

EPIX Pharmaceuticals, Inc.
Form 10-Q
November 05, 2008

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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 **September 30, 2008**

Or

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

For the transition period from _____ to _____

**Commission File Number 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, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company

(Do not check if a smaller reporting company)

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 November 3, 2008, 41,679,996 shares of the registrant's Common Stock, \$0.01 par value per share, were issued and outstanding.

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

| | September 30, 2008 | December 31, 2007 |
|--|-------------------------------|------------------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 19,735,044 | \$ 9,157,973 |
| Available-for-sale marketable securities | 14,750,435 | 51,919,128 |
| Accounts receivable | 3,102,891 | 639,396 |
| Prepaid expenses and other assets | 1,373,990 | 1,523,499 |
| Total current assets | 38,962,360 | 63,239,996 |
| Property and equipment, net | 5,691,876 | 6,044,886 |
| Other assets | 3,217,361 | 3,850,431 |
| Goodwill | 4,939,814 | 4,939,814 |
| Total assets | \$ 52,811,411 | \$ 78,075,127 |
| LIABILITIES AND STOCKHOLDERS DEFICIT | | |
| Current liabilities: | | |
| Accounts payable | \$ 3,891,232 | \$ 3,539,099 |
| Accrued expenses | 8,126,700 | 8,099,539 |
| Contract advances | 3,977,675 | 4,719,201 |
| Current portion of capital lease obligation | 228,281 | 179,859 |
| Deferred revenue | 1,847,434 | 1,372,042 |
| Other current liabilities | 737,930 | 610,867 |
| Total current liabilities | 18,809,252 | 18,520,607 |
| Deferred revenue | 14,101,703 | 15,688,296 |
| Capital lease obligation | 275,421 | 182,748 |
| Other liabilities | 4,448,853 | 4,975,123 |
| Convertible debt | 100,000,000 | 100,000,000 |
| Total liabilities | 137,635,229 | 139,366,774 |
| 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; 41,679,996 and 41,353,079 shares issued and outstanding at September 30, 2008 and December 31, 2007, respectively | 416,800 | 413,530 |
| Additional paid-in-capital | 349,154,450 | 346,289,024 |
| Accumulated deficit | (434,418,354) | (408,157,261) |
| Accumulated other comprehensive income | 23,286 | 163,060 |

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| | | |
|---|---------------|---------------|
| Total stockholders' deficit | (84,823,818) | (61,291,647) |
| Total liabilities and stockholders' deficit | \$ 52,811,411 | \$ 78,075,127 |

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)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|-------------------------------------|-----------------|------------------------------------|-----------------|
| | 2008 | 2007 | 2008 | 2007 |
| Revenues: | | | | |
| Product development revenue | \$ 4,500,280 | \$ 4,192,766 | \$ 23,296,138 | \$ 5,022,245 |
| Royalty revenue | 159,711 | 100,470 | 456,751 | 903,263 |
| License fee revenue | 440,829 | 1,046,459 | 1,111,200 | 3,125,767 |
| Total revenues | 5,100,820 | 5,339,695 | 24,864,089 | 9,051,275 |
| Operating expenses: | | | | |
| Research and development | 10,954,028 | 14,930,082 | 38,687,032 | 43,211,144 |
| General and administrative | 3,580,761 | 3,560,010 | 9,975,042 | 16,652,155 |
| Royalties | 70,241 | 203,475 | 803,721 | 340,571 |
| Restructuring | | | | 350,137 |
| Total operating expenses | 14,605,030 | 18,693,567 | 49,465,795 | 60,554,007 |
| Operating loss | (9,504,210) | (13,353,872) | (24,601,706) | (51,502,732) |
| Interest and other income | 257,537 | 927,549 | 1,175,053 | 4,064,856 |
| Interest expense | (943,970) | (504,397) | (2,834,440) | (2,988,076) |
| Loss before provision for income taxes | (10,190,643) | (12,930,720) | (26,261,093) | (50,425,952) |
| Provision for income taxes | | | | 58,118 |
| Net loss | \$ (10,190,643) | \$ (12,930,720) | \$ (26,261,093) | \$ (50,484,070) |
| Weighted average shares: | | | | |
| Basic and diluted | 41,473,368 | 32,850,191 | 41,395,149 | 32,765,277 |
| Net loss per share, basic and diluted | \$ (0.25) | \$ (0.39) | \$ (0.63) | \$ (1.54) |

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)

| | Nine Months Ended September | |
|---|------------------------------------|-----------------|
| | 30, | |
| | 2008 | 2007 |
| Operating activities: | | |
| Net loss | \$ (26,261,093) | \$ (50,484,070) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation, amortization and asset write offs | 1,388,043 | 1,501,637 |
| Stock compensation expense | 2,576,478 | 3,543,153 |
| Noncash interest expense (credit) from embedded derivative | | (713,861) |
| Amortization of deferred financing costs | 392,400 | 378,592 |
| Accretion of discount on available-for-sale securities | (710,540) | (2,153,647) |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (2,463,495) | (539,804) |
| Prepaid expenses and other current assets | 149,509 | 1,391,485 |
| Other assets and liabilities | (294,867) | 2,481,267 |
| Accounts payable | 352,133 | 728,394 |
| Accrued expenses | 27,161 | 3,828,550 |
| Contract advances | (741,526) | 255,677 |
| Merger consideration payable | | 863,806 |
| Deferred revenue | (1,111,201) | (3,128,454) |
| Net cash used in operating activities | (26,696,998) | (42,047,275) |
| Investing activities: | | |
| Purchases of marketable securities | (24,597,653) | (77,409,870) |
| Sales or redemptions of marketable securities | 62,337,112 | 114,092,444 |
| Purchases of fixed assets | (736,714) | (3,931,823) |
| Other investing activity | 136,330 | 304,485 |
| Net cash provided by investing activities | 37,139,075 | 33,055,236 |
| Financing activities: | | |
| Principal payments on capital leases | (157,224) | (99,786) |
| Proceeds from sale of common stock | 40,076 | |
| Proceeds from stock option exercises | 184,388 | 401,893 |
| Proceeds from employee stock purchase plan | 67,754 | 68,900 |
| Net cash provided by financing activities | 134,994 | 371,007 |
| Net increase (decrease) in cash and cash equivalents | 10,577,071 | (8,621,032) |
| Cash and cash equivalents at beginning of period | 9,157,973 | 30,332,468 |
| Cash and cash equivalents at end of period | \$ 19,735,044 | \$ 21,711,436 |

Supplemental disclosure of noncash financing and investing activities:

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| | | |
|---|------------|------------|
| Purchases of fixed asset with capital lease | \$ 298,319 | \$ 325,154 |
|---|------------|------------|

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 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. and Cystic Fibrosis Foundation Therapeutics, Incorporated.

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 September 30, 2008 are not necessarily indicative of the results expected for the full fiscal year.

As of September 30, 2008, the Company had \$34.5 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 during the remainder of 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. The Company will need to raise additional capital in the next five months to continue its current operations beyond the end of the first quarter of 2009. If the Company is unable to obtain additional capital prior to the end of the first quarter of 2009, it will not be able to sustain its operations and would be required to curtail or cease its operations.

On October 10, 2008, the Company received a letter from The NASDAQ Stock Market LLC (NASDAQ) advising that for the prior 10 consecutive trading days, the Company's market value of listed securities was below the minimum \$50,000,000 requirement for continued inclusion on The NASDAQ Global Market under Marketplace Rule 4450(b)(1)(A) (the Rule). The Company has been provided 30 calendar days, or until November 10, 2008, to regain compliance with the Rule. If at any time before November 10, 2008, the Company's market value of listed securities is \$50,000,000 or more for a minimum of 10 consecutive business days, the NASDAQ staff will determine if the Company complies with the Rule. If the Company does not regain compliance with the minimum market capitalization requirement by November 10, 2008, NASDAQ will provide the Company with written notification that the Company's common stock will be delisted from the NASDAQ Global Market. At that time, the Company may appeal the delisting determination to a NASDAQ Listings Qualifications Panel pursuant to applicable NASDAQ rules. As of November 5, 2008, the Company has not regained compliance with the Rule and, based on the recent trading price of the Company's common stock, does not expect to regain compliance by November 10, 2008. The Company is currently evaluating its alternatives with respect to the listing deficiency, and expects to appeal any delisting determination. A delisting of the Company's common stock from the NASDAQ Stock Market could enable the holders of the Company's \$100 million aggregate principal amount of 3% Convertible Senior Notes to redeem their notes at face value, plus accrued and unpaid interest. The Company currently does not have sufficient funds to repurchase more than a nominal amount of the notes if tendered by the holders. The Company will need to raise significant additional capital if it becomes required to redeem the notes. If the Company is unable to acquire such additional capital, it will be unable to repurchase notes tendered for redemption. Any failure to repurchase tendered notes would constitute an event of default under the indenture.

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 on acceptable terms, the Company's ability to fund its operations, redeem any of its \$100 million aggregate principal amount of 3% Convertible Senior Notes, if tendered, or otherwise respond to competitive pressures would be significantly limited and the Company would be required to curtail or cease its operations.

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.

Table of Contents**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.

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.

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.

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 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

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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 and warrants, 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 and warrants, vesting of restricted stock units and convertible debt 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 diluted net loss per share for the three and nine months ended September 30, 2008 and 2007 because their inclusion would have been antidilutive consisted of the following:

| | 2008 | 2007 |
|--|---------------|---------------|
| Stock options, awards and warrants | 4,352,361 | 3,722,541 |
| Shares issuable on conversion of 3% Convertible Senior Notes (1) | 2,239,393 | 2,239,393 |
| Shares issuable in satisfaction of merger consideration payable | | 3,167,000 |
| Total | 6,591,754 | 9,128,934 |

- (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
September 30,
2008.

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 September 30, 2008 and 2007 was \$10.2 million and \$12.9 million, respectively; and for the nine months ended September 30, 2008 and 2007 was \$26.4 million and \$50.4 million, respectively.

4. Strategic Alliances and Collaborations

Cystic Fibrosis Foundation Therapeutics, Inc.

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,

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depending upon the circumstances, the parties have varying rights and obligations with respect to intellectual property rights and payment obligations.

Bayer Schering Pharma AG, Germany

On September 4, 2008, the Company announced that Bayer Schering Pharma AG, Germany, or Bayer Schering, notified the Company in writing that it is terminating the Amended and Restated Strategic Collaboration Agreement by and between the Company and Bayer Schering, dated as of June 9, 2000 and amended as of December 22, 2000 (the Agreement), effective March 1, 2009. Accordingly, the worldwide commercial rights for the Company's blood pool magnetic resonance angiography agent, Vasovist, will be transferred back to the Company on such date.

Under the Agreement, the Company granted Bayer Schering an exclusive license to co-develop and market Vasovist worldwide. Generally, each party to the Agreement shares equally in Vasovist costs and profits in the United States. Pursuant to the terms of the Agreement, the Company retained responsibility for completing clinical trials and filing for U.S. Food and Drug Administration approval in the United States, and Bayer Schering retained responsibility for clinical and regulatory activities for Vasovist outside the United States. In addition, the Company is entitled to receive a royalty on products sold outside the United States and, if Vasovist is approved and launched in the United States, a percentage of Bayer Schering's operating profit margin on products sold in the United States.

Bayer Schering had the right to terminate the Agreement at any time on a region-by-region basis or in its entirety, upon six months written notice to the Company, which right was exercised as described above. In addition, either party may terminate the Agreement while still in effect upon thirty days notice if there is a material breach. Upon termination of the Agreement, all patent rights granted to Bayer Schering will terminate and Bayer Schering will be required to grant the Company an exclusive, worldwide royalty bearing license for any related patent rights owned by Bayer Schering. In addition, if the Company subsequently enters into a collaboration agreement with a third party for the commercialization of Vasovist, which is the Company's current intention, the Company will be required under the Agreement to reimburse Bayer Schering for a significant portion of their previously paid development costs on a region-by-region basis.

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.

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 September 30, 2008 as follows:

| | Balance at | Fair Value Measurements | | |
|--|-----------------------|-------------------------|---------------|---------|
| | September 30, 2008 | Level 1 | Level 2 | Level 3 |
| Cash and cash equivalents | \$ 19,735,044 | \$ 15,420,292 | \$ 4,314,752 | \$ |
| Available-for-sale marketable securities | \$ 14,750,435 | \$ | \$ 14,750,435 | \$ |

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. Equity

On August 4, 2008, the Company entered into a Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Limited, or Kingsbridge, pursuant to which Kingsbridge committed to purchase, subject to certain conditions, up to the lesser of approximately 8.3 million shares of the Company's common stock or an aggregate of \$50.0 million of common stock during the three years

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following the execution of the CEFF. In September 2008, the Company drew down on the CEFF and issued to Kingsbridge 94,627 shares of the Company's common stock, \$0.01 par value per share, at an aggregate purchase price of \$113,750. Under the CEFF, the Company is able to drawdown funds in tranches of up to a maximum equivalent of 1.5 percent of the closing market value of its common stock on the last trading day prior to the commencement of the drawdown, or \$10.0 million, whichever is less, subject to certain conditions. The purchase price of these shares will be discounted between 6 to 12 percent from the volume-weighted average price of the Company's common stock for each of the eight trading days following the election to sell shares depending on the trading price at the time of the drawdown. Kingsbridge is not obligated to purchase shares at prices below \$1.25 per share or if the volume-weighted average price of the Company's common stock is below 90% of the closing market value of the Company's common stock on the trading day immediately preceding the commencement of the drawdown. The Company did not make any further drawdowns subsequent to September 30, 2008 and based on the Company's stock price of \$0.38 on November 3, 2008, the Company is not able to sell shares under the CEFF and will continue to be restricted from any drawdown unless the Company's common stock price is at least \$1.25. In connection with the CEFF, the Company issued a warrant to Kingsbridge to purchase 400,000 shares of the Company's common stock at a price of \$2.4925 per share exercisable beginning on February 5, 2009 for a period of five years thereafter.

7. Goodwill

The Company assesses the realizability of goodwill annually and whenever events or changes in circumstances indicate it may be impaired. The Company completed its annual test for impairment on July 1, 2008 and, based on impairment indicators that were primarily the result of significant uncertainty about the Company's ability to raise capital given market conditions, tested for impairment as of September 30, 2008. When testing for goodwill impairment, the Company performs a step I goodwill impairment test to identify a potential impairment in accordance with SFAS No. 142, *Goodwill and Other Intangible Assets*. In doing so, the Company compares the fair value of the Company, the sole reporting unit, with its carrying amount. If the carrying amount exceeds the fair value, goodwill may be impaired and a step II goodwill impairment test would be performed to measure the amount of any impairment loss. As the Company had a stockholders' deficit balance as of the testing dates, the Company passed the step I impairment test, and accordingly goodwill was not impaired as of September 30, 2008.

8. New Accounting Pronouncements

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations* (SFAS 141(R)), which 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 adoption of SFAS 141(R) is not anticipated to have a significant impact on the Company's financial position and results of operations.

9. Subsequent Event

On October 23, 2008, the Company notified employees representing approximately 23% of the Company's workforce of their termination from the Company, effective immediately, under a plan of termination pursuant to which charges will be incurred under FASB Statement of Financial Accounting Standards No. 146 *Accounting For Costs Associated With Exit or Disposal Activities*, (the Reduction in Force). The Reduction in Force, which was approved by the Company's compensation committee on October 17, 2008, was initiated in connection with the Company's efforts to reduce its cost structure and narrow the current focus of its research and development efforts. The Company estimates that the charges to be recorded in the fourth quarter of 2008 in connection with the Reduction in Force will be approximately \$0.3 million for cash payments of one-time employee termination benefits, including severance, and other benefits.

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., and Cystic Fibrosis Foundation Therapeutics, Incorporated.

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 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. 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. In March 2008, we discontinued development of one of our clinical-stage programs, PRX-00023, due to lack of efficacy

shown in a recently completed Phase 2b trial in patients with major depressive disorder.

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;

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

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fees paid to access chemical and intellectual property databases;

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.

In October 2008, we eliminated approximately 23% of our workforce in connection with our efforts to reduce our cost structure and narrow the current focus of our research and development efforts. We plan to devote our resources to our lead clinical programs, PRX-03140 being developed for the treatment of Alzheimer's disease and PRX-08066 being developed for the treatment of chronic obstructive pulmonary disease and moderate-to-severe pulmonary hypertension, as well as our partnered preclinical programs with GlaxoSmithKline and Cystic Fibrosis Foundation Therapeutics.

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 resubmitted a New Drug Application, or NDA, to the FDA for Vasovist on June 30, 2008. In July 2008, we received written confirmation from the FDA that our NDA was a complete submission and that the FDA set a user fee goal date of December 31, 2008 for our NDA.

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-03140(1) | Alzheimer's disease | Phase 2b |
| PRX-08066(2) | Pulmonary Hypertension/COPD | Phase 2b |
| PRX-07034(3) | Cognitive impairment | Phase 1b |

(1) 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 (ADAS-Cog) score. Patients will be randomized to one of three trial arms: placebo; 50 mg of PRX-03140 once daily; or 150 mg of PRX-03140 once daily. All patients in the trial must be treated with 10 mg of Aricept® for at least four months prior to enrollment. The six-month trial is expected to enroll approximately 420 adult patients with Alzheimer's disease.

In May 2008, we initiated a second Phase 2b trial of PRX-03140 as monotherapy treatment of Alzheimer's disease. 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 ADAS-Cog score. Patients will be randomized to one of four trial arms: placebo; donepezil (Aricept®) positive control; 50 mg of PRX-03140 once daily; or 150 mg of PRX-03140 once daily. The three-month trial is expected to enroll approximately 240 adult patients with Alzheimer's disease. This monotherapy trial will also include a three-month optional extension.

- (2) In August 2008, we initiated a Phase 2b right-heart catheter study of PRX-08066 in patients with chronic obstructive pulmonary disease (COPD) and moderate-to-severe pulmonary hypertension (PH). This single-arm, open-label, Phase 2b study is designed to evaluate the mean pulmonary artery blood pressure change from baseline as

measured directly
by right-heart
catheterization and

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will also measure the change from baseline in the standard six-minute walk distance test after three months of treatment. Patients will be treated with 500 mg of PRX-08066 on day one of the trial followed by twice-daily dosing of 300 mg of PRX-08066 for three months. The trial is designed to enroll adult patients with COPD and moderate-to-severe PH.

- (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 33 healthy obese adults. 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 healthy obese 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 ($p < 0.005$). 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.

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 patients that participate in the trials;

the length of time required to enroll suitable patient subjects;

the number of sites included 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:

| 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

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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 September 30, 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-03140 | \$ 16.5 million |
| PRX-08066 | \$ 5.6 million |
| PRX-07034 | \$ 9.8 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 and nine months ended September 30, 2008 and 2007:

| | Three Months Ended September 30, | | |
|-----------------------------|---|-----------------------------|----------------|
| | 2008 | 2007 | |
| | Revenue | Growth (Decline) | Revenue |
| Product development revenue | \$ 4,500,280 | 7% | \$ 4,192,766 |
| Royalty revenue | 159,711 | 59% | 100,470 |
| License fee revenue | 440,829 | (58%) | 1,046,459 |
| Total revenues | \$ 5,100,820 | (4%) | \$ 5,339,695 |

| | Nine Months Ended September 30, | | |
|-----------------------------|--|-----------------------------|----------------|
| | 2008 | 2007 | |
| | Revenue | Growth (Decline) | Revenue |
| Product development revenue | \$ 23,296,138 | 364% | \$ 5,022,245 |
| Royalty revenue | 456,751 | (49%) | 903,263 |
| License fee revenue | 1,111,200 | (64%) | 3,125,767 |
| Total revenues | \$ 24,864,089 | 175% | \$ 9,051,275 |

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, or

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Bayer Schering; license fee revenue relating to our agreements with Amgen, GlaxoSmithKline, Bayer Schering, CFFT, Covidien and Bracco; and royalties related to our agreements with Bracco and Bayer Schering. Royalties from Bracco concluded in the second quarter of 2007 and our collaboration agreement with Bayer Schering is scheduled to terminate effective as of March 1, 2009.

Product development revenue increased \$0.3 million and \$18.3 million for the three and nine months ended September 30, 2008, respectively, compared to the corresponding prior year periods. The increase in the three months ended September 30, 2008 primarily related to increased reimbursed research costs earned from our collaboration agreements with GlaxoSmithKline and CFFT, which were partially offset by a \$3.0 million decrease in milestone revenue earned in the 2008 period. The increase in the nine months ended September 30, 2008 primarily related to an increase of \$10.0 million in milestone revenue earned under our collaboration agreement with GlaxoSmithKline and increased reimbursed research costs earned from our collaboration agreements with GlaxoSmithKline and CFFT.

Royalty revenue increased 59% and decreased 49% for the three and nine months ended September 30, 2008, respectively, compared to the corresponding prior year periods. The increase in the three months ended September 30, 2008 was primarily due to increased sales of Vasovist outside of the United States for which we receive a royalty from Bayer Schering. The agreement with Bayer Schering is scheduled to terminate effective as of March 1, 2009. The decrease in the nine months ended September 30, 2008 was primarily due to a reduction in royalties on sales of MultiHance by Bracco as a result of the expiration of patents in 2007.

License fee revenue, which generally represents the amortization of upfront fees received from collaboration agreements, decreased 58% and 64% for the three and nine months ended September 30, 2008, respectively, compared to the corresponding prior year periods. The decreases were primarily 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 \$11.0 million and \$38.7 million for the three and nine months ended September 30, 2008, respectively, reflects a decrease of 27% and 10% from the corresponding prior year periods. The decrease in research and development expense for the three and nine months ended September 30, 2008 was primarily due to lower third-party expenses associated with our three therapeutic clinical development programs and a decrease in third-party costs associated with the discontinued PRX-00023 program. These decreases were partially offset by increased costs to support our preclinical programs during the period. Clinical program costs incurred in the nine months ended September 30, 2008 include costs for the ongoing two Phase 2b clinical trials of PRX-03140 for Alzheimer's disease, the on-going Phase 2b clinical trial of PRX-08066 for chronic obstructive pulmonary disease and moderate-to-severe pulmonary hypertension, and the completion in the first half of 2008 of the Phase 2b clinical trial of PRX-00023 for depression.

General and Administrative Expense

General and administrative expense of \$3.6 million for the three months ended September 30, 2008 is consistent with the prior year period. General and administrative expense of \$10.0 million for the nine months ended September 30, 2008 reflects a 40% decrease from the corresponding prior year period. The decrease in the nine month period ending September 30, 2008 was primarily due to \$5.7 million of nonrecurring legal and accounting costs incurred in 2007 associated with our stock option investigation that was completed in early 2007.

Royalty Expense

Royalty expense of \$0.1 million and \$0.8 million for the three and nine months ended September 30, 2008, respectively, reflects a decrease of \$0.1 million and an increase of \$0.5 million from the corresponding prior year periods. Royalty expense is primarily comprised of payments made relating to our technology licensed from Ramot at Tel Aviv University Ltd. and is based on milestones earned by us under our collaboration agreements. The change in royalty expense corresponds to changes in the amount of milestone revenue earned by us during the periods presented.

Interest and Other Income

Interest and other income of \$0.3 million and \$1.2 million for the three and nine months ended September 30, 2008, respectively, reflects a decrease of 72% and 71% from the corresponding prior year periods, respectively. The decreases were primarily due to a decrease in interest income resulting from lower levels of cash and marketable

securities available to invest due to cash being used to fund operations and due to lower interest rates.

Interest Expense

Interest expense of \$0.9 million and \$2.8 million for the three and nine months ended September 30, 2008, respectively, reflects

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an increase of 87% and a decrease of 5% from the corresponding prior year periods. The increase in interest expense for the three month period was primarily due to a \$0.7 million credit in the 2007 period to interest expense reflecting a decrease in the value of the embedded derivative within the milestone payable to the former shareholders of Predix, partially offset by cash interest expense for the milestone of \$0.3 million for the period. The decrease in interest expense for the nine month period was primarily due to the inclusion of interest expense of \$0.2 million in the 2007 period for the milestone. The milestone was paid to the former shareholders of Predix 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 \$34.5 million at September 30, 2008 as compared to \$61.1 million at December 31, 2007. The decrease in cash, cash equivalents and available-for-sale marketable securities of \$26.6 million during the nine months ended September 30, 2008 was primarily attributable to funding of ongoing operations.

We used approximately \$26.7 million of cash to fund operating activities for the nine months ended September 30, 2008, as compared to \$42.0 million for the same period in 2007. The net use of cash to fund operations for the nine months ended September 30, 2008 primarily resulted from the net loss of \$26.3 million for the period. In addition, accounts receivable increased during the period by approximately \$2.5 million due to increased clinical and preclinical development work with our collaboration partners. The net cash used to fund operations during the nine months ended September 30, 2007 consisted of a net loss of \$50.5 million, which was partially offset by an increase of \$4.6 million in accounts payable and accrued expenses largely resulting from increased clinical trial activity and the receipt of \$3.3 million for landlord allowances towards construction at our Lexington, Massachusetts facility.

Our investing activities provided \$37.1 million of cash during the nine months ended September 30, 2008 as compared to \$33.1 million of cash provided during the same period in 2007. Investing activities in 2008 primarily consisted of \$37.7 million of net redemptions of marketable securities to fund operating activities and \$0.7 million of capital expenditures. The primary source of cash in the 2007 period consisted of \$36.7 million of net redemptions of marketable securities, which was partially offset by \$3.9 million of capital expenditures related to the build out of laboratory space at our Lexington, Massachusetts facility.

Our financing activities provided \$0.1 million of cash during the nine months ended September 30, 2008 as compared to \$0.4 million of cash provided during the same period in 2007. Financing activities in both periods primarily consisted of proceeds from stock option exercises which were partially offset by payments on our capital leases.

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, royalties, 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.

On October 10, 2008, we received a letter from The NASDAQ Stock Market LLC, or NASDAQ, advising that for the prior 10 consecutive trading days, the market value of our listed securities was below the minimum \$50,000,000 requirement for continued inclusion on The NASDAQ Global Market under Marketplace Rule 4450(b)(1)(A), or the Rule. We have been provided 30 calendar days, or until November 10, 2008, to regain compliance with the Rule. If at any time before November 10, 2008, the market value of our listed securities is \$50,000,000 or more for a minimum of 10 consecutive business days, the NASDAQ staff will determine if we comply with the Rule. If we do not regain compliance with the minimum market capitalization requirement by November 10, 2008, NASDAQ will provide us with written notification that our common stock will be delisted from the NASDAQ Global Market. At that time, we

may appeal the delisting determination to a NASDAQ Listings Qualifications Panel pursuant to applicable NASDAQ rules. As of November 5, 2008, we have not regained compliance with the Rule and, based on the recent trading price of our common stock, do not expect to regain compliance by November 10, 2008. We are currently evaluating our alternatives with respect to the listing deficiency, and expect to appeal any delisting determination. A delisting of our common stock from the NASDAQ Stock Market could enable the holders of our \$100 million aggregate principal amount of 3% Convertible Senior Notes to redeem their notes at face value, plus accrued and unpaid interest. We currently do not have sufficient funds to repurchase more than a nominal amount of the notes if tendered by the holders. We will need to raise significant additional capital if we become required to redeem the notes. If we are unable to acquire such additional capital, we will be unable to repurchase notes tendered for redemption. Any failure to repurchase tendered notes would constitute an event of default under the indenture.

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On August 4, 2008, we entered into a Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Limited or Kingsbridge, pursuant to which Kingsbridge committed to purchase, subject to certain conditions, up to the lesser of approximately 8.3 million shares of our common stock or an aggregate of \$50.0 million of our common stock during the next three years. In September 2008, we drew down on the CEFF and issued 94,627 shares of our common stock, \$0.01 par value per share, to Kingsbridge at an aggregate purchase price of \$113,750. Kingsbridge is not obligated to purchase shares at prices below \$1.25 per share or if the volume-weighted average price of our common stock is below 90% of the closing market value of our common stock on the trading day immediately preceding the commencement of the drawdown. We did not receive any additional proceeds from drawdowns subsequent to September 30, 2008 and based on our stock price of \$0.38 on November 3, 2008, we are not able to sell shares under the CEFF and will continue to be restricted from any drawdown unless our common stock price reaches at least \$1.25.

We estimate that cash, cash equivalents and marketable securities on hand as of September 30, 2008 and anticipated revenue we will earn in the remainder of 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 will need to raise additional capital in the next five months to continue our current operations beyond the end of the first quarter of 2009. If we are unable to obtain additional capital prior to the end of the first quarter of 2009, or sooner if our common stock is delisted from the NASDAQ Stock Market and holders of our convertible senior notes require redemption of the notes, we will not be able to sustain our operations and would be required to curtail or cease our operations.

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 September 30, 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.

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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 set forth in our Quarterly Reports on Form 10-Q for the periods ended March 31, 2008 and June 30, 2008 and changes to the risk factors as set forth below to update for the status of our listing eligibility on the NASDAQ and to update for the termination of our collaboration agreement by Bayer Schering Pharma AG, Germany, or Bayer Schering. 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.

If we are not able to maintain continued listing of our common stock on the NASDAQ stock market, noteholders may require us to repurchase the \$100 million aggregate principal amount of our 3.0% Convertible Senior Notes.

On October 10, 2008, we received a letter from The NASDAQ Stock Market LLC, or NASDAQ, advising that for the prior 10 consecutive trading days, the market value of our listed securities was below the minimum \$50,000,000 requirement for continued inclusion on The NASDAQ Global Market under Marketplace Rule 4450(b)(1)(A), or the Rule. We have been provided 30 calendar days, or until November 10, 2008, to regain compliance with the Rule. If at any time before November 10, 2008, the market value of our listed securities is \$50,000,000 or more for a minimum of 10 consecutive business days, the NASDAQ staff will determine if we comply with the Rule. If we do not regain compliance with the minimum market capitalization requirement by November 10, 2008, NASDAQ will provide us with written notification that our common stock will be delisted from the NASDAQ Global Market. At that time, we may appeal the delisting determination to a NASDAQ Listings Qualifications Panel pursuant to applicable NASDAQ rules. As of November 5, 2008, we have not regained compliance with the Rule and, based on the recent trading price of our common stock, do not expect to regain compliance by November 10, 2008. We are currently evaluating our alternatives with respect to the listing deficiency, and expect to appeal any delisting determination. A delisting of our common stock from the NASDAQ Stock Market could enable the holders of our \$100 million aggregate principal amount of 3% Convertible Senior Notes to redeem their notes at face value, plus accrued and unpaid interest. We currently do not have sufficient funds to repurchase more than a nominal amount of the notes if tendered by the holders. We will need to raise significant additional capital if we become required to redeem the notes. If we are unable to acquire such additional capital, we will be unable to repurchase notes tendered for redemption. Any failure

to repurchase tendered notes would constitute an event of default under the indenture.

We will need to raise additional capital in the next five months to continue our current operations beyond the end of the first quarter of 2009.

Since inception, we have funded our operations primarily through our public offerings of common stock, private sales of equity securities, debt financing, equipment lease financings, product development revenue, and royalty and license payments from our strategic partners. Although we believe that we have adequate funding to fund our operations through the first quarter of 2009, we will need to raise substantial additional funds for research, development and other expenses through equity or debt financings, strategic alliances or otherwise. Our future liquidity and capital requirements will depend upon numerous factors, including the following:

the progress and scope of clinical trials;

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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 product candidates gain market acceptance;

the timing and costs of product introductions;

the extent of our ongoing and any new research and development programs;

changes in our strategy or our planned activities;

the costs of training physicians to become proficient with the use of our product candidates; and

the costs of developing marketing and distribution capabilities.

If our common stock is delisted from the NASDAQ Stock Market, the holders of our \$100 million aggregate principal amount of 3% Convertible Senior Notes could redeem their notes at face value, plus accrued and unpaid interest. We currently do not have sufficient funds to repurchase more than a nominal amount of the notes if tendered by the holders. We will need to raise significant additional capital if we become required to redeem the notes.

If we are unable to obtain additional capital prior to the end of the first quarter of 2009, we will not be able to sustain our operations and would be required to curtail or cease our operations. If we raise additional funds through the issuance of equity or convertible debt securities, the percentage ownership of our stockholders could be significantly diluted, and these newly issued securities may have rights, preferences or privileges senior to those of existing stockholders. If we incur additional debt financing, a substantial portion of our operating cash flow may be dedicated to the payment of principal and interest on such indebtedness, thus limiting funds available for our business activities. We cannot assure you that additional financing will be available on terms favorable to us, or at all. The stock market in general, and the NASDAQ Global Market and the market for life sciences companies in particular, have recently experienced extreme price and volume fluctuations that may have been unrelated or disproportionate to the operating performance of the listed companies. There have been dramatic fluctuations in the market prices of securities of biopharmaceutical companies such as us. Broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance, and may adversely impact our ability to raise additional funds. If adequate funds are not available or are not available on acceptable terms, when we desire them, our ability to fund our operations, redeem any of our \$100 million aggregate principal amount of 3% Convertible Senior Notes, if tendered, or otherwise respond to competitive pressures would be significantly limited and we would be required to curtail or cease our operations.

Despite our resubmission of a new drug application with the FDA for Vasovist, we may never obtain approval to market and sell Vasovist in the United States or monetize the potential commercial rights 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 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 resubmitted an NDA to the FDA for Vasovist on June 30, 2008, the 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. If the FDA does not approve Vasovist, we will not receive revenues based on sales of Vasovist in the United States.

In September 2008, Bayer Schering notified us that they are terminating the Amended and Restated Strategic Collaboration

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Agreement, or the Collaboration Agreement, with us, effective March 1, 2009. Accordingly, the worldwide commercial rights for Vasovist will be transferred back to us on such date. We may seek to monetize the commercial rights to Vasovist 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. In addition, our ability to successfully monetize our commercial rights to Vasovist will also be dependent on current and historical sales of Vasovist by Bayer Schering outside the United States. To date, sales of Vasovist outside the United States have not been significant. We cannot assure you that we would be able to enter into an agreement with a third party to monetize such commercial rights, and our failure to do so could materially and adversely affect our ability to generate revenues. Moreover, upon entering into a collaboration agreement for the commercialization of Vasovist, we could be obligated under the Collaboration Agreement to pay Bayer Schering a significant portion of their historical development costs of Vasovist. We cannot assure you that we would be able to monetize the commercial rights for an amount that is greater than the amount that would be due to Bayer Schering. Disagreements with Bayer Schering regarding intellectual property rights, the transfer of information regarding Vasovist or the amount of their historical development costs could also delay or terminate our efforts to successfully monetize our commercial rights to Vasovist. As a result of Bayer Schering's termination of the Collaboration Agreement, if we are unable to monetize our commercial rights in Vasovist we cannot assure you that we would be able to find another collaborator to commercialize Vasovist and our business could be materially harmed.

A substantial portion of our future revenues will be dependent upon our agreements with GlaxoSmithKline and Amgen Inc.

We expect that a substantial portion of our future revenues will be dependent upon our collaboration agreements with GlaxoSmithKline and with Amgen Inc. The agreement with GlaxoSmithKline encompasses the development and commercialization of medicines targeting four G-protein coupled receptors, or GPCRs, for the treatment of a variety of diseases, including an option to license our 5-HT4 partial agonist, PRX-03140, and other medicines arising from the four research programs. The agreement with Amgen encompasses the development and commercialization of products based on our preclinical compounds that modulate the S1P1 receptor and compounds and products that may be identified by or acquired by Amgen and that modulate the S1P1 receptor. If these collaborators were to terminate their agreements with us, fail to meet their obligations or otherwise decrease their commitment there under, our future revenues could be materially adversely affected and the development and commercialization of our product candidates would be interrupted. In addition, if we do not achieve some or any of the development, regulatory and commercial milestones or if GlaxoSmithKline or Amgen does not achieve certain net sales thresholds, in each case, as set forth in the respective agreements, we will not fully realize the expected benefits of the agreements. Further, the achievement of certain of the various milestones under our collaboration agreements with GlaxoSmithKline and Amgen will depend on factors that are outside of our control and most are not expected for several years, if at all. Moreover, our receipt of revenues under our agreements with these collaborators will be directly affected by the level of efforts of such collaborators and we cannot control whether they will devote sufficient resources to development or commercialization of the technology under their respective agreement or whether they will elect to pursue the development or commercialization of alternative products or services. In addition, disagreements with our collaborators could delay or terminate the continued development and commercialization of the licensed products under our agreements or result in litigation, either of which could have a material adverse affect on our business, financial condition and results of operations overall. If any of our agreements with GlaxoSmithKline or Amgen is terminated prior to expiration, we would be required to enter into other strategic relationships or find alternative ways of continuing our product development programs. We cannot assure you that we would be able to enter into similar agreements with other companies with sufficient product development capabilities to commercialize our product candidates, and our failure to do so could materially and adversely affect our ability to generate revenues. For instance, in September 2008, Bayer Schering notified us that it is terminating the Amended and Restated Strategic Collaboration Agreement with us, effective March 1, 2009. Accordingly, the worldwide commercial rights for Vasovist will be transferred back to us on such date. If we are unable to monetize our commercial rights in Vasovist we cannot assure you that we would be able to find another collaborator to commercialize Vasovist and our business could be materially harmed.

Our product candidates require significant biological testing, preclinical testing, manufacturing and pharmaceutical development expertise and investment. We rely primarily on external partners to complete these activities.

We have limited in-house biological and preclinical testing capabilities. Therefore, we rely heavily on third-parties to perform in vitro potency, in vivo functional efficacy, animal toxicology and pharmacokinetics testing prior to advancing our product candidates into clinical trials. We also do not have internal expertise to formulate our therapeutic product candidates. In addition, we do not have, nor do we currently have plans to develop, full-scale manufacturing capability for any of our product candidates, including Vasovist. We currently rely on Aptuit, Inc. and Thermo Fisher Scientific Inc. for our therapeutic drug product manufacturing and testing, and on Aptuit, Inc. and Johnson Matthey Pharma Services for the manufacture and testing of our active therapeutic pharmaceutical ingredients. Although we believe that we could replace these suppliers on commercially reasonable terms, if any of these third-parties fail to fulfill their obligations to us or do not successfully complete the testing in a timely or acceptable manner, our therapeutic product development efforts could be negatively impacted and/or delayed.

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ITEM 6. Exhibits.

| Exhibit number | Description |
|-----------------------|---|
| 4.1 | Warrant issued to Kingsbridge Capital Limited, dated as of August 4, 2008. Filed as Exhibit 4.1 to the Company's Current Report on Form 8-K filed August 5, 2008 and incorporated herein by reference. |
| 10.1# | Employment Agreement between the Company and Kim C. Drapkin, dated as of September 15, 2008. Filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed September 18, 2008 and incorporated herein by reference. |
| 10.2# | Amendment to Employment Agreement between the Company and Chen Schor, dated as of September 16, 2008. Filed as Exhibit 10.2 to the Company's Current Report on Form 8-K filed September 18, 2008 and incorporated herein by reference. |
| 10.3 | Common Stock Purchase Agreement between the Company and Kingsbridge Capital Limited, dated as of August 4, 2008. Filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed August 5, 2008 and incorporated herein by reference. |
| 10.4 | Registration Rights Agreement between the Company and Kingsbridge Capital Limited, dated as of August 4, 2008. Filed as Exhibit 10.2 to the Company's Current Report on Form 8-K filed August 5, 2008 and incorporated herein by reference. |
| 10.5# | Letter Agreement between the Company and Elkan Gamzu, Ph.D., dated as of July 25, 2008. Filed as Exhibit 10.2 to the Company's Current Report on Form 8-K filed July 28, 2008 and incorporated herein by reference. |
| 10.6# | Separation Agreement between the Company and Michael G. Kauffman, M.D., Ph.D., dated as of July 25, 2008. Filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed July 28, 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.*

Identifies a management contract or compensatory plan or agreement in which an executive officer or director of

*the Company
participates.*

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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: November 5, 2008

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

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* *Filed herewith.*

*Identifies a
management
contract or
compensatory
plan or
agreement in
which an
executive officer
or director of*

*the Company
participates.*