance costs.

Operating Activities

Net cash provided by operating activities totaled \$162.2 million in 2008. Cash provided by operating activities during 2008 was primarily driven by the cash payment of \$225.0 million from Pfizer initially recorded to deferred revenue, non-cash stock-based compensation expense of \$8.5 million, and increases in accounts payable and accrued expenses of \$5.4 million and \$3.6 million, respectively, arising in the ordinary course of business as a result of our increasing research and development activities, partially offset by our net loss of \$62.5 million and a cost-sharing receivable from Pfizer of \$3.5 million.

Net cash used in operating activities totaled \$23.4 million in 2007 which was primarily attributable to operating losses of \$31.7 million, partially offset by non-cash stock-based compensation expense of \$5.9 million and an increase in accrued expenses of \$2.2 million arising in the ordinary course of business as a result of our increasing research and development activities. Net cash used in operating activities totaled \$13.0 million in 2006 which was primarily attributable to operating losses of \$15.4 million, partially offset by non-cash stock-based compensation of \$2.5 million.

Investing Activities

Net cash used in investing activities totaled \$149.5 million in 2008. Cash used in investing activities primarily represented net purchases and maturities of short-term investments during 2008. Net cash provided by investing activities totaled \$40.9 million in 2007 and primarily represented net proceeds from purchases and maturities of short-term investments. Net cash used in investing activities totaled \$33.9 million in 2006 and represented net purchases and maturities of short-term investments.

Financing Activities

Net cash provided by financing activities totaled \$15.6 million in 2008. Cash provided by financing activities was primarily due to our sale of our common stock in a registered direct offering, raising net proceeds of approximately \$14.9 million, and \$0.7 million in proceeds from the issuance of common stock related to the exercise of employee stock options.

Net cash provided by financing activities totaled \$21.0 million in 2007. Cash provided by financing activities was primarily due to our sale of common stock to Azimuth Opportunity Ltd., raising net proceeds of \$20.8 million, and \$0.2 million in proceeds from the issuance of common stock related to the exercise of employee stock options.

Net cash provided by financing activities totaled \$47.0 million in 2006. Cash provided by financing activities was primarily due to our sale of our common stock in a registered direct offering, raising net proceeds of approximately \$46.8 million, and \$0.2 million in proceeds from the issuance of common stock related to the exercise of employee stock options.

Commitments and Contingencies

At December 31, 2008, we had minimum future payments under the operating leases for our office facilities as follows (in thousands):

	Payment due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating lease obligations(1)	\$5,369	\$1,246	\$3,814	\$309	\$—

- (1) We have provided irrevocable letters of credit to our landlord to secure performance of our obligations under these leases, and have placed \$843,000 in a restricted account to secure our contingent obligations to the provider of the letter or credit. This amount has been recorded as restricted cash. The lease agreement covering our present facilities expires July 2012 and May 2013. Please refer to Note 15, "Commitments and Contingencies," in the Notes to Financial Statements of Part II, Item 8 of this Form 10-K for further discussion regarding our future operating lease commitments.

Off-Balance Sheet Arrangements

We have no material off-balance sheet arrangements as defined in Regulation S-K 303(a)(4)(ii).

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

Our exposure to market risk for changes in interest rates relates to our cash equivalents on deposit in highly liquid money market accounts and short-term investments in highly liquid U.S. Treasury securities. The primary objective of our cash investment activities is to preserve principal. We do not use derivative financial instruments in our investment portfolio. Our cash and investments policy emphasizes liquidity and preservation of principal over other portfolio considerations. Our investment portfolio is subject to interest rate risk and will fall in value if

market interest rates rise. The \$225.0 million up-front payment we received from Pfizer on October 27, 2008 has been fully invested in short-term U.S. Treasury securities and in money market funds consisting solely of short-term U.S. Treasury securities.

Interest Rate Risk

As of December 31, 2008, we held \$71.5 million in cash and cash equivalents consisting of highly liquid money market accounts. Declines of interest rates over time would reduce our interest income from our highly liquid money market accounts. Based upon our balance of cash and cash equivalents at December 31, 2008, a decrease in interest rates of 100 basis points would cause a corresponding decrease in our annual interest income of approximately \$0.7 million for these investments. Due to the nature of our highly liquid cash equivalents, a change in interest rates would not materially change the fair market value of our cash and cash equivalents.

As of December 31, 2008, we held \$150.0 million in short-term investments, which consisted entirely of U.S. Treasury securities maturing in less than twelve months. The weighted average interest rate of our investments held was approximately 1.35% during 2008. A decline in interest rates over time would reduce our interest income from our short-term investments. Based upon our balance of short-term investments at December 31, 2008, a decrease in interest rates of 100 basis points would cause a corresponding decrease in our annual interest income of approximately \$1.5 million for these investments. Due to the nature of our highly liquid cash equivalents, a change in interest rates would not materially change the fair market value of our short-term investments.

Foreign Currency Exchange Risk

We do not have any material exposure to foreign currency rate fluctuations as we operate primarily in the U.S. Although we conduct some research and development work with vendors outside the U.S., most of our transactions are denominated in U.S. dollars. However, we expect our exposure to foreign currency exchange rate fluctuations to increase due primarily to expansion of our ex-U.S. clinical development activities, which we expect will result in an increase in foreign currency-denominated payment obligations. This trial includes clinical sites in Europe and South America, and certain of our payment obligations with respect to those sites will be denominated in foreign currencies. For the year ended December 31, 2008, we recorded less than \$0.1 million in foreign currency exchange losses. As of December 31, 2008, we have recorded the equivalent of approximately \$0.9 million of foreign denominated vendor payables. A hypothetical change of 10% in currency rates could result in an adjustment to the consolidated statements of operations of approximately \$0.1 million and could result in our paying approximately \$0.1 million more or less in cash than anticipated at December 31, 2008.

Item 8. Financial Statements and Supplementary Data.

All information required by this item is included in Item 15 of Part IV of this Annual Report on Form 10-K and is incorporated into this item by reference.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Based on their evaluation as of December 31, 2008 and subject to the limitations described below, our chief executive officer and chief financial officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) were effective at the reasonable assurance level.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2008. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in Internal Control-Integrated Framework. Our management has concluded that as of December 31, 2008, our internal control over financial reporting was effective based on these criteria.

The effectiveness of our internal control over financial reporting as of December 31, 2008 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which is included below.

Limitations on Effectiveness of Controls

Our management, including our chief executive officer and chief financial officer, does not expect that our procedures or our internal controls will prevent or detect all error and all fraud. An internal control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of our controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met and, as set forth above, our principal executive officer and principal financial officer have concluded, based on their evaluation as of the end of the period covered by this report, that our disclosure controls and procedures were sufficiently effective to provide reasonable assurance that the objectives of our disclosure control system were met. We continue to implement, improve and refine our disclosure controls and procedures and our internal control over financial reporting.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2008 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information regarding directors, executive officers and the board of directors and its committees is incorporated by reference to the information set forth under the captions “Election of Directors,” “Information Regarding the Board of Directors and Corporate Governance,” “Executive Officers” and “Section 16(a) Beneficial Ownership Reporting Compliance” in our Proxy Statement pursuant to Section 14(a) of the Securities Exchange Act of 1934 for the Annual Meeting of Stockholders to be filed with the Commission on or before April 30, 2009.

We have adopted a written code of business conduct and ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons serving similar functions. The code of business conduct and ethics is available on our corporate website at www.meditation.com. If we make any substantive amendments to our code of business conduct and ethics or grant to any of our directors or executive officers any waiver, including any implicit waiver, from a provision of our code of business conduct and ethics, we will disclose the nature of the waiver or amendment on our website or in a Current Report on Form 8-K.

Item 11. Executive Compensation.

Information regarding executive compensation is incorporated by reference to the information set forth under the captions “Executive Compensation”, “Compensation Committee Interlocks and Insider Participation” and “Compensation Committee Report” in our Proxy Statement for the Annual Meeting of Stockholders to be filed with the Commission on or before April 30, 2009.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Information regarding security ownership of certain beneficial owners and management is incorporated by reference to the information set forth under the caption “Security Ownership of Certain Beneficial Owners and Management” and “Equity Compensation Plan Information” in our Proxy Statement for the Annual Meeting of Stockholders to be filed with the Commission by on or before April 30, 2009.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Information regarding certain relationships and related transactions is incorporated by reference to the information set forth under the caption “Transactions with Related Persons” in our Proxy Statement for the Annual Meeting of Stockholders to be filed with the Commission on or before April 30, 2009.

Item 14. Principal Accountant Fees and Services.

Information regarding principal accountant fees and services is incorporated by reference to the information set forth under the caption “Ratification of Selection of Independent Auditors” in our Proxy Statement for the Annual Meeting of Stockholders to be filed with the Commission on or before April 30, 2009.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) The following documents are filed as part of this Annual Report:

1. *Financial Statements*. Our financial statements and the Report of Independent Registered Public Accounting Firm, are included in Part IV of this Report on the pages indicated:

	<u>Page</u>
Report of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm of Medivation, Inc.	53
Report of SingerLewak LLP, former Independent Registered Public Accounting Firm of Medivation, Inc.	54
Consolidated Balance Sheets as of December 31, 2008 and 2007	55
Consolidated Statements of Operations for the years ended December 31, 2008, 2007 and 2006	56
Consolidated Statements of Cash Flows for the years ended December 31, 2008, 2007 and 2006	57
Consolidated Statements of Stockholders' Equity for the period from December 31, 2005 to December 31, 2008	58
Notes to Consolidated Financial Statements	59

2. *Financial Statement Schedules*. All schedules are omitted because they are not applicable or the required information is shown in the financial statements or the notes thereto.

3. *Exhibits*:

Unless otherwise indicated below, the Commission file number to the exhibit is No. 001-32836 for filings made in or after March 2006 and No. 000-20837 for filings made prior to March 2006.

<u>Exhibit No.</u>	<u>Exhibit Description</u>
3.1(a)	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1(a) to the Quarterly Report on Form 10-QSB of Medivation, Inc. for the quarter ended June 30, 2005).
3.1(b)	Certificate of Amendment of Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1(b) to the Quarterly Report on Form 10-QSB of Medivation, Inc. for the quarter ended June 30, 2005).
3.1(c)	Certificate of Amendment to the Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1(c) to the Quarterly Report on Form 10-QSB of Medivation, Inc. for the quarter ended June 30, 2005).
3.1(d)	Certificate of Designations of the Series B Convertible Preferred Stock of Orion Acquisition Corp. II (incorporated by reference to Exhibit 3.1(d) to the Quarterly Report on Form 10-QSB of Medivation, Inc. for the quarter ended June 30, 2005).
3.1(e)	Certificate of Designations of the Series C Junior Participating Preferred Stock of Medivation, Inc. (incorporated by reference to Exhibit 3.1(d) to the Annual Report on Form 10-KSB of Medivation, Inc. for the fiscal year ended December 31, 2007).
3.2	Amended and Restated Bylaws of Medivation, Inc.
4.1	Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registration Statement on Form SB-2 of Medivation, Inc. (formerly Orion Acquisition Corp. II) (No. 333-03252)).

<u>Exhibit No.</u>	<u>Exhibit Description</u>
4.2	Rights Agreement, dated as of December 4, 2006, between Medivation, Inc. and American Stock Transfer & Trust Company, as Rights Agent, which includes the form of Certificate of Designations of the Series C Junior Participating Preferred Stock of Medivation, Inc. as Exhibit A, the form of Right Certificate as Exhibit B and the Summary of Rights to Purchase Preferred Shares as Exhibit C (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed on December 4, 2006).
10.1	Registration Rights Agreement by and among Orion Acquisition Corp. II and Special Situations Fund III, L.P., Special Situations Cayman Fund, L.P. and Special Situations Private Equity Fund, L.P., dated as of December 17, 2004 (incorporated by reference to Exhibit 10.3(a) to the Registration Statement on Form SB-2 of Medivation, Inc. (formerly Orion Acquisition Corp. II) (No. 333-122431)).
10.2(a)	Warrant to purchase Common Stock of Medivation Neurology, Inc. assumed by Orion Acquisition Corp. II issued to Joseph J. Grano, Jr., dated as of June 8, 2004 (incorporated by reference to Exhibit 10.5(a) to the Registration Statement on Form SB-2 of Medivation, Inc. (formerly Orion Acquisition Corp. II) (No. 333-122431)).
10.2(b)	Warrant to purchase Common Stock of Medivation Neurology, Inc. assumed by Orion Acquisition Corp. II issued to Joseph J. Grano, Jr., dated as of August 1, 2004 (incorporated by reference to Exhibit 10.5(b) to the Registration Statement on Form SB-2 of Medivation, Inc. (formerly Orion Acquisition Corp. II) (No. 333-122431)).
10.2(c)	Warrant to purchase Common Stock of Medivation Neurology, Inc. assumed by Orion Acquisition Corp. II issued to Joseph J. Grano, Jr., dated as of September 1, 2004 (incorporated by reference to Exhibit 10.5(c) to the Registration Statement on Form SB-2 of Medivation, Inc. (formerly Orion Acquisition Corp. II) (No. 333-122431)).
10.2(d)	Amendment Agreement by and between Orion Acquisition Corp. II and Joseph J. Grano, Jr., dated as of December 17, 2004 (incorporated by reference to Exhibit 10.5(d) to the Registration Statement on Form SB-2 of Medivation, Inc. (formerly Orion Acquisition Corp. II) (No. 333-122431)).
10.3	Warrant to purchase Common Stock of Medivation Neurology, Inc. assumed by Orion Acquisition Corp. II issued to David T. Hung, M.D., dated as of November 16, 2004 (incorporated by reference to Exhibit 10.6 to the Registration Statement on Form SB-2 of Medivation, Inc. (formerly Orion Acquisition Corp. II) (No. 333-122431)).
10.4(a)*	Amended and Restated 2004 Equity Incentive Award Plan (incorporated by reference to Exhibit 10.4(a) to the Annual Report on Form 10-KSB for the fiscal year ended December 31, 2007).
10.4(b)*	Form of Stock Option Agreement (incorporated by reference to Exhibit 10.7(b) to the Annual Report on Form 10-KSB of Medivation, Inc. (formerly Orion Acquisition Corp. II) for the year ended December 31, 2004).
10.4(c)*	Form of Stock Option Agreement (incorporated by reference to Exhibit 10.7(c) to the Annual Report on Form 10-KSB of Medivation, Inc. (formerly Orion Acquisition Corp. II) for the year ended December 31, 2004).
10.5	Form of Subscription Agreement (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on December 8, 2006).
10.6	Common Stock Purchase Agreement, dated as of September 7, 2007, by and between Medivation, Inc. and Azimuth Opportunity Ltd. (incorporated by reference to Exhibit 10.1 to Medivation, Inc.'s Current Report on Form 8-K filed on September 10, 2007).

<u>Exhibit No.</u>	<u>Exhibit Description</u>
10.7	Form of Purchase Agreement, dated as of June 22, 2008, between Medivation, Inc. and the purchasers of its common stock (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on June 23, 2008).
10.8**	Amended and Restated Collaboration Agreement, dated as of October 20, 2008, between Medivation, Inc. and Pfizer Inc. (incorporated by reference to Exhibit 10.8 to the Quarterly Report on Form 10-Q for the quarter ended September 30, 2008).
10.9*	Bonuses for Fiscal Year 2008 and Base Salaries for Fiscal Year 2009 for Certain Executive Officers (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on November 5, 2008).
10.10*	Medivation, Inc. 2009 Bonus Plan (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on November 5, 2008).
10.11*	Change of Control Severance Benefits Agreement, dated as of February 2, 2009, between Medivation, Inc. and David Hung, M.D.
10.12*	Severance Benefits Agreement, dated as of February 9, 2009, between Medivation, Inc. and Rohan Palekar.
10.13*	Form of Medivation, Inc. Change of Control Severance Benefits Agreement.
16	Letter from SingerLewak LLP to the Securities and Exchange Commission (incorporated by reference to Exhibit 16.1 to the Current Report on Form 8-K filed on March 23, 2007).
21	Subsidiaries of Medivation, Inc.
23.1	Consent of Independent Registered Public Accounting Firm.
23.2	Consent of Former Independent Registered Public Accounting Firm.
24	Power of attorney (contained on signature page).
31.1	Certification pursuant to Rule 13a-14(a)/15d-14(a).
31.2	Certification pursuant to Rule 13a-14(a)/15d-14(a).
32.1	Certifications of Chief Executive Officer and Chief Financial Officer.

* Indicates management contract or compensatory plan or arrangement.

** Confidential treatment has been granted with respect to certain portions of this exhibit.

SIGNATURES

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

MEDIVATION, INC.

/s/ C. PATRICK MACHADO

C. Patrick Machado
Senior Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

Dated: March 16, 2009

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENT, that each person whose signature appears below constitutes and appoints David T. Hung, M.D. and C. Patrick Machado, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place, and stead, in any and all capacities, to sign any and all amendments to this Report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming that all said attorneys-in-fact and agents, or any of them or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

<u>/s/ DAVID T. HUNG, M.D.</u> David T. Hung, M.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	March 16, 2009
<u>/s/ C. PATRICK MACHADO</u> C. Patrick Machado	Senior Vice President and Chief Financial Officer (Principal Accounting and Financial Officer)	March 16, 2009
<u>/s/ DANIEL D. ADAMS</u> Daniel D. Adams	Director	March 16, 2009
<u>/s/ GREGORY H. BAILEY, M.D.</u> Gregory H. Bailey	Director	March 16, 2009
<u>/s/ KIM D. BLICKENSTAFF</u> Kim D. Blickenstaff	Director	March 16, 2009
<u>/s/ W. ANTHONY VERNON</u> W. Anthony Vernon	Director	March 16, 2009

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of
Medivation, Inc.

In our opinion, the accompanying consolidated balance sheets and related consolidated statements of operations, of stockholders' equity and of cash flows present fairly, in all material respects, the financial position of Medivation, Inc. and its subsidiaries (the "Company") at December 31, 2008 and December 31, 2007 and the results of their operations and their cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008 based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements and for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the Management's Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our audits (which was an integrated audit in 2008). We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PricewaterhouseCoopers LLP
San Jose, California
March 13, 2009

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors
Medivation, Inc. and subsidiaries
San Francisco, California

We have audited the consolidated statements of operations, stockholder's equity and cash flows of Medivation, Inc. and subsidiaries (the "Company"), for the year ended December 31, 2006. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the results of operations and cash flows of Medivation, Inc. and subsidiaries for the year ended December 31, 2006, in conformity with U.S. generally accepted accounting principles.

/s/ SingerLewak LLP

Los Angeles, California
February 12, 2007

MEDIVATION, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	December 31,	
	2008	2007
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 71,454	\$ 43,258
Short-term investments	149,968	—
Receivable from collaboration partner (Note 3)	3,522	—
Prepaid expenses and other current assets	1,957	991
Total current assets	226,901	44,249
Property and equipment, net	768	689
Restricted cash	843	500
Intellectual property, net	54	58
Other non-current assets	706	100
Total assets	\$ 229,272	\$ 45,596
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 7,166	\$ 1,747
Accrued expenses	5,772	2,218
Deferred revenue	64,286	—
Other current liabilities	93	70
Total current liabilities	77,317	4,035
Deferred revenue, net of current	148,137	—
Other non-current liabilities	399	492
Series A redeemable preferred stock	11	11
Total liabilities	225,864	4,538
Commitments and contingencies (Note 14)		
Stockholders' equity:		
Preferred stock, \$0.01 par value per share; 1,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, \$0.01 par value per share; 50,000,000 shares authorized; issued and outstanding 30,088,390 shares at December 31, 2008 and 28,837,290 at December 31, 2007	301	288
Additional paid-in capital	125,074	100,970
Accumulated other comprehensive income	693	—
Accumulated deficit	(122,660)	(60,200)
Total stockholders' equity	3,408	41,058
Total liabilities and stockholders' equity	\$ 229,272	\$ 45,596

SEE ACCOMPANYING NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

MEDIVATION, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share data)

	<u>Years ended December 31,</u>		
	<u>2008</u>	<u>2007</u>	<u>2006</u>
Collaboration revenue	\$ 12,578	\$ —	\$ —
Operating expenses:			
Research and development	54,895	23,399	11,825
Selling, general and administrative	21,865	10,364	4,321
Total operating expenses	<u>76,760</u>	<u>33,763</u>	<u>16,146</u>
Loss from operations	(64,182)	(33,763)	(16,146)
Other income (expense):			
Interest income, net	1,206	2,020	785
Other income (expense), net	516	—	(2)
Total other income (expense)	<u>1,722</u>	<u>2,020</u>	<u>783</u>
Net loss	<u>\$(62,460)</u>	<u>\$(31,743)</u>	<u>\$(15,363)</u>
Basic and diluted net loss per share	<u>\$ (2.12)</u>	<u>\$ (1.14)</u>	<u>\$ (0.63)</u>
Weighted average common shares used in the calculation of basic and diluted net loss per share	<u>29,478</u>	<u>27,932</u>	<u>24,248</u>

SEE ACCOMPANYING NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

MEDIVATION, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Years ended December 31,		
	2008	2007	2006
Cash flows from operating activities:			
Net loss	\$ (62,460)	\$(31,743)	\$(15,363)
Adjustments to reconcile net loss to net cash from operating activities:			
Impairment of intellectual property	—	—	68
Depreciation and amortization	193	74	7
Loss on disposal of property and equipment	—	6	—
Accretion of discount on securities	(340)	(70)	(9)
Stock-based compensation	8,547	5,893	2,449
Liquidated damages paid:			
To related parties	—	—	(16)
To other parties	—	—	(256)
Changes in operating assets and liabilities:			
Receivable from collaboration partner	(3,522)	—	—
Prepaid expenses and other current assets	(966)	(328)	(360)
Other assets	(606)	12	(37)
Accounts payable	5,419	55	516
Accrued expenses	3,554	2,214	(4)
Other current liabilities	23	37	33
Deferred revenue	212,423	—	—
Other non-current liabilities	(93)	492	—
Net cash provided by (used in) operating activities	<u>162,172</u>	<u>(23,358)</u>	<u>(12,972)</u>
Cash flows from investing activities:			
Purchase of short-term investments	(248,935)	(24,692)	(56,711)
Maturities of short-term investments	100,000	66,956	22,776
Purchase of property and equipment	(268)	(758)	—
Purchase of restricted cash	(343)	(575)	—
Net cash provided by (used in) investing activities	<u>(149,546)</u>	<u>40,931</u>	<u>(33,935)</u>
Cash flows from financing activities:			
Proceeds from issuance of common stock, net of issuance costs	14,911	20,799	46,751
Stock option exercises	659	237	221
Net cash provided by financing activities	<u>15,570</u>	<u>21,036</u>	<u>46,972</u>
Net increase in cash and cash equivalents	28,196	38,609	65
Cash and cash equivalents at beginning of year	43,258	4,649	4,584
Cash and cash equivalents at end of year	<u>\$ 71,454</u>	<u>\$ 43,258</u>	<u>\$ 4,649</u>

SEE ACCOMPANYING NOTES TO CONSOLIDATED FINANCIAL STATEMENTS.

MEDIVATION, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands, except share data)

	COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED OTHER COMPREHEN- SIVE INCOME	ACCUMULATED DEFICIT	TOTAL STOCKHOLDERS' EQUITY
	SHARES	AMOUNT				
Balances at December 31, 2005	22,075,911	\$221	\$ 24,687	\$—	\$ (13,094)	\$ 11,814
Common stock issued for:						
Cash in the May 2006 financing ...	3,000,000	30	14,220	—	—	14,250
Cash in the December 2006 financing	2,215,384	22	35,978	—	—	36,000
Cashless exercise of B warrants	364,838	3	(3)	—	—	—
Cash upon exercise of stock options	67,399	1	220	—	—	221
Offering expenses	—	—	(3,499)	—	—	(3,499)
Stock-based compensation expense	—	—	2,449	—	—	2,449
Net loss	—	—	—	—	(15,363)	(15,363)
Balances at December 31, 2006	<u>27,723,532</u>	<u>277</u>	<u>74,052</u>	<u>—</u>	<u>(28,457)</u>	<u>45,872</u>
Common stock issued for:						
Azimuth common stock purchase agreement	1,023,548	10	21,240	—	—	21,250
Cashless exercise of B warrants	24,020	—	—	—	—	—
Cash upon exercise of stock options	66,190	1	236	—	—	237
Offering expenses	—	—	(451)	—	—	(451)
Stock-based compensation expense	—	—	5,893	—	—	5,893
Net loss	—	—	—	—	(31,743)	(31,743)
Balances at December 31, 2007	<u>28,837,290</u>	<u>288</u>	<u>100,970</u>	<u>—</u>	<u>(60,200)</u>	<u>41,058</u>
Common stock issued for:						
Cash in the June 2008 financing ...	1,129,518	11	14,989	—	—	15,000
Cashless exercise of B warrants	5,496	1	(1)	—	—	—
Cash upon exercise of stock options	116,086	1	658	—	—	659
Offering expenses	—	—	(89)	—	—	(89)
Stock-based compensation expense	—	—	8,547	—	—	8,547
Comprehensive loss:						
Net loss	—	—	—	—	(62,460)	(62,460)
Unrealized gain on securities available-for-sale	—	—	—	693	—	693
Comprehensive loss	—	—	—	—	—	(61,767)
Balances at December 31, 2008	<u>30,088,390</u>	<u>\$301</u>	<u>\$125,074</u>	<u>\$693</u>	<u>\$(122,660)</u>	<u>\$ 3,408</u>

SEE ACCOMPANYING NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

MEDIVATION, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 31, 2008

1. DESCRIPTION OF BUSINESS

The Company is a biopharmaceutical company focused on the rapid development of novel small molecule drugs to treat serious diseases for which there are limited treatment options. The Company's current lead clinical candidates are directed at treating Alzheimer's disease, Huntington's disease and castration-resistant prostate cancer. The Company's Alzheimer's and Huntington's disease programs are partnered with Pfizer Inc, or Pfizer, and its prostate cancer program remains unpartnered. With Pfizer, the Company is conducting a broad Dimebon clinical development program, including a pivotal and confirmatory Phase 3 trial in patients with mild-to-moderate Alzheimer's disease. The program also includes additional Phase 3 trials beginning this year in both Alzheimer's disease and Huntington's disease. In addition, the Company is conducting a Phase 1-2 clinical trial of MDV3100 in patients with castration-resistant (also known as hormone-refractory) prostate cancer, and plans to seek FDA approval to begin a Phase 3 trial this year.

In September 2008, the Company announced a Collaboration Agreement with Pfizer, which became effective on October 21, 2008. Under the terms of the agreement, the Company and Pfizer will develop and commercialize Dimebon, the Company's investigational drug for treatment of Alzheimer's disease and Huntington's disease. The Company and Pfizer will share the costs and expenses of developing and commercializing Dimebon for the United States market on a 60% Pfizer/40% Medivation basis, and will share profits (or losses) resulting from commercialization of Dimebon in the United States in the same proportions. Outside the United States, Pfizer will bear all development and commercialization costs, and will pay the Company tiered royalties on aggregate net sales of Dimebon. In October 2008, the Company received a non-refundable, up-front cash payment of \$225.0 million pursuant to its Collaboration Agreement with Pfizer.

In the fourth quarter of 2008, the Company recognized \$12.6 million in collaboration revenue attributable to its up-front payment from Pfizer. Previously the Company had not recognized any revenue. The Company has funded its operations primarily through private and public offerings of its common stock, and from the up-front payment and cost-sharing payments from its Collaboration Agreement with Pfizer. As of December 31, 2008, the Company had an accumulated deficit of \$122.7 million and expected to incur substantial and increasing additional losses in the future as it expands its research and development activities.

During the year ended December 31, 2008, the Company exited the development stage. Previously from its inception, the Company was a development stage company in accordance with the Financial Accounting Standards Board, or FASB, Statement of Financial Accounting Standards, or SFAS, No. 7, *Accounting and Reporting by Development Stage Enterprises*.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

(a) Basis of Consolidation; Business Segments

The consolidated financial statements incorporate the accounts of Medivation and its operating subsidiaries. All significant inter-company transactions have been eliminated in consolidation. The Company operates in only one business segment.

(b) Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires that management make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Estimates and assumptions principally relate to the

performance period of the Company's deliverables under its Collaboration Agreement with Pfizer, services performed by third parties but not yet invoiced, estimates of the fair value and forfeiture rates of stock options issued to employees and consultants, and estimates of the probability and potential magnitude of contingent liabilities. Actual results could differ from those estimates.

(c) Cash Equivalents

Cash and cash equivalents are stated at cost, which approximates fair market value. The Company considers all highly liquid investments with a remaining maturity of three months or less at the time of acquisition to be cash equivalents.

(d) Short-Term Investments

The Company considers all highly liquid investments with a remaining maturity at the time of acquisition of more than three months but no longer than twelve months to be short-term investments. The Company classifies its securities as available-for-sale, which are reported at fair value with related unrealized gains and losses included as a component of stockholders' equity. The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included in interest income. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in other income or expense. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest income.

(e) Restricted cash

Restricted cash represents certificates of deposit held in the Company's name with a major financial institution to secure the Company's contingent obligations under irrevocable letters of credit issued to the lessor of the Company's office facilities. Please refer to Note 14 for additional information.

(f) Fair value of financial instruments

The fair value of the Company's cash equivalents and marketable securities is based on quoted market prices. Other financial instruments, including accounts receivable, accounts payable and accrued expenses, are carried at cost, which the Company believes approximates fair value because of the short-term maturities of these instruments.

(g) Concentration of Credit Risk

Financial instruments that potentially subject the Company to credit risk consist of cash, cash equivalents, short-term investments and a receivable from collaboration partner to the extent of the amounts recorded on the balance sheets. The Company's current investment policy is to invest only in a) debt securities issued by, or backed by the full faith and credit of, the U.S. government, b) repurchase agreements that are fully collateralized by such debt securities, and c) money market funds invested exclusively in the types of securities described in a) and b) above. The Company's cash and cash equivalents are primarily invested in deposits and money market accounts with one major bank in the United States. Deposits in these banks may exceed the amount of insurance provided on such deposits. Given this investment policy, the Company does not believe its exposure to credit risk with respect to the issuers of the securities in which it invests is material, and accordingly has no formal policy for mitigating such risk. The Company's receivable from collaborative partner was collected in full subsequent to December 31, 2008.

(h) Property and Equipment

Property and equipment purchases are recorded at cost. Repairs and maintenance costs are expensed in the period incurred. Property and equipment is depreciated on a straight-line basis over the estimated useful lives of the assets as follows:

<u>Description</u>	<u>Estimated Useful Life</u>
Office equipment and furniture	3 years
Software and Computer equipment	3-5 years
Laboratory equipment	5 years
Leasehold improvements and fixtures	Lesser of estimated useful life or life of lease

(i) Intellectual Property

The costs of acquiring intellectual property rights to be used in the research and development process, including licensing fees and milestone payments, are charged to research and development expense as incurred in situations where the Company has not identified an alternative future use for the acquired rights, and are capitalized in situations where it has identified an alternative future use. Capitalized costs are amortized over the estimated useful life of the applicable intellectual property right. Legal and other costs of prosecuting and maintaining intellectual property rights are expensed as incurred.

(j) Impairment or Disposal of Long-lived Assets

The Company evaluates its long-lived assets, primarily its intellectual property, for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets, property and equipment and intangibles may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less cost to sell.

(k) Other Comprehensive Loss

The reconciliation of the Company's other comprehensive loss for the years ended December 31, 2008, 2007 and 2006 is as follows:

	<u>Year ended December 31,</u>		
	<u>2008</u>	<u>2007</u>	<u>2006</u>
		(in thousands)	
Net loss	\$(62,460)	\$(31,743)	\$(15,363)
Unrealized gain on marketable securities classified as available for sale in the current period	693	—	—
Total comprehensive loss	<u>\$(61,767)</u>	<u>\$(31,743)</u>	<u>\$(15,363)</u>

(l) Revenue Recognition

Revenue recognized to date is attributable solely to the non-refundable up-front payment of \$225.0 million the Company received in the fourth quarter of 2008 pursuant to its Collaboration Agreement with Pfizer. For a description of the Collaboration Agreement, see Note 3.

The Collaboration Agreement contains multiple elements and deliverables, and requires evaluation pursuant to EITF Issue No. 00-21; *Accounting for Revenue Arrangements with Multiple Deliverables* ("EITF 00-21"). The

Company evaluated the facts and circumstances of the Collaboration Agreement to determine whether it had obligations constituting deliverables under EITF 00-21. The Company concluded that it had multiple deliverables under the Collaboration, including deliverables relating to the grant of a technology license, and performance of manufacturing, regulatory and clinical development services in the U.S., and estimated that the period in which the Company would perform those deliverables began in the fourth quarter of 2008 and will be completed in the first quarter of 2012. The Company also concluded that these deliverables should be accounted for as a single unit of account under EITF 00-21. Accordingly, the Company will recognize the non-refundable, up-front payment of \$225.0 million as revenue on a straight-line basis over the estimated performance period, using the proportional performance model. Estimation of the performance period of the Company's deliverables requires the use of management's judgment. Significant factors considered in management's evaluation of the estimated performance period include, but are not limited to, its experience, along with Pfizer's experience, in conducting clinical development activities. The Company will review the estimated duration of its performance period on a quarterly basis and make any appropriate adjustments on a prospective basis. Future changes in estimates of the performance period may materially impact the timing of future revenue recognized under the Collaboration Agreement.

Under the Collaboration Agreement, the Company is entitled to receive up to \$500 million in development and regulatory milestone payments. Management evaluated the nature of the events triggering these contingent payments, and concluded that these events – except for those relating solely to development and commercialization in Japan, where the Company has no contractual responsibilities – constituted substantive milestones. This conclusion was based primarily on the facts that each triggering event represents a specific outcome that can be achieved only through successful performance by the Company of one or more of its deliverables, and that achievement of each triggering event was subject to inherent risk and uncertainty and would result in additional payments becoming due to the Company. Management concluded that each of these milestones was substantive, based primarily on the facts that the payments they trigger are non-refundable, that achievement of the milestone entails risk and was not reasonably assured at inception of the Collaboration Agreement, that substantial effort is required to complete each milestone, that the amount of each milestone payment is reasonable in relation to the value created in achieving the milestone, that a substantial amount of time is expected to pass between the up-front payment and the potential milestone payments, and that the milestone payments relate solely to past performance. Based on the foregoing, the Company will recognize any revenue from these milestone payments under the substantive milestone method in the period in which the underlying triggering event occurs.

Under the Collaboration Agreement, the Company is also entitled to receive milestone payments based on development and regulatory events in Japan, milestone payments based on commercial events globally, profit sharing payments on sales of Dimebon products in the U.S., and royalties on sales of Dimebon products outside the U.S. The Company will recognize any revenue from these events based on the revenue recognition criteria set forth in FASB Concept Statements 5. Based on those criteria, the Company considers these potential payments to be contingent revenues, and will recognize them as revenue in the period in which the applicable contingency is resolved.

Under the Collaboration Agreement, the Company and Pfizer share certain Dimebon-related development and commercialization costs in the U.S. on a 60% Pfizer, 40% Medivation basis. The parties make quarterly true-up payments between themselves to ensure that each has borne its applicable percentage of the shared commercialization costs. The Company's policy is to account for cost-sharing true-up payments that it receives from Pfizer as reductions of expense.

(m) Research and Development

Research and development expenses include personnel and facility-related expenses, outside contracted services including clinical trial costs, manufacturing and process development costs, research costs and other

consulting services. Research and development costs are expensed as incurred. In instances where the Company enters into agreements with third parties to provide research and development services to the Company, costs are expensed as services are performed. Amounts due under such arrangements may be either fixed fee or fee for service, and may include upfront payments, monthly payments, and payments upon the completion of milestones or receipt of deliverables.

The Company's cost accruals for clinical trials and other research and development activities are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical trial centers and contract research organizations. In the normal course of business the Company contracts with third parties to perform various research and development activities in the on-going development of its product candidates, including without limitation, third party clinical trial centers and contract research organizations that perform and administer our clinical trials on its behalf. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Payments under these agreements depend on factors such as the achievement of certain events, the successful enrollment of patients, and the completion of portions of the clinical trial or similar conditions. The objective of the accrual policy is to match the recording of expenses in the financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical trials and other research and development activities are recognized based on the estimate of the degree of completion of the event or events specified in the specific agreement.

(n) Stock Based Compensation

The Company applies Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment*, or SFAS No. 123R, to stock-based compensation awards. SFAS No. 123R requires the measurement and recognition of non-cash compensation expense for all share-based payment awards made to employees and directors, including employee stock options and employee stock purchases related to our Restated 2004 Equity Incentive Award Plan, based on estimated fair values. The Company has applied the provisions of Staff Accounting Bulletin No. 107, or SAB 107, and Staff Accounting Bulletin No. 110, or SAB 110, in its adoption of SFAS No. 123R.

Stock compensation arrangements with non-employee service providers are accounted for in accordance with SFAS No. 123 and EITF No. 96-18, *Accounting for Equity Instruments that Are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, using a fair value approach. The compensation costs of these arrangements are subject to remeasurement over the vesting terms as earned.

The Company recognized stock-based compensation expense of \$8.5 million, \$5.9 million and \$2.5 million in the years ended December 31, 2008, 2007 and 2006, respectively. Please refer to Note 10(g) "Stock-Based Compensation" for additional information.

(o) Promotional and Advertising Expense

Promotional and advertising costs are classified as selling, general and administrative expenses, and are expensed as incurred. Promotional and advertising expenses consist primarily of the costs of designing, producing and distributing materials promoting the Company or its product candidates, including its corporate website. Promotional and advertising expenses were insignificant in the years ended December 31, 2008, 2007 and 2006.

(p) Income Taxes

The Company records a valuation allowance to reduce its deferred tax assets to the amount that it believes is more likely than not to be realized. Due to the Company's lack of earnings history, the Company intends to maintain a full valuation allowance on the U.S. deferred tax assets until sufficient positive evidence exists to support reversal of the valuation allowance.

On January 1, 2007, the Company adopted FASB Interpretation No. 48, “Accounting for Uncertainty in Income Taxes—an interpretation of FASB Statement No. 109,” or FIN 48. The Company did not have any unrecognized tax benefits and there was no effect on our financial condition or results of operations as a result of adopting FIN 48. The Company’s practice is to recognize interest and/or penalties related to income tax matters in income tax expense as incurred.

(q) Net Loss per Common Share

Basic net loss per share is computed by dividing the net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed similarly to basic net loss per share, except that the denominator is increased to include all dilute potential common shares, including outstanding options, warrants and common stock subject to repurchase. Potentially dilutive common shares have been excluded from the diluted loss per common share computations in all periods presented because such securities have an anti-dilutive effect on loss per common share due to the Company’s net loss. There are no reconciling items used to calculate the weighted average number of common shares outstanding for basic and diluted net loss per share data.

Potentially dilutive common shares outstanding at December 31, 2008, 2007 and 2006 were as follows:

	<u>At December 31,</u>		
	<u>2008</u>	<u>2007</u>	<u>2006</u>
	(In thousands)		
Outstanding options	4,856	3,359	2,212
Outstanding warrants	316	322	339
Outstanding restricted stock	30	—	—
Total	<u>5,202</u>	<u>3,681</u>	<u>2,551</u>

(r) Reclassification

Certain amounts in prior years’ financial statements have been reclassified to conform to the current period presentation. In the second quarter of 2008, the Company revised the classification of patent-related legal costs from research and development expense to selling, general and administrative expense as such costs typically would be excluded from research and development costs as defined by Statement of Financial Accounting Standards No. 2, *Accounting for Research and Development Costs*. Amounts related to prior periods are not considered material to the financial statements taken as a whole, but were revised for purposes of comparability. Such amounts for the years ended December 31, 2007 and 2006 were \$1,235,000 and \$507,000, respectively. The revision did not affect previously reported total operating expenses, net loss, and basic or diluted net loss per share, assets, liabilities, stockholders’ equity or cash flows.

(s) Recently Issued Accounting Pronouncements

In October 2008, the Financial Accounting Standards Board, or FASB, issued FASB Staff Position, or FSP, FAS 157-3, *Determining the Fair Value of a Financial Asset When the Market for that Asset is not Active*, or FSP 157-3. FSP 157-3 clarified the application of FAS 157. FSP 157-3 demonstrated how the fair value of a financial asset is determined when the market for that financial asset is inactive. FSP 157-3 was effective upon issuance, including prior periods for which financial statements had not been issued. The implementation of this standard did not have an impact on the Company’s consolidated financial statements.

In June 2008, the FASB ratified EITF Issue 07-5, *Determining Whether an Instrument (or Embedded Feature) is Indexed to an Entity’s Own Stock*, effective for us as of January 1, 2009. This standard establishes criteria for determining whether freestanding instruments or embedded features are considered “indexed to an

entity's own stock." This guidance must be applied in assessing the equity conversion features in the Company's outstanding warrants. These conversion features have been exempted from derivative accounting because they are indexed to the Company's own stock and would be classified in stockholders' equity. The Company will have to assess whether they are still considered indexed to its own stock under this new guidance. The standard applies to all outstanding instruments at January 1, 2009, with any transition impacts recognized as a cumulative effect adjustment to the opening balance of retained earnings. The Company is evaluating the impact, if any, this standard will have on its consolidated financial statements.

In February 2008, the FASB issued FASB Staff Position FAS 157-2, *Effective Date of FASB Statement No. 157*, which deferred the effective date of SFAS No. 157 for one year, effective for fiscal years beginning after November 15, 2008, as it relates to non-financial assets and liabilities. The Company does not expect that the adoption of FAS 157-2 will have a significant impact on its consolidated results of operations or financial position.

3. COLLABORATION AGREEMENT

In September 2008, the Company announced a Collaboration Agreement with Pfizer. Under this agreement, the Company and Pfizer will collaborate on development of Dimebon for Alzheimer's disease and Huntington's disease for the United States market, including associated regulatory filings with the FDA. In addition, following FDA approval and launch of Dimebon in the United States, the Company, at its option, and Pfizer will co-promote Dimebon to specialty physicians in the United States, and Pfizer will promote Dimebon to primary care physicians in the United States. Pfizer will be responsible for development and seeking regulatory approval for, and commercialization of, Dimebon outside the United States. After a period of transition from our contract manufacturers to Pfizer, Pfizer will be responsible for all manufacture of product for both clinical and commercial purposes. Both the Company and Pfizer have agreed not to commercialize for the treatment of specified indications any other products directed to the same primary molecular target as Dimebon for a specified time period, subject to certain exceptions.

The agreement establishes several joint committees consisting of an equal number of representatives from both parties that will operate by consensus to oversee the collaboration. In the event that a joint committee is unable to reach consensus on a particular issue, then, depending on the issue, a dispute may be decided at the joint committee level by the party with the final decision on the issue or escalated to senior management of the parties. If a dispute is escalated to senior management and no consensus is reached, then the dispute may be decided by the party to whom the contract grants final decision on such issue. Other issues can only be decided by consensus of the parties, and unless and until the parties' representatives reach agreement on such issue, no decision on such issue will be made, and the status quo will be maintained.

Under the Collaboration Agreement, Pfizer paid the Company an up-front cash payment of \$225 million in the fourth quarter of 2008. The Company is also eligible to receive payments of up to \$500 million upon the attainment of development and regulatory milestones plus additional milestone payments upon the achievement of certain net sales levels for the product. The Company and Pfizer will share the costs and expenses of developing and commercializing Dimebon for the United States market on a 60%/40% basis, with Pfizer assuming the larger share, and the Company and Pfizer will share profits (or losses) resulting from the commercialization of Dimebon in the United States in such proportions. Outside the United States, Pfizer will bear all development and commercialization costs and will pay the Company tiered royalties on the aggregate net sales of Dimebon.

If one of the parties merges with, or acquires or is acquired by, a third party and as a result such party must divest its interest in the Dimebon collaboration due to a governmental requirement, then the other party has the first right to purchase the divesting party's interest in the collaboration, on terms to be negotiated by the parties. In the event that the parties are unable to agree on the terms of this purchase after following the negotiation procedure outlined in the Collaboration Agreement, the divesting party will have a time-limited right to sell its interest in the collaboration to a third party. However, the terms of this sale must be more favorable than any

terms offered by the non-divesting party and the third party will remain bound by the terms of the Collaboration Agreement. In the event the non-divesting party declines to purchase the divesting party's interest, the divesting party may sell its interest in the collaboration to a third party on any terms but such third party will remain bound by the terms of the Collaboration Agreement.

The Company is permitted to terminate the Collaboration Agreement for an uncured material breach by Pfizer. Pfizer has a right to terminate the Collaboration Agreement unilaterally, after 18 months following Dimebon's first commercial sale, but can earlier terminate at its discretion with advance written notice to the Company if clinical data for Dimebon generated after the effective date do not meet certain specified criteria or if regulatory approval is conditioned or delayed. In the event of our uncured material breach of the Collaboration Agreement, Pfizer may elect either to terminate the Collaboration Agreement or to keep the Collaboration Agreement in place, but terminate the Company's right to participate in development, commercialization (other than co-promoting Dimebon) and other activities for Dimebon, including the joint committees and decision making for Dimebon. However, such termination would not affect the Company's financial return or, unless the Company commits an uncured material breach of its co-promotion obligations, the Company's co-promotion rights. Following any termination of the Collaboration Agreement, all rights to develop and commercialize Dimebon will revert to the Company, and Pfizer will grant a license to the Company to enable the Company to continue such development and commercialization, and will supply product to the Company during a specified transition period.

For the year ended December 31, 2008, collaboration revenue recognized pursuant to the Collaboration Agreement was \$12.6 million, representing the amortized portion of the \$225.0 million up-front payment received from Pfizer in the fourth quarter of 2008. The remaining \$212.4 million of the up-front payment has been recorded as deferred revenue, and will be amortized on a straight-line basis over the expected performance period of the Company's deliverables under the Collaboration Agreement. Management currently expects this performance period to end in the first quarter of 2012. Any milestone payments received by the Company pursuant to the Collaboration Agreement will be recognized as revenue in the period in which the underlying milestone event is achieved. Any profit sharing and royalty payments received by the Company pursuant to the Collaboration Agreement will be recognized as revenue in the period in which the underlying product sales occur.

The Company's policy is to present true-up payments of development and commercialization costs, whether to or from the Company, within the applicable expense line in the statement of operations. True-up payments by the Company to Pfizer are thus presented as an increase in expense in the Company's statement of operations, while true-up payments by Pfizer to the Company are presented as a reduction in expense. For the year ended December 31, 2008, the Company recorded development cost and commercialization cost true-up payments receivable from Pfizer of \$3.2 million and \$0.3 million, respectively, and corresponding reductions in research and development expense and selling, general and administrative expense.

4. SHORT-TERM INVESTMENTS

As of December 31, 2008, the amortized cost, gross unrealized gain, and estimated fair value for available-for-sale securities, consisting solely of United States treasury notes maturing in April and June 2009, was \$149.3 million, \$0.7 million and \$150.0 million, respectively. As of December 31, 2007, the Company had no short-term investments.

5. PROPERTY AND EQUIPMENT

The components of the Company's property and equipment and related accumulated depreciation and amortization at December 31, 2008 and 2007 were as follows (in thousands):

	December 31,	
	2008	2007
Furniture and fixtures	\$ 72	\$ 32
Leasehold improvements	594	594
Computer equipment and software	142	38
Laboratory equipment	163	94
Construction in progress	55	—
	<u>1,026</u>	<u>758</u>
Less: accumulated depreciation and amortization	(258)	(69)
	<u>\$ 768</u>	<u>\$689</u>

Depreciation and amortization expense on property and equipment was \$189,000, \$70,000 and \$2,000 for the years ended December 31, 2008, 2007 and 2006, respectively.

6. INTELLECTUAL PROPERTY

At December 31, 2008, intellectual property consisted of patents and patent applications acquired from third parties. This intellectual property is being amortized over periods ranging from 156 months to 248 months. Amortization expense on the Company's intellectual property was \$4,000, \$4,000 and \$5,000 for the years ended December 31, 2008, 2007 and 2006, respectively. Estimated aggregate amortization expense on the Company's intellectual property is \$4,000 per year for each of the five subsequent fiscal years. In the year ended December 31, 2006, the Company wrote off \$68,000, of its historical patent acquisition costs to reflect management's decision to stop work on a patent application that is unrelated to the Company's ongoing development programs. Intellectual property balances, both gross and net of amortization, at December 31, 2008, 2007 and 2006 were as follows:

	Year Ended December 31,		
	2008	2007	2006
	(in thousands)		
Intellectual property	\$ 76	\$ 76	\$ 76
Accumulated amortization	(22)	(18)	(14)
	<u>\$ 54</u>	<u>\$ 58</u>	<u>\$ 62</u>

7. ACCRUED LIABILITIES

Accrued liabilities consisted of the following (in thousands):

	December 31,	
	2008	2007
Payroll and payroll related	\$ 260	\$ 75
Preclinical and clinical trials	4,979	1,583
Other	533	560
Total accrued expenses	<u>\$5,772</u>	<u>\$2,218</u>

8. OTHER NON-CURRENT LIABILITIES

At December 31, 2008 and 2007, other non-current liabilities included the non-current portion of deferred rent and lease incentives on the Company's current and former offices in the amount of \$324,000 and \$417,000, respectively, which will be amortized over the remaining terms of the office leases, and a \$75,000 security deposit received from the subtenant recorded at both December 31, 2008 and 2007.

9. REDEEMABLE PREFERRED STOCK

The Company is authorized to issue 1,000,000 shares of preferred stock with such designations, voting, and other rights and preferences as may be determined from time to time by the Board of Directors, or the Board. The Company has outstanding 110 shares of Series A Redeemable Preferred Stock, which it issued for an aggregate purchase price of \$11,000. The Series A Redeemable Preferred Stock is non-voting, does not bear dividends, and is not convertible into common stock or any other securities of the Company. The Series A Redeemable Preferred Stock is redeemable at any time, at the option of the holders thereof, for a redemption price equal to its original purchase price. No other preferred stock of the Company is outstanding.

10. STOCKHOLDERS' EQUITY

(a) Common Stock

In June 2008, the Company raised \$15.0 million in a public offering of 1,129,518 shares of its Common Stock pursuant to an effective registration statement on Form S-3 previously filed with the Commission. Cash offering costs of \$69,000 incurred in connection with this public offering were charged against additional paid-in capital in the year ended December 31, 2008.

In May and December 2006, the Company issued an aggregate of 5,215,384 shares of its common stock in registered direct offerings, raising gross proceeds of \$50.3 million. Placement agent, legal, accounting, printing and other costs related to these offerings, in the aggregate amount of \$3.5 million and \$5,000, were charged to additional paid-in capital in the years ended December 31, 2006 and 2007, respectively.

(b) Committed Equity Line of Credit

The Company entered into a committed equity line of credit with Azimuth Opportunity Ltd., or Azimuth, pursuant to a Common Stock Purchase Agreement dated September 7, 2007. In October 2007, the Company sold 265,431 shares of its common stock to Azimuth under the equity line of credit, raising gross proceeds of \$6,000,000. In November 2007, the Company sold 758,117 shares of its common stock to Azimuth under the equity line of credit, raising gross proceeds of \$15,250,000. Placement agent, legal, accounting, printing and other costs related to these offerings, in the aggregate amount of \$20,000 and \$446,000, were charged to additional paid-in capital in the years ended December 31, 2008 and 2007. The Azimuth facility expires on April 1, 2009, and the Company does not anticipate making any additional draws under that facility.

(c) Stock Purchase Rights

All shares of the Company's common stock are subject to stock purchase rights. The rights are exercisable only if a person or group acquires twenty percent or more of the Company's common stock or announces a tender or exchange offer which would result in ownership of twenty percent or more of the Company's common stock. Following the acquisition of twenty percent or more of the Company's common stock, the holders of the rights, other than the acquiring person or group, may purchase Medivation common stock at half of its fair market value. In the event of a merger or other acquisition of the Company, the holders of the rights, other than the acquiring person or group, may purchase shares of the acquiring entity at half of their fair market value. The rights were not exercisable at December 31, 2008.

(d) Medivation Equity Incentive Plan

The Medivation Amended and Restated 2004 Equity Incentive Award Plan, or the Medivation Equity Incentive Plan, which is stockholder-approved, provides for the issuance of options and other stock-based awards, including restricted stock and stock appreciation rights, covering up to 7,500,000 shares of Medivation's common stock. Shares issued upon exercise of stock-based awards are new shares that have been reserved for issuance under the plan. The amendments to the Medivation Equity Incentive Plan were approved by the Board and by the stockholders in March and May 2007, respectively.

The Medivation Equity Incentive Plan is administered by the Board, or a committee appointed by the Board, which determines recipients and types of awards to be granted, including the number of shares subject to the awards, the exercise price and the vesting schedule. The term of stock options granted under the Medivation Equity Incentive Plan cannot exceed ten years. Options generally have an exercise price equal to the fair market value of the common stock on the grant date, and generally vest over a period of four years. The options may contain an early exercise feature, pursuant to which the optionee may exercise the option before it has vested. However, so long as an option remains unvested, all shares purchased upon early exercise remain subject to repurchase by Medivation at the option exercise price if the optionee's service with Medivation terminates. For purposes of the following disclosures, early exercise options are not considered to have been exercised, or to be exercisable, until this repurchase right has lapsed. To date, the Company has not issued any shares upon early exercise of stock options. In addition, all outstanding awards under the Medivation Equity Incentive Plan will accelerate and become immediately exercisable upon a "change of control" of Medivation, as defined in the Medivation Equity Incentive Plan.

The following table summarizes stock option activity under the Medivation Equity Incentive Plan for the years ended December 31, 2008, 2007 and 2006:

	<u>Shares Available for Grant</u>	<u>Number of Shares</u>	<u>Weighted Average Exercise price</u>
Options outstanding, December 31, 2005	1,431,820	1,550,200	\$ 2.50
Granted	(876,900)	876,900	\$ 7.70
Exercised	—	(67,399)	\$ 3.28
Forfeited	<u>147,951</u>	<u>(147,951)</u>	\$ 2.58
Options outstanding, December 31, 2006	702,871	2,211,750	\$ 4.53
Additional shares authorized	4,500,000		
Granted	(1,309,566)	1,309,566	\$19.83
Exercised	—	(66,190)	\$ 3.57
Forfeited	<u>95,800</u>	<u>(95,800)</u>	\$18.90
Options outstanding, December 31, 2007	3,989,105	3,359,326	\$10.10
Granted	(1,629,448)	1,629,448	\$17.96
Exercised	—	(116,086)	\$ 5.68
Forfeited	<u>16,783</u>	<u>(16,783)</u>	\$20.83
Options outstanding, December 31, 2008	<u>2,376,440</u>	<u>4,855,905</u>	\$12.81

The weighted-average grant-date fair value of options granted during the years ended December 31, 2008, 2007 and 2006 was \$11.91 per share, \$11.78 per share and \$4.85 per share, respectively. Further information regarding the value of options vested and exercised during the years ended December 31, 2008, 2007 and 2006, is set forth below.

	Year Ended December 31,		
	2008	2007	2006
	(in thousands)		
For value of options vested during period	\$7,717	\$3,916	\$3,674
Intrinsic value of options exercised during period	\$2,198	\$ 915	\$ 654

Further information regarding the stock options outstanding and exercisable as of December 31, 2008, is as follows:

Options Outstanding				Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted Avg. Remaining Contractual Life (yrs)	Weighted Avg. Exercise Price	Number Exercisable	Weighted Avg. Exercise Price
\$ 0.02 – 1.55	549,500	5.7	\$0.96	549,500	\$0.96
2.60 – 4.30	690,970	6.3	3.50	609,994	3.50
4.45 – 11.76	767,900	7.7	7.68	431,311	7.56
13.31 – 20.00	2,043,635	9.2	17.54	199,691	17.86
20.83 – 26.03	803,900	8.9	21.80	201,672	21.15
	<u>4,855,905</u>	8.1	12.81	<u>1,992,168</u>	6.90

The 1,992,168 stock options that were outstanding and exercisable at December 31, 2008 had an aggregate intrinsic value of \$17.3 million and a weighted-average remaining contractual term of 6.9 years. At December 31, 2008, consultants held an aggregate of 130,309 unvested options at a weighted average exercise price of \$20.24 per share.

(e) Restricted Stock Award:

The following table summarizes information about restricted stock award activity for the year ended December 31, 2008:

	Shares	Weighted Average Grant Date Fair Value Per Share	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Restricted Stock Awards:				
Balance at December 31, 2007	—	—		
Granted	30,000	\$15.71		
Vested	—	—		
Cancelled	—	—		
Balance at December 31, 2008	<u>30,000</u>	<u>\$15.71</u>	2.04	\$—

The Company measures the fair value of restricted stock awards using the closing price of the Company's stock on the grant date. The fair value of the restricted stock awards is being amortized on a straight-line basis over the requisite service period of the awards.

(f) Warrants

At December 31, 2008, warrants to purchase an aggregate of 316,173 shares of Medivation common stock at a weighted average exercise price of \$1.94 per share were outstanding. These outstanding warrants expire between 2009 and 2017.

(g) Stock-Based Compensation

The Company applies Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment*, or SFAS No. 123R, to stock-based compensation awards. SFAS No. 123R requires the measurement and recognition of non-cash compensation expense for all share-based payment awards made to employees and directors, including employee stock options and employee stock purchases related to our Restated 2004 Equity Incentive Award Plan, based on estimated fair values. The Company has applied the provisions of Staff Accounting Bulletin No. 107, or SAB 107, and Staff Accounting Bulletin No. 110, or SAB 110, in its adoption of SFAS No. 123R.

Stock compensation arrangements with non-employee service providers are accounted for in accordance with SFAS No. 123 and EITF No. 96-18, *Accounting for Equity Instruments that Are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, using a fair value approach. The compensation costs of these arrangements are subject to remeasurement over the vesting terms as earned.

The Company estimates the fair value of stock options and warrants using the Black-Scholes option valuation model. Estimated volatility is based on the historical stock price volatility of the Company's common stock, the historical stock price volatility of comparable companies' common stock and the implied volatility of the Company's common stock inherent in the market prices of publicly traded options in its common stock. Estimated dividend yield is 0%. The risk-free rate is estimated to equal U.S. Treasury security rates for the applicable terms. The Company does not have sufficient history of exercise behavior to develop estimates of expected term since as of December 31, 2008 only five percent of the options it has issued since inception had been exercised. Accordingly, the Company uses the simplified method of estimating option term provided for in the Commission's Staff Accounting Bulletins 107 and 110 for options granted to employees and directors, which results in an estimated option term of six years. For consultant options, the Company uses an estimated option term of four years, which is equal to the period required for the options to vest in full. As the Company gathers more history regarding its option exercise pattern, and as information regarding the option exercise pattern of comparable companies in its industry becomes publicly available, it will review these estimates and revise them as appropriate. Different estimates of volatility and expected term could materially change the value of an option and the resulting expense.

Stock-based awards granted to employees and directors are valued at their respective grant dates and expensed over the remaining vesting period of the award. The Black-Scholes assumptions used in the years ended December 31, 2008, 2007 and 2006 for employee and director options are as follows:

	Year Ended December 31,		
	2008	2007	2006
Risk-free interest rate	2.96-3.94%	3.83-5.1%	4.45 to 5%
Expected remaining term (in years)	6	6	6
Expected volatility	62-84%	58-60%	57-79%
Expected dividends	None	None	None

Stock-based awards granted to consultants are valued at their respective measurement dates and recognized as expense based on the portion of the total consulting services provided during the applicable period. As further consulting services are provided in each period, the Company will revalue the associated awards and recognize additional expense based on their then-current fair values. The Black-Scholes assumptions used in the years ended December 31, 2008, 2007 and 2006 for consultant options are as follows:

	Year Ended December 31,		
	2008	2007	2006
Risk-free interest rate	0.37–3.36%	3.23–4.94%	4.52–5.1%
Expected remaining term (in years)	0.2–4	1.3–4	1.5–4
Expected volatility	60–87%	54–60%	55–79%
Expected dividends	None	None	None

The Company recognized stock-based compensation expense of \$8.5 million, \$5.9 and \$2.5 million in the years ended December 31, 2008, 2007 and 2006 respectively. The following table summarizes information related to stock-based compensation expense recognized in the income statement (in thousands):

	Year Ended December 31,		
	2008	2007	2006
Stock compensation expense recognized in:			
Research and development expense	\$4,216	\$2,040	\$1,025
Selling, general and administrative expense	4,331	3,853	1,424
Total stock-based compensation expense	<u>\$8,547</u>	<u>\$5,893</u>	<u>\$2,449</u>

Stock-based compensation attributable to employee and director awards was \$7.1 million, \$2.8 million and \$0.7 million in the years ended December 31, 2008, 2007 and 2006, respectively. Stock-based compensation attributable to consultant awards was \$1.5 million, \$3.1 million and \$1.8 million in the years ended December 31, 2008, 2007 and 2006, respectively.

At December 31, 2008, the unrecognized compensation cost attributable to employee and director awards totaled \$27.0 million, which is expected to be recognized as expense over a weighted-average remaining requisite service period of 2.96 years.

11. THIRD PARTY EQUITY INTERESTS IN OPERATING SUBSIDIARIES

(a) Medivation Neurology, Inc.

At December 31, 2008, Medivation owned all of the issued and outstanding stock of its operating subsidiary Medivation Neurology, Inc., or MNI, and there were no outstanding options, warrants or any other third party rights to acquire any MNI stock.

(b) Medivation Prostate Therapeutics, Inc.

At December 31, 2008, Medivation owned all of the issued and outstanding stock of its operating subsidiary Medivation Prostate Therapeutics, Inc., or MPT. MPT has reserved an aggregate of 3,000,000 shares of its common stock for issuance upon the exercise of awards granted under the Medivation Prostate Therapeutics, Inc. Equity Incentive Plan, or the MPT Equity Incentive Plan. At December 31, 2008, one option was outstanding under the MPT Equity Incentive Plan. This option, which was issued to the licensor of MPT's MDV300 series technology, is exercisable without cash payment for 150,000 shares of MPT common stock, but vests and becomes exercisable only upon the occurrence of specified MPT liquidity events including a sale of MPT, a public offering of MPT's common stock, a corporate partnership involving MPT, or receipt of regulatory

approval to market any MPT product. In accordance with EITF Issue No. 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services," no expense will be recognized with respect to this option unless and until such a liquidity event occurs.

12. INCOME TAXES

On January 1, 2007, the Company adopted FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes—an interpretation of FASB Statement No. 109," or FIN 48. The Company did not have any unrecognized tax benefits and there was no effect on our financial condition or results of operations as a result of adopting FIN 48. The Company's practice is to recognize interest and/or penalties related to income tax matters in income tax expense as incurred.

At December 31, 2008, the Company had approximately \$358,000 in total unrecognized tax benefits. A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in thousands):

Balance at January 1, 2007	\$—
Additions based on tax positions related to the current year	—
Reductions based on tax positions related to prior years	—
Settlements	—
Balance at December 31, 2007	\$—
Additions based on tax positions related to the current year	145
Reductions based on tax positions related to prior years	213
Settlements	—
Balance at December 31, 2008	<u>\$358</u>

None of this amount when released would impact the effective tax rate.

The Company currently has no federal or state tax examinations in progress nor has it had any federal or state tax examinations since its inception. As a result of the Company's net operating loss carryforwards, all of its tax years are subject to federal and state tax examination.

At December 31, 2008, the Company had federal and state net operating loss carryforwards of approximately \$105.5 million and \$105.5 million, respectively. Approximately \$2.6 million of the net operating loss carryforwards is attributable to excess employee stock option deductions, the benefit from which will be credited to additional paid-in capital when subsequently utilized in future years. Additionally, the Company had federal and state research and development credits of approximately \$2.3 million and 0.9 million, respectively. The federal net operating loss carryforwards and research and development credit will expire at various dates between the years 2020 and 2027, if not utilized. The state of California net operating loss carryforwards will expire at various dates between the years 2014 and 2019, if not utilized. The California research and development credits can be carried forward indefinitely.

Based on current tax law, \$12.6 million of the \$225.0 million up-front payment we received from Pfizer in the fourth quarter of 2008 was recognized as revenue for both federal and state income tax purposes in the year ended December 31, 2008. The remaining amount of \$212.4 million will be recognized as revenue for both federal and state tax purposes in the year ended December 31, 2009. Accordingly, the Company anticipates that it will therefore have taxable income for that year. The Company's ability to utilize its California net operating loss carryforwards to offset the anticipated 2009 taxable income is limited. In response to budgetary pressures, the State of California has temporarily suspended the use of net operating loss carryforwards for the 2009 tax year. There is also limitation on the amount of credits that can offset California tax. Consequently, the Company

expects to incur state income tax liabilities in 2009. Due to certain exemptions granted to companies regarding the alternative minimum tax the Company does not expect to incur federal income tax liabilities in 2009. If the Company's earnings increase from the forecasts in excess of its federal net operating losses and other tax assets the Company may incur a federal tax liability.

Utilization of the federal and state net operating loss and credit carryforwards may be subject to a substantial annual limitation due to the "change in ownership" provisions of the Internal Revenue Code of 1986. The annual limitation may result in the expiration of net operating losses and credits before utilization. The Company completed section 382 studies through December 31, 2008, and concluded that an ownership change occurred in 2004 and 2007. However, it did not result in a reduction of its net operating loss or in its research and development credits expiring unused. Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets for financial reporting purposes and the amount used for income tax purposes. Significant components of the Company's deferred tax assets for federal and state income taxes are as follows:

	December 31,	
	2008	2007
Deferred tax assets		
Net operating loss carry forward	\$ 41,911	\$ 21,688
Stock-based compensation	4,924	1,386
Research & development credit	2,912	692
Depreciation, amortization and other	115	15
Accruals and reserves	256	220
Total deferred tax assets	50,118	24,001
Valuation allowance	(50,118)	(24,001)
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

Due to the Company's lack of earnings history, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by \$26.1 million, \$12.9 million and \$6.5 million during the years ended December 31, 2008, 2007 and 2006, respectively.

A reconciliation of the statutory federal income tax to the Company's effective tax rates for the periods ended is as follows:

	December 31,		
	2008	2007	2006
Federal tax provision at statutory rate	35.00%	34.00%	34.00%
State taxes (net of federal benefit)	5.73%	5.83%	6.40%
Stock-based compensation expense	(0.86%)	(0.25%)	—
Research and development credits	1.53%	1.31%	—
Other	0.41%	(0.22%)	1.60%
Valuation allowance	(41.81%)	(40.67%)	(42.00%)
Provision for taxes	<u>0.00%</u>	<u>0.00%</u>	<u>0.00%</u>

13. FAIR VALUE OF FINANCIAL INSTRUMENTS

Financial instruments are presented at fair value. Fair value is defined as the price at which an asset could be exchanged in a current transaction between knowledgeable, willing parties. A liability's fair value is defined as the amount that would be paid to transfer the liability to a new obligor, not the amount that would be paid to settle the liability with the creditor. Where available, fair value is based on observable market prices or

parameters or derived from such prices or parameters. Where observable prices or inputs are not available, valuation models are applied. These valuation techniques involve some level of management estimation and judgment, the degree of which is dependent on the price transparency for the instruments or market and the instrument's complexity.

Beginning January 1, 2008, assets and liabilities recorded at fair value in the consolidated balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair value. Hierarchical level – defined by SFAS No. 157 and directly related to the amount of subjectivity associated with the inputs to fair valuation of these assets and liabilities – are as follows:

- Level 1—Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date.

Fair valued assets that are generally included in this category are cash equivalents comprised of money market funds, restricted cash and short-term investments.

- Level 2—Inputs (other than quoted prices included in Level 1) are either directly or indirectly observable for the asset or liability through correlation with market data at the measurement date and for the duration of the instrument's anticipated life.

At December 31, 2008, the Company did not have any fair valued assets or liabilities classified as Level 2.

- Level 3—Inputs reflect management's best estimate of what market participants would use in pricing the asset or liability at the measurement date. Consideration is given to the risk inherent in the valuation technique and the risk inherent in the inputs to the model.

At December 31, 2008, the Company did not have any fair valued assets or liabilities classified as Level 3.

Fair Value on a Recurring Basis

Assets and liabilities measured at fair value on a recurring basis are categorized in the tables below based upon the lowest level of significant input to the valuations as of December 31, 2008 (in thousands):

	<u>Fair value</u>	<u>Fair value measurements using</u>		
	<u>December 31, 2008</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
Assets				
Cash equivalents	\$ 71,454	\$ 71,454	\$—	\$—
Short-term investments	149,968	149,968	—	—
Restricted cash	843	843	—	—
Total assets	<u>\$222,265</u>	<u>\$222,265</u>	<u>\$—</u>	<u>\$—</u>

14. COMMITMENTS AND CONTINGENCIES

The Company rents its office facilities under noncancelable operating leases, which expire at various dates through May 2013. Under the terms of the leases, the Company is responsible for certain taxes, insurance and maintenance expenses.

In April 2007, the Company entered into an operating lease for office space in San Francisco, California. The lease commenced in July 2007 and terminates in July 2012. The total square footage covered by this lease is 16,592 square feet and the Company provided a \$500,000 letter of credit to the landlord as security.

In September 2007, the Company entered into a sublease of its former office through February 2011.

In November 2008, the Company entered into an operating lease for additional office space in San Francisco, California. This lease commenced in November 2008 and terminates in May 2013. The total square footage covered by the lease is 13,723 square feet and the Company provided a \$343,000 letter of credit to the landlord as security.

Aggregate future minimum lease payments under the three operating leases net of sublease income at December 31, 2008 are as follows (in thousands):

2009	\$1,246
2010	1,278
2011	1,410
2012	1,126
2013	309
Total	<u>\$5,369</u>

Rent expense, net of sublease income, for the years ended December 31, 2008, 2007, 2006 was \$615,000, \$368,000 and 136,000, respectively. Sublease income was \$194,000, \$40,000, and \$0 for the years ended December 31, 2008, 2007, 2006, respectively.

15. QUARTERLY RESULTS OF OPERATIONS (UNAUDITED)

The following table presents unaudited quarterly financial data of the Company. The Company's quarterly results of operations for these periods are not necessarily indicative of future results of operations.

	2008 Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
	(in thousands, except per share data)			
Collaboration revenue	\$ —	\$ —	\$ —	\$12,578
Loss from operations	(15,909)	(18,715)	(20,636)	(8,922)
Net loss	(15,530)	(18,543)	(20,456)	(7,931)
Basic and diluted net loss per share	\$ (0.54)	\$ (0.64)	\$ (0.68)	\$ (0.26)
Weighted average common shares used in the calculation of basic and diluted net loss per share	28,847	28,943	30,022	30,082
	2007 Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
	(in thousands, except per share data)			
Collaboration revenue	\$ —	\$ —	\$ —	\$ —
Loss from operations	(6,202)	(7,664)	(9,823)	(10,074)
Net loss	(5,647)	(7,160)	(9,363)	(9,573)
Basic and diluted net loss per share	\$ (0.20)	\$ (0.26)	\$ (0.34)	\$ (0.34)
Weighted average common shares used in the calculation of basic and diluted net loss per share	27,745	27,785	27,797	28,396

EXHIBIT INDEX

Unless otherwise indicated below, the Commission file number to the exhibit is No. 001-32836 for filings made in or after March 2006 and No. 000-20837 for filings made prior to March 2006.

<u>Exhibit No.</u>	<u>Exhibit Description</u>
3.1(a)	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1(a) to the Quarterly Report on Form 10-QSB of Medivation, Inc. for the quarter ended June 30, 2005).
3.1(b)	Certificate of Amendment of Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1(b) to the Quarterly Report on Form 10-QSB of Medivation, Inc. for the quarter ended June 30, 2005).
3.1(c)	Certificate of Amendment to the Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1(c) to the Quarterly Report on Form 10-QSB of Medivation, Inc. for the quarter ended June 30, 2005).
3.1(d)	Certificate of Designations of the Series B Convertible Preferred Stock of Orion Acquisition Corp. II (incorporated by reference to Exhibit 3.1(d) to the Quarterly Report on Form 10-QSB of Medivation, Inc. for the quarter ended June 30, 2005).
3.1(e)	Certificate of Designations of the Series C Junior Participating Preferred Stock of Medivation, Inc. (incorporated by reference to Exhibit 3.1(d) to the Annual Report on Form 10-KSB of Medivation, Inc. for the fiscal year ended December 31, 2007).
3.2	Amended and Restated Bylaws of Medivation, Inc.
4.1	Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registration Statement on Form SB-2 of Medivation, Inc. (formerly Orion Acquisition Corp. II) (No. 333-03252)).
4.2	Rights Agreement, dated as of December 4, 2006, between Medivation, Inc. and American Stock Transfer & Trust Company, as Rights Agent, which includes the form of Certificate of Designations of the Series C Junior Participating Preferred Stock of Medivation, Inc. as Exhibit A, the form of Right Certificate as Exhibit B and the Summary of Rights to Purchase Preferred Shares as Exhibit C (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed on December 4, 2006).
10.1	Registration Rights Agreement by and among Orion Acquisition Corp. II and Special Situations Fund III, L.P., Special Situations Cayman Fund, L.P. and Special Situations Private Equity Fund, L.P., dated as of December 17, 2004 (incorporated by reference to Exhibit 10.3(a) to the Registration Statement on Form SB-2 of Medivation, Inc. (formerly Orion Acquisition Corp. II) (No. 333-122431)).
10.2(a)	Warrant to purchase Common Stock of Medivation Neurology, Inc. assumed by Orion Acquisition Corp. II issued to Joseph J. Grano, Jr., dated as of June 8, 2004 (incorporated by reference to Exhibit 10.5(a) to the Registration Statement on Form SB-2 of Medivation, Inc. (formerly Orion Acquisition Corp. II) (No. 333-122431)).
10.2(b)	Warrant to purchase Common Stock of Medivation Neurology, Inc. assumed by Orion Acquisition Corp. II issued to Joseph J. Grano, Jr., dated as of August 1, 2004 (incorporated by reference to Exhibit 10.5(b) to the Registration Statement on Form SB-2 of Medivation, Inc. (formerly Orion Acquisition Corp. II) (No. 333-122431)).
10.2(c)	Warrant to purchase Common Stock of Medivation Neurology, Inc. assumed by Orion Acquisition Corp. II issued to Joseph J. Grano, Jr., dated as of September 1, 2004 (incorporated by reference to Exhibit 10.5(c) to the Registration Statement on Form SB-2 of Medivation, Inc. (formerly Orion Acquisition Corp. II) (No. 333-122431)).
10.2(d)	Amendment Agreement by and between Orion Acquisition Corp. II and Joseph J. Grano, Jr., dated as of December 17, 2004 (incorporated by reference to Exhibit 10.5(d) to the Registration Statement on Form SB-2 of Medivation, Inc. (formerly Orion Acquisition Corp. II) (No. 333-122431)).

<u>Exhibit No.</u>	<u>Exhibit Description</u>
10.3	Warrant to purchase Common Stock of Medivation Neurology, Inc. assumed by Orion Acquisition Corp. II issued to David T. Hung, M.D., dated as of November 16, 2004 (incorporated by reference to Exhibit 10.6 to the Registration Statement on Form SB-2 of Medivation, Inc. (formerly Orion Acquisition Corp. II) (No. 333-122431)).
10.4(a)*	Amended and Restated 2004 Equity Incentive Award Plan (incorporated by reference to Exhibit 10.4(a) to the Annual Report on Form 10-KSB for the fiscal year ended December 31, 2007).
10.4(b)*	Form of Stock Option Agreement (incorporated by reference to Exhibit 10.7(b) to the Annual Report on Form 10-KSB of Medivation, Inc. (formerly Orion Acquisition Corp. II) for the year ended December 31, 2004).
10.4(c)*	Form of Stock Option Agreement (incorporated by reference to Exhibit 10.7(c) to the Annual Report on Form 10-KSB of Medivation, Inc. (formerly Orion Acquisition Corp. II) for the year ended December 31, 2004).
10.5	Form of Subscription Agreement (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on December 8, 2006).
10.6	Common Stock Purchase Agreement, dated as of September 7, 2007, by and between Medivation, Inc. and Azimuth Opportunity Ltd. (incorporated by reference to Exhibit 10.1 to Medivation, Inc.'s Current Report on Form 8-K filed on September 10, 2007).
10.7	Form of Purchase Agreement, dated as of June 22, 2008, between Medivation, Inc. and the purchasers of its common stock (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on June 23, 2008).
10.8**	Amended and Restated Collaboration Agreement, dated as of October 20, 2008, between Medivation, Inc. and Pfizer Inc. (incorporated by reference to Exhibit 10.8 to the Quarterly Report on Form 10-Q for the quarter ended September 30, 2008).
10.9*	Bonuses for Fiscal Year 2008 and Base Salaries for Fiscal Year 2009 for Certain Executive Officers (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on November 5, 2008).
10.10*	Medivation, Inc. 2009 Bonus Plan (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on November 5, 2008).
10.11*	Change of Control Severance Benefits Agreement, dated as of February 2, 2009, between Medivation, Inc. and David Hung, M.D.
10.12*	Severance Benefits Agreement, dated as of February 9, 2009, between Medivation, Inc. and Rohan Palekar.
10.13*	Form of Medivation, Inc. Change of Control Severance Benefits Agreement.
16	Letter from SingerLewak LLP to the Securities and Exchange Commission (incorporated by reference to Exhibit 16.1 to the Current Report on Form 8-K filed on March 23, 2007).
21	Subsidiaries of Medivation, Inc.
23.1	Consent of Independent Registered Public Accounting Firm.
23.2	Consent of Former Independent Registered Public Accounting Firm.
24	Power of attorney (contained on signature page).
31.1	Certification pursuant to Rule 13a-14(a)/15d-14(a).
31.2	Certification pursuant to Rule 13a-14(a)/15d-14(a).
32.1	Certifications of Chief Executive Officer and Chief Financial Officer.

* Indicates management contract or compensatory plan or arrangement.

** Confidential treatment has been granted with respect to certain portions of this exhibit.