EPIX Pharmaceuticals, Inc.
Form 10-Q
May 09, 2008

Table of Contents

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2008

Or

o **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 0-21863

EPIX Pharmaceuticals, Inc.

(Exact name of Registrant as Specified in its Charter)

Delaware	**04-3030815**
(State of incorporation)	(I.R.S. Employer Identification No.)
4 Maguire Road, Lexington, Massachusetts	**02421**
(Address of principal executive offices)	(Zip Code)

Registrant s telephone number, including area code: **(781) 761-7600**

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 þ No o

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

Large accelerated filer o	Accelerated filer þ	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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

As of May 8, 2008, 41,357,586 shares of the registrant s Common Stock, $0.01 par value per share, were issued and outstanding.

EPIX Pharmaceuticals, Inc.
Quarterly Report on Form 10-Q
INDEX

PART I.	FINANCIAL INFORMATION	3
Item 1.	Financial Statements (unaudited)	
	Condensed Consolidated Balance Sheets March 31, 2008 and December 31, 2007	3
	Condensed Consolidated Statements of Operations Three Months Ended March 31, 2008 and 2007	4
	Condensed Consolidated Statements of Cash Flows Three Months Ended March 31, 2008 and 2007	5
	Notes to Condensed Consolidated Financial Statements	6
Item 2.	Management s Discussion and Analysis of Financial Condition and Results of Operations	10
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	16
Item 4.	Controls and Procedures	16
PART II.	OTHER INFORMATION	16
Item 1.	Legal Proceedings	16
Item 1A.	Risk Factors	16
Item 6.	Exhibits	21
	Signatures	
	Exhibit Index	

EX-10.1 Research, Development and Commercialization Agreement between EPIX Pharmaceuticals, Inc. and Cystic Fibrosis Foundation Therapeutics, Inc., dated as of April 1, 2008.
EX-31.1 Certification Pursuant to Rule 13(a)-14(a) or Rule 15d-14(a) of Securities Exchange Act of 1934.
EX-31.2 Certification Pursuant to Rule 13(a)-14(a) or Rule 15d-14(a) of Securities Exchange Act of 1934.
EX-32.1 Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Table of Contents

PART I. FINANCIAL INFORMATION

EPIX PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)

	March 31, 2008	December 31, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 12,419,384	$ 9,157,973
Available-for-sale marketable securities	34,313,740	51,919,128
Accounts receivable	312,500	
Prepaid expenses and other assets	2,841,226	2,162,895
Total current assets	49,886,850	63,239,996
Property and equipment, net	5,947,364	6,044,886
Other assets	3,545,367	3,850,431
Goodwill	4,939,814	4,939,814
Total assets	$ 64,319,395	$ 78,075,127
LIABILITIES AND STOCKHOLDERS DEFICIT		
Current liabilities:		
Accounts payable	$ 3,244,300	$ 3,539,099
Accrued expenses	8,782,346	8,099,539
Contract advances	4,196,761	4,719,201
Current portion of capital lease obligation	164,257	179,859
Deferred revenue	1,372,042	1,372,042
Other current liabilities	650,855	610,867
Total current liabilities	18,410,561	18,520,607
Deferred revenue	15,345,286	15,688,296
Capital lease obligation	149,451	182,748
Other liabilities	4,803,810	4,975,123
Convertible debt	100,000,000	100,000,000
Total liabilities	138,709,108	139,366,774
Commitments and contigencies		
Stockholders deficit:		
Preferred Stock, $0.01 par value, 1,000,000 shares authorized; no shares issued		
Common Stock, $0.01 par value, 100,000,000 shares authorized; 41,355,575 and 41,353,079 shares issued and outstanding at March 31, 2008 and December 31, 2007, respectively	413,556	413,530
Additional paid-in-capital	346,898,265	346,289,024
Accumulated deficit	(421,891,747)	(408,157,261)
Accumulated other comprehensive income	190,213	163,060

Total stockholders deficit	(74,389,713)	(61,291,647)
Total liabilities and stockholders deficit	$ 64,319,395	$ 78,075,127

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

Table of Contents

EPIX PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)

	Three Months Ended March 31,	
	2008	**2007**
Revenues:		
Product development revenue	$ 1,927,420	$ 434,392
Royalty revenue	137,844	487,658
License fee revenue	343,010	1,032,850
Total revenues	2,408,274	1,954,900
Operating expenses:		
Research and development	12,691,249	13,491,119
General and administrative	3,038,260	8,613,758
Royalties	39,046	53,668
Total operating expenses	15,768,555	22,158,545
Operating loss	(13,360,281)	(20,203,645)
Interest and other income	629,225	1,962,953
Interest expense	(1,003,430)	(1,230,734)
Loss before provision for income taxes	(13,734,486)	(19,471,426)
Provision for income taxes		38,089
Net loss	$ (13,734,486)	$ (19,509,515)
Weighted average shares:		
Basic and diluted	41,353,992	32,586,377
Net loss per share, basic and diluted	$ (0.33)	$ (0.60)

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

Table of Contents

EPIX PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)

	Three Months Ended March 31,	
	2008	**2007**
Operating activities:		
Net loss	$ (13,734,486)	$ (19,509,515)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation, amortization and asset write offs	451,820	516,278
Stock compensation expense	604,923	696,677
Noncash interest expense (credit) from embedded derivative		(27,725)
Amortization of deferred financing costs	128,072	123,511
Accretion of discount on available-for-sale securities	(363,791)	(777,315)
Changes in operating assets and liabilities:		
Accounts receivable	(312,500)	46,367
Prepaid expenses and other current assets	(678,331)	(330,302)
Other assets and liabilities	(102,805)	1,517,178
Accounts payable	(294,799)	1,863,502
Accrued expenses	682,807	3,173,149
Contract advances	(522,440)	149,477
Merger consideration payable		310,345
Deferred revenue	(343,010)	(1,035,536)
Net cash used in operating activities	(14,484,540)	(13,283,909)
Investing activities:		
Purchases of marketable securities	(6,264,238)	(21,859,213)
Sales or redemptions of marketable securities	24,260,570	23,500,000
Restricted cash	148,472	262,422
Purchases of fixed assets	(354,298)	(1,995,181)
Net cash provided by (used in) investing activities	17,790,506	(91,972)
Financing activities:		
Principal payments on capital leases	(48,899)	(22,000)
Proceeds from stock option exercises	4,344	74,362
Net cash provided by (used in) financing activities	(44,555)	52,362
Net incresae (decrease) in cash and cash equivalents	3,261,411	(13,323,519)
Cash and cash equivalents at beginning of period	9,157,973	30,332,468
Cash and cash equivalents at end of period	$ 12,419,384	$ 17,008,949
Supplemental disclosure of noncash financing and investing activities:		
Purchases of fixed asset with capital lease	$	$ 56,960

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

Table of Contents

EPIX PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

1. Nature of Business

EPIX Pharmaceuticals, Inc. (EPIX or the Company) is a biopharmaceutical company focused on discovering and developing novel therapeutics through the use of its proprietary and highly efficient *in silico* drug discovery platform. The Company has a pipeline of internally-discovered drug candidates currently in clinical development to treat diseases of the central nervous system and lung conditions. The Company s blood-pool imaging agent, Vasovist, is approved for marketing in more than 30 countries outside of the United States. The Company also has collaborations with SmithKline Beecham Corporation (GlaxoSmithKline), Amgen Inc., Cystic Fibrosis Foundation Therapeutics, Incorporated, and Bayer Schering Pharma AG, Germany.

2. Basis of Presentation

The unaudited condensed consolidated financial statements of EPIX have been prepared in accordance with accounting principles generally accepted in the United States (U.S.) for interim financial information and the rules of the Securities and Exchange Commission (the SEC or the Commission) for interim reporting. Accordingly, they do not include all of the information and footnotes required to be presented for complete financial statements. The accompanying unaudited condensed consolidated financial statements reflect all adjustments (consisting only of normal recurring adjustments) which are, in the opinion of management, necessary for a fair presentation of the results for the interim periods presented. The results of the interim period ended March 31, 2008 are not necessarily indicative of the results expected for the full fiscal year.

As of March 31, 2008, the Company had $46.7 million of cash, cash equivalents and short-term marketable securities. The Company has experienced and continues to experience negative cash flows from operations and it expects to continue to incur net losses in the foreseeable future. The Company believes that it has sufficient cash, along with anticipated revenue that the Company expects to earn in 2008, to meet its funding requirements through the first fiscal quarter of 2009. This projection is based on the Company s current cost structure and the Company s current expectations regarding operating expenses and anticipated revenues. There can be no assurance as to the availability of additional financing or the terms upon which additional financing may be available in the future if, and when, it is needed. If adequate funds are not available or are not available on acceptable terms, when the Company desires them, the Company s ability to fund its operations, take advantage of unanticipated opportunities or otherwise respond to competitive pressures would be significantly limited.

The unaudited condensed consolidated financial statements and related disclosures have been prepared with the assumption that users of the unaudited condensed consolidated financial statements have read or have access to the audited financial statements for the preceding fiscal year. Accordingly, these unaudited condensed consolidated financial statements should be read in conjunction with the audited financial statements and the related notes thereto included in the Company s Annual Report on Form 10-K for the year ended December 31, 2007.

3. Significant Accounting Policies

Principles of Consolidation

The condensed consolidated financial statements include the financial statements of the Company and those of its wholly owned subsidiary in Israel. All material intercompany balances and transactions have been eliminated.

Income Taxes

The Company provides for income taxes under SFAS No. 109, *Accounting for Income Taxes.* Under this method, deferred taxes are recognized using the liability method, whereby tax rates are applied to cumulative temporary differences between carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes and are based on when and how they are expected to affect the tax return. A valuation allowance is provided to the extent that there is uncertainty as to the Company s ability to generate sufficient taxable income in the future to realize the benefit from its net deferred tax asset.

Segment Information

SFAS No. 131, *Disclosure about Segments of an Enterprise and Related Information,* establishes standards for reporting information regarding operating segments and for related disclosures about products and services and

geographical areas. The Company operates in one business segment, which is the development of pharmaceutical products.

Table of Contents

Revenue

The Company recognizes revenue relating to collaborations in accordance with the SEC s Staff Accounting Bulletin No. 104, *Revenue Recognition in Financial Statements.* Revenue under collaborations may include the receipt of nonrefundable license fees, milestone payments, reimbursement of research and development costs and royalties.

The Company recognizes nonrefundable upfront license fees and guaranteed, time-based payments that require continuing involvement in the form of research and development as license fee revenue:

ratably over the development period; or

based upon the level of research services performed during the period of the research contract.

When the period of deferral cannot be specifically identified from the contract, the Company estimates the period based upon other critical factors contained within the contract. EPIX continually reviews such estimates, which could result in a change in the deferral period and might impact the timing and amount of revenue recognized.

Milestone payments, which represent a significant performance risk, are recognized as product development revenue when the performance obligations, as defined in the contract, are achieved. Performance obligations typically consist of significant milestones in the development life cycle of the related product candidate, such as the filing of investigational new drug applications, initiation of clinical trials, filing for approval with regulatory agencies and approvals by regulatory agencies. Milestone payments that are received at the time of initiation of a collaboration agreement or that do not represent a significant performance risk are recognized ratably over the development period.

Reimbursements of research and development costs are recognized as product development revenue as the related costs are incurred.

Royalties are recognized as revenue when earned, reasonably estimable and collection is probable, which is typically upon receipt of royalty reports from the licensee or cash.

Research and Development Expenses

Research and development costs, including those associated with technology and licenses, are expensed as incurred. Research and development costs primarily include employee salaries and related costs, third-party service costs, the cost of preclinical and clinical trials, supplies, consulting expenses, facility costs and certain overhead costs.

In order to conduct research and development activities and compile regulatory submissions, the Company enters into contracts with vendors who render services over extended periods of time. Typically, the Company enters into three types of vendor contracts: time-based, patient-based or a combination thereof. Under a time-based contract, using critical factors contained within the contract, usually the stated duration of the contract and the timing of services provided, the Company records the contractual expense for each service provided under the contract ratably over the period during which the Company estimates the service will be performed. Under a patient-based contract, the Company first determines an appropriate per patient cost using critical factors contained within the contract, which include the estimated number of patients and the total dollar value of the contract. The Company then records expense based upon the total number of patients enrolled in the clinical study during the period. On a quarterly basis, the Company reviews the assumptions for each contract in order to reflect the Company s most current estimate of the costs incurred under each contract. Adjustments are recorded in the period in which the revisions are estimable. These adjustments could have a material effect on the Company s results of operations.

On January 1, 2008, the Company adopted EITF Issue No. 07-03, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* (EITF 07-03). EITF 07-03 requires companies to defer and capitalize, until the goods have been delivered or the related services have been rendered, non-refundable advance payments for goods that will be used or services that will be performed in future research and development activities. The adoption of EITF 07-03 on January 1, 2008 did not have a material impact on the Company s financial condition or results of operations.

Loss Per Share

The Company computes loss per share in accordance with the provisions of SFAS No. 128, *Earnings per Share.* Basic net loss per share is based upon the weighted-average number of common shares outstanding and excludes the effect of dilutive common stock issuable upon exercise of stock options, vesting of restricted stock units, convertible debt and merger consideration. In computing diluted loss per share, only potential common shares that are dilutive, or

those that reduce earnings per share, are included. The issuance of common stock from the exercise of options, vesting of restricted stock units and convertible debt is not assumed if the result is anti-dilutive, such as when a loss is reported.

Table of Contents

Common stock potentially issuable but excluded from the calculation of dilutive net loss per share for the three months ended March 31, 2008 and 2007 because their inclusion would have been antidilutive consisted of the following

	Three Months Ended March 31,	
	2008	2007
Stock options and awards	4,562,252	3,863,241
Shares issuable on conversion of 3% Convertible Senior Notes (1)	2,239,393	2,239,393
Shares issuable in satisfaction of merger consideration payable (2)		2,647,760
Total	6,801,645	8,750,394

(1) Each $1,000 of senior notes is convertible into 22.39 shares of the Company s common stock (representing a conversion price of approximately $44.66 per share) if (1) the price of the Company s common stock trades above 120% of the conversion price for a specified time period, (2) the trading price of the senior notes is below a certain threshold, (3) the senior notes have been called for redemption, or (4) specified corporate transactions have occurred. None of these conversion

triggers has occurred as of March 31, 2008.

(2) Share amount is calculated as if the merger consideration was payable as of March 31, 2007. Actual settlement occurred on October 29, 2007, at which time the Company issued 3,167,000 shares of common stock and paid $5.8 million in cash.

Comprehensive Loss

In accordance with SFAS No. 130, *Reporting Comprehensive Income,* components of comprehensive loss include net loss and certain transactions that have generally been reported in the statements of stockholders deficit. The Company s comprehensive loss is comprised of its net loss and unrealized gains/losses on the Company s available-for-sale marketable securities. The comprehensive loss for the three months ended March 31, 2008 and 2007 was $13.7 million and $19.5 million, respectively.

4. Strategic Alliances and Collaborations

On April 1, 2008, the Company entered into a new Research, Development and Commercialization Agreement (the Agreement) with Cystic Fibrosis Foundation Therapeutics, Inc. (CFFT), the drug discovery and development affiliate of the Cystic Fibrosis Foundation. The Agreement provides for the continuation of the first research program initiated under a prior Research, Development and Commercialization Agreement between the Company and CFFT dated March 7, 2005, as amended. Under the Agreement, the Company has agreed to conduct additional research activities aimed at developing a compound to correct a malfunction of the cystic fibrosis transmembrane conductance regulator protein. CFFT may make payments of up to $30.7 million under the Agreement for research services and reimbursed research costs. The Company may also be eligible to receive up to an additional $7.0 million for the achievement of certain development milestones.

Upon any commercialization by the Company of a product developed under the Agreement, the Company is required to pay tiered royalties to CFFT based on net sales by the Company of such product. In addition, the Company is required to make certain payments to CFFT if the Company outlicenses a product developed under the Agreement.

The research program is scheduled to conclude on April 1, 2017, but can be extended for up to three additional years if the Company is conducting a certain clinical trial, or by agreement of the parties. The Agreement terminates at such time when there are no longer any royalty payment obligations owing under the Agreement. Upon an earlier termination of the Agreement by either party, depending upon the circumstances, the parties have varying rights and obligations with respect to intellectual property rights and payment obligations.

5. Fair Value Measurements

The Company adopted SFAS No. 157 Fair Value Measurements (SFAS 157) on January 1, 2008 which did not have a material impact on the Company s financial condition or results of operations. SFAS 157 defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. The

standard creates a fair value hierarchy which prioritizes the inputs to valuation techniques used to measure fair value into three broad levels as follows: Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities; Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly; and Level 3 inputs are unobservable inputs that reflect the Company s own assumptions about the assumptions market participants would use in pricing the asset or liability.

Table of Contents

Financial assets and liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. In accordance with SFAS 157, the Company has classified its financial assets and liabilities that are required to be measured at fair value as of March 31, 2008 as follows:

	Balance at March 31, 2008	Fair Value Measurements March 31, 2008		
		Level 1	Level 2	Level 3
Cash and cash equivalents	$12,419,384	$12,419,384	$	$
Available-for-sale marketable securities	$34,313,740	$	$34,313,740	$

On January 1, 2008, the Company adopted SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115* (SFAS 159). SFAS 159 permits an entity to choose to measure many financial instruments and certain other items at fair value at specified election dates. Subsequent unrealized gains and losses on items for which the fair value option has been elected will be reported in earnings. The Company did not elect to measure any additional financial instruments or other items at fair value and the adoption of SFAS 159 did not have a material impact on the Company s financial condition or results of operations.

6. New Accounting Pronouncements

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations* (SFAS 141(R)). This Statement provides greater consistency in the accounting and financial reporting of business combinations. It requires the acquiring entity in a business combination to recognize all assets acquired and liabilities assumed in the transaction, establishes the acquisition-date fair value as the measurement objective for all assets acquired and liabilities assumed, and requires the acquirer to disclose the nature and financial effect of the business combination. SFAS 141(R) is effective for fiscal years beginning after December 15, 2008. The Company is currently assessing the impact the adoption will have on its financial position and results of operations.

Table of Contents

ITEM 2. Management s Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and related notes thereto that appear elsewhere in this Quarterly Report on Form 10-Q and the audited financial statements and related notes thereto and Management s Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the year ended December 31, 2007, which has been filed with the Securities and Exchange Commission. In addition to historical consolidated financial information, the following discussion contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended, and are intended to be covered by the safe harbor created by those sections. In particular, statements contained in this Quarterly Report on Form 10-Q that are not historical facts, including, but not limited to statements concerning management s expectations regarding expected future revenue and expenses, our partnering strategies, the progress of our clinical development programs, our expectations regarding available cash and management s plans, objectives and strategies constitute forward-looking statements. Forward-looking statements, which are based on certain assumptions and reflect our plans, estimates and beliefs, can generally be identified by the use of forward-looking terms such as believes, expects, may, will, should, could, seek, intends, plans, estimates, anticipates or other comparable terms. Our actual results could differ materially from those discussed in the forward-looking statements. We urge you to consider the risks and uncertainties described in Part I, Item 1A. Risk Factors in our Annual Report on Form 10-K for the fiscal year ended December 31, 2007, as well as elsewhere in this report, in evaluating our forward-looking statements. We caution readers not to place undue reliance upon any such forward-looking statements, which speak only as of the date made. Except as otherwise required by the federal securities laws, we disclaim any obligation or undertaking to publicly release any updates or revisions to any forward-looking statement contained herein (or elsewhere) to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based.

Overview

We are a biopharmaceutical company focused on discovering and developing novel therapeutics through the use of our proprietary and highly efficient *in silico* drug discovery platform. We have a pipeline of internally-discovered drug candidates currently in clinical development to treat diseases of the central nervous system and lung conditions. Our blood-pool imaging agent, Vasovist, is approved for marketing in over 30 countries outside of the United States. We also have collaborations with SmithKline Beecham Corporation (GlaxoSmithKline), Amgen Inc., Cystic Fibrosis Foundation Therapeutics, Incorporated, and Bayer Schering Pharma AG, Germany.

The focus of our therapeutic drug discovery and development efforts is on the two classes of drug targets known as G-protein Coupled Receptors, or GPCRs, and ion channels. GPCRs and ion channels are classes of proteins embedded in the surface membrane of all cells and are responsible for mediating much of the biological signaling at the cellular level. We believe that our proprietary drug discovery technology and approach addresses many of the inefficiencies associated with traditional GPCR and ion channel-targeted drug discovery. By integrating computer-based, or in silico, technology with in-house medicinal chemistry, we believe that we can rapidly identify and optimize highly selective drug candidates. We focus on GPCR and ion channel drug targets whose role in disease has already been demonstrated in clinical trials or in preclinical studies. In each of our four clinical-stage therapeutic programs, we used our drug discovery technology and approach to optimize a lead compound into a clinical drug candidate in less than ten months, synthesizing fewer than 80 compounds per program. We moved each of these drug candidates into clinical trials in less than 18 months from lead identification. In March 2008, we discontinued development of one of these four clinical-stage programs, PRX-00023, due to lack of efficacy shown in a recently completed Phase 2b trial in patients with major depressive disorder. We believe our drug discovery technology and approach enables us to efficiently and cost-effectively discover and develop GPCR and ion channel-targeted drugs.

Our business strategy is to develop our internally discovered, novel pharmaceutical product candidates through the point of proof of clinical concept, typically completion of Phase 2 clinical trials, and then to seek third-party collaborators for their continued development, regulatory approval and commercialization. In certain disease areas, such as pulmonary hypertension, where we believe we can efficiently obtain regulatory approval and effectively

market the product through a specialty sales force, we may seek to retain certain commercialization rights.

RESULTS OF OPERATIONS

Research and Development Overview

Research and development expense consists primarily of:

salaries, benefits and related expenses for personnel engaged in research and development activities;

fees paid to contract research organizations to manage and monitor clinical trials;

fees paid to research organizations in conjunction with preclinical studies;

Table of Contents

fees paid to access chemical and intellectual property databases;

costs of materials used in research and development and clinical studies;

academic testing and consulting, license and sponsored research fees paid to third parties; and

costs of facilities and equipment, including depreciation, used in research and development activities.

We expense both internal and external research and development costs as incurred. We expect that a large percentage of our research and development expenses in the future will be incurred in support of our current and future preclinical and clinical therapeutic development programs. These expenditures are subject to numerous uncertainties in timing and cost to completion. We test drug candidates in preclinical studies for safety, toxicology and efficacy. We then conduct early-stage clinical trials for each drug candidate. As we obtain results from trials, we may elect to discontinue or delay clinical trials for certain drug candidates in order to focus our resources on more promising drug candidates.

We currently have one imaging product, Vasovist, which is approved for marketing in more than 30 countries outside of the United States. In January 2008, based on written confirmation from the U.S. Food and Drug Administration, or FDA, regarding our protocol design and statistical analysis plan, we initiated a re-read of the images obtained in prior Phase 3 studies of Vasovist. In April 2008, we announced that we achieved statistically significant positive results from the blinded, independent re-read and had met all pre-specified endpoints prospectively agreed to with the FDA. As a result, we plan to resubmit a New Drug Application, or NDA, to the FDA for Vasovist in mid-2008. Future costs expected to be incurred for Vasovist are currently limited to the costs of resubmitting the NDA to the FDA.

In connection with our acquisition of Predix Pharmaceuticals Holdings, Inc. in August 2006, we incurred a non-recurring charge of $123.5 million for in-process research and development. The in-process research and development charge represents the fair value of purchased in-process technology of Predix for research projects that, as of the closing date of the merger, had not reached technological feasibility and had no alternative future use. The in-process research and development primarily represented the fair value of the following drug candidates: PRX-00023 ($70.9 million) that, as of the date of the merger, was in Phase 3 clinical trials for the treatment of generalized anxiety disorder; PRX-03140 ($23.5 million) that, as of the date of the merger had completed Phase 1 clinical trials for the treatment of Alzheimer s disease; PRX-08066 ($20.2 million) that, as of the date of the merger, had entered Phase 2 clinical trials for the treatment of pulmonary hypertension in association with chronic obstructive pulmonary disease, or COPD; and PRX-07034 ($8.9 million) that, as of the date of the merger, had entered Phase 1 clinical trials for the treatment of obesity. In March 2008, we discontinued the development of PRX-00023 due to a lack of efficacy shown in a recently completed Phase 2b trial in patients with major depressive disorder.

The following summarizes the applicable disease indication and the clinical status of our three current clinical-stage therapeutic drug candidates

Drug Candidate	Disease Indication	Clinical Trial Status
PRX-08066(1)	Pulmonary Hypertension/COPD	Phase 2a
PRX-03140(2)	Alzheimer s disease	Phase 2b
PRX-07034(3)	Cognitive impairment	Phase 1b

(1) We completed a Phase 2a trial of PRX-08066 in pulmonary hypertension associated with chronic obstructive

pulmonary disease, or COPD, in August 2007. This randomized, double-blind, placebo-controlled Phase 2 trial enrolled 71 patients with PH associated with COPD. Patients were randomized to one of three arms; 200 mg of PRX-08066 once-daily; 400 mg of PRX-08066 once-daily; or placebo. The two-week double-blind phase of the study was followed by an open label extension in which 10 patients received 200 mg daily for six weeks. The primary endpoints of the trial were safety and tolerability of PRX-08066. Efficacy was measured by the effect of PRX-08066 compared to placebo on systolic pulmonary artery pressure, or SPAP, and included 62 evaluable patients who completed the double-blind portion of the study. In a population where decreases of 3 mmHg to 4 mmHg in a post-exercise

SPAP are considered clinically significant, the results showed a statistically significant dose-response for the patients that demonstrated a decrease of 4 mmHg or more. In the 400 mg dose group, 45% of the patients had a reduction in post-exercise SPAP of 4 mmHg or more versus 14% on placebo (p=0.043). An analysis of SPAP changes in all subjects revealed a dose trend with median reductions of 1.2 mmHg and 3.38 mmHg in the 200 mg and 400 mg dose groups, respectively, compared with no change on placebo. PRX-08066 was generally well-tolerated. There were no serious adverse events considered related to PRX-08066, and the majority of adverse events were mild or moderate in nature. One subject in the 200 mg dose group who then continued into the six-week open-label

extension experienced a modest increase in liver enzyme levels at the end of the extension that was believed to be drug-related. These values returned to normal within two weeks and the subject remained asymptomatic.

Table of Contents

(2) In May 2008, we initiated a Phase 2b trial in Alzheimer s disease of PRX-03140 in combination with donepezil (Aricept®). This randomized, double-blind, placebo-controlled trial is designed to evaluate the efficacy of PRX-03140 on cognitive function as measured by the change from baseline in the cognitive component of the Alzheimer s Disease Assessment Scale score. The six month trial is expected to enroll approximately 400 adult patients with Alzheimer s disease. We expect to initiate a second Phase 2b trial in Alzheimer s disease of PRX-03140 by the end of the second quarter of 2008. The second trial will evaluate PRX-03140 as a monotherapy.

(3) In April 2007, we completed a Phase 1 multiple ascending dose clinical trial studying the safety, tolerability, pharmacokinetics,

and pharmacodynamics of PRX-07034 administered once-daily for 28 days in a population of 33 otherwise healthy obese adults with body mass indices, or BMI, between 30 and 42 kg/m2. Normal BMI is less than 25 kg/m2. PRX-07034 demonstrated predictable pharmacokinetics with dose proportional increases in exposures, and a half-life supporting once-daily dosing. Signals suggestive of pharmacologic activity were observed for obesity with a greater proportion of subjects on drug experiencing weight loss during the one month period than subjects on placebo. Overall results on cognitive function as measured by the CogScreen test battery, showed a dose dependent trend for improvement. For the predetermined cognitive endpoint that combines speed and accuracy, there was a statistically significant improvement at the

600 mg dose once daily. Subsequently, an independent external analysis of the CogScreen test battery results confirmed a significant drug effect on cognition but was not able to confirm the dose-dependent trend. No dose limiting toxicity was identified, and no serious adverse events were reported.

In October 2007, we completed a randomized, double-blind, placebo-controlled Phase 1 trial of 21 obese, but otherwise healthy, adults. Findings from this study demonstrated that adults taking 600 mg of PRX-07034 twice-daily for 28 days had a weight reduction of an average of 0.45 kg (approximately 1 pound), while adults on placebo gained 1.37 kg (approximately 3 pounds) during the same period, which was statistically significant ($p < 0.005$). Subjects in the study were not required to follow any pre-specified diet or exercise

program. PRX-07034 was associated with a statistically significant (p=0.036) reduction in serum leptin levels, a marker of fat stores in the body. Overall, only one of the subjects (approximately 10%) on placebo lost any weight during the trial, while 7 of the 11 subjects (approximately 64%) on PRX-07034 lost weight. PRX-07034 appeared well-tolerated and there were no serious adverse events reported. An increase in corrected QT interval, or QTc, was apparent at the dose tested, however, with a mean increase over the duration of the study of 10.7 milliseconds for the drug group versus a decrease of 1.7 milliseconds for the placebo group. The corrected QTc is a measurement of the QT interval, which is corrected for heart rate. Prolongations of the QTc are associated with an increased risk for potentially life-threatening heart rhythms and

so this measurement is an important index to measure during the development of new drugs. In addition, of the population of 21 adults, one patient on drug discontinued due to a rash that resolved rapidly. There were no discontinuations on placebo. In the prior Phase 1 trial where doses up to 600 mg once daily were studied for 28 days, no clinically meaningful prolongations of the QTc were noted.

The 21-person trial, which was conducted in an outpatient setting (subjects spent three nights of the total 28-day trial as inpatients to accommodate measurements and physical examinations), included secondary endpoint measures to assess potential effects on body weight, hunger, satiety and exploratory endpoint measures of cognitive function. An analysis of cognitive data in this study showed no difference between drug and

placebo at a dose of 600 mg twice daily. Accordingly, future studies in cognitive impairment are expected to utilize doses less than 600 mg twice daily based on the study results and the positive data in cognition previously demonstrated in lower doses.

Completion of clinical trials may take several years or more, but the length of time can vary substantially according to a number of factors, including the type, complexity, novelty and intended use of a drug candidate. The cost of clinical trials, and therefore the amount and timing of our capital requirements, may vary significantly over the life of a project as a result of differences arising during clinical development, including, among others:

the number of sites included in the trials;

the length of time required to enroll suitable patient subjects;

the number of patients that participate in the trials;

the duration of patient follow-up that seems appropriate in view of results; and

the efficacy and safety profile of the drug candidate.

We could incur increased clinical development costs if we experience delays in clinical trial enrollment, delays in the evaluation of clinical trial results or delays in regulatory approvals. In addition, we face significant uncertainty with respect to our ability to enter into strategic collaborations with respect to our drug candidates. As a result of these factors, it is difficult to estimate the cost and length of a clinical trial. We are unable to accurately and meaningfully estimate the cost to bring a product to market due to the variability in length of time to develop and obtain regulatory approval for a drug candidate.

Table of Contents

We estimate that clinical trials in our areas of focus are typically completed over the following timelines, but delays can occur for many reasons including those set forth above:

Clinical Phase	Objective	Estimated Completion Period
Phase 1	Establish safety in healthy volunteers and occasionally in patients; study how the drug works, is metabolized and interacts with other drugs	1-2 years
Phase 2	Evaluate efficacy, optimal dosages and expanded evidence of safety	2-3 years
Phase 3	Further evaluate efficacy and safety of the drug candidate in a larger patient population	2-3 years

If we successfully complete Phase 3 clinical trials of a drug candidate, we intend to submit the results of all of the clinical trials for such drug candidate to the FDA to support regulatory approval. Even if any of our drug candidates receive regulatory approval, we may still be required to perform lengthy and costly post-marketing studies.

A major risk associated with the timely completion and commercialization of our drug candidates is the ability to confirm safety and efficacy based on the data of long-term clinical trials. For instance, in March 2008, we discontinued development of PRX-00023 due to lack of efficacy shown in a recently completed Phase 2b trial in patients with major depressive disorder. We cannot be certain that any of our drug candidates will prove to be safe or effective, will receive regulatory approvals or will be successfully commercialized. In order to achieve marketing approval, the FDA or foreign regulatory agencies must conclude that our clinical data establishes the safety and efficacy of our drug candidates. If our clinical-stage drug candidates are not successfully developed, future results of operations may be adversely affected.

We do not budget or manage our research and development costs by project on a fully allocated basis. Consequently, fully allocated research and development costs by project are not available. We use our employee and infrastructure resources across several projects and many of our costs are not attributable to an individually-named project but are directed to broadly applicable research projects. As a result, we cannot state precisely the costs incurred for each of our clinical and preclinical projects on a project-by-project basis. We estimate that, from the date we acquired Predix, August 16, 2006, through March 31, 2008, total third-party costs incurred for preclinical study support, clinical supplies and clinical trials associated with our three current therapeutic clinical programs are as follows:

PRX-08066	$ 5.2 million
PRX-03140	$10.6 million
PRX-07034	$ 8.9 million

We also estimate that, from the date we acquired Predix through the date we discontinued clinical development of PRX-00023 in March 2008, the total payments we made to third-parties for preclinical study support, clinical supplies and clinical trials associated with PRX-00023 were $13.1 million. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will receive cash inflows from the commercialization and sale of a product.

Financial Results

Revenues

The following table presents revenue and revenue growth (decline) for the three months ended March 31, 2008 and 2007:

	Three Months Ended March 31,		
	2008		2007
	Revenue	Growth (Decline)	Revenue
Product development revenue	$ 1,927,420	344%	$ 434,392

Royalty revenue	137,844	(72%)	487,658
License fee revenue	343,010	(67%)	1,032,850
Total	$ 2,408,274	23%	$ 1,954,900

Our revenue to date has consisted principally of product development revenue under our collaboration agreements with GlaxoSmithKline, Cystic Fibrosis Foundation Therapeutics, Incorporated, or CFFT, and Bayer Schering Pharma AG, Germany; license fee revenue relating to our agreements with Amgen, GlaxoSmithKline, Bayer Schering Pharma AG, Germany, CFFT,

Table of Contents

Covidien and Bracco; and royalties related to our agreements with Bracco and Bayer Schering Pharma AG, Germany. Royalties from Bracco concluded in the second quarter of 2007.

Product development revenue increased 344% for the three months ended March 31, 2008 compared to the corresponding prior year period primarily as a result of increased reimbursed research costs earned from our collaboration agreements with GlaxoSmithKline and CFFT, as well as an increase in development revenue for Vasovist. The decrease in royalty revenue of 72% for the three months ended March 31, 2008 compared to the corresponding prior year period was primarily due to a reduction in royalties on sales of MultiHance by Bracco due to the expiration of patents in 2007. License fee revenue decreased 67% for the three months ended March 31, 2008 compared to the corresponding prior year period primarily as a result of a decrease in the recognition of deferred revenue from the Amgen collaboration agreement. The deferred revenue from our Amgen agreement was fully recognized in October 2007 when we completed our research obligation.

Research and Development Expense

Research and development expense of $12.7 million for the three months ended March 31, 2008 reflects a decrease of 6% from the corresponding prior year period. The decrease in research and development expense was primarily due to a decrease of $3.0 million in third-party expenses associated with our therapeutic clinical development programs during the three months ended March 31, 2008, which was partially offset by costs incurred for the Vasovist re-read and increased costs to support our preclinical programs during the period. Clinical program costs incurred in the three months ended March 31, 2008 include costs for the completion of the Phase 2b clinical trial of PRX-00023 for depression and costs incurred to support planned clinical trials in 2008 in our three ongoing therapeutic clinical programs.

General and Administrative Expense

General and administrative expense of $3.0 million for the three months ended March 31, 2008 reflects a decrease of 65% from the corresponding prior year period. The decrease was primarily due to $5.0 million of nonrecurring legal and accounting costs incurred during the three months ended March 31, 2007 associated with our stock option investigation that was completed in early 2007.

Interest and Other Income

Interest and other income of $0.6 million for the three months ended March 31, 2008 reflects a decrease of $1.3 million, or 68%, from the comparable period in 2007. The decrease was primarily due to a decrease in interest income relating to lower levels of cash and investments available to invest due to cash being used to fund operations. In addition, the 2007 period includes $0.6 million of other income from the settlement of a contract dispute.

Interest Expense

Interest expense of $1.0 million for the three months ended March 31, 2008 represents a decrease of 18% from the comparable period in 2007. The decrease in interest expense was primarily due to the inclusion of interest expense in the 2007 period for the milestone payable to the former shareholders of Predix, which was paid in October 2007.

Provision for Income Taxes

The provision for income taxes in 2007 represents income taxes withheld in Italy on Bracco royalties for MultiHance sales. Royalties on these sales were discontinued in the second quarter of 2007.

LIQUIDITY AND CAPITAL RESOURCES

Our principal sources of liquidity consist of cash, cash equivalents and available-for-sale marketable securities of $46.7 million at March 31, 2008 as compared to $61.1 million at December 31, 2007. The decrease in cash, cash equivalents and available-for-sale marketable securities of $14.4 million was primarily attributable to funding of ongoing operations during the fiscal quarter.

We used approximately $14.5 million of cash to fund operating activities for the three months ended March 31, 2008, as compared to $13.3 million for the same period in 2007. The net use of cash to fund operations for the three months ended March 31, 2008 primarily resulted from the net loss of $13.7 million, as well as an increase in accounts receivable and prepaid expenses of approximately $1.0 million due to increased development work with our collaboration partners and the timing of our insurance renewals. The net cash used to fund operations during the three months ended March 31, 2007 consisted of a net loss of $19.5 million, which was partially offset by $1.2 million of cash received for landlord allowances towards construction at our Lexington, Massachusetts facility and an increase of

$5.0 million in accounts payable and accrued expenses largely resulting from costs incurred for the stock option investigation in that quarter.

Table of Contents

Our investing activities provided $17.8 million of cash during the three months ended March 31, 2008 as compared to $0.1 million of cash used during the same period in 2007. Investing activities in 2008 primarily consisted of $18.0 million of net redemptions of marketable securities to fund operating activities. The primary use of cash in the 2007 period consisted of $2.0 million of capital expenditures related to the build out of laboratory space at our Lexington, Massachusetts facility, which was partially offset by net redemptions of marketable securities of $1.6 million during the quarter.

Our primary sources of cash include payments from CFFT and GlaxoSmithKline for research services and milestones earned and monthly interest income on our cash, cash equivalents and available-for-sale marketable securities. Future potential cash inflows may include research funding, cost reimbursements, milestone and option payments from our current strategic collaborators, GlaxoSmithKline, Amgen, and CFFT. Because of anticipated spending for the continued development of our preclinical and clinical compounds, we do not expect positive cash flow from operating activities for at least the next several years.

Known outflows, in addition to our ongoing research and development and general and administrative expenses, include interest on our $100.0 million convertible notes at a rate of 3% payable semi-annually on June 15 and December 15 and a milestone payment of $2.5 million owed to Covidien, in the event the FDA approves Vasovist.

We estimate that cash, cash equivalents and marketable securities on hand as of March 31, 2008 and anticipated revenue we will earn in 2008 will fund our operations through the first quarter of 2009. This projection is based on our current cost structure and our current expectations regarding operating expenses and anticipated revenues. Our future liquidity and capital requirements will depend on numerous factors, including the following: the progress and scope of clinical and preclinical trials; the timing and costs of filing future regulatory submissions; the timing and costs required to receive both U.S. and foreign governmental approvals; the cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights; the extent to which our products, if any, gain market acceptance; the timing and costs of product introductions; the extent of our ongoing and new research and development programs; the costs of training physicians to become proficient with the use of our potential products; and, if necessary, once regulatory approvals are received, the costs of developing marketing and distribution capabilities. In addition, if holders of our convertible senior notes require redemption of the notes, we would be required to repay $100.0 million, plus accrued and unpaid interest, on June 15, 2011, 2014 and 2019 and upon certain other designated events under the notes, which include a change of control or termination of trading of our common stock on the NASDAQ Stock Market. We may need to raise substantial additional funds to cover our future capital requirements through equity or debt financings, strategic alliances or otherwise. We cannot assure you that additional financing will be available on terms favorable to us, or at all. If adequate funds are not available or are not available on acceptable terms, when we desire them, our ability to fund our operations, take advantage of unanticipated opportunities or otherwise respond to competitive pressures would be significantly limited.

Table of Contents

ITEM 3. Quantitative and Qualitative Disclosures About Market Risk.

The objective of our investment activities is to preserve principal, while at the same time maximizing yields without significantly increasing risk. To achieve this objective, in accordance with our investment policy, we invest our cash in a variety of financial instruments, principally restricted to government-sponsored enterprises, high-grade bank obligations, high-grade corporate bonds, high-grade asset-backed securities, and certain money market funds. These investments are denominated in U.S. dollars.

Investments in both fixed rate and floating rate interest earning instruments carry a degree of interest rate risk. Fixed rate securities may have their fair market value adversely impacted due to a rise in interest rates, while floating rate securities may produce less income than expected if interest rates fall. Due in part to these factors, our future investment income may fall short of expectations due to changes in interest rates or we may suffer losses in principal if forced to sell securities that have seen a decline in market value due to changes in interest rates. A hypothetical 10% increase or decrease in interest rates would result in an insignificant change in the fair market value of our total portfolio at March 31, 2008.

ITEM 4. Controls and Procedures.

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) as of the end of the period covered by this report. Based on that evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures as of the end of the period covered by this report were effective in ensuring that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission s rules and forms. We believe that a control system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

There was no significant change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during the period covered by this report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. Legal Proceedings.

From time to time we are a party to various legal proceedings arising in the ordinary course of our business. The outcome of litigation cannot be predicted with certainty and some lawsuits, claims or proceedings may be disposed of unfavorably to us. Intellectual property disputes often have a risk of injunctive relief which, if imposed against us, could materially and adversely affect our financial condition or results of operations. From time to time, third parties have asserted and may in the future assert intellectual property rights to technologies that are important to our business and have demanded and may in the future demand that we license their technology.

On December 8, 2006, we created a special board committee of independent directors to conduct a review of our historical stock option practices. The special committee completed its investigation and concluded that certain employees, including certain members of our former senior management, prior to the change in our senior management in connection with the merger with Predix in August 2006, had retrospectively selected dates for the grant of certain stock options and re-priced, as defined by financial accounting standards, certain options during the period from 1997 through 2005. As a result, in connection with the filing of our 2006 Form 10-K, we restated our financial statements to record additional non-cash stock-based compensation expense and related payroll tax effects, with regard to these past stock option grants. The SEC is conducting an informal inquiry into our stock option grants and practices and related accounting. Our past stock option practices and the restatement of our prior financial statements expose us to greater risks associated with litigation, regulatory, or other proceedings, as a result of which we could be required to pay significant fines or penalties.

ITEM 1A. Risk Factors.

We operate in a rapidly changing environment that involves a number of risks that could materially affect our business, financial condition or future results, some of which are beyond our control. In addition to the other information set forth in this report, the risks and uncertainties that we believe are most important for you to consider

are discussed in Part I, Item 1A. Risk Factors in our Annual Report on Form 10-K for the fiscal year ended December 31, 2007. There are no material changes to the risk factors described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2007 other than changes to the risk factors as set forth below and other changes to the risk factors to delete references to the PRX-00023 clinical development program to reflect that we have

Table of Contents

discontinued development of PRX-00023 due to lack of efficacy shown in a recently completed Phase 2b trial in patients with major depressive disorder. Additional risks and uncertainties not presently known to us, which we currently deem immaterial or which are similar to those faced by other companies in our industry or business in general, may also impair our business operations. If any of the foregoing risks or uncertainties actually occurs, our business, financial condition and operating results would likely suffer.

We have never had a commercially available product in the United States and we may never succeed in developing marketable products.

We have never had any product candidates receive regulatory approval for commercial sale in the United States and do not expect to have any commercial therapeutic products available in the United States for at least the next several years, if at all. In September 2006, results from our pivotal Phase 3 clinical trial of our PRX-00023 product candidate for generalized anxiety disorder demonstrated that PRX-00023 did not achieve a statistically significant improvement over placebo for the primary endpoint with respect to generalized anxiety disorder. Prior to obtaining results from this trial, PRX-00023 was our most advanced therapeutic drug candidate. Based on these trial results, however, we have discontinued our development efforts with respect to PRX-00023 in anxiety and focused our development efforts for this product candidate in depression. In March 2008, we discontinued development of PRX-00023 due to lack of efficacy shown in a recently completed Phase 2b trial in patients with major depressive disorder.

In addition, each of our current clinical-stage therapeutic drug candidates in the United States require additional clinical studies: PRX-08066 for the treatment of two types of pulmonary hypertension pulmonary hypertension associated with chronic obstructive pulmonary disease and pulmonary arterial hypertension; PRX-03140 for the treatment of Alzheimer s disease; and PRX-07034 for the treatment of cognitive impairment. Prior to the initiation of our Phase 2 clinical trial, PRX-08066 had never been tested in patients with pulmonary hypertension associated with chronic obstructive pulmonary disease and has never been tested in patients with primary pulmonary arterial hypertension. PRX-07034 has only been tested in obese but otherwise healthy subjects and has never been tested in subjects with cognitive impairment. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in early-stage clinical development. For example, Sanofi-Aventis discontinued the development of its product candidate for the treatment of Alzheimer s disease designed to target the 5-HT4 protein receptor due to lack of efficacy. This compound is believed to have the same mechanism of action as PRX-03140, was more advanced in clinical development and was more potent in vitro assays. Accordingly, the results from the completed and ongoing studies and trials for our product candidates may not be predictive of the results we may obtain in later-stage clinical trials. If we are unable to develop one or more marketable products in the United States, or elsewhere, our results of operations, business and future prospects would be materially harmed.

If clinical trials for our product candidates are prolonged or delayed, we may be unable to commercialize our product candidates on a timely basis, which would require us to incur additional costs and delay our receipt of any revenue from potential product sales.

We may encounter problems with our completed, ongoing or planned clinical trials for our product candidates that will cause us or any regulatory authority to delay or suspend those clinical trials or delay the analysis of data derived from them. A number of events, including any of the following, could delay the completion of, or terminate, our ongoing and planned clinical trials for our product candidates and negatively impact our ability to obtain regulatory approval or enter into collaborations for, or market or sell, a particular product candidate, including any of our current clinical-stage product candidates:

- conditions imposed on us by the FDA or any foreign regulatory authority regarding the scope or design of our clinical trials;

- delays in obtaining, or our inability to obtain, required approvals from institutional review boards or other reviewing entities at clinical sites selected for participation in our clinical trials;

delay in developing, or our inability to obtain, a clinical dosage form, insufficient supply or deficient quality of our product candidates or other materials necessary to conduct our clinical trials;

negative or inconclusive results from clinical trials, or results that are inconsistent with earlier results, that necessitate additional clinical study or termination of a clinical program;

serious and/or unexpected product-related side effects experienced by subjects in clinical trials; or

failure of our third-party contractors or our investigators to comply with regulatory requirements or otherwise meet their contractual obligations to us in a timely manner.

Table of Contents

Regulatory authorities, clinical investigators, institutional review boards, data safety monitoring boards and the hospitals at which our clinical trials are conducted all have the power to stop our clinical trials prior to completion. Our clinical trials for our product candidates may not begin as planned, may need to be restructured, and may not be completed on schedule, if at all. For example, in September 2001, after discussions with the FDA, we expanded our initial target indication for Vasovist from one specific body region, the aortoiliac region, to a broader indication that included the entire body s vascular system, except for the heart. This expansion required us to add two new clinical trials to our then existing Phase 3 clinical trial program. This change to the Phase 3 clinical trial program and the associated delay in the startup of new clinical centers resulted in an approximate 15-month delay in our NDA submission and an increase in costs associated with the program. Delays in clinical trials may result in increased development costs for our product candidates. In addition, if our clinical trials for our product candidates are delayed, our competitors may be able to bring product candidates to market before we do and the commercial viability of our product candidates could be significantly reduced. In addition, the number and complexity of clinical trials needed to achieve regulatory approval for our therapeutic drug candidates, including but not limited to PRX-03140, our product candidate for the treatment of Alzheimer s disease, could be significant. Achieving primary efficacy endpoints in clinical trials can be difficult in certain disease areas due to the placebo effect commonly observed in trials in certain patient populations. For example, our results from the completed Phase 3 and Phase 2b clinical studies of PRX-00023 in September 2006 and March 2008 indicated that PRX-00023 did not achieve a statistically significant improvement over placebo for their respective primary endpoints with respect to generalized anxiety disorder and major depressive disorder. Therefore, we discontinued our development efforts with respect to PRX-00023.

Our clinical trials may not yield results that will enable us to obtain regulatory approval for our product candidates.

We will only receive regulatory approval to commercialize a product candidate if we can demonstrate to the satisfaction of the FDA or the applicable foreign regulatory agency, in well-designed and conducted clinical trials, that the product candidate is safe and effective and otherwise meets the appropriate standards required for approval for a particular indication. Clinical trials are lengthy, complex and extremely expensive processes with uncertain results. For example, results from our recently completed Phase 2b clinical trial of PRX-00023 in major depressive disorder in March 2008, which was designed to evaluate the efficacy of PRX-00023 as measured by the change from baseline in the Montgomery Asberg Depression Rating Scale compared to placebo, demonstrated that PRX-00023 did not achieve a statistically significant improvement over placebo for the primary endpoint with respect to major depressive disorder. Based on these results, we have discontinued our development efforts of PRX-00023. We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals for our product candidates, including filing and prosecuting the applications necessary to gain approval by the FDA. Our NDA for Vasovist has not been, and may never be, approved by the FDA and we have not submitted an NDA to the FDA for any of our other product candidates. This limited experience may result in longer regulatory processes in connection with our efforts to obtain approval of our product candidates. With respect to both our current product candidates in human clinical trials and our research product candidates which may be suitable for testing in human clinical trials at some point in the future, we face risks including that:

- the product candidate may not prove to be safe and efficacious;
- the dosage form of the product candidate may not deliver reproducible amounts of product to patients;
- patients may die or suffer other adverse effects for reasons that may or may not be related to the product candidate being tested;
- the results of later-stage clinical trials may not confirm the positive results of earlier trials;
- the results may not meet the level of statistical significance required by the FDA or other regulatory agencies for approval; and
- the FDA or other regulatory agencies may require additional or expanded trials.

Of the large number of product candidates in development, only a small percentage result in the submission of an NDA to the FDA and even fewer are approved for commercialization. If we fail to demonstrate the safety and efficacy of our product candidates, we will not be able to obtain the required regulatory approvals to commercialize these product candidates. Certain of our preclinical and clinical product candidates have in the past and may in the future demonstrate safety concerns. The results from preclinical testing of a product candidate that is under development may not be predictive of results that will be obtained in human clinical trials. In addition, the results of early human clinical trials may not be predictive of results that will be obtained in larger scale, advanced-stage clinical trials. Our current product candidates and any other product candidates we may seek to develop in the future may never complete the clinical testing necessary to obtain the appropriate regulatory approvals for us to begin selling them.

Our competitors may develop products that are less expensive, safer or more effective, which may diminish or eliminate the commercial success of any future products that we may commercialize.

Competition in the pharmaceutical and biotechnology industries is intense and expected to increase. We face competition from pharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies engaged in product discovery activities or funding, both in the United States and abroad. Some of these competitors have therapeutic products or are pursuing the development of therapeutic product candidates that target the same diseases and conditions that are the focus of our clinical-stage therapeutic product candidates, including the following:

Table of Contents

PRX-03140. If approved, PRX-03140, the drug candidate we are developing for the treatment of Alzheimer s disease, may compete with approved products from such pharmaceutical companies as Forest Laboratories, Inc., Johnson & Johnson, Novartis AG and Pfizer, Inc., and may compete with drug candidates in clinical development from other companies, including Myriad Genetics, Inc., GlaxoSmithKline plc and Neurochem Inc. We are studying PRX-03140 both as monotherapy and in combination with approved products, such as Aricept which is marketed by Pfizer Inc. We believe that there are over 70 therapeutic product candidates in clinical trials for the treatment of Alzheimer s disease.

PRX-08066. If approved, PRX-08066, the drug candidate we are developing for the treatment of pulmonary arterial hypertension (PAH), may compete with approved products from such pharmaceutical companies as Actelion Pharmaceuticals Ltd., GlaxoSmithKline plc, Pfizer Inc., Gilead Sciences Inc., and United Therapeutics Corporation, and may compete with drug candidates in clinical development by other companies, such as Encysive Pharmaceuticals Inc. and Bayer Schering Pharma AG. We believe that there are approximately ten therapeutic product candidates in clinical trials or that have been submitted for approval for the treatment of pulmonary arterial hypertension and/or pulmonary hypertension associated with chronic obstructive pulmonary disease.

PRX-07034. If approved for the treatment of cognitive impairment (associated with schizophrenia or Alzheimer s disease), PRX-07034 may compete with approved products from such pharmaceutical companies as Forest Laboratories, Johnson & Johnson, Novartis AG and Pfizer, Inc., and may compete with several therapeutic product candidates in clinical development from other companies, including GlaxoSmithKline plc, AstraZeneca and Memory Pharmaceuticals Corp. We believe that there are over 60 therapeutic product candidates in clinical trials for the treatment of cognitive impairment in association with schizophrenia. If approved for the treatment of obesity, PRX-07034 may compete with approved products from such pharmaceutical companies as Abbott Laboratories and Roche Holding Ltd., and may compete with several therapeutic product candidates in clinical development by other companies, such as Sanofi-Aventis and Arena Pharmaceuticals, Inc. We believe that there are over 40 therapeutic product candidates in clinical trials for the treatment of obesity.

We expect that many patents covering commercial therapeutic products for these indications will expire in the next four to nine years, which will result in greater competition in these indications resulting from companies producing generic versions of the commercial products. Many of our competitors have therapeutic products that have been approved or are in advanced development and may develop superior technologies or methods to identify and validate therapeutic product targets and to discover novel small-molecule products. Our competitors may also develop alternative therapies that could further limit the market for any therapeutic products that we may develop.

In addition, there are a number of general use MRI agents approved for marketing in the United States, and in certain foreign markets that, if used or developed for magnetic resonance angiography, are likely to compete with Vasovist. Such products include Magnevist and Gadovist by Bayer Schering Pharma AG, Germany, Dotarem by Guerbet, S.A., Omniscan by GE Healthcare, ProHance and MultiHance by Bracco and OptiMARK by Covidien Ltd. We are aware of six agents under clinical development that have been or are being evaluated for use in magnetic resonance angiography: Bayer Schering Pharma AG, Germany s Gadomer and SHU555C, Guerbet, S.A. s Vistarem, Bracco s B-22956/1, Ferropharm GmbH s Code VSOP-C184, and Advanced Magnetics Inc. s Ferumoxytol. Moreover, there are several well-established medical imaging methods that currently compete and will continue to compete with MRI, including digital subtraction angiography, which is an improved form of X-ray angiography, computed tomography angiography, nuclear medicine and ultrasound, and there are companies that are actively developing the capabilities of these competing methods to enhance their effectiveness in vascular system imaging.

Despite our successful re-read of images obtained from prior Phase 3 clinical trials of Vasovist, we may never obtain approval to market and sell Vasovist in the United States or monetize the potential royalty stream therefrom, either of which would materially harm our revenues.

Vasovist has not been approved for marketing and sale in the United States by the FDA. In connection with a new drug application, or NDA, that we submitted for Vasovist in December 2003, we received an approvable letter from the FDA in January 2005 in which the FDA requested additional clinical trials prior to approval. In May 2005, we submitted a response to the FDA approvable letter, which was accepted by the FDA as a complete response in June 2005. In November 2005, the FDA provided us with a second approvable letter which indicated that at least one additional clinical trial and a re-read of images obtained in certain previously completed Phase 3 trials will be necessary before the FDA could approve Vasovist. After considering the parameters of the

Table of Contents

additional clinical trials requested by the FDA, we filed a formal appeal with the FDA asking the FDA to approve Vasovist and to utilize an advisory committee as part of the appeal process. In August 2006, the FDA denied our appeal and suggested that we conduct two new clinical trials for Vasovist. In February 2007, we filed our second formal appeal with the FDA asking the FDA to approve Vasovist and to utilize an advisory committee as part of the appeal process. On June 15, 2007, we received a letter from the FDA denying our second formal appeal, but indicated that a blinded re-read, or reanalysis, of the images obtained in our previously completed Phase 3 clinical trials of Vasovist could provide the potential evidence to support approval of Vasovist if the results of the re-read are positive. In January 2008, we initiated the re-read of the images obtained in prior Phase 3 studies, and in April 2008 we announced that we met all pre-specified endpoints for the re-read prospectively agreed to with the FDA. Although we plan to resubmit an NDA to the FDA for Vasovist in mid-2008, the approval, timeliness of approval and labeling of Vasovist remains subject to significant uncertainties related to a number of factors, including the FDA s review process and conclusions regarding the NDA resubmission. We cannot assure you that the FDA will approve Vasovist upon the resubmission of the NDA. If the FDA does not approve Vasovist, we will not receive revenues based on sales of Vasovist in the United States.

In addition, pursuant to our collaboration with Bayer Schering Pharma AG, Germany, we are entitled to a percentage of Bayer Schering Pharma AG, Germany s operating profit margin on sales of Vasovist in the United States. We may seek to monetize these potential royalties to fund our clinical pipeline. Any failure or delay by the FDA in approving Vasovist could materially and adversely affect our ability to enter into any such agreements. We cannot assure you that we would be able to enter into an agreement with a third party to monetize such royalties, and our failure to do so could materially and adversely affect our ability to generate revenues. In addition, disagreements with Bayer Schering Pharma AG, Germany regarding our collaboration or otherwise could delay or terminate our efforts to successfully monetize our share of U.S. royalties on Vasovist.

Table of Contents

ITEM 6. Exhibits.

Exhibit number	Description
10.1*+	Research, Development and Commercialization Agreement between EPIX Pharmaceuticals, Inc. and Cystic Fibrosis Foundation Therapeutics, Inc., dated as of April 1, 2008.
10.2#	Form of Restricted Stock Unit Agreement under the Amended and Restated 1992 Incentive Plan. Filed as Exhibit 10.1 to the Company s Current Report on Form 8-K filed February 22, 2008 and incorporated herein by reference.
10.3#	Form of Restricted Stock Unit Agreement under the Amended and Restated 2003 Stock Option and Incentive Plan. Filed as Exhibit 10.2 to the Company s Current Report on Form 8-K filed February 22, 2008 and incorporated herein by reference.
31.1*	Certification Pursuant to Rule 13(a)-14(a) or Rule 15d-14(a) of Securities Exchange Act of 1934.
31.2*	Certification Pursuant to Rule 13(a)-14(a) or Rule 15d-14(a) of Securities Exchange Act of 1934.
32.1*	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* *Filed herewith.*

\+ *Confidential treatment has been requested for portions of this exhibit.*

\# *Identifies a management contract or compensatory plan or agreement in which an executive officer or director of the Company participates.*

Table of Contents

SIGNATURES

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

EPIX Pharmaceuticals, Inc.

Date: May 9, 2008

By: /s/ Kim Cobleigh Drapkin
Kim Cobleigh Drapkin
Chief Financial Officer
(Authorized Officer and Principal Financial Officer)

Table of Contents

Exhibit Index

Exhibit number	Description
10.1*+	Research, Development and Commercialization Agreement between EPIX Pharmaceuticals, Inc. and Cystic Fibrosis Foundation Therapeutics, Inc., dated as of April 1, 2008.
10.2#	Form of Restricted Stock Unit Agreement under the Amended and Restated 1992 Incentive Plan. Filed as Exhibit 10.1 to the Company s Current Report on Form 8-K filed February 22, 2008 and incorporated herein by reference.
10.3#	Form of Restricted Stock Unit Agreement under the Amended and Restated 2003 Stock Option and Incentive Plan. Filed as Exhibit 10.2 to the Company s Current Report on Form 8-K filed February 22, 2008 and incorporated herein by reference.
31.1*	Certification Pursuant to Rule 13(a)-14(a) or Rule 15d-14(a) of Securities Exchange Act of 1934.
31.2*	Certification Pursuant to Rule 13(a)-14(a) or Rule 15d-14(a) of Securities Exchange Act of 1934.
32.1*	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* *Filed herewith*

\+ *Confidential treatment has been requested for portions of this exhibit.*

\# *Identifies a management contract or compensatory plan or agreement in which an executive officer or director of the Company participates.*