EPIX MEDICAL INC
Form 10-Q
May 15, 2001

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(MARK ONE)

[X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2001

or

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

For the transition period from _____ to _____.

Commission File Number 0-21863

EPIX MEDICAL, INC.
(Exact name of Registrant as Specified in its Charter)

DELAWARE	04-30
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer I

71 ROGERS STREET CAMBRIDGE, MASSACHUSETTS	02
(Address of principal executive offices)	(Zip

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 X No ___

As of May 10, 2001, 14,048,522 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)

	MARCH 31, 2001

Assets:	
Current assets:	
Cash and cash equivalents	$ 2,925
Available-for-sale marketable securities	23,680
Due from strategic partner	
Prepaid expenses and other current assets	545
Total current assets	27,151
Property and equipment, net	1,385
Other assets	134
Total assets	$ 28,671
Liabilities and Stockholders' Equity:	
Current liabilities:	
Accounts payable	$ 1,418
Accrued expenses	4,247
Contract advances	3,394
Accrued reacquisition costs	
Current portion of capital lease obligations	253
Current portion of note payable	338
Deferred revenue	1,690
Total current liabilities	11,342
Capital lease obligations, less current portion	
Accrued reacquisition costs, less current portion	2,400
Loan payable to strategic partner	3,004
Deferred revenue	4,159
Stockholders' equity:	
Common stock, $.01 par value, 40,000,000 shares authorized; 13,816,173 and 13,203,991 shares issued and outstanding at March 31, 2001 and December 31, 2000, respectively	138
Additional paid-in capital	85,355
Stock subscriptions receivable	(65
Accumulated deficit	(77,689
Other comprehensive income	25
Total stockholders' equity	7,765
Total liabilities and stockholders' equity	$ 28,671

See accompanying notes.

EPIX MEDICAL, INC.

CONDENSED STATEMENTS OF OPERATIONS

(UNAUDITED)

	THREE MONTHS ENDED MARCH 31, 2001
Revenues	$ 1,731,673
Operating expenses:	
Research and development	5,322,031
General and administrative	1,586,835
Total operating expenses	6,908,866
Operating loss	(5,177,193)
Interest income	361,677
Interest expense	(154,870)
Loss before cumulative effect of change in accounting principle	$ (4,970,386)
Cumulative effect of change in accounting principle	-
Net loss	$ (4,970,386)
Weighted average shares--basic and diluted	13,638,913
Net loss per share, basic and diluted:	
Loss before cumulative effect of change in accounting principle	$ (0.36)
Cumulative effect of change in accounting principle	-
Net loss	$ (0.36)

See accompanying notes.

EPIX MEDICAL, INC.

CONDENSED STATEMENTS OF CASH FLOWS
(UNAUDITED)

	THREE MONTHS ENDED MARCH 31, 2001
Operating activities:	
Net loss	$ (4,970,386)
Adjustments to reconcile net loss to cash used by operating activities:	
Cumulative effect of change in accounting principle	-
Depreciation and amortization	205,425
Interest income related to stock option loans	-
Change in operating assets and liabilities:	
Due from strategic partner	3,000,000
Prepaid expenses and other assets	(173,671)
Accounts payable	(381,345)
Accrued expenses	569,439
Contract advances	931,836
Payment of reacquisition costs	(2,800,000)
Deferred revenue	(422,727)
Net cash used by operating activities	(4,041,429)
Investing activities:	
Purchase of fixed assets	(129,374)
Purchases of marketable securities	(84,883,535)
Proceeds from sales or redemptions of marketable securities	85,532,000
Net cash provided by investing activities	519,091
Financing activities:	
Proceeds from collection of stock option loan and related interest	-
Proceeds from issuance of loan payable to strategic partner	-
Repayment of capital lease obligations	(70,633)
Repayment of note payable	(35,569)
Proceeds from issuance of shares to Acqua Wellington	6,119,218
Proceeds from issuance of stock options and warrants	32,329
Net cash provided by financing activities	6,045,345
Increase in cash and cash equivalents	2,523,007
Cash and cash equivalents at beginning of period	402,621
Cash and cash equivalents at end of period	$ 2,925,628
Supplemental disclosure of noncash investing and financing activities:	
Stock subscription receivable	$ 65,000
Supplemental cash flow information:	

Cash paid for interest	$ 212,077

See accompanying notes.

EPIX MEDICAL, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS
MARCH 31, 2001
(UNAUDITED)

1. BASIS OF PRESENTATION

The unaudited condensed financial statements 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 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 March 31, 2001 are not necessarily indicative of the results expected for the full fiscal year.

The operating results for the quarter ended March 31, 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.

The 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 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, 2000.

2. COMPREHENSIVE INCOME

Financial Standards No. 130, "Reporting Comprehensive Income" ("SFAS 130") requires unrealized gains or losses on the Company's available-for-sale securities to be included in other comprehensive income. Total comprehensive loss for the quarter ended March 31, 2001 amounted to $4,951,679 compared to $9,248,688 in the same period in 2000.

3. DERIVATIVES AND HEDGING ACTIVITIES

Statement of Financial Accounting Standards (SFAS) No. 133, "Accounting for Derivative Instruments and Hedging Activities" ("SFAS 133"), SFAS 133, as amended by SFAS 137, 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, 2000, the Company adopted SFAS No. 133. The adoption of this new statement of accounting standard did not have a significant effect on the Company's financial position or result of operations.

4. EARNINGS (LOSS) PER SHARE

The Company computes earnings (loss) per share in accordance with the provisions of SFAS No. 128, "Earnings per Share." Basic net earnings (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 earnings (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 earnings (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.

5. SUBSEQUENT EVENTS

Subsequent to March 31, 2001, the Company issued 20,636, 31,110, and 181,629 shares of common stock to Acqua Wellington North American Equities Fund Ltd. ("Acqua Wellington") in the draw down periods ending April 5, 2001, April 20, 2001 and May 08, 2001, respectively, for a total of 233,375 shares of common stock providing additional net proceeds of $1,929,927. Of the 20,636 shares issued in the draw down period ending April 5, 2001, 6,845 shares valued at $65,000 were subscribed to by Acqua Wellington during the quarter ending March 31, 2001 and are recorded as stock subscriptions receivable on the accompanying Balance Sheet.

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 March 31, 2001 aggregating approximately $77.7 million.

We have received revenues in connection with various licensing and collaboration agreements. In June 2000, we entered into a strategic collaboration agreement pursuant to which we granted Schering AG an exclusive license to co-develop and market MS-325 worldwide, exclusive of Japan, and amended our strategic collaboration with Mallinckrodt, Inc ("Mallinckrodt") to enable us to enter into the strategic collaboration agreement with Schering AG, as well as to grant Mallinckrodt a non-exclusive, worldwide license to manufacture MS-325 for clinical development and commercial use. In December 2000, we reacquired the rights to develop and commercialize MS-325 in Japan from Daiichi Radioisotope Laboratories, Ltd. ("Daiichi") and simultaneously amended our strategic collaboration agreement with Schering AG to grant Schering AG exclusive rights to develop and market MS-325 in Japan. In connection with the strategic collaboration agreement entered into with Schering AG and the amendment to the strategic collaboration with Mallinckrodt, Schering AG paid us an up-front fee of $10.0 million, which we then paid to Mallinckrodt. Schering AG also made a

$20.0 million equity investment in us at $17.98 per share of common stock, through its affiliate, Schering Berlin Venture Corporation ("Schering BV"). We may receive up to an additional $20.0 million in milestone payments under the strategic collaboration agreement with Schering AG and may be required to pay up to an additional $5.0 million in milestones to Mallinckrodt pursuant to the terms of the amended Mallinckrodt agreement. Under the terms of the December 2000 amendment with Schering, Schering AG paid us an up-front fee of $3.0 million and may be required to pay us an additional $7.0 million upon our achievement of certain milestones. Under the terms of the reacquisition agreement with Daiichi, we agreed to pay Daiichi a total of $5.2 million. In January 2001, we paid Daiichi $2.8 million in fees and we will pay an additional $2.4 million in the future.

We expect continued operating losses for the next several years as we incur expenses to support research, development and 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 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 or MRA for the evaluation of peripheral vascular disease and are currently conducting a Phase II feasibility trial to test the safety and feasibility of MS-325-enhanced MRA for the evaluation of coronary artery disease. In June 1999, we initiated a Phase III clinical trial to determine the efficacy of MS-325-enhanced MRA for the detection of aortoiliac occlusive 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. 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.

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 MARCH 31, 2001 AND 2000

The net loss for the first quarter of 2000 reflects our adoption of SEC Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" ("SAB 101"), retroactively to January 1, 2000, changing our method of recognizing revenue. In the first quarter of 2000, in accordance with the adoption of SAB 101, we recorded a cumulative effect of change in accounting principle in the

amount of $4.4 million. Included in both 2001 and 2000 first quarter revenues is $0.3 million of revenue that was recognized in prior years relating to the adoption of SAB 101.

REVENUES. First quarter revenues were approximately $1.7 million and $1.1

million in 2001 and 2000, respectively, and were derived from product development contracts with Schering AG in the first quarter of 2001 and Mallinckrodt in the first quarter of 2000. The increase in revenues during the first quarter of 2001 was due to the impact of development funding terms under our strategic collaboration agreement with Schering AG and revenue earned pursuant to a license fee paid to us by Schering for the marketing rights to MS-325 in Japan.

RESEARCH AND DEVELOPMENT EXPENSES. Research and development expenses for the three months ended March 31, 2001 were $5.3 million as compared to $5.1 million for the three months ended March 31, 2000. The increase was primarily due to the effect of the funding development terms under the agreement entered into with Schering AG, and increased costs for personnel and resources to support research and development of our thrombus imaging program. These increased costs were partially offset by the absence of manufacturing costs related to our agreement with Daiichi for the development of MS-325 in Japan, which was terminated in December 2000. The manufacturing costs will now be incurred by Schering AG, pursuant to the December 2000 amendment to our strategic agreement.

GENERAL AND ADMINISTRATIVE EXPENSES. General and administrative expenses for the three months ended March 31, 2001 were $1.6 million as compared to $1.0 million for the three months ended March 31, 2000. The increase was primarily due to increased legal costs associated with ongoing patent and general corporate activities.

INTEREST INCOME AND EXPENSE. Interest income increased approximately $0.2 million in the first quarter of 2001 as compared to the first quarter of 2000 mainly due to higher average levels of invested cash, cash equivalents and marketable securities in the first quarter of 2001. The increase in interest expense of approximately $59,000 in the first quarter of 2001 was associated with the loan payable to Mallinckrodt.

LIQUIDITY AND CAPITAL RESOURCES

Our principal sources of liquidity consist of cash, cash equivalents and marketable debt securities, which totaled $26.6 million at March 31, 2001, as compared to $24.7 at December 31, 2000.

In June 2000, we entered into a strategic collaboration agreement pursuant to which we granted Schering AG an exclusive license to co-develop and market MS-325 worldwide, exclusive of Japan. In December 2000, we amended this strategic collaboration agreement to grant to Schering AG the exclusive rights to develop and market MS-325 in Japan. In connection with this strategic collaboration agreement and in connection with the amendment to the strategic collaboration agreement between us and Mallinckrodt, as further described below, Schering AG paid us an up-front fee of $10.0 million, which we then paid to Mallinckrodt. Schering AG also made a $20.0 million dollar equity investment in us at $17.98 per share of common stock, through its affiliate, Schering BV. In return for their investment, we issued 1,112,075 shares of our common stock to Schering BV. We may receive up to an additional $20.0 million in milestone payments under the strategic collaboration agreement. Under the terms of the December 2000 amendment, Schering AG paid us an up-front fee of $3.0 million and may be required to pay us an additional $7.0 million upon our achievement of certain milestones.

In June 2000, in connection with the exclusive license that we granted to Schering AG, we amended our strategic collaboration with Mallinckrodt to grant Mallinckrodt 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 Mallinckrodt and Schering AG, and to enable us to enter into the strategic collaboration agreement with Schering AG

described above. In connection with this amendment, we paid Mallinckrodt an up-front fee of $10.0 million and may be required to pay up to an additional $5.0 million in milestones. We will pay Mallinckrodt a share of operating margins in the US and a royalty on gross profits outside the US on sales of MS-325.

In October 1999, we entered into a Non-Negotiable Promissory Note and Security Agreement (the "Loan") with Mallinckrodt under which we were eligible to borrow our share of development costs, on a quarterly basis, up to a total of $9.5 million. In June 2000, pursuant to the amended collaboration agreement with Mallinckrodt and the new strategic collaboration with Schering AG, Schering AG assumed the development cost sharing obligation for MS-325 from Mallinckrodt as of January 1, 2000. As a result, the terms of the Loan were amended to allow funding under the Loan for our portion of development costs through December 31, 1999. The Loan balance at December 31, 2000 of $3,004,607 represented our share of third and fourth quarter 1999 MS-325 development costs. No additional funding is available to us 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.

In March 1996, we entered into a development and license agreement with Daiichi pursuant to which we 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. We retained the right and obligation to manufacture MS-325 for development activities and commercial sale under the agreement. In December 2000, we reacquired the rights to develop and commercialize MS-325 in Japan from Daiichi. Under the terms of this Reacquisition Agreement, we agreed to pay Daiichi a total of $5.2 million. In January 2001, we paid Daiichi $2.8 million in fees and we will pay an additional $2.4 million in the future. Daiichi will also receive a royalty from us on net sales of MS-325 in Japan. Simultaneously with our reacquisition from Daiichi of the MS-325 development and marketing rights in Japan, we assigned these rights to Schering AG as described above.

During the quarter ended March 31, 2001, we used approximately $4.0 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 program and other new research and development programs.

In September 2000, we entered into an agreement with Acqua Wellington North American Equities Fund Ltd. ("Acqua Wellington") for an equity 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 $8,934,543 to date in net proceeds from Acqua Wellington under this facility, $1,929,927 of which we received subsequent to March 31, 2001.

We estimate that existing cash, cash equivalents and marketable securities, as well as our equity financing facility with Acqua Wellington, will be sufficient to fund our operations through the first quarter of 2004. 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 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 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. We also have a lease for nearby office space, which expires in December 2002.

We have incurred tax losses to date and therefore have not paid significant federal or state income taxes since inception. At December 31, 2000, we had loss carryforwards of approximately $59.0 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, as amended (the "Code"). 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 in 1997 and any other future ownership changes may further limit utilization of losses and credits in any one year. We also are eligible for research and development tax credits that can be carried forward to offset federal taxable income. The annual limitation and the timing of attaining profitability may result in the expiration of net operating loss and tax credit carryforwards before utilization.

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

FORWARD-LOOKING STATEMENTS

The discussion included in this section as well as elsewhere in this Quarterly Report on Form 10-Q contains forward-looking statements based on our current expectations. Such statements are subject to risks and uncertainties that could cause actual results to differ materially from those projected. See "Important Factors Regarding Forward-Looking Statements" attached as Exhibit 99.1 and incorporated herein by reference to our Annual Report on Form 10-K for the year ended December 31, 2000 as previously filed with the Commission. Readers are cautioned not to place undue reliance on the forward-looking statements which speak only as of the date thereof. We undertake no obligation to release publicly the result of any revisions to these forward-looking statements which may be made to reflect events or circumstances occurring after the date hereof or to reflect the occurrence of unanticipated events.

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 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 and weighted-average remaining maturity of marketable securities at March 31, 2001 was 4.64% and approximately 1-1/4 months, respectively. The fair market value of securities held at March 31, 2001 was $23,680,495.

The interest rate on our note payable to Mallinckrodt is adjustable on a quarterly basis and therefore subjects the Company to interest rate risk. However, based on the outstanding loan balance of $3,004,607 at March 31, 2001, a 100 basis point increase in interest rates would not result in a significant increase in the Company's annual interest expense.

The interest rates on our capital lease obligations are fixed and therefore not subject to interest rate risk.

PART II. OTHER INFORMATION

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(A) EXHIBITS

99.1	Important Factors Regarding Forward-Looking Statements filed as Exhibit 99.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000 and incorporated herein by reference.

(B) REPORTS ON FORM 8-K

No reports on Form 8-K were filed by the Company during the quarter ended March 31, 2001.

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: May 15, 2001 By: /s/ PAMELA E. CAREY

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