

SECURITIES AND EXCHANGE COMMISSION

FORM 10-Q

Quarterly report pursuant to sections 13 or 15(d)

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FILER

**PHYSIOMETRIX INC**

CIK: **1010397** | IRS No.: **770238187** | State of Incorporation: **DE** | Fiscal Year End: **1231**  
Type: **10-Q** | Act: **34** | File No.: **000-27956** | Film No.: **1697685**  
SIC: **3845** Electromedical & electrotherapeutic apparatus

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# SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

## FORM 10-Q

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

For the quarterly period ended June 30, 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 1010397

\_\_\_\_\_

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## **PHYSIOMETRIX, INC.**

(Exact name of registrant as specified in its charter)

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**Delaware**

**77-0248588**

(State or other jurisdiction of  
incorporation or organization)

(IRS Employer identification No.)

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**Five Billerica Park, N. Billerica, MA**

**01862-1256**

(Address of principal executive offices)

(Zip code)

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**(978) 670-2422**

(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.

ITEM 1 - Yes  No

ITEM 2 - Yes  No

The number of shares outstanding of each of the issuer's classes of common stock as of

Class \_\_\_\_\_

Outstanding at June 30, 2001 \_\_\_\_\_

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**PHYSIOMETRIX, INC.**  
**UNAUDITED CONDENSED BALANCE SHEETS**

	<b>December 31</b>	<b>June 30</b>
	<b>2000</b>	<b>2001</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 3,399,310	\$1,964,845
Short-term investments	18,450,817	14,346,229
Accounts receivable, net	1,342,076	37,677
Inventories	1,010,466	3,173,872
Prepaid expenses	336,412	242,293
Total current assets	24,539,081	19,764,916
Property, plant and equipment	947,169	1,218,228
Less allowances for depreciation	(486,893)	(589,181)
	460,276	629,047
Due from officer	84,000	84,000
Other assets	12,822	12,822

Total assets	\$ 25,096,179	\$20,490,785
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**LIABILITIES AND STOCKHOLDERS' EQUITY**

Current liabilities:

Accounts payable	\$ 1,072,527	\$771,940
Accrued expenses	1,040,095	764,913

Total current liabilities	2,112,622	1,536,853
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Stockholders' equity

Preferred stock: \$.001 par value; 10,000,000 shares authorized: none issued and outstanding	-	-
Common stock: \$.001 par value; 50,000,000 shares authorized: 8,416,182 shares in 2000 and 8,420,703 shares in 2001 issued and outstanding	8,416	8,421
Additional paid-in capital	57,448,021	57,162,498
Deferred compensation	(388,489)	(60,937)
Accumulated deficit	(34,084,391)	(38,156,050)

Total stockholders' equity	22,983,557	18,953,932
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Total liabilities and stockholders' equity	\$ 25,096,179	\$20,490,785
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See accompanying notes

**PHYSIOMETRIX, INC.  
UNAUDITED CONDENSED STATEMENTS OF OPERATIONS**

	Three Months Ended June 30		Six Months Ended June 30	
	2000	2001	2000	2001
Revenues	\$91,662	\$474,852	\$178,904	\$2,557,941
Costs and expenses:				
Cost of products sold	252,476	681,984	477,107	2,725,763
Research and development	509,678	997,741	1,440,030	1,833,751
Selling, general and administrative	424,087	1,614,999	822,157	2,605,981
	1,186,241	3,294,724	2,739,294	7,165,495
Operating loss	(1,094,579)	(2,819,872)	(2,560,390)	(4,607,554)
Interest income	314,457	213,987	430,994	535,895
Net loss	\$(780,122)	\$(2,605,885)	\$(2,129,396)	\$(4,071,659)

Basic and diluted net loss per common share	\$(0.10	) \$(0.31	) \$(0.29	) \$(0.48	)
Shares used in computing basic and diluted net loss per common share	8,015,075	8,420,703	7,286,544	8,419,486	

See accompanying notes.

**PHYSIOMETRIX, INC.**  
**UNAUDITED CONDENSED STATEMENTS OF CASH FLOWS**

	<b>Six Months Ended June 30</b>	
	<b>2000</b>	<b>2001</b>
<b>Operating activities:</b>		
Net loss	\$(2,129,396	)\$(4,071,659
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	44,996	102,288
Stock based compensation in connection with issuance of stock options to consultants	195,095	17,012
Changes in operating assets and liabilities:		
Accounts receivable	5,059	1,304,399
Inventories	(575,325	)(2,163,406
Prepaid expenses and other assets	(15,320	)94,119
Accounts payable and accrued expenses	245,922	(575,769
Net cash used in operating activities	(2,228,969	)(5,293,016
<b>Investing activities:</b>		
Purchase of equipment	(39,436	)(271,059
Purchase of short-term investments	(32,341,553	)(13,160,052
Proceeds from maturity of short-term investments	13,617,142	17,264,640
Net cash provided by (used in) investing activities	(18,763,847	)3,833,529
<b>Financing activities:</b>		
Proceeds from issuance of common stock, net	21,547,499	25,022
Net cash provided by financing activities	21,547,499	25,022
Net increase (decrease) in cash and cash equivalents	554,683	(1,434,465
Cash and cash equivalents at beginning of period	1,365,002	3,399,310
Cash and cash equivalents at end of period	\$1,919,685	\$1,964,845

See accompanying notes.

## PHYSIOMETRIX, INC.

### Notes to Unaudited Condensed Financial Statements

#### Note A - 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 in accordance with the instructions for Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included.

Operating results for the interim periods presented are not necessarily indicative of the results that may be expected for the year ending December 31, 2001 or any other interim period. The accompanying financial statements should be read in conjunction with the audited financial statements for the period ended December 31, 2000.

#### Note B - Accounting Pronouncements

The Company adopted SFAS 133, "Accounting For Derivative Instruments and Hedging Activities" in the first quarter of 2001 and its adoption did not have any impact on the Company's financial statements.

#### Note C - Inventories

Inventory is recorded at the lower of cost (first-in, first-out) or market, and consists of the following:

	December 31, 2000	June 30, 2001
Purchased components	\$986,128	\$3,044,248
Work in process	17,190	29,624
Finished units	7,148	100,000
	<u>\$1,010,466</u>	<u>\$3,173,872</u>

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

### Results of Operations

The following discussion of the financial condition and results of operations of Physiometrix, Inc. should be read in conjunction with the Financial Statements and related Notes thereto included elsewhere in this Form 10-Q. This Form 10-Q contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Actual events or results may differ materially from those projected in the forward-looking statements as a result of the factors described herein and other risks detailed from time to time in the Company's SEC reports, including its annual report on Form 10-K for the year ended December 31, 2000. Such forward-looking statements include, but are not limited to, statements concerning (i) business strategy; (ii) products under development; (iii) other products; (iv) marketing and distribution; (v) research and development; (vi) manufacturing; (vii) competition; (viii) government regulation especially as it relates to FDA approvals; (ix) third-party reimbursement (x) operating and capital requirements and (xi) clinical trials.

## Overview

Since its inception in January 1990, Physiometrix has been engaged primarily in the design and development and more recently the manufacture and sale of noninvasive, advanced medical products. The Company's products, which incorporate proprietary materials and electronics technology, are used in neurological monitoring applications. The Company's initial products are its e-Net headpiece and disposable HydroDot biosensors and custom electronics, which are packaged as the HydroDot NeuroMonitoring System. The Company also has two additional neurological monitoring products, the Equinox EEG System, which was commercially introduced in February 1997 and discontinued in June 1998, and the Patient State Analyzer (PSA) which received FDA 510(k) approval on June 30, 2000. The Company began shipments of the PSA in the third quarter of 2000 to Baxter Healthcare Corporation, our exclusive U.S. distribution partner.

Physiometrix has a limited history of operations and has experienced significant operating losses since its inception. As of June 30, 2001, the Company had an accumulated deficit of approximately \$38.2 million. The Patient State Analyzer and the HydroDot NeuroMonitoring System are currently the Company's principal commercial products. The Company's headcount increased from 22 employees at June 30, 2000 to 54 at June 30, 2001 due to the introduction and continued development of the Patient State Analyzer. The Company anticipates that its operating results will fluctuate on a quarterly basis for the foreseeable future due to several factors, including actions relating to regulatory and reimbursement matters, the extent to which the Company's products gain market acceptance, introduction of alternative means for neurophysiological monitoring and competition. Results of operations will also be affected by the progress of clinical trials and in-house development activities, and the extent to which the Company establishes distribution channels for its products domestically and internationally. For the period ended June 30, 2001, substantially all of the Company's sales were to Baxter Healthcare Corporation. There can be no assurance the Company will achieve significant commercial revenues or profitability.

### Three Months Ended June 30, 2001 and 2000

#### *Revenues*

Revenues increased 418% to \$475,000 for the three months ended June 30, 2001 from \$92,000 for the three months ended June 30, 2000. This increase is primarily due to the Company's distribution agreement with Baxter Healthcare Corporation entered into in 2000, which resulted in sales of 90 units of the Patient State Analyzer during the second quarter of 2001. Sales of the Company's HydroDot NeuroMonitoring products were relatively unchanged compared with the same quarter last year. The Company continues to explore options to either license the HydroDot NeuroMonitoring technology to another company or transition out of the business.

On a quarter-to-quarter basis, revenues decreased significantly from \$2.1 million in the first quarter of 2001 to \$475,000 in the second quarter of 2001. This decrease was due to Baxter's accumulation of inventory of Patient State Analyzer products, which reduced Baxter's requirements for these products during the quarter. The Company believes that this reduced demand was due to the generally slower level of sales of patient monitoring products, which has been influenced by economic conditions generally and in the healthcare sector in particular, as well as marketing programs being implemented by one of our competitors. The Company cannot predict Baxter's product requirements for the remainder of 2001 and beyond.

#### *Cost of Products Sold*

Cost of goods sold increased 170% to \$682,000 for the three months ended June 30, 2001 from \$252,000 for the three months ended June 30, 2000. This increase was primarily due to product costs of the Patient State Analyzer, which began during the third quarter of 2000, and additional headcount and expenses in the manufacturing group.

#### *Gross Margin*

The negative gross profit margin during the second quarter of 2001 results from costs of the product and the level of headcount and overhead required in the Company's manufacturing group. The negative gross profit margin in the same period of 2000 resulted from costs of the product and the level of headcount and overhead required in the Company's manufacturing group.

#### *Research and Development Expenses*

Research and development expenses consisting principally of headcount related expenses and consulting fees increased 96% to \$998,000 for the three months ended June 30, 2001 from \$510,000 for the three months ended June 30, 2000. This increase is primarily due to increased headcount, outside consulting and product development costs associated with continued development of the Patient State Analyzer.

#### *Selling, General and Administrative Expenses*

Selling, general and administrative expenses increased 281% to \$1,615,000 for the three months ended June 30, 2001 from \$424,000 for the three months ended June 30, 2000. This increase is due to increased headcount related expenses and sales and marketing expenses incurred related to the commercialization of the Patient State Analyzer.

#### *Interest Income and Expense:*

Interest income decreased to \$214,000 for the three months ended June 30, 2001 from \$314,000 for the three months ended June 30, 2000. This was due to lower average cash balances available for investment in 2001.

### **Six Months Ended June 30, 2001 and 2000**

#### *Revenues*

Revenues increased significantly to \$2,558,000 for the six months ended June 30, 2001 from \$179,000 for the six months ended June 30, 2000. This increase is primarily due to the Company's distribution agreement with Baxter Healthcare Corporation entered into in 2000, which resulted in sales of 490 units of the Patient State Analyzer during the first six months of 2001. Sales of the Company's HydroDot NeuroMonitoring products were relatively unchanged compared with the same quarter last year.

#### *Cost of Products Sold*

Cost of goods sold increased 471% to \$2,726,000 for the six months ended June 30, 2001 from \$477,000 for the six months ended June 30, 2000. This increase was primarily due to product costs of the Patient State Analyzer, which began during the third quarter of 2000, and additional headcount and expenses in the manufacturing group.

#### *Gross Margin*

The negative gross profit margin during the first six months of 2001 results from selling PSA units at a volume less than what is needed to cover fixed and variable costs in the manufacturing group. The negative gross profit margin in the same period of 2000 resulted from costs of the product and the level of headcount and overhead required in the Company's manufacturing group.

#### *Research and Development Expenses*

Research and development expenses consisting principally of headcount related expenses and consulting fees increased 27% to \$1,834,000 for the six months ended June 30, 2001 from \$1,440,000 for the six months ended June 30, 2000. This increase is primarily due to increased headcount, outside consulting and product development costs associated with continued development of the PSA.

#### *Selling, General and Administrative Expenses*

Selling, general and administrative expenses increased 217% to \$2,606,000 for the six months ended June 30, 2001 from \$822,000 for the six months ended June 30, 2000. This increase is due to increased headcount related expenses and sales and marketing expenses incurred related to the commercialization of the Patient State Analyzer.

#### *Interest Income and Expense:*



Interest income increased to \$536,000 for the six months ended June 30, 2001 from \$431,000 for the six months ended June 30, 2000. This was due to higher average cash balances available for investment in 2001 as a result of a private placement of the Company's common stock during the first quarter of 2000 which raised \$21.5 million in net proceeds and warrant exercises which raised \$4.4 million during 2000.

### **Liquidity and Capital Resources**

At June 30, 2001, the Company's cash, cash equivalents and short-term investments were \$16,311,000 as compared to \$21,850,000 at year ended December 31, 2000.

The Company's operating activities used cash of \$5,293,000 in the six months ended June 30, 2001 as compared to \$2,229,000 in the six months ended June 30, 2000. The increase in net cash used in 2001 compared to 2000 was primarily the result of increased inventory of the Patient State Analyzer and a decrease in accounts payable and accrued liabilities. The Company has a substantial \$3.2 million investment in inventory and will need to convert purchased components to finished units to subsequently sell to customers. The sale of these finished units will be subject to market conditions which are generally outside the Company's control. The Company expects to be able to sell these units at a price exceeding cost but we cannot assure you that we will be able to do so.

Net cash provided by investing activities in the six months ended June 30, 2001 was \$3,834,000, as compared with \$18,764,000 used in the six months ended June 30, 2000. The increase was due to the proceeds from the sale of short-term investments during the first half of 2001.

The Company's financing activities provided cash of \$25,000 in the six months ended June 30, 2001 as compared to \$21,547,000 in the six months ended June 30, 2000. During the first quarter of 2000, the Company completed a private placement of common stock that raised \$21.5 million in net proceeds.

The Company's principal source of liquidity at June 30, 2001 consists of cash, cash equivalents and short-term investments in the amount of \$16.3 million. The Company believes it has the necessary cash, cash equivalents and short-term investments on hand to fund its operations through at least the next 12 months.

The Company believes that the success of the Patient State Analyzer is the most critical component to the Company's ability to become profitable. The Company shipped the first units of the Patient State Analyzer to its exclusive U.S. distributor during the third quarter of 2000. During the fourth quarter of 2000 and first quarter of 2001, shipments exceeded the minimum amounts required to permit the U.S. distributor to maintain its exclusive distributorship of the PSA in the U.S. During the second quarter of 2001, orders by and consequently shipments to the U.S. distributor were not sufficient to meet the exclusivity provisions of the distribution agreement. The Company is currently in discussion with its U.S. distributor regarding purchase commitments for the remainder of 2001, but no agreement has yet been reached.

### **ITEM 3. RISK FACTORS**

You should carefully consider the risks described below before making an investment decision. If any of the following risks actually occur, our business, financial condition and operating results could be seriously harmed. As a result, the trading price of our common stock could decline, and you could lose all or part of the value of your investment.

**We are dependent upon the Patient State Analyzer system, and if we are unable to introduce and successfully commercialize this product, our business will be seriously harmed.**

Our business is completely dependent upon the Patient State Analyzer, or PSA, system. After introduction of the PSA system, we will need to build market acceptance for the system. Because we will depend upon our PSA system for substantially all of our future revenue and we have no other significant products, if we are unable to commence commercial sales of or achieve widespread market acceptance for the PSA system, we will not be able to sustain or grow our business. In this event, our business and operating results would be seriously harmed and our stock price would likely decline.

**We will not be able to achieve revenue growth or profitability if hospitals and anesthesia service providers do not buy and use the PSA system in sufficient quantities.**

Our revenue growth and prospects will depend on customer acceptance and usage of the PSA system. Customers may determine that the cost of the PSA system exceeds cost savings in drugs, personnel and post-anesthesia care recovery resulting from use of the PSA system. In addition, hospitals and anesthesia providers may not accept the PSA system as an accurate means of assessing a patient's level of consciousness during surgery if patients regain consciousness during surgery while being monitored with the PSA system or if they do not consider the PSA system to be a clinically reliable measuring system for other reasons. If extensive or frequent malfunctions occur, these providers may also conclude that the PSA system is unreliable. If hospitals and anesthesia providers do not accept the PSA system as cost-effective, accurate or reliable, they will not buy and use the PSA system in sufficient quantities to enable us to be profitable. In this event, our business, operating results and long-term prospects would be seriously harmed. Our stock price would also likely decline.

During the second quarter of 2001, we experienced a general slowdown in orders and in end-user demand for the PSA system. We believe that this slowdown is due in part to economic conditions generally and in the healthcare sector in particular. In addition, marketing programs instituted by one of our competitors have adversely affected our ability to sell PSA products. Finally, as a result of market feedback, we have concluded that we need to introduce a simpler headpiece for use with the PSA system. This headpiece is currently under development and is expected to be available for commercial sale by the end of 2001. At this point, we are currently unable to accurately predict future demand for the PSA, and we cannot assure you that the current economic environment and current product market environment will not continue.

**We expect to continue to incur losses in the future, and we cannot assure you that we will ever become profitable.**

We have incurred net losses in each year since inception. We expect to increase our research and development, sales and marketing and general and administrative expenses in future periods. We will spend these amounts before we receive any incremental revenue from these efforts. Therefore, our losses will be greater than the losses we would incur if we developed our business more slowly. In addition, we may find that these efforts are more expensive than we currently anticipate, which would further increase our losses. Failure to become and remain profitable may depress the market price of our common stock and our ability to raise capital and continue our operations.

**We have a limited operating history that you may use to assess our prospects, and we have no operating experience or history related to the PSA system, our current principal product.**

We have a limited history of operations. Since our inception in January 1990, we have been primarily engaged in research and development of neurophysiological monitoring products. To date, we have sold only a small number of units of our HydroDot NeuroMonitoring System and these sales have generated only limited revenues. Furthermore, these products are not central to our core business, which relates to the development and commercialization of the PSA system. We have had limited revenues from commercial sales of the PSA system. Accordingly, our historical results of operations may be of limited utility in evaluating our future prospects. In addition, we do not have experience in manufacturing, marketing or selling our products in quantities necessary for achieving profitability. Whether we can successfully manage the transition to a larger scale commercial enterprise will depend upon the successful development of our manufacturing capability, the development of our marketing and distribution network, obtaining U.S. FDA and foreign regulatory approvals for future products and other potential products and strengthening our financial and management systems, procedures and controls. With respect to our PSA system, we will need to develop in collaboration with third parties, a sales and marketing effort targeted towards anesthesiologists, rather than neurologists to whom we have previously marketed our products. Accordingly, due to the significant change in our business associated with the PSA, our historical financial information is of limited utility in evaluating our future prospects, and we cannot assure that we will be able to achieve or sustain revenue growth or profitability.

**We face intense competition and may not be able to compete effectively, which could harm the market for our products and our operating results.**

We expect to face substantial competition from larger medical device companies that have greater financial, technical, marketing and other resources than we do. As our resources in these areas are extremely limited, any current or potential competitor of ours is likely to have greater resources in these areas. In particular, Aspect Medical markets an anesthesia monitoring system that competes with the PSA. Aspect has received FDA clearance for this system and is marketing it in the U.S. and internationally. We may not be able to compete effectively

with Aspect or other potential competitors. Other companies may develop anesthesia-monitoring systems that perform better than the PSA system and/or sell for less. Competition in the sale of anesthesia monitoring systems could result in the inability of the PSA to achieve market acceptance, price reductions, fewer orders, reduced gross margins and inability to establish or erosion of market share. Any of these events would harm our business and operating results and cause our stock price to decline.

**We may not be able to keep up with new products or alternative techniques developed by competitors, which could impair our future growth and our ability to compete.**

The medical industry in which we market our products is characterized by rapid product development and technological advances. Our current or planned products are at risk of obsolescence from:

new monitoring products, based on new or improved technologies,  
new products or technologies used on patients or in the operating room during surgery in lieu of monitoring devices,  
electrical or mechanical interference from new or existing products or technologies,  
alternative techniques for evaluating the effects of anesthesia,  
significant changes in the methods of delivering anesthesia, and  
the development of new anesthetic agents.

We may not be able to improve our products or develop new products or technologies quickly enough to maintain a competitive position in our markets and continue to grow our business.

**If we do not successfully develop and introduce new or enhanced products, we could lose revenue opportunities and customers.**

As the market for anesthesia monitoring equipment matures, we need to develop and introduce new products for anesthesia monitoring or other applications. We face at least the following risks:

we may not successfully adapt the PSA system to function properly in the intensive care unit, for procedural sedation, when used with anesthetics we have not tested or with patient populations we have not studied, such as infants and young children, and  
our technology is complex, and we may not be able to develop it further for applications outside anesthesia monitoring.

If we do not successfully adapt the PSA system for new products and applications both within and outside the field of anesthesia monitoring, then we could lose revenue opportunities and customers.

**We have experienced significant operating losses to date, and our future operating results could fluctuate significantly.**

We have experienced significant operating losses since inception and, as of June 30, 2001 had an accumulated deficit of approximately \$38.2 million. The development and commercialization of the PSA system and other new products, if any, will require substantial development, clinical, regulatory and other expenditures. We expect our operating losses to continue for at least the next year as we continue to expend substantial resources to expand marketing and sales activities, scale up manufacturing capabilities, continue research and development and support regulatory and reimbursement approvals. Results of operations may fluctuate significantly from quarter to quarter and will depend upon numerous factors, including actions relating to regulatory and reimbursement matters, including particularly if the PSA system is able to garner market acceptance. In addition, competition, availability of third party reimbursement and other factors may affect our future results of operations.

**We may need additional funds, and such funds may not be available on commercially reasonable terms when we need them.**

We plan to continue to expend substantial funds for obtaining regulatory approvals, expansion of sales and marketing activities and research and development. We may be required to expend greater than anticipated funds if unforeseen difficulties arise in the course of obtaining necessary regulatory approvals or in other aspects of our business. Although we believe that our existing cash balances will be sufficient to meet our operating and capital requirements during the next 12 months, we may require additional financing within this time frame. Our future liquidity and capital requirements will depend upon numerous factors, including actions relating to regulatory matters, and the extent to which the PSA system gains market acceptance. Any additional financing, if required, may not be available on satisfactory terms or at all. Future equity financings may result in substantial dilution to the holders of our common stock. Future debt financings may require us to pledge assets and to comply with financial and operational covenants.

**Our reliance on sole and limited source suppliers could harm our ability to meet customer requirements in a timely manner or within budget.**

Some of the components that are necessary for the assembly of our PSA system are currently provided to us by separate sole suppliers or a limited group of suppliers. We purchase components through purchase orders rather than long-term supply agreements and generally do not maintain large volumes of inventory. We have experienced shortages and delays in obtaining some of the components of our PSA systems in the past, and we may experience similar delays or shortages in the future. The disruption or termination of the supply of components could cause a significant increase in the costs of these components, which could affect our profitability. A disruption or termination in the supply of components could also result in our inability to meet demand for our products, which could lead to customer dissatisfaction and damage our reputation. Furthermore, if we are required to change the manufacturer of a key component of the PSA system, we may be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could delay our ability to manufacture PSA systems in a timely manner or within budget.

**Our business depends on our intellectual property rights, and measures we take to protect those rights may not be sufficient.**

Our ability to compete effectively will depend in part on its ability to develop and maintain proprietary aspects of its technology. We cannot assure you that our issued patents or any patents that may be issued as a result of our U.S. or international patent applications will offer any degree of protection. We cannot assure you that any patents that may be issued to us or any of our patent applications will not be challenged, invalidated or circumvented in the future. In addition, we cannot assure you that competitors, many of which have substantial resources and have made substantial investments in competing technologies, will not seek to apply for and obtain patents that will prevent, limit or interfere with the our ability to make, use or sell its products either in the U.S. or in international markets.

In addition to patents, we rely on trade secrets and proprietary know how, which we seek to protect, in part, through appropriate confidentiality and proprietary information agreements. These agreements generally provide that all confidential information developed or made known to the individual by us during the course of the individual's relationship with us, is to be kept confidential and not disclosed to third parties, except in specific circumstances. The agreements generally provide that all inventions conceived by the individual in the course of rendering services to us are our exclusive property. However, some of our agreements with consultants, who typically are employed on a full time basis by academic institutions or hospitals, do not contain assignment of invention provisions. We cannot assure you that proprietary information or confidentiality agreements with employees, consultants and others will not be breached, that we would have adequate remedies for any breach, or that our trade secrets will not otherwise become known to or independently developed by competitors.

**We could become involved in litigation relating intellectual property rights, and any such litigation, even if resolved favorably to us, will result in significant cost and diversion of management' s time and effort.**

The medical device industry has been characterized by extensive litigation regarding patents and other intellectual property rights, and companies in the medical device industry have employed intellectual property litigation to gain a competitive advantage. We cannot assure you that we will not in the future become subject to patent infringement claims and litigation or interference proceedings declared by the U.S. Patent and Trademark Office to determine the priority of inventions. The defense and prosecution of intellectual property suits, USPTO interference proceedings and related legal and administrative proceedings are both costly and time consuming. Litigation may be necessary to enforce patents issued to us, to protect trade secrets or know how owned by us or to determine the enforceability, scope and validity of the proprietary rights of others.

Any litigation or interference proceedings will result in substantial expense to us and significant diversion of effort by our technical and management personnel. An adverse determination in litigation or interference proceedings to which we may become a party could subject us to significant liabilities to third parties or require us to seek licenses from third parties. Costs associated with licensing or similar arrangements that may be involved in statement of intellectual property disputes, including patent disputes, may be substantial and could include ongoing royalties. Furthermore, there can be no assurance that necessary licenses would be available to us on satisfactory terms if at all. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing, marketing and selling our products, which would seriously harm our business and operating results and would likely cause our stock price to decline.

**Our business entails the risk of product liability claims, and these claims could harm our financial condition and our ability to maintain insurance coverage.**

The manufacture and sale of our products expose us to product liability claims and product recalls, including those which may arise from misuse or malfunction of, or design flaws in, our products or use of our products with components or systems not manufactured or sold by us. Product liability claims or product recalls, regardless of their ultimate outcome, could require us to spend significant time and money in litigation or to pay significant damages. We currently maintain insurance; however, it might not cover the costs of any product liability claims made against us. Furthermore, we may not be able to obtain insurance in the future at satisfactory rates or in adequate amounts.

**If we do not attract and retain skilled personnel, we will not be able to expand our business.**

Our products are based on complex technology. Accordingly, we require skilled personnel to develop, manufacture, sell and support our products. In addition, as we move toward commercialization of our products, we will require additional personnel skilled in the sales and marketing of medical device products. Our future success will depend largely on our ability to continue to hire, train, retain and motivate additional skilled personnel, particularly sales representatives and clinical specialists who are responsible for customer education and training and post-installation customer support. We continue to experience difficulty in recruiting and retaining skilled personnel because the pool of experienced persons is small and we compete for personnel with other companies, many of which have greater resources than we do. Consequently, if we are not able to attract and retain skilled personnel, we will not be able to expand our business.

**Failure of users of the PSA system to obtain adequate reimbursement from third party payors could limit market of the system, which could prevent us from growing our business.**

Anesthesia providers are generally not reimbursed separately for patient monitoring activities, including any such activities that would involve use of the PSA system. Accordingly, potential users of the PSA system would have to justify its use based on the clinical and cost benefits they believe use of the system provides. For hospitals and outpatient surgical centers, when reimbursement is based on charges or costs, patient monitoring with the PSA system may reduce reimbursements for surgical procedures, because charges or costs may decline as a result of monitoring with the PSA system. Failure by hospitals and other users of the PSA system to obtain adequate reimbursement from third-party payors, or any reduction in the reimbursement by third-party payors to hospitals and other users as a result of using the PSA system could limit market acceptance of the PSA system, which could prevent us from growing our revenues and our business.

**Our stock price may fluctuate, which may cause your investment in our stock to suffer a decline in value.**

The market price of our common stock has fluctuated significantly in the past and may fluctuate significantly in the future in response to factors which are beyond our control. In addition, the stock market in general has recently experienced extreme price and volume fluctuations. In addition, the market prices of securities of technology and medical device companies have been extremely volatile, and have experienced fluctuations that often have been unrelated or disproportionate to the operating performance of these companies. These broad market fluctuations could result in extreme fluctuations in the price of our common stock, which could cause a decline in the value of your shares.

**We may incur significant costs from securities class litigation due to our stock price volatility.**

Our stock price may fluctuate for many reasons, including timing of regulatory actions relating to the PSA system, variations in our quarterly operating results and changes in market valuations of medical device companies. Recently, when the market price of a stock has

been volatile as our stock price may be, holders of that stock have occasionally instituted securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit of this type against us, even if the lawsuit is without merit, we could incur substantial costs defending the lawsuit. The lawsuit could also divert the time and attention of our management.

**Anti-takeover provisions in our charter documents and under Delaware law could prevent or delay transactions that stockholders may favor.**

Provisions of our restated certificate of incorporation and amended and restated by-laws may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions include:

authorizing the issuance of "blank check" preferred stock without any need for action by stockholders,

requiring supermajority stockholder voting to effect certain amendments to our restated certificate of incorporation and amended and restated by-laws,

eliminating the ability of stockholders to call special meetings of stockholders,

prohibiting stockholder action by written consent, and

establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

**PHYSIOMETRIX, INC.**

**June 30, 2001**

**PART II Other Information**

ITEM 1 Legal Proceedings:  
Not applicable.

ITEM 2 Changes in Securities:  
Not applicable.

ITEM 3 Defaults upon Senior Securities:  
Not applicable.

ITEM 4 Submission of matters to a vote of security holders:

On June 1, 2001, the company held its annual meeting of shareholders. The following items were submitted for a vote of the shareholders.

Election of James Saalfield as a class II director.

For: 6,649,364

Against: 298,545

Abstain: 0

Ratification of Ernst & Young as independent auditors for the year ended December 31, 2001.

For: 6,940,527

Against: 145

Abstain: 7,237

Approval of the 2001 Stock Option Plan.

For: 2,670,020

Against: 2,432,741

Abstain: 61,825

Non-Vote: 1,783,323

ITEM 5 Other information:  
None.

ITEM 6 Exhibits and reports on Form 8-K:

(a) Exhibits - None

(b) Reports on Form 8-K - None

**June 30, 2001**

**SIGNATURE**

Pursuant to the requirements 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.

PHYSIOMETRIX, INC.

DATE: August 3, 2001

BY: /s/John A. Williams

John A. Williams  
President, Chief Executive  
Officer

BY: /s/Daniel W. Muehl

Daniel W. Muehl  
Vice President and Chief  
Financial Officer  
(Principal Financial and  
Accounting Officer)