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# Furiex™

Pharmaceuticals | *Fast. Focused. Expert.*



## FAST. FOCUSED. EXPERT.

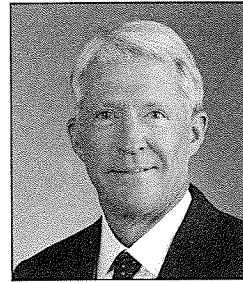
2010 Annual Report

Furiex Pharmaceuticals, Inc. is a drug development company offering drug developers an external development model that shares risk and provides an experienced team to advance drug candidates rapidly to market. Our flexible risk-sharing model enables partners to fund early-stage drug candidates and our small nimble team of experts uses innovative clinical development strategies that enables quick and effective decisions, bringing products to market faster. As the biopharmaceutical industry faces increased challenges with patent expirations and fewer successful therapies reaching the market, Furiex's proven model helps innovators grow asset value and deliver drug products to the market more efficiently.

PHASE OF DEVELOPMENT									
Program	Indication	Preclinical	PI	PII	PIII	Marketing Application Submission	Market	Collaborator <sup>1</sup>	
Priligy™	Premature Ejaculation	→				→ US	→ EU/ex-US		Janssen-Cilag
Alogliptin/Nesina®	Type 2 Diabetes	→				→ EU	→ US	→ JP	Takeda
Alogliptin/Actos® Combination	Type 2 Diabetes	→				→ EU	→ US	→ JP	Takeda
Alogliptin/Metformin Combination	Type 2 Diabetes	→							Takeda
JNJ-Q2	Antibiotic	→ Complicated Skin Infections		→ Bacterial Pneumonia					Janssen Pharmaceutica N.V. <sup>2</sup>
MuDelta	IBS-diarrheal	→							Janssen Pharmaceutica N.V. <sup>2</sup>
PPD10558	Cholesterol Lowering	→							

<sup>1</sup>Refers to late-stage development and commercialization collaborator.

<sup>2</sup>At the completion of Phase II, Janssen will have the option to continue development and commercialization of each compound.



Fred N. Eshelman, Pharm.D.



June S. Almenoff, M.D., Ph.D.

## To Our Stockholders,

In mid-2010, Furiex was launched as an independent company through a spin-off from Pharmaceutical Product Development, Inc. We have an exciting business strategy of quickly advancing and delivering de-risked drug candidates to partners while sharing the financial risks and rewards of clinical development with them. Our new independent company is in a position of strength with an experienced management team and the potential for milestones and royalties from our partnered products. We believe that our new structure as a small independent company will allow us to operate with the financial and strategic flexibility that we believe will optimize shareholder value.

We are pleased to report that we have already begun to deliver on our strategy: advancing our pipeline with skill and speed, creating value for all of our assets, thereby positioning our company for future success.

### Significant Progress with Our Pipeline of Novel Agents for Conditions with High Unmet Medical Need

JNJ-Q2 is a novel fluoroquinolone antibiotic with a low propensity for development of drug resistance and potent bactericidal activity against a broad variety of pathogens, including methicillin resistant *Staphylococcus aureus* (MRSA) and *Streptococcus pneumoniae* (including multi-drug resistant strains). In November 2010, we reported positive results for a Phase II proof-of-concept study of acute bacterial skin and skin structure infections. The drug had a favorable efficacy and safety profile, exhibiting potent bactericidal activity against all strains isolated from patients in the study (more than half of which were MRSA). We are proud of our expert development team for completing the study several months ahead of schedule.

MuDelta is a novel oral agent that we are studying in a Phase II clinical trial for the treatment of diarrhea-predominant irritable bowel syndrome, or IBS-D. Based on its novel mechanism of action, MuDelta is predicted to improve both the pain and diarrheal symptoms of patients with IBS-D, without causing side effects of constipation. We met our goal of completing an interim analysis in the MuDelta Phase II study at the end of 2010. The study is ongoing and continues to meet ambitious timelines. In January 2011, the

MuDelta clinical development program was granted a Fast Track designation by the FDA. Fast Track is a process for facilitating the development and expediting the review of drugs to treat serious diseases and fill an unmet medical need. Receipt of the Fast Track designation opens up the opportunity to bring this important new drug to the patient sooner.

PPD10558 is a novel statin that we refer to as a muscle-sparing statin. It has the potential to be a valuable new therapy for the large population of statin-users who cannot adequately lower their cholesterol levels due to muscle symptoms caused by statins. Furiex had a successful meeting with the FDA, leading to agreement on our Phase II proof-of-concept study design and a path forward for further clinical development of PPD10558 in patients who are unable to tolerate other statins due to muscle symptoms known as statin-associated myalgia.

### Highlights for 2010

We are proud of our achievements during our first six months as a new, independent company. Furiex made significant progress in all development programs and met a number of important goals that strengthened our company and built stockholder value. Some highlights:

- Completed two Phase I studies: a pharmacokinetic study of JNJ-Q2, our novel, broad-spectrum antibiotic using an intravenous form of the drug; and a QT cardiac safety study.
- Completed a successful proof-of-concept Phase II study for JNJ-Q2 that demonstrated highly effective oral treatment of severe acute bacterial skin and skin structure infections.
- Commenced a Phase II proof-of-concept trial for MuDelta, our novel oral treatment for diarrhea-predominant irritable bowel syndrome, in Q2-2010, and conducted an interim data analysis at the end of Q4-2010, resulting in a decision to continue the study to completion.
- Had a successful meeting with the FDA regarding PPD10558, our novel muscle-sparing statin that could potentially help millions of patients with high cholesterol who cannot tolerate currently marketed statins due to muscle pain.



FOCUSED ON A SPECIFIC STAGE OF  
**DRUG DEVELOPMENT**

RATHER THAN ON A PARTICULAR

THERAPEUTIC AREA.



- Granted a key U.S. patent for the method for treatment of premature ejaculation using dapoxetine, which is currently marketed by our partner Janssen-Cilag under the trademark PRILIGY™, in a number of countries outside the United States.
- Received approximately \$0.7 million of U.S. government grants for ongoing research in all three of our development programs. These grants were awarded through the Therapeutic Tax Credit program.
- Alogliptin (Nesina®) received marketing approval in Japan through the efforts of our partner Takeda Pharmaceuticals, for which we received a \$7.5 million milestone.

### Looking Ahead

Our team is highly engaged and we are executing well on our business strategy. We believe we are well positioned to progress our three pipeline programs and poised to create significant value for the shareholders. We are excited about the potential of our pipeline products to improve the health of millions of patients.

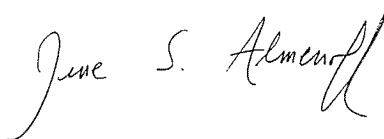
As a new company, we will aim to expand our stockholder base by continuing to increase our visibility in the investor and scientific communities. We are committed to building sustainable growth, value and long-term profitability for our stockholders.

The team at Furiex thanks each of our stockholders for their support. We look forward to updating you regularly on our progress in the upcoming year.

Sincerely yours,



Fred N. Eshelman, Pharm.D.  
*Executive Chairman*



June S. Almenoff, M.D., Ph.D.  
*President and Chief Medical Officer*

AT FURIEX, WE BELIEVE  
**OUR PEOPLE AND THEIR EXPERTISE**  
ARE OUR GREATEST ASSETS.

**Project Team**

We are dedicated to innovative drug design and scientific excellence. All of our project leaders hold advanced degrees and our leadership team collectively has more than 70 years of drug development experience. The team applies its expertise to design innovative drug development programs with parallel processes resulting in fewer decision gates while mitigating risks through contingency planning. We have successfully delivered two Phase III ready compounds, Priligy™ and Nesina®, to our partners, with both products now on the market.



*A strong passion for  
bringing life-improving  
therapies to patients*

From the left:

Rocio Lopez, Lisa Liverman, Scott Dove, Tim Costello, Michelle Usher and Laura Bonifacio



**Furiex™**  
Pharmaceuticals | *Fast. Focused. Expert.*

2010 Form 10-K

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

FORM 10-K

Received SBC  
APR 11 2011  
Washington, DC 20549

(Mark One)

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

For the fiscal year ended December 31, 2010

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 001-34641

**FURIEX PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

27-1197863  
(IRS Employer  
Identification No.)

3900 Paramount Parkway, Suite 150  
Morrisville, North Carolina 27560  
(Address of principal executive offices, including zip code)

(919) 456-7800  
(Registrant's telephone number, including area code):

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

Common Stock, par value \$0.001 per share  
(Title of each class)

Nasdaq Global Market  
(Name of each exchange on which registered)

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its Corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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 definition of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

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 common stock held by non-affiliates of the registrant was approximately \$93.9 million as of June 30, 2010, based on the closing price of the Common Stock on that date on the Nasdaq Global Market. Shares of common stock held by each executive officer and director and by each person who owns 10% or more of the outstanding common stock have been excluded in that such person might be deemed to be an affiliate. This determination of affiliate status might not be conclusive for other purposes.

As of March 11, 2011, there were 9,881,340 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The Company's definitive Proxy Statement for its 2011 Annual Meeting of Stockholders (certain parts, as indicated in Part III).

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**This report 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. These forward-looking statements are subject to risks and uncertainties, including those set forth under “Item 1A. Risk Factors” and “Cautionary Statement” included in “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this report, that could cause actual results to differ materially from historical results or anticipated results. Unless otherwise indicated or required by the context, the terms “we,” “our,” “us” and the “Company” refer to Furiex Pharmaceuticals, Inc. and all of its subsidiaries.**



## PART I

### Item 1. Business

#### Our Business

##### About Furiex Pharmaceuticals

We are a drug development collaboration company that uses innovative, clinical development strategies to increase the value of pharmaceutical assets and accelerate their development timelines. We collaborate with pharmaceutical and biotechnology companies to increase the value of early stage drug candidates by applying our novel approach to drug development. We believe this approach expedites research and development decision-making and can shorten drug development timelines. We share the risk with our collaborators by running and financing drug development up to agreed clinical milestones, and in exchange, we share the potential rewards, receiving milestone and royalty payments for any successful drug candidates. This business model is designed to help feed product pipelines and deliver therapies to improve lives. The Company's operations are headquartered in Morrisville, North Carolina.

Our company continues the compound partnering business started by Pharmaceutical Product Development, Inc., or PPD, in 1998. In June 2010, PPD spun-off its compound partnering business through a tax-free, pro-rata dividend distribution of all of the shares of the Company to PPD shareholders. PPD does not have any ownership or other form of equity interest in the Company following the spin-off.

##### Business Description

Our goal is to in-license from or form strategic alliances with pharmaceutical and biotechnology businesses to develop and commercialize therapeutics in which the risks and rewards are shared. We seek to collaborate with pharmaceutical and biotechnology companies to increase the value of early stage drug candidates by applying our novel approach to drug development that we believe expedites research and development decision-making and can shorten drug development timelines. Furiex's team is staffed with the same key PPD team members who demonstrated proven success in the drug development collaboration business while at PPD, as well as highly-qualified new members. Our strategy is to invest in drug candidates that have a relatively straightforward path to regulatory approval and a large addressable market. Every drug candidate we review is subjected to our rigorous due diligence process by our team of experts who possess experience in all aspects of the drug development process.

Once we in-license or form an alliance, we use our drug development experience and financial resources to advance the drug candidate through clinical development. We apply a novel approach that shortens drug development timelines that we believe transforms research and development into revenues more rapidly than the typical development cycle for such collaborations. Specifically, we set the development strategy based on a product candidate's best market position, design and manage nonclinical and clinical studies, manage the drug manufacturing programs, and evaluate the efficacy and safety data necessary to obtain regulatory approvals for the drug candidate. Furiex uses service providers to execute the tasks needed to develop and commercialize its product candidates.

Most of the large pharmaceutical companies with which we collaborate have the option to continue late stage clinical development and commercialization of the drug candidate after it has reached the specified pre-determined milestones. If our collaborator is unable or unwilling to perform late stage development and commercialization, then we have the option to seek a new development and commercialization partner.

In exchange for our drug development efforts and sharing the risk with our collaborator, we are entitled to receive milestone payments and royalties based on the continued development and commercialization success of the drug candidate.

Currently, we have rights to several compounds in various stages of development and commercialization, including:

- Rights to royalties and sales-based milestones from the collaboration with ALZA Corporation, an affiliate of Janssen-Cilag Pharmaceutica, N.V., on Priligy™, the first approved treatment in the world for premature ejaculation. Priligy is currently marketed in 14 countries.
- Rights to royalties and regulatory and sales-based milestone payments from Takeda Pharmaceutical Limited for alogliptin. Takeda received regulatory and pricing approval in Japan during the second quarter of 2010 for alogliptin for the treatment of type 2 diabetes. Takeda markets alogliptin in Japan under the name NESINA®. A cardiovascular trial requested by the United States Food and Drug Administration, or FDA, is ongoing.
- A fluoroquinolone antibiotic licensed from Janssen-Cilag, an affiliate of Johnson & Johnson, in November 2009 for the treatment of acute bacterial skin and skin structure infections, such as abscesses that occur deep in the skin layers, and respiratory infections. We recently completed a Phase II clinical trial using the oral formulation for acute bacterial skin infections and are enrolling patients in a Phase II proof-of-concept trial for respiratory infections.
- A compound that is a mu-opioid receptor agonist and delta-opioid receptor antagonist, which we call MuDelta, licensed from Janssen-Cilag in November 2009 for the treatment of diarrhea-predominant irritable bowel syndrome. We initiated a Phase II clinical trial during the second quarter of 2010.
- A novel statin compound we refer to as PPD-10558 licensed from Ranbaxy Laboratories, Ltd. for the treatment of dyslipidemia, which is an excessive level of blood lipids such as cholesterol. Preclinical and Phase I human studies suggest that PPD-10558 has similar cholesterol-lowering properties as a leading marketed statin, and also has pharmacologic properties which suggest that it may have a lower risk of myopathy, a statin side effect involving pain and/or muscle weakness, than currently marketed statins. PPD-10558 may therefore be a useful treatment option for statin-intolerant patients. In early 2011, we initiated start up activities for a Phase II proof-of-concept trial of PPD-10558.

The following chart summarizes the status of our pipeline of compounds:

		Phase of Development						Licensor	Collaborator <sup>1</sup>
Program	Indication	Preclinical	PI	PII	PIII	Marketing Application Submission	Market		
Priligy®	Premature Ejaculation	US						Eli Lilly & Co. <sup>2</sup>	Janssen-Cilag
		EU / ex-US							
Alogliptin	Type 2 Diabetes	US						Syrrx, Inc.	Takeda
		EU							
		JP							
Alogliptin / Actos® combination	Type 2 Diabetes	US						Syrrx, Inc.	Takeda
		EU							
		JP							
Alogliptin / Metformin combination	Type 2 Diabetes							Syrrx, Inc.	Takeda
Fluoroquinolone	Antibiotic	ABSSSI <sup>3</sup>						Janssen Pharmaceutica N.V.	Janssen Pharmaceutica N.V. <sup>4</sup>
		Bacterial Pneumonia							
Mu Delta	IBS-diarrheal							Janssen Pharmaceutica N.V.	Janssen Pharmaceutica N.V. <sup>4</sup>
PPD 10558	Cholesterol Lowering							Ranbaxy Laboratories	

1 Refers to late-stage development and commercialization collaborator.

2 Furixex originally licensed compound from Eli Lilly.

3 Acute bacterial skin and skin structure infections

4 At the completion of Phase II, Janssen will have option to continue development and commercialization of each compound.

## Our Solution

The drug development industry is under increasing economic pressure to develop new products more quickly and efficiently. To address this industry issue, we have developed what we believe is a novel approach to drug development. Our approach to drug development involves applying proven solutions from our extensive global drug development experience to reduce development timelines and expedite the decision-making cycle, planning for success and bridging steps in development by conducting earlier elements of a program while simultaneously planning for later phases of development.

In order to obtain regulatory approval from the FDA to market a drug, certain data about the safety and efficacy of the drug is required by the FDA. To obtain such data, drug developers frequently choose to run studies sequentially. For example, they may run one study, wait to see the results, and then they run the next study. Developers prefer this approach primarily to limit upfront expenditures since the success of any given study is not known and the decision may be made not to move forward due to negative data. This sequential approach slows down the development process.

We approach drug development by minimizing the time it takes to bring products to the market. Our novel approach manages drug development with parallel processing and efficient decision-making. We use our drug development experience to predict possible outcomes of a study and take risks based on those predictions. By assuming success at each critical decision point in advance, as opposed to waiting for results, time is reduced. In addition, we seek to mitigate risks by contingency planning for potential problems. As a result, we can accelerate the development process by bridging steps across the developmental program as well as between studies, as was

evidenced with alogliptin where it took just 39 months from the filing of the Investigational New Drug application, or IND, to the filing of the New Drug Application, or NDA. Additionally, we focus our efforts on only those essential studies necessary for regulatory approval. This helps to shorten developmental timelines.

Two key elements to our approach are our due diligence process and our planning for the success of each compound. Before we enter into a collaboration for a compound, we subject it to an intense due diligence review covering every step in the development process, from preclinical and clinical studies through marketing approval. We generally look for and enter into collaborations with respect to compounds that have the following characteristics:

- large market potential;
- a straightforward regulatory path;
- a reasonable development time;
- reasonable predictability of non-clinical models;
- clinical evidence no later than Phase Ib;
- a solid patent estate;
- acceptable estimated cost of goods; and
- attractive economic terms with the compound's innovator and ultimate commercial collaborator.

If a compound passes our rigorous diligence review hurdles, we then plan the entire development timeline upfront, using a set of assumptions. Part of the upfront planning involves initiating long-term studies, such as carcinogenicity studies, earlier than usual. We also use real-time data analysis tools to monitor the clinical study data of a drug candidate. By initiating long-term studies earlier and reviewing data in real time, we can significantly reduce the time needed after the conclusion of clinical studies to complete the necessary documentation for regulatory filing.

We believe this approach works well because the core development team is empowered to make decisions, real-time technology tools facilitate rapid data review, development programs are designed to optimize market position, and timelines are driven by science and "must have" studies. The resulting ability to reduce development timelines in turn allows us to capitalize more quickly on our investment. We believe our success evolves from our development efficiency.

According to the Tufts University Center for the Study of Drug Development Outlook 2009, since 2002 the average time from the filing of an IND application to the filing of an NDA is over eight years. By contrast, we advanced alogliptin as a treatment for type 2 diabetes (for the monotherapy program) from IND to NDA in only 39 months.

We believe our over 12 years of development experience has earned us a reputation in the pharmaceutical industry such that pharmaceutical companies approach us as a potential compound collaborator. We believe our most recent partnering project, which we entered into in November 2009 with Janssen-Cilag, evolved from our reputation for success.

### **Our Business Strategy**

Our strategy is to leverage our drug development experience to in-license, develop and out-license novel early stage drug candidates that address medical conditions with large unmet markets. We look to invest in drugs whose targets have scientific or clinical validation, and to study disease indications that have a relatively straightforward path to regulatory approval and a large addressable market. We subject every potential drug candidate we consider to a rigorous due diligence review process by our team, who possess experience in all aspects of the drug development process and commercial and intellectual property assessment. This approach has enabled us to build what we believe is a strong, diversified portfolio of products and product candidates. We plan to continue to build our pipeline by seeking to identify and in-license or acquire promising compounds and by developing strong partnerships in the pharmaceutical and biotechnology sectors.

## Our Portfolio

We have three products in clinical development. In addition we have two compounds that are commercialized by collaborators for which we are eligible to receive regulatory milestone payments plus worldwide sales royalty and milestone payments. These compounds, Priligy and Nesina, are currently marketed outside of the United States, and require no further cost or development obligations from us.

### Compounds in Clinical Development

#### *MuDelta*

Diarrhea-predominant irritable bowel syndrome, or IBS-d, affects approximately 28 million patients in the United States and the five major E.U. countries and is characterized by chronic abdominal pain and frequent diarrhea. Studies have demonstrated that IBS-d is associated with work absenteeism, high medical costs and low quality of life. We believe the market for prescription treatments for IBS-d is underserved due to the limited number of available treatments and the adverse side effects associated with those treatments. MuDelta is a novel agent that we are studying for the treatment of IBS-d. It is a mu-opioid receptor agonist and a delta-opioid receptor antagonist. Pharmacology data suggest that this drug acts locally in the digestive tract, thus we believe it should have a low risk of systemic side effects.

We commenced a Phase II trial for patients with IBS-d in the second quarter of 2010. If enrollment continues as expected, we anticipate having data available during the fourth quarter of 2011.

We have recently achieved two important milestones for this program:

- After a planned interim analysis to assess the dose-response and safety of the product, we have elected to continue the study to completion. This analysis was performed by a closed committee and in order to preserve the integrity of the study, we do not plan to disclose the interim results. Although Furiex has elected to continue the study, you should not assume the study will reach its endpoints.
- In January 2011, the FDA granted Fast Track designation to the MuDelta IBS program. Fast Track is a process for facilitating the development and expediting the review of drugs to treat serious diseases and fill an unmet medical need. The purpose is to facilitate bringing important new drugs to the patient earlier.

In November 2009 we entered into a development and license agreement with Janssen-Cilag under which they have the right to continue development and commercialization of the product after we complete Phase II development. In that case, Janssen-Cilag would bear the expenses for development, manufacture and marketing of the compound after Phase II, and Furiex would be eligible to receive up to \$90.0 million in regulatory milestone payments and up to \$75.0 million in sales-based milestone payments, as well as sales-based royalty payments increasing from mid-single digit to low initial double digit percentages based on worldwide sales. In the event Janssen-Cilag elects not to continue the program, we have the option to continue developing and commercializing the compound and Janssen-Cilag may receive up to \$50.0 million in regulatory milestone payments and up to \$75.0 million in sales-based milestone payments, and, if approved for marketing, sales-based royalties increasing from the mid to upper single digit percentages as sales volume increases. Royalties are to be paid for a period of ten years after the first commercial sale or, if later, the expiration of the last valid patent claim or the expiration of patent exclusivity. As of December 31, 2010, we had paid Janssen-Cilag \$3.5 million as an up-front in-licensing payment.

According to a market report by GlobalData, the global IBS market was estimated to be worth \$1.7 billion in 2009 and forecast to grow at 6.0% annually for the next seven years to reach \$2.7 billion by 2017. This estimated growth is primarily attributable to high levels of unmet need in the market, which is expected to be served by pipeline candidates. The growth is further expected to be supported by the high prevalence rates of the disease.

### *Fluoroquinolone (JNJ-Q2)*

Community-acquired bacterial pneumonia, or CABP, and acute bacterial skin and skin structure infections, or ABSSSI, are a growing public-health threat due to increasing drug resistance of established antibiotics to causative pathogens.

JNJ-Q2 is a novel broad-spectrum fluoroquinolone antibiotic that also has broad coverage against two important drug resistant pathogens: methicillin-resistant *Staphylococcus* (“Staph”) *aureus*, or MRSA; and drug-resistant *Streptococcus pneumoniae*. In addition, it is highly active against other common and difficult to treat bacteria, including those that are gram-negative, gram-positive, atypical or anaerobic infections, and has a low propensity for development of drug resistance. We are developing JNJ-Q2 in both intravenous and oral formulations, to enable use in a variety of clinical settings. Taken together, the above characteristics of JNJ-Q2 suggest that it has the potential to be an important agent for the treatment of serious skin and respiratory infections.

In November 2010, we reported positive results for our randomized, double-blind, multicenter Phase II clinical trial comparing the efficacy, safety and tolerability of JNJ-Q2 with linezolid (Zyvox®). The study used a non-inferiority design to test the efficacy of JNJ-Q2 relative to linezolid. One hundred sixty-one patients with ABSSSI received oral treatment twice a day with either JNJ-Q2 (250 mg twice daily) or linezolid (600 mg twice daily) for 7 to 14 days.

JNJ-Q2 had positive results for both clinical cure and early response endpoints. Results for the intent-to-treat population are provided herein. JNJ-Q2 was statistically non-inferior to linezolid for all clinical test-of-cure endpoints at various times in the intent-to-treat population. The following clinical cure endpoints are based on clinical assessment by the treating physicians, who were blinded to the study treatment:

- At seven days of therapy, 44.6% of patients receiving JNJ-Q2 were assessed as cured, compared with 37.2% of patients receiving linezolid;
- At 10 to 14 days of therapy, 66.3% of patients receiving JNJ-Q2 were assessed as cured, compared with 61.5% of patients receiving linezolid; and
- At the traditional test-of-cure endpoint, namely short-term follow-up done 2 to 14 days after treatment was completed, 83.1% of patients receiving JNJ-Q2 were assessed as cured, compared with 82.1% of patients receiving linezolid.

In this trial we assessed both (1) cessation of skin lesion spread or reduction in lesion size, and (2) absence of fever. JNJ-Q2 showed a slightly inferior response rate of 74.7% versus linezolid’s 79.5% at 36 to 84 hours after starting treatment. However, we reached statistical non-inferiority in an analysis of the clinical response within 48 to 72 hours after starting treatment, consistent with the latest FDA draft guidance, with a slightly higher response rate for JNJ-Q2 at 62.7% than for linezolid at 57.7%. In this protocol, all patients required at least one systemic sign of infection (e.g, abnormal temperature, increased white blood cell count, etc.) for inclusion in the study. Five percent of patients in the study had baseline temperatures of 100°F or greater.

JNJ-Q2 had a favorable safety profile and was well tolerated. Serious adverse events were infrequent in both treatment groups. Nausea and vomiting were more frequent with JNJ-Q2 than linezolid, however, symptoms were mild for both treatment groups. Nausea rates were 22.9% for JNJ-Q2 and 11.4% for linezolid; vomiting rates were 12.0% JNJ-Q2 and 6.3% for linezolid. The vast majority of these events occurred on day 1 to 2 of treatment. Long-term clinical follow-up data collected 12 weeks after the last dose of medication showed similar low rates of recurrent infections for both treatment groups, 1.2% for JNJ-Q2 and 2.6% for linezolid.

This study represents an important milestone for JNJ-Q2, demonstrating its potential value in the treatment of acute bacterial skin infections, particularly those caused by methicillin-resistant and fluoroquinolone-resistant



*Staphylococcus aureus*. JNJ-Q2's demonstrated ability to successfully treat severe skin infections as an oral agent differentiates it from a number of other approved and developmental products for treating MRSA, which are only available for intravenous treatment.

In 2010, there were a number of impactful publications by both Furiex and by Johnson and Johnson Pharmaceutical Research and Development, describing the broad spectrum and potent bactericidal activity of JNJ-Q2 toward a diverse variety of drug-resistant pathogens. Additional studies have demonstrated the low propensity of bacteria to develop resistance to JNJ-Q2 compared with ciprofloxacin, a commonly prescribed quinolone.

We believe that the broad spectrum and potent activity of JNJ-Q2 makes it well suited to a wide variety of indications with large markets. To leverage this significant potential, we initiated a Phase II study in severe community-acquired pneumonia in late 2010. Enrollment of this study has been slower than expected and we have taken steps to increase the rate of enrollment. These steps include adding a number of global sites and potentially modifying the study protocol. Given that these changes will be implemented over the next six months, it will be easier to project the enrollment later in 2011.

In November 2009 we entered into a development and license agreement with Janssen-Cilag, under which Janssen-Cilag has the right to continue development and commercialization of the product after we complete Phase II development. In that case, Janssen-Cilag would bear the expenses for development, manufacture and marketing of the compound after Phase II, and Furiex would be eligible to receive up to \$90.0 million in regulatory milestone payments and up to \$75.0 million in sales-based milestone payments, as well as sales-based royalty payments increasing from mid-single digit to low initial double digit percentages based on worldwide sales. In the event Janssen-Cilag elects not to continue the program, we have the option to continue developing and commercializing the compound and Janssen-Cilag may receive up to \$50.0 million in regulatory milestone payments and up to \$75.0 million in sales-based milestone payments, and, if approved for marketing, sales-based royalties increasing from the mid to upper single digit percentages as sales volume increases. Royalties are to be paid for a period of ten years after the first commercial sale or, if later, the expiration of the last valid patent claim or the expiration of patent exclusivity. As of December 31, 2010, we had paid Janssen-Cilag \$3.5 million as an up-front in-licensing payment.

Because of the emerging resistance to established antibiotics, there is a large unmet need for antibiotics such as JNJ-Q2, that cover a broad range of pathogens, including resistant Staph and Strep, and that have the potential for both intravenous and oral use. Bacterial infections are a major cause of morbidity and mortality, and antibiotic resistant infections have become a growing public health concern. More than 14 million ambulatory physician visits each year are related to skin and soft-tissue infections, and approximately 94,000 Americans developed serious MRSA infections in 2005, according to a recent study published in the *Journal of the American Medical Association*. We estimate that the worldwide market for antibiotics to treat MRSA is approximately \$2.0 billion annually, based on 2009 sales of \$1.14 billion for Zyvox, \$538 million for Cubicin®, \$303 million for Tygacil® and \$185 million for generic vancomycin, which are the products primarily used to treat MRSA. Fluoroquinolone antibiotics generated \$7 billion in sales in 2009.

#### *Novel statin compound (PPD-10558)*

Our novel statin, which we call PPD-10558, is a potential treatment for dyslipidemia, a condition characterized by high cholesterol. We licensed exclusive rights to PPD-10558 for this indication from Ranbaxy. Ranbaxy retained co-marketing rights for the compound in India, and for generic forms of the compound in countries where such generic forms are already being sold.

Statins are highly-effective therapies for lowering cholesterol leading to prevention of heart attacks and strokes, leading to lower death rates from these potentially devastating events. One of the most common side effects of statins is chronic muscle pain, sometimes associated with weakness, known as statin-associated myalgia, or SAM. Chronic muscle problems are reported to occur in up to 10% of statin users, limiting both their

exercise tolerance as well as their ability to reach their target cholesterol levels. Given that the overall high cholesterol market is estimated to be more than \$35 billion, the statin-intolerant population represents a large potential market.

PPD-10558 is a muscle-sparing statin that could be a valuable new therapy for the large population of statin-users who cannot reach their target cholesterol levels due to SAM. Pre-clinical and Phase I human studies demonstrate that PPD-10558 has similar cholesterol-lowering efficacy as atorvastatin (Lipitor®), a best-in-class statin. The pharmacologic and toxicological profile of PPD-10558 suggests that it should have lower risk of muscle-related toxicity than currently marketed statins.

In addition to its muscle-sparing properties, PPD-10558 does not interact with cytochrome P450 metabolizing enzymes, which mitigates the risk of toxic drug interactions that can occur with most other statins. Also, PPD-10558 can be safely used with gemfibrozil, a triglyceride-lowering agent. This is in contrast to several popular statins, which can cause significant toxicity if used concomitantly with gemfibrozil due to significant drug-drug interactions.

A number of pre-clinical studies have previously been conducted to investigate the muscle toxicity of PPD-10558 in comparison to atorvastatin. These studies showed that high doses of atorvastatin cause severe muscle necrosis and death in rats. In contrast, the same dosing regimen of PPD-10558 did not cause any toxicity. We have pre-clinical results that further support our hypothesis that PPD-10558 could be a muscle-sparing statin. In a drug distribution study, rats were treated with high doses of atorvastatin or PPD-10558; drug concentrations in muscle of atorvastatin-treated rats were approximately 40-fold higher relative to drug concentrations in muscle of rats treated with PPD-10558. The findings from these studies suggest that accumulation of atorvastatin in rat muscle tissue is related to muscle toxicity, and the lack of muscle toxicity seen in the rat following dosing of PPD-10558 is consistent with the low levels of PPD-10558 seen in the rat muscle. Taken together, these data support the clinical hypothesis that PPD-10558 could be as effective as atorvastatin, yet with lower risk of muscle side effects.

In December 2010, Furiex had a teleconference with the FDA as well as additional follow-up correspondence. The following points were communicated by the agency: (1) the FDA accepts our Phase II study design, (2) the FDA concurs with Furiex's development strategy to seek an indication for cholesterol-lowering in patients with SAM, and (3) there is not an expectation that a cardiac outcomes study will be needed. We have finalized the protocol for Phase II proof-of-concept study, which will test whether PPD-10558 is better tolerated by SAM patients than atorvastatin. We are currently recruiting study sites and have received indications of interest from investigators; we anticipate that we will be able to start enrolling patients around mid-2011.

If we further develop PPD-10558 and it were to be approved and commercialized, and it meets specific commercialization and sales milestones, the potential clinical and sales-based milestones that we are obligated to pay Ranbaxy would total \$43.0 million. We also would be obligated to pay Ranbaxy sales-based royalties of a mid-single digit percentage. We will be solely responsible and will bear all costs and expenses for the development, manufacture, and marketing of the compound and licensed products. If advanced, we estimate the costs of development could be \$15.0 to \$20.0 million over the next two years. If we exercise our right to terminate early, other than for safety or efficacy reasons, a material product failure or Ranbaxy breach, we must pay Ranbaxy \$1 million. As of December 31, 2010, we had paid Ranbaxy \$1.5 million in up-front and development milestone payments.

The American Heart Association estimates that there are more than 35 million adults in the U.S. with total cholesterol greater than or equal to 240 milligrams per deciliter of blood, or mg/dL, and that there are more than 71 million adults in the U.S. with low-density lipoprotein, or LDL, equal to or greater than 130 mg/dL. The American Heart Association has determined that a total cholesterol level of 240 mg/dL and above presents high risk for heart disease and that an LDL level of between 130 and 159 mg/dL presents borderline high risk of heart disease. In 2009, worldwide sales of lipid regulators amounted to \$35.3 billion.

## Marketed Products

### *Nesina (alogliptin)*

Nesina, which is marketed by Takeda, is the trade name for alogliptin, a member of a relatively new class of drugs for the oral treatment of Type-2 diabetes, or T2D. Nesina is a highly selective dipeptidyl peptidase-4, or DPP-4, inhibitor that slows the inactivation of hormones known as incretins, which play a major role in regulating blood sugar levels and might improve pancreatic function. Pivotal trials demonstrated that Nesina was well-tolerated when given as a single daily dose and it significantly improved glycemic control in T2D patients without raising the incidence of hypoglycemia. Additionally, Nesina has been shown to enhance glycemic control when used in combination with other commonly prescribed diabetes drugs.

In 2003, PPD entered into a collaboration agreement to develop Syrrx's orally active DPP4 inhibitors to treat type 2 diabetes and other major human diseases. In March 2005, Takeda acquired Syrrx. In July 2005, Takeda acquired development and commercialization rights to these DPP4 inhibitors from PPD for an upfront payment, potential milestone payments and royalties associated with the future development and commercialization of specified DPP4 inhibitors and the right to serve as the sole provider of clinical and bioanalytical services to Takeda for Phase II and Phase III trials of DPP4 inhibitors conducted in the United States and Europe.

In December 2007, Takeda submitted an NDA for alogliptin to the FDA. In September 2008, Takeda submitted an NDA for alogliptin in Japan. In September 2008, Takeda also submitted an NDA for a fixed dose product containing alogliptin and Actos® to the FDA. In June 2009, the FDA issued a complete response to Takeda on its alogliptin NDA. A complete response letter indicates that the review cycle for an application is complete and that the application cannot be approved in its present form, and informs sponsors of changes that must be made before an application can be approved, with no implication as to the ultimate approvability of the application. In the complete response letter, the FDA requested Takeda to conduct an additional cardiovascular safety trial that satisfies the FDA's December 2008 guidance on anti-diabetes therapies. In September 2009, the FDA issued a complete response to Takeda on its NDA for the fixed dose combination of alogliptin and Actos, stating that further review would be dependent on the cardiovascular safety data that would be submitted in support of the alogliptin monotherapy NDA. This trial is ongoing. The European Medicines Agency, or EMA, issued draft guidance with respect to cardiovascular safety requirements for its Type 2 diabetes drugs on February 10, 2010. Takeda has indicated that it intends to pursue marketing approval of Nesina, Nesina/Actos and Nesina/Metformin both in the United States and Europe, and they anticipate launches in the 2012 and 2013-2014 time frames, respectively.

Nesina received regulatory and pricing approval in Japan during the second quarter of 2010 and for co-administration of Nesina with thiazolidinediones, including Takeda's Actos (pioglitazone), which is a multi-billion dollar a year product, in August 2010. In February 2011, Takeda reported that the Japanese Ministry of Health, Labour and Welfare approved combination therapy for Nesina with sulfonylureas and combination therapy for Nesina with biguanides.

Under our agreement with Takeda, we will be entitled to receive up to \$45.0 million in future regulatory milestone payments, and up to \$33.0 million in sales-based milestone payments, if targets are achieved. In addition, we are entitled to receive payments on worldwide sales of Nesina based on royalty rates of 7% to 12% in the U.S., 4% to 8% in Europe and Japan and 3% to 7% in regions other than the U.S., Europe or Japan. These royalty payments are subject to a reduction of up to 0.5% for a portion of payments by Takeda to a licensor for intellectual property related to Nesina. As of December 31, 2010, we had received \$55.5 million in development and regulatory milestone payments. Royalties are to be paid for the later of ten years following the first commercial sale or two years following the expiration of the last to expire patent.

The Centers for Disease Control and Prevention estimates that there are approximately 25.8 million people in the U.S. with type 1 and type 2 diabetes. The World Health Organization estimates that more than 170 million people worldwide have type 1 and type 2 diabetes and that the number will double by 2030. Worldwide sales of antidiabetic treatments in 2009 were \$30.4 billion.

In addition to all the rights to receive milestone payments and royalties, Furiex received from PPD the following material rights and/or obligations:

- to indemnify Takeda for various claims and losses arising out of or under the agreement; and
- to not discover, develop, or commercialize any product directed to the DPP4 inhibitors.

#### *Priligy (dapoxetine)*

Priligy is the trade name for dapoxetine, a drug in tablet form specifically indicated for the “on-demand” treatment of premature ejaculation, or PE. Priligy is a unique, short-acting, selective serotonin reuptake inhibitor, or SSRI, designed to be taken only when needed, one to three hours before sexual intercourse, rather than every day. It is the first oral medication to be approved for PE anywhere in the world, and no products are currently approved for the treatment of premature ejaculation in the United States. The reported percentage of men affected with PE at some point during their lives ranges from 4% to 30%, depending on the methodology and criteria used. Priligy has been studied in five randomized, placebo-controlled Phase III clinical trials involving more than 6,000 men with PE and is marketed in 14 countries in Europe, Asia-Pacific and Latin America. In December 2004, Janssen-Cilag, an affiliate of ALZA, submitted an NDA to the FDA for dapoxetine. Janssen-Cilag received a “not approvable” letter from the FDA in October 2005, but continued its global development program. Janssen-Cilag is conducting additional studies with Priligy in the United States and abroad.

PPD acquired an exclusive license from Eli Lilly and Company in 1998 to develop and commercialize dapoxetine for genitourinary indications, including premature ejaculation. In December 2003, PPD acquired Lilly’s patents and remaining rights to develop and commercialize dapoxetine in the field of genitourinary disorders. PPD developed the compound through Phase II proof-of-concept and, in January 2001, out-licensed it to ALZA, which is now part of Johnson & Johnson. ALZA is responsible for all clinical, regulatory, manufacturing, sales and marketing costs associated with the compound. As of December 31, 2010, we had received \$35.9 million in combined development and regulatory milestone payments. Under our license agreement with ALZA, we have the right to receive up to \$15.0 million in additional regulatory milestone payments, up to \$50.0 million in sales-based milestone payments, and sales-based royalties ranging from 10% to 20% for sales of patented products without generic competition and ranging from 10% to 17.5% for non-patented products without generic competition, in both cases the percentages rise as sales volume increases, and a royalty of 7.5% for patented and non-patented products with generic competition regardless of sales volume based on the level of Priligy sales worldwide. We must pay Lilly a royalty of 5% on annual sales in excess of \$800.0 million.

ALZA has worldwide rights to develop and commercialize dapoxetine. In addition to all the rights to receive milestone payments and royalties, Furiex has the following material rights and/or obligations:

- to prosecute patent applications and maintain granted patents, and allow ALZA to comment on such prosecution;
- to notify ALZA of any actual, potential or suspected infringement of licensed patents by a third party of which Furiex becomes aware and of any claim of infringement of a third party’s proprietary rights of which Furiex receives notice with regard to the license grant;
- to not publish any data regarding dapoxetine;
- to not assert any patent or other intellectual property right owned by the Company against ALZA;
- to indemnify ALZA for various claims and losses arising out of or under the agreement;

- to defend licensed patents against infringers (in the event ALZA does not desire to defend) and be entitled to all recoveries, damages or awards if it defends.

### **Our Drug Development Capabilities**

Our drug development capabilities embody over 12 years of research and development experience. This experience includes a deep understanding of the biological causes of human diseases and the factors that impact all aspects of successful drug development such as manufacturing, formulation, the cause of drug side effects, drug interactions and drug pharmacokinetics. We believe that our drug development capability and proven success rate will continue to provide a pipeline of unique compounds. Depending upon the availability of our development resources, our preclinical candidates might be added to our own internal clinical pipeline, or out-licensed to other companies for clinical development and commercialization.

### **Our Patents and Other Proprietary Rights**

Patents and other proprietary rights are important to our business. It is our policy to seek patent protection for our assets, and also to rely upon trade secrets, know-how and licensing opportunities to develop and maintain our competitive position.

We own or have exclusively licensed six issued U.S. patents and have approximately 290 pending patent applications. We have a policy to seek worldwide patent protection for our products and have foreign patent rights corresponding to most of our U.S. patents.

On May 18, 2010, the United States Patent and Trademark Office, or USPTO, issued a patent for the method for treatment of premature ejaculation using dapoxetine (trademark Priligy). U.S. Patent No. 7,718,705 includes claims directed to dosing dapoxetine on an as-needed basis, capturing the advantage dapoxetine has over other compounds in the same class, which require a pre-loading period for efficacy. The patent term will expire in 2022. Furiex has received grants of similar patent claims in over 45 countries around the world including major and emerging markets.

We license the rights to the following patents related to our product candidates:

- PPD-10558. Licensed from Ranbaxy. The license expires 10 years after the first commercial sale or expiration of the last to expire enforceable patent claim. As of December 31, 2010, nine U.S. and foreign patents have been issued to Ranbaxy in this patent family. The USPTO issued a Notice of Allowance of claims covering the PPD-10558 compound. This patent has also received a patent term adjustment from the USPTO that extends the patent term to 2026. Corresponding foreign patent applications and additional U.S. and foreign patent applications are still pending;
- MuDelta. Licensed from Janssen-Cilag. The license expires upon the exercise of an option by Janssen to continue the development and commercialization of MuDelta after completion of Phase II studies. If Janssen rejects the option, then the license continues until no further payments are owed to Janssen. As of December 31, 2010, over 10 U.S. and foreign patents have been issued to Janssen in this patent family. Additional U.S. and foreign patent applications are still pending; and
- Fluoroquinolone. Licensed from Janssen-Cilag. The license expires upon the exercise of an option by Janssen to continue the development and commercialization of fluoroquinolone after completion of Phase II studies. If Janssen rejects the option, then the license continues until no further payments are owed to Janssen. As of December 31, 2010, over 30 U.S. and foreign patents have been issued to Janssen in this patent family. Additional U.S. and foreign patent applications are still pending.

Pursuant to the terms of the Uruguay Round Agreements Act, patents issued from applications filed on or after June 8, 1995, have a term of 20 years from the date of filing, no matter how long it takes for the patent to

issue. Because patent applications in the pharmaceutical industry often take a long time to issue, this method of patent term calculation can result in a shorter period of patent protection afforded to us compared to the prior method of term calculation, which was 17 years from the date of issue. Our issued U.S. patents expire between 2023 and 2029, excluding any potential patent term extension available under U.S. federal law. We actively seek full patent term adjustment following allowance of a patent. We also actively seek patent term extensions covering products following marketing approval. Under the Drug Price Competition and Patent Term Restoration Act of 1984 and the Generic Animal Drug and Patent Term Restoration Act of 1988, a patent that claims a product, use or method of manufacture covering drugs may be extended for up to five years to compensate the patent holder for a portion of the time required for FDA review. However, we might not be able to take advantage of the patent term extension provisions of this law.

While we file and prosecute patent applications to protect our inventions, our pending patent applications might not result in the issuance of patents or our issued patents might not provide competitive advantages. Also, our patent protection might not prevent others from developing competitive products using related or other technology.

In addition to seeking the protection of patents and licenses, we also rely upon trade secrets, know-how and continuing technological innovation, which we seek to protect, in part, by confidentiality agreements with employees, consultants, suppliers and licensees. If these agreements are not honored, we might not have adequate remedies for any breach. Additionally, our trade secrets might otherwise become known or patented by our competitors.

The scope, enforceability and effective term of issued patents can be highly uncertain and often involve complex legal and factual questions. No consistent policy has emerged regarding the breadth of claims in pharmaceutical patents, so that even issued patents might later be modified or revoked by the relevant patent authorities or courts. Moreover, the issuance of a patent in one country does not assure the issuance of a patent with similar claim scope in another country, and claim interpretation and infringement laws vary among countries, so we are unable to predict the extent of patent protection in any country. The patents we obtain and the unpatented proprietary technology we hold might not afford us significant commercial protection. Additional information regarding risks associated with our patents and other proprietary rights that affect our business is contained under the headings “We must protect our patents and other intellectual property rights to succeed” and “We might need to obtain patent licenses from others in order to manufacture or sell our potential products and we might not be able to obtain these licenses on terms acceptable to us or at all” under the heading “Risk Factors”.

### **Manufacturing and Supply**

We currently rely on our collaborators and contract manufacturers to produce drug substances and drug products required for our clinical trials under current good manufacturing practices, with oversight by our internal managers. We plan to continue to rely upon contract manufacturers and collaboration partners to manufacture commercial quantities of our drug candidates if and when approved for marketing by the applicable regulatory agency. We generally rely on one manufacturer for the active pharmaceutical ingredient and another manufacturer for the formulated drug product for each of our drug candidate programs. At the early stage of clinical studies, we do not believe that we are substantially dependent on any supplier, or that additional manufacturers would be beneficial due the possibility of changes in the method of manufacturing of the drug candidate. As a drug candidate moves to later stages of development and the drug formulation method is established, we then seek additional manufacturers for the drug.

### **Sales and Marketing**

We currently have no marketing, sales or distribution capabilities. We plan to rely on third party collaborators to market our products, like ALZA for Priligy and Takeda for Nesina, and therefore we are subject to the strategic marketing decisions of such third parties. We generally plan to out-license our commercial rights



in a territory to a third party with marketing, sales and distribution capabilities in exchange for one or more of the following: up-front payments; research funding; development funding; milestone payments; and royalties on drug sales. In some instances, however, we might choose to develop our own staff for marketing, sales or distribution.

### **Government Regulation**

The manufacturing, testing, labeling, approval and storage of our products are subject to rigorous regulation by numerous governmental authorities in the United States and other countries at the federal, state and local level, including the FDA. The process of obtaining approval for a new pharmaceutical product or for additional therapeutic indications within this regulatory framework requires expenditure of substantial resources and usually takes several years. Companies in the pharmaceutical and biotechnology industries, including us, have suffered significant setbacks in various stages of clinical trials, even in advanced clinical trials after promising results had been obtained in earlier trials.

The process for obtaining FDA approval of drug candidates customarily begins with the filing of an IND with the FDA for the use of a drug candidate to treat a particular indication. If the IND is accepted by the FDA, we would then start human clinical trials to determine, among other things, the proper dose, safety and efficacy of the drug candidate in the stated indication. The clinical trial process is customarily divided into three phases—Phase I, Phase II and Phase III. Each successive phase is generally larger and more time-consuming and expensive than the preceding phase. Throughout each phase we are subject to extensive regulation and oversight by the FDA. Even after a drug is approved and being marketed for commercial use, the FDA may require that we conduct additional trials, including Phase IV trials, to further study safety or efficacy.

As part of the regulatory approval process, we must demonstrate to the FDA the ability to manufacture a pharmaceutical product before we receive marketing approval. We and our manufacturing collaborators must conform to rigorous standards regarding manufacturing and quality control procedures in order to receive FDA approval. The validation of these procedures is a costly endeavor. Pharmaceutical manufacturers are subject to inspections by the FDA and local authorities as well as inspections by authorities of other countries. To supply pharmaceutical products for use in the United States, foreign manufacturers must comply with these FDA-approved guidelines. These foreign manufacturers are also subject to periodic inspection by the FDA or by corresponding regulatory agencies in these countries under reciprocal agreements with the FDA. Moreover, state, local and other authorities may also regulate pharmaceutical product manufacturing facilities. Before we are able to manufacture commercial products, we or our contract manufacturer, as the case may be, must meet FDA guidelines.

Both before and after marketing approval is obtained, a pharmaceutical product, its manufacturer and the holder of the Biologics License Application, or BLA, or NDA for the pharmaceutical product are subject to comprehensive regulatory oversight. The FDA may deny approval to a BLA or NDA if applicable regulatory criteria are not satisfied. Moreover, even if regulatory approval is granted, such approval may be subject to limitations on the indicated uses for which we may market the pharmaceutical product. Further, marketing approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems with the pharmaceutical product occur following approval. In addition, under a BLA or NDA, the manufacturer of the product continues to be subject to facility inspections and the applicant must assume responsibility for compliance with applicable pharmaceutical product and establishment standards. Violations of regulatory requirements at any stage may result in various adverse consequences, which may include, among other adverse actions, withdrawal of the previously approved pharmaceutical product or marketing approvals or the imposition of criminal penalties against the manufacturer or BLA or NDA holder.

For the development of pharmaceutical products outside the United States, we and our collaborators are subject to foreign regulatory requirements and the ability to market a drug is contingent upon receiving marketing authorizations from the appropriate regulatory authorities. The requirements governing the conduct of

clinical trials and marketing authorization vary widely from country to country. In countries other than European Union countries, foreign marketing authorizations are applied for at a national level. Within the European Union, procedures are available to companies wishing to market a product in more than one European Union member state. Clinical trial applications must be filed with the relevant regulatory authority in each country in which we would want to conduct a clinical trial. Assuming approval and the success of any clinical trial, we would then need to seek marketing approval for the drug. The process for obtaining marketing approval of drug candidates in the European Union begins with the filing with the European Medicines Agency, or EMA, of a Marketing Authorization Application, or MAA, for the use of a drug candidate to treat a particular indication. Similar processes and outcomes of such human clinical trials that are required by the FDA are also required by the EMA including testing for dose, safety and efficacy in three phases. Similar to the FDA, we are subject to extensive regulation and oversight by the European regulators throughout each phase. Even after a drug is approved and being marketed for commercial use, the EMA may require that we conduct additional trials, including Phase IV trials, to further study safety or efficacy. As a result, the EMA regulatory approval process includes all of the risks associated with FDA approval set forth above.

If and when necessary, we will choose the appropriate route of European or other international regulatory filing to accomplish the most rapid regulatory approvals. Requirements relating to manufacturing, conduct of clinical trials and product licensing vary widely in different countries, and the chosen regulatory strategy might not secure regulatory approvals or approvals of our chosen product indications. In addition, if a particular product to be used outside of the United States is manufactured in the United States, FDA requirements and U.S. export provisions will apply.

Outside of the United States, many countries require us to obtain pricing approval in addition to regulatory approval prior to launching the product in the approving country. We or our licensees may encounter difficulties or unanticipated costs or price controls in our respective efforts to secure necessary governmental approvals. Failure to obtain pricing approval in a timely manner or approval of pricing which would support an adequate return on investment or generate a sufficient margin to justify the economic risk might delay or prohibit the commercial launch of the product in those countries.

The marketing and sale of approved pharmaceutical product is subject to strict regulation. Promotional materials and activities must comply with the approving agency's regulations and other guidelines. Physicians may prescribe pharmaceutical or biologic products for uses that are not described in a product's labeling or differ from those approved by the approving agency. While such "off-label" uses are common and regulatory agencies do not regulate physicians' choice of treatments, many approving agencies restrict a company's communications on the subject of "off-label" use. Companies cannot promote approved pharmaceutical or biologic products for off-label uses. If any advertising or promotional activities we undertake fail to comply with applicable regulations or guidelines regarding "off-label" use, we may be subject to warnings or enforcement action.

## **Competition**

The pharmaceutical industry is highly competitive. Many of our competitors are worldwide conglomerates with substantially greater resources than we have to develop and commercialize their drugs and drug candidates. Potential competitors have developed and are developing compounds for treating the same indications as our product candidates. In addition, a number of academic and commercial organizations are actively pursuing similar technologies, and several companies have developed or may develop technologies that might compete with our compounds.

Priligy, indicated for premature ejaculation, competes with Cromadyn, a generic paroxetine sold by More Pharmaceuticals in Mexico. We are aware of three other compounds in development for premature ejaculation: PD502, a novel metered-dose aerosol formulation of lidocaine and prilocaine being developed by Shionogi; DMI-7958, a opioid mu receptor agonist, 5-HT receptor agonist, being developed by Ampio Pharma, and GSK-557296, a oxytocin receptor antagonist, being developed by GSK. All of these products are in late stage (Phase II/III) development.

Nesina competes in the type 2 diabetes space with two DPP4 inhibitors currently on the market, Bristol-Myers Squibb/AstraZeneca's Onglyza® (saxagliptin) and Merck's Januvia® (sitagliptin). Merck also markets Janumet®, a fixed-dose combination of sitagliptin and metformin and Bristol-Myers Squibb/AstraZeneca, Kombiglyze®, a combination of saxagliptin and extended release metformin. Novartis markets the DPP4 inhibitor Galvus® (vildagliptin) and Eucreas® (vildagliptin/metformin) in Europe. Other marketed oral anti-diabetic competitors include generic metformin, generic sulfonylureas, and thiazolidinediones, including GlaxoSmithKline's Avandia® (rosiglitazone) and Takeda's Actos (pioglitazone). Generic competitors to Avandia and Actos are expected to enter the market in 2012.

The diabetes pipeline is crowded, with, to our knowledge, approximately 50 compounds in Phase I development, approximately 70 in Phase II development, and approximately 30 in Phase III development or preregistration. In addition to DPP4 inhibitors, competitors are also developing GLP-1 agonists, SGLT-2 antagonists, PPAR agonists, and compounds with other mechanisms for treatment of diabetes. Other companies with DPP4 inhibitors in clinical development of which we are aware include Amgen/Servier, Arisaph Pharmaceuticals, Boehringer Ingelheim, Dong-A Pharmaceuticals (South Korea), Dainippon Sumitomo Pharma, Phenomix, Glenmark Pharmaceuticals, Kyorin Pharmaceuticals, LG Life Sciences (South Korea), Mitsubishi Tanabe Pharma, and Sanwa Kagaku Kenkyusho (Japan). In addition, Merck is developing a fixed-dose combination of sitagliptin and pioglitazone (Actos), currently in Phase III development.

If approved, PPD-10558, indicated for the treatment of dyslipidemia, would compete with a wide variety of lipid lowering drugs. Generic statins are expected to dominate the market by 2012 when Pfizer's Lipitor® (atorvastatin) patent expires. PPD-10558 may be differentiated from these products if it is proved to be safe in patients who cannot tolerate currently marketed statins due to muscle pain symptoms. There are several competing statins and statin combination products in development, including AstraZeneca/Abbott's Certrid® (rosuvastatin/fibrate), Merck's MK-0524A (laropiprant/niacin/simvastatin), Sciele Pharma's fenofibrate/pravastatin combination, Abbott/Solvay's Zolip® (fenofibrate/simvastatin), and NicOx's NCX-6560, a novel statin. Companies developing compounds with other mechanisms of action for use in hyperlipidemia of which we are aware include Aegerion Pharmaceuticals, Amarin Corporation, Bristol-Myers Squibb, Cortria Corporation, Dr. Reddys Laboratories, Esperion Therapeutics, Essentialis, Genfit, GlaxoSmithKline, Isis Pharmaceuticals/Genzyme, Japan Tobacco, Karo Bio, Kythera Biopharmaceuticals, The Medicines Company, Merck, Metabasis Therapeutics, Metabolex, Mitsubishi Tanabe Pharma, Sanofi-Aventis, and Surface Logix.

If approved, the fluoroquinolone antibiotic compound licensed from Janssen-Cilag will compete with other fluoroquinolones currently on the market, including Johnson and Johnson's Levaquin® (levofloxacin), Bayer/Merck's Avelox® (moxifloxacin), Bayer/Merck's Cipro® (ciprofloxacin), and Oscient's Factive® (gemifloxacin). Generic versions of ciprofloxacin are currently available, and generic versions of moxifloxacin and levofloxacin will likely become available when the patents covering these products expire in 2014 and 2011, respectively. If the fluoroquinolone from Janssen-Cilag is found to be effective against MRSA infections, it would compete with Pfizer's Zyrox® (linezolid), Cubist's Cubicin (daptomycin), Wyeth's Tygacil (tigecycline), Theravance's Vibativ® (telavancin), Forest's Teflro™ (ceftaroline), and the generic drug vancomycin.

Companies developing compounds to treat MRSA infections in clinical trials include Baselia, Trius, Paratek/Novartis, Cempra, Durata, e-Therapeutics, FAB Pharma, Medicines Company, Novoxel (now AstraZeneca), Phico Therapeutics, PolyMedix, Rib-X Pharmaceuticals, TaiGen, Theravance, and Wockhardt (India). The Rib-X and Wockhardt compounds are both fluoroquinolones. In addition, MerLion Pharmaceuticals is developing a fluoroquinolone in Phase II. Merck and Nabi Biopharmaceuticals are both developing vaccines against staphylococcus aureus.

If approved, the MuDelta compound, also licensed from Janssen-Cilag, will compete with Lotronex® (alosetron), marketed by Prometheus Laboratories, and over-the-counter treatments for diarrhea-predominant irritable bowel syndrome (IBS) such as loperamide (Imodium®). The pipeline for diarrhea-predominant IBS includes: asimadoline, which is being developed by Tioga Pharmaceuticals and is entering Phase III;

mesalamine, currently in Phase II, crofelemer, currently in Phase III and rifaximin, an approved product subject of an sNDA, by Salix Pharmaceuticals; AST-120, currently in Phase II development by Ocera; ibodutant, currently in Phase II development by Menarini Group; YM060, currently in Phase II development by Astellas Pharma; dextofisopam, currently in Phase II development by Pharmos Corporation; and LX1031, currently in Phase II development by Lexicon Pharmaceuticals.

Competitors might succeed in more rapidly developing and marketing technologies and products that are more effective than our products or that would render our products or technology obsolete or noncompetitive. Our collaborators might also independently develop products that are competitive with products that we have licensed to them. Any product that we or our collaborators succeed in developing and for which regulatory approval is obtained must then compete for market acceptance and market share. The relative speed with which we and our collaborators can develop products, complete clinical testing and approval processes, and supply commercial quantities of the products to the market compared to competitive companies will affect market success. In addition, the amount of marketing and sales resources, and the effectiveness of the marketing used with respect to a product will affect its success. In addition, some CRO services providers and private equity funds are developing risk sharing models to finance the pharmaceutical industry's pipeline. NovaQuest, a subsidiary of Quintiles Transnational, is active in this business. As these types of business models evolve, there will be increasing competition for compounds and funds that will affect our ability to add to our portfolio.

Other competitive factors affecting our business generally include:

- product efficacy and safety;
- timing and scope of regulatory approval;
- product availability, marketing and sales capabilities;
- reimbursement coverage;
- the amount of clinical benefit of our product candidates relative to their cost;
- method of and frequency of administration of any of our product candidates which may be commercialized;
- patent protection of our product candidates;
- the capabilities of our collaborators; and
- the ability to hire qualified personnel.

## **Employees**

We have approximately 25 full-time employees, a majority of whom are engaged in research and development activities. Our success depends in large part on our ability to attract and retain skilled and experienced employees. None of our employees is covered by a collective bargaining agreement. We consider our relations with our employees to be good.

## **Item 1A. Risk Factors**

*Our business operations face a number of risks. These risks should be read and considered with other information provided in this report.*

### **Risks Relating to Furiex's Business**

**We anticipate that we will incur additional losses. We might never achieve or sustain profitability. If additional capital is not available, we might have to curtail or cease operations.**

Our business has experienced significant net losses. We had net income of \$5.8 million in 2008, and a net loss of \$8.9 million and \$54.7 million in 2009 and 2010, respectively. The results for 2008, 2009 and 2010

included aggregate milestone payments of \$18.0 million, \$5.0 million, and \$7.5 million, respectively. We expect to continue to incur additional net losses as we continue our research and development activities and incur significant preclinical and clinical development costs. Since we or our collaborators or licensees might not successfully develop additional products, obtain required regulatory approvals, manufacture products at an acceptable cost or with appropriate quality, or successfully market products with desired margins, our expenses might continue to exceed any revenues we receive. Our commitment of resources to the continued development of our products might require significant additional funds for development. Our operating expenses also might increase if we:

- move our earlier stage potential products into later stage clinical development, which is generally a more expensive stage of development;
- encounter problems during clinical development that require a change in scope and/or timelines resulting in higher costs;
- select additional preclinical product candidates for preclinical development and then clinical development;
- pursue clinical development of our potential products in new indications;
- increase the number of patents we are prosecuting or otherwise expend additional resources on patent prosecution or defense;
- invest in or acquire additional technologies, product candidates or businesses although we have no current agreements to do so; or
- impair any of our investments in our product candidates.

In the absence of substantial licensing, milestone and other revenues from third-party collaborators, royalties on sales of products licensed under our intellectual property rights, future revenues from our products in development or other sources of revenues, we will continue to incur operating losses and might require additional capital to fully execute our business strategy. The likelihood of reaching, and time required to reach, sustained profitability are highly uncertain.

Although we expect that we will have sufficient cash to fund our operations and working capital requirements for at least the next 12 months based on current operating plans, we might need to raise additional capital in the future to:

- acquire complementary businesses or technologies;
- respond to competitive pressures;
- fund our research and development programs; or
- commercialize our product candidates.

Our future capital needs depend on many factors, including:

- the scope, duration and expenditures associated with our research and development programs;
- continued scientific progress in these programs;
- the outcome of potential licensing transactions, if any;
- competing technological developments;
- our proprietary patent position, if any, in our product candidates;
- the regulatory approval process for our product candidates; and
- the cost of attracting and retaining employees.

We might seek to raise necessary funds through public or private equity offerings, debt financings or additional collaborations and licensing arrangements. We might not be able to obtain additional financing on terms favorable to us, if at all. General market conditions might make it difficult for us to seek financing from the capital markets. We might have to relinquish rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us, in order to raise additional funds through collaborations or licensing arrangements. If adequate funds are not available, we might have to delay, reduce or eliminate one or more of our research or development programs and reduce overhead expenses, or restructure or cease operations. These actions might reduce the market price of our common stock.

**Our near-term revenue is largely dependent on the success of Priligy and Nesina as well as our other drug candidates, and we cannot be certain that we will be able to obtain regulatory approval for or commercialize any of these drug candidates.**

We currently are relying on Priligy and Nesina to generate revenue for us to supplement our cash. While Priligy is approved for marketing outside of the U.S., it has not been approved in the U.S. and the FDA issued a not approvable letter to our collaborative partner Janssen-Cilag in October 2005. Janssen-Cilag is investigating regulatory strategies for a potential refiling with the FDA. Takeda, our collaborative partner on Nesina must perform a cardiovascular safety trial for alogliptin and does not expect results from that trial to be available for submission to the FDA for approximately two years after that trial began. We have also invested a significant amount of time and financial resources in the development of fluoroquinolone. FDA guidance for developing drugs to treat community acquired bacterial pneumonia includes challenging requirements for the drug developer. Our future success will depend on our ability to successfully complete the clinical trial for this pneumonia indication using our fluoroquinolone in view of the FDA guidelines. We have also invested a significant amount of time and financial resources in the development of our other drug candidates. We anticipate that our success will depend largely on the receipt of regulatory approval and successful commercialization of these drug candidates. The future success of these drug candidates will depend on several factors, including the following:

- our ability to provide acceptable evidence of their safety and efficacy;
- receipt of marketing approval from the FDA and any similar foreign regulatory authorities;
- obtaining and maintaining commercial manufacturing arrangements with third-party manufacturers or establishing commercial-scale manufacturing capabilities;
- collaborating with pharmaceutical companies or contract sales organizations to market and sell any approved drug;
- acceptance of any approved drug in the medical community and by patients and third-party payors; and
- successful completion of the alogliptin cardiovascular safety trial that generates safety data acceptable to the FDA.

Many of these factors are beyond our control. Accordingly, we cannot assure you that we will be able to continue generating revenues through the sale of Priligy or Nesina or generate any revenue from the sale of other drug candidates.

**Our milestone and royalty payments from collaborators depend on our collaborators continuing to develop and commercialize drug candidates.**

Our ability to succeed in our drug development business will depend on our collaborators successfully executing late-stage development and commercialization of drug candidates. We generally conduct our drug development business in two stages. During the first stage, we in-license a drug candidate from a collaborator and develop that candidate through Phase II clinical trials. If the drug candidate successfully completes Phase II testing, we enter a second stage during which we seek a collaborator, which might be the same collaborator as in the first stage, for the continued late stage development and ultimate commercialization of the drug candidate.



The drug development industry is under increasing economic pressure. The third parties that we collaborate with might not perform their obligations as expected or they might breach or terminate their agreements with us or otherwise fail to conduct their collaborative activities successfully or in a timely manner. Further, parties collaborating with us might elect not to develop the product candidates or devote sufficient resources to the development, manufacture, regulatory strategy and approvals, marketing or sale of these product candidates. If the parties to our collaborative agreements do not fulfill their obligations, elect not to develop a candidate or fail to devote sufficient resources to it, our business could be materially and adversely affected. If we cannot find a collaborator for final development and commercialization, we might not be able to complete the development and commercialization on our own due to the significant costs associated with these activities. As a result, we may not be able to recoup all or any part of our investment in the drug candidate.

**If our collaborations are not successful or are terminated by our collaborators, we might not effectively develop and market some of our product candidates.**

We have agreements under which we rely on collaborators to manufacture our product candidates and essential components for those product candidates, design and conduct clinical trials, compile and analyze the data received from these trials, obtain regulatory approvals and, if approved, market these products. As a result, we may have limited or no control over the manufacturing, development and marketing of these potential products. In addition, the performance of our collaborators may not be sufficient or appropriate for regulatory review and approval for our product candidates. Further, we often rely on one manufacturer or other collaborator for such services, the loss of which could significantly delay the development of any of our drug candidates.

Our collaborators can terminate our collaborative agreements under certain conditions, and Janssen-Cilag can do so on short notice under our development agreements for the fluoroquinolone and MuDelta compounds. Ranbaxy can terminate our license to its statin if we fail to meet development milestones on a timely basis. A collaborator may terminate its agreement with us or separately pursue alternative products, therapeutic approaches or technologies as a means of developing treatments for the diseases targeted by us, or our collaborative effort. Even if a collaborator continues to contribute to the arrangement, it may nevertheless decide not to actively pursue the development or commercialization of any resulting products. In these circumstances, our ability to further develop potential products could be severely limited. While we generally seek non-compete terms in our agreements with our collaborators for the products we are developing, the enforcement of a non-compete can be expensive and difficult to monitor and enforce and might be subject to being invalidated by a court or judge.

Continued funding and participation by collaborators will depend on the continued timely achievement of our research and development objectives, the retention of key personnel performing work under those agreements and on each collaborator's own financial, competitive, marketing and strategic capabilities and priorities. These considerations include:

- the commitment of each collaborator's management to the continued development of the licensed products or technology;
- the relationships among the individuals responsible for the implementation and maintenance of the development efforts; and
- the relative advantages of alternative products or technology being marketed or developed by each collaborator or by others, including their relative patent and proprietary technology positions, and their ability to manufacture potential products successfully.

The willingness of our existing collaborators to continue development of our potential products and our ability to enter into new relationships depends upon, among other things, our patent position with respect to such products. If we are unable to successfully obtain and maintain patents, we might be unable to collect royalties on existing licensed products or enter into additional agreements.

In addition, our collaborators might independently develop products that are competitive with products that we have licensed to them. This could reduce our revenues or the likelihood of achieving revenues under our agreements with these collaborators.

**If we are unable to enter into agreements with third parties to market and sell our drug candidates or are unable to establish our own sales and marketing capabilities, we might be unable to generate product revenue.**

We do not currently have the resources to sell, market or distribute any pharmaceutical products. In order to market any of our products that receive regulatory approval, we must make arrangements with third parties to perform these services, or build our sales, marketing, managerial and other non-technical capabilities. If we are unable to do so, we might not be able to generate product revenue and might not become profitable.

**We might obtain future financing through the issuance of debt or equity, which might have an adverse effect on our shareholders or otherwise adversely affect our business.**

If we raise funds through the issuance of debt or equity, any debt securities or preferred stock issued will have rights, preferences and privileges senior to those of holders of our common stock in the event of liquidation. In such event, there is a possibility that once all senior claims are settled, there might be no assets remaining to pay out to the holders of our common stock. In addition, if we raise funds through the issuance of additional equity, whether through private placements or public offerings, such an issuance would dilute the ownership of our then current shareholders.

The terms of debt securities might also impose restrictions on our operations, which might include limiting our ability to incur additional indebtedness, to pay dividends on or repurchase our capital stock, or to make certain acquisitions or investments. In addition, we might be subject to covenants requiring us to satisfy certain financial tests and ratios, and our ability to satisfy such covenants may be affected by events outside of our control.

**Our operating expenses and results and any revenue likely will fluctuate in future periods.**

Our revenues and expenses are unpredictable and likely will fluctuate from quarter to quarter due to, among other things, the timing and the unpredictable nature of clinical trials and related expenses, including payments owed by us and to us under collaborative agreements for reimbursement of expenses, future milestone revenues under collaborative agreements, sales of Priligy and Nesina and any future sales of other products. In addition, the recognition of clinical trial and other expenses that we otherwise would recognize over a period of time under applicable accounting principles might be accelerated or expanded in certain circumstances. In such a case, it might cause our expenses during that period to be higher than they otherwise would have been had the circumstances not occurred. For example, if we terminate a clinical trial for which we paid non-refundable upfront fees to a clinical research organization and in which we did not accrue all of the patient costs, the recognition of the expense associated with those fees that we were recognizing as we accrued patient costs would be accelerated and recognized in the period in which the termination occurred.

**We are dependent on the performance of service providers.**

We rely on service providers, such as contract manufacturers, clinical research organizations, medical institutions and clinical investigators, including physician sponsors, to conduct nearly all of our clinical trials, including recruiting and enrolling patients in the trials. In connection with the spin-off, we entered into a Master Development Services Agreement with PPD pursuant to which PPD provides us clinical development services at discounted rates on a preferred provider basis. If PPD or any of these other parties do not successfully carry out their contractual duties or meet expected deadlines, we might be delayed or may not obtain regulatory approval for or be able to commercialize our product candidates. If any of the third parties upon whom we rely to conduct our clinical trials do not comply with applicable laws, successfully carry out their obligations or meet expected deadlines, our clinical trials may be extended, delayed or terminated.

If the quality or accuracy of the clinical data obtained by third party contractors is compromised due to their failure to adhere to applicable laws or our clinical protocols, or for other reasons, we might not obtain regulatory approval for or successfully commercialize any of our product candidates. If our relationship with any of these organizations or individuals terminates, replacing any of these third parties could delay our clinical trials and could jeopardize our ability to obtain regulatory approvals and commercialize our product candidates on a timely basis, if at all.

### **Risks Relating to Our Operations**

#### **We might not successfully operate the compound partnering business as an independent entity.**

It takes many years for a drug development business like ours to generate revenue and income. Although we have experience operating our compound partnering business within PPD's discovery sciences segment since 1998, we might not be successful in operating this business as a stand-alone company. Generating revenue and income, consistently or at all, from our drug development business and compound partnering activities depends on our ability to:

- develop products internally or obtain rights to them from others on favorable terms;
- successfully complete non-clinical and clinical studies;
- obtain clinical trial materials of sufficient quality or quantity;
- obtain and maintain intellectual property rights to these products;
- obtain and maintain regulatory approvals;
- enter into agreements with third parties to continue the development and commercialization of drug candidates; and
- enter into arrangements with third parties to manufacture products on our behalf and to provide sales and marketing functions.

#### **We must attract and retain key employees in order to succeed.**

To be successful, our unique business model requires that our personnel have extensive experience in designing and implementing drug development programs that will run faster than typical studies in the industry. We also require qualified personnel, experienced at building and maintaining relationships with our collaborators. We rely on the services of our senior management, particularly our President and Chief Medical Officer, June Almenoff, our Senior Vice President—Research, Gail McIntyre, and our Senior Vice President—Clinical Operations, Paul Covington, as well as our Chief Financial Officer, Marshall Woodworth, our Vice President—Legal Affairs, Nadine Chien, and our Vice President—Strategic Development, Sailash Patel, the loss of any of whom could adversely impact our operations. We do not carry key man insurance on any of these individuals or any of our other officers or employees. Any inability to hire additional qualified personnel might also require an increase in the workload for both existing and new personnel. We might not be successful in attracting new scientists or management, or in retaining or motivating our existing personnel. The shortage of experienced scientists and managers capable of working within our unique business model might lead to increased recruiting, relocation and compensation costs for these professionals, which might exceed our forecasts. If we are unable to attract and retain any of these personnel, our ability to execute our business plan will be adversely affected.

#### **If our product identification efforts are not successful, we might not be able to effectively develop new products.**

Our product candidates are in various stages of development and some are in an early development stage. Some or all of our product candidates may never be developed for any number of reasons, including failure to meet clinical trial tests and failure to receive regulatory approval. For example, we suspended our MAG-131

dermatology therapeutic program due to unfavorable efficacy data that was discovered in late 2009 and closed our dermatology therapeutic discovery unit business entirely in May 2010. To maintain our business, we need to have a sufficient pipeline of product candidates. Our success in identifying new product candidates depends upon our ability to identify and validate new targets through in-licensing or collaborative arrangements. In order to increase the possibilities of identifying compounds with a reasonable chance for success in clinical studies, part of our business strategy is to identify a higher number of potential targets than we expect to be able to progress through clinical development. If we are unsuccessful in our efforts to identify or obtain rights to new product candidates that lead to the required regulatory approvals and the successful commercialization of products, our business could be harmed.

**Many of our drug candidates are in development and we might not be able to obtain regulatory approval for our product candidates.**

The development and commercialization of pharmaceutical products are subject to extensive governmental regulation in the United States and foreign countries. Government approvals are required to develop, market and sell the potential drug candidates we develop alone or with others under our risk-sharing arrangements. Especially for the early-stage compounds we target for in-licensing, obtaining government approval to develop, market and sell drug candidates is time-consuming and expensive. Further, clinical trial results for a particular drug candidate might not satisfy requirements to obtain government approvals. For example, in late 2005, Janssen-Cilag, our collaborator on dapoxetine, received a “not approvable” letter from the FDA. In addition, governmental approvals might not be received in a timely manner, if at all, and we and our collaborative partners might not be able to meet other regulatory requirements for our products. For example, in late 2008, the FDA notified Takeda that it would not be able to complete its review of the alogliptin NDA before the Prescription Drug Use Fee Act date due to the lack of internal resources. In addition, requirements for government approval to market and sell drug candidates are subject to change. For example, the Division of Endocrinologic and Metabolic Drug Products in the Center for Drug Evaluation and Research decided that concerns about cardiovascular risk should be more thoroughly addressed during drug development programs, and, in December 2008, issued final guidance on the topic titled “Guidance for Industry—Diabetes Mellitus—Evaluating Cardiovascular Risk in New Antidiabetic Therapies to Treat Type 2 Diabetes”. As a result, in June 2009 and September 2009, the FDA issued complete responses to Takeda on its NDAs for the alogliptin monotherapy and the fixed-dose combination of alogliptin and Actos requesting an additional cardiovascular safety trial on alogliptin prior to further regulatory review. Finally, even if we are successful in obtaining all required approvals to market and sell a drug candidate, post-approval requirements and the failure to comply with other regulations could result in suspension or limitation of government approvals.

In connection with drug development activities outside the United States, we and our collaborators will be subject to foreign regulatory requirements governing the testing, approval, manufacture, labeling, marketing and sale of pharmaceutical products. These requirements vary from country to country. Even if approval has been obtained for a product in the United States, approvals in foreign countries must be obtained prior to marketing the product in those countries. The approval process in foreign countries may be more or less rigorous and the time required for approval may be longer or shorter than that required in the United States. Clinical studies conducted outside of any particular country may not be accepted by that country, and the approval of a pharmaceutical product in one country does not assure that the product will be approved in another country.

**The failure to gain market acceptance of our product candidates among the medical community would adversely affect our revenue.**

Even if approved, our product candidates might not gain market acceptance among physicians, patients, third-party payors and the medical community. We might not achieve market acceptance even if clinical trials demonstrate safety and efficacy and we obtain the necessary regulatory and reimbursement approvals. The degree of market acceptance of any product candidates that we develop will depend on a number of factors, including:

- establishment and demonstration of clinical efficacy and safety;

- cost-effectiveness of our product candidates versus competing products;
- their potential advantage over alternative treatment methods;
- pricing requirements in various markets;
- reimbursement policies of government and third-party payors; and
- marketing and distribution support for our product candidates, including the efforts of our collaborators where they have marketing and distribution responsibilities.

Physicians will not recommend our products until clinical data or other factors demonstrate the safety and efficacy of our product as compared to conventional drug and other treatments. Even if we establish the clinical safety and efficacy of our product candidates, physicians might elect not to use our product for any number of other reasons, including whether the mode of administration of our products is effective for certain indications. The failure of our product candidates to achieve significant market acceptance would materially harm our business, financial condition and results of operations.

**We face significant competition.**

We face significant competition, including from entities that have substantially greater resources and more experience in the commercialization and marketing of pharmaceuticals than we have. Potential competitors in the United States and other countries include major pharmaceutical and biotechnology companies and specialized pharmaceutical companies. These entities have developed and are developing compounds that might compete with our products in development. These competitors might succeed in more rapidly developing and marketing technologies and products that are more effective than our product candidates or technologies or that would render any future commercialized products or technology obsolete or noncompetitive. Our product candidates and any future commercialized products might also face significant competition from both brand-name and generic manufacturers that could adversely affect any future sales of our products.

Any product that we or our collaborators succeed in developing and for which regulatory approval is obtained must then compete for market acceptance and market share. The relative speed with which we and our collaborators can develop products, complete the clinical testing and approval processes, and supply commercial quantities of the products to the market compared to competitive companies will affect market success. In addition, the amount of marketing and sales resources and the effectiveness of the marketing used with respect to a product will affect its marketing success. Other factors affecting the ability of our products to compete include their efficacy and safety, the manner and frequency of their administration, and the extent of any reimbursement coverage.

In addition, some CRO services providers and private equity funds are developing risk sharing models to finance the pharmaceutical industry's pipeline. As these types of business models evolve, there will be increasing competition for compounds and funds to develop those compounds.

**We must protect our patent and other intellectual property rights to succeed.**

Our success is dependent in significant part on our ability to develop and protect patent and other intellectual property rights and operate without infringing the intellectual property rights of others.

Our pending patent applications might not result in the issuance of valid patents or the claim scope of our issued patents may not provide competitive advantages. Also, our patent protection might not prevent others from developing competitive products using related or other technology that does not infringe our patent rights. In addition, our patent for Priligy is for method of use and not composition of matter. Further, patent applications are confidential for a period of time after filing. We therefore might not know that a competitor has filed a patent application covering subject matter similar to subject matter in one of our patent applications or that we were the first to invent the innovation we seek to patent. This might lead to disputes including interference proceeding or litigation to determine rights to patentable subject matter. These disputes are often expensive and might result in our being unable to patent an innovation.

The scope, enforceability and effective term of patents can be highly uncertain and often involve complex legal and factual questions and proceedings. No consistent policy has emerged regarding the breadth of claims in pharmaceutical or biotechnology patents, so that even issued patents might later be modified or revoked by the relevant patent authorities or courts. These proceedings could be expensive, last several years and either prevent issuance of additional patents to us or result in a significant reduction in the scope or invalidation of our patents. Any limitation in claim scope could reduce our ability to negotiate future collaborative research and development agreements based on these patents. Moreover, the issuance of a patent in one country does not assure the issuance of a patent with similar claim scope in another country, and claim interpretation and infringement laws vary among countries, so we are unable to predict the extent of patent protection in any country.

In certain cases, we are reliant on our collaborator to file, negotiate and maintain patents covering a licensed product. Our collaborators may fail to adequately obtain and maintain such patents.

In addition to seeking the protection of patents and licenses, we also rely upon trade secrets, know-how and continuing technological innovation that we seek to protect, in part, by confidentiality agreements with employees, consultants, suppliers and licensees. If these agreements are not honored, we might not have adequate remedies for any breach. Additionally, our trade secrets might otherwise become known or patented by our competitors.

**We might need to obtain patent licenses from others in order to manufacture or sell our potential products and we might not be able to obtain these licenses on terms acceptable to us or at all.**

Other companies, universities and research institutions might obtain patents that could limit our ability to use, import, manufacture, market or sell our products or impair our competitive position. As a result, we might need to obtain licenses from others before we could continue using, importing, manufacturing, marketing, or selling our products. We might not be able to obtain required licenses on terms acceptable to us, if at all. If we do not obtain required licenses, we might encounter significant delays in product development while we redesign potentially infringing products or methods or we might not be able to market our products at all.

**We or our collaborators might not be able to attract a sufficient number of sites or enroll a sufficient number of patients in a timely manner in order to complete our clinical trials.**

The rate of completion of clinical trials is significantly dependent upon the rate of patient enrollment. Patient enrollment is a function of many factors, including:

- changing regulatory requirements;
- the size of the patient population;
- perceived risks and benefits of the drug under study;
- availability of competing therapies, including those in clinical development;
- availability of clinical drug supply;
- participation of qualified clinical trial sites;
- availability and willingness of potential participants to enroll in clinical trials;
- design of the protocol;
- proximity of and access by patients to clinical sites;
- patient referral practices of physicians;
- eligibility criteria for the study in question; and
- efforts of the sponsor of and clinical sites involved in the trial to facilitate timely enrollment.

For example, patient enrollment for our Phase II proof-of-concept trial of our fluoroquinolone in hospitalized pneumonia patients has been slower than expected. We might have additional difficulties obtaining sufficient patient enrollment or clinician support to conduct this and/or our other clinical trials as planned, and we might need to expend additional funds to obtain access to resources or delay or modify our plans significantly. These considerations might result in our being unable to successfully achieve our projected development timelines, or potentially even lead us to consider the termination of ongoing clinical trials or development of a product for a particular indication.

**Changes in the U.S. and international healthcare industry, including reimbursement rates, could adversely affect the commercial value of our development product candidates.**

The U.S. and international healthcare industry is subject to changing political, economic and regulatory influences that may significantly affect the purchasing practices and pricing of pharmaceuticals. The laws and regulations governing and issued by applicable regulatory agencies may change and additional government regulations might be enacted, which could prevent or delay regulatory approval of our product candidates. The U.S. Congress adopted healthcare reform and might adopt other legislation that could have the effect of putting downward pressure on the prices that pharmaceutical and biotechnology companies can charge for prescription drugs. Cost-containment measures, whether instituted by healthcare providers or imposed by government health administration regulators or new regulations, could result in greater selectivity in the purchase of drugs. As a result, third-party payors might challenge the price and cost effectiveness of our products. In addition, in many major markets outside the United States, pricing approval is required before sales may commence. As a result, significant uncertainty exists as to the reimbursement status of approved healthcare products.

We might not be able to obtain or maintain our desired price for the products we develop. Any product we introduce might not be considered cost-effective relative to alternative therapies. As a result, adequate third-party reimbursement might not be available to enable us to obtain or maintain prices sufficient to realize an appropriate return on our investment in product development. Also, the trend towards managed healthcare in the United States and the concurrent growth of organizations such as health maintenance organizations, as well as legislative proposals to reform healthcare or reduce government insurance programs, might all result in lower prices, reduced reimbursement levels and diminished markets for our products. These factors will also affect the products that are marketed by our collaborators and licensees. We cannot predict the likelihood, nature or extent of adverse government regulation that might arise from legislation or administrative action, either in the United States or abroad. If we are not able to maintain regulatory compliance, we might not be permitted to market our future products and our business could suffer.

**Manufacturing changes might result in delays in obtaining regulatory approval or marketing for our products.**

If we make changes in the manufacturing process for any of our products, we might be required to demonstrate to the applicable regulatory agencies that the changes have not caused the resulting drug material to differ significantly from the drug material previously produced. Further, any significant manufacturing changes for the production of our product candidates could result in delays in development or regulatory approval or in the reduction or interruption of commercial sales of our product candidates. Our contract manufacturers' inability to maintain manufacturing operations in compliance with applicable regulations within our planned time and cost parameters could materially harm our business, financial condition and results of operations.

We have made manufacturing changes and could make additional manufacturing changes for the production of our products currently in clinical development. These manufacturing changes or an inability to immediately show comparability between the older material and the newer material after making manufacturing changes could result in delays in development or regulatory approvals or in reduction or interruption of commercial sales and could impair our competitive position.

**Our business might be harmed if we cannot obtain sufficient quantities of raw materials.**

We depend on outside vendors for the supply of raw materials used to produce our product candidates for use in clinical trials. Once a supplier's materials have been selected for use in the manufacturing process, the supplier in effect becomes a sole or limited source of that raw material due to regulatory compliance procedures. If the third-party suppliers were to cease production or otherwise fail to supply us with quality raw materials and we were unable to contract on acceptable terms for these services with alternative suppliers, our ability to produce our products and to conduct preclinical testing and clinical trials of product candidates would be adversely affected. This could impair our competitive position. If the third-party suppliers were to cease production or otherwise fail to supply us with quality raw materials and we were unable to contract on acceptable terms for these services with alternative suppliers, our ability to produce our products and to conduct preclinical testing and clinical trials of product candidates would be adversely affected. This could impair our competitive position.

**We must comply with extensive government regulations and laws.**

We and our collaboration partners are subject to extensive regulation by federal government, state governments, and the foreign countries in which we conduct our business.

In particular, we are subject to extensive and rigorous government regulation as a developer of drug candidates. For example, the FDA regulates, among other things, the development, testing, research, manufacture, record-keeping, labeling, storage, approval, quality control, adverse event reporting, advertising, promotion, sale and distribution of pharmaceutical products. Our product candidates are subject to extensive regulation by foreign governments. The regulatory review and approval process, which includes preclinical studies and clinical trials of each product candidate, is lengthy, expensive and uncertain.

We must rely on our contract manufacturers and third-party suppliers for regulatory compliance and adhering to the FDA's current Good Manufacturing Practices, or cGMP, requirements. If these manufacturers or suppliers fail to comply with applicable regulations, including FDA pre-or post-approval inspections and cGMP requirements, then the FDA could sanction us. These sanctions could include fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delay, suspension or withdrawal of approvals, license revocation, product seizures or recalls, operational restrictions or criminal prosecutions, any of which could significantly and adversely affect our operating results.

If our operations are found to violate any applicable law or other governmental regulations, we might be subject to civil and criminal penalties, damages and fines. Similarly, if the hospitals, physicians or other providers or entities with which we do business are found non-compliant with applicable laws, they might be subject to sanctions, which could also have a negative impact on us. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations, and additional legal or regulatory change. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business and damage our reputation.

We expend a significant amount of resources on compliance efforts and such expenses are unpredictable and might adversely affect our operating results. Changing laws, regulations and standards might also create uncertainty and increase insurance costs. We are committed to compliance and maintaining high standards of corporate governance and public disclosure. As a result, we intend to invest all reasonably necessary resources to comply with evolving standards, and this investment might result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities.



**We might incur significant costs in order to comply with environmental regulations or to defend claims arising from accidents involving the use of hazardous materials.**

We are subject to federal, state and local laws and regulations governing the use, discharge, handling and disposal of materials and wastes used in our operations. As a result, we might be required to incur significant costs to comply with these laws and regulations. We cannot eliminate the risk of accidental contamination or injury from these materials. In the event of such an accident, we could be held liable for any resulting damages and incur liabilities, which exceed our resources. In addition, we cannot predict the extent of the adverse effect on our business or the financial and other costs that might result from any new government requirements arising out of future legislative, administrative or judicial actions.

**We might be subject to product liability claims, and our insurance coverage and indemnification rights might not be adequate to cover these claims.**

We face an inherent business risk of exposure to product liability and other types of claims in the event that the use of products during research and development efforts or after commercialization results in death, personal injury or other adverse effects. This risk exists even with respect to any products that receive regulatory approval for commercial sale. While we will procure and maintain liability insurance with coverage up to \$10 million per occurrence and in the aggregate and generally have indemnification rights under our collaboration agreements, our insurance might not be sufficient to satisfy any or all liabilities that may arise and our indemnification rights might not apply or be sufficient to cover such claims. Also, adequate insurance coverage might not be available in the future at acceptable cost, if at all.

**Our operations might be affected by the occurrence of a natural disaster or other catastrophic event.**

We depend on our collaboration partners, service providers and other facilities for the continued operation of our business. Natural disasters or other catastrophic events, including terrorist attacks, pandemic flu, hurricanes and ice storms, could disrupt our operations or those of our collaboration partners, which could also affect us. Even though we carry business interruption insurance policies and typically have provisions in our contracts that protect us in certain events, we might suffer losses as a result of business interruptions that exceed the coverage available under our insurance policies or for which we do not have coverage. Any natural disaster or catastrophic event affecting us or our collaboration partners could have a significant negative impact on our operations and financial performance.

**Risks Resulting from Our Spin-Off From PPD**

**Our historical financial information is not necessarily indicative of our future financial position, future results of operations or future cash flows and does not reflect what our financial position, results of operations or cash flows would have been as a stand-alone company during the periods presented.**

Our historical financial information included in this Form 10-K does not necessarily reflect what our financial position, results of operations or cash flows would have been as a stand-alone publicly traded company during the periods presented prior to June 2010. In addition, it is not necessarily indicative of our future financial position, future results of operations or future cash flows. This is primarily a result of the following factors:

- Prior to our separation, our business was operated by PPD as part of its broader corporate organization and we did not operate as a stand-alone company;
- Most general administrative functions were performed by PPD for the combined entity, so although our historical combined financial statements reflect allocations of costs for services shared with PPD, these allocations may differ from the costs we will incur for these services as an independent company;
- After the completion of our separation, the cost of capital for our business might be higher than PPD's cost of capital prior to our separation; and

- Prior to the separation, our financial statements include revenues and expenses of services that we did not continue subsequent to the separation.

**Our internal controls and resources might not be adequately prepared to meet the regulatory reporting and other requirements to which we are subject as a stand-alone entity.**

Our financial results prior to the spin-off were included within the consolidated results of PPD. However, we were not directly subject to the reporting and other requirements of the Securities Exchange Act of 1934, as amended, which we refer to as the Exchange Act. As a result of the separation, we became directly subject to the reporting and other obligations under the Exchange Act immediately after the separation. In addition, we expect to be subject to the requirements of Section 404 of the Sarbanes-Oxley Act of 2002 beginning with our financial statements for the year ending December 31, 2011, which will require annual management assessments of the effectiveness of our internal control over financial reporting and a report by our independent registered public accounting firm addressing the effectiveness of our internal control over financial reporting. These reporting and other obligations will place significant demands on our management and administrative and operational resources, including accounting resources.

To comply with these requirements, we might need to acquire or upgrade our systems, including information technology, implement additional financial and management controls, reporting systems and procedures and hire additional legal, accounting and finance staff. If we are unable to establish our financial and management controls, reporting systems, information technology and procedures in a timely and effective fashion, our ability to comply with our financial reporting requirements and other rules that apply to reporting companies could be impaired. In addition, if we are unable to conclude that our internal control over financial reporting is effective (or if the auditors are unable to express an opinion on the effectiveness of our internal controls), we could lose investor confidence in the accuracy and completeness of our financial reports.

Our management will be responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) under the Exchange Act. Our 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 accounting principles generally accepted in the United States. Any failure to achieve and maintain effective internal controls could have an adverse effect on our business, financial position and results of operations.

**As a stand-alone company, we no longer receive any of the revenue or cash flows derived from PPD's CRO Business.**

For fiscal 2009, PPD earned \$1.4 billion or approximately 99.6% of its revenue from continuing operations from services revenues derived from PPD's CRO Business. As a separate company, we no longer receive any such revenue. PPD initially contributed to us cash and cash equivalents of \$100.0 million, and we assumed the assets and liabilities of the compound partnering business as of the closing date of the spin-off, with the exception of the dermatology therapeutic discovery unit and any spin-off related expense, which was paid by PPD. We assumed approximately \$4.5 million in liabilities. We expect that this cash contribution, together with the revenue we have received to date, will fund Furiex's operations and working capital requirements for at least the next 12 months, based on current operating plans. In addition to this cash contribution, we have received and expect to receive future payments from our existing collaborations that will provide additional support for our operations and working capital requirements. Despite these resources and potential future revenue, we cannot assure you that such funds will meet our working capital and operational needs or that our working capital requirements will not increase beyond our current expectations. We might need to obtain additional financing from banks or other lenders, or through public offerings or private placements of debt or equity securities, strategic relationships or other arrangements to fully execute our business strategy.

**We have a limited history operating as an independent company upon which you can evaluate us.**

We have a limited operating history as a stand-alone entity. While our compound partnering business has constituted a part of the historic operations of PPD since 1998, we have only operated as a stand-alone company without the CRO Business since June 2010. Following the spin-off, as an independent company, our ability to satisfy our obligations and achieve profitability will be solely dependent upon the future performance of our compound partnering business, and we will not be able to rely upon the capital resources and cash flows of the CRO Business remaining with PPD.

**We might have received better terms from unaffiliated third parties than the terms we receive in our agreements with PPD.**

The agreements we entered into with PPD in connection with the spin-off, including the Master Development Services Agreement, the sublease, the Employee Matters Agreement and the Transition Services Agreement, were negotiated while we were still part of PPD. The terms of these agreements relate to, among other things, drug development services to be provided to us by PPD, the subleasing of our offices, employee benefit matters and the provision of transition services to us by PPD. The Master Development Services Agreement requires us to use PPD for specified drug development services for three years contingent on PPD's expertise and capabilities to provide the needed services. While we believe the terms and conditions of these agreements with PPD are reasonable and acceptable to us, they might not reflect the same terms and conditions that we could have obtained had we sought competitive bids from and negotiated with unaffiliated parties.

**The ownership by some of our executive officers and our directors of shares of common stock and/or options to purchase shares of common stock of PPD might create, or might create the appearance of, conflicts of interest.**

Due to their current or former employment with or service to PPD, several of our executive officers and directors own shares of common stock of PPD and hold options to purchase shares of common stock of PPD. As of March 1, 2011, the following individuals owned the following amounts of common stock and options to purchase common stock of PPD (exercisable within 60 days of March 1, 2011): Fred N. Eshelman, our founding Chairman and a director, 7,473,314 shares and 924,650 options; Stuart Bondurant, a director, 20,199 shares and 47,138 options; Gail McIntyre, our Senior Vice President—Research, 3,277 shares and 85,045 options; and Paul S. Covington, our Senior Vice President—Clinical Development and Operations, 881 shares and 60,381 options. If the options were exercised, Dr. Eshelman would own 7.3% and the other individuals would own less than 1.0% of PPD's outstanding common stock as of that date. These individual holdings of common stock and/or options to purchase common stock of PPD may be significant compared to the individual's total assets. This ownership by our directors and officers, after our separation, of common stock and/or options to purchase common stock of PPD creates, or, might create the appearance of, conflicts of interest when these directors and officers are faced with decisions that could have different implications for PPD than for us.

**If the distribution or internal transactions undertaken in anticipation of the separation are determined to be taxable for U.S. federal income tax purposes, we and our shareholders that are subject to U.S. federal income tax could incur significant U.S. federal income tax liabilities.**

PPD received a private letter ruling from the Internal Revenue Service regarding the U.S. federal income tax consequences of the distribution of our common stock to the PPD shareholders substantially to the effect that the distribution, except for cash received in lieu of a fractional share of our common stock, qualified as tax-free under Sections 368(a)(1)(D) and 355 of the Code. The private letter ruling also provides that any internal transactions undertaken in anticipation of the separation will qualify for favorable treatment under the Code. The private letter ruling relies on facts and assumptions, and representations and undertakings, from us and PPD regarding the past and future conduct of our respective businesses and other matters. Notwithstanding the private letter ruling, the Internal Revenue Service could determine on audit that the distribution or the internal

transactions should be treated as taxable transactions if it determines that any of these facts, assumptions, representations or undertakings is not correct or has been violated, or that the distribution should be taxable for other reasons, including as a result of significant changes in stock or asset ownership after the distribution.

Under the terms of the Tax Sharing Agreement that we entered into with PPD, in the event the distribution or the internal transactions were determined to be taxable and such determination was the result of actions taken after the distribution by us or PPD, the party responsible for such actions would be responsible for all resulting taxes imposed on us or PPD. If such determination is not the result of actions taken after the distribution by us or PPD, then PPD would be responsible for any resulting taxes imposed on us or PPD. These taxes could be significant.

**We might not be able to engage in desirable strategic transactions and equity issuances because of restrictions relating to U.S. federal income tax requirements for tax-free distributions.**

Our ability to engage in significant equity transactions could be limited or restricted in order to preserve for U.S. federal income tax purposes the tax-free nature of the distribution by PPD. In addition, similar limitations and restrictions will apply to PPD. Even if the distribution otherwise qualifies for tax-free treatment under Sections 368(a)(1)(D) and 355 of the Code, it might result in corporate-level taxable gain to PPD under Section 355(e) of the Code if 50% or more, by vote or value, of our shareholder equity or PPD shareholder equity is acquired or issued as part of a plan or series of related transactions that includes the distribution. For this purpose, any acquisitions or issuances of PPD's shareholder equity within two years before the distribution, and any acquisitions or issuances of our shareholder equity or PPD shareholder equity within two years after the distribution, generally are presumed to be part of such a plan, although we or PPD might be able to rebut that presumption. If an acquisition or issuance of our shareholder equity or PPD shareholder equity triggers the application of Section 355(e) of the Code, PPD would recognize taxable gain as described above, and could incur significant U.S. federal income tax liabilities as a result of the application of Section 355(e) of the Code.

Under the Tax Sharing Agreement, there are restrictions on our ability to take actions that could cause the distribution or internal transactions undertaken in anticipation of the separation to fail to qualify as tax-favored, which could include entering into, approving or allowing any transaction that results in a change in ownership of more than 50% of our common shares, a redemption of equity securities, a sale or other disposition of a substantial portion of our assets, an acquisition of a business or assets with shareholder equity to the extent one or more persons would acquire 50% or more of our shareholder equity, or engaging in certain internal transactions. These restrictions apply at any time after the distribution, unless we obtain a private letter ruling from the Internal Revenue Service or an opinion that such action will not cause the distribution or the internal transactions undertaken in anticipation of the separation to fail to qualify as tax-favored transactions, and such letter ruling or opinion, as the case may be, is acceptable to the parties. PPD is subject to similar restrictions under the Tax Sharing Agreement. Moreover, the Tax Sharing Agreement generally provides that a party thereto is responsible for any taxes imposed on any other party thereto as a result of the failure of the distribution or internal transactions to qualify as a tax-favored transaction under the Code if the failure is attributable to post-distribution actions taken by or in respect of the responsible party or its shareholders, regardless of whether the other parties consent to such actions or such party obtains a favorable letter ruling or opinion as described above. For example, we would be responsible for the acquisition of us by a third party at a time and in a manner that would cause such failure. These restrictions might prevent us from entering into transactions that might be advantageous to our shareholders, or might increase the cost of the transactions.

## **Risks Relating to Our Common Stock**

### **Various factors could negatively affect the market price or market of our common stock, which has traded publicly only since June 2010.**

Our stock has a limited trading history because we only became a separate public company in June 2010, which could make investing in our stock riskier than more established companies. In addition, market prices for securities of pharmaceutical companies have been highly volatile, and we expect such volatility to continue for the foreseeable future, so that investment in our securities involves substantial risk. Additionally, the stock market from time to time has experienced significant price and volume fluctuations unrelated to the operating performance of particular companies. The following are some of the factors that might have a significant effect on the market price of our common stock:

- developments or disputes as to patent or other proprietary rights;
- approval or introduction of competing products and technologies;
- results of clinical trials;
- failures or unexpected delays in timelines for our potential products in development, including the obtaining of regulatory approvals;
- delays in manufacturing or clinical trial plans;
- fluctuations in our operating results;
- market reaction to announcements by other biotechnology or pharmaceutical companies;
- initiation, termination or modification of agreements with our collaborators or disputes or disagreements with collaborators;
- loss of key personnel;
- litigation or the threat of litigation;
- public concern as to the safety of drugs developed by us;
- sales of our common stock held by our directors and executive officers; and
- comments and expectations of results made by securities analysts or investors.

If any of these factors causes us to fail to meet the expectations of securities analysts or investors, or if adverse conditions prevail or are perceived to prevail with respect to our business, the price of our common stock would likely drop significantly. A significant drop in the price of a company's common stock often leads to the filing of securities class action litigation against such a company. This type of litigation against us could result in substantial costs and a diversion of management's attention and resources.

### **Your percentage ownership in Furiex might be diluted in the future.**

Your percentage ownership in Furiex might be diluted in the future because of equity awards that we expect will be granted to our directors, officers and employees, as well as any future equity financing.

### **Provisions in our amended and restated certificate of incorporation and bylaws and of Delaware law might prevent or delay an acquisition of our company, which could decrease the trading price of our common stock.**

Our amended and restated certificate of incorporation, bylaws and Delaware law contain provisions that are intended to deter coercive takeover practices and inadequate takeover bids by making such practices or bids unacceptably expensive to the raider and to encourage prospective acquirors to negotiate with our Board rather than to attempt a hostile takeover. These provisions include, among others:

- no right of our shareholders to act by written consent;

- procedures requiring advance notice of shareholder proposals or nominations for directors for election at shareholder meetings;
- the right of our Board to issue preferred stock without shareholder approval; and
- no shareholder rights to call a special shareholders meeting.

Delaware law also imposes some restrictions on mergers and other business combinations between us and any holder of 15% or more of our outstanding common stock. For more information, see “Description of Capital Stock”.

We believe these provisions protect our shareholders from coercive or otherwise unfair takeover tactics by requiring potential acquirors to negotiate with our Board and by providing our Board with more time to assess any acquisition proposal. These provisions are not intended to make our company immune from takeovers. However, these provisions apply even if the offer might be considered beneficial by some shareholders and could delay or prevent an acquisition that our Board determines is not in the best interests of our company and our shareholders.

**Item 1B. Unresolved Staff Comments**

None.

**Item 2. Properties**

Our headquarters is located in Morrisville, North Carolina, where we occupy approximately 4,650 square feet of office space under a lease expiring in 2012. We have the option to extend the term of our lease from PPD for up to one year. We own substantially all of the equipment used in our facilities.

**Item 3. Legal Proceedings**

In the normal course of business, we might be a party to various claims and legal proceedings. As of this time, there are no outstanding claims that management believes will have a material effect upon our financial condition, results of operations or cash flows.

**Item 4. (Removed and Reserved)**

**Executive Officers of the Registrant**

The following table sets forth information regarding individuals who serve as our executive officers, including their positions.

<u>Name</u>	<u>Age</u>	<u>Position</u>
June S. Almenoff . . . . .	54	President and Chief Medical Officer
Gail McIntyre . . . . .	48	Senior Vice President-Research
Paul S. Covington . . . . .	54	Senior Vice President-Clinical Development and Operations
Marshall Woodworth . . . . .	53	Chief Financial Officer, Treasurer and Assistant Secretary

*June S. Almenoff* has served as our President and Chief Medical Officer since March 2010. Dr. Almenoff had over 12 years of pharmaceutical industry experience at GlaxoSmithKline, or GSK, from 1997 to 2010. Most recently, she was Vice President in the Clinical Safety and Pharmacovigilance organization at GSK, where she served on the company’s senior governing medical boards and managed a diverse therapeutic portfolio supporting numerous regulatory approvals. Dr. Almenoff led the GSK teams that developed three pioneering systems for minimizing risk in early- and late-stage drug development, which have been widely implemented by pharmaceutical companies and regulatory agencies, and their impact on the industry has been recognized by the Wall Street Journal Technology Innovation Award and several other prestigious awards. During her tenure at GSK, Dr. Almenoff chaired the Pharma-FDA working group on safety signal detection and was lead author on its

influential position paper. She also led the scientific diligence effort for the acquisition of Stiefel Laboratories and established a licensing program for a drug development unit. Prior to joining GSK, Dr. Almenoff was on the faculty of Duke University Medical Center. She has more than 45 publications and one pending patent. Dr. Almenoff received her B.A. cum laude from Smith College. She graduated from the M.D.-Ph.D. program at the Mt. Sinai School of Medicine and completed a residency in Internal Medicine and a Fellowship in Infectious Diseases at Stanford University Medical Center. Dr. Almenoff is a board-certified Fellow of the American College of Physicians with 10 years of clinical practice experience.

**Gail McIntyre** has served as our Senior Vice President—Research since April 2010. Prior to joining us, Dr. McIntyre was with PPD for 12 years and served as head of the company's compound partnering business from October 2003 until joining Furiex in 2010. Dr. McIntyre has more than 19 years of experience in the drug discovery and development industry. Her experience covers multiple therapeutic areas including oncology, infectious diseases, central nervous system and metabolic/endocrine as well as various therapies including small drugs, treatment vaccines, immunomodulators, antibodies, immunoconjugates and peptide mimetics. Dr. McIntyre has prepared more than 30 regulatory submissions and ushered compounds through the lead optimization phase to early drug development and from early drug development through the IND and NDA phases. Dr. McIntyre earned a bachelor's degree in biology from Merrimack College. Both her master's degree and doctorate are in biochemistry and biophysics from the University of North Carolina at Chapel Hill. Dr. McIntyre is board certified in clinical pathology (hematology and clinical chemistry) and toxicology. She is a member of the American College of Toxicology, the American Society of Clinical Pathologists, the Drug Information Association and the American Association for the Advancement of Science.

**Paul S. Covington** became our Senior Vice President-Clinical Development and Operations in January 2010. Dr. Covington has more than 17 years of drug development experience. As PPD's Executive Vice President and Chief Medical Officer from 2002 to 2008, he designed and implemented the development programs for all PPD's compound partnering alliances. Dr. Covington was responsible for the successful Phase I and Phase II development of Priligy and Alogliptin, both of which were partnered to large pharmaceutical companies following completion of the proof-of-concept studies. As part of his contribution to PPD's compound partnering programs, Dr. Covington also participated in joint development committees with each alliance partner. At PPD, Dr. Covington also oversaw all aspects of medical and regulatory affairs services for quality drug development including pharmacovigilance, medical writing and program management. He was at the forefront of establishing monitoring processes for patient safety and data integrity for complex studies involving extremely ill patients. Dr. Covington joined PPD in 1991 as a Medical Director. From 2008 to 2010, Dr. Covington was an independent consultant. Prior to joining PPD, Dr. Covington served in various medical roles in both hospital and private practice settings, where he was lead investigator in multiple protocols. He was medical director at Future HealthCare Research Centers in Birmingham, Alabama from 1991 to 1992, and chief of staff, director of cardio respiratory and director of critical care at Central Alabama Community Hospital from 1985 to 1990. He completed his residency at Carraway Methodist Medical Center in Birmingham. Dr. Covington received his bachelor's and medical degrees from the University of Alabama in Birmingham.

**Marshall Woodworth** has served as our Chief Financial Officer, Treasurer and Assistant Secretary since February 2011. He joined us in January 2010 as our Vice President—Finance and Treasurer. Prior to that, Mr. Woodworth has more than 24 years of financial experience of which more than 14 years were in pharmaceutical and life science-related companies. Mr. Woodworth served as Vice President of Finance with Xerium Technologies, Inc. from 2006 to 2009. He served in various financial management roles with Milliken & Company including Division Finance Leader and European Financial Leader from 2000 to 2006. Prior to Milliken & Company, Mr. Woodworth held various financial management positions with Monsanto, Dow Chemical, and Eli Lilly. Mr. Woodworth received his bachelor's degree in science from the University of Maryland and an M.B.A. from the Indiana University at Bloomington. He is a Certified Management Accountant and Certified Financial Manager.

## PART II

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

#### Market Information

Our common stock is traded under the symbol "FURX" and is quoted on the Nasdaq Global Market. The following table sets forth the high and low sales prices for shares of our common stock, as reported by Nasdaq for the periods indicated.

	2010	
	High	Low
First Quarter*	\$ —	\$ —
Second Quarter*	\$20.00	\$ 8.69
Third Quarter	\$11.95	\$ 9.29
Fourth Quarter	\$15.61	\$10.94

\* Our common stock began trading on the Nasdaq Global Market on May 28, 2010, on a "when-issued" basis. On June 15, 2010, the first trading day after the distribution, "when-issued" trading with respect to our common stock ended and "regular way" trading began. As a result, our stock was not listed in the first quarter of 2010 and only listed for twenty-three trading days in the second quarter of 2010.

#### Holder

As of March 11, 2011 there were 172 stockholders of record, which excludes stockholders whose shares were held in nominee or street name by brokers.

On March 11, 2011 the closing price for the common stock as reported on the Nasdaq Global Market was \$16.63.

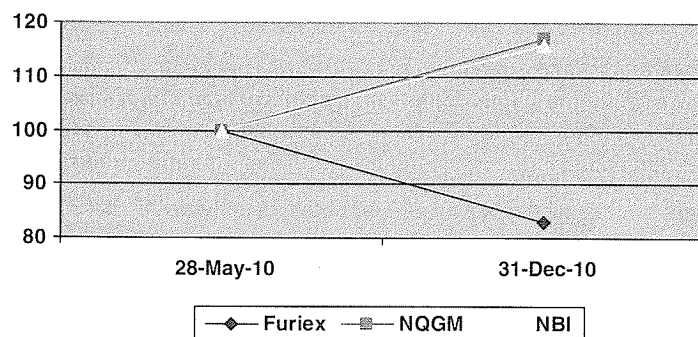
#### Equity Compensation Plans

The information required by Item 5 of Form 10-K regarding equity compensation plans is incorporated herein by reference to "Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters".



## Performance Graph

The following graph compares our cumulative total stockholder return from May 28, 2010, when our common stock began trading on a “when issued” basis, with those of the Nasdaq Global Market Composite Index (NQGM) and the Nasdaq Biotechnology Index (NBI). The graph assumes that U.S. \$100 was invested on May 28, 2010 in (1) our common stock, (2) the Nasdaq Global Market Composite Index and (3) the Nasdaq Biotechnology Index. The measurement points utilized in the graph consist of the last trading day in each calendar year, which closely approximates the last day of the respective fiscal year of the Company. The historical stock performance presented below is not intended to and may not be indicative of future stock performance.



	<u>5/28/10</u>	<u>12/31/10</u>
FURX .....	\$100	\$ 83
Nasdaq Global Market Composite Index .....	\$100	\$117
Nasdaq Biotech Index .....	\$100	\$116

## Dividends

We have never declared or paid cash dividends on our common stock. We currently expect to retain future earnings, if any, for use in the operation and expansion of business and do not anticipate paying any cash dividends in the foreseeable future.

## Item 6. Selected Financial Data

The tables below set forth selected historical financial information of the Company that has been derived from the audited financial statements as of December 31, 2008, 2009 and 2010, and for the four years in the period ended December 31, 2010, as well as from the Company's unaudited financial statements as of December 31, 2006 and 2007, and for the year ended December 31, 2006. For all periods presented, the weighted-average shares outstanding are calculated based on the 9,881,340 shares issued in connection with the spin-off on June 14, 2010.

The selected historical financial data should be read in conjunction with the combined and consolidated financial statements and related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations", included elsewhere in this Form 10-K.

### Combined and Consolidated Statements of Operations Data (in thousands):

(in thousands, except per share data)	Year Ended December 31,				
	2006	2007	2008	2009	2010
Total revenue	\$15,857	\$ 560	\$18,419	\$ 6,312	\$ 8,983
Operating expenses	3,604	23,316	11,645	14,621	58,504
Income (loss) from operations <sup>(1)</sup>	12,253	(22,756)	6,774	(8,309)	(49,521)
Other income (expense), net	(329)	19	14	10	9
Provision for income taxes	—	—	—	—	14
Income (loss) from continuing operations	11,924	(22,737)	6,788	(8,299)	(49,526)
Discontinued operations, net <sup>(2)</sup>	(4,066)	(185)	(976)	(632)	(5,133)
Net income (loss)	\$ 7,858	\$ (22,922)	\$ 5,812	\$ (8,931)	\$ (54,659)
Income (loss) from continuing operations per basic and diluted share	\$ 1.21	\$ (2.30)	\$ 0.69	\$ (0.84)	\$ (5.01)
Income (loss) from discontinued operations, net of income taxes per basic and diluted share	\$ (0.41)	\$ (0.02)	\$ (0.10)	\$ (0.06)	\$ (0.52)
Net income (loss) per basic and diluted share	\$ 0.80	\$ (2.32)	\$ 0.59	\$ (0.90)	\$ (5.53)
Weighted-average shares used to compute net income (loss) per basic and diluted share:	9,881	9,881	9,881	9,881	9,881

### Combined and Consolidated Balance Sheet Data (in thousands):

(in thousands)	As of December 31,				
	2006	2007	2008	2009	2010
Total assets	63,581	63,265	61,138	55,877	132,559
Total shareholders' equity	—	—	—	—	118,504
PPD net investment <sup>(3)</sup>	58,895	56,870	55,524	49,270	—

(1) Impairments of intangible assets are included in income (loss) from operations. For 2009, the impairment of intangible asset was related to in-process research and development for the MAG-131 compound obtained through the acquisition of Magen Biosciences. For 2008, the impairment of intangible asset related to the remaining unamortized value of our royalty interest in SinuNase and other Accentia antifungal products. For further details, see Note 3 and 6 in the notes to the combined and consolidated financial statements.

(2) In 2009, PPD completed dispositions of Piedmont Research Center, LLC and PPD Biomarker Discovery Sciences, LLC. Results of operations for these dispositions are included in discontinued operations. In May 2010, PPD closed the dermatology therapeutic discovery unit, PPD Dermatology, Inc., formerly Magen Biosciences, Inc. For further details, see Note 3 in the notes to the combined and consolidated financial statements.

(3) Prior to June 14, 2010, the financial statements of the company represent a combination of various components of PPD comprising the Discovery Sciences segment. Because a direct ownership relationship did not exist among all the components comprising the company prior to the spin-off, PPD's net investment in the company is shown within the statements of shareholders' equity in the combined and consolidated financial statements prior to December 31, 2010. The net investment account represents the cumulative investments in, distributions from and earnings (loss) of the company.

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

*This Form 10-K includes forward-looking statements. All statements other than statements of historical facts are forward-looking statements, including any projections of milestones, royalties or other financial items, any statements of the plans and objectives of management for future operations, any statements concerning research and development, clinical development timelines, proposed new products or licensing or collaborative arrangements, any statements regarding future economic conditions or performance, and any statement of assumptions underlying any of the foregoing. In some cases, forward-looking statements can be identified by the use of terminology such as "believes", "might", "will", "expects", "plans", "anticipates", "estimates", "potential" or "continue", or the negative thereof or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained in this Form 10-K are reasonable, there can be no assurance that such expectations or any of the forward-looking statements will prove to be correct, and actual results could differ materially from those projected or assumed in the forward-looking statements. Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including the risk factors set forth below, and for the reasons described elsewhere in this Form 10-K, any of which could significantly adversely impact our business. All forward-looking statements and reasons why results might differ included in this Form 10-K are made as of the date hereof, and we assume no obligation to update these forward-looking statements or reasons why actual results might differ.*

### **Results of Operations**

On June 14, 2010 we became an independent company upon the spin-off by Pharmaceutical Product Development, Inc., or PPD. As part of and prior to the spin-off, PPD transferred \$100 million in cash to us and current accounts receivable and payable associated with the compound partnering business.

The Company's business consists solely of compound development and partnering activities. Accordingly, the Company operates in one reportable business segment. Historically, our revenues consisted primarily of milestone and royalty payments from collaborators from out-licensed compounds. For the year ended December 31, 2009, our year-to-date revenue included \$5.0 million in regulatory approval milestones and \$0.9 million in royalties from the sale of Priligy by our collaborator, Alza. For the year ended December 31, 2010, our year-to-date revenue includes \$7.5 million in regulatory approval milestones resulting from regulatory and pricing approval of Nesina in Japan in addition to \$1.3 million in royalty revenue from the sale of Priligy and Nesina by our collaborators, Alza and Takeda.

We incurred research and development expenses of \$11.8 million and \$50.1 million for the year ended December 31, 2009 and 2010, respectively. Our research and development expenses include costs incurred for our current and previous pre-clinical and clinical-stage drug candidates, including the novel statin, PPD-10558, and the two compounds in-licensed from Janssen-Cilag. Research and development expenses associated with the JNJ-Q2 drug candidate were lower than initially expected for the year ended December 31, 2010, as the enrollment of the bacterial pneumonia study for JNJ-Q2 was slower than previously forecasted; however, the Company has taken steps to increase the rate of enrollment going forward, which could increase the cost of the study. In addition, research and development expenses associated with the PPD-10558 drug candidate were lower than initially expected for the year ended December 31, 2010, as expected guidance from the FDA about PPD-10558 was delayed later than expected in the fourth quarter of 2010. We expect this study to start in early 2011.

We expect research and development expenses to increase from the quarter ended December 31, 2010, to be fairly consistent for the next two fiscal quarters, and then to decline as we continue work on Phase II clinical trials for our three drug candidates. These expenses include CRO services provided by PPD, nonclinical testing and clinical trial material manufacturing provided by third parties, and the direct cost of our personnel managing the programs and payments to third parties. All research and development expenses for our drug candidates and external collaborations are expensed as incurred.

The timing and amount of any future expenses, completion dates, and revenues related to our drug candidates are subject to significant uncertainty due to the nature of our development programs. We do not know if we will be successful in developing any of our drug candidates. The timing and amount of our research and development expenses will depend upon the costs associated with the present and potential future clinical trials of our drug candidates, any related expansion of our research and development organization, regulatory requirements, advancement of our pre-clinical programs and manufacturing costs. There are numerous risks and uncertainties associated with the duration and cost of clinical trials, which vary significantly over the life of a project as a result of events arising during clinical development. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those which we currently anticipate to complete clinical development of a drug candidate, or if we experience significant delays in enrollment in any of our clinical trials, we would be required to expend significant additional financial resources and time on the completion of clinical development. The timing and amount of revenues, if any, are equally dependent upon the success of the clinical trials as well as the commercial success of these products in the marketplace, all of which are subject to a variety of risk factors and uncertainties.

For the year ended December 31, 2010, we reported an operating loss of \$49.5 million and net loss of \$54.7 million, including a loss from discontinued operations of \$5.1 million. We expect to continue to incur significant net losses for the foreseeable future, and that our losses will fluctuate from quarter to quarter and that such fluctuations might be substantial.

Our business is subject to various risks and uncertainties. See "Risk Factors" described in Part 1 Item A for information on these risks and uncertainties.

#### *Basis of Accounting*

The accompanying combined financial statements for periods prior to June 14, 2010, have been derived from the combined financial statements and accounting records of PPD, and from the historical cost basis of the assets and liabilities of the various activities that reflect the combined results of operations, financial condition and cash flows of the discovery sciences segment of PPD. All the business components of the discovery sciences segment have been included in the historical statements because they were managed by common PPD segment management, and because they reflected historical performance of segment management.

In 2009, PPD completed its disposition of Piedmont Research Center, LLC and PPD Biomarker Discovery Sciences, LLC. Due to the unique service offerings of these two subsidiaries, PPD determined these business units were no longer a long-term strategic fit and elected to sell them. In May 2010, PPD discontinued operations of its wholly owned subsidiary PPD Dermatology, Inc., formerly Magen Biosciences, Inc., due to unfavorable efficacy data associated with the MAG-131 program. These business units are recorded as discontinued operations in the statements of operations. Additionally, the discovery sciences segment included pre-clinical consulting services not offered by us. All rights and obligations related to pre-clinical consulting services and the definitive purchase agreements related to Piedmont Research Center, LLC, PPD Biomarker Discovery Sciences, LLC and PPD Dermatology, Inc. have been retained by PPD.

For periods prior to the June 14, 2010 spin-off, we were allocated certain expenses from PPD such as executive oversight, risk management, accounting, tax, legal, investor relations, human resources, information technology, facilities and depreciation, but were not allocated the underlying productive assets, such as certain information systems equipment, and furniture and facilities that were not assigned to us, but from which we have benefited. Such expenses have been reflected in the combined and consolidated financial statements as expense allocations from PPD. The basis of these allocations included full-time equivalent employees for the respective periods presented and square footage of occupied space. See Note 14 in the notes to our combined and consolidated financial statements for further discussion of the allocations.

Management believes that the assumptions and allocations underlying the combined and consolidated financial statements are reasonable. For periods prior to the June 14, 2010 spin-off, the financial information in

these combined and consolidated financial statements does not include all expenses that would have been incurred had we been a separate, stand-alone publicly traded entity. For periods prior to the June 14, 2010 spin-off, the combined and consolidated financial statements include assets, liabilities and operations for Piedmont Research Center, LLC, PPD Biomarker Discovery Sciences, LLC, PPD Dermatology, Inc. and pre-clinical consulting services that are not included in our operations after the spin-off. As a result, the financial information herein does not reflect our financial position, results of operations or cash flows had we been a separate, stand-alone entity during the historical periods presented.

### Year Ended December 31, 2009 versus Year Ended December 31, 2010

The following table sets forth amounts from our combined and consolidated financial statements for the year ended December 31, 2009 compared to the year ended December 31, 2010.

(in thousands)	Year Ended December 31,	
	2009	2010
Revenue:		
Milestones .....	\$ 5,000	\$ 7,500
Royalties .....	923	1,330
Service .....	389	75
Other .....	—	78
Total revenue .....	<u>6,312</u>	<u>8,983</u>
Direct expenses .....	265	21
Research and development expenses .....	11,795	50,112
Selling, general and administrative expenses .....	2,551	8,262
Depreciation and amortization .....	10	109
Total operating expenses .....	<u>14,621</u>	<u>58,504</u>
Operating loss .....	(8,309)	(49,521)
Other income, net .....	10	9
Loss from continuing operations before provision for income taxes .....	(8,299)	(49,512)
Provision for income taxes .....	—	14
Loss from continuing operations .....	(8,299)	(49,526)
Loss from discontinued operations, net of income taxes .....	(632)	(5,133)
Net loss .....	<u><u>\$ (8,931)</u></u>	<u><u>\$ (54,659)</u></u>

#### Revenue

Total revenue increased \$2.7 million to \$9.0 million for the year ended December 31, 2010 from 2009. The increase in total revenue was primarily attributable to a \$2.5 million increase in milestone revenue from the \$7.5 million milestone payment we earned as a result of regulatory and pricing approvals of Nesina in Japan, partially offset by a non-recurring milestone payment in 2009 of \$5.0 million earned as a result of regulatory approvals of Priligy in Finland and Sweden. Royalty revenue is based on the sale of approved products by our collaborators. For the year ended December 31, 2010, we received royalties of \$1.3 million from sales of Priligy in various countries outside the United States, and from the sale of Nesina in Japan. Service revenues were related to consulting services provided to customers of PPD. All service contracts remained with PPD upon the spin-off.

### Expenses

Research and development, or R&D, expenses increased \$38.3 million to \$50.1 million for the year ended December 31, 2010 from 2009. The increase in R&D expense was primarily due to development costs related to the two therapeutic compounds in-licensed from Janssen-Cilag in November 2009, partially offset by the \$7.0 million of in-licensing payments related to these compounds paid to Janssen-Cilag in 2009.

The following table sets forth amounts from our combined and consolidated statements of operations for R&D expenses along with the dollar amount of the changes for the year ended December 31, 2009 compared to the year ended December 31, 2010.

(in thousands)	Year Ended December 31,		\$ Inc (Dec)
	2009	2010	
R&D expense by project:			
MuDelta .....	\$ 572	\$24,670	\$24,098
Fluoroquinolone (JNJ-Q2) .....	1,595	22,668	21,073
Novel statin (PPD-10558) .....	1,288	1,197	(91)
Upfront payments to Janssen Pharmaceutica .....	7,000	—	(7,000)
Other R&D expense .....	1,340	1,577	237
Total R&D expense .....	<u>\$11,795</u>	<u>\$50,112</u>	<u>\$38,317</u>

R&D expenses might fluctuate significantly from period to period for a variety of reasons, including the number of compounds under development, the stages of development and changes in development plans. We expect the costs related to the programs for the two compounds in-licensed from Janssen-Cilag, if successful, will be \$40.0 to \$50.0 million over the next two years until the programs are out-licensed to a collaborator. We are progressing PPD-10558 to a phase II proof of concept study. We estimate the costs of development could be \$15.0 to \$20.0 million over the next two years. We plan to continue evaluating other compound partnering opportunities, which could result in significant additional R&D expense in future periods.

Selling, general and administrative, or SG&A expenses, increased \$5.7 million to \$8.3 million for the year ended December 31, 2010 from 2009. The increase in SG&A expenses was the result of \$2.6 million in costs incurred in connection with the spin-off, additional costs associated with being a stand-alone publicly traded company, including increases in professional service fees, and increases in stock compensation expense.

### Income Taxes

During 2009 and 2010, we did not record a tax benefit related to our operating losses because we have provided full valuation allowances against our assets based on our history of operating losses. Additionally, with the exception of the pre-acquisition federal and state tax filings for Magen BioSciences, Inc. and certain separate state filings through the June 14, 2010 spin-off our operations were included in the consolidated federal and combined state tax returns of PPD, and the resulting tax attributes have been fully utilized by PPD and are no longer available to us for future use. Subsequent to June 14, 2010, we will file federal and state returns separately from PPD and will be able to use our tax attributes accordingly. However, we anticipate that we will require a full valuation allowance against any deferred tax assets until such time as we are able to demonstrate a consistent pattern of profitability.

### Results of Operations

Operating loss increased \$41.2 million from a loss of \$8.3 million in 2009 to a loss of \$49.5 million in 2010. This increase in loss from operations resulted primarily from the \$38.3 million increase in R&D expense and the \$5.7 million increase in SG&A, as described above, partially offset by an increase of \$2.7 million in revenue.

In May 2009, PPD completed the disposition of substantially all of the assets of Piedmont Research Center, LLC. Piedmont Research Center, LLC provided pre-clinical research services for clients with anti-cancer agents and other therapeutic candidates. In December 2009, PPD completed the disposition of its wholly owned subsidiary, PPD Biomarker Discovery Sciences, LLC. PPD Biomarker Discovery Sciences, LLC provided biomarker discovery services and participant sample analysis. In May 2010, PPD discontinued operations of its wholly owned subsidiary PPD Dermatology, Inc. due to unfavorable efficacy data associated with the MAG-131 program. As a result, these business units are shown as discontinued operations for 2009 and 2010. Loss from discontinued operations was \$0.6 and \$5.1 million for the year ended December 31, 2009 and 2010, respectively.

Net loss of \$54.7 million in 2010 represents a \$45.8 million increase from net loss of \$8.9 million in 2009. This increase in our net loss resulted primarily from the \$38.3 million increase in R&D expense, the \$5.7 million increase in SG&A expense, and the \$4.5 million increase in loss from discontinued operations, partially offset by an increase of \$2.7 million in revenue.

### Year Ended December 31, 2008 versus Year Ended December 31, 2009

The following table sets forth amounts from our combined and consolidated financial statements for the year ended December 31, 2008 compared to the year ended December 31, 2009.

(in thousands)	Year Ended December 31,	
	2008	2009
Revenue:		
Milestones .....	\$18,000	\$ 5,000
Royalties .....	—	923
Service .....	419	389
Other .....	—	—
Total revenue .....	<u>18,419</u>	<u>6,312</u>
Direct expenses .....	153	265
Research and development expenses .....	8,053	11,795
Selling, general and administrative expenses .....	1,738	2,551
Depreciation and amortization .....	94	10
Impairment of intangible assets .....	1,607	—
Total operating expenses .....	<u>11,645</u>	<u>14,621</u>
Operating income (loss) .....	6,774	(8,309)
Other income, net .....	14	10
Income (loss) from continuing operations before provision for income taxes .....	6,788	(8,299)
Provision for income taxes .....	—	—
Income (loss) from continuing operations .....	6,788	(8,299)
Loss from discontinued operations, net of income taxes .....	(976)	(632)
Net income (loss) .....	<u>\$ 5,812</u>	<u>\$ (8,931)</u>

#### Revenue

Total revenue decreased \$12.1 million to \$6.3 million for the year ended December 31, 2009 from 2008. Milestone revenue decreased by \$13.0 million based on the timing and progress of the various out-licensed products being developed by our collaborators. Milestone revenues for 2008 included a \$15.0 million milestone we earned from Takeda as a result of the FDA's acceptance of the Nesina NDA and a \$3.0 million milestone payment we earned from Takeda's submission of the Nesina NDA in Japan, while 2009 milestone revenue

included a \$5.0 million milestone earned as a result of regulatory approvals of the Priligy in Finland and Sweden. Royalty revenues are dependent on the approval and sale of products by our collaborators. In 2009, we received our first royalties of \$0.9 million from sales of Priligy as a result of the marketing approval in various countries outside the United States. Service revenues were related to consulting services provided to customers of PPD. All service contracts remained with PPD upon the spin-off.

### Expenses

R&D expenses increased \$3.7 million to \$11.8 million for the year ended December 31, 2009 from 2008. The increase in R&D expense was due primarily to \$7.0 million of upfront payments and \$2.2 million in development costs related to the two therapeutic compounds in-licensed from Janssen-Cilag in November 2009, offset by a \$5.6 million reduction in the spending on our novel statin compound in-licensed from Ranbaxy.

The following table sets forth amounts from our combined and consolidated statements of operations for R&D expenses along with the dollar amount of the changes for the year ended December 31, 2008 compared to the year ended December 31, 2009.

(in thousands)	Year Ended December 31,		\$ Inc (Dec)
	2008	2009	
R&D expense by project:			
MuDelta .....	\$ —	\$ 572	\$ 572
Fluoroquinolone (JNJ-Q2) .....	—	1,595	1,595
Novel statin (PPD-10558) .....	6,848	1,288	(5,560)
Upfront payments to Janssen Pharmaceutica .....	—	7,000	7,000
Other R&D expense .....	<u>1,205</u>	<u>1,340</u>	<u>135</u>
Total R&D expense .....	<u>\$8,053</u>	<u>\$11,795</u>	<u>\$ 3,742</u>

SG&A expenses increased \$0.9 million to \$2.6 million for the year ended December 31, 2009 from 2008. The increase in SG&A expenses was the result of costs incurred related to the spin-off, and the additional SG&A expense related to the post-acquisition operations of Magen BioSciences, Inc., which we acquired in April 2009.

### Impairment

In 2008, Accentia announced its Phase III clinical trial for SinuNase failed to meet its goal in treating chronic sinusitis participants and therefore discontinued the sales of anti-fungal products on which we received royalties and declared bankruptcy. As a result, we wrote off the \$1.6 million of remaining unamortized value of our royalty interest in the anti-fungal products of Accentia.

### Income Taxes

During 2008 and 2009, respectively, we did not record a tax provision or benefit related to our operating income or loss, based on our history of operating losses. In 2009, we have provided full valuation allowances against our deferred tax assets. Additionally, with the exception of the pre-acquisition federal and state tax filings for Magen BioSciences, Inc. and certain separate state filings through the June 14, 2010 spin-off our operations were included in the consolidated federal and combined state tax returns of PPD, and the resulting tax attributes have been fully utilized by PPD and are no longer available to us for future use. Subsequent to June 14, 2010, we will file federal and state returns separately from PPD and will be able to use our tax attributes accordingly. However, we anticipate that we will require a full valuation allowance against any deferred tax assets until such time as we are able to demonstrate a consistent pattern of profitability.



### *Results of Operations*

Operating income (loss) decreased \$15.1 million from income of \$6.8 million in 2008 to a loss of \$8.3 million in 2009. This decrease in our income from operations resulted from the \$3.7 million increase in R&D expense, the \$0.9 million increase in SG&A expense, and a decrease of \$12.1 million in revenue, partially offset by the \$1.6 million impairment of intangible assets in 2009.

In May 2009, PPD completed the disposition of substantially all of the assets of Piedmont Research Center, LLC. Piedmont Research Center, LLC provided pre-clinical research services for clients with anti-cancer agents and other therapeutic candidates. In December 2009, PPD completed the disposition of its wholly owned subsidiary, PPD Biomarker Discovery Sciences, LLC. PPD Biomarker Discovery Sciences, LLC provided biomarker discovery services and participant sample analysis. As a result, the Piedmont Research Center, LLC and PPD Biomarker Discovery Sciences, LLC units are shown as discontinued operations for 2008 and 2009. In May 2010, PPD discontinued operations of its wholly owned subsidiary PPD Dermatology, Inc. due to unfavorable efficacy data associated with the MAG-131 program. As a result, the PPD Dermatology, Inc. business unit is shown as discontinued operations for 2009. Loss from discontinued operations was \$1.0 and \$0.6 million for the years ended December 31, 2008 and 2009, respectively.

Net loss of \$8.9 million in 2009 represents a \$14.7 million decrease from net income of \$5.8 million in 2008. This decrease in our net income resulted primarily from the \$3.7 million increase in R&D expense and a decrease of \$12.1 million in revenue, partially offset by the \$1.6 million impairment of intangible assets in 2009.

### **Liquidity and Capital Resources**

Upon the spin-off on June 14, 2010, PPD provided us with a cash contribution of \$100.0 million and we assumed the assets and liabilities of the compound partnering business as of the closing date of the spin-off, with the exception of the dermatology therapeutic discovery unit and any spin-off related cost, which remained with PPD. We expect that this cash contribution will fund our operations and working capital requirements for at least 12 months, based on current operating plans. In addition to this cash contribution, we expect to receive future payments from our existing collaborations that should provide additional support for our operations and working capital requirements.

Our future capital requirements will depend on numerous factors, including, among others: the cost and expense of continuing the research and development activities of our existing candidates; new collaborative agreements that we might enter into in the future; progress of product candidates in clinical trials as it relates to the cost of development and the receipt of future milestone payments, if any; the ability of our licensees to obtain regulatory approval and successfully manufacture and market licensed products; the continued or additional support by our collaborators or other third parties of R&D efforts and clinical trials; time required to gain regulatory approvals; the demand for our potential products, if and when approved; potential acquisitions of technology, product candidates or businesses by us; and the costs of defending or prosecuting any patent opposition or litigation necessary to protect our proprietary technologies. In order to develop and obtain regulatory approval for our potential product candidates we might need to raise additional funds through equity or debt financings, collaborative arrangements, the use of sponsored research efforts or other means. Additional financing might not be available on acceptable terms, if at all, and such financing might only be available on terms dilutive to our stockholders.

For the year ended December 31, 2010, our operating activities used \$43.3 million in cash as compared to \$24.1 million used for the same period in 2009. The increase in net cash used in operating activities of \$19.2 million was due primarily to an increase in research and development expenses of \$38.3 million, an increase in selling, general and administrative expenses of \$5.7 million, an increase in loss from discontinued operations of \$4.5 million, offset by an increase in revenue of \$2.7 million and a decrease in net gain on sale of businesses of \$26.7 million from 2009.

For the year ended December 31, 2010, our investing activities provided \$2.8 million in cash. The purchaser of Piedmont Research Center, LLC had an indemnification holdback of \$3.5 million, which PPD received during 2010, which was offset by purchases of property and equipment of \$0.7 million.

For the year ended December 31, 2010, our financing activities provided \$122.6 million of cash from the \$100.0 million in cash contributed by PPD at the spin-off and the \$22.6 million net change in investment from parent.

As of December 31, 2010, we had three collaborations that involve potential future expenditures. The first is our collaboration with Alza for Priligy. In connection with this collaboration, we have an obligation to pay a royalty to Lilly of 5% on annual net sales of the compound in excess of \$800.0 million. If the related triggering events and product sales occur, we are entitled to receive from Alza future regulatory milestone payments of \$15.0 million, sales-based milestone payments of up to \$50.0 million, and sales-based royalties ranging from 10% to 20% for sales of patented products without generic competition and ranging from 10% to 17.5% for non-patented products without generic competition, in both cases the percentages rise as sales volume increases, and a royalty of 7.5% for patented and non-patented products with generic competition regardless of sales volume. There are currently no ongoing costs of development for this compound.

The second collaboration involving future expenditures is with Janssen-Cilag, which includes two separate agreements, involving the Fluoroquinolone (JNJ-Q2) and MuDelta compounds. The expenses associated with the development of our in-licensed compounds from Janssen-Cilag are expected to be between \$40.0 and \$50.0 million over the next two years. At the completion of Phase II of each compound, Janssen-Cilag will have the option to continue development and commercialization of each compound. In exchange, we may receive, for each compound, up to \$90.0 million in regulatory milestone payments and up to \$75.0 million in sales-based milestone payments and, if approved for marketing, sales-based royalties increasing from the mid to upper single digit percentages as sales volume increases. At this point in time, potential sales of any of these compounds, as well as the time sales might begin, are too uncertain to forecast with any degree of accuracy.

The third collaboration involving future expenditures is with Ranbaxy for a novel statin compound (PPD-10558). If we develop this product and it attains regulatory approval, and in addition, the product meets specific commercialization and sales milestones, the total amount of potential clinical and sales-based milestones that we are obligated to pay Ranbaxy would be \$43.0 million. We also would be obligated to pay Ranbaxy sales-based royalties of a mid-single digit percentage. We will be solely responsible and will bear all costs and expenses for the development, manufacture, and marketing of the compound and licensed products. If advanced, we estimate the costs of development could be \$15.0 to \$20.0 million over the next two years.

We actively evaluate potential acquisitions and in-licensing that might require additional external financing, and we might seek funds from public or private issuances of equity or debt securities. While we believe we will have adequate sources of liquidity to fund our operations for at least 12 months, our sources of liquidity over that time period could be affected by: risks and cost related to our development efforts, regulatory approval and commercialization of our product candidates; changes in regulatory compliance requirements; personal injury or other tort claims; international risks; environmental or intellectual property claims; or other factors described under "Risk Factors" in Part 1 Item 1A.

### Contractual Obligations

As of December 31, 2010, future minimum payments on all our contractual obligations for years subsequent to December 31, 2010 were as follows related to operating leases in the following locations: Morrisville, NC; Wilmington, NC; Rockville, MD; Richmond, VA; Blue Bell, PA; and Austin, TX:

(in thousands)	
2011 .....	\$105
2012 .....	47
	<u>\$152</u>

As of December 31, 2010, we were contingently obligated under collaboration agreements that have not been included in the table above due to the inherent uncertainty in the amounts and timing of payments. For more information, see "Liquidity and Capital Resources."

### **Off-balance Sheet Arrangements**

We have no off-balance sheet arrangements except for operating leases entered into in the normal course of business.

### **Critical Accounting Policies and the Use of Estimates**

The preparation of our combined and consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in our combined and consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates. The items in our combined and consolidated financial statements requiring significant estimates and judgments are as follows:

#### *Revenue Recognition*

The Company generates revenue in the form of upfront payments, development and regulatory milestone payments, royalties and sales-based milestone payments in connection with the out-licensing of compounds. The payment of future milestones and royalties will depend on the success of the Company's compound development and the Company's collaborators' success in developing and commercializing compounds. Upfront payments are generally paid within a short period of time following the execution of an out-license and collaboration agreement. Milestone payments are typically one-time payments to the Company triggered by the collaborator's achievement of specified development and regulatory events such as the commencement of Phase III trials or regulatory submission approval. Royalties are payments received by the Company based on net product sales of a collaborator. Sales-based milestone payments are typically one-time payments to the Company triggered when aggregate net sales of product by a collaborator for a specified period (for example, an annual period) reach an agreed upon threshold amount. The Company recognizes upfront payments, development and regulatory payments, royalty payments, and sales-based milestone payments from its collaborators when the event which triggers the obligation of payment has occurred, there is no further obligation on the Company's part in connection with the payment, and collection is reasonably assured.

The Company has also historically recorded revenue from service contracts, other than time-and-material contracts, on a proportional performance basis. To measure performance under these contracts on a given date, the Company compared effort expended to date to the estimated total effort to be expended to complete the contract using metrics such as the number of units to be delivered. Changes in the estimated total effort required to complete a contract without a corresponding proportional change to the contract value resulted in a cumulative adjustment to the amount of revenue recognized in the period the change in estimate was determined. For time-and-material contracts, the Company recognized revenue as hours were worked, multiplied by the applicable hourly rate. All service contracts remained with PPD.

#### *Goodwill*

The Company reviews goodwill for impairment annually on October 1 and whenever events or changes in circumstances indicate that the carrying amount of an asset might not be recoverable. In performing the annual impairment test, the fair value of the Company was determined using the income approach. The Company has a single reporting unit. For purposes of the income approach, fair value was determined based on the present value of estimated future cash flows, discounted at an appropriate risk-adjusted rate. The Company made assumptions about the amount and timing of future expected cash flows, probability of future compound development and appropriate discount rates. The compound development estimates are highly subjective due to the uncertainty

associated with the amounts and timing of expected milestone and royalty payments. The amount and timing of future cash flows within the Company's analysis is based on its most recent operational budgets, long range strategic plans and other estimates. Actual results may differ from those assumed in the Company's forecasts, which could have a material impact on the Company's combined and consolidated financial statements. The Company uses estimates of market participant weighted average cost of capital as a basis for determining the discount rates to apply to the Company's future expected cash flows, adjusted for the risks and uncertainty inherent in its industry generally and in its internally developed forecasts. Based on the review as of October 1, 2010, the Company's calculated fair value of equity was in excess of carrying value by approximately 38%.

The fair value of goodwill could be materially impacted by future adverse changes such as future declines in operating results, a decline in the valuation of pharmaceutical and biotechnology company stocks, including the valuation of the Company's own common stock, a further significant slowdown in the worldwide economy or the pharmaceutical and biotechnology industry, failure to meet the performance projections included in forecasted operating results or the delay or abandonment of any research and development programs.

#### *Other Intangible Assets*

The Company evaluates intangible assets, which previously consisted of royalty rights and acquired in-process research and development, at any time the Company believes indicators of impairment exist. These intangible assets are initially recorded at fair value and the Company uses fair value measurements to evaluate impairment. The fair value of our intangible assets is determined by estimating the costs to develop the acquired technology into commercially viable products, estimating the resulting net cash flows from the programs, and discounting the net cash flows to present value. Additionally, Company estimates take into account the relevant market size and growth factors, expected trends in technology, and the nature and expected timing of new product introductions by us and our competitors. The resulting net cash flows from such programs are based on management's estimates of cost of sales, operating expenses, and income taxes from such programs. The rates utilized to discount the net cash flows to their present value were commensurate with the stage of development of the program and uncertainties in the economic estimates used in the projections described above. During 2008, the Company reported an impairment of \$1.6 million related to the royalty rights purchased from Accentia as a result of Accentia's discontinuation of the sale of antifungal products and subsequent bankruptcy. The Company suspended the MAG-131 program due to unfavorable efficacy data that was discovered in late 2009. As a result, the Company evaluated the asset for impairment using forecasts based on then currently available data, and determined that this asset was impaired. The Company recorded a \$10.4 million impairment of acquired in-process research and development as of December 31, 2009. As of December 31, 2009 and 2010, there were no intangible assets other than goodwill recorded on the Company's combined and consolidated balance sheets.

#### *Share-Based Compensation*

The Company recognizes compensation expense using a fair-value based method related to stock options and other share-based compensation. The expense is measured based on the grant date fair value of the awards that are expected to vest and is recorded over the applicable requisite service period. In the absence of an observable market price for a share-based award, the fair value is based upon a valuation methodology that takes into consideration various factors, including the exercise price of the award, the expected term of the award, the current price of the underlying shares, the expected volatility of the underlying share price based on peer companies, the expected dividends on the underlying shares and the risk-free interest rate. A change in the assumptions used in the fair-value based calculation could have a significant impact on the fair value of options. See Note 9 in the notes to our combined and consolidated financial statements for details regarding the assumptions used in estimating fair value for the years ended December 31, 2008, 2009 and 2010 regarding equity awards granted to Furiex's employees by PPD and Furiex.

### *Tax Valuation Allowances*

The provision for income taxes has been determined using the asset and liability approach of accounting for income taxes. Under this approach, deferred taxes represent the future tax consequences expected to occur when the reported amounts of assets and liabilities are recovered or paid. The provision for income taxes represents income taxes paid or payable for the year, plus the change in deferred taxes during the year. Deferred taxes result from differences between the financial reporting and tax basis of the Company's assets and liabilities. Deferred tax assets and liabilities are measured using the currently enacted tax rates that apply to taxable income in effect for the years in which those tax attributes are expected to be recovered or paid, and are adjusted for changes in tax rates and tax laws when changes are enacted.

Valuation allowances are recorded to reduce deferred tax assets when it is more likely than not that a tax benefit will not be realized. The assessment of whether or not a valuation allowance is required often requires significant judgment, including the long-range forecast of future taxable income and the evaluation of tax planning initiatives. Adjustments to the deferred tax valuation allowances are made to earnings in the period when such assessments are made. Due to the historical losses from the Company's operations, a full valuation allowance on deferred tax assets has been recorded.

For the year ended December 31, 2010, the Company has recorded an insignificant amount of income tax expense. This amount relates to the adjustment of a deferred tax liability associated with historical goodwill, which is deductible for tax purposes, but is an indefinite lived intangible asset for financial reporting. The amounts reflected in the statements of operations for the year ended December 31, 2010 are the tax effect of the tax amortization of this item. Because the associated deferred tax liability relates to an indefinite lived intangible, the Company does not consider this item in computing the valuation allowance related to the Company's net deferred tax assets. As of December 31, 2010, the deferred tax liability associated with this intangible asset, reflected in other long-term liabilities within the combined and consolidated balance sheets, was approximately \$0.2 million.

### **Recent Accounting Pronouncements**

In March 2010, the Financial Accounting Standards Board, or FASB, issued a new accounting standard, the objective of which is to establish a revenue recognition model for contingent consideration that is payable upon the achievement of an uncertain future event, referred to as a milestone. This consensus will apply to milestones in single or multiple-deliverable arrangements involving research and development transactions, and will be effective for fiscal year (and interim periods within those fiscal years) beginning on or after June 15, 2010. We do not expect the adoption of this standard to have a material impact on our combined and consolidated financial statements.

In October 2009, the FASB issued a new accounting standard related to the accounting for revenue arrangements with multiple deliverables. This standard applies to all deliverables in contractual arrangements in all industries in which a vendor will perform multiple revenue-generating activities. This standard also addresses the unit of accounting for an arrangement involving multiple deliverables and how arrangement consideration should be allocated. This standard will be effective for fiscal years beginning on or after June 15, 2010. We do not expect the adoption of this standard to have a material impact on our combined and consolidated financial statements.

### **Income Taxes**

Except for the pre-acquisition federal and state tax filings for Magen BioSciences, Inc. and certain separate state filings through the June 14, 2010 spin-off, our operations have been included in the consolidated federal and combined state tax returns of PPD. As such, except for the pre-acquisition tax attributes of Magen BioSciences, Inc. and some losses from certain separate filing states, the tax attributes of our operations prior to June 14, 2010 have been utilized or paid by PPD. Thus, the tax attributes which have been included in PPD's combined returns have not been accounted for in the results of our operations.

### **Potential Volatility of Annual Operating Results**

Our annual operating results have fluctuated in the past, and we expect that they will continue to fluctuate in the future. Factors that could cause these fluctuations to occur include:

- the success of achieving milestones and the timing of our milestone payments or other revenue, if any;
- our dependence on a small number of compounds and collaborations;
- the success or failure of clinical trials and other aspects of developing and commercializing our product candidates;
- our ability to properly manage our growth;
- the timing and amount of costs associated with R&D and compound partnering collaborations;
- our ability to recruit and retain experienced personnel;
- the timing and extent of new government regulations; and
- intellectual property risks.

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

Under our current investment policies, we invest our cash and cash equivalents in money market funds which invest in short-term U.S. Treasury securities with insignificant rates of return. Our purchases of raw materials and finished goods are denominated primarily in U.S. dollars, purchases denominated in currencies other than the U.S. dollar are insignificant. Additionally, our net assets denominated in currencies other than the U.S. dollar are insignificant and have not historically exposed us to material risk associated with fluctuations in currency rates. Given these facts, we have not considered it necessary to use foreign currency contracts or other derivative instruments to manage changes in currency rates. We do not now, nor do we plan to, use derivative financial instruments for speculative or trading purposes. However, these circumstances might change.

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

The information required by this Item is set forth in the Combined and Consolidated Financial Statements and Notes thereto beginning at page F-1 of this Report.

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

None.

### **Item 9A. Controls and Procedures**

#### **Disclosure Controls and Procedures**

Disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e)) are designed only to provide reasonable assurance that information to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our President (our principal executive officer) and Chief Financial Officer and Treasurer (our principal financial and accounting officer), of the effectiveness of our disclosure controls and procedures pursuant to Exchange Act Rule 13a-15(b). Based upon that evaluation, our President and Chief Financial Officer and Treasurer have concluded that our disclosure controls and procedures were effective as of the end of the period covered by this report to provide the reasonable assurance discussed above.

#### **Internal Control Over Financial Reporting**

No change to our internal control over financial reporting occurred during the last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**Management's Report on Internal Control over Financial Reporting**

This annual report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the company's registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

**Item 9B. Other Information**

None.

## PART III

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

Information required by this Item concerning our directors is incorporated by reference from the section captioned "Proposal No. 1—Election of Directors" contained in our proxy statement related to the 2011 Annual Meeting of Stockholders scheduled to be held on May 19, 2011 which we intend to file with the SEC within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K.

The Board of Directors has determined that the members of the Audit Committee are independent as defined in Rule 4200(a)(15) of the National Association of Securities Dealers' listing standards. The Board of Directors has also determined that Committee Chair Robert P. Ruscher is an "audit committee financial expert" as defined in Item 401(h) of Regulation S-K.

Our Board of Directors adopted a code of conduct that applies to all of our directors and employees. Our Board also adopted a separate code of ethics for our President (principal executive officer), Chief Financial Officer and Treasurer (principal financial and accounting officer), and Corporate Controller, or persons performing similar functions. We will provide copies of our code of conduct and code of ethics without charge upon request. To obtain a copy of our code of conduct and code of ethics, please send your written request to Furiex Pharmaceuticals, Inc., 3900 Paramount Parkway, Suite 150, Morrisville, North Carolina 27560, Attn: Investor Relations. In addition, you can find those codes on our website at <http://www.furiex.com/investors/corporate-governance/>.

The information required by this Item concerning executive officers of the Registrant is set forth at the end of Part I of this report.

The information required by this Item concerning compliance with Section 16(a) of the United States Securities Exchange Act of 1934, as amended, is incorporated by reference from the section of the proxy statement captioned "—Section 16(a) Beneficial Ownership Reporting Compliance."

### Item 11. Executive Compensation

The information required by this Item is incorporated by reference to the information under the sections captioned "—Compensation for Non-Employee Directors," "—Compensation Discussion and Analysis," "—Summary Compensation Table," "—Grants of Plan Based Awards in Fiscal 2010," "—Outstanding Equity Awards at Fiscal Year-End 2010," "—Compensation Committee Report," and "—Compensation Committee Interlocks and Insider Participation" contained in the proxy statement.

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

#### Equity Compensation Plans

The following table sets forth the indicated information as of December 31, 2010 with respect to our equity compensation plans:

<u>Plan Category</u>	<u>Number of securities to be issued upon exercise of outstanding options, warrants and rights</u>	<u>Weighted-average exercise price of outstanding options, warrants and rights</u>	<u>Number of securities remaining available for future issuance under equity compensation plans</u>
Equity compensation plans approved by our shareholders .....	838,357	\$9.11	940,284
Equity compensation plans not approved by our shareholders .....	—	—	—
Total .....	838,357	\$9.11	940,284



Our equity compensation plan consists of the 2010 Stock Plan, which was approved by our stockholders. We do not have any equity compensation plans or arrangements that have not been approved by our stockholders.

The other information required by this Item is incorporated by reference to the information under the section captioned “—Security Ownership of Management and Certain Beneficial Owners” contained in the proxy statement.

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

The information required by this Item is incorporated by reference to the information under the section captioned “—Related Party Transactions” and “Proposal No. 1—Election of Directors—Information About the Board of Directors and its Committees” contained in the proxy statement.

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

The information required by this Item is incorporated by reference to the information under the section captioned “—Report of the Audit Committee” and “—Fees Paid to the Independent Registered Public Accounting Firm” contained in the proxy statement.

## PART IV

### Item 15. Exhibits, Financial Statement Schedules

#### (a) Financial Statements

Our combined and consolidated financial statements filed as part of this report are listed in the attached Index to Combined and Consolidated Financial Statements. There are no schedules to our combined and consolidated financial statements.

#### (b) Exhibits

<u>Exhibit No.</u>	<u>Exhibit Description</u>	<u>Registrant's Form</u>	<u>Dated</u>	<u>Exhibit Number</u>	<u>Filed Herewith</u>
2.1	Separation and Distribution Agreement by and between Furiex Pharmaceuticals, Inc. and Pharmaceutical Product Development, Inc.	8-K	6/18/10	2.1	
3.1	Amended and Restated Certificate of Incorporation.	10-12B	2/24/10	3.1	
3.2	Amended and Restated Bylaws.	10-12B	2/24/10	3.2	
10.1	Sublease Agreement dated as of June 14, 2010 by and between Furiex Pharmaceuticals, Inc. and PPD Development, LP.	8-K	6/18/10	10.2	
10.2	Tax Sharing Agreement dated as of June 14, 2010 by and between Furiex Pharmaceuticals, Inc. and Pharmaceutical Product Development, Inc.	8-K	6/18/10	10.3	
10.3	Employee Matters Agreement dated as of June 14, 2010 by and between Furiex Pharmaceuticals, Inc. and Pharmaceutical Product Development, Inc.	8-K	6/18/10	10.4	
10.4	Transition Services Agreement dated as of June 14, 2010 by and between Furiex Pharmaceuticals, Inc. and Pharmaceutical Product Development, Inc.	8-K	6/18/10	10.5	
10.5†	Master Development Services Agreement dated as of June 14, 2010 by and between Furiex Pharmaceuticals, Inc. and PPD Development, LP.	8-K	6/18/10	10.6	
10.6†	Mudelta Development and License Agreement dated as of November 16, 2009 by and between Janssen Pharmaceutica, N.V. and PPD Therapeutics, Inc., as amended February 9, 2010.	10-12B/A	5/14/10	10.6	
10.7†	Mudelta Master Services Agreement dated as of November 16, 2009 by and between Janssen Pharmaceutica, N.V. and PPD Therapeutics, Inc.	10-12B	2/24/10	10.7	
10.8†	Topo Development and License Agreement, dated as of November 16, 2009 by and between Janssen Pharmaceutica, N.V. and PPD Therapeutics, Inc., as amended February 15, 2010.	10-12B/A	5/14/10	10.8	
10.9†	Topo Master Services Agreement dated as of November 16, 2009 by and between Janssen Pharmaceutica, N.V. and PPD Therapeutics, Inc.	10-12B	2/24/10	10.9	

<u>Exhibit No.</u>	<u>Exhibit Description</u>	<u>Registrant's Form</u>	<u>Dated</u>	<u>Exhibit Number</u>	<u>Filed Herewith</u>
10.10†	License Agreement dated as of January 2, 2001 by and among Pharmaceutical Product Development, Inc., GenuPro, Inc. and ALZA Corporation, as amended December 26, 2003 and October 16, 2009.	10-12B/A	5/25/10	10.10	
10.11†	Agreement between Takeda San Diego, Inc, Takeda Pharmaceutical Company Limited, Development Partners LLC, and Pharmaceutical Product Development, Inc., dated as of July 13, 2005, as amended October 10, 2005.	10-12B/A	5/27/10	10.11	
10.12†	Termination and License Agreement dated as of December 18, 2003 by and among Eli Lilly and Company, Pharmaceutical Product Development, Inc., GenuPro, Inc. and APBI Holdings, LLC.	10-12B	2/24/10	10.12	
10.13†	Option and License Agreement effective as of December 15, 2006 among Pharmaco Investments, Inc. and Ranbaxy Laboratories Ltd.	10-12B/A	5/25/10	10.13	
10.16	Employment Agreement effective as of March 16, 2010 between Furiex Pharmaceuticals, Inc. and June S. Almenoff, M.D. Ph.D.	10-12B/A	5/14/10	10.16	
10.17	Employment Agreement effective as of April 1, 2010 between Furiex Pharmaceuticals, Inc. and Gail McIntyre.	10-12B/A	5/14/10	10.17	
10.18	Employment Agreement effective as of January 15, 2010 between Furiex Pharmaceuticals, Inc. and Paul S. Covington, M.D.	10-12B/A	5/14/10	10.18	
10.19	Employment Agreement effective as of January 29, 2010 between Furiex Pharmaceuticals, Inc. and Marshall Woodworth.	10-12B/A	5/14/10	10.19	
10.20	Form of Severance Agreement between Furiex Pharmaceuticals, Inc. and various individuals.	10-12B	2/24/10	10.20	
10.21	2010 Stock Plan.	10-12B	2/24/10	10.21	
10.22	Consulting Agreement by and between Furiex Pharmaceuticals, Inc., Elk Mountain Consulting, LLC, and Fredric N. Eshelman.	8-K	6/18/10	10.7	
21.1	Subsidiaries of Furiex Pharmaceuticals, Inc.				X
23.1	Consent of Independent Registered Public Accounting Firm.				X
31.1	Certification by the principal executive officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification by the principal financial officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1	Certification by the principal executive officer pursuant to 18 U.S.C. 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
32.2	Certification by the principal financial officer pursuant to 18 U.S.C. 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X

## 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.

FURIEX PHARMACEUTICALS, INC.

Date: March 18, 2011

By:                   /s/ JUNE S. ALMENOFF                    
 Name: **June S. Almenoff**  
 Title: **President**  
           **(Principal Executive Officer)**

By:                   /s/ MARSHALL WOODWORTH                    
 Name: **Marshall Woodworth**  
 Title: **Chief Financial Officer**  
           **(Principal Financial Officer)**

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/ JUNE S. ALMENOFF          </u> <b>June S. Almenoff</b>	President (Principal Executive Officer)	March 18, 2011
<u>          /s/ MARSHALL WOODWORTH          </u> <b>Marshall Woodworth</b>	Chief Financial Officer (Principal Financial and Accounting Officer)	March 18, 2011
<u>          /s/ FREDRIC N. ESHELMAN          </u> <b>Fredric N. Eshelman</b>	Chairman	March 18, 2011
<u>          /s/ STUART BONDURANT          </u> <b>Stuart Bondurant</b>	Director	March 18, 2011
<u>          /s/ PETER B. CORR          </u> <b>Peter B. Corr</b>	Director	March 18, 2011
<u>          /s/ WENDY L. DIXON          </u> <b>Wendy L. Dixon</b>	Director	March 18, 2011
<u>          /s/ STEPHEN W. KALDOR          </u> <b>Stephen W. Kaldor</b>	Director	March 18, 2011
<u>          /s/ ROBERT P. RUSCHER          </u> <b>Robert P. Ruscher</b>	Director	March 18, 2011

**FURIEX PHARMACEUTICALS, INC. AND SUBSIDIARIES**  
**INDEX TO COMBINED AND CONSOLIDATED FINANCIAL STATEMENTS**

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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of  
Furiex Pharmaceuticals, Inc.  
Morrisville, North Carolina

We have audited the accompanying combined and consolidated balance sheets of Furiex Pharmaceuticals, Inc. and subsidiaries (the "Company") as of December 31, 2009 and 2010, and the related combined and consolidated statements of operations, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2010. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such combined and consolidated financial statements present fairly, in all material respects, the financial position of Furiex Pharmaceuticals, Inc. and subsidiaries as of December 31, 2009 and 2010, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2010, in conformity with accounting principles generally accepted in the United States of America.

/s/ DELOITTE & TOUCHE LLP  
Raleigh, North Carolina

March 18, 2011

**FURIEX PHARMACEUTICALS, INC. AND SUBSIDIARIES**  
**COMBINED AND CONSOLIDATED STATEMENTS OF OPERATIONS**  
**FOR THE YEARS ENDED DECEMBER 31, 2008, 2009 AND 2010**  
*(in thousands)*

	<u>2008</u>	<u>2009</u>	<u>2010</u>
Revenue:			
Milestones .....	\$18,000	\$ 5,000	\$ 7,500
Royalties .....	—	923	1,330
Service .....	419	389	75
Other .....	—	—	78
Total revenue .....	<u>18,419</u>	<u>6,312</u>	<u>8,983</u>
Direct expenses .....	153	265	21
Research and development expenses (Note 14) .....	8,053	11,795	50,112
Selling, general and administrative expenses .....	1,738	2,551	8,262
Depreciation and amortization .....	94	10	109
Impairment of intangible assets .....	1,607	—	—
Total operating expenses .....	<u>11,645</u>	<u>14,621</u>	<u>58,504</u>
Operating income (loss) .....	6,774	(8,309)	(49,521)
Other income, net .....	14	10	9
Income (loss) from continuing operations before provision for income taxes .....	6,788	(8,299)	(49,512)
Provision for income taxes .....	—	—	14
Income (loss) from continuing operations .....	6,788	(8,299)	(49,526)
Loss from discontinued operations, net of income taxes .....	(976)	(632)	(5,133)
Net income (loss) .....	<u>\$ 5,812</u>	<u>\$ (8,931)</u>	<u>\$ (54,659)</u>
Income (loss) from continuing operations per basic and diluted share .....	<u>\$ 0.69</u>	<u>\$ (0.84)</u>	<u>\$ (5.01)</u>
Loss from discontinued operations, net of income taxes per basic and diluted share .....	<u>\$ (0.10)</u>	<u>\$ (0.06)</u>	<u>\$ (0.52)</u>
Net income (loss) per basic and diluted share .....	<u>\$ 0.59</u>	<u>\$ (0.90)</u>	<u>\$ (5.53)</u>
Weighted-average shares used to compute net income (loss) per basic and diluted share <sup>(1)</sup> : .....	9,881	9,881	9,881

(1) See discussion of share computation at Note 1.

The accompanying notes are an integral part of these combined and consolidated financial statements.

**FURIEX PHARMACEUTICALS, INC. AND SUBSIDIARIES**  
**COMBINED AND CONSOLIDATED BALANCE SHEETS**  
**AS OF DECEMBER 31, 2009 AND 2010**  
*(in thousands)*

	December 31, 2009	December 31, 2010
<b>Assets</b>		
Current assets:		
Cash and cash equivalents .....	\$ —	\$ 82,030
Accounts receivable and unbilled services, net .....	561	259
Prepaid expenses .....	41	226
Other current assets .....	3,464	740
Current assets of discontinued operations .....	1,969	—
Total current assets .....	6,035	83,255
Property and equipment, net .....	—	188
Goodwill .....	49,116	49,116
Long-term assets of discontinued operations .....	726	—
Total assets .....	\$55,877	\$132,559
<b>Liabilities and Shareholders' Equity</b>		
Current liabilities:		
Accounts payable .....	\$ 75	\$ 96
Accrued expenses (Note 14) .....	3,350	13,767
Current liabilities of discontinued operations .....	3,139	—
Total current liabilities .....	6,564	13,863
Other long-term liabilities .....	—	192
Long-term liabilities of discontinued operations .....	43	—
Total liabilities .....	6,607	14,055
Commitments and contingencies (Note 12)		
Common stock, \$0.001 par value, 40,000,000 shares authorized; 9,881,340 shares issued and outstanding at December 31, 2010 .....	—	10
Preferred stock, \$0.001 par value, 10,000,000 shares authorized; No shares issued and outstanding at December 31, 2010 .....	—	—
Paid-in capital .....	—	153,638
Pharmaceutical Product Development, Inc. net investment .....	49,270	—
Accumulated deficit .....	—	(35,144)
Total shareholders' equity .....	49,270	118,504
Total liabilities and shareholders' equity .....	\$55,877	\$132,559

The accompanying notes are an integral part of these combined and consolidated financial statements.



**FURIEX PHARMACEUTICALS, INC. AND SUBSIDIARIES**  
**COMBINED AND CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY**  
**FOR THE YEARS ENDED DECEMBER 31, 2008, 2009 AND 2010**  
*(in thousands)*

	Common Stock			Accumulated deficit	Parent Company Investment	Total
	Shares	Par value	Paid-in capital			
<b>Balance January 1, 2008</b> .....	—	\$—	\$ —	\$ —	\$ 56,870	\$ 56,870
Net transfers to parent .....	—	—	—	—	(7,158)	(7,158)
Net income .....	—	—	—	—	5,812	5,812
<b>Balance December 31, 2008</b> .....	—	\$—	\$ —	\$ —	\$ 55,524	\$ 55,524
Net transfers from parent .....	—	—	—	—	2,677	2,677
Net loss .....	—	—	—	—	(8,931)	(8,931)
<b>Balance December 31, 2009</b> .....	—	\$—	\$ —	\$ —	\$ 49,270	\$ 49,270
Net transfers from parent .....	—	—	—	—	16,046	16,046
Net liability retained by parent .....	—	—	—	—	6,637	6,637
Stock compensation expense .....	—	—	1,210	—	—	1,210
Contribution of cash and cash equivalents from parent .....	—	—	—	—	100,000	100,000
Contribution of net operating assets and liabilities to Furiex Pharmaceuticals, Inc. and issuance of common shares to Pharmaceutical Product Development, Inc. shareholders .....	9,881	10	152,428	—	(152,438)	—
Net loss and comprehensive loss .....	—	—	—	(35,144)	(19,515)	(54,659)
<b>Balance December 31, 2010</b> .....	<u>9,881</u>	<u>\$ 10</u>	<u>\$153,638</u>	<u>\$(35,144)</u>	<u>\$ —</u>	<u>\$118,504</u>

The accompanying notes are an integral part of these combined and consolidated financial statements.

**FURIEX PHARMACEUTICALS, INC. AND SUBSIDIARIES**  
**COMBINED AND CONSOLIDATED STATEMENTS OF CASH FLOWS**  
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*(in thousands)*

	<u>2008</u>	<u>2009</u>	<u>2010</u>
Cash flows from operating activities:			
Net income (loss) .....	\$ 5,812	\$ (8,931)	\$ (54,659)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Depreciation and amortization .....	1,413	1,271	1,169
Impairment of intangible assets .....	1,607	10,361	—
Stock compensation expense .....	—	—	1,210
Net gain on sale of businesses .....	—	(26,707)	—
Loss on disposal of assets, net .....	—	7	—
Changes in operating assets and liabilities, net of acquisitions:			
Accounts receivable and unbilled services, net .....	810	377	302
Prepaid expenses and other current assets .....	185	506	1,038
Accrued income taxes .....	(58)	—	—
Accounts payable .....	1,019	(1,050)	21
Accrued expenses .....	(1,739)	1,058	7,446
Deferred rent .....	(147)	(675)	(43)
Unearned income .....	144	(364)	—
Other long-term liabilities .....	—	—	192
Net cash provided by (used in) operating activities .....	<u>9,046</u>	<u>(24,147)</u>	<u>(43,324)</u>
Cash flows from investing activities:			
Purchases of property and equipment .....	(1,816)	(512)	(683)
Net proceeds from sale of businesses .....	—	40,267	3,464
Changes in restricted cash .....	—	(2,198)	—
Net cash paid for acquisition .....	—	(11,729)	—
Net cash provided by (used in) investing activities .....	<u>(1,816)</u>	<u>25,828</u>	<u>2,781</u>
Cash flows from financing activities:			
Net change in investment from parent .....	(7,230)	(1,675)	22,567
Cash contributed by parent .....	—	—	100,000
Net cash provided by (used in) financing activities .....	<u>(7,230)</u>	<u>(1,675)</u>	<u>122,567</u>
Net increase in cash and cash equivalents .....	—	6	82,024
Cash and cash equivalents, beginning of the year <sup>(2)</sup> .....	—	—	6
Cash and cash equivalents, end of the year .....	<u>\$ —</u>	<u>\$ 6</u>	<u>\$ 82,030</u>

(2) Cash and cash equivalents at December 31, 2009 related to discontinued operations. See Note 3.

The accompanying notes are an integral part of these combined and consolidated financial statements.

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**1. Summary of Operations and Significant Accounting Policies**

**Organization and Business Description**

In October 2009, the Board of Directors of Pharmaceutical Product Development, Inc. (“PPD” or the “Parent Company”) authorized management of PPD to proceed with preparations to spin-off its compound partnering business, previously part of the discovery science segment of PPD, from its contract research organization, or CRO, business. In order to carry out the proposed spin-off of the compound partnering business, PPD formed a new wholly-owned subsidiary, Furiex Pharmaceuticals, Inc., a Delaware corporation (“Furiex” or the “Company”), into which PPD transferred the compound partnering business, including assets, employees, intellectual property rights and liabilities comprising that business, and \$100.0 million in cash, as of the closing date of the spin-off, June 14, 2010. PPD effected the spin-off through a tax-free, pro-rata dividend distribution of all of the shares of the Company to PPD shareholders. PPD does not have any ownership or other form of equity interest in the Company following the spin-off.

In connection with the spin-off, the Company and PPD entered into a series of agreements, including a separation and distribution agreement, transition services agreement, sublease and license agreements, employee matters agreement, tax sharing agreement and a master development services agreement.

Furiex is a drug development company that continues the compound partnering business started by PPD in 1998. The goal of compound partnering is to in-license from, or form strategic alliances with, pharmaceutical and biotechnology companies to develop therapeutics in which the risks and rewards are shared. The Company’s operations are headquartered in Morrisville, North Carolina.

The Company has incurred losses and negative cash flows from operations since spin-off. Based on current operating plans, the Company believes it has sufficient liquidity to continue its planned operations beyond 2011. The Company’s long term liquidity needs will largely be determined by the success of its products already in commercialization with partners, key development and regulatory events that may impact the Company’s ability to out-license its development compounds and the receipt of milestone payments related to various development activities. Depending upon the success and timing of receipt of various milestone payments and royalties it may be necessary to do one or more of the following in the future (a) raise additional capital through equity or debt financings or from other sources; (b) reduce spending on one or more research and development programs; and (c) restructure the Company’s operations. The Company currently receives revenue from royalties on sales of Nesina and Priligy. The Company will continue to incur operating losses until revenues from all sources reach a level sufficient to support its ongoing operations.

**Basis of Accounting**

The accompanying combined and consolidated financial statements, through the date of the spin-off from PPD, have been derived from the combined financial statements and accounting records of PPD from the historical cost basis of the assets and liabilities of the various activities that reflect the combined results of operations, financial condition and cash flows of the discovery sciences segment of PPD. All the business components of the discovery sciences segment have been included in the historical statements because they were managed by common segment management, and because they reflect the historical performance of PPD segment management.

Because a direct ownership relationship did not exist among all the components comprising the Company, PPD’s net investment in the Company is shown in lieu of shareholders’ equity in the combined financial

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statements prior to the spin-off. The net investment account for 2009 represents the cumulative investments in, distributions from and earnings (loss) of the Company.

Prior to the spin-off, all cash was held and managed by PPD. Accordingly, cash used to pay the Company's expenses or cash collected from collaboration agreements, royalties or customer contracts by PPD on behalf of the Company was recorded as an increase or decrease in PPD's net investment, with the exception of a small amount of petty cash that was part of an acquisition in 2009 that is included in the combined and consolidated balance sheet within current assets of discontinued operations as of December 31, 2009.

In 2009, PPD completed its disposition of Piedmont Research Center, LLC and PPD Biomarker Discovery Sciences, LLC, both of which were included in the discovery sciences segment of PPD. Due to the unique service offerings of these two subsidiaries, PPD determined these business units were no longer a long-term strategic fit and elected to sell them. In May 2010, PPD discontinued the operations of its wholly owned subsidiary, PPD Dermatology, Inc., due to unfavorable efficacy data associated with its MAG-131 program. These business units are recorded as discontinued operations in the accompanying combined and consolidated financial statements. Additionally, the discovery sciences segment of PPD included pre-clinical consulting services that are not being offered by Furiex after the spin-off. All rights and obligations related to pre-clinical consulting services and the definitive purchase agreements related to Piedmont Research Center, LLC, PPD Biomarker Discovery Sciences, LLC and PPD Dermatology, Inc. were retained by PPD.

The Company was allocated certain expenses from PPD, such as executive oversight, risk management, accounting, tax, legal, investor relations, human resources, information technology, stock compensation, and facilities services and depreciation, but was not allocated the underlying productive assets, such as certain information systems equipment, furniture and facilities that were not assigned to the Company but from which the Company benefited. Such expenses have been included in the combined and consolidated financial statements as expense allocations from PPD for periods prior to the spin-off. The basis of these allocations included full-time equivalent employees for the respective periods presented and square footage of occupied space. See Note 14 for further discussion of the allocations.

Management believes that the assumptions and allocations underlying the combined and consolidated financial statements are reasonable. The financial information in these combined and consolidated financial statements does not include all of the expenses that would have been incurred had the Company been a separate, stand-alone publicly traded entity prior to the spin-off. The combined and consolidated financial statements include the operations of Piedmont Research Center, LLC, PPD Biomarker Discovery Sciences, LLC, and PPD Dermatology, Inc. Pre-clinical consulting services were not contributed to the Company at the time of the spin-off. As such, the financial information herein does not reflect the results of operations or cash flows of the Company had it been a separate, stand-alone entity during the periods presented.

**Principles of Combination and Consolidation**

The accompanying combined and consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP, and include the accounts of Furiex Pharmaceuticals, Inc. and Subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

**Use of Estimates in Preparation of the Financial Statements**

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and

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liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

**Earnings Per Share**

The net income (loss) per basic and diluted share is calculated by dividing net income (loss) by the weighted-average number of shares outstanding during the reporting period. For all periods presented, the computation of net income (loss) per basic and diluted share and the weighted-average shares outstanding are calculated based on the 9,881,340 shares issued in connection with the spin-off on June 14, 2010. The calculation of net income (loss) per diluted share is the same as net income (loss) per basic share since the inclusion of any potentially dilutive securities would be anti-dilutive for the year ended December 31, 2010. For the years ended December 31, 2008 and 2009, the calculation of net income (loss) per diluted share is the same as net income (loss) per basic share since there were no outstanding dilutive securities for those periods. As discussed in Note 9, all potentially dilutive securities relate to 839,642 stock options issued as part of the Company's share-based compensation plan in June 2010 after the spin-off from PPD.

**Separation Costs**

The Company incurred legal, tax and other costs specifically associated with the spin-off, which are recorded as a component of selling, general and administrative expenses. These amounts for the year ended December 31, 2010 were \$2.6 million.

**Revenue Recognition**

The Company generates revenue in the form of upfront payments, development and regulatory milestone payments, royalties and sales-based milestone payments in connection with the out-licensing of compounds. The payment of future milestones and royalties will depend on the success of the Company's compound development and the Company's collaborators' success in developing and commercializing compounds. Upfront payments are generally paid within a short period of time following the execution of an out-license and collaboration agreement. Milestone payments are typically one-time payments to the Company triggered by the collaborator's achievement of specified development and regulatory events such as the commencement of Phase III trials or regulatory submission approval. Royalties are payments received by the Company based on net product sales of a collaborator. Sales-based milestone payments are typically one-time payments to the Company triggered when aggregate net sales of product by a collaborator for a specified period (for example, an annual period) reach an agreed upon threshold amount. The Company recognizes upfront payments, development and regulatory payments, royalty payments, and sales-based milestone payments from its collaborators when the event which triggers the obligation of payment has occurred, there is no further obligation on the Company's part in connection with the payment, and collection is reasonably assured.

The Company has also historically recorded revenue from service contracts, other than time-and-material contracts, on a proportional performance basis. To measure performance under these contracts on a given date, the Company compared effort expended to date to the estimated total effort to be expended to complete the contract using metrics such as the number of units to be delivered. Changes in the estimated total effort required to complete a contract without a corresponding proportional change to the contract value resulted in a cumulative adjustment to the amount of revenue recognized in the period the change in estimate was determined. For time-and-material contracts, the Company recognized revenue as hours were worked, multiplied by the applicable hourly rate. All service contracts remained with PPD.

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**Concentration of Credit Risk**

The Company's collaborators, which are its current sources of revenue, are primarily pharmaceutical companies. One collaborator accounted for the majority of the Company's revenue for the year ended December 31, 2009. A different collaborator accounted for the majority of the Company's revenue for the year ended December 31, 2010. A concentration of credit risk with respect to revenue exists due to the small number of collaborators. One collaborator accounted for 100% of the Company's receivable balance as of December 31, 2009. Two collaborators accounted for 100% of the Company's receivable balance as of December 31, 2010.

**Research and Development Expenses**

Research and development costs consist primarily of costs associated with pre-clinical studies, non-clinical studies and the clinical trials of the Company's product candidates, development materials, patent costs, labor and related benefit charges associated with personnel performing research and development work, supplies associated with this work, consulting services, and an allocation of facility and information technology costs. The Company charges research and development costs to operations as incurred, and discloses them in the combined and consolidated statements of operations.

These costs include clinical research services provided by PPD, pre-clinical testing and clinical drug manufacturing provided by third parties, the direct cost of the Company's personnel managing the programs and upfront and milestone payments to the Company's collaborators.

**Income Taxes**

The income tax provision for the periods prior to June 14, 2010 has been calculated using the separate return basis as if the Company had filed separate income tax returns under its existing structure. The provision for income taxes subsequent to the spin-off has been determined using the asset and liability approach of accounting for income taxes. Under this approach, deferred taxes represent the future tax consequences expected to occur when the reported amounts of assets and liabilities are recovered or paid. The provision for income taxes represents income taxes paid or payable for the year, plus the change in deferred taxes during the year. Deferred taxes result from differences between the financial reporting and tax basis of the Company's assets and liabilities. Deferred tax assets and liabilities are measured using the currently enacted tax rates that apply to taxable income in effect for the years in which those tax attributes are expected to be recovered or paid, and are adjusted for changes in tax rates and tax laws when changes are enacted.

Valuation allowances are recorded to reduce deferred tax assets when it is more likely than not that a tax benefit will not be realized. The assessment of whether or not a valuation allowance is required often requires significant judgment, including the long-range forecast of future taxable income and the evaluation of tax planning initiatives. Adjustments to the deferred tax valuation allowances are made to earnings in the period when such assessments are made. Due to the historical losses from the Company's operations, a full valuation allowance on deferred tax assets has been recorded.

**Share-Based Compensation**

The Company recognizes compensation expense using a fair-value based method related to stock options and other share-based compensation. The expense is measured based on the grant date fair value of the awards that are expected to vest and is recorded over the applicable requisite service period. In the absence of an observable market price for a share-based award, the fair value is based upon a valuation methodology that takes

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into consideration various factors, including the exercise price of the award, the expected term of the award, the current price of the underlying shares, the expected volatility of the underlying share price based on peer companies, the expected dividends on the underlying shares and the risk-free interest rate.

**Property and Equipment**

The Company records property and equipment at cost less accumulated depreciation. The Company records depreciation using the straight-line method, based on the following estimated useful lives:

Furniture and equipment .....	5-10 years
Computer equipment and software .....	2-5 years

**Operating Leases**

The Company records rent expense for operating leases on a straight-line basis over the term of the lease. The Company begins amortization on the date of initial possession, which is generally when the Company enters the space and begins to make improvements in preparation for its intended use. The Company accounts for the difference between rent expense and rent paid as deferred rent. The Company records a deferred rent liability at the inception of the lease term and amortizes the deferred rent over the term of the lease as a reduction to rent expense.

**Goodwill**

The excess of the purchase price of a business acquired over the fair value of net tangible assets and identifiable intangible assets at the date of the acquisition has been assigned to goodwill. The Company evaluates goodwill for impairment on an annual basis at October 1 or more frequently if events or changes in circumstances indicate that goodwill might be impaired. Any impairment could have a material adverse effect on the Company's financial condition and results of operations.

**Acquired In-Process Research and Development (IPR&D)**

Acquired IPR&D represents the fair value assigned to research and development programs that the Company acquires that have not been completed at the date of acquisition and which have no future alternative use. The value assigned to acquired IPR&D is determined by estimating the costs to develop the acquired technology into commercially viable products, estimating the resulting net cash flows from the projects, and discounting the net cash flows to present value. Additionally, the Company's estimates take into account the relevant market size and growth factors, expected trends in technology, and the nature and expected timing of new product introductions by the Company and its competitors. The resulting net cash flows from such programs are based on management's estimates of cost of sales, operating expenses, and income taxes from such programs. The rates utilized to discount the net cash flows to their present value were commensurate with the stage of development of the program and uncertainties in the economic estimates used in the projections described above. Acquired IPR&D assets are amortized, once the related project has been successfully developed and regulatory approval for a product launch obtained, over their estimated useful lives. As of December 31, 2009 and 2010, there was no IPR&D recorded on the Company's combined and consolidated balance sheets.

**Realizability of Carrying Value of Long-Lived Assets**

The Company reviews the recoverability of long-lived and finite-lived intangible assets when circumstances indicate that the carrying amount of assets might not be recoverable. This evaluation is based on various

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analyses, including undiscounted cash flow projections. In the event undiscounted cash flow projections indicate impairment, the Company would record an impairment based on the fair value of the assets at the date of the impairment.

**Recent Accounting Pronouncements**

In March 2010, the Financial Accounting Standards Board, or FASB, issued a new accounting standard, the objective of which is to establish a revenue recognition model for contingent consideration that is payable upon the achievement of an uncertain future event, referred to as a milestone. This consensus will apply to milestones in single or multiple-deliverable arrangements involving research and development transactions, and will be effective for fiscal years (and interim periods within those fiscal years) beginning on or after June 15, 2010. The Company does not expect the adoption of this standard to have a material impact on its combined and consolidated financial statements.

In October 2009, the FASB issued a new accounting standard related to the accounting for revenue arrangements with multiple deliverables. This standard applies to all deliverables in contractual arrangements in all industries in which a vendor will perform multiple revenue-generating activities. This standard also addresses the unit of accounting for an arrangement involving multiple deliverables and how arrangement consideration should be allocated. This standard will be effective for fiscal years beginning on or after June 15, 2010. The Company does not expect the adoption of this standard to have a material impact on its combined and consolidated financial statements.

**2. Spin-off from Pharmaceutical Product Development Inc.**

On June 14, 2010, PPD spun off its compound partnering business through the spin-off of Furiex. PPD contributed substantially all of the compound partnering business components of the discovery sciences segment and \$100 million of cash to Furiex. All outstanding shares of Furiex were then distributed to PPD shareholders of record on June 1, 2010 as a pro-rata, tax-free dividend of one share of Furiex common stock for every twelve shares of PPD's common stock.

In connection with the spin-off, PPD and Furiex entered into a series of agreements, including a separation and distribution agreement, transition services agreement, sublease and license agreements, employee matters agreement, tax sharing agreement and a master development services agreement.

The total amount of the Furiex contribution of \$152.4 million was based on the book value of the net assets that were transferred to Furiex in connection with the spin-off, as follows:

	<b>2010</b>
Net book value of assets transferred:	
Cash . . . . .	\$100,000
Accounts receivable . . . . .	7,705
Prepaid expenses . . . . .	100
Property and equipment, net . . . . .	18
Goodwill . . . . .	49,116
Accounts payable . . . . .	(758)
Accrued expenses and other current liabilities . . . . .	(3,542)
Long-term liabilities . . . . .	(201)
Net assets transferred . . . . .	\$152,438



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**3. Acquisitions and Dispositions**

**Magen Biosciences, Inc.**

In April 2009, PPD acquired 100 percent of the outstanding equity interests of Magen BioSciences, Inc., or Magen, a biotechnology company focused on the development of dermatologic therapies, for total consideration of \$14.9 million. Of this amount, PPD paid \$13.1 million at closing and deposited the remaining \$1.8 million into an escrow account to secure indemnification claims. None of the business assets or liabilities of Magen, including the funds in the escrow account, were contributed to the Company in the spin-off, and all rights and liabilities remained with PPD after the spin-off on June 14, 2010.

Acquisition costs related to Magen were \$0.2 million and were included in selling, general and administrative expenses in the combined and consolidated statements of operations.

PPD accounted for this acquisition under the purchase method of accounting. Accordingly, the purchase price for this acquisition was allocated to the estimated fair value of assets acquired and liabilities assumed, which are set forth in the following table:

	<u>Magen</u>
Assets acquired:	
Current assets, including cash of \$939 .....	\$ 2,991
Net property and equipment .....	609
Goodwill .....	3,987
Value of identifiable intangible assets:	
In-process research and development .....	10,361
Total assets acquired .....	\$17,948
Liabilities assumed:	
Current liabilities .....	\$ 3,082
Total liabilities assumed .....	3,082
Net assets acquired .....	\$14,866

The goodwill associated with PPD's acquisition of Magen was associated with PPD's anticipated access to additional dermatology compounds. The acquired in-process research and development listed above was related solely to the MAG-131 research program. PPD filed an IND for MAG-131 in October 2009 but subsequently suspended the program for that compound due to unfavorable efficacy data that was discovered in late 2009. As a result, PPD evaluated the asset for impairment and determined the asset was impaired and recorded a charge of \$10.4 million as of December 31, 2009, presented in discontinued operations in the accompanying combined and consolidated statement of operations. As described below, in May 2010, PPD subsequently discontinued the operations of its wholly owned subsidiary PPD Dermatology, Inc., formerly Magen.

**Piedmont Research Center, LLC and PPD Biomarker Discovery Sciences, LLC**

In May 2009, PPD completed its disposition of substantially all of the assets of its wholly owned subsidiary Piedmont Research Center, LLC for total consideration of \$46.0 million. The purchaser had an indemnification

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holdback of \$3.5 million which PPD had included as a component of other current assets. PPD received this additional payment in the first quarter of 2010. Piedmont Research Center, LLC provided pre-clinical research testing services for clients with anti-cancer and other therapeutic candidates.

In December 2009, PPD completed its disposition of PPD Biomarker Discovery Sciences, LLC for total consideration of \$0.1 million and the right to receive a percentage of future revenues. This right remained with PPD as part of the spin-off. PPD Biomarker Discovery Sciences, LLC provided biomarker discovery services.

**Discontinued Operations**

Due to the unique service offerings of Piedmont Research Center, LLC and PPD Biomarker Discovery Sciences, LLC, PPD determined these business units were no longer a long-term strategic fit and elected to sell them. As a result, these business units are shown as discontinued operations for 2008 and 2009.

Due to unfavorable efficacy data associated with the MAG-131 program, PPD discontinued the operations of its wholly owned subsidiary PPD Dermatology, Inc. As a result, this business unit is shown as discontinued operations for 2009 and 2010.

The results of these business units are reported as discontinued operations within the combined and consolidated statements of operations as set forth in the following table:

	<u>2008</u>	<u>2009</u>	<u>2010</u>
Revenue .....	\$18,517	\$ 7,058	\$ —
Gain on sale of business .....	—	26,707	—
Loss from discontinued operations .....	<u>(976)</u>	<u>(27,339)</u>	<u>(5,133)</u>
Loss from discontinued operations, net of income taxes .....	<u>\$ (976)</u>	<u>\$ (632)</u>	<u>\$(5,133)</u>

Included in the combined and consolidated balance sheet as of December 31, 2009 were the following assets and liabilities related to discontinued operations:

Current assets of discontinued operations:	
Cash and cash equivalents .....	\$ 6
Prepaid expenses .....	128
Other current assets .....	<u>1,835</u>
Total current assets of discontinued operations .....	<u>\$1,969</u>
Total long-term assets of discontinued operations:	
Property and equipment, net .....	<u>\$ 726</u>
Total current liabilities of discontinued operations:	
Accrued expenses .....	<u>\$3,139</u>
Total long-term liabilities of discontinued operations:	
Deferred rent .....	<u>\$ 43</u>

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**4. Accounts Receivable and Unbilled Services**

Accounts receivable and unbilled services consisted of the following amounts on the dates set forth below:

	<u>December 31,</u>	
	<u>2009</u>	<u>2010</u>
Billed .....	\$551	\$259
Unbilled .....	10	—
Total accounts receivable and unbilled services .....	<u>\$561</u>	<u>\$259</u>

The Company did not record a provision for doubtful accounts as of December 31, 2009 and 2010 based on its assessment of collection risks. The December 31, 2010 balance of accounts receivable and unbilled services relate entirely to royalty receivables related to Priligy and Nesina based on net product sales by the Company's collaborators.

**5. Property and Equipment**

Property and equipment, stated at cost, consisted of the following amounts on the dates set forth below:

	<u>December 31,</u>	
	<u>2009</u>	<u>2010</u>
Furniture and equipment .....	\$—	\$ 30
Computer equipment and software .....	17	214
Total property and equipment .....	—	244
Less accumulated depreciation .....	(17)	(56)
Total property and equipment, net .....	<u>\$—</u>	<u>\$188</u>

**6. Goodwill and Intangible Assets**

The Company reviews goodwill for impairment annually on October 1 and whenever events or changes in circumstances indicate that the carrying amount of an asset might not be recoverable. This analysis utilizes a discounted cash flow method using the expected future inflows and outflows of the business and an appropriate discount rate. Based on the review as of October 1, 2010, the Company's calculated fair value of equity was in excess of carrying value by approximately 38%.

The fair value of goodwill could be materially impacted by future adverse changes such as future declines in operating results, a decline in the valuation of pharmaceutical and biotechnology company stocks, including the valuation of the Company's own common stock, a further significant slowdown in the worldwide economy or the pharmaceutical and biotechnology industry, failure to meet the performance projections included in forecasted operating results or the delay or abandonment of any research and development programs.

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Changes in the carrying amount of goodwill for the twelve months ended December 31, 2009 and 2010 were as follows:

	<b>Total</b>
Balance as of January 1, 2009 .....	\$45,129
Goodwill recorded during the period for acquisition .....	3,987
Balance as of December 31, 2009 .....	\$49,116
Year-to-date activity .....	—
Balance as of December 31, 2010 .....	\$49,116

During 2009, PPD acquired in-process research and development of \$10.4 million through the acquisition of Magen, which was related solely to the MAG-131 research program. At the time of acquisition, this program was in the pre-IND application phase of research. PPD estimated that it would take approximately four to five years to complete research and development. The fair value of the in process research and development was determined using the discounted cash flow method. The discounted cash flow was determined based upon projected revenue, expenses and contributory assets related to the specific project and a discount rate based upon the overall weighted average cost of capital for the asset and the additional risk related to the uncertainty of the project. PPD also assessed the current status of development, nature and timing of efforts to complete such development, uncertainties, and other factors when estimating the fair value.

PPD filed an IND for MAG-131 in October 2009 but subsequently suspended the program for that compound due to unfavorable efficacy data that was discovered in late 2009. As a result, PPD evaluated the asset for impairment. PPD reassessed the fair value of the program using a discounted cash flow model based on Level 3 inputs such as the estimated remaining costs to develop the acquired technology into commercially viable products, estimated net cash flows from the program, and a discount rate commensurate with the stage of development of the program. Based on this analysis, PPD determined that the acquired in-process research and development asset was impaired and recorded a charge of \$10.4 million as of December 31, 2009, presented in discontinued operations in the accompanying combined and consolidated statements of operations. Because the intangible asset was an indefinite-lived asset, PPD had not amortized this asset during 2009.

In September 2004, PPD entered into a royalty agreement with Accentia Biopharmaceuticals, Inc. under which it paid \$2.5 million to Accentia in exchange for the right to receive royalties on sales of specified antifungal products, primarily SinuNase. During 2008, Accentia reported that SinuNase did not meet its goal in treating chronic sinusitis patients in its Phase III clinical trial, discontinued the sale of all antifungal products, and filed for bankruptcy. As a result, PPD determined that the right under its agreement with Accentia to receive royalties on future sales of SinuNase was impaired, and recorded an impairment of \$1.6 million for the remaining unamortized value of its royalty interest in SinuNase as of December 31, 2008, presented in continuing operations in the accompanying combined and consolidated statements of operations.

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**7. Accrued Expenses**

Accrued expenses consisted of the following amounts on the dates set forth below:

	December 31,	
	2009	2010
Accrued salaries, wages, benefits and related costs .....	\$ 397	\$ 1,225
Accrued research and development costs .....	825	12,225
Professional fees .....	1,773	131
Other .....	355	186
	\$3,350	\$13,767

**8. Lease Obligations**

The Company is currently obligated under noncancellable operating subleases for six locations. These subleases with PPD expire at various dates through 2011 and 2012, with renewal terms for up to one year, relating to office space and associated building expenses. Prior to the spin-off, the Company recognized noncancellable operating lease expense for leases which were acquired as part of the Magen acquisition. However, these operating leases obligations remained with PPD as of the spin-off date.

Rental expense related to operating leases has been recorded in continuing operations in the amounts of \$0.09 million for the year ended December 31, 2010 and in discontinued operations in the amounts of \$0.0 million and \$0.3 million for the year ended December 31, 2008 and 2009, respectively.

As of December 31, 2010, future minimum payments for lease obligations for subsequent years were as follows:

2011 .....	\$105
2012 .....	47
	\$152

**9. Share-Based Compensation**

**Equity Compensation Plan—Furiex Plan**

The Company has adopted an equity incentive plan, the Furiex Pharmaceuticals, Inc. 2010 Stock Plan (the "Plan"). The Company is authorized to issue a total of 1,778,641 shares under the Plan. The Plan is intended to provide incentives to employees, directors and consultants through the issuance of common stock-based awards, including restricted stock, stock options, stock appreciation rights and other equity based awards. The plan is administered by a committee designated by its board of directors.

During the year ended December 31, 2010, the Company granted 839,642 stock options to employees, directors, and consultants, with a weighted-average exercise price of \$9.11. All options were granted with an exercise price equal to the fair value of the Company's common stock on the grant date. The fair value of the Company's common stock on the grant date is equal to the most recent Nasdaq closing price of the Company's stock on the date of grant.

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The Company recognizes compensation expense using a fair-value based method related to stock options and other share-based compensation. The expense is measured based on the grant date fair value of the awards that are expected to vest and is recorded over the applicable requisite service period on a straight-line basis. The options granted vest either after a period of one year or ratably over three years on the anniversary date of grant. The options expire on the earlier of ten years from the date of grant, or within specified time limits following termination of employment, retirement or death. Shares are issued from authorized, but unissued stock. The Company does not pay dividends on unexercised options.

The weighted-average grant date fair value per share was determined using the Black-Scholes option-pricing method. The weighted-average grant date fair value per share and aggregate fair value of options granted to employees and directors during the year ended December 31, 2010 was \$5.95 and \$3.8 million, respectively. The weighted-average grant date fair value per share and aggregate fair value of options granted to consultants during the year ended December 31, 2010, was \$7.36 and \$1.5 million, respectively.

The amount of stock compensation expense related to consultant option grants, classified in selling, general and administrative expenses within the combined and consolidated statements of operations, is marked to market at the end of each financial reporting period until such options vest using the Black-Scholes option-pricing method and the period end closing stock price. These non-employee grants relate to a consulting agreement executed with the Company's founding Chairman, Dr. Fred Eshelman. The terms of this consulting agreement provide for a grant of stock options to purchase shares of the Company's common stock equal to 2.0% of the Company's common stock outstanding immediately after the completion of the spin-off, and additional stock options for an additional 1.0% on the second anniversary of the spin-off date.

For the year ended December 31, 2010, stock-based compensation cost for the Company's employees, directors and consultants under the Plan totaled \$1.2 million and is included in the accompanying combined and consolidated financial statements. For the year ended December 31, 2010, no cash was received by the Company from the exercise of stock options granted by the Company as no options vested during the year.

A summary of option activity for the Plan as of December 31, 2010, and changes during the year, is presented below:

	<u>Shares</u>	<u>Weighted-Average Exercise Price</u>	<u>Weighted-Average Remaining Contractual Life</u>	<u>Aggregate Intrinsic Value</u>
Outstanding at January 1, 2010 . . . . .	—	\$ —		
Granted . . . . .	840	9.11		
Exercised . . . . .	—	—		
Forfeited . . . . .	(1)	9.11		
Expired . . . . .	—	—		
Outstanding at December 31, 2010 . . . . .	<u>839</u>	<u>\$9.11</u>		
Exercisable at December 31, 2010 . . . . .	—	—		—
Vested or expected to vest at December 31, 2010 . . . . .	<u>794</u>	<u>\$9.11</u>	<u>9.5 years</u>	<u>\$4,237</u>

The aggregate fair value of the Plan's options granted to the Company's employees, directors and consultants during the years ended December 31, 2010 was \$5.3 million. The total intrinsic value (the amount by

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which the market value of the Company's common stock exceeded the exercise price of the options on the date of exercise) of options exercised during the year ended December 31, 2010 was zero as no options vested, and none were exercised during the year.

A summary of the status of unvested options held by the Company's employees, directors and consultants as of December 31, 2010, and changes during the year then ended, is presented below:

<u>Unvested Options</u>	<u>Shares</u>	<u>Weighted-Average Grant Date Fair Value</u>
Unvested at January 1, 2010 .....	—	\$ —
Granted .....	840	5.99
Vested .....	—	—
Forfeited .....	<u>(1)</u>	<u>5.97</u>
Unvested at December 31, 2010 .....	<u>839</u>	<u>\$5.99</u>

As of December 31, 2010, unrecognized compensation expense related to the unvested portion of the Company's stock options granted to employees, directors and consultants was approximately \$4.7 million, and will be recognized over a weighted-average period of 2.33 for employees and directors and 2.46 years for consultants.

The following table indicates the assumptions used in estimating fair value of each Plan option granted to employees and directors for the years ended December 31, 2010.

	<u>2010</u>
Expected term (years) .....	5.50-6.00
Dividend yield (%) .....	—
Risk-free interest rate (%) .....	2.19-2.40
Expected volatility (%) .....	70.99-71.94

The following table indicates the assumptions used in estimating fair value of each Plan option granted to consultants for the years ended December 31, 2010.

	<u>2010</u>
Expected term (years) .....	10.00
Dividend yield (%) .....	—
Risk-free interest rate (%) .....	3.27
Expected volatility (%) .....	73.81

Expected option lives were based on the simplified method and volatilities used in fair valuation calculations are based on a benchmark of peer companies with similar expected lives. The Company does not currently intend to pay dividends on common stock; as a result, no dividend yield has been utilized in the fair valuation calculation. The risk-free interest rate is based on the rate at the date of grant for actively traded non-inflation-indexed issues adjusted to constant maturities with a term that approximates the expected term of the option.

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**Equity Compensation Plan—PPD Plan**

For the periods prior to June 14, 2010, some Company employees participated in PPD's equity compensation plan (the "PPD Plan"). The PPD Plan provided for the grant of incentive stock options, non-qualified stock options, restricted stock and other types of equity awards to its directors, officers, employees and consultants. The plan was administered by a committee designated by PPD's board of directors. Some employees of the Company have historically received awards from PPD. Accordingly, the following information regarding share-based compensation has been derived from the equity awards granted to Company employees by PPD prior to June 14, 2010. All unvested options granted under the PPD Plan to Company employees were forfeited as of the spin-off date.

The exercise price of each option granted under the PPD Plan was equal to the market price of PPD's common stock on the date of grant, and the maximum exercise term of each option granted did not exceed ten years. Options were granted upon approval of the compensation committee of the board of directors of PPD. The majority of the options vested ratably over a period of three years. The options expire on the earlier of ten years from the date of grant, or within specified time limits following termination of employment, retirement or death. Shares are issued from authorized, but unissued stock. PPD does not pay dividends on unexercised options.

For the years ended December 31, 2008, 2009 and 2010, stock-based compensation cost for the Company's employees under the PPD Plan totaled \$0.4 million, \$0.3 million and \$0.1 million, respectively, and is included in the accompanying combined and consolidated financial statements.

For the years ended December 31, 2008, 2009 and 2010, the amount of cash received by PPD from the exercise of PPD stock options granted to the Company's employees was \$0.7 million, \$1.1 million and \$0.0 million, respectively.



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A summary of option activity under PPD's plan for the Company's employees as of December 31, 2008, 2009 and 2010, and changes during the years, is presented below:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding at January 1, 2008	210	\$25.60		
Granted	78	37.77		
Exercised	(47)	21.41		
Forfeited	(6)	33.34		
Expired	—	—		
Outstanding at December 31, 2008	<u>235</u>	<u>\$30.33</u>		
Exercisable at December 31, 2008	<u>120</u>	<u>\$24.40</u>		
Outstanding at January 1, 2009	235	\$30.33		
Granted	95	27.01		
Exercised	(5)	16.46		
Forfeited	(60)	32.01		
Expired	(28)	28.82		
Outstanding at December 31, 2009	<u>237</u>	<u>\$29.02</u>		
Exercisable at December 31, 2009	<u>154</u>	<u>\$27.96</u>		
Outstanding at January 1, 2010	237	\$29.02		
Granted	—	—		
Exercised	—	—		
Forfeited	(100)	28.88		
Expired	(1)	37.42		
Outstanding at December 31, 2010	<u>136</u>	<u>\$27.38</u>		
Exercisable at December 31, 2010	<u>136</u>	<u>\$27.38</u>	4.8 years	\$(191)
Vested at December 31, 2010	<u>136</u>	<u>\$27.38</u>	4.8 years	\$(191)

The following table summarizes information about PPD's stock options outstanding for the Company's employees as of December 31, 2010:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding at 12/31/10	Weighted-Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable at 12/31/10	Weighted- Average Exercise Price
\$19.94 – 21.00	71	5.9 years	\$20.45	71	\$20.45
\$21.01 – 34.00	46	3.8 years	\$31.29	46	\$31.29
\$34.01 – 43.26	19	6.7 years	\$42.26	19	\$42.26
	<u>136</u>	<u>4.8 years</u>	<u>\$27.38</u>	<u>136</u>	<u>\$27.38</u>

All PPD Plan options granted during the years ended December 31, 2008 and 2009 were granted with an exercise price equal to the fair value of PPD's common stock on the grant date. The fair value of PPD's common

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stock on the grant date is equal to the Nasdaq closing price of the stock on the date of grant. The weighted-average grant date fair value per share of PPD Plan options granted to the Company's employees during the years ended December 31, 2008 and 2009 was \$9.33 and \$7.55, respectively. The aggregate fair value of PPD Plan options granted to the Company's employees during the years ended December 31, 2008 and 2009 was \$0.7 million and \$0.7 million, respectively. The total intrinsic value (the amount by which the market value of PPD's common stock exceeded the exercise price of the options on the date of exercise) of options exercised during the years ended December 31, 2008 and 2009 was approximately \$1.0 million and \$0.02 million, respectively.

A summary of the status of unvested PPD options held by the Company's employees as of December 31, 2010, and changes during the year then ended, is presented below:

<u>Unvested Options</u>	<u>Shares</u>	<u>Weighted-Average Grant Date Fair Value</u>
Unvested at January 1, 2010 . . . . .	83	\$7.80
Granted . . . . .	—	—
Vested . . . . .	(25)	8.88
Forfeited . . . . .	(58)	7.34
Unvested at December 31, 2010 . . . . .	<u>—</u>	<u>\$ —</u>

As of December 31, 2010, there was no unrecognized compensation cost related to unvested PPD stock options held by the Company's employees as all unvested PPD Plan options which were not vested as of the spin-off date were forfeited. The total fair value of shares vested during the years ended December 31, 2008, 2009 and 2010 was \$0.7 million, \$0.6 million and \$0.2 million, respectively.

The fair value of each PPD Plan option grant was estimated on the grant date using the Black-Scholes option-pricing model. The following table indicates the assumptions used in estimating fair value for the years ended December 31, 2008 and 2009.

	<u>2008</u>	<u>2009</u>
Expected term (years) . . . . .	3.75	3.50
Dividend yield (%) . . . . .	0.93-1.21	1.72-2.74
Risk-free interest rate (%) . . . . .	2.05-3.22	1.14-1.67
Expected volatility (%) . . . . .	29.88-30.94	36.58-39.27

The expected term represents an estimate of the period of time options are expected to remain outstanding and is based on historical exercise and termination data. The dividend yield was based on the most recent dividend payment over the market price of the PPD stock at the beginning of the period. The risk-free interest rate was based on the rate at the date of grant for a zero-coupon U.S. Treasury bond with a term that approximates the expected term of the option. Expected volatilities were based on the historical volatility of PPD's stock price over the expected term of the options.

**Employee Stock Purchase Plan—PPD Plan**

For the periods prior to December 31, 2009, some of the Company's employees participated in PPD's employee stock purchase plan (the "PPD ESPP"). No Company employees participated in PPD's employee stock purchase plan during the year ended December 31, 2010.

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The PPD ESPP had two six-month offering periods (each an “Offering Period”) each year, beginning January 1 and July 1, respectively. Eligible employees could elect to make payroll deductions from 1% to 15% of their base pay during each payroll period of an Offering Period. None of the contributions made by eligible employees to purchase PPD’s common stock under the PPD ESPP were tax-deductible to the employees. The purchase price was 90% of the lesser of (a) the reported closing price of PPD’s common stock for the first day of the Offering Period or (b) the reported closing price of the common stock for the last day of the Offering Period.

Employees eligible to participate in the PPD ESPP included employees of the Company, except employees who customarily worked less than 20 hours per week or five months in a year.

The fair value of each PPD ESPP share was estimated using the Black-Scholes option-pricing model. The following table indicates the assumptions used in estimating fair value for the years ended December 31, 2008 and 2009.

	<u>2008</u>	<u>2009</u>
Expected term (years) . . . . .	0.50	0.50
Dividend yield (%) . . . . .	0.93-0.99	1.72-2.58
Risk-free interest rate (%) . . . . .	2.12-3.37	0.27-0.35
Expected volatility (%) . . . . .	31.47-31.99	31.32-36.68

The Company’s compensation costs for the PPD ESPP, as determined based on the fair value of the discount and option feature of the underlying PPD ESPP grant, were approximately \$0.1 million for each of the years ended December 31, 2008 and 2009. The weighted-average grant date fair value per share during the years ended December 31, 2008 and 2009 was \$6.83 and \$4.16, respectively. As of December 31, 2009, there was no unrecognized compensation cost related to PPD ESPP shares.

For the years ended December 31, 2008 and 2009, the value of stock issued to Company employees for PPD ESPP purchases was \$0.3 million and \$0.3 million, respectively.

During each of the years ended December 31, 2008 and 2009, the Company’s employees contributed \$0.3 million, to the PPD ESPP for the purchase of approximately 8,200 and 13,300 shares, respectively. The aggregate fair value of shares purchased during the years ended December 31, 2008 and 2009 was \$0.3 million and \$0.4 million, respectively. Contributions for the second Offering Period of 2009 were not used to purchase shares until January 2010.

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**10. Income Taxes**

Taxes computed at the statutory U.S. federal income tax rate of 35% are reconciled to the provision for income taxes as follows:

	Year Ended December 31,		
	2008	2009	2010
Effective tax rate .....	0 %	0 %	0 %
Statutory rate of 35% .....	\$ 2,376	\$(2,905)	\$(17,329)
State taxes, net of federal benefit .....	—	—	(2,031)
Permanent differences .....	(203)	(22)	111
Change in valuation allowance .....	(3,492)	3,776	10,119
Net operating loss and related items offset by consolidated group .....	1,319	(849)	9,144
Provision for income taxes .....	\$ —	\$ —	\$ 14

Components of the current deferred tax assets (liabilities) were as follows:

	December 31,	
	2009	2010
Future benefit of carryforward losses .....	\$ 434	\$ —
Accrued expenses .....	1,205	254
Valuation allowance .....	(1,641)	(254)
Other .....	2	—
Total current deferred tax asset (liability) .....	\$ —	\$ —

Components of the long-term deferred tax assets (liabilities) were as follows:

	December 31,	
	2009	2010
Other depreciation and amortization .....	\$ 6,018	\$ 2,938
Deferred rent .....	27	—
Stock options .....	468	349
Deferred compensation .....	26	—
Valuation allowance .....	(9,099)	(16,864)
Future benefit of carryforward losses .....	2,446	13,385
Other .....	114	—
Total long-term deferred tax asset (liability) .....	\$ —	\$ (192)

For the year ended December 31, 2010, the Company has recorded an insignificant amount of income tax expense. This amount relates to the adjustment of a deferred tax liability associated with historical goodwill, which is deductible for tax purposes, but is an indefinite lived intangible asset for financial reporting. The amounts reflected in the statements of operations for the year ended December 31, 2010 are the tax effect of the tax amortization of this item. Because the associated deferred tax liability relates to an indefinite lived intangible,

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the Company does not consider this item in computing the valuation allowance related to the Company's net deferred tax assets. As of December 31, 2010, the deferred tax liability associated with this intangible asset, reflected in other long-term liabilities within the combined and consolidated balance sheets, was approximately \$0.2 million.

The Company has determined that any uncertain tax positions for the tax years open for examination would have no material impact on the combined and consolidated financial statements of the Company.

The Company has federal operating loss carry forwards of approximately \$33.4 million that will expire in 2030. The Company also has state operating loss carry forwards of approximately \$41.5 million that will begin to expire in 2013.

#### **11. Employee Savings Plan**

##### **Savings plan**

For the periods prior to June 14, 2010, Company employees participated in PPD's 401(k) Retirement Savings Plan. PPD's plan matched 50% of an employee's savings up to 6% of pay and those contributions vested ratably over a four-year period. PPD's contributions to the plan, net of forfeitures, were \$0.2 million, \$0.1 million and \$0.09 million for the years ended December 31, 2008, 2009 and 2010, respectively.

For the period after June 14, 2010, Company employees participate in the Furiex 401(k) Retirement Savings Plan. The Company's plan matches 100% of an employee's savings up to 4% of the employee's deferral, and those contributions vest immediately. The Company's contributions to the plan, net of forfeitures, were \$0.06 million for the year ended December 31, 2010.

##### **Non-Qualified Deferred Compensation Plans**

For periods prior to December 31, 2009, certain employees of the Company participated in PPD's non-qualified, unfunded deferred compensation plans that permitted certain highly paid executive employees to defer current income for future financial and retirement needs. There were not any Company contributions to these plans other than accruals for interest or dividend equivalents; all amounts credited to these plans were derived from elective deferrals of compensation otherwise payable to participants. Cash amounts deferred each quarter accrued interest based upon the three-month LIBOR rate plus 1.5%. The total liability related to this plan was \$0.08 million at December 31, 2009 and is included as a component of accrued expenses.

#### **12. Commitments and Contingencies**

The Company currently maintains insurance for risks associated with the operation of its business. These policies provide coverage for a variety of potential losses, including loss or damage to property, bodily injury, general commercial liability and product liability.

The Company is involved in compound development and commercialization collaborations. The Company developed a risk-sharing research and development model with pharmaceutical and biotechnology companies to advance compounds to commercialization. Through collaborative arrangements based on this model, the Company works with its collaborators by sharing the risks and potential rewards associated with the development and commercialization of drugs with its collaborators. As of December 31, 2010, the Company's four main

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collaborations were with Janssen-Cilag Pharmaceutica, N.V., or Janssen-Cilag (an affiliate of Johnson & Johnson), Ranbaxy Laboratories, Ltd., or Ranbaxy, Alza Corporation, or Alza, and Takeda Pharmaceuticals Company Limited, or Takeda, and relate to, respectively, the Fluoroquinolone (JNJ-Q2) and MuDelta compounds, a novel statin compound (PPD-10558), the product Priligy, and the product Nesina. These collaborations involve the potential future receipt of one or more of the following forms of revenue: payments upon the achievement of specified regulatory and sales-based milestones; and royalty payments if the compound is approved for sale. As of December 31, 2010, over twenty countries have approved Priligy for marketing. The Company received a \$2.5 million milestone on each of the first two of these national approvals, for a total of \$5.0 million, in the first quarter of 2009. The Company is entitled to royalties on net sales of Priligy and sales-based milestones if requisite sales levels are reached. The Company recorded the first royalties from the sales of Priligy in 2009. With regard to Nesina, in June 2010, the Company received a \$7.5 million milestone related to pricing approval in Japan. The Company is entitled to royalties on net sales of Nesina and sales-based milestones if requisite sales levels are reached. The Company recorded the first royalties from the sales of Nesina in 2010. The compounds related to Janssen-Cilag are still in development and have not yet generated any regulatory milestone payments. Due to the risks associated with drug development and commercialization, including poor or unexpected non-clinical and clinical trial results, obtaining regulatory approval to sell in any country and changing regulatory requirements, the Company might not receive any further milestone payments, royalties or other payments with respect to any of the Company's drug development collaborations.

As of December 31, 2010, the Company had three collaborations that involve potential future expenditures. The first is its collaboration with Alza for Priligy. In connection with this collaboration, the Company has an obligation to pay a royalty to Eli Lilly and Company, or Lilly, of 5% on annual net sales of the compound in excess of \$800.0 million. If the related triggering events and product sales occur, the Company is entitled to receive from Alza future regulatory milestone payments of \$15.0 million, sales-based milestone payments of up to \$50.0 million, and royalties ranging from 10% to 20% for sales of patented products without generic competition and ranging from 10% to 17.5% for non-patented products without generic competition, in both cases the percentages rise as sales volume increases, and a royalty of 7.5% for patented and non-patented products with generic competition regardless of sales volume. There are no ongoing costs of development for this compound.

The second collaboration involving future expenditures is with Janssen-Cilag, which includes two separate agreements involving the Fluoroquinolone (JNJ-Q2) and MuDelta compounds. The Company expects expenses associated with the development of the compounds in-licensed from Janssen-Cilag to be between \$40.0 and \$50.0 million over the next two years. At the completion of Phase II of each compound, Janssen-Cilag will have the option to continue development and commercialization of each compound. In exchange, the Company may receive, for each compound, up to \$90.0 million in regulatory milestone payments and up to \$75.0 million in sales-based milestone payments, as well as sales-based royalty payments increasing from mid-single digit to low initial double digit percentages as sales volume increase. In the event Janssen-Cilag elects not to continue either program, the Company has the option to continue developing and commercializing the compound for both programs and the Company would be obligated to pay Janssen-Cilag, for each compound, up to \$50.0 million in regulatory milestone payments and up to \$75.0 million in sales-based milestone payments, and, if approved for marketing, sales-based royalties increasing from the mid to upper single digit percentages as sales volume increases. During 2009, the Company expensed \$7.0 million of in-licensing payments related to the two therapeutic compounds in-licensed as part of the agreement with Janssen-Cilag.

The third collaboration involving future expenditures is with Ranbaxy for a novel statin compound (PPD-10558). If the Company develops this product and it attains regulatory approval, and in addition, the

**FURIEX PHARMACEUTICALS, INC. AND SUBSIDIARIES**  
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product meets specific commercialization and sales milestones, the total amount of potential clinical and sales-based milestones that the Company is obligated to pay Ranbaxy would be \$43.0 million. The Company would also be obligated to pay Ranbaxy sales-based royalties of a mid-single digit percentage. The Company will be solely responsible and will bear all costs and expenses for the development, manufacture, and marketing of the compound and licensed products. If advanced, the estimated costs of development could be \$15.0 to \$20.0 million over the next two years. If we exercise our right to terminate early, other than for safety or efficacy reasons, a material product failure or Ranbaxy breach, we must pay Ranbaxy \$1.0 million.

**13. Fair Value of Financial Instruments**

**Cash and Cash Equivalents, Accounts Receivable, Accounts Payable and Accrued Expenses**

The carrying amount of cash and cash equivalents, accounts receivable, accounts payable and accrued expenses approximates fair value because of the short maturity of these items. The Company considers all cash on deposit and money market accounts with original maturities of three months or less to be cash and cash equivalents. The Company invests cash and cash equivalents in money market funds which invest in short-term U.S. Treasury securities with insignificant rates of return.

**14. Related Party Transactions**

**Pharmaceutical Product Development, Inc. Net Investment**

The following table reflects a summary of the transfers to/from parent included in the combined and consolidated statements of shareholders' equity related to changes in Pharmaceutical Product Development, Inc. net investment for the periods prior to the spin-off date:

	<u>2008</u>	<u>2009</u>	<u>2010</u>
Corporate overhead allocations . . . . .	\$ 850	\$ 712	\$ 1,007
Research and development services . . . . .	3,689	4,416	8,376
Cash from parent for acquisitions . . . . .	—	21,503	—
Transfer of proceeds from sale of businesses . . . . .	—	(40,267)	(3,464)
Transfers to (from) parent, net . . . . .	<u>(11,697)</u>	<u>16,313</u>	<u>10,127</u>
Total . . . . .	<u>\$ (7,158)</u>	<u>\$ 2,677</u>	<u>\$16,046</u>

**Corporate Overhead Allocations**

For the periods prior to June 14, 2010, the Company's operations were fully integrated with PPD, including executive services, finance, treasury, corporate income tax, human resources, information technology, facilities, legal services and investor relations services. The accompanying combined and consolidated financial statements reflect the application of estimates and allocations of operating expenses. Management believes the methods used to allocate these operating expenses are reasonable. The allocation methods included relative time devoted by executive management to the Company's business, and the related benefit received by the Company for other services.

Allocations of expense for these services of \$0.3 million, \$0.1 million, and \$0.6 million associated with continuing operations and \$0.5 million, \$0.6 million, and \$0.5 million associated with discontinued operations for the years ended December 31, 2008, 2009 and 2010, respectively, are reflected in the accompanying combined and consolidated statements of operations.

**FURIEX PHARMACEUTICALS, INC. AND SUBSIDIARIES**  
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**Research and Development Services**

PPD performed drug development work for the Company as a related party prior to June 14, 2010 and the expenses related to these services are included in research and development expenses in the accompanying combined and consolidated set of financial statements. Such amounts were \$3.7 million, \$4.4 million and \$8.4 million for the years ended December 31, 2008, 2009 and 2010, respectively.

The Company was provided services by PPD after the spin-off on June 14, 2010. Two members of the Company's Board of Directors hold board positions with PPD. Expenses paid to PPD for the year ended December 31, 2010 by the Company, was approximately \$24.5 million. As of December 31, 2010, the Company owed PPD approximately \$7.9 million for services rendered.

**Cash Transferred from Parent for Acquisitions**

During 2009, PPD acquired Magen Biosciences, Inc. (see Note 3) and entered into the Janssen-Cilag collaboration (see Note 12). These transactions were funded by PPD through transfers of \$21.5 million in cash and assets to the Company.

**Transfer of Proceeds from Sale of Business**

As discussed in Note 3, PPD disposed of Piedmont Research Center, LLC and PPD Biomarker Discovery Sciences, LLC during 2009. The cash proceeds of \$40.3 million received from these transactions in 2009 were transferred to PPD. The cash proceeds of \$3.5 million received from these transactions in 2010 for the payment of an outstanding escrow account were transferred to PPD.

**15. Segment Information**

The Company's business consists solely of compound development and partnering activities. Accordingly, the Company operates in one reportable business segment.



**FURIEX PHARMACEUTICALS, INC. AND SUBSIDIARIES**  
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**16. Quarterly Financial Data (unaudited)**

<u>2009</u>	<u>First</u>	<u>Second</u>	<u>Third</u>	<u>Fourth</u>	<u>Total</u>
Total revenue <sup>(a)</sup> .....	\$ 5,162	\$ 162	\$ 442	\$ 546	\$ 6,312
Operating income (loss) .....	3,729	(991)	(225)	(10,822)	(8,309)
Income (loss) from continuing operations .....	3,729	(960)	(219)	(10,849)	(8,299)
Income (loss) from discontinued operations, net of income taxes <sup>(b)</sup> .....	(546)	29,927	(5,477)	(24,536)	(632)
Net income (loss) <sup>(b)</sup> .....	3,183	28,967	(5,696)	(35,385)	(8,931)
Income (loss) from continuing operations per basic and diluted share .....	\$ 0.38	\$ (0.10)	\$ (0.02)	\$ (1.10)	\$ (0.84)
Income (loss) from discontinued operations, net of income taxes per basic and diluted share .....	\$ (0.05)	\$ 3.03	\$ (0.56)	\$ (2.48)	\$ (0.06)
Net income (loss) per basic and diluted share .....	\$ 0.33	\$ 2.93	\$ (0.58)	\$ (3.58)	\$ (0.90)
 <u>2010</u>					
Total revenue <sup>(c)</sup> .....	\$ 293	\$ 8,113	\$ 288	\$ 289	\$ 8,983
Operating loss .....	(8,595)	(8,101)	(21,175)	(11,650)	(49,521)
Loss from continuing operations .....	(8,590)	(8,103)	(21,180)	(11,653)	(49,526)
Loss from discontinued operations, net of income taxes .....	(2,090)	(3,043)	—	—	(5,133)
Net loss .....	(10,680)	(11,146)	(21,180)	(11,653)	(54,659)
Loss from continuing operations per basic and diluted share .....	\$ (0.87)	\$ (0.82)	\$ (2.14)	\$ (1.18)	\$ (5.01)
Loss from discontinued operations, net of income taxes per basic and diluted share .....	\$ (0.21)	\$ (0.31)	\$ —	\$ —	\$ (0.52)
Net loss per basic and diluted share .....	\$ (1.08)	\$ (1.13)	\$ (2.14)	\$ (1.18)	\$ (5.53)

- (a) The first quarter of 2009 includes \$5.0 million in milestone revenue resulting from a milestone payment earned as a result of regulatory approvals of Priligy in Finland and Sweden.
- (b) The second quarter of 2009 includes a gain on the sale of Piedmont Research Center of \$35.5 million. The fourth quarter of 2009 includes a loss on the sale of Biomarker of \$8.8 million, and an impairment of an intangible asset of \$10.4 million relating to in-process R&D obtained in the Magen acquisition.
- (c) The second quarter of 2010 includes \$7.5 million in milestone revenue resulting from a milestone payment earned upon regulatory and pricing approvals of Nesina in Japan.

Amounts above vary from amounts originally reported due to the reclassification of discontinued operations.

**17. Subsequent Events**

On November 1, 2010, the Company received notification from the U.S. Department of the Treasury that it was granted approximately \$0.7 million of grants related to investments in qualifying therapeutic discovery projects under section 48D of the Internal Revenue Code. These grants related to the on-going research and development programs related to the JNJ-Q2, MuDelta, and PPD-10558 compounds.

These funds were received in early February 2011 and are reflected in other current assets within the accompanying combined and consolidated balance sheets as of December 31, 2010 and as a reduction to research and development expenses within the accompanying combined and consolidated statements of operations for the year ended December 31, 2010.

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**Subsidiaries of Furiex Pharmaceuticals, Inc.**

<u>Subsidiary</u>	<u>Jurisdiction</u>
APBI Holdings, LLC .....	Delaware
Development Partners, LLC .....	Delaware
Genupro, Inc. ....	North Carolina

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**Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in Registration Statement No. 333-167552 on Form S-8 of our report dated March 18, 2011 relating to the combined and consolidated financial statements of Furiex Pharmaceuticals, Inc. and Subsidiaries, appearing in this Annual Report on Form 10-K of Furiex Pharmaceuticals, Inc. for the year ended December 31, 2010.

/s/ DELOITTE & TOUCHE LLP  
Raleigh, North Carolina  
March 18, 2011

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**CERTIFICATION PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, June S. Almenoff, certify that:

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

March 18, 2011

/s/ June S. Almenoff

June S. Almenoff  
President and Chief Medical Officer  
(principal executive officer)

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**CERTIFICATION PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Marshall H. Woodworth, certify that:

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

March 18, 2011

/s/ Marshall Woodworth

Marshall Woodworth  
Chief Financial Officer, Treasurer and Assistant Secretary  
(principal financial and accounting officer)

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**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Furiex Pharmaceuticals, Inc. (the "Company") on Form 10-K for the period ended December 31, 2010 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, June S. Almenoff, President and Chief Medical Officer (principal executive officer), of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, to my knowledge that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of, and for, the periods presented in the Report.

/s/ June S. Almenoff

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June S. Almenoff  
President and Chief Medical Officer  
(principal executive officer)

March 18, 2011

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**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Furiex Pharmaceuticals, Inc. (the "Company") on Form 10-K for the period ended December 31, 2010 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Marshall H. Woodworth, Chief Financial Officer, Treasurer and Assistant Secretary (principal financial and accounting officer) of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, to my knowledge that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of, and for, the periods presented in the Report.

/s/ Marshall Woodworth

Marshall Woodworth  
Chief Financial Officer, Treasurer and Assistant Secretary  
(principal financial and accounting officer)

March 18, 2011

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Board of Directors

Fred N. Eshelman, Pharm.D.  
*Chairman, Furiex Pharmaceuticals, Inc.  
Executive Chairman, PPD*

Stuart Bondurant, M.D.  
*Emeritus Dean and Emeritus Professor,  
School of Medicine,  
University of North Carolina at  
Chapel Hill*

Peter Corr, Ph.D.  
*General Partner,  
Celtic Therapeutics Management LLP  
Retired Senior Vice President for  
Science & Technology, Pfizer Inc.*

Wendy Dixon, Ph.D.  
*Formerly Chief Marketing Officer and  
President of Global Marketing,  
Bristol-Myers Squibb*

Stephen W. Kaldor, Ph.D.  
*Venture Partner, Versant Ventures  
Acting CEO, QuantiCell*

Robert Ruscher  
*Formerly Executive Chairman,  
President & CEO,  
Salix Pharmaceuticals, Ltd.*



Principal Officers

Gail McIntyre, Ph.D., DABT  
*Senior Vice President, Research*

Paul S. Covington, M.D.  
*Senior Vice President, Clinical  
Development and Operations*

June S. Almenoff, M.D., Ph.D.  
*President and Chief Medical Officer*

Marshall Woodworth  
*Chief Financial Officer, Treasurer and  
Assistant Secretary*



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