ENPATH MEDICAL INC
Form 10-Q
May 04, 2005

United States
Securities and Exchange Commission

Washington, D.C. 20549

Form 10-Q

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

For the quarterly period ended March 31, 2005

Or

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

For the transition period from to

Commission File Number 0-19467

Enpath Medical, Inc.

(Exact name of registrant as specified in its charter)

Minnesota	**41-1533300**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

15301 Highway 55 West, Plymouth, MN 55447

(Address of principal executive office, including zip code)

(763) 559-2613

(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ý No o

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2).

Yes o No ý

The number of shares of Registrant s common stock outstanding on May 3, 2005 was 5,947,960.

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Balance Sheets

	March 31, 2005 Unaudited	December 31, 2004
ASSETS		
Current assets:		
Cash and cash equivalents	$ 21,471	$ 362,625
Accounts receivable, less allowance for doubtful accounts of $69,000	2,981,596	3,660,049
Inventories, less allowance for slow-moving inventory of $162,000 and $124,000, respectively	4,847,107	4,624,183
Prepaid expenses and other assets	251,558	230,443
Income taxes receivable	499,185	310,683
Deferred income taxes	194,000	194,000
Total current assets	**8,794,917**	**9,381,983**
Property and equipment:		
Equipment	6,302,573	6,148,662
Office furniture, fixtures and computers	1,766,894	1,736,531
Leasehold improvements	1,673,329	1,576,759
	9,742,796	**9,461,952**
Less accumulated depreciation and amortization	(4,687,981)	(4,285,866)
Net property and equipment	**5,054,815**	**5,176,086**
Goodwill	9,607,975	9,593,662
Intangible assets with finite lives, net	5,744,552	5,861,045
Deferred income taxes	1,154,964	1,154,964
TOTAL ASSETS	**$ 30,357,223**	**$ 31,167,740**
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Bank line of credit payable	$ 575,000	$ 881,652
Current maturities of note payable to bank	1,000,000	1,000,000
Current installments of capital lease obligations	50,997	64,420
Accounts payable	966,334	927,196
Accrued compensation	873,353	810,016
Other accruals	342,463	260,946
Accrued acquisition payments	120,000	217,771
Total current liabilities	**3,928,147**	**4,162,001**
Long-term liabilities:		
Notes payable to bank, less current maturities	2,583,322	2,833,324
Capital lease obligations, less current installments		6,473
Accrued acquisition payments		391,085
Total long-term liabilities	**2,583,322**	**3,230,882**
Total liabilities	**6,511,469**	**7,392,883**
Commitments and contingencies		
Shareholders equity:		
Preferred stock-undesignated, authorized 1,000,000 shares		
Common stock-$.01 par value, authorized 20,000,000 shares; issued and outstanding 5,947,960 and 5,887,929 shares, respectively	59,479	58,879
Additional paid-in capital	21,704,050	21,283,676
Retained earnings	2,082,225	2,432,302

Total shareholders equity		**23,845,754**		**23,774,857**
TOTAL LIABILITIES AND SHAREHOLDERS EQUITY	**$**	**30,357,223**	**$**	**31,167,740**

See accompanying notes to financial statements

Income Statements (Unaudited)

	Three Months Ended	
	March 31, 2005	**March 31, 2004**
Net sales	$ 6,616,752	$ 7,297,054
Cost of sales	4,250,227	4,528,820
Gross profit	**2,366,525**	**2,768,234**
Operating expenses:		
Research and development	1,377,973	1,046,703
Selling, general and administrative	1,456,569	1,276,080
Total operating expenses	**2,834,542**	**2,322,783**
Operating income (loss)	**(468,017)**	**445,451**
Other expense (income):		
Interest expense	63,002	47,665
Interest income		(1,395)
Other	7,561	(3,283)
Total other expense	**70,563**	**42,987**
Income (loss) before income taxes	**(538,580)**	**402,464**
Income tax benefit (expense)	188,503	(129,331)
Net income (loss)	**$ (350,077)**	**$ 273,133**
Net income (loss) per common share:		
Basic	$ (0.06)	$ 0.05
Diluted	$ (0.06)	$ 0.05
Weighted average common and common equivalent shares outstanding:		
Basic	5,899,571	5,718,653
Diluted	5,899,571	6,048,947

See accompanying condensed notes to financial statements

Statement of Shareholders Equity (Unaudited)

	Common Stock		Additional Paid-In	Retained	
	Shares	**Amount**	**Capital**	**Earnings**	**Total**
Balances at December 31, 2004	**5,887,929**	**$ 58,879**	**$ 21,283,676**	**$ 2,432,302**	**$ 23,774,857**
Options exercised	26,200	262	29,627		29,889
Stock issued for contingent payment	33,831	338	390,747		391,085
Net loss for the three months ended March 31, 2005				(350,077)	(350,077)
Balances at March 31, 2005	**5,947,960**	**$ 59,479**	**$ 21,704,050**	**$ 2,082,225**	**$ 23,845,754**

See accompanying notes to financial statements

Statements of Cash Flows (Unaudited)

	Three Months Ended	
	March 31, 2005	**March 31, 2004**
Cash flows from operating activities:		
Net income (loss)	$ (350,077)	$ 273,133
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation and amortization	608,039	631,928
Changes in operating assets and liabilities:		
Accounts receivable	678,453	618,331
Inventories	(222,924)	141,910
Prepaid expenses and other assets	(21,115)	(188,677)
Income taxes receivable	(188,502)	99,931
Accounts payable	39,138	89,982
Accrued expenses	144,854	(26,338)
Income taxes payable		24,899
Net cash provided by operating activities	**687,866**	**1,665,099**
Cash flows from investing activities:		
Purchase of property and equipment, net of retirements	(280,844)	(116,476)
Additions to intangible assets	(103,744)	(176,855)
Additional cash paid for acquisition	(97,771)	(1,990,476)
Net cash used in investing activities	**(482,359)**	**(2,283,807)**
Cash flows from financing activities:		
Principal payments on capital lease obligations	(19,896)	(18,239)
Principal payments on long-term debt	(250,002)	(250,002)
Payments on line of credit	(306,652)	
Proceeds from exercise of options and warrants	29,889	101,682
Net cash used in financing activities	**(546,661)**	**(166,559)**
Net decrease in cash and cash equivalents	**(341,154)**	**(785,267)**
Cash and cash equivalents, beginning of period	**362,625**	**1,067,935**
Cash and cash equivalents, end of period	**$ 21,471**	**$ 282,668**
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	$ 63,002	$ 47,665
Cash paid during the period for income taxes	$	$ 4,500
Supplemental schedule of noncash investing activity:		
Common stock issued in payment of contingent purchase price	$ 391,085	$ 1,819,473

See accompanying condensed notes to financial statements

Condensed Notes to Financial Statements

Three Months Ended March 31, 2005

(Unaudited)

1. Basis of presentation

The financial statements included in this Form 10-Q have been prepared by the Company, without audit, pursuant to the rules and regulations of the Securities and Exchange Commission. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States have been condensed or omitted pursuant to these rules and regulations, although management believes the disclosures are adequate to make the information presented not misleading. These statements should be read in conjunction with the Company s Annual Report on Form 10-K for the year ended December 31, 2004.

The financial statements presented herein as of March 31, 2005 and for the three months ended March 31, 2005 and 2004 reflect, in the opinion of management, all material adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the financial position, results of operations and cash flows for these interim periods.

2. Inventories

Inventories are stated at the lower of cost, determined on a first-in, first-out (FIFO) basis, or market. Inventories consist of the following:

	March 31, 2005	December 31, 2004
Purchased parts and subassemblies	$ 3,046,192	$ 3,326,998
Work in process	1,100,242	513,608
Finished goods	700,673	783,577
Total Inventories	**$ 4,847,107**	**$ 4,624,183**

3. Finite Life Intangible Assets

Finite life intangible assets at March 31, 2005 and December 31, 2004 are as follows:

	Estimated Lives (Years)	Gross Carrying Amount	March 31, 2005 Accumulated Amortization	Net Value
Licensed technology	2	$ 115,000	$ 43,125	$ 71,875
Core technology	12	2,650,000	312,851	2,337,149
Developed technology	8	1,500,000	265,625	1,234,375
Customer relationships	6	615,000	145,214	469,786
Patents and inventions	5 to 9	1,434,229	393,814	1,040,415
Trade name	30	545,000	25,738	519,262
Other	5 to 10	94,963	23,273	71,690
Totals		**$ 6,954,192**	**$ 1,209,640**	**$ 5,744,552**

	Estimated Lives (Years)	December 31, 2004 Gross Carrying Amount	Accumulated Amortization	Net Value
Licensed technology	2	$ 115,000	$ 28,750	$ 86,250
Core technology	12	2,650,000	257,642	2,392,358
Developed technology	8	1,500,000	218,750	1,281,250
Customer relationships	6	615,000	119,588	495,412
Patents and inventions	5 to 9	1,346,676	338,756	1,007,920
Trade name	30	545,000	21,196	523,804
Other	5 to 10	93,085	19,034	74,051
Totals		**$ 6,864,761**	**$ 1,003,716**	**$ 5,861,045**

Amortization expense related to these assets is as follows:

Quarter ended March 31, 2005	$	205,924
Quarter ended March 31, 2004	$	239,253
Year ended December 31, 2004	$	883,550

Estimated amortization expense for these assets over the next five fiscal years is as follows:

Year		Amount
2005	$	828,000
2006	$	801,000
2007	$	772,000
2008	$	753,000
2009	$	584,000

4. Net Income (Loss) Per Common Share

Basic per-share amounts are computed, generally, by dividing net income (loss) by the weighted-average number of common shares outstanding. Diluted per-share amounts assume the conversion, exercise, or issuance of all potential common stock instruments unless their effect is not dilutive.

5. Income Taxes

Income tax benefit for the first quarter ended March 31, 2005, was computed using an estimated combined federal and state tax rate of 35%. A combined rate of 32% was used for the quarter ended March 31, 2004. The overall tax rate is expected to remain at approximately 35% for the remainder of 2005 due to the availability of research and development tax credits.

6. Employee Stock Based Compensation

At March 31, 2005, the Company had two stock-based employee compensation plans. The Company accounts for these plans under the APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations. No stock-based employee compensation cost is reflected in net income (loss), as all options granted under these plans had an exercise price equal to the market value of the underlying common stock on the date of grant.

The Company also grants options and warrants to non-employees for goods and services and in conjunction with certain agreements. These grants are accounted for under FASB Statement No. 123 based on the grant date fair values.

In December 2004, the Financial Accounting Standards Board (FASB) published FASB Statement No. 123 (revised 2004), *Share-Based Payment* (FAS 123(R) or the Statement). FAS 123(R) requires that the compensation cost relating to share-based payment transactions, including grants of employee stock options, be recognized in financial statements. That cost will be measured based on the fair value of the equity or liability instruments issued. FAS 123(R) covers a wide range of share-based compensation arrangements including stock options,

restricted share plans, performance-based awards, share appreciation rights, and employee share purchase plans. FAS 123(R) is a replacement of FASB Statement No. 123, *Accounting for Stock-Based Compensation*, and supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and its related interpretive guidance (APB 25).

This Statement will require entities to measure the cost of employee services received in exchange for stock options based on the grant-date fair value of the award, and to recognize the cost over the period the employee is required to provide services for the award. FAS 123(R) permits entities to use any option-pricing model that meets the fair value objective in the Statement. The Company will be required to apply FAS 123(R) beginning with the first quarter of 2006.

FAS 123(R) allows two methods for determining the effects of the transition: the modified prospective transition method and the modified retrospective method of transition. The Company has not yet completed its study of the transition methods or made any decisions about how it will adopt FAS 123(R). The pro forma compensation costs presented below and in prior filings for the Company have been calculated using a Black-Scholes option pricing model and may not be indicative of amounts which should be expected in future years. No decisions have been made by management as to which option pricing model is most appropriate for the Company for future awards.

The following table illustrates the effect on net income (loss) and net income (loss) per common share if the Company had applied the fair value recognition provisions of FASB Statement No. 123, *Accounting for Stock-Based Compensation*, to stock-based employee compensation:

	Quarter Ended	
	March 31, 2005	**March 31, 2004**
Net income (loss) - as reported	$ (350,077)	$ 273,133
Deduct: Total stock-based employee compensation (expense determined under the fair value based method for all awards)	(168,776)	(205,713)
Pro forma net income (loss)	**$ (518,853)**	**$ 67,420**
Net income (loss) per common share:		
Basic net income (loss) per share - as reported	$ (0.06)	$ 0.05
Basic net income (loss) per share - pro forma	$ (0.09)	$ 0.01
Diluted net income (loss) per share - as reported	$ (0.06)	$ 0.05
Diluted net income (loss) per share - pro forma	$ (0.09)	$ 0.01
Weighted average common shares outstanding		
Basic	5,899,571	5,718,653
Diluted	5,899,571	6,048,947

The above pro forma effects on net income (loss) and net income (loss) per common share are not likely to be representative of the effects on reported net income (loss) or net income (loss) per common share for future years because options vest over several years and additional awards generally are made each year. In addition, see Part II, Item 5, Acceleration of Stock Option Vesting Schedule.

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

The following discussion and analysis provides information that management believes is relevant to an assessment and understanding of the results of operations and financial condition. This discussion should be read in conjunction with the accompanying financial statements and footnotes.

Overview

We are a medical products company engaged in:

the design, development, manufacture and marketing of percutaneous vessel introducers, safety needles and related vascular delivery products;

the design, development, manufacture and marketing of implantable stimulation leads, lead delivery systems, and lead accessories for cardiac rhythm management, neuromodulation, and hearing restoration markets; and

the manufacture of medical devices and components for other medical product companies on a contract basis.

On October 23, 2003, we completed our acquisition of the operating assets of BIOMEC Cardiovascular Inc. (BCI) from BIOMEC Inc. and began to operate the BCI business through our wholly-owned subsidiary, Enpath Lead Technologies, Inc. (ELT). We paid $18 million less assumed liabilities of approximately $1 million plus a working capital adjustment of $897,000. In addition, we made a contingent payment of $3 million on March 31, 2004, based on the final 2003 sales results of the acquired BCI business. This payment consisted of $1.2 million in cash and $1.8 million in common stock (133,588 shares @ $13.62 per share). We also made a second contingent payment on March 31, 2005 which was based on the increase in proprietary sales in 2004 over 2003, as defined in the Asset Purchase Agreement. This contingent payment totaled $488,856 and was paid out as $97,771 in cash and $391,085 in common stock (33,381 shares @ $11.56 per share).

During 2004, Enpath Medical, Inc. operated as two divisions: The Enpath Delivery Systems Division (EDS , formerly Medamicus, Inc.) and the Enpath Lead Technologies Division (ELT , formerly BCI). The divisions were aggregated into one reportable segment: the manufacture and sale of medical devices. The divisions have similar technology, manufacturing, customers and regulatory activities and we combined our sales and marketing and research and development activities to take advantage of similarities in customers and product development. Effective January 1, 2005, the divisional structure was eliminated and we now operate as one organization located in two facilities. Additionally, on March 15, 2005, we merged the Enpath Lead Technologies, Inc. subsidiary into Enpath Medical, Inc.

The table below shows the breakdown of the purchase price we paid to date to acquire the operating assets of BCI and how we assigned it to our assets and liabilities:

Purchase Price Summary

		Amount
Initial payment (cash and stock)	$	17,010,000
Working capital adjustment		897,000
Direct acquisition costs		1,263,000
First contingent payment (cash and stock)		3,032,000
Second contingent payment (cash and stock)		489,000
Total Consideration	**$**	**22,691,000**

Values Assigned to Assets & Liabilities

		Amount
Current assets	$	3,756,000
Current liabilities		(1,011,000)
Property & equipment		1,733,000
Acquired in-process R&D		2,650,000
Identifiable intangibles		5,955,000
Goodwill		9,608,000
Net Assets Acquired	**$**	**22,691,000**

We wrote off the $2,650,000 of acquired in-process R&D in the fourth quarter of 2003. We continue to amortize the $5,955,000 of identifiable intangibles over five to thirty years which will result in amortization expense in 2005 of approximately $153,000 per quarter.

Results of Operations

Three months ended March 31, 2005 compared to three months ended March 31, 2004

Total net sales were $6,616,752 for the three months ended March 31, 2005, compared to $7,297,054 for the three months ended March 31, 2004, representing a 9.3% decrease.

Delivery Systems Product Line

Sales of our core introducer products were $4,058,325 for the three months ended March 31, 2005, compared to $3,741,631 for the three months ended March 31, 2004, representing an 8.5% increase. This increase was primarily due to increased sales of our FlowGuard valved introducer, as well as continued growth in sales to both new and existing customers. We expect sales of introducer products over the next several quarters to remain flat and approximate the sales achieved in the first quarter of 2005 due to the fact that our FlowGuard introducer has been in the marketplace for almost one year and sales patterns have stabilized after the initial ramp-up.

Sales of our advanced delivery products were $232,153 for the three months ended March 31, 2005, compared to $707,225 for the three months ended March 31, 2004, representing a 67.2% decrease. This decrease was primarily due to reduced shipments of advanced delivery components and kits to Medtronic in support of their Cardiac Re-Synchronization Therapy devices. We previously announced the transition of these products from our facility to Medtronic s and we continue to see volatility in the order patterns as this transition continues. We expect sales of these components and kits to Medtronic to be higher in the second quarter of 2005. The growth opportunity for our advanced delivery product line lies with the development and sale of sophisticated delivery catheters that will have utility in the treatment of atrial fibrillation, percutaneous mitral valve repair, carotid stent placement, and a variety of renal and peripheral interventions. We are continuing our work with several different customers on these catheters. Each of these delivery catheters is based on our proprietary technology and could potentially be used in new treatments being developed by our customers addressing large patient populations. Some of our partners are further along than others, and on track to bring their therapeutic device to market sometime in 2005. We expect advanced delivery product sales to increase in the second half of 2005 as our customers begin to launch their new devices into the marketplace with our delivery systems.

Sales of our safety products were $94,150 for the three months ended March 31, 2005, compared to $175,571 for the three months ended March 31, 2004, representing a 46.4% decrease. As we reported in our Form 10-K for 2004, our two largest

safety needle customers, Medtronic, Inc. and Cook Incorporated, both informed us in June 2004 that market acceptance of the safety needle was very modest. As a result, we determined that the current fair value of our safety needle assets at June 30, 2004 was $315,000. This resulted in a one-time impairment charge of approximately $2.8 million which we reflected in the results from operations for the three months ended June 30, 2004. We expect sales of safety needles to remain soft for the foreseeable future and we are continuing to evaluate our options for this product. On March 31, 2005, we had inventory of safety needles totaling $250,000 which amounted to approximately 5% of total inventory. We are continuing to sell safety needles on a monthly basis and continue to make the required royalty payments based on these sales. We are also reducing the inventory levels of these products and we estimate that we have approximately a 12 month supply of safety needle inventory on hand.

Contract manufacturing sales were $160,699 for the three months ended March 31, 2005, compared to $133,673 for the three months ended March 31, 2004, representing a 20.2% increase. Contract manufacturing is a very small part of our overall sales and we do not actively seek this type of business. We expect to see reduced contract manufacturing sales for each of the remaining three quarters when compared to first quarter 2005 sales.

Other sales, consisting of engineering services and freight charges were $338,295 for the three months ended March 31, 2005, compared to $113,080 for the three months ended March 31, 2004, representing a 199.2% increase. This increase was primarily due to increased engineering service sales on behalf of our customers as we continue to work on new development projects. We expect other sales over the next several quarters to be lower than the first quarter of 2005 as we complete our work on several of the development projects for our customers.

Gross profits were $2,028,726 for the three months ended March 31, 2005, compared to $2,256,340 for the three months ended March 31, 2004, representing a 10.1% decrease. Total gross profit as a percent of sales decreased from 46.3% in 2004 to 41.5% in 2005 primarily due to the decrease in sales of high margin advance delivery products, as well as inefficiencies related to lower levels of production than in previous quarters. We are also incurring ramp-up costs as we bring up production capabilities for advanced steerable introducer manufacturing. We expect gross profit as a percent of sales to increase slightly in the second quarter due to anticipated sales increases of advanced delivery components to Medtronic. However, we do not expect to see large increases in gross profit as a percent of sales until we begin selling advanced delivery catheters and begin to absorb some of the increased overhead associated with this product.

Lead Technologies Product Line

Sales of our proprietary products, consisting of implantable stimulation leads, lead delivery systems and adaptors were $713,739 for the three months ended March 31, 2005, compared to $1,080,212 for the three months ended March 31, 2004, representing a 33.9% decrease. This decrease was primarily due to continued reduced sales of leads and adaptors to our largest lead customer. In the first quarter of 2004, this customer informed us that they had a significant overstock situation and that they would be reducing orders until it was rectified. Recent forecasts from this customer would indicate that this situation is beginning to rectify itself. On March 21, 2005, we received European approval to begin selling the Myopore Rx steroid lead through one of our OEM customers and the first shipment of these leads was made in April 2005. We expect to receive European approval for our second Myopore Rx OEM customer within the next 4-6 weeks and shipments to that customer should also commence in the second quarter. While we expect proprietary product sales to increase in the second quarter of 2005 due to the European approvals and pending release of our Fastac Flex device, we do not expect to see large increases in proprietary product sales until the FDA situation is resolved with regard to our Myopore Rx device, as described below.

Our history on the Myopore Rx Pre Market Approval ("PMA") submission with the FDA began in April 2004, when we met with the FDA to determine the regulatory pathway for this product. We received a determination from the FDA that this product would be an appropriate candidate for a Paper PMA, requiring an approved GMP animal study combined with a review of the clinical literature, but no human clinical trials. By adhering to these determination guidelines, we submitted the first complete PMA application in August 2004. In early December 2004, we received a non-approvable letter from the FDA with the major deficiencies citing the results of the animal study as not meeting the expectations of the FDA (even though the study results met the study objectives) and the clinical literature review provided lacked

robustness. In early January 2005, we again met with the FDA to review updated animal study data, more retrospective clinical information, and a draft of the clinical section for the instructions for use. In early March, after repeated attempts to reach the FDA, they informed us that what we had provided in January was not sufficient for approval. Most recently we met with the FDA in Washington on Monday, April 11, 2005. These meetings were held to discuss our proposal for collecting prospective human clinical data on our steroid epicardial lead and to review administrative issues surrounding our PMA submission. Because of the magnitude of the human clinical study suggested by the FDA, it is unlikely that we could accommodate its request due to the cost and time required to conduct such a study. We are therefore using the FDA appeal process as our next course of

action. We are currently scheduled to present our appeal to the FDA on June 1, 2005. The FDA will then have 30-60 days to decide whether to overturn the previous decision and grant approval or stick with their original non-approval decision. If the FDA decides to stick with their original non-approval decision, there is yet another appeal level that is available to us, should we so choose.

Sales of our contract manufacturing products were $899,515 for the three months ended March 31, 2005 compared to $1,333,766 for the three months ended March 31, 2004, representing a 32.6% decrease. This decrease was primarily due to discontinuing several contract manufacturing projects during the second quarter of 2004 because the margins were unacceptable and the projects were inconsistent with our product focus. Contract manufacturing sales were also affected by our largest lead customer s overstock situation, although recent forecasts from this customer would indicate that this situation is beginning to rectify itself. We expect contract manufacturing product sales to increase slightly over each of the next three quarters when compared to the first quarter of 2005.

Engineering service sales were $119,873 for the three months ended March 31, 2005, compared to $11,896 for the three months ended March 31, 2004, representing a 907.7% increase. This increase was primarily due to an increased number of projects underway on behalf of our customers related to new lead development. We expect these sales to increase over the next three quarters as we continue working on development projects for our customers.

Gross profits were $337,799 for the three months ended March 31, 2005, compared to $511,894 for the three months ended March 31, 2004, representing a 34.0% decrease. Total gross profit as a percent of sales decreased from 21.1% in 2004 to 19.5% in 2005, primarily due to the fact that we simply have too much fixed overhead at our Lead Technologies facility to spread over the current sales level. We expect to see some improvement in these margins as sales begin to accelerate, but it is unlikely that we will achieve margin levels in the 40% plus range similar to the Delivery Systems facility until we are in full scale production of the Myopore Rx and Fastac Flex.

Expenses

Research and development expenses were $1,377,973 or 20.8% of sales for the three months ended March 31, 2005 compared to $1,046,703 or 14.3% of sales for the three months ended March 31, 2004. A significant portion of our increased research and development expenditures centers around the use of consultant advisors to respond to the various issues being raised by the FDA in our application for marketing clearance on the Myopore Rx. In addition, we spent significant resources on modifying certain product features of the Fastac Flex to make it more robust. The improved product will be available for sale in the US by early May, although at this time our distribution partners are uncertain as to the timing of the launch of the Fastac Flex in light of the Myopore Rx FDA situation. We also incurred significant costs related to providing clinical use product for a number of our steerable introducer customers. Manufacturing sophisticated products by hand the first time typically results in inefficiencies and yield costs which we absorb into our development process. We expect research and development expenditures in the second quarter to be slightly higher than the first quarter as we continue finalizing some of our development projects, with reductions in spending commencing in the third quarter.

Sales and marketing expenses were $435,235 or 6.6% of sales for the three months ended March 31, 2005 compared to $367,131 or 5.0% of sales for the three months ended March 31, 2004. This increase was primarily due to increased spending on salaries, printed supplies, physician education activities and insurance. We hired an additional product marketing manager and started rolling out our new corporate branding logo to the market. We expect sales and marketing expenses to increase slightly on a quarterly basis for the remaining three quarters of 2005 as we begin to roll out our new products and associated marketing programs.

General and administrative expenses were $1,021,334 or 15.4% of sales for the three months ended March 31, 2005 compared to $908,949 for the three months ended March 31, 2004. This increase was primarily due to increased spending on accounting and legal services, consulting and insurance. We are continuing our efforts on complying with new governance and disclosure requirements, and we also incurred some one-time

costs related to recruitment and contract negotiation activities. We expect general and administrative expenses over each of the next three quarters to be slightly lower than the expenses experienced in the first quarter of 2005.

Interest income decreased $1,395 and interest expense increased $15,337 for the three months ended March 31, 2005 compared with the same period in 2004. Interest income decreased primarily due to lower cash balances resulting from the use of our cash to fund the BCI acquisition. Interest expense increased primarily due to increased interest payments on the line of credit borrowings.

As a result, we had a net loss of $350,077 or $.06 per diluted share for the three months ended March 31, 2005, compared to net income of $273,133 or $.05 per diluted share for the three months ended March 31, 2004.

Finally, we regularly grant incentive stock options to our employees pursuant to our shareholder-approved Enpath Medical, Inc. 1999 Incentive Stock Option Plan. During the three month period ended March 31, 2005, we granted options from this plan to purchase a total of 151,000 shares of our common stock. Of this total, Enpath Medical Executive Officers James D. Hartman, Mark C. Kraus, James L. Mellor, Michael D. Erdmann, James E. McCrave and James M. Reed received grants of 10,000 shares, 15,000 shares, 15,000 shares, 4,000 shares, 3,000 shares and 3,000 shares, respectively, on February 16, 2005, at a price of $8.52 per share, which was the last sale price of the stock on that date.

Liquidity and Capital Resources

Net cash provided by operating activities for the three months ended March 31, 2005 was $687,866, consisting of a net loss of $350,077, adjusted for non-cash items of depreciation and amortization of $608,039, plus a net change in operating assets and liabilities of $429,904. Accounts receivable decreased $678,453, primarily due to lower sales levels in the first quarter of 2005, compared to the fourth quarter of 2004, as well as faster customer payments during the quarter. Collections from customers averaged 40 days at the end of March 2005 compared to 45 days at the end of December 2004. Inventory increased $222,924, primarily due to lower sales during the quarter, as well as continuing our new distribution strategy of maintaining higher levels of finished goods for our customers. While this strategy has the short-term impact of increasing our inventories, it significantly shortens the lead times our customers experience when they order our products. We had cash totaling $21,471 as of March 31, 2005. Because we have been utilizing our bank line of credit, we have been using excess cash to pay down the credit line in order to minimize interest expense. We will continue to maintain a small cash balance while we utilize our line of credit.

Net cash used in investing activities for the three months ended March 31, 2005 was $482,359. Equipment was purchased totaling $280,844 and we had additions to intangible assets of $103,744. We also paid BIOMEC Inc. an additional $97,771 in cash as part of the second contingent payment related to the acquisition.

Net cash used in financing activities for the three months ended March 31, 2005 was $546,661. We made note payments in the amount of $250,002, capital lease payments of $19,896 and paid down our line of credit by $306,652. This was offset by cash received upon the exercise of options of $29,889.

As a result, our cash and cash equivalents were $21,471 as of March 31, 2005 compared to $362,625 at December 31, 2004. Working capital decreased slightly from $5.2 million as of December 31, 2004 to $4.9 million as of March 31, 2005.

We currently have two major customers that account for more than 10% of our sales. One customer accounted for 27% and 37% of our sales and 18% and 27% of our accounts receivable and a second customer accounted for 20% and 17% of our sales and 24% and 16% of our accounts receivable for the three months ended March 31, 2005 and 2004, respectively.

On October 23, 2003, we entered into a financing arrangement with a bank that included a five-year term loan of $5 million, which was used to finance a portion of the BCI acquisition, and a $3 million line of credit. On March 31, 2005, the bank renewed the line of credit, increased the limit to $4 million and revised the expiration date to April 30, 2006. The borrowings are secured by substantially all of our assets and also contain financial covenants that must be met on a quarterly basis. The agreement also prohibits the payment of dividends without the consent of the lender.

Payments on the term loan consist of monthly principal payments of $83,334 plus interest at Libor plus 2.5%. These payments commenced in November 2003. The line of credit bears interest at Libor plus 2.25% with no minimum interest due and expires on April 30, 2006. The

availability under the line is subject to borrowing base requirements, and advances are at the discretion of the lender. There were borrowings of $575,000 outstanding under the line of credit at March 31, 2005 with $3,425,000 still available for use. This commitment is summarized as described below:

Other Commercial Commitment	Total Amount Committed	Outstanding at 03/31/05	Date of Expiration
Line of credit	$ 4,000,000	$ 575,000	April 30, 2006

A summary of our contractual cash obligations at March 31, 2005 is as follows:

		Payments due by period			
Contractual Obligations	**Total**	**2005**	**2006**	**2007**	**2008**
Long-term debt, including interest	$ 3,977,846	$ 924,915	$ 1,128,265	$ 1,071,506	$ 853,160
Operating leases	$ 1,058,087	348,974	337,050	191,108	180,955
Total contractual cash obligations	**$ 5,035,933**	**$ 1,273,889**	**$ 1,465,315**	**$ 1,262,614**	**$ 1,034,115**

While we believe that we have sufficient resources with our current cash and credit facility to make payments required under the acquisition, to meet our long-term debt obligations and fund our planned operations for fiscal 2005, there is no assurance that we will not need additional capital in the future. Sources of additional capital may include additional debt financing or the sale of debt or equity securities. There can be no assurance that we will be able to successfully obtain additional capital on favorable terms.

Critical Accounting Policies and Estimates

Our significant accounting policies and estimates are summarized in the footnotes to our annual consolidated financial statements. Some of our accounting policies require management to exercise significant judgment in selecting the appropriate assumptions for calculating financial estimates. These judgments are subject to an inherent degree of uncertainty. These judgments are based on our historical experience, known trends in our industry, terms of existing contracts and other information from outside sources, as appropriate. Actual results may differ from these estimates under different assumptions and conditions. Certain of the most critical policies that require significant judgment are as follows:

Revenue Recognition

We recognize revenue in accordance with Staff Accounting Bulletin 104, *Revenue Recognition in Financial Statements* when all of the following criteria are met: persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the selling price is fixed or determinable and collectability is reasonably assured.

Allowance for Doubtful Accounts

We establish estimates of the uncollectability of accounts receivable. Our management analyzes accounts receivable, historical write-offs as bad debts, customer concentrations, customer credit-worthiness, current economic trends and changes in customer payment terms when evaluating the adequacy of the allowance for doubtful accounts. We maintain an allowance for doubtful accounts at an amount that we estimate to be sufficient to provide adequate protection against losses resulting from collecting less than full payment on receivables. A considerable amount of judgment is required when assessing the realizability of receivables, including assessing the probability of collection and the current credit-worthiness of each customer. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, an additional provision for doubtful accounts may be required. We have not experienced significant bad debt expense and our reserve for doubtful accounts of $69,000 should be adequate for any exposure to loss in our March 31, 2005 accounts receivable.

Allowance for Excess and Slow-Moving Inventory

Inventories, which are composed of purchased parts and subassemblies, work in process and finished goods, are valued at the lower of cost or market with cost being determined by the first-in, first-out method. On a periodic basis, we analyze the level of inventory on hand, its cost in relation to market value and estimated customer requirements to determine whether write-downs for excess or slow-moving inventory are required. Actual customer requirements in any future periods are inherently uncertain and thus may differ from estimates. If actual or expected requirements were significantly greater or lower than the established reserves, a reduction or increase to the obsolescence allowance would be recorded in the period in which such a determination was made. We have established reserves for excess and slow-moving inventories and believe the reserve of $162,000 at March 31, 2005 is adequate.

Valuation of Goodwill and Long-Lived Assets including Intangible Assets with Finite Lives

As a matter of policy, we review our major assets for impairment at least annually, and whenever events or changes in circumstances indicate that the carrying value may not be recoverable. The test for impairment of finite life assets requires us to make estimates of the fair value of our long-lived assets, primarily based on projected future cash flows using discount rates determined by management to be commensurate with the risk inherent in the current business model or another valuation technique. For indefinite life intangibles, we determine whether the carrying amount of the reporting unit s net assets exceeds its expected future cash flows. If we determine that the carrying value of these assets may not be recoverable, we will be required to reduce the valuation of these assets on our financial statements. Significant intangible assets include the following:

Goodwill

The estimate of the fair value of the goodwill that resulted from our recent acquisition of BCI and the annual impairment test of this asset are significant estimates and require judgment in projecting future cash flows as well as considering the current amount recorded of $9.6 million.

Safety Needle

The determination of the safety needle intangible and equipment impairments during 2004 was a significant estimate in 2004. In addition, the realization of our remaining investment in the license agreement and manufacturing equipment related to the safety needle (aggregate net balance of $237,375 at March 31, 2005) is dependent upon attaining a sustained level of sales of this product. We currently are comfortable projecting a level of future sales that is sufficient to allow us to fully realize the adjusted investment we have remaining in the safety needle inventory and equipment. However, if actual sales fail to reach these levels, our adjusted investment in this product may not be fully realizable in the future.

Other Intangibles with Finite Lives

Other intangibles with finite lives consist primarily of purchased technology, trade name, patents, customer relationships and trademarks (aggregate net balance of $5.7 million at March 31, 2005) are being amortized on a straight-line method over their estimated useful lives, ranging from 2 to 30 years.

Allocation of Purchase Price Paid for the BCI Acquisition

As a result of our acquisition of BCI, we were required to allocate the consideration paid for BCI between tangible assets, identifiable intangible assets, including in-process research and development (IPR&D), and goodwill. The value assigned to IPR&D was determined by identifying those acquired specific in-process research and development projects that would be continued and for which (a) technological feasibility had not been established at the acquisition date, (b) there was no alternative future use, and (c) the fair value was estimable with reasonable reliability. We were required to make significant estimates to determine the portion of the purchase price allocated to IPR&D and other intangible assets. We engaged an independent valuation firm to assist in the determination of the fair values of the intangible assets. The amount of the purchase price allocated to IPR&D and other intangible assets was determined by estimating the future cash flows of each project or technology and discounting the net cash flows back to their present values. The discount rates used in calculating the present value of the various intangibles were in accordance with accepted valuation methods and for IPR&D also included the consideration of the risks of not achieving commercial feasibility. The goodwill that resulted from this acquisition represents the excess of the total purchase price over the fair value of the total tangible and identifiable intangible net assets acquired.

In-Process Research and Development (IPR&D)

Development projects, that had not yet reached technological feasibility and had no alternative future use, were classified as in-process research and development. The purchase price assigned to those projects was immediately expensed on the acquisition date and was reflected as an expense in the 2003 consolidated statements of operations. The in-process research and development projects were as follows: steroid leads ($1.3 million), adapters ($1 million) and an implant tool ($350,000). The estimated value of these projects was determined using a discounted cash flow model. The discount rates used considered the stage of completion and the risk surrounding the successful development and commercialization of each of the purchased in-process technology projects. Some of the original assumptions related to these projects were as follows:

Initial Assumptions October 23, 2003

Category	Leads	Tool	Adaptor
Costs incurred as of 10/23/03	$ 47,000	$ 203,000	$ 75,000
Estimated cost to complete	$ 602,000	$ 658,000	$ 529,000
Percent complete (dollars)	7.2%	23.6%	12.4%

Months spent up to 10/23/03	12	12	12
Estimated months to complete	24	12	12
Percent complete (months)	33.3%	50.0%	50.0%
Year revenues estimated to begin	2005	2004	2004
Regulatory approval received	No	No	No

The discount rates used in valuing the developed, core and in-process technologies ranged from 26% to 50%. A higher discount rate was used to value the in-process research and development, due to the inherent uncertainties surrounding the successful development of the in-process projects, FDA approval, and the market acceptance of the products. The percentage of completion for each of the in-process projects was determined using costs incurred to date on each project as compared to the remaining estimated costs to be incurred to bring each of the projects to technological feasibility.

We believe that the three in-process projects described above will reach technological feasibility. However, because of the risks associated with the commercial viability of these products, there can be no assurance that these projects will actually achieve commercialization. These risks include the delay or failure to obtain the necessary regulatory approvals or the

failure to achieve market acceptance. We have received European approval to begin selling the steroid lead through one OEM partner, as well as FDA approval to begin selling the Fastac Flex tool. We anticipate receiving European approval for the steroid lead for a second OEM partner in May or June 2005, but do not anticipate FDA approval on this lead anytime soon. Updated information related to these three projects is summarized below:

Status On March 31, 2005

Category	Leads	Tool	Adaptor
Costs incurred as of 03/31/05	$ 1,236,000	$ 905,000	$ 104,000
Estimated cost to complete	$ 150,000	$ 95,000	$ 100,000
Percent complete (dollars)	89.2%	90.5%	51.0%
Months spent up to 03/31/05	29	29	29
Estimated months to complete	9	4	5
Percent complete (months)	76.3%	87.9%	85.3%
Year revenues estimated to begin	2005	2005	2005
Regulatory approval received			
FDA	No	Yes	No
European	Yes(1)	No	No

(1) Approval for one partner

The scope of the adaptor project has been significantly reduced due to entering into an exclusive arrangement with a major CRM company for IS-4 adaptors.

Forward Looking Statements

Statements included in this Quarterly Report on Form 10-Q, in our annual and quarterly reports, in filings by us with the Securities and Exchange Commission, in our press releases, and oral statements made with the approval of an authorized executive officer that are not historical or current facts are forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Certain important factors could cause results to differ materially from those anticipated by some of these statements. Investors are cautioned that all forward-looking statements involve risks and uncertainties. A number of factors that could cause results to differ materially are those discussed in our Annual Report on Form 10-K for the year ended December 31, 2004 entitled Risk Factors. All forward-looking statements made by us, whether written or oral, and whether made by or on behalf of us are expressly qualified by these cautionary statements. Additional factors that could cause results to differ materially are the following: our ability to complete the integration of the ELT operation; our dependence upon a limited number of key customers for our revenue; our ability to complete development of our Myopore Rx steroid epicardial lead and Fastac Flex delivery tool and obtain all necessary FDA and European approval to market these devices; our ability and our distribution partners ability to successfully introduce the Myopore Rx and Fastac Flex; the ability of our customers to successfully develop and market therapies that utilize our advanced delivery systems, including our steerable catheter delivery system; our ability to obtain FDA clearance to market our steerable catheter delivery system; our dependence upon licensing agreements with third parties for the technology underlying some of our products, our ability to effectively manufacture our products, including the new Myopore Rx steroid lead and the Fastac Flex delivery tool in anticipated required quantities; our ability to develop or acquire new products to increase revenues; our ability to attract and retain key personnel; introduction of competitive products; our ability to successfully protect our intellectual property against misappropriation or claims of infringement by third parties; government regulatory matters; economic conditions; and our ability to raise capital. All our forward-looking statements, whether written or oral are expressly qualified by these cautionary statements. In addition, we disclaim any obligation to update forward-looking statements to reflect events or circumstances after the date hereof.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to changes in interest rates primarily as a result of our borrowing activities used to maintain liquidity. Our earnings have not been materially affected by changes in interest rates on our floating interest rate debt because interest rates have remained fairly stable and we only started utilizing our line of credit beginning in June 2004. Based on our current borrowings and anticipated line of credit requirements in 2005, an increase of 100 basis points in prevailing interest rates would increase our annual interest expense by less than $100,000.

Item 4. **Controls and Procedures**

(a) Evaluation of Disclosure Controls and Procedures.

Management, with the participation of the Company s principal executive officer, James D. Hartman, has evaluated the effectiveness of the design and operation of the disclosure controls and procedures, as defined in Rules 13a-15(e) under the Securities Exchange Act of 1934, as of the end of the period covered by this report. Management has concluded that the Company s disclosure controls and procedures are effective to ensure that information required to be disclosed in the reports that the Company files under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC and that the disclosure controls are also effective to ensure that information required to be disclosed in the Company s Exchange Act reports is accumulated and communicated to management, including the principal executive officer, to allow timely decisions regarding required disclosure.

(b) Changes in Internal Controls.

There have been no changes in internal control over financial reporting that occurred during the fiscal quarter covered by this report that have materially affected, or are reasonably likely to materially affect, the registrant s internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1 Legal Proceedings

None

Item 2 Unregistered Sale of Equity Securities and Use of Proceeds

None

Item 3 Defaults Upon Senior Securities

None

Item 4 - Submission of Matters to a Vote of Security Holders

(a). The Company held its annual meeting of shareholders on April 28, 2005.

(b). The Company solicited proxies from its shareholders to vote on the following items:

To elect six directors to serve until the next Annual Meeting of Shareholders or until their successors are duly elected.

To amend the Enpath Medical, Inc. 1999 Non-Employee Director and Medical Advisory Board Stock Option Plan to (a) increase the number of shares of common stock authorized for issuance thereunder by 200,000, from 200,000 shares to 400,000 shares, and (b) to amend the Plan to allow for grants of restricted stock.

To amend the Enpath Medical, Inc. 1999 Incentive Stock Option Plan to allow for grants of restricted stock

To ratify the appointment of McGladrey & Pullen, LLP as independent registered public accounting firm for the Company for the fiscal year ending December 31, 2005.

A total of 5,510,837 votes were cast in person or by proxy at the annual meeting and the vote counts were as follows:

Proposal	For	Against	Withhold	Abstain	Broker Non Vote	Totals
Election of Directors						
Thomas L. Auth	5,058,743		452,094			5,510,837
Michael D. Dale	5,055,256		455,581			5,510,837
Albert Emola	5,219,875		290,962			5,510,837
James D. Hartman	5,220,704		290,133			5,510,837
Trevor O. Jones	5,058,252		452,585			5,510,837
Richard F. Sauter	5,221,967		288,870			5,510,837
Amend 1999 Director Plan	3,125,023	655,102		67,071	1,663,641	5,510,837
Amend 1999 Incentive Plan	3,314,785	467,690		64,721	1,663,641	5,510,837
Ratify Auditors	5,259,697	216,387		34,753		5,510,837

Accordingly, each nominee was elected to serve as a director, the amendment to the 1999 Non-Employee Director Plan, the amendment to the 1999 Incentive Plan and the appointment of McGladrey & Pullen, LLP as the Company s independent auditor were ratified.

Item 5 Other Information

2005 Salaried Employee Bonus Plan

On April 28, 2005, the Compensation Committee and the Board of Directors of the Company approved the general guidelines for the Company s 2005 salaried employee bonus plan. All fulltime salaried employees, including officers of the Company, are eligible to participate in this program, subject to employment dates. Under the plan, participants may earn a bonus of up to 3% of base pay by completing individually measured objectives, provided the Company achieves a specified minimum level of profitability, slightly above break-even for the year 2005. In addition, an additional bonus of up to 3% of base pay may be earned if the Company achieves specified higher levels of profitability beyond those currently anticipated.

Amendment of the Enpath Medical, Inc. 1999 Non-Employee Director and Medical Advisory Board Stock Option Plan

On April 28, 2005, the shareholders of the Company approved amendments to the Enpath Medical, Inc. 1999 Non-Employee Director and Medical Advisory Board Stock Option Plan that (a) increased the number of shares of common stock authorized for issuance under the Plan by 200,000, from 200,000 shares to 400,000 shares, and (b) allows for future grants of restricted stock under the Plan in the future.

Amendment of Enpath Medical, Inc. 1999 Incentive Stock Option Plan to Allow Grants of Restricted Stock.

On April 28, 2005, the shareholders of the Company approved an amendment to the Enpath Medical, Inc. 1999 Incentive Stock Option Plan that allows for future grants of restricted stock under the Plan.

Acceleration of Stock Option Vesting Schedule

On April 28, 2005, the Board of Directors of the Company took action to accelerate vesting of all outstanding employee stock options of the Company. Summary information related to these options is shown below.

Employees	Total	Vested	Unvested
Underwater Options	561,900	122,100	439,800
In The Money Options	108,500	91,900	16,600
Total Options	**670,400**	**214,000**	**456,400**

As of that date, the Company had a total of 670,400 employee options outstanding, of which 214,000 were vested and 456,400 were unvested. The Board accelerated the vesting schedule of the 456,400 unvested employee options, of which 439,800 were underwater and 16,600 were in the money. Unvested options that were granted to Board members were not subject to the accelerated vesting.

The Board took the action to accelerate the vesting of the options to eliminate approximately $1.3 million in compensation expense that the Company would otherwise have incurred over four years beginning in 2006, upon the adoption of FAS 123(R). Under this statement, the Company would have been required to recognize the expense associated with these option grants as the options vest.

In connection with the accelerated vesting of these options, the Board of Directors is re-examining the Company s method of compensating employees and Board members through equity awards. The Board expects that future equity compensation will consist of restricted stock awards or a combination of restricted stock and stock options. As noted above, on April 28, 2005, shareholders of the Company approved amendments to the Enpath Medical, Inc. 1999 Non-Employee Director and Medical Advisor Board Plan and the Incentive Stock Option Plan to allow the issuance of restricted stock grants.

Item 6 Exhibits

(a) Exhibits:

Exhibit 31: Certification of principal executive officer and principal financial officer pursuant to Section 301 of the Sarbanes-Oxley Act of 2002 (Rules 13a-14 and 15d-14 of the Exchange Act)

Exhibit 32: Certification pursuant to Section 906 of the Sarbanes Oxley Act of 2002 (18 U.S.C. Section 1350)

SIGNATURE

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized:

Enpath Medical, Inc.

Date: May 3, 2005

By: /s/ James D. Hartman
Chairman, Chief Executive Officer and Chief Financial Officer