EPIX Pharmaceuticals, Inc.
Form 10-Q
November 02, 2005

# UNITED STATES

# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 10-Q

**(Mark One)**

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

**For the quarterly period ended September 30, 2005**

**Or**

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

**For the transition period from to .**

**Commission File Number 0-21863**

# EPIX Pharmaceuticals, Inc.

(Exact name of Registrant as Specified in its Charter)

| **Delaware** | **04-3030815** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |
| **161 First Street**<br>**Cambridge, Massachusetts**<br>(Address of principal executive offices) | **02142**<br>(Zip Code) |

Registrant s telephone number, including area code: **(617) 250-6000**

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

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

**Common Stock, $.01 par value per share**

(Title of Class)

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 ý No o

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes ý No o

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

As of October 28, 2005, 23,274,997 shares of the registrant s Common Stock, $.01 par value per share, were issued and outstanding.

**EPIX Pharmaceuticals, Inc.**

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**PART I. FINANCIAL INFORMATION**

**ITEM 1. CONDENSED FINANCIAL STATEMENTS**

**EPIX PHARMACEUTICALS, INC.**

**BALANCE SHEETS**

**(unaudited)**

| | September 30, 2005 | December 31, 2004 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 81,502,706 | $ 73,364,538 |
| Available-for-sale marketable securities | 64,431,943 | 91,075,630 |
| Accounts receivable | 251,746 | 322,546 |
| Prepaid expenses and other assets | 694,374 | 585,138 |
| Total current assets | 146,880,769 | 165,347,852 |
| Property and equipment, net | 2,842,161 | 2,490,804 |
| Other assets | 3,095,861 | 3,448,270 |
| Total assets | $ 152,818,791 | $ 171,286,926 |
| | | |
| **LIABILITIES AND STOCKHOLDERS EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,151,074 | $ 938,498 |
| Accrued expenses | 5,560,570 | 4,218,834 |
| Contract advances | 6,610,619 | 6,150,013 |
| Loan payable to strategic partner | 15,000,000 | 15,000,000 |
| Deferred revenue | 618,997 | 2,387,882 |
| Total current liabilities | 28,941,260 | 28,695,227 |
| Deferred revenue | 796,249 | 1,209,725 |
| Convertible debt | 100,000,000 | 100,000,000 |
| Commitments and Contigencies | | |
| Stockholders equity: | | |
| Preferred Stock, $0.01 par value, 1,000,000 shares authorized; no shares issued | | |
| Common stock, $0.01 par value, 40,000,000 shares authorized; 23,274,997 and 23,190,154 shares issued and outstanding at September 30, 2005 and December 31, 2004, respectively | 232,749 | 231,900 |
| Additional paid-in-capital | 197,277,711 | 196,730,731 |
| Accumulated deficit | (174,345,170) | (155,333,774) |
| Accumulated other comprehensive loss | (84,008) | (246,883) |
| Total stockholders equity | 23,081,282 | 41,381,974 |
| Total liabilities and stockholders equity | $ 152,818,791 | $ 171,286,926 |

See accompanying notes.

**EPIX PHARMACEUTICALS, INC.**

**STATEMENTS OF OPERATIONS**

**(unaudited)**

| | Three months ended September 30, | | Nine months ended September 30, | |
|---|---|---|---|---|
| | **2005** | **2004** | **2005** | **2004** |
| Revenues: | | | | |
| Product development revenue | $ 1,297,720 | $ 2,273,957 | $ 3,087,565 | $ 6,887,949 |
| Royalty revenue | 798,484 | 700,601 | 1,821,094 | 2,398,116 |
| License fee revenue | 165,894 | 263,585 | 497,686 | 822,048 |
| Total revenues | 2,262,098 | 3,238,143 | 5,406,345 | 10,108,113 |
| Operating expenses: | | | | |
| Research and development | 5,498,385 | 6,508,418 | 16,668,962 | 17,094,950 |
| General and administrative | 2,617,410 | 2,878,916 | 7,931,650 | 8,170,522 |
| Total operating expenses | 8,115,795 | 9,387,334 | 24,600,612 | 25,265,472 |
| Operating loss | (5,853,697) | (6,149,191) | (19,194,267) | (15,157,359) |
| Interest income | 1,104,448 | 688,424 | 2,900,959 | 1,199,047 |
| Interest expense | (910,508) | (935,069) | (2,718,088) | (1,234,099) |
| Loss before provision for income taxes | (5,659,757) | (6,395,836) | (19,011,396) | (15,192,411) |
| Provision for income taxes | | 16,676 | | 46,342 |
| Net loss | $ (5,659,757) | $ (6,412,512) | $ (19,011,396) | $ (15,238,753) |
| | | | | |
| Weighted average shares: | | | | |
| Basic and diluted | 23,273,075 | 22,987,878 | 23,252,486 | 22,810,300 |
| | | | | |
| Net loss per share, basic and diluted | $ (0.24) | $ (0.28) | $ (0.82) | $ (0.67) |

See accompanying notes.

**EPIX PHARMACEUTICALS, INC.**

**STATEMENTS OF CASH FLOWS**

**(unaudited)**

| | Nine months ended September 30, 2005 | 2004 |
|---|---|---|
| Operating activities: | | |
| Net loss | $ (19,011,396) | $ (15,238,753) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 828,803 | 701,417 |
| Non-employee stock compensation expense | 3,419 | |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | 70,800 | (797,823) |
| Prepaid expenses and other current assets | (109,236) | (194,737) |
| Other assets | 352,409 | 145,457 |
| Accounts payable | 212,576 | (723,036) |
| Accrued expenses | 1,341,736 | 1,151,865 |
| Contract advances | 460,606 | 793,873 |
| Deferred revenue | (2,182,361) | (2,754,845) |
| Net cash used in operating activities | (18,032,644) | (16,916,582) |
| Investing activities: | | |
| Purchases of marketable securities | (71,385,618) | (79,366,215) |
| Sale or redemption of marketable securities | 98,192,180 | 23,699,122 |
| Purchases of fixed assets | (1,180,160) | (2,019,826) |
| Net cash provided by (used in) investing activities | 25,626,402 | (57,686,919) |
| Financing activities: | | |
| Proceeds from loan payable from strategic partner | 45,000,000 | 37,500,000 |
| Repayment of loan payable to strategic partner | (45,000,000) | (30,000,000) |
| Net proceeds from issuance of convertible debt | | 96,350,000 |
| Proceeds from stock options | 474,115 | 4,223,727 |
| Proceeds from Employee Stock Purchase Plan | 70,295 | 126,702 |
| Net cash provided by financing activities | 544,410 | 108,200,429 |
| Net increase in cash and cash equivalents | 8,138,168 | 33,596,928 |
| Cash and cash equivalents at beginning of period | 73,364,538 | 36,658,557 |
| Cash and cash equivalents at end of period | $ 81,502,706 | $ 70,255,485 |
| | | |
| Supplemental cash flow information: | | |
| Cash paid for interest | $ 1,620,014 | $ 123,055 |
| Cash paid for taxes | $ | $ 34,356 |
| | | |
| Supplemental disclosure of noncash financing and investing activities: | | |
| Issuance of common stock in connection with Intellectual Property Agreement | $ | $ 2,339,040 |

See accompanying notes.

**EPIX PHARMACEUTICALS, INC.**

**NOTES TO CONDENSED FINANCIAL STATEMENTS**

**(unaudited)**

**1. Nature of Business**

EPIX Pharmaceuticals, Inc. ( EPIX or the Company ), formerly known as EPIX Medical, Inc., is developing targeted contrast agents both to improve the capability and expand the use of magnetic resonance imaging ( MRI ) as a tool for diagnosing human disease. The Company s lead product under development, Vasovist™, or MS-325, is an injectable contrast agent specifically designed for vascular imaging using magnetic resonance angiography ( MRA ) to diagnose atherosclerotic vascular disease. Vasovist™ is being co-developed by EPIX and its partner, Schering Aktiengesellschaft ( Schering AG ). In December 2003, the Company submitted a New Drug Application ( NDA ) to the U.S. Food and Drug Administration ( FDA ) for Vasovist™. In June 2004, Schering AG submitted a Marketing Authorization Application ( MAA ) for Vasovist™ to the European Medicines Agency ( EMEA ). In January 2005, the Company received an approvable letter from the FDA for Vasovist™ in which the FDA requested additional clinical studies prior to approval. In May 2005, the Company submitted a response to the FDA approvable letter, which was accepted by the FDA as a complete response in June 2005. In October 2005, the EMEA granted approval of Vasovist™ for all 25 member states of the European Union ( E.U. ). The Company is also collaborating with Schering AG on the development of its second drug candidate, EP-2104R, for detecting human thrombus, or blood clots, using MRI. This compound entered Phase II clinical trials in April 2005. In July 2005, the Company announced that it would be amending its Phase II proof-of-concept clinical trial protocols for EP-2104R to include additional patient safety monitoring based on a review by the FDA of data from a 14-day, repeat dose preclinical toxicology study. The additional patient monitoring in the Phase II trials will extend the timeline and increase the cost for EP-2104R development. The Company is also collaborating with Schering AG in a joint research program for the discovery of novel MRI product candidates for clinical development. In October 2005, the Company announced that an amendment to the research collaboration agreement has been entered into with Schering AG. This amendment narrows the definition of the field of collaboration and further indicates the parties non-binding intent to enter into a new research collaboration agreement by the end of 2005 and to discuss possible modifications of the collaboration. We are also engaged in research activities to explore the application of our proprietary fibrin-binding technology to the discovery of novel antithrombotic therapeutics. The Company is exploring the diversification of its product pipeline through the potential acquisition of therapeutic drug programs.

**2. Basis of Presentation**

The unaudited condensed financial statements of EPIX have been prepared in accordance with accounting principles generally accepted in the United States ( U.S. ) for interim financial information and the instructions to Form 10-Q and the rules of the Securities and Exchange Commission ( the Commission ). Accordingly, they do not include all of the information and footnotes required to be presented for complete financial statements. The accompanying unaudited condensed 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 periods ended September 30, 2005 are not necessarily indicative of the results expected for the full fiscal year.

The unaudited condensed financial statements and related disclosures have been prepared with the assumption that users of the unaudited condensed financial statements have read or have access to the audited financial statements for the preceding fiscal year. Accordingly, these unaudited condensed 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, 2004.

**3. Significant Accounting Policies**

**Revenue Recognition**

*Product development revenue*

In June 2000, the Company entered into a strategic collaboration agreement with Schering AG, whereby each party to the agreement shares equally in Vasovist™ development costs and U.S. operating profits and the Company will receive royalties related to non-U.S. sales. The Company recognizes product development revenue at the time it performs research and development activities for which Schering AG and other collaborators are obligated to reimburse the Company. Product development revenues from Schering AG are recorded net of the Company s portion of Schering AG s actual or most recent estimate of their Vasovist™ research and development costs.

In May 2003, the Company entered into a development agreement with Schering AG for EP-2104R and a collaboration

agreement with Schering AG for MRI research. Under the EP-2104R development agreement, Schering AG agreed to make fixed payments to the Company totaling approximately $9.0 million over two years, which period began in the second quarter of 2003 and ended in the fourth quarter of 2004, to cover a portion of the Company s expenditures in the feasibility program. The Company recognizes reimbursement from Schering AG for the EP-2104R feasibility program, as revenue proportionate to actual cost incurred relative to the expected total program costs. Total estimated costs of the feasibility program are based on management s assessment of costs to complete the program based upon an evaluation of the portion of the program completed, costs incurred to date and expected future costs of the program. To the extent that estimated costs to complete the feasibility program change materially from previous periods, adjustments to revenue will be recorded. In July 2005, the Company announced that it would be amending its Phase II proof-of-concept clinical trial protocols for EP-2104R to include additional patient safety monitoring based on a review by the FDA of data from a 14-day, repeat dose preclinical toxicology study. The additional patient monitoring in the Phase II trials will extend the timeline and increase the costs for EP-2104R development. As a result of the amendment to the Phase II trial protocols, management increased its estimated cost-to-complete the feasibility program to $16.1 million during the second quarter of 2005 from its previous estimate of $13.6 million. The impact of increasing the estimated cost-to-complete the feasibility program during 2005 resulted in a reduction in product development revenue of $1.5 million recognized in the first and second quarters of 2005. Revenue under the MRI research collaboration is recognized at the time services are provided and for which Schering AG is obligated to reimburse the Company.

Payments received by the Company from Schering AG in advance of EPIX performing research and development activities are recorded as contract advances.

*Royalty revenue*

The Company earns royalty revenues pursuant to its sub-license on certain of its patents to Bracco Imaging S.p.A. ( Bracco ). Royalty revenues are recognized based on actual revenue as reported by Bracco to the Company. Prior to the fourth quarter of 2004, the Company recognized royalty revenues based on royalty reports received from Bracco or on Bracco s estimates, historical revenues and trends when royalty reports from Bracco were not available in a timely manner. In December 2004, Bracco notified the Company that it had overstated non-U.S. royalties to the Company for the period 2001 to 2004, and that Bracco would offset the amount of the overstatement against its payments to the Company, including those triggered by FDA approval of MultiHance® in the U.S. Although the Company is disputing Bracco s assertion regarding the overstatement, the Company recognized the impact of Bracco s claimed overstatement by reducing its 2004 royalty revenue. In addition, because the Company no longer believes that it has a reasonable basis to make royalty estimates under the agreement with Bracco, it has, commencing in the fourth quarter of 2004, only recognized royalties from Bracco in the period in which royalty reports are received.

In connection with the execution of the sub-licensing arrangement in September 2001, Bracco made a $4.0 million refundable advance royalty payment to the Company, which was accounted for as deferred revenue. When royalty revenue is earned, it is offset against the $4.0 million refundable advance royalty. At September 30, 2005, the remaining balance of the refundable advance royalty was $75,172.

Massachusetts General Hospital ( MGH ) owns the patents that are the subject of the Company s agreement with Bracco and has exclusively licensed those patents to the Company, which have in turn been sub-licensed to Bracco by the Company. The Company owes MGH a percentage of all royalties received from its sub-licenses. Royalties owed to MGH, which totaled $78,444 and $107,915 for the nine months ended September 30, 2005 and 2004, respectively, are classified as general and administrative expenses in the Statements of Operations.

Pursuant to the License Agreement between the Company and Schering AG, the Company is entitled to a worldwide royalty on sales of certain Schering AG products covered by the agreement. In late 2004, Schering AG launched its new product, Primovist, which has been approved in the E.U. and is covered under this agreement. In the first quarter of 2005, the Company began to recognize royalty revenue based on sales of Primovist as reported to the Company by Schering AG.

*License fee revenue*

The Company records license fee revenues in accordance with SEC Staff Accounting Bulletin No. 104, *Revenue Recognition* ( SAB 104 ). Pursuant to SAB 104, the Company recognizes revenues from non-refundable license fees and milestone payments, not specifically tied to a separate earnings process, ratably over the period during which the Company has a substantial continuing obligation to perform services under the contract. When milestone payments are specifically tied to a separate earnings process, revenue is recognized when the specific performance obligations associated with the payment are completed.

In September 2001, the Company sub-licensed certain patents to Bracco and received a $2.0 million license fee from Bracco.

This license fee was included in deferred revenue and is being recorded as revenue ratably from the time of the payment until the expiration of MGH s patent in 2006.

As part of the strategic collaboration agreement the Company entered into with Schering AG in 2000, the Company granted Schering AG an exclusive license to co-develop and market Vasovist™ worldwide, exclusive of Japan. Later in 2000, the Company amended this strategic collaboration agreement to grant Schering AG exclusive rights to develop and market Vasovist™ in Japan, with the Company receiving a $3.0 million license fee from Schering AG. This license fee was included in deferred revenue and is being recorded as revenue ratably from the time of the payment until anticipated approval in Japan. The Company will continue to review this estimate and make appropriate adjustments as information becomes available.

Pursuant to a collaboration agreement with Mallinckrodt, Inc, a subsidiary of Tyco/Mallinckrodt, the Company has recorded $4.4 million of deferred revenue that is being recorded as revenue ratably from the time of payment until anticipated approval of Vasovist™ in the U.S. The Company will continue to review this estimate and make appropriate adjustments as information becomes available.

**Research and Development Expenses**

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

In order to conduct research and development activities and compile regulatory submissions, the Company enters into contracts with vendors who render services over an extended period of time, generally one to three years. 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 it estimates the service will be performed. Under a patient-based contract, the Company first determines an appropriate per patient cost using critical factors contained within the contract, which include the estimated number of patients and the total dollar value of the contract. The Company then records expense based upon the total number of patients enrolled during the period. On a quarterly basis, the Company reviews both the timetable of services to be rendered and the timing of services actually received. Based upon this review, revisions may be made to the forecasted timetable or the extent of services performed, or both, in order to reflect the Company s most current estimate of the contract.

**Loss per Share**

Basic and diluted net loss per share are computed using the weighted-average number of common shares outstanding during the period. For the three and nine months ended September 30, 2005 and 2004, the Company was in a net loss position and, therefore, the basic and diluted net loss per share are the same. Basic net loss per share excludes any dilutive effect from outstanding stock options and awards and from the conversion of convertible senior notes.

Common stock potentially issuable but excluded from the calculation of dilutive net loss per share for the three and nine months ended September 30, 2005 and 2004 because their inclusion would have been antidilutive consisted of the following:

| | 2005 | 2004 |
|---|---|---|
| Stock options and awards | 3,423,969 | 3,687,615 |
| Shares issuable on conversion of 3% Convertible Senior Notes | 3,359,090 | 3,359,090 |
| | 6,783,059 | 7,046,705 |

**Comprehensive Loss**

Comprehensive loss is comprised of net loss and unrealized gains or losses on the Company s available-for-sale marketable securities. The Company s comprehensive loss for the three months ended September 30, 2005 and 2004 amounted to $5.7 million

and $6.3 million, respectively, and for the nine months ended September 30, 2005 and 2004 amounted to $18.8 million and $15.4 million, respectively.

**Employee Stock Compensation**

The Company has elected to follow Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* ( APB 25 ), in accounting for its stock-based compensation plans under the intrinsic value method, rather than the alternative fair value accounting method provided for under SFAS No. 123, *Accounting for Stock-Based Compensation* ( SFAS 123 ), as amended by SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure* , ( SFAS No. 148 ). Under APB 25, because the exercise price of the Company s employee stock options is equal to the market price of the underlying stock on the date of grant, no compensation expense is recognized.

The following table illustrates the effect on net loss and net loss per share if the Company had applied the fair value recognition provisions of SFAS 123 to stock-based employee compensation:

| | Three months ended September 30, | | Nine months ended September 30, | |
|---|---|---|---|---|
| | 2005 | 2004 | 2005 | 2004 |
| Net loss - as reported | $ (5,659,757) | $ (6,412,512) | $ (19,011,396) | $ (15,238,753) |
| Add: employee stock-based compensation included in net loss as reported | | | | |
| Less: pro forma adjustment for stock-based compensation | (767,442) | (1,670,110) | (3,303,290) | (4,387,454) |
| Net loss - pro forma | $ (6,427,199) | $ (8,082,622) | $ (22,314,686) | $ (19,626,207) |
| | | | | |
| Net loss per share | | | | |
| As reported | $ (0.24) | $ (0.28) | $ (0.82) | $ (0.67) |
| Pro forma | (0.28) | (0.35) | (0.96) | (0.86) |

The weighted-average fair value of stock options granted during the three months ended September 30, 2005 and 2004 was $6.02 and $15.52, per share, respectively, and for the nine months ended September 30, 2005 and 2004 was $5.57 and $15.89, respectively, on the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions:

| | Options | | ESPP | |
|---|---|---|---|---|
| | Three Months Ended September 30, | | | |
| | 2005 | 2004 | 2005 | 2004 |
| Expected life of option (years) | 6.4 | 7.2 | 0.5 | 0.5 |
| Expected stock price volatility | 0.82 | 0.83 | 0.83 | 0.86 |
| Weighted average risk-free interest rate | 4.22% | 3.52% | 3.12% | 1.01% |

| | Nine Months Ended September 30, | | | |
|---|---|---|---|---|
| | 2005 | 2004 | 2005 | 2004 |
| Expected life of option (years) | 6.9 | 7.3 | 0.5 | 0.5 |

| | | | | |
|---|---|---|---|---|
| Expected stock price volatility | 0.84 | 0.85 | 0.83 | 0.86 |
| Weighted average risk-free interest rate | 3.74% | 3.24% | 3.12% | 1.01% |

Because options vest over several years and the Company expects to grant options in future years, the above pro forma results of applying the provisions of SFAS 123, as amended by SFAS No. 148, are not necessarily indicative of the pro forma results in future years.

**4. Loan Payable to Strategic Partner**

In May 2003, the Company entered into a Non-Negotiable Note and Security Agreement (the Loan Agreement ) with Schering AG under which the Company is eligible to borrow up to a total of $15.0 million. The Loan Agreement carries a variable, market-based interest rate, which was 10.75% and 9.25% at September 30, 2005 and December 31, 2004, respectively. The entire $15.0 million amount under the Loan Agreement was available and drawn as of September 30, 2005. The entire outstanding balance of $15.0 million, plus accrued interest, was repaid to Schering AG in October 2005. Of the $15.0 million available under the Loan Agreement, $7.5 million is available to be redrawn by the Company until May of 2007 and the remaining $7.5 million is available to be redrawn until May 2008, subject to specified conditions and covenants contained in the Loan Agreement, including a commitment to maintain cash and cash equivalents of at least $2.0 million. The Company was in compliance with such covenants at September 30, 2005 and December 31, 2004, respectively. Any outstanding balance under the Loan Agreement is repayable beginning in May 2007 and there is no penalty for prepayment. The Loan Agreement is secured by a first priority security interest in certain of the Company s intellectual property. The carrying value of the loan balance approximated fair value due to its variable interest rate.

**5. Convertible Debt**

In June 2004, the Company completed a sale, pursuant to Rule 144A under the Securities Act of 1933, of $100.0 million of 3% convertible senior notes due 2024 for net proceeds of approximately $96.4 million. Each $1,000 of senior notes is convertible into 33.5909 shares of the Company s common stock at a conversion rate of approximately $29.77 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. Each of the senior notes is also convertible into the Company s common stock in certain other circumstances. The senior notes bear an interest rate of 3%, payable semiannually on June 15 and December 15, beginning on December 15, 2004. The senior notes are unsecured and are subordinated to secured debt, including the loan payable to Schering AG.

The Company has the right to redeem the notes on or after June 15, 2009 at an initial redemption price of 100.85%, plus accrued and unpaid interest. Noteholders may require the Company to repurchase the notes at par, plus accrued and unpaid interest, on June 15, 2011, 2014 and 2019 and upon certain other events, including change of control and termination of trading.

In connection with the issuance of the senior notes, the Company incurred $3.65 million of issuance costs, which primarily consisted of investment banker fees and legal and other professional fees. The costs are being amortized as interest expense using the effective interest method over the term from issuance through the first date that the holders are entitled to require repurchase of the senior notes (June 2011). Amortization of the issuance costs for the three months ended September 30, 2005 and 2004 were $116,966 and $113,380, respectively, and for the nine months ended September 30, 2005 and 2004 were $352,409 and $141,200, respectively.

**6. Recent Accounting Pronouncements**

In December 2004, the Financial Accounting Standards Board (FASB) issued SFAS No. 123 (revised 2004), *Share-Based Payment An Amendment of FASB Statements No. 123 and 95* , ( SFAS 123R ). SFAS 123R supersedes APB 25, *Accounting for Stock Issued to Employees* , and amends SFAS No. 95, *Statement of Cash Flows* . Generally, the approach in SFAS 123R is similar to the approach described in SFAS 123. However, SFAS 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative.

SFAS 123R must be adopted by companies with fiscal years starting after June 15, 2005. Early adoption will be permitted in periods in which financial statements have not yet been issued. The Company expects to adopt SFAS 123R on January 1, 2006.

SFAS 123R permits public companies to adopt its requirements using one of two methods:

A modified prospective method in which compensation cost is recognized beginning with the effective date (a) based on the requirements of SFAS 123R for all share-based payments granted after the effective date and (b) based on the requirements of SFAS 123R for all awards granted to employees prior to the effective date of SFAS 123R that remain unvested on the effective date.

A modified retrospective method which includes the requirements of the modified prospective method described above, but also permits entities to restate based on the amounts previously recognized under SFAS 123R for purposes of pro forma disclosures either (a) all prior periods presented or (b) prior interim periods of the year of adoption.

The Company has not yet determined which method it will use.

As permitted by SFAS 123R, the Company currently accounts for share-based payments to employees using APB 25 s intrinsic value method and, as such, generally recognizes no compensation cost for employee stock options. Accordingly, the adoption of SFAS 123R s fair value method will have a significant impact on the Company s results of operations, although it will have no impact on its overall financial position. The impact of adoption of SFAS 123R cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had the Company adopted SFAS 123R in prior periods, the impact of that standard would have approximated the impact of SFAS 123R as described in the disclosure of pro forma net loss and net loss per share discussed above.

In May 2005, the FASB issued SFAS No. 154, *Accounting Changes and Error Corrections*, ( SFAS 154 ), a replacement of APB No. 20, *Accounting Changes*, and SFAS No. 3, *Reporting Accounting Changes in Interim Financial Statements*, ( SFAS 3 ). SFAS 154 replaces the provisions of SFAS 3 with respect to reporting accounting changes in interim financial statements. SFAS 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. Early adoption is permitted for accounting changes and corrections of errors made in fiscal years beginning after June 1, 2005. The Company does not believe the adoption of SFAS 154 will have a material impact on its overall financial position or results of operations.

**ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

**OVERVIEW**

We develop innovative pharmaceuticals designed to improve the diagnostic quality of images produced by MRI. Since commencing operations in 1992, we have been principally engaged in research and development activities related to our product candidates as well as seeking various regulatory clearances and patent protection. We have had no revenues from sales of our products and have incurred cumulative losses since inception through September 30, 2005 aggregating to approximately $174.3 million. Most of our revenues to date have come from license fees and product development revenues from collaboration agreements for our product candidates.

Our primary activities relate to three projects: 1) Vasovist™, or MS-325, for which we submitted an NDA to the FDA in December 2003, received an FDA approvable letter requesting additional clinical studies in January 2005, and submitted our response in May 2005 to the FDA s approvable letter, which was accepted by the FDA as a complete response in June 2005; 2) EP-2104R, which entered Phase II clinical development in April 2005 and whose Phase II clinical trial protocols were amended in July 2005 to include additional patient monitoring based on a review by the FDA of data from a 14-day, repeat dose preclinical toxicology study; and 3) our joint MRI research program with Schering Aktiengesellschaft, or Schering AG, which was amended in September 2005.

Vasovist™ is an injectable intravascular contrast agent intended to enhance the quality of MR images and provide physicians with an improved method for diagnosing diseases affecting the vasculature. We completed our Phase III clinical trial program to test the safety and efficacy of Vasovist™-enhanced MR angiography, or MRA, for the evaluation of non-coronary vascular disease and submitted our NDA for Vasovist™ to the FDA in December 2003. In February 2004, we were notified by the FDA that the NDA for Vasovist™ had been accepted for filing and had been designated for a standard 10-month review cycle. In October 2004, we were notified by the FDA that it had extended the action date for completion of its review of Vasovist™ by 90 days to January 2005. In January 2005, we received an approvable letter from the FDA for Vasovist™ in which the FDA requested additional clinical studies to demonstrate efficacy prior to approval. In May 2005, we submitted our response to the approvable letter received from the FDA in January 2005 and it was accepted by the FDA as a complete response in June 2005. In its acceptance of the complete response, the FDA encouraged EPIX to consider a re-read of the images from the Phase III trials to provide additional information about the usefulness of dynamic and steady-state images, and to schedule a meeting with the FDA to discuss the merits and design of such a study. In the meantime, the FDA agreed to conduct its review of the NDA, including the complete response. In July 2005, EPIX requested a meeting with the FDA to discuss the design and implementation of a Phase IV study to investigate the relative contributions of dynamic and steady-state images in the use of Vasovist™. In August 2005, the FDA notified EPIX that such a meeting was premature. We are continuing our dialogue with the FDA in order to determine the next steps we will need to take in the regulatory pathway for Vasovist™. During its review of the complete response, the FDA could again request additional studies or other information before granting approval of Vasovist™ or it could decide not to approve Vasovist™ without asking for additional studies or other information.

In June 2004, Schering AG submitted Vasovist™ to the European Medicines Agency (EMEA) for marketing approval in the European Union (E.U.). In June 2005, the European Committee for Medicinal Products for Human Use (CHMP) recommended granting E.U. marketing authorization for Vasovist™. In October 2005, the EMEA granted approval of Vasovist™ for all 25 member states of the E.U. Following regulatory approval, our partner, Schering AG, will have primary responsibility for the product launch and marketing of Vasovist™ in all regions of the world. In May 2005, we completed enrollment in the OPTIMUM clinical trial study of Vasovist™ for high resolution vascular MRA in peripheral vascular disease. This trial was designed to provide high quality vascular MRA images for marketing and customer education upon product launch. In August 2005, we completed enrollment in a Phase II clinical trial to assess the feasibility of combined imaging of cardiac perfusion and coronary arteries with MRI using Vasovist™. Evaluation of data from this study is expected to be complete by the first quarter of 2006. Although we have not completed review of the data, the images we have reviewed to date would not support a label expansion for broad coronary use. In 2004, Schering AG completed enrollment in Phase I trials in Japanese subjects in support of the Japanese development program for Vasovist™, but the details of the developments plan for Japan remains under discussion between the companies.

If our Vasovist™ NDA is approved by the FDA in a timely manner, we believe that we will have a significant opportunity related to revenues generated from sales of Vasovist™. Any revenues from sales of Vasovist™ and other products will depend on the success of commercialization efforts by Schering AG and us, as well as on the success and timing of clinical trials and regulatory approvals for our products. The successful commercialization of Vasovist™ and other products will also be affected by the development, regulatory approval and commercialization of competing products and on the intellectual property claims in the field of diagnostic imaging. More broadly, the markets for our products will be subject to the effects of a number of additional factors, including developments in reimbursement policies in the U. S. and other countries and changes in the cost of and demand for diagnostic procedures for cardiovascular disease. If approved,

the Company believes that Vasovist™-enhanced MRA will offer a cost-effective and less invasive procedure for evaluating vascular disease relative to catheter-based x-ray angiography.

EP-2104R is an injectable MRI contrast agent that is specifically targeted to fibrin, the dominant protein in blood clots, or thrombi. It is designed to provide a bright MR image of blood clots anywhere in the vascular system and may allow clinicians to identify patients at risk from the early development of blood clots. Finding blood clots is of critical medical significance in the evaluation and diagnosis of patients with stroke, chest pain, heart attack, irregular heartbeat and clots in the lungs and legs. We designed EP-2104R to bind reversibly to fibrin. In May 2003, we entered into a collaboration agreement with Schering AG for the development and commercialization of EP-2104R. Under terms of the agreement, we are responsible for the execution of a clinical feasibility program for EP-2104R in humans for which Schering AG is obligated to make fixed payments to us of approximately $9.0 million over a two-year period. At the end of the feasibility program, Schering AG may exercise an option to develop EP-2104R by paying an option fee to the Company, following which Schering AG will receive an exclusive, worldwide license for EP-2104R and become responsible for all further development, manufacturing, marketing and sales. In 2004, we completed Phase I clinical trials of EP-2104R in which the drug was observed to be well tolerated in healthy volunteers. We initiated our Phase II clinical trial to study the feasibility of blood clot imaging using EP-2104R in patients in April 2005. In July 2005, we announced that we would be amending our Phase II proof-of-concept clinical trial protocols for EP-2104R to include additional patient safety monitoring based on a review by the FDA of data from a 14-day, repeat dose preclinical toxicology study. The additional patient monitoring in the Phase II trials has resulted in slower than expected enrollment in this trial and will extend the timeline and increase the cost for EP-2104R development. As a result, it is unlikely that we will meet our goal of obtaining final results from this trial in mid-2006. We have added sites and taken other steps to improve enrollment. We expect to be able to evaluate the success of these measures by year end.

We are engaged in research activities to discover other pharmaceutical product candidates, including efforts to explore the application of our proprietary fibrin binding technology to the development of novel antithrombotic therapeutics. In May 2003, we entered into an agreement with Schering AG covering an exclusive research collaboration to discover novel compounds for diagnosing human disease using MRI. Under the terms of the three-year joint research agreement, we and Schering AG are exclusively combining our existing research programs in the field of MRI to discover novel MRI product candidates for clinical development. Under the agreement, Schering AG agreed to fund a portion of our related personnel costs, fund third party research costs of up to $2.0 million per year and make available to us a loan facility of up to $15 million, with principal repayment beginning in 2007. In October 2005, the Company announced that it had entered into an amendment to the research collaboration agreement with Schering AG. This amendment narrows the definition of the field of collaboration and further indicates the parties non-binding intent to enter into a new research collaboration agreement by the end of 2005 and to discuss possible modifications of the collaboration. We are also engaged in research activities to explore the application of our proprietary fibrin-binding technology to the discovery of novel antithrombotic therapeutics. The Company is exploring the diversification of its product pipeline through the potential acquisition of therapeutic drug programs.

We expect continued operating losses for at least three years, and possibly thereafter, as we continue to incur expenses to support research and development efforts to obtain FDA approval, to support Schering AG in the commercialization of our initial product candidate, Vasovist™ and to support other research and development activities.

Our financial results have been, and in the future will continue to be, affected significantly by the scope and speed of our clinical trial programs and by our interaction with the FDA related to the regulatory review of Vasovist™. We filed an investigational new drug (IND) application and initiated a Phase I clinical trial for Vasovist™ in 1996. We completed a Phase II clinical trial in 1998 to test the safety and preliminary efficacy of Vasovist™-enhanced MRA for the evaluation of non-coronary vascular disease and also completed a Phase II trial in 2001 that was designed to compare the diagnostic accuracy of five different doses of Vasovist™-enhanced MRA with that of X-ray angiography in the aortoiliac arteries. From 1998 to 2000, we also completed feasibility trials to test Vasovist™ in detecting coronary artery disease, in detecting breast cancer and in diagnosing female sexual arousal dysfunction. We completed two Phase III studies, with results announced in 2002 and 2003, to determine the efficacy of Vasovist™-enhanced MRA for the detection of aortoiliac

occlusive disease. In 2001, after discussions with the FDA, we expanded our clinical program for Vasovist™ beyond aortoiliac occlusive disease to include two additional Phase III trials in support of a broader vascular disease indication, which we expected would include the entire vasculature, except for the heart. These two new trials included one for MRA of the renal arteries and one for MRA of pedal arteries. These two additional trials were completed and results announced in 2003. We submitted our NDA to the FDA in December 2003 and our NDA was accepted for filing by the FDA in February 2004. In October 2004, we were notified by the FDA that it had extended the action date for completion of its review of Vasovist™ by 90 days to January 2005. In January 2005, we received an approvable letter from the FDA for Vasovist™ in which the FDA requested additional clinical studies to demonstrate efficacy prior to approval. In May 2005, we submitted our response to the approvable letter received from the FDA in January 2005 and it was accepted by the FDA as a complete response in June 2005. We are continuing to evaluate and try to discuss with the FDA the appropriate next steps in the regulatory and clinical development of Vasovist™. In October 2005, the EMEA granted approval of Vasovist™ for the E.U. We are currently evaluating data from a Phase II clinical trial to assess the feasibility of imaging cardiac perfusion and coronary arteries with MRI

using Vasovist™. Although we have not completed review of the data, the images we have reviewed to date would not support a label expansion for broad coronary use.

We anticipate fluctuations in our results of operations due to several factors, including the timing of fees and milestone payments received from strategic partners; the formation of new strategic alliances between us and third parties; the timing and magnitude of expenditures in connection with research and development activities, including preclinical and clinical trials; the timing of product introductions and expense of associated launches, marketing and sales activities; and the timing and extent of product acceptance for different indications and geographical areas of the world.

In September 2005, the Company named Michael J. Astrue as interim Chief Executive Officer. Mr. Astrue, the former CEO of Transkaryotic Therapies, succeeds Michael Webb, who will remain as a consultant to the Company. Mr. Astrue will help the Company to execute its business plan in the imaging field and to define and pursue opportunities for growth beyond imaging. The Company is exploring the diversification of its product pipeline through the potential acquisition of therapeutic drug programs.

**CRITICAL ACCOUNTING POLICIES AND ESTIMATES**

The discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these financial statements requires us to make estimates and judgments that affect our reported assets and liabilities, revenues and expenses, and other financial information. Actual results may differ significantly from the estimates under different assumptions and conditions.

Our significant accounting policies are more fully described in Note 2 of the Company s Financial Statements for the year ended December 31, 2004 and in Note 3 to the financial statements set forth in Item 1 above. Not all significant accounting policies require management to make difficult, subjective or complex judgments or estimates. We believe that our accounting policies related to revenue recognition, research and development and employee stock compensation, as described below, require critical accounting estimates and judgments.

**Revenue Recognition**

We recognize revenues from non-refundable license fees and milestone payments not specifically tied to a separate earnings process ratably over the period during which we have substantial continuing obligations to perform services under the contract. When milestone payments are specifically tied to a separate earnings process, revenue is recognized when the specific performance obligations associated with the payment are completed. When the period of deferral cannot be specifically identified from the contract, we estimate the period of deferral based upon our obligations under the contract. We continually review these estimates and, if any of these estimates change, adjustments are recorded in the period in which they become reasonably estimable. These adjustments could have a material effect on our results of operations.

Under the Vasovist™ program, we recognize product development revenue at the time we perform research and development activities, for which Schering AG is obligated to reimburse us. Product development revenues from Schering AG are recorded net of the Company s portion of Schering AG s actual or most recent estimate of its Vasovist™ research and development costs.

We recognize product development revenue from Schering AG for the EP-2104R feasibility program as revenue proportionate to our actual cost incurred relative to our estimate of the total cost of the feasibility program. Total estimated costs of the feasibility program are based on an evaluation of the portion of the program completed, costs incurred to date, planned program activities, anticipated program timelines and the expected future costs of the program. Adjustments to revenue are recorded if estimated costs to complete change materially from previous periods. To the extent that our estimated costs change materially, our revenues recorded under this activity could be materially affected and such change could have a material adverse effect on our operations in future periods. During the second quarter of 2005, management increased its estimated cost-to-complete the feasibility program to $16.1 million from its previous estimate of $13.6 million. This increase in the cost-to-complete the feasibility program is directly attributed to the additional patient safety monitoring related to amending the Phase II proof-of-concept clinical trial protocols for EP-2104R announced in July 2005. The impact of increasing the estimated cost-to-complete the feasibility program during 2005 resulted in a reduction in product development revenue of $1.5 million recognized in the first and second quarters of 2005.

Revenue under our research collaboration with Schering AG in MRI is recognized as services are provided, for which Schering AG is obligated to reimburse us.

Royalty revenue is recognized based on actual revenues reported to us by Bracco Imaging S.p.A, or Bracco, and Schering AG.

Prior to the fourth quarter of 2004, we recognized royalty revenue based on royalty reports received from Bracco or on Bracco s estimates, historical revenues and trends when royalty reports from Bracco were not available in a timely manner. In December 2004, we were notified that Bracco was asserting that it had overstated its non-U.S. royalties to us for the period 2001 to 2004, and that Bracco would offset the amount of the overstatement against its payments to us, including those triggered by FDA approval of MultiHance® in the U.S. Although we are disputing Bracco s position regarding the overstatement, we recognized the impact of Bracco s claimed overstatement by reducing our 2004 royalty revenue. In addition, because we no longer believe that we have a reasonable basis to make royalty estimates under the agreement with Bracco, we have, commencing in the fourth quarter of 2004, only recognized royalties from Bracco in the period in which royalty reports are received.

**Research and Development**

Research and development costs, including those associated with technology, licenses and patents, are expensed as incurred. Research and development costs include employee salaries and related costs, third party service costs, the costs of preclinical and clinical trial supplies and consulting expenses.

In order to conduct research and development activities and compile regulatory submissions, we enter into contracts with vendors who render services over extended periods of time, generally one to three years. Typically, we enter 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, we record the contractual expense for each service provided under the contract ratably over the period during which we estimate the service will be performed. Under a patient-based contract, we first determine 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. We then record expense based upon the total number of patients enrolled during the period. On a quarterly basis, we review both the timetable of services to be rendered and the timing of services actually rendered. Based upon this review, revisions may be made to the forecasted timetable or to the extent of services performed, or both, in order to reflect our most current estimate of the contract. Adjustments are recorded in the period in which the revisions are estimable. These adjustments could have a material effect on our results of operations.

**Employee Stock Compensation**

We have elected to follow Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees,* or APB 25, and related interpretations in accounting for our employee stock options under the intrinsic value method, rather than the alternative fair value accounting provided for under Statement of Financial Accounting Standards No. 123(R), *Share-Based Payments An Amendment of FASB Statement No. 123 and 95* or SFAS 123R. Under APB 25, because the exercise price is equal to the market price of the underlying stock on the date of the grant, no compensation expense is recognized.

Our financial results could be materially adversely affected with the required adoption of SFAS 123R, effective January 1, 2006, to the extent of the additional compensation expense that we would have to recognize, which could change significantly from period to period based on several factors, including the number of stock options granted and fluctuations in our stock price and/or interest rates. See Note 3 to the Notes to Condensed Financial Statements (unaudited).

**RESULTS OF OPERATIONS**

**Comparison of Three Months Ended September 30, 2005 versus 2004**

**Revenues**

Our revenues arise principally from our collaboration agreements with Schering AG for Vasovist™, EP-2104R and MRI discovery research; from license fee revenues relating to our agreements with Schering AG, Tyco/Mallinckrodt and Bracco; and from royalties related to our agreements with Bracco and Schering AG. Revenues for the three months ended September 30, 2005 and 2004 were $2.3 million and $3.2 million, respectively. Revenues for 2005 consisted of $1.3 million of product development revenue from Schering AG, $798,000 of royalty revenue related to the Bracco and Schering AG agreements and $166,000 of license fee revenue related to the Schering AG, Tyco/Mallinckrodt strategic collaboration and Bracco agreements. The decrease in total revenues of $976,000 for the three months ended September 30, 2005 compared to the same period last year resulted from lower product development and license fee revenues, partly offset by higher royalty revenue. The lower product development revenues of $976,000 primarily resulted from the lower reimbursable costs by us related to Vasovist™ and to lower costs incurred by us on the EP-2104R proof-of-concept program during the quarter. The lower license fee revenue was due to the change in the estimated approval date for Vasovist™ made in the first quarter of 2005. The increase in royalty revenue was primarily attributed to royalties from Schering AG s product launch of Primovist in the first

quarter of 2005 and to higher Bracco sales of MultiHance® in the U.S. reported to us.

**Research and Development Expenses**

Our research and development expenses arise from our development activities for Vasovist™ and EP-2104R and from our discovery research programs. Research and development expenses for the three months ended September 30, 2005 were $5.5 million compared to $6.5 million for the same period in 2004. The decrease of approximately $1.0 million was attributed to lower spending on our Vasovist™ and EP-2104R development programs, partly offset by higher spending on our MRI and therapeutics research programs.

Both the timeframe and costs involved in developing Vasovist™ and EP-2104R, gaining regulatory approval and commercializing the products might vary greatly from current plans for several reasons, including the following:

We conduct our clinical trials in accordance with specific protocols, which we have filed with the FDA or other relevant authorities. If the FDA requires us to perform additional studies, to perform additional procedures in our studies or to increase patient numbers in those studies, we could incur significant additional costs and additional time to complete our clinical trials, assuming we are able to reach agreement with the FDA on protocols for any additional studies or procedures. This could result in a delay in our ability to make regulatory submissions and a delay in the commercialization, increased competition or slower sales growth of our product.

We rely on third party clinical trial centers to find suitable patients for our clinical trial program. If these clinical trial centers do not find suitable patients in the timeframe for which we have planned, we will not be able to complete our clinical trials according to our expected schedule. Such a delay could result in an increase in development costs for Vasovist™ or EP-2104R, a delay in making regulatory submissions and a delay in the commercialization, increased competition or slower sales growth of our product.

We rely on third party contract research organizations for a variety of activities in our development program, including conducting blinded reading activities, lab testing and analysis of clinical samples, data collection, cleanup and analysis and drafting study reports and regulatory submissions. A delay in these activities could result in an increase in costs, a delay in making regulatory submissions and a delay in the commercialization, increased competition or slower sales growth of our product.

The length of time that the FDA or other regulatory authorities take to review our regulatory submissions and the length of time it takes us to respond to the FDA or other regulatory authorities questions can also vary widely. In January 2005, we received an approvable letter from the FDA for Vasovist™ in which the FDA requested additional clinical studies to demonstrate efficacy prior to approval. In May 2005, we submitted our

response to the approvable letter received from the FDA in January 2005 and it was accepted by the FDA as a complete response in June 2005. During its review of the complete response, the FDA could again request additional studies or other information before granting approval of Vasovist™, or it could decide not to approve Vasovist™ without asking for additional studies or other information. The process of obtaining agreement with the FDA for conducting necessary clinical trial studies is subject to significant uncertainties in terms of timing, costs and success. The additional time and any other delays in the regulatory approval process could result in a longer delay in commercialization or slower sales growth of our product.

Our partner, Schering AG, is responsible for the commercial launch and marketing of Vasovist™. If Schering AG does not launch the product in a timely manner or market the product effectively following regulatory approval, we may incur a delay in receiving revenues after the launch of Vasovist™ or may not receive enough revenue to enable us to become profitable.

Current plans for developing and commercializing Vasovist™ and EP-2104R reflect our best estimate of the time involved in the development program based on factors currently known to us. The third parties described above have the ability to greatly impact this timetable and we may not have control over or be able to respond within our current plan to changes they cause. Any such delays could result in a significant increase in costs to develop Vasovist™ or EP-2104R as well as a delay in product launch, which could enable competition to intensify.

Under our EP-2104R agreement, Schering AG has made fixed payments to us totaling approximately $9.0 million over a two year period, which was initially intended to cover most of our costs of the feasibility program. The amount of expenditure necessary to execute the feasibility program is subject to numerous uncertainties, which may adversely affect our cash outlay, net of Schering AG s reimbursement to us. In July 2005, we announced that we would be amending our Phase II proof-of-concept clinical trial protocols for EP-2104R to include additional patient safety monitoring based on a review by the FDA of data from a 14-day, repeat dose preclinical

toxicology study. The additional patient monitoring in the Phase II trials has resulted in slower than expected enrollment in this trial and will extend the timeline and increase the estimated costs to $16.1 million for EP-2104R development. As a result, it is unlikely that we will meet our goal of obtaining final results from this trial in mid-2006. We have added sites and taken other steps to improve enrollment. We expect to be able to evaluate the success of these measures by year end. In addition, we cannot predict whether Schering AG will exercise its option to develop EP-2104R or, if Schering AG does exercise its option, whether we will exercise our option to bear a portion of the development costs in return for an increase in our royalty rate. If Schering AG does not exercise its option, then we would have to bear the additional cost of a clinical program to develop EP-2104R, which may adversely affect our liquidity and capital resources, or cancel the program. Consequently, at this time, we cannot predict the amount of additional research and development costs that we will incur with regards to the development and commercialization of EP-2104R.

The cost to execute our joint research plan with Schering AG, which was amended in September 2005 to narrow the definition of the field of collaboration, indicate the parties non-binding intent to enter into a new research collaboration agreement by the end of 2005 and discuss possible modifications of the collaboration, is subject to numerous uncertainties, which may adversely affect our liquidity and capital resources.

The duration and cost of bringing a product to market may vary significantly over the life of a project as a result of various matters arising during and after clinical trials, including among others, the following:

Time needed for regulatory approval;

Number of patients, costs per patient and the rate of patient recruitment in the clinical trial program;

Complexity and cost of project management, data collection and data management services provided by outside vendors; and

Unanticipated adverse safety and efficacy results from the pre-clinical or clinical trials.

We test our potential product candidates in numerous pre-clinical studies to identify disease indications for which they may be used. We may conduct multiple clinical trials to cover a variety of potential indications for each product candidate. As we obtain results from trials, we may elect to discontinue clinical trials for certain product candidates or for certain indications in order to focus on more promising product candidates or indications. In addition, the FDA may require us to modify our future clinical trial plans or to conduct additional clinical trials in ways that we cannot currently anticipate. Such modifications or additional clinical trials could result in an increase in costs of our product development and a delay in the commercialization or slower sales growth of our product.

**General and Administrative Expenses**

General and administrative expenses, which consist primarily of salaries, benefits, outside professional services and related costs associated with our executive, finance and accounting, business development, marketing, human resources, legal and corporate communications activities, were $2.6 million for the three months ended September 30, 2005 as compared to $2.9 million for the three months ended September 30, 2004. The decrease of $262,000 was primarily attributed to lower spending by EPIX and Schering AG for Vasovist™ marketing, partly offset by higher liability insurance premiums and higher corporate administration, primarily attributed to legal costs. General

and administrative expenses also include royalties payable to Massachusetts General Hospital, or MGH, based on sales by Bracco of MultiHance®. Royalty expenses totaled $32,000 and $31,000 for the three months ended September 30, 2005 and 2004, respectively.

**Interest Income and Interest Expense**

Interest income for the three months ended September 30, 2005 was $1.1 million as compared to $688,000 for the three months ended September 30, 2004. The increase of $416,000 was primarily due to higher interest rates on our invested cash, cash equivalents and marketable securities during the period. Interest expense for the three months ended September 30, 2005 and 2004 was $911,000 and $935,000, respectively. The decrease in interest expense of $24,000 for the three months ended September 30, 2005 resulted from the reduction in the outstanding balance of interest-bearing prepaid royalties from Bracco. The Schering AG loan facility of $15.0 million, which was entirely drawn down as of September 30, 2005, was repaid to Schering AG with accrued interest in October 2005.

**Provision for Income Taxes**

The provision for income taxes, which represents Italian income taxes related to the Bracco agreement, was $0 for the three months ended September 30, 2005 as compared to $17,000 for the three months ended September 30, 2004. Since all of the royalty revenue earned from Bracco sales during the three months ended September 30, 2005 was offset against various prepaid royalties, no withholding taxes were accrued or paid during the current period.

**Comparison of Nine Months Ended September 30, 2005 versus 2004**

**Revenues**

Revenues for the nine months ended September 30, 2005 and 2004 were $5.4 million and $10.1 million, respectively. Revenues for 2005 consisted of $3.1 million of product development revenue from Schering AG, $1.8 million of royalty revenue related to the Bracco and Schering AG agreements and $498,000 of license fee revenue related to the Schering AG, Tyco/Mallinckrodt strategic collaboration and Bracco agreements. The decrease in total revenues of $4.7 million for the nine months ended September 30, 2005 compared to the same period last year resulted from lower product development, royalty and license fee revenues. Lower product development revenue accounted for $3.8 million of the decrease between the two periods and resulted from the revenue adjustments related to the increases in the cost-to-complete the EP-2104R development program as a result of amending our Phase II proof-of-concept clinical trial protocols for EP-2104R to include additional patient safety monitoring based on a review by the FDA of data from a 14-day, repeat dose preclinical toxicology study, and to lower reimbursable costs by us for the Vasovist™ program, partly offset by higher development revenue under the research collaboration agreement with Schering AG. The reduction in royalty revenue during 2005 was primarily attributed to Bracco s revised determination of sales by affiliates made with its December 2004 royalty overpayment assertion; partly offset by royalties from U.S. sales by Bracco of MultiHance® and Schering sales of Primovist. The lower license fee revenue was due to the change in the estimated approval date for Vasovist™ made in the first quarter of 2005.

**Research and Development Expenses**

Research and development expenses for the nine months ended September 30, 2005 were $16.7 million compared to $17.1 million for the same period in 2004. The decrease in research and development expenses of $426,000 resulted from lower spending for the Vasovist™ and EP-2104R development programs during the nine months ended September 30, 2005, partly offset by higher spending from our MRI and therapeutics research programs.

**General and Administrative Expenses**

General and administrative expenses were $7.9 million for the nine months ended September 30, 2005 as compared to $8.2 million for the nine months ended September 30, 2004. A decrease in spending of $239,000 by us and Schering AG for Vasovist™ marketing was partly offset by higher liability insurance premiums and higher corporate administration, primarily attributed to legal costs, combined with higher business development costs. General and administrative expenses also include royalties payable to Massachusetts General Hospital, or MGH, based on sales by Bracco of MultiHance®. Royalty expenses totaled $78,000 and $108,000 for the nine months ended September 30, 2005 and 2004, respectively.

**Interest Income and Interest Expense**

Interest income for the nine months ended September 30, 2005 was $2.9 million as compared to $1.2 million for the nine months ended September 30, 2004. The increase of $1.7 million was primarily due to higher interest rates and higher average levels of invested cash, cash equivalents and marketable securities during the period, which was related to net proceeds from the issuance of $100.0 million convertible senior notes in June 2004. Interest expense for the nine months ended September 30, 2005 and 2004 was $2.7 million and $1.2 million, respectively. The increase in interest expense of $1.5 million for the nine months ended September 30, 2005 resulted from the issuance of convertible senior notes in June 2004 and the drawdown of the entire $15.0 million loan facility made available to us by Schering AG as part of the joint MRI research collaboration, partly offset by the reduction in the outstanding balance of interest-bearing prepaid royalties from Bracco. The entire principal balance of the loan facility, which was $15.0 million as of September 30, 2005, plus accrued interest, was repaid in October 2005.

**Provision for Income Taxes**

The provision for income taxes, which represents Italian income taxes related to the Bracco agreement, was $0 for the nine months ended September 30, 2005 as compared to $46,000 for the nine months ended September 30, 2004. Since all of the royalty revenue earned from Bracco sales during the first nine months ended September 30, 2005 was offset against various prepaid royalties, no withholding taxes were accrued or paid during the period.

**LIQUIDITY AND CAPITAL RESOURCES**

Our principal sources of liquidity consist of cash, cash equivalents and available-for-sale marketable securities of $145.9 million

at September 30, 2005 as compared to $164.4 million at December 31, 2004. The decrease in cash, cash equivalents and available-for-sale marketable securities was primarily attributed to funding of ongoing operations.

We used approximately $18.0 million of net cash to fund operations for the nine months ended September 30, 2005, which compares to $16.9 million for the same period last year. The net use of cash of $18.0 million to fund operations during the nine months ended September 30, 2005 resulted from the net loss of $19.0 million combined with the reduction in deferred revenue of $2.2 million, offset by increases in contract advances of $461,000, accrued expenses and accounts payable of $1.6 million and depreciation of $829,000. The reduction in deferred revenue resulted from the offsets of prepaid royalties from Bracco, plus other license fee revenue recognition related to payments from Schering AG, Tyco/Mallinckrodt and Bracco, which are being amortized into revenue in accordance with the requirements of SAB 104. The increase in contract advances is primarily attributed to Schering AG s funding of our Vasovist™ pre-launch marketing activities. The increase in accrued expenses is due to higher legal related accruals, partly offset by lower clinical accruals. For the nine months ended September 30, 2004, net cash used for operating activities of $16.9 million was primarily attributable to our net loss of $15.2 million, combined with reduction in deferred revenue of $2.8 million and an increase in accounts receivables of $797,000, partly offset by a reduction in accrued expenses of $1.2 million and contract advances of $794,000. The reduction in deferred revenue resulted from royalty revenues from sales by Bracco of MultiHance®, which were offset against advanced payments. The increase in accounts receivable resulted from an increase in the billings to Schering AG related to Vasovist™ pre-launch activities and to product development activities. The increase in accrued expenses was due to higher accrued clinical trial costs and higher accrued interest related to the convertible senior notes, partly offset by the issuance of common stock to Dr. Martin Prince in early January 2004 in connection with the Intellectual Property Agreement entered into in November of 2003. The increase in contract advances related to funding of both our and Schering AG s Vasovist™ pre-launch activities. Also during the first nine months of 2004, we received a $2.5 million milestone payment from Schering AG related to the acceptance of the filing of the NDA with the FDA for Vasovist™. Immediately following this receipt, we paid Tyco/Mallinckrodt $2.5 million in recognition of the same milestone. These payments were offset in our Statements of Operations, resulting in no impact on revenues, expenses or net loss.

Our investing activities resulted in net cash provided of $25.6 million for the nine months ended September 30, 2005 as compared to net cash used of $57.7 million for the same period last year. During the nine months ended September 30, 2005, we sold or redeemed available-for-sale marketable securities of $98.2 million, partly offset by the cash used to purchase $71.4 million of available-for-sale marketable securities that was primarily funded from the rollover of securities within our portfolio. During the same period in 2004, we purchased $79.4 million of available-for-sale marketable securities, which was partly funded from the funds received from the convertible debt issuance and partly offset by cash generated from the redemption of available-for-sale marketable securities of $23.7 million. Other investing activities included capital expenditures of $1.2 million for the nine months ended September 30, 2005 as compared to $2.0 million for the same period last year. The higher capital expenditures in 2004 were primarily attributed to leasehold improvements and to the acquisition of equipment, including lab equipment, computer equipment and software, related to the refurbishment of our laboratory space.

Cash provided by financing activities was $544,000 for the nine months ended September 30, 2005. The primary sources of financing during the nine months ended September 30, 2005 came from the cumulative drawdown of the loan facility of $45.0 million with Schering AG, of which $15.0 million was outstanding at September 30, 2005, and proceeds from stock option exercises and our Employee Stock Purchase Plan of $544,000. Also during this period, we cumulatively repaid $45.0 million on our loan facility with Schering AG. During the nine months ended September 30, 2004, we received net proceeds of $96.4 million from the issuance of convertible senior notes and another $4.4 million from stock option exercises and proceeds from our Employees Stock Purchase Plan. In addition, we cumulatively borrowed $37.5 million and repaid $30.0 million during the nine months ended September 30, 2004 on our loan facility with Schering AG.

We currently receive quarterly cash payments from Schering AG for its share of development costs of Vasovist™ and for its share of research costs on our joint MRI research collaboration. We also receive monthly interest income on our cash, cash equivalents and available-for-sale marketable securities. We are also scheduled to receive quarterly royalty payments from Bracco for a portion of the royalty revenue actually earned from the sales of MultiHance®. In December 2004, Bracco asserted that it had overstated non-U.S. royalties to us for the period 2001 to 2004 and that it would offset the amount of the overstatement against its payment to us, including those triggered by FDA approval of MultiHance® in the U.S. Although we are disputing Bracco s position, we recognized the impact of Bracco s claimed overstatement by reducing 2004 royalty revenues. Other potential cash inflows include: a milestone payment of $1.3 million from Schering AG, which is dependent on the FDA s approval of Vasovist™, and up to $22.0 million in additional milestone payments from Schering AG as well as our share of the profits earned on sales of Vasovist™ worldwide. Additional future cash flows from our EP-2104R collaboration with Schering AG of up to $15 million depend on the successful completion of the EP-2104R feasibility program, on Schering AG s decision to exercise its development option and on the success of further development, regulatory and commercialization work by Schering AG, none of which is assured at this time. Additional future cash flows from our MRI research collaboration with Schering AG depend on the success of the research program and the success of further development, regulatory and commercialization activities with respect to any products generated. Pursuant to the License Agreement between us and Schering AG, we

are entitled to a worldwide royalty on sales of certain Schering AG products covered by the agreement.

Known outflows, in addition to our ongoing research and development and general and administrative expenses, include the semi-annual royalties that we owe to MGH on sales by Bracco of MultiHance®; a milestone payment of $2.5 million owed to Tyco/Mallinckrodt, which is dependent on the FDA s approval of Vasovist™; a share of profits due Tyco/Mallinckrodt on sales of Vasovist™ worldwide; a royalty to Daiichi on sales of Vasovist™ in Japan and a royalty due MGH on our share of the profits of Vasovist™ worldwide. We will also be required to repay Bracco any unearned prepaid royalties upon termination of our license agreement with Bracco. As of September 30, 2005, unearned prepaid royalties equaled approximately $75,000 according to Bracco s restatement of royalties due to us.

We expect that our cash, cash equivalents and marketable securities on hand as of September 30, 2005 will be sufficient to fund our operations for at least the next several years. As of September 30, 2005, we had outstanding the entire balance of our $15.0 million loan facility available from Schering AG as part of our MRI research collaboration. We repaid the entire $15.0 million loan, plus accrued interest, in October 2005, but expect to redraw the $15.0 million loan as needed. We expect to be able to redraw the $15.0 million from the Schering AG loan facility, of which $7.5 million can be redrawn until May 2007 and the remaining $7.5 million until May 2008, but could be unable to redraw under the terms of the loan if we fail to meet certain covenants or conditions precedent in the loan. As of September 30, 2005, we were in compliance with the covenants of the loan facility. If holders of our convertible senior notes require redemption of the notes, we may be required to repay $100.0 million in June 2011. Our future liquidity and capital requirements will depend on numerous factors, including the following: the progress and scope of clinical and preclinical trials; the timing and costs of filing future regulatory submissions; the timing and costs required to receive both U.S. and foreign governmental approvals; the cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights; the extent to which our products, if any, gain market acceptance; the timing and costs of product introductions; the extent of our ongoing and new research and development programs; the costs of training physicians to become proficient with the use of our potential products; and, if necessary, once regulatory approvals are received, the costs of developing marketing and distribution capabilities.

Because of anticipated spending to support new research programs as well as the continued development of Vasovist™ and EP-2104R, we do not expect positive cash flow from operating activities for any future quarterly or annual period prior to commercialization of Vasovist™ in the U.S. Our ability to reach positive cash flow subsequent to the commercialization of Vasovist™ will depend on its market acceptance and successful launch by our partner Schering AG as well as the ability of our partner Tyco/Mallinckrodt to manufacture sufficient quantities of Vasovist™ to support Schering AG s sales and marketing activities. We anticipate continued investments in fixed assets, including equipment and facilities expansion to support new and continuing research and development programs.

We have not entered into any material contractual obligations since the presentation of our table of Contractual Obligations as set forth in our Annual Report on Form 10-K for the fiscal year ended December 31, 2004.

We have incurred tax losses to date and therefore have not paid significant federal or state income taxes since inception. As of December 31, 2004, we had federal net operating loss carryforwards of approximately $154.2 million available to offset future taxable income. These amounts expire at various times through 2024. As a result of ownership changes resulting from sales of equity securities, our ability to use the net operating loss carryforwards is subject to limitations as defined in Sections 382 and 383 of the Internal Revenue Code of 1986, or the Code, as amended. We currently estimate that the annual limitation on our use of net operating losses generated through May 31, 1996 to be approximately $900,000. Pursuant to Sections 382 and 383 of the Code, the change in ownership resulting from public equity offerings in 1997 and any other future ownership changes may further limit utilization of losses and credits in any one year. We also are eligible for research and development tax credits that can be carried forward to offset federal taxable income. The annual limitation and the timing of attaining profitability may result in the expiration of net operating loss and tax credit carryforwards before utilization.

**Certain Factors That May Affect Future Results of Operations**

This report contains certain forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. Such statements are based on management s current expectations and are subject to a number of factors and uncertainties, which could cause actual results to differ materially from those described in the forward-looking statements. We caution investors that there can be no assurance that actual results or business conditions will not differ materially from those projected or suggested in such forward-looking statements as a result of various factors, including, but not limited to the following: the inability to establish and maintain strong business relationships with leading pharmaceutical companies and medical device and/or equipment manufacturers; the failure to comply with federal and state statutes and regulations relating to EPIX Pharmaceuticals products, including FDA requirements; that the completion of clinical studies may not prove the superiority of EPIX Pharmaceuticals products; the inability to recruit a sufficient

number of patients for clinical trials; the inability to adequately address issues raised by FDA in its review of EPIX Pharmaceuticals submissions; the decision of the FDA regarding the scheduling of an Advisory Committee meeting to review EPIX Pharmaceuticals NDA submission; the inability of EPIX Pharmaceuticals partner(s) to achieve regulatory approval in the countries in which they plan to sell EPIX Pharmaceutical products; the inability of EPIX Pharmaceuticals partner(s) to achieve meaningful sales in the countries in which EPIX Pharmaceuticals products are sold; the inability of EPIX Pharmaceuticals to consummate a transaction with (an) appropriate strategic acquisition candidate(s); the inability of EPIX Pharmaceuticals to identify and interest potential partners in its technologies and products; and the inability to protect EPIX Pharmaceuticals intellectual property and the cost of enforcing or defending EPIX Pharmaceuticals in litigation relating to intellectual property rights. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. As a result, our future development efforts involve a high degree of risk. For further information, refer to the more specific risks and uncertainties discussed below or throughout our Annual Report on Form 10-K for the year ended December 31, 2004.

**RISK FACTORS**

*An investment in our common stock involves a high degree of risk. You should carefully consider the following risk factors and other information in our periodic reports filed with the SEC. If any of the following risks actually occur, our business, financial condition or results of operations could be materially and adversely affected.*

**We have never generated revenues from commercial sales of our products and, if Vasovist™ does not receive approvals from the applicable regulatory agencies in major market countries, such as in the U.S., we, and our partner Schering AG, will have no products to market in the foreseeable future.**

We currently have no products for sale and we cannot guarantee that we will ever have marketable products. Vasovist™ and EP-2104R are currently our only product candidates that have undergone human clinical trials and we cannot be certain that any of our other R&D projects will yield a product candidate suitable for substantial human clinical testing. As a result, our initial revenues and profits from commercial sales of our products, if any, will be derived from sales of Vasovist™. In January 2005, we received an approvable letter from the FDA for Vasovist™ in which the FDA requested additional clinical studies to demonstrate efficacy prior to approval. In its approvable letter, the FDA indicated that its principal questions relate to the non-contrast MRA comparator scans used in the Phase III trials and to the statistical treatment of uninterpretable scans. In May 2005, we submitted our response to the approvable letter received from the FDA in January 2005 and it was accepted by the FDA as a complete response in June 2005. In its acceptance of the complete response, the FDA encouraged us to consider a re-read of the images from the Phase III trials to provide additional information about the usefulness of dynamic and steady-state images, and to schedule a meeting with the FDA to discuss the merits and design of such a study. We expect to continue our dialogue with the FDA in order to determine the next steps we will need to take in the regulatory pathway for Vasovist™. Although we remain confident in the safety and efficacy profile of Vasovist™, the approval, timeliness of approval or labeling of Vasovist™ are subject to significant uncertainties related to a number of factors including the process of reaching agreement with the FDA on the clinical data and on any clinical study protocol required for regulatory approval of Vasovist™, the timing and process of conducting any clinical or preclinical studies required, obtaining the desired outcomes of any required clinical trials and the FDA s review process and conclusions regarding any additional Vasovist™ regulatory submissions. We cannot assume that we will be able to reach agreement with the FDA on the design or clinical endpoints required for additional clinical studies or re-read of images from the Phase III trials. Further, we cannot assume that any such agreed upon clinical studies will be feasible for us to conduct or whether such studies will be

completed in a commercially reasonable timeframe, if at all. Any further clinical studies that are required could take several years to complete. In October 2005, the EMEA granted approval of Vasovist™ for all 25 member states of the E.U. Our partner, Schering AG, will have primary responsibility for the product launch and marketing of Vasovist™ in the E.U. If Vasovist™ fails to achieve regulatory approval in the U.S. or market acceptance in the E.U., and if we do not succeed in bringing any of our other product candidates to human clinical trials and achieve regulatory approval and market acceptance for them, our business will fail, and as a result, you may lose all or part of your investment.

To date, we have received revenues from payments made under licensing, royalty arrangements and product development and marketing agreements with strategic collaborators. In particular, our revenue for the nine months ended September 30, 2005 was $5.4 million and consisted of $3.1 million from the product development portion of our collaboration agreements with Schering AG for Vasovist™, EP-2104R and MRI research; $1.8 million from the royalty agreements with Bracco and Schering AG and $498,000 of license fee revenue related to the strategic collaboration agreements for the development, manufacturing and marketing of Vasovist™ with Schering AG and Tyco/Mallinckrodt and patent licensing with Bracco. In addition to these sources of revenue, we have financed our operations to date through public stock and debt offerings, private sales of equity securities and equipment lease financings.

Although we are currently in compliance with the terms of our collaboration and licensing agreements, the revenues derived from them are subject to fluctuation in timing and amount. We may not receive anticipated revenue under our existing collaboration or licensing

agreements, these agreements may be subject to disputes and, additionally, these agreements may be terminated upon certain circumstances. Therefore, to achieve profitable and sustainable operations, we, alone or with others, must successfully develop, obtain regulatory approval for, introduce, market and sell products. We may not receive revenue from the sale of any of our product candidates for the next several years because we, and our partners, may not:

- successfully complete our product development efforts;
- obtain required regulatory approvals in a timely manner, if at all;
- manufacture our product candidates at an acceptable cost and with acceptable quality; or
- successfully market any approved products.

As a result, we may never generate revenues from sales of our product candidates and our failure to generate positive cash flow could cause our business to fail.

**We anticipate future losses and may never become profitable.**

Our future financial results are uncertain. We have experienced significant losses since we commenced operations in 1992. Our accumulated net losses as of September 30, 2005 were approximately $174.3 million. These losses have primarily resulted from expenses associated with our research and development activities, including pre-clinical and clinical trials, and general and administrative expenses. We anticipate that our research and development expenses will remain significant in the future and we expect to incur losses over at least the next three years as we continue our research and development efforts, pre-clinical testing and clinical trials and as we implement manufacturing, marketing and sales programs. In particular, we may be required to conduct additional clinical trials in order to achieve FDA approval of Vasovist™, which trials would be expensive and which could contribute to our continuing to incur losses beyond the next three years. As a result, we cannot predict when we will become profitable, if at all, and if we do, we may not remain profitable for any substantial period of time. If we fail to achieve profitability within the timeframe expected by investors, the market price of our common stock may decline and consequently our business may not be sustainable.

**If the market does not accept our technology and products, we may not generate sufficient revenues to achieve or maintain profitability.**

The commercial success of Vasovist™ and our other product candidates, if approved for marketing by the FDA and corresponding foreign agencies, depends on their acceptance by the medical community and third party payors as clinically useful, cost-effective and safe. While contrast agents are currently used in an estimated 25% to 35% of all MRI exams, there are no MRI agents approved by the FDA for vascular imaging. Furthermore, clinical use of MRA has been limited and use of MRA for some vascular disease imaging has occurred mainly in research and academic centers. Market acceptance, and thus sales of our products, will depend on several factors, including:

safety;

cost-effectiveness relative to alternative vascular imaging methods;

availability of third party reimbursement;

ease of administration;

clinical efficacy; and

availability of competitive products.

Market acceptance will also depend on our ability and that of our strategic partners to educate the medical community and third party payors about the benefits of diagnostic imaging with MRA enhanced with Vasovist™ compared to imaging with other technologies. Vasovist™ represents a new approach to imaging the non-coronary vascular system, and market acceptance both of MRA as an appropriate imaging technique for the non-coronary vascular system, and of Vasovist™, is critical to our success. If Vasovist™ or any of our other product candidates, when and if commercialized, do not achieve market acceptance, we may not generate sufficient revenues to achieve or maintain profitability.

**We may need to raise additional funds necessary to fund our operations, and if we do not do so, we may not be able to implement our business plan.**

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 and product development revenue, royalty and license payments from our strategic partners. Although we believe that we have adequate funding for the foreseeable future, we may 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;

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 gain market acceptance;

the timing and costs of product introductions;

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

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

the costs of developing marketing and distribution capabilities.

Based on our current plans, expense rates, targeted timelines and our view regarding acceptance of Vasovist™ in the marketplace, we estimate that cash, cash equivalents and marketable securities on hand as of September 30, 2005 will be sufficient to fund our operations for at least the next several years. If we consider other opportunities or change our planned activities, we may require additional funding. The Company is exploring the diversification of its product pipeline through the potential acquisition of therapeutic drug programs. As of September 30, 2005, we had outstanding the entire $15.0 million loan facility available from Schering AG as part of our MRI research collaboration. We repaid the $15.0 million loan, plus accrued interest, in October 2005. We expect to redraw the $15.0 million loan as needed, but could be unable to draw under the terms of the loan if we fail to meet certain covenants or conditions precedent in the loan agreement.

**Extensive government regulation may delay or prevent us from marketing Vasovist™ or our other products under development.**

We are subject to extensive U.S. and foreign governmental regulatory requirements and lengthy approval processes for our product candidates. The development and commercial use of our product candidates will be regulated by numerous federal, state, local and foreign governmental authorities in the U.S., including the FDA and foreign regulatory agencies. The nature of our research and development and manufacturing processes requires the use of hazardous substances and testing on certain laboratory animals. Accordingly, we are subject to extensive federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials and wastes as well as the use of and care for laboratory animals. Although we believe we are in compliance with all such laws and maintain policies and procedures to ensure that we remain in compliance, if we fail to comply or if an accident occurs, we may be exposed to legal risk and be required to pay significant penalties or be held liable for any damages that result. Such liability could exceed our financial resources. Furthermore, current laws could change and new laws could be passed that may force us to change our policies and procedures, an event which could impose significant costs on us.

Specifically, Vasovist™ and EP-2104R are regulated by the FDA as drugs. The FDA has established substantial requirements for the research, development, manufacture and marketing of pharmaceutical drugs. The process required by the FDA before Vasovist™ and our other product candidates may be marketed in the U.S. typically involves the performance of pre-clinical laboratory and animal tests; submission of an investigational new drug application, or IND; completion of human clinical trials; submission of a NDA to the FDA; and FDA approval of the NDA.

This regulatory approval process is lengthy and expensive. Although some of our employees have experience in obtaining regulatory approvals, we have only limited experience in filing or pursuing applications necessary to gain regulatory approvals. Pre-clinical testing of our product development candidates is subject to Good Laboratory Practices, as prescribed by the FDA, and the manufacture of any products developed by us will be subject to Good Manufacturing Practices, as prescribed by the FDA. We may not obtain the necessary FDA clearances and subsequent approvals in a timely manner, if at all. Until we have received FDA clearance, we cannot be sure as to the length of the clinical trial period or the number of patients that will be required to be tested in the clinical trials in order to establish the safety and efficacy of Vasovist™ for regulatory clearance in the U.S. or any of our future product candidates. Our clinical trials may not be successful and we may not complete them in a timely manner. We could report serious side effects as the clinical trials proceed. Our results from early clinical trials may not predict results that we obtain in later clinical trials, even after promising results in earlier trials. The rate of completion of our clinical trials depends upon, among other things, the rate of patient enrollment and subsequent blinded reading of images and data analysis.

Furthermore, we, or the FDA or other regulatory authorities may alter, suspend or terminate clinical trials at any time. For example, in September 2001, after discussions with the FDA, we expanded our initial target indication for Vasovist™ from one specific body region, the aortoiliac region, to a broader indication that included the entire body s vascular system, except for the heart. This expansion required us to add two new clinical trials to our then existing Phase III clinical trial program; one to determine the efficacy of Vasovist™-enhanced MRA for the detection of vascular disease in the renal arteries, and another to determine the efficacy of Vasovist™-enhanced MRA for the detection of vascular disease in the pedal arteries. Although providing us with greater market potential for the sale of Vasovist™ upon approval, this change to our Phase III clinical trial program and the associated delay in the startup of new clinical

centers resulted in an approximate fifteen month delay in our NDA submission and an increase in costs associated with the program. If we do not successfully complete clinical trials for our product candidates, we will not be able to market these product candidates.

In addition, we may encounter unanticipated delays or significant costs in our efforts to secure necessary approvals. In October 2004, we were notified by the FDA that it had extended the action date for completion of its review of the Vasovist™ NDA by 90 days, to January 2005. In January 2005, we received an approvable letter from the FDA for Vasovist™ in which the FDA requested additional clinical studies to demonstrate efficacy prior to approval. In its approvable letter, the FDA indicated that its principal questions related to the non-contrast MRA comparator scans used in the Phase III trials and to the statistical treatment of uninterpretable scans. 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 its acceptance of the complete response, the FDA encouraged us to consider a re-read of the images from the Phase III trials to provide additional information about the usefulness of dynamic and steady-state images, and to schedule a meeting with the FDA to discuss the merits and design of such a study. In the meantime, the FDA agreed to conduct its review of the NDA, including the complete response. In July 2005, we requested a meeting with the FDA to discuss the design and implementation of a Phase IV study to investigate the relative contributions of dynamic and steady-state images in the use of Vasovist™. In August, the FDA notified us that such a meeting was premature. We are continuing our dialogue with the FDA in order to determine the next steps we will need to take in the regulatory pathway for Vasovist™. Although we remain confident in the safety and efficacy profile of Vasovist™, the approval, timeliness of approval or labeling of Vasovist™ are subject to significant uncertainties related to a number of factors, including the process of reaching agreement with the FDA on the clinical data or any new clinical trial protocol required for regulatory approval of Vasovist™, the timing and process of conducting any clinical studies required, obtaining the desired outcomes of any required clinical studies and the FDA s review process and conclusions regarding any additional Vasovist™ regulatory submissions. We cannot assume that we will be able to reach agreement with the FDA on the design or clinical endpoints required for additional clinical studies. Further, we cannot assume that any such agreed upon clinical trials will be feasible for us to conduct or whether such trials will be completed in a commercially reasonable timeframe, if at all. Any further clinical trials that are required could take several years to complete. We may not obtain regulatory approval, even after the performance of clinical trials and the passage of time and the expenditure of such resources, for Vasovist™ or any other product candidates that we develop. For example, in July 2005, we announced that we would be amending our Phase II proof-of-concept clinical trial protocols for EP-2104R to include additional patient safety monitoring based on a review by the FDA of data from a 14-day, repeat dose preclinical toxicology study. The additional patient monitoring in the Phase II trials will extend the timeline and increase EP-2104R development. Our analysis of data obtained from pre-clinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent FDA regulatory approval. In addition, the FDA may require us to modify our future clinical trial plans or to conduct additional clinical trials in ways that we cannot currently anticipate, resulting in delays in our obtaining regulatory approval. Delays in obtaining government regulatory approval could adversely affect our, or our partner s, marketing as well as the ability to generate significant revenues from commercial sales.

Future U.S. legislative or administrative actions also could prevent or delay regulatory approval of our product candidates. Even if we obtain regulatory approvals, they may include significant limitations on the indicated uses for which we may market a product. A marketed product also is subject to continual FDA and other regulatory agency review and regulation. Later discovery of previously unknown problems or failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions. Further, many academic institutions and companies conducting research and clinical trials in the MRI contrast agent field are using a variety of approaches and technologies. If researchers obtain any adverse results in pre-clinical studies or clinical trials, it could adversely affect the regulatory environment for MRI contrast agents in general. In addition, if we obtain marketing approval, the FDA may require post-marketing testing and surveillance programs to monitor the product s efficacy and side effects.

Results of these post-marketing programs may prevent or limit the further marketing of the monitored product. If we or our partners, such as Schering AG, cannot successfully market our products, we will not generate sufficient revenues to achieve or maintain profitability.

Our strategic partners and we are also subject to numerous and varying foreign regulatory requirements governing the design and conduct of clinical trials and the manufacturing and marketing of our products. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval set forth above and we may not obtain foreign regulatory approvals on a timely basis, if at all, thereby compromising our ability to market our products abroad.

**We have a limited manufacturing capability and we intend to outsource manufacturing of Vasovist™ to third parties, who may not perform as we expect.**

We do not have, nor do we currently have plans to develop, full-scale manufacturing capability for Vasovist™. While we have manufactured small amounts of Vasovist™ for research and development efforts, we rely on, and we intend to continue to rely on, Tyco/Mallinckrodt as the primary manufacturer of Vasovist™ for any future human clinical trials and commercial use. Together with Schering AG, we are considering alternative manufacturing arrangements for Vasovist™ for commercial use, including the transfer of manufacturing to Schering AG. In the event that Tyco/Mallinckrodt fails to fulfill its manufacturing responsibilities satisfactorily,

Schering AG has the right to purchase Vasovist™ from a third party or to manufacture the compound itself. However, either course of action could materially delay the manufacture and development of Vasovist™. Schering AG may not be able to find an alternative manufacturer. In addition, Schering AG may not be able to manufacture Vasovist™ itself in a timely manner. If we experience a delay in manufacturing, it could result in a delay in the approval or commercialization of Vasovist™ and have a material adverse effect on our business, financial condition and results of operations.

**If MRI manufacturers are not able to enhance their hardware and software sufficiently, we will not be able to complete development of our contrast agent for the evaluation of cardiac indications.**

Although MRI hardware and software is sufficient for the evaluation of non-coronary vascular disease, which is our initial target indication, we believe that the technology is not as advanced for cardiac applications. Our initial NDA filing for Vasovist™ is related to non-coronary vascular disease. Imaging sequences on scanners currently allow for the use of Vasovist™-enhanced MRA for diagnosing non-coronary vascular disease, our lead indication. Based on feasibility studies we completed in 2001, however, the imaging technology available for cardiac applications, including coronary angiography and cardiac perfusion imaging, was not developed to the point where there was clear visualization of the cardiac region due to the effects of motion from breathing and from the beating of the heart. In 2004, we initiated Phase II feasibility studies of Vasovist™ for cardiac indications using available software and hardware that can be adapted for coronary and cardiac perfusion data acquisition, and preliminary review of the data indicates that we have not resolved the technical issues related to this use of Vasovist™. We have collaborated with a number of leading academic institutions and with GE Healthcare, Siemens Medical Systems and Philips Medical Systems to help optimize cardiac imaging with Vasovist™. We do not know when, or if, these techniques will enable Vasovist™ to provide clinically relevant images in cardiac indications. If MRI device manufacturers are not able to enhance their scanners to perform clinically useful cardiac imaging, we will not be able to complete our development activities of Vasovist™ for that application, thereby reducing the potential market for a product in this area.

**Our competitors may have greater financial resources, superior products or product candidates, manufacturing capabilities and/or marketing expertise, and we may not be able to compete with them successfully.**

Medical technology is subject to intense competition and rapid technological change. We have many competitors, including pharmaceutical, biotechnology and chemical companies, a number of which, including our strategic partners, are actively developing and marketing products that could compete with our product candidates. Specifically, although there are no MRI contrast agents that are FDA-approved for vascular imaging, there are a number of general use MRI agents approved for other clinical applications in the U.S. and certain foreign markets that are likely to compete with Vasovist™, if Vasovist™ is approved for MRA. Collectively, these general use agents are referred to as extracellular agents and include: Magnevist® and Gadovist® by Schering AG, Dotarem® by Guerbet, S.A., Omniscan® by GE Healthcare, ProHance® and MultiHance® by Bracco and OptiMark® by Tyco/Mallinckrodt. Extracellular agents are broadly accepted in the market as general use MRI agents. None of these agents is currently approved by the FDA for MRA, but their use in applications outside of the primary indication described in the product labeling is increasing and could present significant adoption hurdles for Vasovist™ if such uses become entrenched in the marketplace. Additionally, we believe that some of these general use agents are in clinical trials for an MRA indication. However, these general use agents are not specifically designed for vascular imaging, and because they leak out of the blood vessels into the extracellular space, they do not provide the extended imaging window associated

with Vasovist™. In addition, we are aware of five agents under clinical development for use with MRA: Schering AG s Gadomer and SHU555C, Guerbet s Vistarem®, Bracco s B-22956/1 and Advanced Magnetics Code 7228. Public information on the status of clinical development and performance characteristics for these agents is limited. However, many of these competitors have substantially greater capital and other resources than we do and may represent significant competition for us. These companies may succeed in developing technologies and products that are more effective or less costly than any of those that we may develop. In addition, these companies may be more successful than we are in developing, manufacturing and marketing their products.

Moreover, there are several well-established medical imaging methods that currently compete and will continue to compete with MRI, including Digital Subtraction Angiography, or DSA, which is an improved form of X-ray angiography, computed tomography angiography, or CTA, nuclear medicine and ultrasound, and there are companies that are actively developing the capabilities of these competing methods to enhance their effectiveness in cardiovascular system imaging. DSA is currently considered the clinical gold standard for cardiovascular angiography, but all methods offer advantages and disadvantages, which are described in the following table:

| | Advantages | Disadvantages |
|---|---|---|
| MRI | Three dimensional images<br>Minimally-invasive<br>Favorable safety profile<br>High quality images | Requires high level of training<br>Inadvisable for patients with cardiac pacemakers<br>Less widely available |
| CT Angiography | Rapid exam time<br>Easy data acquisition | Radiation<br>Varying levels of toxicity<br>Calcium and bone artifacts<br>Time consuming post-processing |
| DSA<br>(X-ray angiography) | Significant clinical experience<br>Opportunity to treat in same procedure<br>Highest resolution | Invasive<br>Radiation<br>Varying levels of toxicity<br>Significant safety risks<br>Two-dimensional images<br>Expensive<br>Patient recuperation time |
| Ultrasound | Low cost<br>Fast<br>Widely available<br>Non-invasive | Operator dependent<br>Lack of anatomic detail<br>Bone precludes use in many vascular beds<br>Inability to visualize small vessels |

We cannot guarantee that we will be able to compete successfully in the future, or that developments by others will not render Vasovist™ or our future product candidates obsolete or non-competitive, or that our collaborators or customers will not choose to use competing technologies or products. Any inability to compete successfully on our part will have a materially adverse impact on our operating results.

**We currently depend on our strategic collaborators for support in product development and the regulatory approval process and, in the future, will depend on them for product marketing support as well. These efforts may suffer if we experience problems with our collaborators.**

We depend on strategic collaborators for support in product development and the regulatory approval process as well as a variety of other activities including manufacturing, marketing and distribution of our products in the U.S. and abroad, when, and if, the FDA and corresponding foreign agencies approve our product candidates for marketing. To date, we have entered into strategic alliances and collaborations with Schering AG, Tyco/Mallinckrodt, GE Healthcare, Philips Medical Systems and Siemens Medical Systems. Four of our key agreements include three collaboration agreements with Schering AG to perform joint research and to develop and commercialize Vasovist™, EP-2104R and other MRI vascular agents worldwide, and an agreement with Tyco/Mallinckrodt granting Tyco/Mallinckrodt rights to enter into an agreement with Schering AG to manufacture Vasovist™ for clinical development and commercial use. We may not receive milestone payments from these alliances should Vasovist™ or EP-2104R fail to meet certain performance targets in development and commercialization. Further, our receipt of revenues from strategic alliances is affected by the level of efforts of our collaborators. Our collaborators may not devote the resources necessary to complete development and commence marketing of Vasovist™, EP-2104R or other products in their respective

territories, or they may not successfully market Vasovist™, EP-2104R or other products. In addition, Schering AG and Tyco/Mallinckrodt currently manufacture imaging agents for other technologies that will compete against Vasovist™ and Schering AG will be responsible for setting the price of the product worldwide. However, Schering AG may not set prices in a manner that maximizes revenues for us. Our failure to receive future milestone payments, or a reduction or discontinuance of efforts by our partners would have a material adverse effect on our business, financial condition and results of operations.

Furthermore, our collaboration agreement with Schering AG may be terminated early under certain circumstances, including if there is a material breach of the agreement by either of us. In October 2005, we announced that we had entered into an amendment to our research collaboration agreement with Schering AG. This amendment narrows the definition of the field of collaboration and further indicates the parties non-binding intent to enter into a new research collaboration agreement by the end of 2005 and to discuss possible

modifications of the collaboration. We cannot assure you that we will be able to negotiate this amendment in a timely manner or on terms that are mutually agreeable. In addition, we intend to seek additional collaborations with third parties who may negotiate provisions that allow them to terminate their agreements with us prior to the expiration of the negotiated term under certain circumstances. If Schering AG or any other third party collaborator were to terminate their agreements with us, if we are unable to negotiate an acceptable agreement with Schering AG relating to a new research agreement or if Schering AG or any other third party collaborator otherwise fail to perform their obligations under our collaboration or to complete them in a timely manner, we could lose significant revenue. If we are unable to enter into future strategic alliances with capable partners on commercially reasonable terms, we may delay the development and commercialization of future product candidates and could possibly postpone them indefinitely.

In addition, we rely on certain of our collaborators, such as GE Healthcare, Siemens Medical Systems and Philips Medical Systems, to develop software that can be used to enhance or suppress veins or arteries from Vasovist™-enhanced MRA images. Although not required for clinical use of Vasovist™, the ability to separate veins from arteries using Vasovist™-enhanced MRA may be useful to clinicians in reading Vasovist™-enhanced images for the evaluation of vascular disease. Therefore, if our collaborators do not develop or implement the required software successfully, some clinicians may not be able to easily interpret the information provided from Vasovist™-enhanced images and may not be inclined to use the product. Our inability to market Vasovist™ successfully to clinicians would have a material adverse effect on our business.

**We depend on exclusively licensed technology from the Massachusetts General Hospital and if we lose this license, it is unlikely we could obtain this technology elsewhere, which would have a material adverse effect on our business.**

Under the terms of a license agreement that we have with Massachusetts General Hospital, or MGH, we are the exclusive licensee to certain technology, including patents expiring in 2006, which relate to royalties we receive and to Vasovist™. The license agreement imposes various commercialization, sublicensing, royalty and other obligations on us. If we fail to comply with these and other requirements, our license could convert from exclusive to nonexclusive, or terminate entirely. It is unlikely that we would be able to obtain this technology elsewhere. Any such event would mean that we would not receive royalties from Bracco for MultiHance® or Schering AG for Primovist, and that we or Schering AG could not sell Vasovist™, and would therefore have a material adverse effect on our business, financial condition and results of operations. Currently, we believe we are in compliance with the terms of the license agreement and we do not have any reason to believe that this license may be terminated.

**We depend on patents and other proprietary rights, and if they fail to protect our business, we may not be able to compete effectively.**

The protection of our proprietary technologies is material to our business prospects. We pursue patents for our product candidates in the U.S. and in other countries where we believe that significant market opportunities exist. We own or have an exclusive license to patents and patent applications on aspects of our core technology as well as many specific applications of this technology. Specifically, patents and patent applications related to our core technology consist of two U.S. patents that are exclusively licensed to us from MGH as well as their counterpart patents and applications in foreign countries; nine U.S. patents and their counterpart patents and applications in certain foreign countries that we own; 20 U.S. patent applications as well as their counterpart patents and applications in certain foreign countries and four U.S. provisional patent applications. One of our issued patents covers the Vasovist™ composition of matter. Another issued patent covers aspects of the process by which Vasovist™ is manufactured. Four of our patents cover certain methods of imaging with Vasovist™. We have eight patent applications relating to EP-2104R, fibrin binding peptides and methods of imaging. Even though

we hold these patents and have made these patent applications, because the patent positions of pharmaceutical and biopharmaceutical firms, including ours, generally include complex legal and factual questions, our patent positions remain uncertain. For example, because most patent applications are maintained in secrecy for a period after filing, we cannot be certain that the named applicants or inventors of the subject matter covered by our patent applications or patents, whether directly owned or licensed to us, were the first to invent or the first to file patent applications for such inventions. Third parties may oppose, challenge, infringe upon, circumvent or seek to invalidate existing or future patents owned by or licensed to us. A court or other agency with jurisdiction may find our patents invalid, not infringed or unenforceable and we cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future. Even if we have valid patents, these patents still may not provide sufficient protection against competing products or processes. If we are unable to successfully protect our proprietary methods and technologies, or if our patent applications do not result in issued patents, we may not be able to prevent other companies from practicing our technology and, as a result, our competitive position may be harmed.

**We may need to initiate lawsuits to protect or enforce our patents and other intellectual property rights, which could incur substantial costs and which could result in the forfeiture of these rights.**

We may need to bring costly and time-consuming litigation against third parties in order to enforce our issued patents, protect our

trade secrets and know how, or to determine the enforceability, scope and validity of proprietary rights of others. In addition to being costly and time-consuming, such lawsuits could divert management s attention from other business concerns. These lawsuits could also result in the invalidation or a limitation in the scope of our patents or forfeiture of the rights associated with our patents or pending patent applications. We may not prevail and a court may find damages or award other remedies in favor of an opposing party in any such lawsuits. During the course of these suits, there may be public announcements of the results of hearings, motions and other interim proceedings or developments in the litigation. Securities analysts or investors may perceive these announcements to be negative, which could cause the market price of our stock to decline. In addition, the cost of such litigation could have a material adverse effect on our business and financial condition.

**Other rights and measures that we rely upon to protect our intellectual property may not be adequate to protect our products and services and could reduce our ability to compete in the market.**

In addition to patents, we rely on a combination of trade secrets, copyright and trademark laws, non-disclosure agreements and other contractual provisions and technical measures to protect our intellectual property rights. While we require employees, collaborators, consultants and other third parties to enter into confidentiality and/or non-disclosure agreements, where appropriate, any of the following could still occur:

the agreements may be breached;

we may have inadequate remedies for any breach;

proprietary information could be disclosed to our competitors; or

others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose such technologies.

If for any of the above reasons our intellectual property is disclosed or misappropriated, it would harm our ability to protect our rights and our competitive position. Moreover, several of our management and scientific personnel were formerly associated with other pharmaceutical and biotechnology companies and academic institutions. In some cases, these individuals are conducting research in similar areas with which they were involved prior to joining us. As a result, we, as well as these individuals, could be subject to claims of violation of trade secrets and similar claims.

**Our success will depend partly on our ability to operate without infringing the intellectual property rights of others, and if we are unable to do so, we may not be able to sell our products.**

Our commercial success will depend, to a significant degree, on our ability to operate without infringing upon the patents of others in the U.S. and abroad. There may be pending or issued patents held by parties not affiliated with us relating to technologies we use in the development or use of certain of our contrast agents. For example, in November 2003, we entered into an Intellectual Property Agreement with Dr. Martin R. Prince, an early innovator in the field of MRA relating to dynamic MRA, which involves capturing MRA images during the limited time, typically 30 to 60 seconds, available for imaging with extracellular MRI contrast agents. In this agreement, Dr. Prince made certain covenants and agreements and granted us certain discharges and releases in connection with the use of any magnetic resonance imaging drug product containing Vasovist™. Dr. Prince also granted to us a non-exclusive license to make, use, sell or otherwise transfer Vasovist™. Although we are not aware of any other similar patent claims in the field of MRA, they may exist.

If any judicial or administrative proceeding upholds these or any third party patents as valid and enforceable, we could be prevented from practicing the subject matter claimed in such patents, or would be required to obtain licenses from the owners of each such patent, or to redesign our products or processes to avoid infringement. If we are unable to obtain a required license on acceptable terms, or are unable to design around these or any third party patents, we may be unable to sell our products, which would have a material adverse effect on our business.

**Product liability claims could increase our costs and adversely affect our results of operations.**

The clinical testing of our approved products and the manufacturing and marketing of any approved products may expose us to product liability claims and we may experience material product liability losses in the future. We currently have limited product liability insurance for the use of our product candidates in clinical research, but our coverage may not continue to be available on terms acceptable to us or adequate for liabilities we actually incur. We do not have product liability insurance coverage for the commercial sale of our products, but intend to obtain such coverage when and if we commercialize our product candidates. However, we may not be able to obtain adequate additional product liability insurance coverage on acceptable terms, if at all. A successful claim brought against us in excess of available insurance coverage, or any claim or product recall that results in significant adverse publicity against us, may have a material adverse effect on our business and results of operations.

**If we fail to get adequate levels of reimbursement from third party payors for our product candidates after they are approved in the U.S. and abroad, we may have difficulty commercializing our product candidates.**

We could be adversely affected by changes in reimbursement policies of governmental or private healthcare payors, particularly to the extent any such changes affect reimbursement for procedures in which our product candidates would be used. Failure by physicians, hospitals and other users of our products to obtain sufficient reimbursement from third party payors for the procedures in which our products would be used or adverse changes in governmental and private third party payors policies toward reimbursement for such procedures may have a material adverse effect on our ability to market our products and, consequently, it could have an adverse effect on our business, financial condition and results of operations. If we obtain the necessary foreign regulatory approvals, market acceptance of our product candidates in international markets would be dependent, in part, upon the availability of reimbursement within prevailing healthcare payment systems. Reimbursement and healthcare payment systems in international markets vary significantly by country, and include both government sponsored health care and private insurance. We and our strategic partners intend to seek international reimbursement approvals, although we cannot assure you that any such approvals will be obtained in a timely manner, if at all, and failure to receive international reimbursement approvals could have an adverse effect on market acceptance of our products in the international markets in which such approvals are sought.

**We depend on our key personnel, the loss of whom would hurt our ability to compete.**

Our future business and operating results depend in significant part upon the continued contributions of our senior management and key technical personnel. If any such personnel were to be hired away from us by a competitor, or if for any reason, they could not continue to work for us, we could have difficulty hiring officers with equivalent skills in general, financial and research management, and our ability to achieve our business objectives or to operate or compete in our industry may be seriously impaired. The loss of any key employee, the failure of any key employee to perform in his or her current position, or our inability to attract and retain skilled employees, as needed, could have a material adverse effect on our business, financial condition and results of operations. Our future business and operating results also depend, in significant part, upon our ability to attract and retain qualified management, operational and technical personnel. Competition for personnel is intense and we may not be successful in attracting or retaining such personnel. If we were to lose these employees to our competitors, we could spend a significant amount of time and resources to replace them, which would impair our research and development or commercialization efforts. We may also incur significant costs relating to retention or severance of employees if the FDA requires us to perform additional studies or other procedures for the approval of Vasovist™ and if we undertake an acquisition designed to diversify our business into the field of therapeutics.

**Our stock price is volatile. It is possible that you may lose all or part of your investment.**

The market prices of the capital stock of medical technology companies have historically been very volatile and the market price of the shares of our common stock fluctuates. The market price of our common stock is affected by numerous factors, including:

- actual or anticipated fluctuations in our operating results;
- announcements of technological innovation or new commercial products by us or our competitors;
- new collaborations entered into by us or our competitors;
- developments with respect to proprietary rights, including patent and litigation matters;

results of pre-clinical and clinical trials;

the timing of our achievement of regulatory milestones;

conditions and trends in the pharmaceutical and other technology industries;

adoption of new accounting standards affecting such industries;

changes in financial estimates by securities analysts; and

degree of trading liquidity in our common stock and general market conditions.

During the nine months ended September 30, 2005, the closing price of our common stock ranged from $17.39 to $6.54. The last reported closing price for our common stock on September 30, 2005 was $7.70. If our stock price declines significantly, we may be unable to raise additional capital. Significant declines in the price of our common stock could also impede our ability to attract and retain qualified employees and reduce the liquidity of our common stock.

In addition, the stock market has from time to time experienced significant price and volume fluctuations that have particularly affected the market prices for the common stock of similarly staged companies. These broad market fluctuations may adversely affect the market price of our common stock. In the past, following periods of volatility in the market price of a particular company s securities, shareholders have often brought class action securities litigation against that company. Such litigation could result in substantial costs and a diversion of management s attention and resources. On January 27, 2005, a securities class action was filed in U.S. District Court for the District of Massachusetts against the Company and certain of its officers on behalf of persons who

purchased the Company s common stock between July 10, 2003 and January 14, 2005. The complaint alleges that the defendants violated the Securities Exchange Act of 1934 by issuing a series of materially false and misleading statements to the market throughout the class period, which statements had the effect of artificially inflating the market price of the Company s securities. After this initial complaint was filed, other similar actions were filed against us and the same officers in the U.S. District Court for the District of Massachusetts. One of these later-filed complaints purports to be brought on behalf of persons who purchased the Company s common stock between March 18, 2002 and January 14, 2005. **Since these actions were filed, various plaintiffs have filed motions to consolidate the related actions, and to appoint a lead plaintiff and lead counsel. On September 27, 2005, these motions were consolidated by the U.S. District Court.** We anticipate the filing of the consolidated amended complaint by December 9, 2005. Assuming the allegations in the amended complaint mirror those in the extant complaints, we intend to file a motion to dismiss, arguing that the allegations are without merit. Damages sought by the plaintiff are unspecified.

Although the Company maintains insurance to protect against losses which could result from such securities lawsuits, we are not presently able to estimate the potential losses, if any, related to these lawsuits, and the potential losses due to these lawsuits could exceed the limits of our insurance coverage.

**We have significantly increased our leverage as a result of the sale of our 3.00% Convertible Senior Notes due 2024.**

In connection with the sale of our 3.00% Convertible Senior Notes due 2024, we have incurred new indebtedness of $100.0 million. The amount of our indebtedness could, among other things:

make it difficult for us to make payments on the notes;

make it difficult for us to obtain financing for working capital, acquisitions or other purposes on favorable terms, if at all;

make us more vulnerable to industry downturns and competitive pressures; and

limit our flexibility in planning for, or reacting to changes in, our business.

Our ability to meet our debt service obligations will depend upon our future performance, which will be subject to regulatory approvals and sales of our products, as well as other financial and business factors affecting our operations, many of which are beyond our control.

**Certain anti-takeover clauses in our charter and by-law provisions and in Delaware law and the change of control provisions of our convertible senior notes may make an acquisition of us more difficult.**

Our Restated Certificate of Incorporation authorizes the Board of Directors to issue, without stockholder approval, up to 1,000,000 shares of preferred stock with voting, conversion and other rights and preferences that could adversely affect the voting power or other rights of the holders of common stock. The issuance of preferred stock or of rights to purchase preferred stock could be used to discourage an unsolicited acquisition proposal. In addition, the possible issuance of preferred stock could discourage a proxy contest, make more difficult the acquisition of a substantial block of our common stock or limit the price that investors might be willing to pay for shares of our common stock. The

Restated Certificate provides for staggered terms for the members of the Board of Directors. A staggered Board of Directors and certain provisions of our By-laws and of Delaware law applicable to us could delay or make more difficult a merger, tender offer or proxy contest involving us. We are subject to Section 203 of the General Corporation Law of Delaware, which, subject to certain exceptions, restricts certain transactions and business combinations between a corporation and a stockholder owning 15% or more of the corporation s outstanding voting stock for a period of three years from the date the stockholder becomes an interested stockholder. These provisions may have the effect of delaying or preventing a change in control of us without action by the stockholders and, therefore, could adversely affect the price of our stock. In addition, the indenture governing the terms of our bonds contains provisions requiring repayment of the entire debt upon a change of control, which could be a substantial impediment to our effecting a merger.

The Company is actively pursuing merger opportunities in order to diversify its portfolio of product candidates from diagnostics into therapeutics. The Company may not be able to complete a transaction of this type and, if it does, there are many factors including but not limited to product failure, competitive pressures and unforeseen expenses that may make a merger unsuccessful and increase the Company s losses to a greater extent than could have been predicted at the time of any such merger.

**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 U.S. government issues, high-grade bank obligations, high-grade corporate bonds and certain money market funds. These investments are denominated in U.S. dollars.

Investments in both fixed rate and floating rate interest earning instruments carry a degree of interest rate risk. Fixed rate securities may have their fair market value adversely impacted due to a rise in interest rates, while floating rate securities may produce less income than expected if interest rates fall. Due in part to these factors, our future investment income may fall short of expectations due to changes in interest rates or we may suffer losses in principal if forced to sell securities that have seen a decline in market value due to changes in interest rates. A hypothetical 10% increase or decrease in interest rates would result in a decrease in the fair market value of our total portfolio of approximately $87,000, and an increase of approximately $87,000, respectively, at September 30, 2005.

**ITEM 4. CONTROLS AND PROCEDURES**

(a) *Evaluation of Disclosure Controls and Procedures*. Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this Quarterly Report on Form 10-Q, have concluded that, based on such evaluation, our disclosure controls and procedures were adequate and effective to ensure that material information relating to us was made known to them by others within those entities, particularly during the period in which this Quarterly Report on Form 10-Q was being prepared.

*(b) Changes in Internal Controls*. There were no significant changes in our internal control over financial reporting identified in connection with the evaluation of such internal control that occurred during our last fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**PART II. OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

On January 27, 2005, a securities class action was filed in U.S. District Court for the District of Massachusetts against us and certain of its officers on behalf of persons who purchased the Company s common stock between July 10, 2003 and January 14, 2005. The complaint alleges that the Company and certain of its officers violated the Securities Exchange Act of 1934 by issuing a series of materially false and misleading statements to the market throughout the class period, which statements had the effect of artificially inflating the market price of the Company s securities. After this initial complaint was filed, other similar actions were filed against the Company and the same officers in the U.S. District Court for the District of Massachusetts. One of these later-filed complaints purports to be brought on behalf of persons who purchased the Company s common stock between March 18, 2002 and January 14, 2005**. Since these actions were filed, various plaintiffs have filed motions to consolidate the related actions, and to appoint a lead plaintiff and lead counsel. On September 27, 2005, these motions were consolidated by the U.S. District Court.** We anticipate the filing of the consolidated amended complaint by December 9, 2005. Assuming the allegations in the amended complaint mirror those in the extant complaints, we intend to file a motion to dismiss, arguing that the allegations are without merit. Damages sought by the plaintiff are unspecified. We are not presently able to estimate the potential losses, if any, related to these lawsuits**. Total legal costs related to these lawsuits for the nine months ending September 30, 2005 were approximately $509,000.**

We are not a party to any other material pending legal proceedings.

**ITEM 6. EXHIBITS**

| Exhibit Number | Description |
|---|---|
| 3.1 | Restated Certificate of Incorporation of the Company. Filed as Exhibit 4.1 to the Company s Registration Statement on Form S-8 (File No. 333-30531) and incorporated herein by reference. |
| 3.2 | Certificate of Amendment of Restated Certificate of Incorporation of the Company. Filed as Exhibit 3.2 to the Company s Annual Report on Form 10-K for the year ended December 31, 2001 (File No. 000-21863) and incorporated herein by reference. |
| 3.3 | Certificate of Amendment of Restated Certificate of Incorporation of the Company. Filed as Exhibit 3.2 to the Company s Quarterly Report on Form 10-Q for the period ended September 30, 2004 (File No. 000-21863) and incorporated herein by reference. |
| 3.4 | Form of Amended and Restated By-Laws of the Company. Filed as Exhibit 4.2 to the Company s Registration Statement on Form S-8 (File No. 333-30531) and incorporated herein by reference. |
| 4.1 | Specimen certificate for shares of Common Stock of the Company. Filed as Exhibit 4.1 to the Company s Registration Statement on Form S-1 (File No. 333-17581) and incorporated herein by reference. |
| 4.2 | Indenture dated as of June 7, 2004 between the Company and U.S. Bank National Association as Trustee, relating to 3% Convertible Senior Notes due June 15, 2024. Filed as Exhibit 4.1 to the Company s Current Report on Form 8-K filed June 7, 2004 (File No. 000-21863) and incorporated herein by reference. |
| 10.1 | Amendment to the Collaborative Research Agreement dated as of May 26, 2003, between the Company and Schering Aktiengesellschaft, dated September 30, 2005. Filed as Exhibit 99.1 to the Company s Current Report on Form 8-K filed October 7, 2005 (File No. 000-21863) and incorporated herein by reference. |
| 10.2 | Employment Agreement between the Company and Michael J. Astrue, dated September 21, 2005. |
| 10.3 | Severance and Incentive Agreement between the Company and Andrew Uprichard, M.D., dated September 14, 2005. |
| 10.4 | Separation Agreement between the Company and Michael D. Webb, dated September 14, 2005. |
| 31.1 | Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for Michael J. Astrue. |
| 31.2 | Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for Robert B. Pelletier. |
| 32 | Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code) |

**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 1, 2005

By: /s/ ROBERT B. PELLETIER

Robert B. Pelletier
Executive Director of Finance and Principal Accounting Officer