EPIX MEDICAL INC
Form 10-Q
August 14, 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 June 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	**02142**
(Address of principal executive offices)	(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 August 9, 2002, 17,036,339 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)

	June 30, 2002	December 31, 2001
Assets:		
Current assets:		
Cash and cash equivalents	$ 5,834,363	$ 13,609,883
Available-for-sale marketable securities	37,894,022	11,355,785
Royalties receivable	153,821	96,948
Prepaid expenses and other current assets	930,205	491,702
Total current assets	44,812,411	25,554,318
Property and equipment, net	1,468,736	1,243,842
Other assets	82,512	112,533
Total assets	$ 46,363,659	$ 26,910,693
Liabilities and Stockholders Equity (Deficit):		
Current liabilities:		
Accounts payable	$ 1,965,873	$ 1,431,013
Accrued expenses	6,899,618	4,981,255
Contract advances	3,773,203	5,169,953
Current portion of capital lease obligations	21,841	78,760
Loan payable to strategic partner	3,004,607	3,004,607
Deferred revenue	2,735,792	2,611,961
Total current liabilities	18,400,934	17,277,549
Accrued reacquisition costs, less current portion	2,400,000	2,400,000
Deferred revenue	8,967,896	10,443,636
Stockholders equity (deficit):		
Preferred Stock, $0.01 par value, 1,000,000 shares authorized at June 30, 2002 and December 31, 2001, no shares issued and outstanding at June 30, 2002 and December 31, 2001, respectively		
Common stock, $.01 par value, 40,000,000 shares authorized; 17,036,658 and 14,238,087 shares issued and outstanding at June 30, 2002 and December 31, 2001, respectively	170,367	142,381
Additional paid-in capital	119,612,063	88,620,094
Accumulated deficit	(103,245,007)	(91,966,743)
Accumulated other comprehensive income (loss)	57,406	(6,224)
Total stockholders equity (deficit)	16,594,829	(3,210,492)
Total liabilities and stockholders equity (deficit)	$ 46,363,659	$ 26,910,693

See accompanying notes.

EPIX Medical, Inc.

CONDENSED STATEMENTS OF OPERATIONS

(Unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2002	**2001**	**2002**	**2001**
Revenues	$ 3,737,260	$ 2,197,422	$ 5,803,475	$ 3,929,095
Operating expenses:				
Research and development	9,002,603	6,352,953	14,414,117	11,674,984
General and administrative	1,670,328	1,264,498	3,048,785	2,851,333
Total operating expenses	10,672,931	7,617,451	17,462,902	14,526,317
Operating loss	(6,935,671)	(5,420,029)	(11,659,427)	(10,597,222)
Interest income	369,355	294,667	617,864	656,344
Interest expense	(96,352)	(1,519)	(192,263)	(156,389)
Loss before provision for foreign income taxes	(6,662,668)	(5,126,881)	(11,233,826)	(10,097,267)
Provision for foreign income taxes	25,949		44,438	
Net loss	$ (6,688,617)	$ (5,126,881)	$ (11,278,264)	$ (10,097,267)
Weighted average shares, basic and diluted	16,985,677	14,022,893	16,703,111	13,832,893
Net loss per share, basic and diluted	$ (0.39)	$ (0.37)	$ (0.68)	$ (0.73)

See accompanying notes.

EPIX Medical, Inc.

CONDENSED STATEMENTS OF CASH FLOWS

(Unaudited)

	Six months ended June 30,	
	2002	**2001**
Operating activities:		
Net loss	$ (11,278,264)	$ (10,097,267)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	476,036	460,797
Change in operating assets and liabilities:		
Due from strategic partner		3,000,000
Royalties receivable	(56,873)	
Prepaid expenses and other assets	(408,482)	(216,509)
Accounts payable	534,860	(714,727)
Accrued expenses	1,918,363	1,987,385
Contract advances	(1,396,750)	(224,936)
Accrued reacquisition costs		(2,800,000)
Deferred revenue	(1,351,909)	(845,454)
Net cash used in operating activities	(11,563,019)	(9,450,711)
Investing activities:		
Purchases of fixed assets	(700,930)	(344,862)
Purchases of available-for-sale marketable securities	(40,477,224)	(140,174,025)
Proceeds from sales or redemptions of available-for-sale marketable securities	14,002,617	142,380,669
Net cash (used in) provided by investing activities	(27,175,537)	1,861,782
Financing activities:		
Repayment of capital lease obligations	(56,919)	(142,760)
Repayment of note payable		(183,395)
Proceeds from employee stock purchase plan purchases, exercise of stock options and warrants	913,989	196,034
Proceeds from sale of common stock	30,105,966	8,667,365
Net cash provided by financing activities	30,963,036	8,537,244
Net (decrease) increase in cash and cash equivalents	(7,775,520)	948,315
Cash and cash equivalents at beginning of period	13,609,883	402,621
Cash and cash equivalents at end of period	$ 5,834,363	$ 1,350,936
Supplemental cash flow information:		
Cash paid for interest	$ 231,206	$ 212,077

See accompanying notes.

EPIX Medical, Inc.

Notes to Condensed Financial Statements

June 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 (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 period ended June 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 interim 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 two quarters of 2002 and 2001 reflect the Company's adoption of Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements* (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 each of the three and six month periods ended June 30, 2002 and 2001 is $273,000 and $545,000, 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 conducting a Phase III clinical trial program for its lead product candidate, MS-325. In September 2001, after discussions with the Food and Drug Administration, or FDA, the Company expanded its initial target indication for MS-325 beyond aortoiliac occlusive disease to a broad peripheral vascular disease indication which the Company expects will include the entire vasculature except the heart. As a result of this expansion, the Company added two new Phase III trials to its Phase III clinical trial program, one in the renal arteries and one in the feet. While the patient recruitment rate at clinical trial centers that are enrolling patients is on track with management's projections, the start-up of new centers has been slower than anticipated due primarily to individual hospital and country specific process delays. Management currently anticipates patient enrollment in the Phase III clinical trial program to be completed in the first quarter of 2003, delaying the MS-325 New Drug Application or NDA filing for the U.S. by three to six months from the Company's prior estimate of March 2003. Based on the Company's current estimates of patient enrollment, the Company expects this three to six month delay to reduce certain clinical trial expenses in 2002 and increase such expenses in 2003, as well as to delay the recognition of certain MS-325 related revenue the Company records from its strategic collaboration agreements from 2002 to future years. The Company is currently projecting a delay in recording 2002 revenue of approximately $900,000 and a delay in recording expenses of approximately $1.5 million, resulting in a delay in net loss of $600,000.

2. Significant Accounting Policies

Revenue Recognition

Product development revenue

In June 2000, the Company entered into a strategic collaboration agreement with Schering AG, 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 in advance of EPIX performing research activities are recorded as contract advances.

Royalty revenue

The Company earns royalty revenues pursuant to its sublicense of certain of its patents to Bracco Imaging S.p.A. In connection with the execution of the sublicensing arrangement in 2001, Bracco made a $4.0 million refundable advance royalty payment to the Company, which was accounted for as deferred revenue. The balance of the original $4.0 million advance royalty at June 30, 2002 and December 31, 2001 was $3.3 million and $3.6 million, respectively. The patents sublicensed 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 sublicenses.

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 $3.0 million license fee from Bracco, which is contingent upon Multihance® gaining market 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 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 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, the Company records 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 treated 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.

Comprehensive Income

Statement of Financial Accounting Standards (SFAS) No. 130, *Reporting Comprehensive Income* (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 income for the quarter ended June 30, 2002 amounted to $6,400,160 compared to total comprehensive income of $5,130,771 in the same period in 2001. Total comprehensive income for the six months ended June 30, 2002 amounted to $11,214,634 compared to $10,082,450 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 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 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.

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 with 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. 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, Schering AG paid the Company an up-front fee of $10.0 million, which the Company then paid to Tyco. 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 product 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 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 Massachusetts General Hospital and is exclusively licensed to us. 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 Imgaing 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, 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 will be paid upon NDA filing and $2.5 million will be paid upon product approval. The Company will also pay Tyco a share of our 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 collaboration agreement with Tyco and the new strategic collaboration 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 June 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 is repayable in full on October 1, 2002. The loan is secured by a first priority security interest in all of the Company's intellectual property.

Daiichi

In March 1996, the Company entered into a development and license agreement with Daiichi pursuant to which EPIX granted Daiichi an exclusive license to develop and commercialize MS-325 in Japan. Under this arrangement, 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 Imaging S.p.A. a worldwide, non-exclusive royalty bearing sub-license to certain of 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 marketing 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 future royalties, originally $4.0 million, this balance, $3.3 million at June 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 Agreement or the other party becomes bankrupt, insolvent, dissolves or is wound up.

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 June 30, 2002 aggregating approximately $103.2 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.

Our initial product candidate, MS-325, is currently our only product candidate undergoing human clinical trials. We filed an investigational new drug (IND) application for MS-325 in July 1996. We initiated a Phase I clinical trial in 1996 and a Phase I dose escalation study in 1997, both of which have been completed. We completed a Phase II clinical trial in June 1998 to test the safety and preliminary efficacy of MS-325-enhanced magnetic resonance angiography (MRA) for the evaluation of peripheral vascular disease (PVD), and also completed a Phase II trial in June 2001 that was designed to compare the diagnostic accuracy of five different doses of MS-325-enhanced MRA with that of X-ray angiography in the aortoiliac vascular bed. In 2001, we completed enrollment in the first study of a two-arm Phase III clinical trial, which was initiated in June 1999, and was designed to determine the efficacy of MS-325-enhanced MRA for the detection of aortoiliac occlusive disease. In September 2001, after discussions with the FDA, we expanded our initial target indication for MS-325 beyond aortoiliac occlusive disease to a broad peripheral vascular disease indication, which the Company expects will include the entire vasculature except the heart. As a result of this expansion, we added two new Phase III trials to our Phase III clinical trial program, one in the renal arteries and one in the feet. While the patient recruitment rate at clinical trial centers that are enrolling patients is on track with management's projections, the start-up of new centers has been slower than anticipated due primarily to individual hospital and country specific process delays. Management currently anticipates patient enrollment in the Phase III clinical trial program to be completed in the first quarter of 2003, delaying the MS-325 NDA filing for the U.S. by three to six months from the Company's prior estimate of March 2003. Based on our current estimates of patient enrollment, we expect this three to six month delay to reduce certain clinical trial expenses in 2002 and increase such expenses in 2003, as well as to delay the recognition of certain MS-325 related revenue we record from our strategic collaboration agreements from 2002 to future years. We are currently projecting a delay in recording 2002 revenue of approximately $900,000 and a delay in recording expenses of approximately $1.5 million, resulting in a delay in net loss of $600,000.

To complete our safety database for our NDA submission, in April 2002, we closed our MS-325-enhanced MRA Phase II feasibility trial for coronary artery disease. In addition, 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.

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.

Results of Operations

Comparison of Three Months Ended June 30, 2002 and 2001

Revenues. Second quarter 2002 revenues of $3.7 million consisted of $2.8 million from the product development portion of the strategic collaboration agreement for the development of MS-325 with Schering AG, $538,000 from a patent licensing and royalty agreement entered into with Bracco in September 2001 and $423,000 of license fee revenue related to the strategic collaboration agreements for the development and marketing of MS-325 with Schering AG and Tyco. Second quarter 2001 revenues of $2.2 million consisted of $1.8 million from the product development portion of the strategic collaboration agreement for the development of MS-325 with Schering AG and $423,000 of license fee revenue related to the strategic collaboration agreements for the development and marketing of MS-325 with Schering AG and Tyco.

Research and development expenses. Research and development expenses for the three months ended June 30, 2002 were $9.0 million as compared to $6.4 million for the three months ended June 30, 2001. The increase was primarily due to increased company headcount and clinical trial costs related to the expanded MS-325 Phase III clinical trial program in 2002.

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 $1.7 million and $1.3 million for the three months ended June 30, 2002 and 2001, respectively. The increase was primarily due to increased consulting, personnel and legal costs. General and administrative expenses also

include royalties payable to Massachusetts General Hospital, or MGH, on sales by Bracco of Multihance®. Royalty expenses totaled $20,000 and $0 for the three months ended June 30, 2002 and 2001 respectively.

Interest income and expense. Interest income increased approximately $75,000 in the second quarter of 2002 as compared to the second quarter of 2001 mainly due to higher average levels of invested cash during the second quarter of 2002. The increase in interest expense of approximately $95,000 in the second 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. For the three months ended June 30, 2002 and 2001, there were no realized gains or losses on available-for-sale securities.

Provision for foreign income taxes. Income tax expense for the three months ended June 30, 2002 was $26,000 as compared to $0 for the three months ended June 30, 2001. The increase represents Italian income taxes related to the Bracco agreement signed in September 2001, which we are unable to offset against net operating losses.

Comparison of Six Months Ended June 30, 2002 and 2001

Revenues. Revenues for the six months ended June 30, 2002 and June 30, 2001 were approximately $5.8 million and $3.9 million, respectively. The 2002 revenues consisted of $4.0 million from the product development portion of the strategic collaboration agreement for the development of MS-325 with Schering AG, $950,000 from a patent licensing and royalty agreement entered into with Bracco in September 2001 and $845,000 of license fee revenue related to the strategic collaboration agreements for the development and marketing of MS-325 with Schering AG and Tyco. The 2001 revenues of $3.9 million consisted of $3.1 million from the product development portion of the strategic collaboration agreement for the development of MS-325 with Schering AG and $845,000 of license fee revenue related to the strategic collaboration agreements for the development and marketing of MS-325 with Schering AG and Tyco.

Research and development expenses. Research and development expenses for the six months ended June 30, 2002 were $14.4 million as compared to $11.7 million for the six months ended June 30, 2001. The increase was primarily due to increased headcount and clinical trial costs related to the expanded MS-325 Phase III clinical trial program in 2002.

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 $3.0 million and $2.9 million for the six months ended June 30, 2002 and 2001, respectively. The increase was primarily due to increased consulting and personnel costs offset by decreased legal expenses. General and administrative expenses also include royalties payable to MGH, on sales by Bracco of Multihance®. Royalty expenses totaled $35,000 and $0 for the six months ended June 30, 2002 and 2001 respectively.

Interest income and expense. Interest income decreased approximately $38,000 in the six months end June 30, 2002 as compared to the same period in 2001 mainly due to lower interest rates during 2002. The increase in interest expense of approximately $36,000 for 2002 was associated with 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. For the six months ended June 30, 2002 and 2001, there were no realized gains or losses on available-for-sale securities.

Provision for foreign income taxes. Income tax expense for the six months ended June 30, 2002 was $44,000 as compared to $0 for the six months ended June 30, 2001. The increase represents Italian income taxes related to the Bracco agreement signed in September 2001, which we are unable to offset against net operating losses.

Liquidity and Capital Resources

Our principal sources of liquidity consist of cash, cash equivalents and available-for-sale marketable securities, which totaled $43.7 million at June 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.

We used approximately $11.6 million of net cash in operations for the six months ended June 30, 2002 compared to $9.5 million in operations for the six months ended June 30, 2001. For the six months ended June 30, 2002, net cash used in operating activities was primarily attributable to our net loss of $11.3 million.

Our investing activities resulted in net cash used of $27.2 million for the six months ended June 30, 2002 and net cash provided of $1.9 million for the six months ended June 30, 2001. For the six months ended June 30, 2002, we purchased $40.5 million of available-for-sale marketable securities. A majority of the funds used for these purchases were derived from the proceeds of the common stock offering completed on January 18, 2002. We also received proceeds of $14 million primarily as a result of investment maturities.

Capital expenditures were $701,000 for the six months ended June 30, 2002, and $345,000 for the six months ended June 30, 2001. Our capital expenditures consist primarily of purchases of property and equipment, including lab equipment, computer equipment and software. We expect that our capital expenditures will increase in the future as we continue to enhance and expand our principal lab space.

Cash provided by financing activities was $31.0 million for the six months ended June 30, 2002 and $8.5 million for the six months ended June 30, 2001. The principal source of financing for the six months ended June 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 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 due 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, $3.3 million at June 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 June 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 thrombosus, 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 commericalization 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. We have in place 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 March 31, 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 st
You 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 $12,000, and an increase of approximately $12,000, respectively, at June 30, 2002.

PART II. OTHER INFORMATION

Item 4. Submission of Matters to a Vote of Security Holder

The Company held its Annual Meeting of Stockholders on June 12, 2002, and the following matters were voted on at that meeting:

1. The re-election of Christopher F.O. Gabrieli and Michael D. Webb as members of the Board of Directors to serve for a term ending in 2005 and until their respective successors are duly elected and qualified. The following chart shows the number of votes cast for the matter, as well as the number of votes withheld:

DIRECTOR	FOR	VOTES WITHHELD
Christopher F.O. Gabrielli	14,295,157	293,429
Michael D. Webb	13,621,837	966,749

2. The proposal to increase by 500,000 shares the aggregate number of shares of the Company s Common Stock, $.01 par value per share (the Common Stock), for which stock options may be granted under the Company s Amended and Restated 1992 Equity Incentive Plan. The following chart shows the number of votes cast for or against the proposal, as well as the number of votes withheld:

FOR	AGAINST	VOTES WITHHELD
10,843,893	3,735,939	8,754

Item 6. Exhibits and Reports on Form 8-K

(A) EXHIBITS

10.31	Third Amendment, dated May 1, 2002, to the Short Form Lease dated as of July 7, 1998 with a commencement date as of January 1, 1998 between the Company and the Trustees of The Cambridge East Trust.
99.1	Certification of Principal Executive Officer and Principal Financial Officer
99.2	EPIX Medical, Inc. Amended and Restated 1992 Equity Incentive Plan

(B) REPORTS ON FORM 8-K

No reports on Form 8-K were filed during the quarter ended June 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: August 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)

Exhibit Index

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