

EPIX Pharmaceuticals, Inc.  
Form 10-Q  
May 08, 2007

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

**(Mark One)**

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

**For the quarterly period ended March 31, 2007**

**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 0-21863**

**EPIX Pharmaceuticals, Inc.**

(Exact name of Registrant as Specified in its Charter)

**Delaware**

(State of incorporation)

**04-3030815**

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

**4 Maguire Road, Lexington, Massachusetts**

(Address of principal executive offices)

**02421**

(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 ☒ No ☐

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

Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No ☒

As of April 30, 2007, 32,600,099 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**  
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**EPIX PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
**(unaudited)**

	<b>March 31, 2007</b>	<b>December 31, 2006</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 17,008,949	\$ 30,332,468
Available-for-sale marketable securities	77,948,017	79,210,430
Accounts receivable		46,367
Prepaid expenses and other assets	2,905,567	2,575,265
Total current assets	97,862,533	112,164,530
Property and equipment, net	5,128,433	3,592,570
Other assets	4,311,191	4,330,578
Goodwill	4,939,814	4,939,814
Total assets	\$ 112,241,971	\$ 125,027,492
<b>LIABILITIES AND STOCKHOLDERS DEFICIT</b>		
Current liabilities:		
Accounts payable	\$ 3,845,534	\$ 1,982,032
Accrued expenses	10,868,696	7,695,548
Contract advances	4,754,556	4,605,079
Merger consideration payable	18,786,704	18,504,084
Current portion of capital lease obligation	116,184	84,633
Deferred revenue	2,958,985	3,665,120
Other current liabilities	485,753	446,137
Total current liabilities	41,816,412	36,982,633
Deferred revenue	16,771,764	17,101,165
Capital lease obligation	105,487	102,077
Other liabilities	4,314,646	2,862,898
Convertible debt	100,000,000	100,000,000
Total liabilities	163,008,309	157,048,773
Commitments and contingencies		
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; 32,597,971 and 32,524,726 shares issued and outstanding at March 31, 2007 and December 31, 2006, respectively	325,979	325,247
Additional paid-in-capital	313,755,169	312,984,862

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Accumulated deficit	(364,878,213)	(345,368,698)
Accumulated other comprehensive income	30,727	37,308
Total stockholders' deficit	(50,766,338)	(32,021,281)
Total liabilities and stockholders' deficit	\$ 112,241,971	\$ 125,027,492

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

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

	<b>Three Months Ended March 31,</b>	
	<b>2007</b>	<b>2006</b>
Revenues:		
Product development revenue	\$ 434,392	\$ 1,082,867
Royalty revenue	487,658	457,778
License fee revenue	1,032,850	161,597
Total revenues	1,954,900	1,702,242
Operating expenses:		
Royalties	53,668	43,795
Research and development	13,491,119	3,865,001
General and administrative	8,613,758	2,422,528
Restructuring		289,633
Total operating expenses	22,158,545	6,620,957
Operating loss	(20,203,645)	(4,918,715)
Interest and other income	1,962,953	1,304,573
Interest expense	(1,230,734)	(869,363)
Loss before provision for income taxes	(19,471,426)	(4,483,505)
Provision for income taxes	38,089	43,816
Net loss	\$ (19,509,515)	\$ (4,527,321)
Weighted average shares:		
Basic and diluted	32,586,377	15,523,207
Net loss per share, basic and diluted	\$ (0.60)	\$ (0.29)

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

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

	<b>Three Months Ended March 31,</b>	
	<b>2007</b>	<b>2006</b>
Operating activities:		
Net loss	\$ (19,509,515)	\$ (4,527,321)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation, amortization and asset write offs	516,278	409,899
Stock compensation expense	696,677	792,755
Noncash interest expense from embedded derivative	(27,725)	
Amortization of deferred financing costs	123,511	119,109
Accretion of premium (discount) on available-for-sale securities	(777,315)	8,985
Changes in operating assets and liabilities:		
Accounts receivable	46,367	54,588
Prepaid expenses and other current assets	(330,302)	(132,987)
Other assets and liabilities	1,517,178	
Accounts payable	1,863,502	(727,177)
Accrued expenses	3,173,149	(415,476)
Contract advances	149,477	(687,231)
Merger consideration payable	310,345	
Deferred revenue	(1,035,536)	(161,596)
Net cash used in operating activities	(13,283,909)	(5,266,452)
Investing activities:		
Purchases of marketable securities	(21,859,213)	(22,788,633)
Sales or redemptions of marketable securities	23,500,000	32,154,558
Restricted cash	262,422	
Purchases of fixed assets	(1,995,181)	(638,821)
Net cash provided by (used in) investing activities	(91,972)	8,727,104
Financing activities:		
Principal payments on capital leases	(22,000)	
Proceeds from stock option exercises	74,362	
Net cash provided by financing activities	52,362	
Net increase (decrease) in cash and cash equivalents	(13,323,519)	3,460,652
Cash and cash equivalents at beginning of period	30,332,468	72,502,906
Cash and cash equivalents at end of period	\$ 17,008,949	\$ 75,963,558
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.





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**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, developing and commercializing novel pharmaceutical products through the use of proprietary technologies to better diagnose, treat and manage patients. The Company has four internally discovered therapeutic candidates in clinical trials. These drug candidates are targeting conditions such as depression, Alzheimer's disease, cardiovascular disease and obesity. In addition, the Company has two imaging agents, one of which is approved for marketing in 32 countries outside of the United States and one that has completed a Phase 2a clinical trial. The Company also has collaborations with leading organizations, including 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 instructions to Form 10-Q and the rules of the Securities and Exchange Commission (the SEC or the Commission ). 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, 2007 are not necessarily indicative of the results expected for the full fiscal year.

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, as amended, for the year ended December 31, 2006.

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### **3. Significant Accounting Policies**

#### ***Principles of Consolidation***

The 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***

In June 2006, the Financial Accounting Standards Board (FASB) issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* ( FIN 48 ). FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with Statement of Financial Accounting Standards (SFAS) No. 109, *Accounting for Income Taxes*. This interpretation prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition of tax benefits, classification on the balance sheet, interest and penalties, accounting in interim periods, disclosure, and transition. The Company's adoption of FIN 48 effective January 1, 2007 did not have a material effect on the Company's financial position or results of operations.

#### ***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 discovery and development of pharmaceutical products.

#### ***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 non-refundable 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 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 are recognized as 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 technology, such as initiation of clinical trials, filing for approval with regulatory agencies and approvals by regulatory agencies.

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

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

#### ***Research and Development Expenses***

Research and development costs, including those associated with technology, licenses and patents, 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.

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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 during the period. On a quarterly basis, the Company reviews the assumptions for each contract in order to reflect its 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.

***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, 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, convertible debt and merger consideration is not assumed if the result is anti-dilutive, such as when a loss is reported.

Common stock potentially issuable but excluded from the calculation of dilutive net loss per share for the three months ended March 31, 2007 and 2006 because their inclusion would have been antidilutive consisted of the following:

	<b>Three Months Ended March 31,</b>	
	<b>2007</b>	<b>2006</b>
Stock options and awards	3,863,241	1,657,744
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	
	<b>8,750,394</b>	<b>3,897,137</b>

(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, 2007.

- (2) Share amount calculated as if the merger consideration was payable to the former Predix security holders as of March 31, 2007. Actual settlement date for the merger consideration is October 29, 2007. The remaining merger consideration is payable in EPIX common stock to the extent that such payment in shares would not cause the former Predix shareholders, warrant holders and option

holders  
aggregate  
interest in EPIX  
to exceed  
49.99%.

***Comprehensive Income (Loss)***

In accordance with SFAS No. 130, *Reporting Comprehensive Income* components of comprehensive income (loss) include net loss and certain transactions that have generally been reported in the statements of stockholders equity (deficit). The Company's comprehensive loss is comprised of 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, 2007 and 2006 was \$19.5 million and \$4.5 million, respectively.

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Certain items in the prior year's consolidated financial statements have been reclassified to conform to the current presentation of the financial statements.

**4. Acquisition of Predix**

On August 16, 2006, EPIX completed its acquisition of Predix Pharmaceuticals Holdings, Inc. (Predix) pursuant to the terms of the merger agreement. Pursuant to the merger agreement, Predix merged with and into EPIX Delaware, Inc. and became a wholly-owned subsidiary of EPIX. The merger with Predix was primarily a stock transaction valued at approximately \$125.0 million, including the assumption of net debt at closing. The results of Predix have been included in the statement of operations from August 16, 2006.

The following pro forma financial information presents the results of operations as if the merger had occurred at the beginning of 2006 (in thousands, except per share amount). The pro forma financial information excludes the write-off of in-process research and development of \$123,500,000 as it has no continuing impact after the merger. The pro forma information does not purport to indicate the results that would have actually been obtained had the merger been completed on the assumed date or which may be realized in the future.

	<b>Three Months Ended March 31, 2006</b>
Revenues	\$ 2,487
Net loss	\$ (12,620)
Net loss per share, basic and diluted	\$ (0.43)

**5. Restructuring Charges**

At December 31, 2006, the Company had a \$229,976 restructuring liability for on-going lease obligations related to restructuring charges recorded in 2006. During the three-months ended March 31, 2007, the Company paid \$53,749 resulting in a liability balance of \$176,227 at March 31, 2007.

**6. Recent Accounting Pronouncements**

On September 15, 2006, the FASB issued SFAS No. 157 *Fair Value Measurements*. SFAS 157 defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. SFAS 157 is effective for the Company as of January 1, 2008. The Company is currently evaluating the potential impact of adopting SFAS 157.

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### **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, 2006, 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. 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, 2006, 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, developing and commercializing novel pharmaceutical products through the use of proprietary technologies to better diagnose, treat and manage patients. We have four internally discovered therapeutic candidates in clinical trials. These drug candidates are targeting conditions such as depression, Alzheimer's disease, cardiovascular disease and obesity. In addition we have two imaging agents, one of which is approved for marketing in 32 countries outside of the United States and one that has completed a Phase 2a clinical trial. We also have collaborations with leading organizations, including 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 have 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 have moved each of these drug candidates into clinical trials in less than 18 months from lead identification. We believe our drug discovery technology and approach enables us to efficiently and cost-effectively discover and develop GPCR and ion channel-targeted drugs.

#### **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;

fees paid to access chemical and intellectual property databases;



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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 32 countries outside of the United States. We are appealing the U.S. Food and Drug Administration's (FDA) decision to require additional clinical trials for approval of Vasovist in the United States. We also have one imaging agent, EP-2104R, in clinical development. We completed a Phase 2a clinical trial of EP-2104R in the second quarter of 2006. We do not intend to continue development of EP-2104R and are actively pursuing a partner to continue further development. Future costs expected to be incurred for Vasovist are currently limited to legal and consulting costs related to the on-going FDA appeal. Future costs expected to be incurred for EP-2104 are limited to our partnering efforts.

In connection with our acquisition of Predix, we incurred a 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 have 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 ( 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 September 2006, we completed a pivotal Phase 3 clinical trial for the treatment of generalized anxiety disorder with PRX-00023. Results from this trial demonstrated that PRX-00023 did not achieve a statistically significant improvement over placebo for the primary endpoint of efficacy with respect to generalized anxiety disorder at the dose tested (80mg once daily). The trial was statistically powered to evaluate the efficacy of PRX-00023 compared to placebo as measured by the change from baseline in the Hamilton Rating Scale for Anxiety or HAM-A. The HAM-A scale is the accepted standard for the evaluation of anti-anxiety drug activity for the FDA. Effects of PRX-00023 on symptoms of depression, which was a secondary endpoint of the Phase 3 clinical trial, were assessed using the Montgomery-Asberg Depression Rating Scale or MADRS, an FDA-recommended assessment for depression. The data from this trial showed a statistically significant improvement from baseline with PRX-00023 treatment compared to placebo in the MADRS score, indicating that PRX-00023 reduced symptoms of depression present in the patients in this trial. In this Phase 3 trial, PRX-00023 was well tolerated, and the rate of discontinuation due to adverse events was very low (1.4% with PRX-00023 vs. 2.9% with placebo). To date, there have been no serious adverse events associated with treatment in more than 250 subjects who have received PRX-00023.

Based on the Phase 3 trial results, we have discontinued clinical development of PRX-00023 at a dose of 80mg once daily in generalized anxiety disorder. We are currently focusing our development efforts for this drug candidate on depression. We initiated a randomized, blinded Phase 2b clinical trial of PRX-00023 in major depression in March 2007.

The following summarizes the applicable disease indication and the clinical status of our four therapeutic drug candidates:



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<b>Drug Candidate</b>	<b>Disease Indication</b>	<b>Clinical Trial Status</b>
	Pulmonary Hypertension/COPD	Phase 2a
PRX-08066		
PRX-00023	Depression	Phase 2b
PRX-03140	Alzheimer's disease	Phase 2a
	Obesity/cognitive impairment	Phase 1b
PRX-07034		

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.

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:

<b>Clinical Phase</b>	<b>Objective</b>	<b>Estimated Completion Period</b>
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. 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 loaded 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

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date we acquired Predix, August 16, 2006, through March 31, 2007, total third party costs incurred for preclinical study support, clinical supplies and clinical trials associated with our four therapeutic clinical programs are as follows:

PRX-08066	\$3.3 million
PRX-00023	\$5.3 million
PRX-03140	\$2.5 million
PRX-07034	\$4.3 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, 2007 and 2006:

	<b>Three Months Ended March 31,</b>		
	<b>2007</b>	<b>Growth (Decline)</b>	<b>2006</b>
	<b>Revenue</b>		<b>Revenue</b>
Product development revenue	\$ 434,392	(60)%	\$ 1,082,867
Royalty revenue	487,658	7%	457,778
License fee revenue	1,032,850	539%	161,597
Total	\$ 1,954,900	15%	\$ 1,702,242

Our revenues to date have arisen principally from our collaboration agreements with Bayer Schering Pharma AG, Germany (for Vasovist, EP-2104R and MRI discovery research) and Cystic Fibrosis Foundation Therapeutics (CFFT); from license fee revenues relating to our agreements with Amgen, GlaxoSmithKline, Bayer Schering Pharma AG, Germany, CFFT, Tyco and Bracco; and from royalties related to our agreements with Bracco and Bayer Schering Pharma AG, Germany. Our MRI discovery research collaboration and our development agreement for EP-2104R with Bayer Schering Pharma AG, Germany concluded in May 2006 and August 2006, respectively.

Product development revenue decreased 60% in the three months ended March 31, 2007 compared to the prior year period primarily as a result of the completion of the MRI discovery research program in May 2006 and the EP-2104R program in August 2006. In addition, Vasovist development revenue was significantly lower in the current quarter due to lower development costs in 2007 as we continue to appeal the FDA's decision to require additional clinical trials.

The increase in royalty revenue of 7% in the three months ended March 31, 2007 compared to the prior year period resulted from royalties of \$0.1 million from sales of Vasovist in Europe, which was first marketed in the second quarter of 2006, partially offset by a reduction in the royalties on sales of MultiHance by Bracco. We do not expect royalty income on the European sales of Vasovist to be significant in 2007. In addition, we expect royalty revenue from Bracco to end in the second quarter of 2007 due to the expiration of patents.

License fee revenue increased 539% in the three months ended March 31, 2007 compared to the prior year period primarily as a result of the recognition of deferred revenue from the Amgen and GlaxoSmithKline agreements. Partially offsetting this increase was a decrease in revenue from the recognition of the Bracco license fee as this fee was fully recognized by June 2006.

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### *Research and Development Expenses*

Research and development expenses of \$13.5 million for the three months ended March 31, 2007 reflects an increase of 249% from the prior year. The increase in research and development expenses was primarily due to third party expenses of \$7.6 million associated with our clinical development programs as well as costs for the preclinical programs and internal costs which began after the Predix acquisition was completed on August 16, 2006. Clinical program costs incurred in the current quarter include initiation costs for Phase 2b clinical trial for depression with PRX-00023; costs incurred for the ongoing Phase 2a clinical trial of PRX-03140 for the treatment of Alzheimer's disease, costs incurred for the ongoing Phase 2a clinical trial of PRX-08066 for the treatment of pulmonary hypertension in association with COPD, and costs incurred for the completion of the Phase 1b multiple ascending dose clinical trial of PRX-07034 for the treatment of obesity and cognitive impairment. The increased costs in the three months ended March 31, 2007 as described above were partially offset by the discontinuation of spending on imaging programs subsequent to the merger with Predix, notably the EP-2104R development program and the MRI research programs. Spending during 2007 and 2006 for Vasovist primarily involved costs related to our appeal to the FDA and was not significant.

### *General and Administrative Expenses*

General and administrative expenses of \$8.6 million for the three months ended March 31, 2007 reflects an increase of 256% from the prior year. The increase in general and administrative expenses was primarily due to nonrecurring legal and accounting costs of approximately \$5.0 million associated with the stock option investigation that was recently completed as well as increased costs associated with the increase in personnel and infrastructure relating to the Predix business that was acquired on August 16, 2006. In addition, legal expenses for patent-related matters and general corporate items increased due to the increasing complexity of the post merger entity.

### *Restructuring Costs*

Restructuring costs of \$0.3 million in the three months ended March 31, 2006 represent additional costs related to the December 2005 restructuring whereby we reduced our workforce by 48 employees, or approximately 50%, in response to the FDA's second approvable letter regarding Vasovist. The reductions, which were completed in January 2006, affected both the research and development and the general and administrative areas of the company. The 2006 costs included severance costs as well as costs related to vacating certain leased space and the write-off of leasehold improvements.

We expect to incur restructuring costs of approximately \$0.5 in the second quarter of 2007 for the consolidation of our leased laboratory facility in Cambridge to our Lexington location. The timing and amount of the additional restructuring costs will depend upon the completion of laboratory construction at our Lexington facility, which is currently anticipated to be June 2007.

### *Interest and Other Income*

Interest and other income of \$2.0 million for the three months ended March 31, 2007 reflects an increase of \$0.7 million or 50% from the prior year. The increase was primarily due to \$0.6 million of other income received from the settlement of a contractual dispute.

### *Interest Expense*

Interest expense of \$1.2 million for the three months ended March 31, 2007 reflects an increase of \$0.4 million or 42% from the prior year. The increase in interest expense was primarily the result of \$0.3 million of interest related to the \$15.0 million milestone payment due to the former Predix security holders on October 29, 2007. We record interest expense on the milestone at the greater of the stated rate of 10% or the value of the embedded derivative included in the milestone, which provides for the milestone payment to be paid in shares of our common stock based on 75% of the 30-day average closing price of our common stock ending on the trading day that is ten days prior to the payment date. This embedded derivative is recorded at its fair value and changes in the fair value are recorded as interest expense. Under the terms of the merger agreement, if the milestone cannot be paid in shares of our common stock due to terms of the agreement, the payment plus 10% interest will be made in cash. The change in the value of the derivative was not significant in the first quarter of 2007.

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### *Provision for Income Taxes*

The provision for income taxes represents Italian income taxes required to be withheld on Bracco royalties for MultiHance sales.

## **LIQUIDITY AND CAPITAL RESOURCES**

Our principal sources of liquidity consist of cash, cash equivalents and available-for-sale marketable securities of \$95.0 million at March 31, 2007 as compared to \$109.5 million at December 31, 2006. The decrease in cash, cash equivalents and available-for-sale marketable securities of \$14.5 million was primarily attributable to funding of ongoing operations during the current quarter.

We used approximately \$13.3 million of cash to fund operating activities for the three months ended March 31, 2007, as compared to \$5.3 million used to fund operations for the same period in 2006. The use of cash for the current quarter primarily resulted from the net loss of \$19.5 million, which was partially offset by an increase of \$5.0 million in accounts payable and accrued expenses largely resulting from costs incurred for the recently completed stock option investigation. These costs will be paid in the second quarter of 2007. We also received approximately \$1.2 million during the current quarter of landlord allowances related to the laboratory construction at our Lexington facility. The net cash used to fund operations during the three months ended March 31, 2006 of \$5.3 million was primarily due to the net loss of \$4.5 million for the quarter and the reduction of approximately \$1.1 million of accounts payable and accrued expenses due to a decrease in development activity in the quarter.

Our investing activities used \$0.1 million of cash during the three months ended March 31, 2007 as compared to \$8.7 million of cash provided during the same period last year. The primary uses of cash from investing activities in 2007 was \$2.0 million of capital expenditures primarily related to the build out of laboratory space at our Lexington facility, which was partially offset by net redemptions of marketable securities of \$1.6 million during the quarter. The primary source of cash from investing activities in the 2006 period was the net redemption of marketable securities of \$9.3 million which was partially offset by \$0.6 million of capital spending.

Our primary sources of cash include quarterly payments from CFRT for research services and monthly interest income on our cash, cash equivalents and available-for-sale marketable securities. In addition, in the second half of 2006, we began receiving royalty payments (approximately \$75,000 for 2006) from sales of Vasovist by Bayer Schering Pharma AG, Germany following the commercial launch of the product in Europe, which began on a country-by-country basis in the second quarter of 2006. We expect royalty payments from sales of Vasovist to slowly increase as the product is introduced in other countries where it has been approved. Despite this, we do not expect the royalties received on non-United States sales of Vasovist to be significant in the near term. Other potential cash inflows include milestone payments from our current strategic collaborators, GlaxoSmithKline, Amgen, CFRT and Bayer Schering Pharma AG, Germany.

Known outflows, in addition to our ongoing research and development and general and administrative expenses, include the following: \$15.0 million milestone payment to the former Predix security holders due on October 29, 2007 primarily payable in shares of our stock if certain conditions are met or otherwise payable in cash plus interest accrued at a rate of 10%; and interest on our \$100.0 million convertible notes at a rate of 3% payable semi-annually on June 15 and December 15.

We estimate that cash, cash equivalents and marketable securities on hand as of March 31, 2007 and anticipated revenue we will earn in 2007 and 2008, exclusive of any significant milestone payments or opt-in fees, will fund our operations through 2008. Our past stock option practices and the restatement of our prior financial statements expose us to greater risks associated with litigation and regulatory proceedings. In the event of any litigation or regulatory proceeding involving a negative finding or assertion by the SEC, U.S. Attorney, court of law or any third party claim related to our stock option practices, we may be liable for damages, fines or other civil or criminal remedies or remedial actions, or be required to further restate prior period financial statements or adjust current period financial statements. In addition, considerable legal and accounting expenses related to these matters have been incurred to date and significant expenditures may continue to be incurred in the future.

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 of us or termination of trading of our common stock on





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the NASDAQ Global Market. 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.

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.

### **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 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 a change in the fair market value of our total portfolio of approximately \$0.1 million at March 31, 2007.

### **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. In the period covered by this report, in connection with our investigation of our historical stock option practices, we adopted an equity award grant policy that formalizes how we grant equity awards by setting a regular schedule for grants, outlining grant approval requirements and specifying how awards are priced.

## **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.



**Table of Contents***Provision for Income Taxes*

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 Pharmaceuticals Holdings, Inc. on August 16, 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 of this review, we restated our financial statements to record additional non-cash stock-based compensation expense, and related payroll tax effects, with regard to certain past stock option grants. 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 found liable for damages, fines or other civil or other remedies or remedial actions, or be required to further restate prior period financial statements or adjust current period financial statements. In addition, the SEC is conducting an informal inquiry into our stock option grants and practices and related accounting. We could be required to pay significant fines or penalties resulting from the inquiry.

**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, 2006. 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.

**ITEM 6. Exhibits.****Exhibit  
number****Description**

- 3.1 Amended and Restated By-Laws of the Company.
- 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.

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**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 8, 2007

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

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**Exhibit Index**

<b>Exhibit number</b>	<b>Description</b>
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