EPIX MEDICAL INC
Form 10-Q
November 15, 2002

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, 2002

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 Medical, 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.)
71 Rogers Street **Cambridge, Massachusetts** (Address of principal executive offices)	**02142** (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

As of November 12, 2002, 17,059,155 shares of the registrant s Common Stock, $.01 par value per share, were issued and outstanding.

EPIX Medical, Inc.

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EPIX Medical, Inc.

CONDENSED BALANCE SHEETS

(Unaudited)

	September 30, 2002	December 31, 2001
Assets:		
Current assets:		
Cash and cash equivalents	$ 6,566,254	$ 13,609,883
Available-for-sale marketable securities	29,849,061	11,355,785
Royalties receivable	130,988	96,948
Prepaid expenses and other current assets	684,202	491,702
Total current assets	37,230,505	25,554,318
Property and equipment, net	1,466,934	1,243,842
Other assets	74,184	112,533
Total assets	$ 38,771,623	$ 26,910,693
Liabilities and Stockholders Equity (Deficit):		
Current liabilities:		
Accounts payable	$ 1,074,046	$ 1,431,013
Accrued expenses	6,586,854	4,981,255
Contract advances	3,364,673	5,169,953
Current portion of capital lease obligations		78,760
Loan payable to strategic partner	3,004,607	3,004,607
Deferred revenue	2,415,295	2,611,961
Total current liabilities	16,445,475	17,277,549
Accrued reacquisition costs	2,400,000	2,400,000
Deferred revenue	8,695,304	10,443,636
Stockholders equity (deficit):		
Preferred Stock, $0.01 par value, 1,000,000 shares authorized at September 30, 2002 and December 31, 2001, no shares issued and outstanding at September 30, 2002 and December 31, 2001, respectively		
Common stock, $.01 par value, 40,000,000 shares authorized; 17,059,155 and 14,238,087 shares issued and outstanding at September 30, 2002 and December 31, 2001, respectively	170,592	142,381
Additional paid-in capital	119,621,287	88,620,094
Accumulated deficit	(108,839,482)	(91,966,743)
Accumulated other comprehensive income (loss)	278,447	(6,224)
Total stockholders equity (deficit)	11,230,844	(3,210,492)
Total liabilities and stockholders equity (deficit)	$ 38,771,623	$ 26,910,693

See accompanying notes.

EPIX Medical, Inc.

CONDENSED STATEMENTS OF OPERATIONS

(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2002	2001	2002	2001
Revenues	$ 2,755,171	$ 3,615,864	$ 8,558,646	$ 7,544,959
Operating expenses:				
Research and development	6,966,702	5,358,701	21,380,819	17,033,685
General and administrative	1,453,275	1,337,407	4,502,060	4,188,740
Total operating expenses	8,419,977	6,696,108	25,882,879	21,222,425
Operating loss	(5,664,806)	(3,080,244)	(17,324,233)	(13,677,466)
Interest income	184,539	195,139	802,403	851,483
Interest expense	(95,550)	(57,378)	(287,813)	(213,767)
Loss before provision for foreign income taxes	(5,575,817)	(2,942,483)	(16,809,643)	(13,039,750)
Provision for foreign income taxes	(18,658)	(1,082,000)	(63,096)	(1,082,000)
Net loss	$ (5,594,475)	$ (4,024,483)	$ (16,872,739)	$ (14,121,750)
Weighted average shares, basic and diluted	17,038,125	14,160,239	16,816,010	13,942,833
Net loss per share, basic and diluted	$ (0.33)	$ (0.28)	$ (1.00)	$ (1.01)

See accompanying notes.

EPIX Medical, Inc.

CONDENSED STATEMENTS OF CASH FLOWS

(Unaudited)

	Nine months ended September 30,	
	2002	**2001**
Operating activities:		
Net loss	$ (16,872,739)	$ (14,121,750)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	737,701	682,998
Change in operating assets and liabilities:		
Due from strategic partner		3,000,000
Royalties receivable	(34,040)	
Prepaid expenses and other assets	(154,151)	(257,251)
Accounts payable	(356,967)	(687,203)
Accrued expenses	1,605,599	2,370,259
Contract advances	(1,805,280)	(541,030)
Accrued reacquisition costs		(2,800,000)
Deferred revenue	(1,944,998)	7,404,298
Net cash used in operating activities	(18,824,875)	(4,949,679)
Investing activities:		
Purchases of fixed assets	(960,793)	(497,248)
Purchases of available-for-sale marketable securities	(42,426,503)	(169,142,130)
Proceeds from sales or redemptions of available-for-sale marketable securities	24,217,898	179,640,681
Net cash (used in) provided by investing activities	(19,169,398)	10,001,303
Financing activities:		
Repayment of capital lease obligations	(78,760)	(209,317)
Repayment of note payable		(298,583)
Proceeds from employee stock purchase plan purchases, exercise of stock options and warrants	923,438	286,367
Proceeds from sale of common stock	30,105,966	8,667,365
Net cash provided by financing activities	30,950,644	8,445,832
Net (decrease) increase in cash and cash equivalents	(7,043,629)	13,497,456
Cash and cash equivalents at beginning of period	13,609,883	402,621
Cash and cash equivalents at end of period	$ 6,566,254	$ 13,900,007
Supplemental cash flow information:		
Cash paid for interest	$ 360,919	$ 213,910

See accompanying notes.

EPIX Medical, Inc.

Notes to Condensed Financial Statements

September 30, 2002

(Unaudited)

1. Basis of Presentation

The unaudited condensed financial statements of EPIX Medical, Inc. referred to here as EPIX or the Company, have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and the instructions to Form 10-Q and the rules of the Securities and Exchange Commission, or the Commission. Accordingly, they do not include all of the information and footnotes required to be presented for complete financial statements. The accompanying unaudited condensed financial statements reflect all adjustments (consisting of normal recurring adjustments, other than the adjustment discussed under Research and Development in Note 2) which are, in the opinion of management, necessary for a fair presentation of the results for the interim periods presented. The results of the interim period ended September 30, 2002 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, 2001.

The operating results for each of the first three quarters of 2002 and 2001 reflect the Company s adoption of Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements* or SAB 101, retroactively to January 1, 2000, changing the Company s method of recognizing revenue. In the first quarter of 2000, in accordance with the adoption of SAB 101, the Company recorded a cumulative effect of change in accounting principal in the amount of $4.4 million. Included in revenues for the three and nine month periods ended September 30, 2002 and 2001 is $213,000, $273,000 and $759,000, $818,000, respectively, of revenue that was recognized in prior years relating to the adoption of SAB 101. Prior year results have been restated for the retroactive adoption of SAB 101 to January 1, 2000.

The Company is currently in Phase III clinical trials to test the safety and efficiency of MS-325 enhanced magnetic resonance angiography for the evaluation of peripheral vascular disease. The Phase III clinical trial program consists of four separate clinical trials. Two of these trials are designed to detect peripheral vascular disease in the aortoiliac arteries while the remaining trials are designed to detect peripheral vascular disease in the arteries related to the feet and the kidneys, respectively. In 2001, the Company completed patient enrollment in its first aortoiliac trial and, in October 2002, EPIX announced that it completed its patient enrollment in the second of these trials as well. Management continues to expect the completion of patient enrollment for the remaining Phase III clinical trials associated with the arteries in the feet and the kidneys in the first quarter of 2003, and its filing of a New Drug Application, or NDA, with the FDA approximately six months after completion of such patient enrollment.

2. Significant Accounting Policies

Revenue Recognition

Product development revenue

In June 2000, the Company entered into a strategic collaboration agreement with Schering AG, or Schering, whereby, generally, each party to the agreement will share equally in MS-325 costs and profits. Revenue is recognized by the Company at the time it performs research activities for which Schering is obligated to reimburse the Company. Payments received by the Company from Schering AG in advance of EPIX performing research activities are recorded as contract advances.

Royalty revenue

The Company earns royalty revenues pursuant to its sub-license of certain of its patents to Bracco Imaging S.p.A. or Bracco. 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. This amount is recorded as revenue when royalties are earned, as, according to the agreement, a portion of the royalties earned are credited to the deferred revenue amount and the remaining portion is paid to the Company in cash. The balance of the original $4.0 million advance royalty at September 30, 2002 and December 31, 2001 was $3.2 million and $3.6 million, respectively. The patents sub-licensed to Bracco are owned by the Massachusetts General Hospital, or MGH, and have been exclusively licensed to the Company. The Company owes MGH a percentage of all royalties received from its sub-licenses.

License fee revenue

In the fourth quarter of 2000, the Company adopted SAB 101 retroactively to January 1, 2000, changing its method of recognizing certain types of revenue. As a result, for the year ended December 31, 2000, the Company recorded a cumulative effect of change in accounting principle, in accordance with the adoption of SAB 101, in the amount of $4.4 million, which related to up-front and milestone fees paid in 1996 and 1997 by Tyco International Ltd., or Tyco (formerly Mallinckrodt Inc.), the Company s previous marketing partner for MS-325.

Under the new accounting method, after the adoption of SAB 101, 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.

In September 2001, the Company received a $2.0 million license fee from Bracco, pursuant to the Company s sub-license agreement of certain patents. 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 the patent, which is currently 2006.

In September 2001, the Company also received a $3.0 million license fee from Bracco, which is contingent upon MultiHance® gaining FDA approval in the US. This license fee is included in deferred revenue in the accompanying balance sheet and will be recorded as revenue ratably over the remaining patent life beginning upon FDA approval. If MultiHance® does not gain FDA approval, the Company is obligated to repay the $3.0 million, first as an offset against royalties due, and then in cash to the extent such royalties are insufficient to meet the entire obligation.

Research and Development

Research and development costs, including those associated with technology, licenses and patents, are expensed as incurred. Research and development costs include primarily employee salaries and related costs, third party service costs and consulting expenses.

In order to conduct the clinical trials required for the Company s initial product, MS-325, the Company enters into contracts with vendors who render various clinical trial related services over an extended period of time. Typically, the Company enters into two types of vendor contracts, time based and patient based.

Under a time based contract, using critical factors contained within the contract, typically the stated duration of the contract and the timing of services provided, the Company records a significant portion of the contractual expense ratably over the length of the contract, which represents the Company s best estimate of the period over which the services 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.

Periodically, 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 to the extent of services performed, or both, in order to reflect the Company s most current estimate of the contract expenses.

In the second quarter of 2002, as a result of management s periodic review, the Company announced an approximate six month delay in the completion of patient enrollment for its MS-325 Phase III clinical trial program from the third quarter of 2002 to the first quarter of 2003. This delay reduced certain clinical trial expenses that were expected to be incurred in 2002 and will increase such expenses in 2003, resulting in a delay, as well, in the recognition of certain MS-325 related revenue the Company earns from its strategic collaboration agreements with Schering AG and Tyco. The financial statement effects of the delay in the clinical trials are that clinical trial expenses of $1.5 million and related revenue of $900,000 will be recognized in 2003 and not 2002 as originally planned.

In the third quarter of 2002, as a result of management s periodic review of its estimates of clinical trial progress compared to actual progress, the Company determined that its actual costs to date and expected costs to complete such trials were less than it had previously estimated and accrued. Consequently, the Company reduced such accruals, which had the effect of reducing research and development expense during the third quarter of 2002 by approximately $1.0 million.

Comprehensive Income

Statement of Financial Accounting Standards No. 130, *Reporting Comprehensive Income* or SFAS 130 requires unrealized gains or losses on the Company s available-for-sale marketable securities to be included in other comprehensive income (loss). Total comprehensive loss for the quarter ended September 30, 2002 amounted to $5,373,434 compared to total comprehensive loss of $4,040,750 in the same period in 2001. Total comprehensive loss for the nine months ended September 30, 2002 amounted to $16,588,068 compared to $14,123,200 in the same period in 2001.

Loss Per Share

The Company computes loss per share in accordance with the provisions of SFAS No. 128, *Earnings per Share.* Basic net loss per share is based upon the weighted-average number of common shares outstanding and excludes the effect of dilutive potential common stock issuable upon exercise of stock options. Diluted net loss per share includes the effect of dilutive potential common stock issuable upon exercise of stock options using the treasury stock method. In computing diluted loss per share, only potential common shares that are dilutive, or those that reduce earnings per share, are included. The exercise of options is not assumed if the result is antidilutive, such as when a loss is reported. Accordingly, basic and diluted net loss per share is the same for all periods presented.

3. Recent Accounting Pronouncements

In July 2001, the Financial Accounting Standards Board (FASB) issued Statement No. 143, *Accounting for Asset Retirement Obligations.* This Statement requires capitalizing any retirement costs as part of the total cost of the related long-lived asset, and subsequently allocating the total expense to future periods using a systematic and rational method. Adoption of this Statement is required in the beginning of fiscal year 2003. The Company does not anticipate a significant impact on its financial position or results of operations upon adoption of this Statement.

In April 2002, the FASB issued Statement No. 145, *Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Correction.* This Statement eliminates extraordinary accounting treatment for operating gain or loss of debt extinguishment, and

amends other existing authoritative pronouncements to make various technical corrections, clarifies meanings, or describes their applicability under changed conditions. The provisions of this Statement are effective for the Company in the beginning of fiscal year 2003, however, early application of the Statement is encouraged. Debt extinguishments reported as extraordinary items prior to scheduled or early adoption of this Statement would be reclassified in most cases following adoption. The Company does not anticipate a significant impact on financial position or results of operations upon adoption of this Statement.

In June 2002, the FASB issued Statement No. 146, *Accounting for Costs Associated with Exit or Disposal Activities.* This Statement requires recording costs associated with exit or disposal activities at their fair values when a liability has been incurred. Under previous guidance, certain exit costs were accrued upon management s commitment to an exit plan, which is generally before an actual liability has been incurred. Adoption of this Statement is required with the beginning of fiscal year 2003. The Company does not anticipate a significant impact on its financial position or results of operations upon adoption of this Statement.

4. Strategic Alliances and Collaborations

The Company s business strategy includes entering into alliances with companies primarily in the pharmaceutical industry to facilitate the development, manufacture, marketing, sale and distribution of EPIX products.

Schering AG

In June 2000, the Company entered into a strategic collaboration agreement pursuant to which EPIX granted Schering AG an exclusive license to co-develop and market MS-325 worldwide, exclusive of Japan. In December 2000, the Company amended this strategic collaboration agreement to grant to Schering AG the exclusive rights to develop and market MS-325 in Japan while simultaneously reaquiring the Japanese rights from Daiichi (see Daiichi below). Generally, each party to the agreement shares equally in MS-325 costs and profits. Under the agreement, the Company will assume responsibility for completing clinical trials and filing for FDA approval in the United States and Schering AG will manage clinical activities for the product outside the United States. In addition, the Company granted Schering AG an exclusive option to develop and market an unspecified cardiovascular MRI blood pool agent from EPIX s product pipeline. In connection with this strategic collaboration and the amendment to the Company s strategic collaboration agreement with Tyco (see Tyco below), Schering AG paid the Company an up-front fee of $10.0 million, which the Company then paid to Tyco. The Company did not reflect the receipt and the disbursement of the $10.0 million in its statement of operations on the basis that Schering AG s payment to the Company did not constitute an earnings process, nor did the Company s payment to Tyco represent an expense. Such payments were, however, reflected in the statement of cash flows. Under the agreement, Schering AG also paid the Company $20.0 million in exchange for shares of the Company s common stock through its affiliate, Schering Berlin Venture Corporation, or Schering BV. The Company may receive up to an additional $20.0 million in milestone payments under the strategic collaboration agreement, of which up to $2.5 million will be earned upon NDA filing and up to $2.5 million will be earned upon FDA approval. Under the terms of the December 2000 amendment, Schering AG paid the Company an up-front fee of $3.0 million and may be required to pay the Company an additional $7.0 million upon the Company s achievement of certain milestones.

Under the strategic collaboration agreement, the Company also has options to acquire certain participation rights with respect to two of Schering AG s products currently in clinical trials, SHU 555C and Gadomer-17. The Company is entitled to exercise these options on a region-by-region basis upon the payment of certain fees. The Company is entitled to exercise the SHU 555C option for a period of twelve months after the date the option becomes exercisable. Once the Company exercises the SHU 555C option, the Company will enter into a definitive agreement with Schering AG with respect to SHU 555C, pursuant to which Schering AG will be responsible for the conduct of all development, marketing and sales activities in connection with SHU 555C. The Company is entitled to exercise the Gadomer-17 option for a period of 120 days following Schering AG s performance of certain milestones. Once the Company exercises the Gadomer-17 option, the Company will enter into a definitive agreement with Schering AG with respect to Gadomer-17, pursuant to which the Company will share development costs incurred from the date of the option exercise, as well as profits, equally with Schering AG.

Under the terms of the strategic collaboration agreement, either party may terminate the agreement upon thirty days notice if there is a material breach of the contract or if either party fails to meet certain milestones. In addition, Schering AG may terminate the agreement at any time on a region-by-region basis or in its entirety, upon six months written notice to the Company; and the Company may terminate the agreement with respect to development of MS-325 in the European Union, or EU, upon ninety days written notice to Schering AG, if Schering AG has failed to meet its obligations in connection with the regulatory approval of MS-325 in the EU.

On May 8, 2000, the Company granted to Schering AG a worldwide, royalty-bearing license to patents covering Schering AG s development project, Eovist injection, an MRI contrast agent for imaging the liver, currently in Phase III clinical trials. Also on May 8, 2000, Schering AG granted the Company a non-exclusive, royalty-bearing license to certain of its Japanese patents. The Company agreed to withdraw its

invalidation claim of Schering AG s Japanese patent number 1,932,626 in the Japanese Patent Office pursuant to this license agreement. As more fully described in the section entitled Bracco below, Schering AG had been an opposing party in the Company s European patent case prior to the licensing agreement. On May 9, 2000, the Opposition Division of the European Patent Office maintained the Company s European patent in a slightly amended form. The patent is owned by MGH and is exclusively licensed to the Company. The remaining opposing parties initially elected to appeal the May 9, 2000 decision. However, in September 2001, the Company settled this patent dispute with

such opposing parties by entering into a non-exclusive royalty bearing license agreement with Bracco Imaging S.p.A. See Bracco for further discussion of this settlement.

Tyco

In June 2000, in connection with the exclusive license that the Company granted to Schering AG, the Company amended its strategic collaboration with Tyco to grant Tyco a non-exclusive, worldwide license to manufacture MS-325 for clinical development and commercial use in accordance with a manufacturing agreement entered into in June 2000 between Tyco and Schering AG, and to enable the Company to enter into the strategic collaboration agreement with Schering AG described above. In connection with this amendment, and only after receiving the $10.0 million up-front fee from Schering AG, the Company paid Tyco an up-front fee of $10.0 million and may pay up to an additional $5.0 million in milestone payments, of which $2.5 million is due upon NDA filing and $2.5 million is due upon FDA approval. The Company will also pay Tyco a share of its MS-325 operating profit margins in the US and a royalty on MS-325 gross profits outside the US, except in Japan where no payments are due Tyco.

In October 1999, the Company entered into a Non-Negotiable Promissory Note and Security Agreement, or the Loan, with Tyco, the Company s strategic partner, under which the Company was eligible to borrow its share of MS-325 development costs, on a quarterly basis, up to a total of $9.5 million. In June 2000, pursuant to the amended strategic collaboration agreement with Tyco and the new strategic collaboration agreement with Schering AG, Schering AG assumed the development cost sharing obligation for MS-325 from Tyco as of January 1, 2000. As a result, the Company amended the terms of the Loan to allow funding for its portion of development costs through December 31, 1999. The balance due under the Loan as of September 30, 2002 and December 31, 2001 was $3,004,607 and represents the Company s share of the third and fourth quarter MS-325 development costs in 1999. No additional funding is available to the Company under the Loan. The Loan bears interest, adjustable on a quarterly basis, at the Prime Rate published in the Wall Street Journal and was repayable in full on October 1, 2002. The loan was secured by a first priority security interest in all of the Company s intellectual property. On October 1, 2002 the Company paid Tyco $3,040,580, which consisted of its outstanding loan balance of $3,004,607 plus accrued interest of $35,973, to fully satisfy its obligation in accordance with the terms of the Loan.

Daiichi

In March 1996, the Company entered into a development and license agreement with Daiichi Radioisotope Laboratories, or Daiichi, pursuant to which EPIX granted Daiichi an exclusive license to develop and commercialize MS-325 in Japan. Under this agreement, Daiichi assumed primary responsibility for clinical development, regulatory approval, marketing and distribution of MS-325 in Japan. The Company retained the right and obligation to manufacture MS-325 for development activities and commercial sale under the agreement. In December 2000, the Company reacquired the rights to develop and commercialize MS-325 in Japan from Daiichi. Under the terms of this reacquisition agreement with Daiichi, the Company agreed to pay Daiichi a total amount of $5.2 million. In January 2001, the Company paid Daiichi $2.8 million in up-front fees and the Company will pay an additional $2.4 million upon the earlier of regulatory approval of MS-325 in either the U.S. or Japan or December 31, 2003. Daiichi will also receive a royalty from the Company based on net sales of MS-325 in Japan. Simultaneously with the Company s reacquisition from Daiichi of the MS-325 development and marketing rights in Japan, the Company assigned these rights to Schering AG as described above.

Bracco

In September 2001, pursuant to a Settlement and Release Agreement and Worldwide License Agreement, referred to as the License Agreement, the Company granted Bracco a worldwide, non-exclusive royalty bearing sub-license to certain EPIX patents. The Company received $10.0 million ($9.0 million net of Italian income taxes) in up-front payments pursuant to the License Agreement, which consisted of a $2.0 million license fee, $1.0 million of royalties on past sales of MultiHance®, $4.0 million of prepaid royalties and a $3.0 million contingent license fee based upon FDA approval in the US. In addition, Bracco is obligated to pay EPIX a quarterly royalty on its sales of MultiHance® beginning in January 2001 and ending on the patent expiration date in each country that MultiHance® is sold, which is currently 2006 in the US and Europe.

If upon termination of the License Agreement, any balance remains of the prepaid royalties, originally $4.0 million, this balance, $3.2 million at September 30, 2002, must be repaid to Bracco. In addition, if MultiHance® does not gain FDA approval, the Company is obligated to repay the $3.0 million contingent license fee, first as an offset against royalties due, and then in cash to the extent that such royalties are insufficient to meet the entire obligation. The License Agreement may be terminated by either party upon thirty days notice if there is a material breach of the License Agreement or the other party becomes bankrupt.

5. Subsequent Event

On October 1, 2002 the Company paid Tyco $3,040,580, which consisted of its outstanding loan balance of $3,004,607 plus accrued interest of $35,973, to fully satisfy its obligation in accordance with the terms of the loan.

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

Overview

Since commencing operations in 1992, we have been principally engaged in the research and development of our product candidates, as well as seeking various regulatory clearances and patent protection. We have had no revenues from product sales and have incurred cumulative losses since inception through September 30, 2002 aggregating approximately $109 million.

We expect continued operating losses for the next several years as we incur expenses to support research and development efforts to obtain regulatory approvals.

We are currently in Phase III clinical trials to test the safety and efficacy of MS-325 enhanced magnetic resonance angiography for the evaluation of peripheral vascular disease. The Phase III clinical trial program consists of four separate clinical trials. Two of these trials are designed to detect peripheral vascular disease in the aortoiliac arteries while the remaining trials are designed to detect peripheral vascular disease in the arteries related to the feet and the kidneys, respectively. In 2001, we completed patient enrollment in our first aortoiliac trial and, in October 2002, we announced that we had completed patient enrollment in the second of these trials as well. We continue to expect the completion of patient enrollment for the remaining Phase III clinical trials in the first quarter of 2003, and the filing of a New Drug Application, or NDA, with the FDA approximately six months after completion of such patient enrollment.

In March 2000, we completed enrollment in a Phase II clinical trial to test the safety and feasibility of MS-325 for detecting breast cancer, and in March 2001, we completed enrollment in a Phase II feasibility trial which we conducted in collaboration with Pfizer, Inc. to explore the efficacy of MS-325-enhanced MRA in the diagnosis of female sexual arousal disfunction. In April 2002, to complete our safety database for our NDA submission, we closed our MS-325-enhanced MRA Phase II feasibility trial for coronary artery disease.

We anticipate fluctuations in our quarterly 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 of expenditures in connection with research and development activities; the timing of product introductions and associated launch, marketing and sales activities; and the timing and extent of product acceptance for different indications and geographical areas of the world.

Critical Accounting Policies

In December 2001, the Commission requested that all registrants discuss their most critical accounting policies in Managements Discussion and Analysis of Financial Condition and Results of Operations. The Commission indicated that a critical accounting policy is one which is both important to the portrayal of the company s financial condition and results and requires management s most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. The Company s critical accounting policies were included in the annual report on Form 10-K for the year ended December 31, 2001. The following critical accounting policy, research and development, is updated below as a result of changes in estimates made late in the second quarter and during the third quarter of 2002.

Research and Development

As detailed in Note 2, Significant Accounting Policies, the Company periodically reviews both the timetable of services to be rendered and the timing of services actually received related to clinical trials for MS-325. 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 the Company s most current estimate of the contract.

In second quarter of 2002, as a result of management s periodic review, the Company announced an approximate six month delay in the completion of patient enrollment for its MS-325 Phase III clinical trial program from the third quarter of 2002 to the first quarter of 2003. This delay reduced certain clinical trial expenses in 2002 and increased such expenses in 2003, resulting in a delay, as well, in the recognition of certain MS-325 related revenue the Company earns from its strategic collaboration agreements with Schering AG and Tyco. The financial statement effects of the delay in the clinical trials are that clinical trial expenses of $1.5 million and related revenue of $900,000 will be recognized in 2003 and not 2002 as originally planned.

In the third quarter of 2002, as a result of management s periodic review of its estimates of clinical trial progress compared to actual progress, the Company determined that its actual costs to date and expected costs to complete such trials were less than it had previously estimated and accrued. Consequently, the Company reduced such accruals, which had the effect of reducing research and development expenses during the third quarter of 2002 by approximately $1.0 million. Excluding the impact of this change in estimate, net loss and the related earnings per share amounts for the three and nine months ended September 30, 2002 was $6.6 million and $0.39 per share and $17.9 million and $1.06 per share, respectively.

Further adjustments to accrued expenses could result as the Company receives information on changes to the forecasted timeline or the extent of services performed.

Results of Operations

Comparison of Three Months Ended September 30, 2002 and 2001

Revenues. Third quarter 2002 revenues of $2.8 million consisted of $2.0 million from the product development portion of the strategic collaboration agreement for the development of MS-325 with Schering, $416,000 from a patent sub-licensing and royalty agreement entered into with Bracco in September 2001 and $363,000 of license fee revenue related to the strategic collaboration agreements for the development and marketing of MS-325 with Schering and Tyco. Third quarter 2001 revenues of $3.6 million included $1.5 million of one-time revenue from the patent sub-licensing and royalty agreement entered into with Bracco in September 2001, which represented royalties earned on MultiHance® product sales prior to July 2001. The remaining $2.1 million of third quarter 2001 revenues consisted of $1.4 million from the product development portion of the strategic collaboration agreement for the development of MS-325 with Schering, $300,000 of royalty revenue from the patent sub-licensing and royalty agreement with Bracco, and $423,000 of license fee revenue related to the strategic collaboration agreements for the development and marketing of MS-325 with Schering and Tyco.

Research and development expenses. Research and development expenses for the three months ended September 30, 2002 were $7.0 million as compared to $5.4 million for the three months ended September 30, 2001. The increase

was primarily due to increased research and development personnel and costs related to the advancement of MS-325 through Phase III clinical trials. Third quarter 2002 research and development expenses includes a reversal of approximately $1.0 million of certain previously expensed MS-325 costs, which had been based on management s estimates of costs incurred from services provided. As part of the final closing of certain studies, the Company concluded that its accruals for services provided under the contracts ultimately exceeded the amounts due under such contracts and, consequently, reduced its expense for such contracts.

General and administrative expenses. General and administrative expenses which consist primarily of salaries, benefits, outside professional services and related overhead costs associated with our executive, finance and accounting, human resources, legal, marketing and corporate communications groups were $1.5 million and $1.3 million for the three months ended September 30, 2002 and 2001, respectively. The increase was primarily due to increased MS-325 market research and personnel costs. General and administrative expenses also include royalties payable to MGH, on sales by Bracco of MultiHance®. Royalty expenses totaled $16,000 and $65,000 for the three months ended September 30, 2002 and 2001 respectively.

Interest income and expense. Interest income decreased approximately $11,000 in the third quarter of 2002 as compared to the third quarter of 2001 mainly due to lower interest rates offset by higher average levels of invested cash during the third quarter of 2002 as compared to the third quarter of 2001. The increase in interest expense of approximately $38,000 in the third quarter of 2002 was associated with our increased interest expense associated with the Bracco agreement. Realized gains and losses on available-for-sale marketable securities are recorded as part of interest income. Realized gains for the three months ended September 30, 2002 were $81,000 as compared to none for the three months ended September 30, 2001.

Provision for foreign income taxes. Income tax expense for the three months ended September 30, 2002 was $19,000 as compared to $1.1 million for the three months ended September 30, 2001. The decrease in foreign income tax expense is directly attributable to the receipt of $10.0 million from Bracco in September 2001 upon the execution of the License Agreement.

Comparison of Nine Months Ended September 30, 2002 and 2001

Revenues. Revenues for the nine months ended September 30, 2002 and September 30, 2001 were approximately $8.6 million and $7.5 million, respectively. The 2002 revenues consisted of $6.0 million from the product development portion of the strategic collaboration agreement for the development of MS-325 with Schering, $1.4 million from the patent sub-licensing and royalty agreement entered into with Bracco in September 2001 and $1.2 million of license fee revenue related to the strategic collaboration agreements for the development and marketing of MS-325 with Schering and Tyco. The 2001 revenues of $7.5 million consisted of $4.5 million from the product development portion of the strategic collaboration agreement for the development of MS-325 with Schering, $1.8 million from the patent sub-licensing and royalty agreement entered into with Bracco and $1.3 million of licensing fee revenue related to the strategic collaboration agreements for the development and marketing of MS-325 with Schering and Tyco/Mallinckrodt. Included in the $1.8 million of revenue from Bracco were $1.0 million of royalties earned on

Bracco MultiHance® product sales prior to January 1, 2001.

Research and development expenses. Research and development expenses for the nine months ended September 30, 2002 were $21.4 million as compared to $17.0 million for the nine months ended September 30, 2001. The increase was primarily due to increased research and development personnel and clinical trial costs related to the advancement of MS-325 through Phase III clinical trials. Third quarter 2002 research and development expenses includes a reversal of approximately $1.0 million of certain previously expensed MS-325 costs, which had been based on management s estimates of costs incurred from services provided. As part of the final closing of certain studies, the Company concluded that its accruals for services provided under the contracts ultimately exceeded the amounts due under such contracts and, consequently, reduced its expense for such contracts.

General and administrative expenses. General and administrative expenses which consist primarily of salaries, benefits, outside professional services and related overhead costs associated with our executive, finance and accounting, human resources, legal, marketing and corporate communications groups were $4.5 million and $4.2 million for the nine months ended September 30, 2002 and 2001, respectively. The increase was primarily due to increased MS-325 market research and personnel costs. General and administrative expenses also include royalties payable to MGH, on sales by Bracco of MultiHance®. Royalty expenses totaled $51,000 and $65,000 for the nine months ended September 30, 2002 and 2001 respectively.

Interest income and expense. Interest income decreased approximately $49,000 in the nine months ended September 30, 2002 as compared to the same period in 2001 due to lower interest rates offset by higher average levels of invested

cash during the nine months ended September 2002 as compared to the same time period of 2001. The increase in interest expense of approximately $74,000 for 2002 was associated with our increased interest expense associated with the Bracco agreement. Realized gains and losses on available-for-sale marketable securities are recorded as part of interest income. Realized gains for the nine months ended September 30, 2002 were $81,000 as compared to none for the nine months ended September 30, 2001.

Provision for foreign income taxes. Income tax expense for the nine months ended September 30, 2002 was $63,000 as compared to $1.1 million for the nine months ended September 30, 2001. The decrease in foreign income tax expense is directly attributable to the payment of $1.0 million of Italian income taxes in connection with our receipt of $10.0 million (gross) from Bracco in September 2001 upon the execution of the License Agreement.

Liquidity and Capital Resources

Our principal sources of liquidity consist of cash, cash equivalents and available-for-sale marketable securities, which totaled $36.4 million at September 30, 2002, as compared to $25.0 million at December 31, 2001.

On January 18, 2002, we raised $30.1 million through the issuance and sale of 2.575 million shares of our common stock pursuant to our previously filed shelf registration statement, bringing our cash, cash equivalents and marketable securities to $53.8 million as of that date.

In the nine months ended September 30, 2002, we used approximately $18.8 million of cash to fund operations compared to $4.9 million for the same period in 2001. The nine month period ended September 30, 2001 includes a $9.0 million up-front payment from Bracco received in September 2001. Excluding this $9.0 million up-front payment, the Company used cash of approximately $13.9 million to fund operations. The increase in net cash used for operations of $4.9 million in 2002 is due to increased operating expenses discussed previously.

In the nine months ended September 30, 2002, we used approximately $19.2 million in investing activities compared to cash provided by investing activities of $10.0 million in the same period in 2001. Net cash used in investing activities reflects the investment of the proceeds of our January 18, 2002 common stock offering and purchases of lab equipment, computer equipment and software. The same period in 2001 reflects net proceeds from maturities of investments offset by less capital expenditures. We expect that our capital expenditures will continue to increase as we expand and enhance our principal lab space.

Cash provided by financing activities was $31.0 million for the nine months ended September 30, 2002 and $8.4 million for the nine months ended September 30, 2001. As noted previously, the principal source of financing for the nine months ended September 30, 2002 was the issuance and sale of 2.575 million shares of our common stock pursuant to our previously filed shelf offering in January 2002, which resulted in net proceeds to us of $30.1 million.

We currently receive quarterly cash payments from Schering AG for their share of development costs of MS-325, quarterly royalty payments from Bracco on their sales of MultiHance® and interest income earned on our cash, cash equivalents and available-for-sale marketable securities. In the future, we may also receive proceeds from debt financing, strategic alliances or from the sale of additional shares of our

common stock pursuant to a shelf registration statement on Form S-3, which we filed with the Commission, on March 20, 2002, in order to register 5 million shares of our common stock. Such filing has not yet been declared effective by the Commission. Certain additional future cash flows depend on the successful filing of an NDA, FDA approval and product launch of MS-325, and include up to $27.0 million in milestone payments from Schering AG and our share of the profits earned on sales of MS-325 worldwide. We may also receive royalties on sales of Schering AG s Eovist product if it is approved for sale by the FDA pursuant to a license agreement with Schering AG.

Known outflows of cash, in addition to our ongoing research and development and general and administrative expenses, include the $3.0 million loan payable to Tyco at September 30, 2002, which we repaid in October 2002, semi-annual royalties we owe MGH on sales by Bracco of MultiHance®, and $2.4 million payable to Daiichi in December 2003 under the terms of a reacquisition agreement. Other potential future outflows depend on the successful filing of an NDA, FDA approval and product launch of MS-325, and include $5.0 million of milestone

payments due Tyco, a share of operating profits due Tyco on sales of MS-325 worldwide except Japan, a royalty to Daiichi on sales of MS-325 in Japan and a royalty due MGH on our share of the profits of MS-325 worldwide. We will also be required to repay Bracco any unearned prepaid royalties, $3.2 million at September 30, 2002, upon termination of the License Agreement, plus an additional $3.0 million if MultiHance® does not receive FDA approval.

We estimate that cash, cash equivalents and marketable securities on hand as of September 30, 2002 will be sufficient to fund our operations through November 2003. We believe that we will need to raise additional funds for research, development and other expenses through equity or debt financing, strategic alliances or otherwise, in order to achieve commercial introduction of any of our product candidates. Our future liquidity and capital requirements will depend on numerous factors, including the following: the rate of patient enrollment in, and the progress and scope of our clinical trials; the timing and costs of filing future regulatory submissions; the timing and costs required to receive both United States 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 research and development programs; the costs of training physicians to become proficient with the use of our 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 MS-325 and Thrombus, an agent to detect thrombosis, we do not expect positive cash flow from operating activities for any future quarterly or annual period prior to commercialization of MS-325, which is currently forecast to commence in the second half of 2004. Our ability to reach positive cash flow subsequent to the commercialization of MS-325 will depend on its market acceptance and successful launch by our partner Schering AG, as well as the ability of our partner Tyco to manufacture sufficient quantities of MS-325 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. In the second quarter of 2002, the Company signed a lease agreement which increased our future lease commitments by $3,431,439 that will enable us to utilize our current principal scientific facilities through December 31, 2007. We also have a lease for nearby office space, which expires in December 2002. We are currently negotiating an extension for our office space. There have been no significant changes in contractual obligations or commercial commitments since June 30, 2002.

We have incurred tax losses to date and therefore have not paid significant federal or state income taxes since inception. As of December 31, 2001, we had federal loss carryforwards of approximately $71.0 million available to offset future taxable income. These amounts expire at various times through 2020. As a result of ownership changes resulting from sales of equity securities, our ability to use the 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 through May 31, 1996 will be approximately $900,000. Pursuant to Sections 382 and 383 of the Code, the change in ownership resulting from public equity offerings to date 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.

Forward-Looking Statements

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act that involve risks and uncertainties. Discussions containing forward looking statements may be found in the material set forth under Management s Discussion and Analysis of Financial Condition and Results of Operations as well as in this report generally. We generally used words such as believe, may, could, will, intend, expect, anticipate, plan, and similar expressions to identify forward-looking statem should not place undue reliance on these forward-looking statements for many reasons, including the risks described in our Annual Report on Form10-K for the year ended December 31, 2001, as previously filed with the Commission.

Although we believe the expectations reflected in the forward looking statements are reasonable, they relate only to events as of the date on which the statements are made, and we cannot assure you that our future results, levels of activity, performance or achievements will meet these expectations. Moreover, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. We do not intend to update any of the forward-looking statements after the date of this report to conform these statements to actual results or to changes in our expectations, except as required by law.

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 United States 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 $32,000, and an increase of approximately $32,000, respectively, at September 30, 2002.

Item 4. Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we have evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-14(c) and 15d-14(c)) within 90 days of the filing date of this quarterly report, and, based on such evaluation, our principal executive officer and principal financial officer have concluded that these disclosure controls and procedures were adequate and effective to ensure that material information relating to the Company was made known to them by others within the Company, 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 controls or in other factors that could significantly affect these controls subsequent to the date of their evaluation, nor were there any significant deficiencies or material weaknesses in our internal controls. Accordingly, no corrective actions were required or undertaken.

Item 6. Exhibits and Reports on Form 8-K

(A) EXHIBITS

Not applicable

(B) REPORTS ON FORM 8-K

No reports on Form 8-K were filed during the quarter ended September 30, 2002.

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 Medical, Inc.

Date: November 14, 2002 By: /s/ Pamela E. Carey

Pamela E. Carey
Vice President of Finance and Administration, Chief Financial Officer
(Principal Financial Officer and Accounting Officer)

Certification

Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Michael D. Webb, Chief Executive Officer of EPIX Medical, Inc., certify that:

1. I have reviewed this quarterly report on Form 10-Q of EPIX Medical, Inc.;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4. The registrant s other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:

a. designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

b. evaluated the effectiveness of the registrant s disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the Evaluation Date); and

c. presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant s other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant s auditors and the audit committee of registrant s board of directors (or persons performing the equivalent functions):

a. all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant s ability to record, process, summarize and report financial data and have identified for the registrant s auditors any material weaknesses in internal controls;

b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant s internal controls; and

6. The registrant s other certifying officers and I have indicated in this quarterly report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 14, 2002

/s/ Michael D. Webb
Michael D. Webb
Chief Executive Officer of EPIX Medical, Inc.

Certification

Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Pamela E. Carey, Vice President of Finance and Administration and Chief Financial Officer of EPIX Medical, Inc., certify that:

1. I have reviewed this quarterly report on Form 10-Q of EPIX Medical, Inc.;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4. The registrant s other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:

a. designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

b. evaluated the effectiveness of the registrant s disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the Evaluation Date); and

c. presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant s other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant s auditors and the audit committee of registrant s board of directors (or persons performing the equivalent functions):

a. all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant s ability to record, process, summarize and report financial data and have identified for the registrant s auditors any material weaknesses in internal controls;

b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant s internal controls; and

6. The registrant s other certifying officers and I have indicated in this quarterly report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 14, 2002

/s/ Pamela E. Carey
Pamela E. Carey
Vice President of Finance and Administration and Chief Financial Officer of EPIX Medical, Inc.

Exhibit Index