EPIX MEDICAL INC
Form 10-Q
November 13, 2001

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, 2001

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	**02142-1118**
(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 November 6, 2001 14,201,252 shares of the registrant's Common Stock, $.01 par value per share, were issued and outstanding.

EPIX MEDICAL, INC.

TABLE OF CONTENTS

EPIX MEDICAL, INC.
CONDENSED BALANCE SHEETS
(UNAUDITED)

		September 30, 2001		December 31, 2000
Assets:				
Current assets:				
Cash and cash equivalents	$	13,900,077	$	402,621
Available-for-sale marketable securities		13,810,252		24,310,253
Due from strategic partner		-		3,000,000
Prepaid expenses and other current assets		638,474		371,318
Total current assets		28,348,803		28,084,192
Property and equipment, net		1,275,693		1,461,443
Other assets		125,047		134,952
Total assets	$	29,749,543	$	29,680,587
Liabilities and Stockholders' Equity:				
Current liabilities:				
Accounts payable	$	1,112,843	$	1,800,046
Accrued expenses		6,048,092		3,677,833
Contract advances		1,921,310		2,462,340
Accrued reacquisition costs		-		2,800,000
Current portion of capital lease obligations		114,431		259,308
Current portion of note payable		75,200		373,783
Deferred revenue		3,490,909		1,690,909
Total current liabilities		12,762,785		13,064,219
Capital lease obligations, less current portion		-		64,440
Accrued reacquisition costs, less current portion		2,400,000		2,400,000
Loan payable to strategic partner		3,004,607		3,004,607
Deferred revenue		10,186,116		4,581,818
Stockholders' equity:				
		141,756		132,040

Common stock, $.01 par value, 40,000,000 shares authorized; 14,175,553 and 13,203,991 shares issued and outstanding at September 30, 2001 and December 31, 2000, respectively				
Additional paid-in capital		88,088,928		79,144,912
Accumulated deficit		(86,840,470)		(72,718,720)
Accumulated other comprehensive income		5,821		7,271
Total stockholders' equity		1,396,035		6,565,503
Total liabilities and stockholders' equity	$	29,749,543	$	29,680,587

See accompanying notes.

EPIX MEDICAL, INC.
CONDENSED STATEMENTS OF OPERATIONS
(UNAUDITED)

	Three months ended September 30, 2001	Three months ended September 30, 2000*	Nine months ended September 30, 2001	Nine months ended September 30, 2000*
Revenues	$ 3,615,864	$ 1,908,554	$ 7,544,959	$ 5,600,137
Operating expenses:				
Research and development	5,358,701	5,535,849	17,033,685	16,043,125
General and administrative	1,337,407	1,041,168	4,188,740	3,522,892
Total operating expenses	6,696,108	6,577,017	21,222,425	19,566,017
Operating loss	(3,080,244)	(4,668,463)	(13,677,466)	(13,965,880)
Interest income	195,139	505,951	851,483	817,317
Interest expense	(57,378)	(144,521)	(213,767)	(344,019)
Loss before income taxes and cumulative effect of change in accounting principle	(2,942,483)	(4,307,033)	(13,039,750)	(13,492,582)
Provision for income taxes	(1,082,000)	-	(1,082,000)	-
Loss before cumulative effect of change in accounting principle	(4,024,483)	(4,307,033)	(14,121,750)	(13,492,582)
Cumulative effect of change in accounting principle	-	-	-	(4,363,636)
Net loss	$ (4,024,483)	$ (4,307,033)	$ (14,121,750)	$ (17,856,218)
Weighted average shares basic and diluted:	14,160,239	13,022,045	13,942,833	12,207,011
Loss per share basic and diluted:				
Loss before cumulative effect of change in accounting principle	$ (0.28)	$ (0.33)	$ (1.01)	$ (1.11)

Cumulative effect of change in accounting principle	-	-	-	(0.37)
Net loss	$ (0.28)	$ (0.33)	$ (1.01)	$ (1.48)

* Includes the effects of SAB 101. See Note 1.

See accompanying notes.

EPIX MEDICAL, INC.
CONDENSED STATEMENTS OF CASH FLOWS
(UNAUDITED)

	Nine months ended September 30, 2001	Nine months ended September 30, 2000
Operating activities:		
Net loss	$ (14,121,750)	$ (17,856,218)
Adjustments to reconcile net loss to net cash used in operating activities:		
Cumulative effect of change in accounting principle	-	4,363,636
Depreciation and amortization	682,998	722,959
Stock compensation expense	-	98,945
Interest income related to stock option loans	-	(6,902)
Changes in operating assets and liabilities:		
Due from strategic partner	3,000,000	-
Prepaid expenses, other current assets and other assets	(257,251)	469,501
Accounts payable	(687,203)	(660,369)
Accrued expenses	2,370,259	2,108,681
Contract advances	(541,030)	2,440,032
Accrued reacquisition costs	(2,800,000)	-
Deferred revenue	7,404,298	(818,180)
Receipt of cash from Schering AG for marketing rights	-	10,000,000
Disbursement of cash to Mallinckrodt for marketing rights	-	(10,000,000)
Net cash used in operating activities	(4,949,679)	(9,137,915)
Investing activities:		
Purchases of fixed assets	(497,248)	(18,603)
Purchases of marketable securities	(169,142,130)	(289,210,144)
Proceeds from sales or redemptions of marketable securities	179,640,681	277,671,896
Net cash provided by (used in) investing activities	10,001,303	(11,556,851)
Financing activities:		
Proceeds from collection of stock option loan and related interest	-	394,331
Proceeds from issuance of loan payable to strategic partner	-	3,019,590
Repayment of capital lease obligations	(209,317)	(306,150)
Repayment of note payable	(298,583)	(293,460)
Proceeds from ESPP purchases	90,218	69,984
Proceeds from Acqua Wellington stock purchases	8,667,365	-
Proceeds from Schering BV stock purchase	-	20,000,000
Proceeds from issuance of stock options	196,149	1,345,553
Net cash provided by financing activities	8,445,832	24,229,848
Increase in cash and cash equivalents	13,497,456	3,535,082
Cash and cash equivalents at beginning of period	402,621	430,124

Cash and cash equivalents at end of period	$	13,900,077	$	3,965,206
Supplemental disclosure of non-cash investing and financing activities:				
Issuance of stock option loans for exercise of stock options	$	-	$	207,109
Stock subscription receivable	$	-	$	757,898
Supplemental cash flow information:				
Cash paid for interest	$	213,910	$	255,630

See accompanying notes.

EPIX MEDICAL, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
SEPTEMBER 30, 2001
(UNAUDITED)

1. BASIS OF PRESENTATION

The accompanying unaudited condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X promulgated under the Securities Act of 1933, as amended. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the three - and nine- month periods ended September 30, 2001 are not necessarily indicative of the results that may be expected for the year ending December 31, 2001.

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Significant estimates in these unaudited condensed financial statements include the useful lives for depreciation and amortization and contract revenues and related costs. Actual results could differ from those estimates.

The condensed balance sheet at December 31, 2000 has been derived from the audited financial statements at that date but does not include all the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements.

For further information, refer to the financial statements and footnotes thereto included in EPIX Medical Inc. s (the Company) annual report on Form 10-K for the year ended December 31, 2000.

The operating results for the nine months ended September 30, 2000 reflect the adoption of Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" ("SAB 101") in 2000, retroactive to January 1, which resulted in a cumulative effect of change in accounting principle of $4.4 million or $0.37 per share. Included in revenues for each of the three - and nine - month periods ended September 30, 2001 and 2000 is $273,000, and $819,000, respectively, of revenue that was recognized in prior years relating to the adoption of SAB 101. Prior year financial results have been restated for the retroactive adoption of SAB 101 to January 1, 2000.

2. SIGNIFICANT AGREEMENT

In September 2001, pursuant to a Settlement and Release Agreement and Worldwide License Agreement the Company entered into a worldwide, non-exclusive royalty bearing sub-license agreement (the Agreement) with Bracco Imaging S.p.A. ("Bracco"). Under the Agreement, the Company sub-licensed certain patents relating to Bracco products, including Bracco s proprietary product MultiHance . The patents sub-licensed to Bracco are owned by the Massachusetts General Hospital (MGH) and are licensed exclusively to the Company.

The Company received from Bracco $10,000,000 ($9,000,000 net of Italian income taxes) in up-front payments comprised of a license fee, royalties on past sales of MultiHance , prepayment of future royalties and a contingent licensing fee based upon marketing approval of MultiHance in the United States. The license fee of $2,000,000, will be recognized ratably over the term of the Agreement because of ongoing obligations of the Company over such term. $1,000,000 of royalties on past sales of MultiHance made by Bracco prior to January 1, 2001, was recognized as revenue in the third quarter of 2001. Prepaid future royalties total $4,000,000; $3,000,000 of which is required, pursuant to the Agreement, to be applied against a portion of royalties earned commencing January 1, 2001; the remaining $1,000,000 will be applied against royalties earned commencing on January 1, 2005. As of September 30, 2001, $328,000 of the $3,000,000 had been applied against royalties earned in the nine - month period ended September 30, 2001. The remaining $3,000,000 represents a contingent licensing fee for MultiHance ™ FDA approval, which will be recognized as revenue ratably in the period beginning with FDA approval, through the remaining term of the Agreement, because of ongoing obligations of the Company over such term.

Bracco is also required to pay royalties to the Company for its sales of MultiHance on a quarterly basis retroactive to January 1, 2001 through the term of the Agreement, or November 2006. $800,000 of royalty revenue has been earned in the nine - month period ended September 30, 2001.

Of the $10,000,000 received from Bracco, any amount not recognized as revenue in the nine - month period ended September 30, 2001 has been recorded on the balance sheet as deferred revenue, classified as short term and long term according to the year the amount will be recognized as revenue.

In connection with the Agreement, Bracco is withdrawing its oppositions to the licensed patents in the European and Japanese Patent Offices, and the parties have settled ongoing litigation with respect to the patents in Europe.

3. COMPREHENSIVE INCOME

Statement of Financial Accounting Standard (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. Total comprehensive loss for the quarter ended September 30, 2001 amounted to $4,040,750 compared to $4,281,611 in the same period in 2000. Total comprehensive loss for the nine months ended September 30, 2001 amounted to $14,123,200 compared to $17,795,674 in the same period in 2000.

4. DERIVATIVES AND HEDGING ACTIVITIES

SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities" as amended by SFAS 137 and 138, requires companies to record derivatives on the balance sheet as assets or liabilities, measured at fair value. Gains or losses resulting from changes in the values of those derivatives would be accounted for depending on the use of the derivative and whether it qualifies for hedge accounting.

Effective January 1, 2001, the Company adopted SFAS No. 133. The adoption of this new statement of financial accounting standard did not have a significant impact on the Company's financial position or results of operations.

5. EARNINGS (LOSS) PER SHARE

The Company computes earnings (loss) per share in accordance with the provisions of SFAS No. 128, "Earnings per Share" and related interpretations and amendments. Basic net earnings (loss) per share is based upon the weighted-average number of common shares outstanding and excludes the effect of potentially dilutive common stock issuable upon exercise of stock options.

In computing diluted earnings (loss) per share, only common shares that are potentially 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 from continuing operations is reported.

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

OVERVIEW

Since commencing operations in 1992, we have been engaged principally 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 losses since inception through September 30, 2001 aggregating approximately $86.8 million.

In September 2001, pursuant to a Settlement and Release Agreement and Worldwide License Agreement the Company entered into a worldwide, non-exclusive royalty bearing sub-license agreement (the Agreement) with Bracco Imaging S.p.A. ("Bracco"). Under the Agreement, the Company sub-licensed certain patents relating to Bracco products, including Bracco s proprietary product MultiHance . The patents sub-licensed to Bracco are owned by the Massachusetts General Hospital (MGH) and are licensed exclusively to the Company.

The Company received from Bracco $10,000,000 ($9,000,000 net of Italian income taxes) in up-front payments comprised of a license fee, royalties on past sales of MultiHance , prepayment of future royalties and a contingent licensing fee based upon marketing approval of MultiHance in the United States. The license fee of $2,000,000, will be recognized ratably over the term of the Agreement because of ongoing obligations of the Company over such term. $1,000,000 of royalties on past sales of MultiHance made by Bracco prior to January 1, 2001, was recognized as revenue in the third quarter of 2001. Prepaid future royalties total $4,000,000; $3,000,000 of which is required, pursuant to the Agreement, to be applied against a portion of royalties earned commencing January 1, 2001; the remaining $1,000,000 will be applied against royalties earned commencing on January 1, 2005. As of September 30, 2001, $328,000 of the $3,000,000 had been applied against royalties earned in the nine - month period ended September 30, 2001. The remaining $3,000,000 represents a contingent licensing fee for MultiHance ™ FDA approval, which will be recognized as revenue ratably in the period beginning with FDA approval, through the remaining term of the Agreement, because of ongoing obligations of the Company over such term.

Our initial product candidate, MS-325, is currently our only product candidate undergoing human clinical trials. We filed an investigational new drug 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 September 1998 to test the safety and preliminary efficacy of MS-325-enhanced magnetic resonance angiography or MRA for the evaluation of peripheral vascular disease. In September 1999, we initiated a Phase III clinical trial to determine the efficacy of MS-325-enhanced MRA for the detection of aortoiliac occlusive disease. Enrollment in the first arm of this Phase III trial was completed in September 2001. 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. 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 magnetic resonance imaging in the diagnosis of female sexual arousal dysfunction. In September 2001 we announced the results of a completed Phase II clinical trial to compare the diagnostic accuracy of five different doses of MS-325-enchanced MRI with that of x-ray angiography in the aortoiliac vascular bed.

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 by us; 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 SEPTEMBER 30, 2001 AND 2000

REVENUES. Third quarter revenues were approximately $3.6 million and $1.9 million in 2001 and 2000, respectively. The $3.6 million of third quarter 2001 revenues consisted of $1.8 million from a product development contract with Schering Aktiengesellschaft, or Schering A.G., and $1.8 million from a patent sub-licensing and royalty agreement with Bracco. 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 and $0.8 million in royalties earned on Bracco MultiHance product sales from January 1 to September 30, 2001. Third quarter 2000 revenues of $1.9 million were derived from the product development contract with Schering A.G.

RESEARCH AND DEVELOPMENT EXPENSES. Research and development expenses for the three months ended September 30, 2001 were $5.4 million as compared to $5.5 million for the three months ended September 30, 2000. The decreased research and development expenses, were primarily due to a slight decrease in costs related to the MS-325 program. This decrease in research and development expenses for the three months ended September 30, 2001 is not necessarily indicative of the results that may be expected for the year ending December 31, 2001.

GENERAL AND ADMINISTRATIVE EXPENSES. General and administrative expenses for the three months ended September 30, 2001 were $1.3 million as compared to $1.0 million for the corresponding period of 2000. The increase of approximately $300,000 was primarily due to an increase in personnel to support operations, ongoing corporate activities, and an increase in royalty expense directly related to the Bracco Agreement.

INTEREST INCOME AND EXPENSE. Net interest income decreased approximately $224,000 in 2001 as compared to 2000 due to higher average levels of invested cash during the third quarter of 2000 offset by lower rates of return during the third quarter of 2001.

PROVISION FOR INCOME TAXES. Income taxes for the three months ended September 2001 were $1.1 million as compared to none due for the corresponding period of 2000. The increase is due to Italian income taxes paid pursuant to the Bracco Agreement.

COMPARISON OF NINE MONTHS ENDED SEPTEMBER 30, 2001 AND 2000

REVENUES. Revenues for the nine-months ended September 30, 2001 and September 30, 2000 were approximately $7.5 million and $5.6 million, respectively. The 2001 revenues consisted of $5.7 million from a product development contract with Schering A.G., and $1.8 million from a patent sub-licensing and royalty agreement entered into with Bracco in September 2001. The 2000 revenues were derived from the product development contract with Schering A.G..

RESEARCH AND DEVELOPMENT EXPENSES. Research and development expenses for the nine months ended September 30, 2001 were $17.0 million as compared to $16.0 million for the nine months ended September 30, 2000. The increased research and development expenses, approximately $1.0 million, was primarily due to increased costs, including personnel and resources, incurred in the Company s Thrombus imaging development program, and costs associated with advancing MS-325 through clinical trials.

GENERAL AND ADMINISTRATIVE EXPENSES. General and administrative expenses for the nine months ended September 30, 2001 were $4.2 million as compared to $3.5 million for the corresponding period of 2000. The increase was primarily due to an increase in personnel to support operations, ongoing corporate activities, corporate communications and marketing, and an increase in royalty expense directly related to the Bracco Agreement.

INTEREST INCOME AND EXPENSE. Net interest income increased approximately $164,000 in 2001 as compared to 2000, due to higher average levels of invested cash offset by lower rates of return during the nine months ended September 30, 2001.

PROVISION FOR INCOME TAXES. Income taxes for the nine months ended September 2001 were $1.1 million as compared to none due for the corresponding period of 2000. The increase is due to Italian income taxes paid pursuant to the Bracco Agreement.

LIQUIDITY AND CAPITAL RESOURCES

Our principal sources of liquidity consist of cash, cash equivalents and marketable securities, which totaled $27.7 million at September 30, 2001, as compared to $24.7 million at December 31, 2000.

During the nine months ended September 30, 2001, we used approximately $4.9 million of cash for operating activities. We expect that our cash needs for operations will increase significantly in future periods due to planned clinical trials and other expenses associated with the development of MS-325, continued research and development activities of our Thrombus imaging development program and other new research and development programs.

In September 2000, we entered into an agreement for an equity line financing facility covering the sale of up to $45 million of our common stock over a 28-month period. These shares may be sold at our discretion at a small discount to the market price of our shares at the time of the sale. The total amount of the investment is dependent, in part, on our stock price, with us controlling the amount and timing of the stock sold. We have received approximately $9.5 million to date in net proceeds under this equity line financing facility and issued approximately 981,000 shares of common stock. During the second quarter of 2001, the Securities and Exchange Commission (the SEC) issued guidance regarding equity line financing facilities that preclude a company from issuing more than ten percent, on the date the agreement is signed, of its outstanding non-affiliate shares, in a single equity line financing facility. The impact of this guidance on our current equity line financing facility is to reduce such equity line from $45.0 million, approximately 3,000,000 shares of common stock, to $16.8 million, approximately 1,086,000 shares of common stock. The Company has issued substantially all of the common stock allowable under the equity line financing facility. We intend to utilize our current effective shelf registration statement, which has remaining approximately 2,019,000 shares of common stock, to continue to finance our operations as needed, consistent with SEC guidance and, as a result, we do not expect the new SEC guidance to have a material impact on our ability to continue to finance our operations.

We estimate that existing cash, cash equivalents and marketable securities, as well as the potential use of our effective shelf registration statement, assuming a current stock price of approximately $7.00 per share, will be sufficient to fund our operations into the second quarter of 2003. We will need to raise additional funds for research, development, and other expenses through equity or debt financing, strategic alliances or otherwise, prior to commercialization of any of our product candidates. There can be no assurance that additional financing will be available on terms acceptable to us, or at all. Our future liquidity and capital requirements will depend on numerous factors, including the following: the progress and scope of clinical trials; the timing and costs of filing future regulatory submissions; the timing and costs required to receive both 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 development of MS-325 and new research programs, we do not expect to generate positive cash flow from operating activities for any future quarterly or annual period prior to commercialization of MS-325. 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 that will enable us to utilize our current principal scientific facilities through December 31, 2002, and we have an option to extend the lease for an additional three or five years at 95% of the then market rate. We also have a lease for nearby office space, which expires in December 2002.

We do not believe that inflation has had a material impact on our operations.

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 use 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. Our actual results could differ materially from those anticipated in the forward-looking statements for many reasons, including the risks described in our Annual Report on Form 10-K for the year ended December 31, 2000, as previously filed with the SEC.

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

We invest our cash in a variety of financial instruments, including bank time deposits, and taxable and tax-advantaged variable rate and fixed rate obligations of corporations, municipalities, and local, state and national governmental entities and agencies. 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 fixed rate securities that have seen a decline in market value due to changes in interest rates. A hypothetical 100 basis point increase or decrease in interest rates, however, would not have a material adverse effect on our financial condition. The weighted average interest rate (yield to maturity at market) and weighted-average remaining maturity of marketable securities at September 30, 2001 was 2.84% and approximately 26 days, respectively. The fair market value of marketable securities held at September 30, 2001 was $13.8 million.

The interest rate on our note payable to Mallinckrodt is adjustable on a quarterly basis and therefore subjects the Company to interest rate risks. However, based on the outstanding loan balance of $3,004,607 at September 30, 2001, a 100 basis point increase in interest rates would not result in a significant increase in the Company's annual interest expense.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

A Settlement and Release Agreement was made and entered into as of September 25, 2001, by and among us, Bracco and The General Hospital Corporation (GHC) (the Settlement Agreement), pursuant to which all parties thereto agreed to settle and terminate in their entirety the intellectual property disputes that were pending worldwide pertaining to certain patents and patent applications owned by GHC and licensed to us (referred to here as the licensed patents) and certain pharmaceutical products or formulations sold by Bracco or its affiliates, including, but not limited to, the product identified by Bracco s trademark MultiHance (referred to here as the licensed products).

In accordance with the Settlement Agreement, Bracco and its affiliates agreed to terminate all current actions and legal proceedings instituted by them against the licensed patents in the United Kingdom, Italy, the European Patent Office, the Japanese Patent Office and any other territory, and we and GHC agreed to terminate all current actions and legal proceedings brought by us against Bracco in relation to the licensed products in France, Germany and any other territory. All of the parties to the Settlement Agreement agreed to bear their respective attorneys fees and costs with respect to the actions and their termination, without application for reimbursement for court costs or fees from any party.

ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS

Not Applicable

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not Applicable

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

Not Applicable

ITEM 5. OTHER INFORMATION

Not Applicable

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(A) EXHIBITS

3.1	Restated certificate of Incorporation of the Company. Filed as Exhibit 4.1 to the Company s Registration Statement on Form S-8 (file no. 333-30531) and incorporated herein by reference.
3.2	Form of Amended and Restated By-laws of the Company filed as exhibit 4.2 to the Company s Registration Statement or Form S-8 (file no. 333-30531) and incorporated herein by reference.
4.1	Specimen certificate for shares of common stock of the Company. Filed as exhibit 4.1 to the Company s Registration Statement on Form S-1 (file no. 333-17581) and incorporated herein by reference.

(B) REPORTS ON FORM 8-K

The following report on Form 8-K was filed during the quarter ended September 30, 2001:

(i) On September 25, 2001, the Company filed with the Securities and Exchange Commission a current report on Form 8-K reporting the worldwide, non exclusive royalty bearing license agreement the Company entered into with Bracco Imaging S.P.A.

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 9, 2001 By: /s/ Pamela E. Carey

Pamela E. Carey

Vice President of Finance and Administration,
Chief Financial Officer (Principal Financial Officer and
Accounting Officer)