HEMOSENSE INC
Form 10-Q
August 12, 2005
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2005

¨ 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: 001-32541

HEMOSENSE, INC.

(Exact name of registrant as specified in its charter)

Delaware	**77-0452938**

(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

651 River Oaks Parkway, San Jose, California 95134

(Address of principal executive offices) (Zip Code)

(408) 719-1393

(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 ¨ No x

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

As of August 1, 2005, 9,589,942 shares of the registrant s common stock were outstanding.

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PART I - FINANCIAL INFORMATION

ITEM 1. CONDENSED FINANCIAL STATEMENTS

HEMOSENSE, INC.

UNAUDITED CONDENSED BALANCE SHEETS

(in thousands, except per share and share data)

	June 30, 2005	September 30, 2004
Assets		
Current assets:		
Cash and cash equivalents	$ 620	$ 433
Accounts receivable	1,341	907
Prepaid expenses and other current assets	361	230
Inventories	1,892	1,299
Deferred public offering costs	1,301	
Total current assets	5,515	2,869
Property and equipment, net	705	1,113
Technology licenses and prepaid royalties	1,395	1,964
Other assets	267	256
Total assets	$ 7,882	$ 6,202
Liabilities and Shareholders Deficit		
Current liabilities:		
Accounts payable	$ 1,666	$ 539
Accrued expenses and other liabilities	1,306	691
Capital lease, current portion	37	38
Borrowings, current portion	3,418	529
Total current liabilities	6,427	1,797
Capital lease, net of current portion	63	91
Borrowings, net of current portion	5,218	2,855
Total liabilities	11,708	4,743
Redeemable convertible preferred stock, $0.001 par value authorized: 25,749,840 shares at September 30, 2004 and 53,386,560 at June 30, 2005; Issued and outstanding: 23,635,791 shares at September 30, 2004 and 21,956,251 at June 30, 2005	34,115	36,679
Shareholders deficit:		

Common stock, $0.001 par value Authorized: 50,000,000 shares; Issued and outstanding: 588,378 and 337,347 at June 30, 2005 and September 30, 2004, respectively		
Additional paid-in capital	6,410	220
Accumulated deficit	(44,352)	(35,440)
Total shareholders deficit	(37,941)	(35,220)
Total liabilities and shareholders deficit	$ 7,882	$ 6,202

The accompanying notes are an integral part of these unaudited condensed financial statements.

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HemoSense, Inc,

UNAUDITED CONDENSED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

	Three months Ended June 30,		Nine months Ended June 30,	
	2005	2004	2005	2004
Revenue	$ 2,454	$ 889	$ 5,871	$ 2,156
Cost of goods sold	2,487	1,511	6,826	3,420
Gross loss	(33)	(622)	(955)	(1,264)
Operating expenses:				
Research and development	266	356	806	1,064
Sales and marketing	1,677	1,469	4,877	3,735
General and administrative	449	377	1,321	1,192
Total operating expenses	2,392	2,202	7,004	5,991
Loss from operations	(2,425)	(2,824)	(7,959)	(7,255)
Interest income	8	2	18	12
Interest expense	(523)	(105)	(973)	(179)
Other income (expense)	(7)	(24)	2	(27)
Net loss	$ (2,947)	$ (2,951)	$ (8,912)	$ (7,449)
Net loss per share:				
Basic and diluted	$ (5.29)	$ (8.76)	$ (19.59)	$ (22.10)
Shares used to compute net loss per share:				
Basic and diluted	557	337	455	337

The accompanying notes are an integral part of these unaudited condensed financial statements.

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HemoSense, Inc,

UNAUDITED CONDENSED STATEMENTS OF CASH FLOWS

(in thousands)

	Nine months Ended June 30,	
	2005	**2004**
Cash flows from operating activities:		
Net loss	$ (8,912)	$ (7,449)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	952	544
Amortization of debt issuance cost	279	43
Provision/write-off of inventories	105	100
Amortization of prepaid royalties	229	20
Accrued interest on note payable	70	
Changes in assets and liabilities:		
Accounts receivable	(434)	(596)
Prepaid expenses and other assets	(255)	102
Inventories	(698)	(207)
Accounts payable	390	(36)
Accrued expenses and other liabilities	159	453
Net cash used in operating activities	(8,115)	(7,026)
Cash flows from investing activities:		
Acquisition of property and equipment	(216)	(359)
Net cash used in investing activities	(216)	(359)
Cash flows from financing activities:		
Proceeds from issuance of common stock	33	
Proceeds from issuance of preferred stock, net of issuance cost	3,331	3,047
Principal payments on capital lease obligation	(29)	(33)
Proceeds from borrowing	6,093	2,907
Repayment of borrowings	(910)	(936)
Net cash provided by financing activities	8,518	4,985
Net increase (decrease) in cash and cash equivalents	187	(2,400)
Cash and cash equivalents at beginning of period	433	5,445
Cash and cash equivalents at end of period	$ 620	$ 3,045
Supplemental disclosure of cash flow information		
Cash paid during the period for interest	973	140
Non-cash financing activities		
Issuance of warrants in connection with debt	264	354

Issuance of preferred stock in exchange for supply and license agreement and prepaid royalties	565
Public offering costs included in accrued expenses and accounts payable	(1,301)

The accompanying notes are an integral part of these unaudited condensed financial statements.

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HEMOSENSE, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

1) Organization and Basis of Presentation

Organization

HemoSense, Inc. (the Company) develops, manufactures and sells easy-to-use, handheld blood coagulation monitoring systems for use by patients and healthcare professionals in the management of warfarin medication. Our product, the INRatio® System, measures the patient s blood clotting time to ensure that patients with a propensity to form clots are maintained within the therapeutic range with the proper dosage of oral anticoagulant therapy. Our system is 510(k) cleared by the Food and Drug Administration (FDA) for use by healthcare professionals as well as for patient self-testing. Our system also has European Conformity (CE marked) in Europe. The Company was incorporated in the state of Delaware in March 1997.

Initial Public Offering

The Company registered the initial public offering of its common stock, par value $0.001 per share, on a Registration Statement on Form S-1 (Registration No. 333-123705), which was declared effective on June 28, 2005. On July 1, 2005 the Company closed the initial public offering of our common stock by selling 3.5 million shares at $5.50 per share. Additionally on July 27, 2005, the underwriters of the Company s initial public offering exercised their over-allotment option to purchase 12,207 shares at $5.50 per share. Gross proceeds from the offering were $19.3 million. Total expenses from the offering were $2.6 million, which included underwriting discounts and commissions of $1.3 million, and $1.3 million in other offering-related expenses. Net offering proceeds, after deducting total expenses were $16.7 million. Upon the closing of the IPO, all of the outstanding shares of the Company s redeemable convertible preferred stock converted into 5,489,045 shares of the Company s common stock. Also, warrants for convertible preferred stock were converted into 126,977 warrants for the Company s common stock.

Basis of Presentation

The accompanying unaudited condensed financial statements of HemoSense, Inc. (the Company) have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. The unaudited interim financial statements have been prepared on the same basis as the annual financial statements. In the opinion of management, all adjustments, consisting of normal recurring adjustments necessary for the fair statement of the financial statements, have been included. The results of operations of any interim period are not necessarily indicative of the results of operations for the full year or any other interim period. Further, the preparation of unaudited condensed financial statements requires management to make estimates and assumptions that affect the recorded amounts reported therein. Actual results could differ from those estimates. A change in facts or circumstances surrounding the estimate could result in a change to estimates and impact future operating results.

The financial statements and related disclosures have been prepared with the presumption that users of the interim financial statements have read or have access to the audited financial statements for the preceding fiscal year. Accordingly, these financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended September 30, 2004 included in our Registration Statement on Form S-1 filed with the Securities and Exchange Commission. The

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results of operations for the three and nine month periods ended June 30, 2005 are not necessarily indicative of the results for the year ending September 30, 2005 or any future interim period.

2) Summary Of Significant Accounting Policies

The Company s significant accounting policies are disclosed in our Registration Statement on Form S-1 for the year ended September 30, 2004 which was filed with the Securities and Exchange Commission. The Company s significant accounting policies have not materially changed as of June 30, 2005.

Warranty

The Company records an accrual for estimated warranty costs when revenue is recognized. Warranty covers replacement costs of defective meters and related test strips. The warranty period is one year. The Company has processes in place to estimate accruals for warranty exposure. The processes include estimated failure rates and replacement costs, and known design changes. Although the Company believes it has the ability to reasonably estimate warranty expenses, unforeseen changes in factors impacting the estimate for warranty could occur and such changes could cause a material change in the Company s warranty accrual estimate. Such a change would be recorded in the period in which the change was identified. Changes in the Company s product warranty liability during the three and nine months ended June 30, 2005 and June 30, 2004, respectively, were as follows (in thousands)

	Three Months Ended June 30,		Nine months Ended June 30,	
	2005	2004	2005	2004
Balance, at the beginning of the period	$ 10	$ 3	$ 6	$ 2
Accruals and charges for warranty for the period	21	2	50	6
Cost of repairs and replacements	(18)	(1)	(43)	(4)
Balance, at the end of the period	$ 13	$ 4	$ 13	$ 4

Stock-Based Compensation

The Company accounts for stock-based compensation using the intrinsic value method prescribed in Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*. The Company s policy is to grant options with an exercise price equal to the estimated fair value of the Company s stock on the grant date. Accordingly, no compensation cost has been recognized in the Company s statement of operations for employee stock options. The Company provides additional pro forma disclosures as required under Statement of Financial Accounting Standard No. 123 (SFAS 123), Accounting for Stock-Based Compensation, as amended by SFAS No 148, *Accounting for stock-based compensation, transition and disclosure*.

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Under APB Opinion No. 25, compensation expense is based on the difference, if any, on the date of the grant, between the estimated fair value of the Company s stock and the exercise price. SFAS No. 123 defines a fair value based method of accounting for an employee stock option or similar equity instrument.

Had compensation cost for options granted to employees under the Plan been determined based on the fair value of the options at the grant date for awards, under the provisions prescribed by SFAS No. 123, as amended by SFAS No. 148, the Company s net loss would have been as follows (in thousands, except per share data):

	Three months Ended June 30,		Nine months Ended June 30,	
	2005	2004	2005	2004
Net loss as reported	$ (2,947)	$ (2,951)	$ (8,912)	$ (7,449)
Deduct: total stock-based employee compensation expense determined under fair value based method for all awards	18	9	42	37
Pro forma net loss	$ (2,965)	$ (2,960)	$ (8,954)	$ (7,486)
Net loss per share:				
Basic and diluted				
As reported	$ (5.29)	$ (8.76)	$ (19.59)	$ (22.10)
Pro forma	$ (5.32)	$ (8.78)	$ (19.68)	$ (22.21)

The fair value of each stock option is estimated on the date of the grant using the minimum value method for grants made prior to the filing of the Registration Statement on Form S-1 and the Black-Scholes method for grants made subsequently, with the following weighted average assumptions:

	Three months Ended June 30,		Nine months Ended June 30,	
	2005	2004	2005	2004
Stock Options:				
Expected volatility	62%	0%	62%	0%
Risk free interest rate	4.21%	5.21%	4.41%	4.39%
Dividend yield	0.0%	0.0%	0.0%	0.0%
Expected life	5 Years	5 Years	5 Years	5 Years

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS No. 123 and Emerging Issues Task Force Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services* which requires that such equity instruments are recorded at their fair value on the measurement date. The measurement of stock-based compensation is subject to periodic adjustment as the underlying equity instruments vest.

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Balance Sheet Data

Inventories

The components of inventories are as follows (in thousands):

	June 30, 2005	September 30, 2004
Raw materials	$ 608	$ 773
Work-in-process	854	292
Finished goods	430	234
	$ 1,892	$ 1,299

Accrued Liabilities

Accrued liabilities are as follows (in thousands):

	June 30, 2005	September 30, 2004
Public offering costs	$ 457	$
Payroll and related	599	424
Professional services	60	25
Other liabilities	190	242
Accrued expenses	$ 1,306	$ 691

3) Net Loss Per Share

Basic earnings per share is computed by dividing net loss (numerator) by the weighted average number of common shares outstanding (denominator) during the period. Diluted earnings per share gives effect to all potential dilutive common stock outstanding during a period, if dilutive.

The following outstanding options, redeemable convertible preferred stock and warrants were excluded from the computation of diluted net loss per common share for the periods presented because including them would have had an antidilutive effect (in thousands):

	Three months Ended June 30,		Nine months Ended June 30,	
	2005	2004	2005	2004
Redeemable convertible preferred stock (as if converted)	5,489	5,909	5,489	5,909
Options to purchase common stock	1,000	680	1,000	680
Warrants to purchase redeemable convertible preferred stock	127	98	127	98
Warrants to purchase common stock	55	45	55	45

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4) Recent Accounting Pronouncements

In November 2004, the Financial Accounting Standards Board, or FASB issued SFAS No. 151, *Inventory Costs*, an amendment of Accounting Research Bulletin, or ARB, No. 43, Chapter 4. SFAS No. 151 clarifies the accounting for abnormal amounts of idle facility expense, freight, handling costs and wasted material. SFAS No. 151 is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. We do not believe the adoption of SFAS No. 151 will have a material effect on our financial position, results of operations or cash flows.

In December 2004, the FASB issued SFAS No. 123R, *Share-Based Payment*, which will replace SFAS No. 123 and supersede APB 25. SFAS No. 123R addresses the accounting for share-based payment transactions in which a company receives employee services in exchange for either equity instruments of the company or liabilities that are based on the fair value of the company s equity instruments or that may be settled by the issuance of such equity instruments. Under SFAS No. 123R, companies will no longer be able to account for share-based compensation transactions using the intrinsic method in accordance with APB 25, but will be required to account for such transactions using a fair-value method and recognize the expense in the consolidated statement of earnings. SFAS No. 123R is effective at the beginning of fiscal 2006. We have not yet determined which fair-value method and transitional provision we will follow and have not yet determined the impact on our financial statements of SFAS No. 123R.

In June 2005, the FASB issued as final FSP No. FAS 105-5 Issuers Accounting under FASB Statement No. 150 for Freestanding Warrants and Other Similar Instruments on Shares that are Redeemable . The FSP clarifies that freestanding warrants and similar instruments on shares that are redeemable should be accounted for as liabilities under FASB Statement No. 150 Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity regardless of the timing of the redemption feature or price, even though the underlying shares may be classified as equity. The FSP is effective for the first reporting period beginning after June 30, 2005. Although the Company does have outstanding warrants, the shares issued upon exercise of the warrants are not redeemable; consequently, FSP No. FAS 150-5 has no impact on the Company s results of operations or financial condition.

On June 7, 2005, the FASB issued Statement No. 154, Accounting Changes and Error Corrections, a replacement of APB Opinion No. 20, Accounting Changes, and Statement No. 3, Reporting Accounting Changes in Interim Financial Statements . FAS No. 154 changes the requirements for the accounting for, and reporting of, a change in accounting principle. Previously, most voluntary changes in accounting principles were required to be recognized by way of a cumulative effect adjustment within net income during the period of the change. FAS 154 requires retrospective application to prior periods financial statements, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. FAS 154 is effective for accounting changes made in fiscal years beginning after December 15, 2005; however, the Statement does not change the transition provisions of any existing accounting pronouncements. We do not believe that the adoption of FAS 154 will have a material effect on the Company s financial position, results of operations or cash flows.

5) Contingencies

The Company is not presently party to any material litigation.

6) Segment Reporting

The Company derives significant revenue from outside the United States, primarily in Europe. Revenue by geographic area, based on the customer shipment location, were as follows, (in thousands)

	Three months Ended June 30,		Nine months Ended June 30,	
Revenue By Market	**2005**	**2004**	**2005**	**2004**
United States	$ 1,867	$ 674	$ 4,295	$ 1,647
Germany	291	166	897	400
Other	296	49	679	109
Total Revenue	$ 2,454	$ 889	$ 5,871	$ 2,156

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7) Subsequent Events

Notes Payable Repayment

On July 1, 2005 the Company repaid $1.5 million of unsecured promissory notes to stockholders of the Company.

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

Certain statements in this Quarterly Report on Form 10-Q are forward-looking statements within the meaning of federal securities laws. These statements relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as may , will , should , expect , plan , anticipate , believe , estimate , predict , potential , continue or the negative of these terms or other comparable terminology. Forward-looking statements include, but are not limited to, the statement regarding: opportunities for revenue growth from expanding indications; the financial impact of our future royalty obligations; our ability to generate positive gross margins on our test strips; and future trends in revenue, cost of goods sold and operating expenses. In evaluating these statements, you should specifically consider various factors, including the risks outlined under Factors Affecting Future Operating Results. These factors may cause our actual results to differ materially from any forward-looking statements.

Overview

We develop, manufacture and sell easy-to-use, handheld blood coagulation monitoring systems for use by patients and healthcare professionals in the management of warfarin medication. Our product, the INRatio® System, measures the patient s blood clotting time to ensure that patients with a propensity to form clots are maintained within the therapeutic range with the proper dosage of oral anticoagulant therapy. Our system is 510(k) cleared by the Food and Drug Administration (FDA) for use by healthcare professionals as well as for patient self-testing. Our system also has European Conformity (CE marked) in Europe. The INRatio® System is targeted to both the professional, or point-of-care, market as well as the patient self-testing market, the latter being an opportunity that has emerged primarily following the establishment of Medicare reimbursement in 2002 for mechanical heart valve patients

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We believe the key factors underlying our past and anticipated future revenue growth include:

- the ease of use and reliability of our INRatio System with quality controls integrated into the test strip;
- continued and expanded reimbursement by insurance companies and Medicare;
- our network of national, regional and international distribution partners;
- our field sales personnel and marketing programs;
- placing additional meters worldwide in the point-of-care environment;
- rapid development of a patient self-testing market;
- adoption of the INRatio System by patients and their treating physicians; and
- the continual improvement of our technology.

Currently, Medicare and private payors reimburse PT/INR testing in the point-of-care environment for all indications. Medicare reimburses patient self-testing only for patients with mechanical heart valves, while reimbursement policies among private payors vary. Our revenue growth is dependent on such reimbursement continuing without any significant erosion in the reimbursement amounts. We believe that there is a significant opportunity in patient self-testing for other indications, such as atrial fibrillation, in the event that reimbursement is expanded. If Medicare reimbursement for patient self-testing by atrial fibrillation patients is not established in a timely fashion or at all, our revenue growth will be substantially limited.

Our cost of goods sold represents the cost of manufacturing our products. Our meters are manufactured for us by an electronics manufacturing service company, and we incur direct labor costs to assemble meters into packaged kits at our facility. Our cost of goods sold for the meter also includes an allowance for product warranty obligations. Our disposable test strips are manufactured by us at our facility, and our cost of goods sold is comprised of cost of materials, direct labor, associated overhead, yield losses and lot rejects, royalties on sales, and license fee costs. Included in royalties on sales is a royalty payable in connection with our settlement with Inverness Medical Innovations. While this royalty does not become payable until July 2006, we capitalized a portion of the settlement amount as prepaid royalties and are expensing that amount through 2009, the term of the royalty agreement, as a cost of goods sold and do not believe that our obligation to pay royalties in 2006 will have an adverse effect on our results of operations or cash flows.

While we have a positive margin on meters, until higher production volume is realized in test strip manufacturing to absorb the manufacturing overhead, the manufacturing cost per test strip will be high and in excess of our worldwide average selling price. The manufacturing cost structure for our test strips currently includes a large component of fixed costs which is being spread over production that has not been maximized. Increases in production volume will be a significant factor for cost reduction for our test strips. We anticipate that this, along with other cost reduction efforts under way, will generate positive gross margins.

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Results of Operations

The following table sets forth our results of operations (in thousands) expressed as a percentage of total revenue. Our historical operating results are not necessarily indicative of the results for any future period.

	Three months Ended June 30,					
	2005		2004			
	Amount	% of Sales	Amount	% of Sales	Amount of Increase (Decrease)	Percent Increase (Decrease)
Revenue	$ 2,454	100%	$ 889	100%	$ 1,565	176%
Cost of goods sold	2,487	101	1,511	170	976	65
Gross loss	(33)	(1)	(622)	(70)	589	(95)
Operating expenses						
Research and development	266	11	356	40	(90)	(25)
Sales and marketing	1,677	68	1,469	165	208	14
General and administrative	449	18	377	42	72	19
Total operating expenses	2,392	97	2,202	247	190	9
Loss from operations	(2,425)	(98)	(2,824)	(317)	399	(14)
Interest income	8		2		6	300
Interest and other expense	(530)	(22)	(129)	(15)	(401)	311
Net loss	$ (2,947)	(120)%	$ (2,951)	(332)%	$ 4	0%

The following table sets forth our results of operations (in thousands) expressed as a percentage of total revenue. Our historical operating results are not necessarily indicative of the results for any future period.

	Nine months Ended June 30,					
	2005		2004			
	Amount	% of Sales	Amount	% of Sales	Amount of Increase (Decrease)	Percent Increase (Decrease)
Revenue	$ 5,871	100%	$ 2,156	100%	$ 3,715	172%

Cost of goods sold	6,826	116	3,420	159	3,406	100
Gross loss	(955)	(16)	(1,264)	(59)	309	(24)
Operating expenses						
Research and development	806	14	1,064	49	(258)	(24)
Sales and marketing	4,877	83	3,735	173	1,142	31
General and administrative	1,321	23	1,192	55	129	11
Total operating expenses	7,004	120	5,991	277	1,013	17
Loss from operations	(7,959)	(136)	(7,255)	(336)	(704)	10
Interest income	18		12	1	6	50
Interest and other expense	(971)	(17)	(206)	(10)	(765)	371
Net loss	$ (8,912)	(153)%	$ (7,449)	(345)%	$ (1,463)	(20)%

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Revenue. For the three months ended June 30, 2005, revenue increased $1.6 million, or 176%, to $2.5 million from $889,000 for the three months ended June 30, 2004. The revenue increase, both in the United States and internationally, was attributed to increased penetration by our distribution partners into the markets they serve. The increase in revenue was primarily attributable to the sale of test strips which increased $1.0 million, or 231%, from $451,000 for the three months ended June 30, 2004 to $1.5 million for the three months ended June 30. Revenue from sales of our meters and accessories was $960,000 for the three months ended June 30, 2005 as compared to $438,000 for the three months ended June 30, 2004. We anticipate revenue for all products to increase over the balance of the current fiscal year.

For the three months ended June 30, 2005, revenue generated in the United States increased $1.2 million or 177%, to $1.9 million from $674,000 for the three months ended June 30, 2004. International revenue increased $372,000, or 173%, to $587,000 for the three months ended June 30, 2005 from $215,000 for the three months June 30, 2004. For the remainder of the current fiscal year, we anticipate revenue generated from the United States to increase and international revenue to either remain constant or decrease due to European demand fluctuations during the summer months.

For the nine months ended June 30, 2005, revenue increased $3.7 million, or 172%, to $5.9 million from $2.2 million for the nine months ended June 30, 2004. The revenue increase, both in the United States and internationally, was attributed to increased penetration by our distribution partners into the markets they serve. Sales of test strips increased $2.1 million, or 178%, from $1.2 million for the nine months ended June 30, 2004 to $3.3 million for the nine months ended June 30, 2005. Revenue for our meters and accessories increased $1.6 million, or 165%, to $2.6 million for the nine months ended June 30, 2005 from $1.0 million for the nine months ended June 30, 2004.

For the nine months ended June 30, 2005, revenue generated in the United States increased $2.6 million, or 161%, to $4.3 million from $1.6 million for the nine months ended June 30, 2004. International revenue increased $1.1 million, or 210%, to $1.6 million for the nine months ended June 30, 2005 from $509,000 for the nine months ended June 30, 2004

Cost of Goods Sold. Cost of goods sold includes direct labor, direct material, overhead, license fees and royalties. Cost of goods sold increased $976,000, or 65%, to $2.5 million for the three months ended June 30, 2005 from $1.5 million for the three months ended June 30, 2004. Most of the increase related to increased product revenue shipments for the three months ended June 30, 2005 compared to the same period last year. Gross loss was 1% and 70% of revenue for the three months ended June 30, 2005 and June 30, 2004, respectively. The improvement in gross loss was attributed to increased production volume and process improvements for test strips for the three months ended June 30, 2005 over the three months ended June 30, 2004.

For the nine months ended June 30, 2005, cost of goods sold increased $3.4 million, or 100%, to $6.8 million from $3.4 million for the nine months ended June 30, 2004. The increase in cost of goods sold primarily related to an increase in product revenue shipments due to the 172% increase in revenue. As a percentage of sales, the gross loss was 16% and 59% for the nine months ended June 30, 2005 and June 30, 2004, respectively. The improvement in gross loss related to increased production volume and manufacturing

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efficiencies for test strips. Over the balance of the fiscal year, we expect the cost of goods sold to decrease as a percentage of revenue as the Company s test strips production processes continues to improve.

Research and Development Expenses. Research and development expenses include salaries, bonuses, professional consulting service expenses, supplies and depreciation of capital equipment. Research and development expenses decreased $90,000, or 25%, to $266,000, for the three months ended June 30, 2005 from $356,000 for the three months ended June 30, 2004. The decrease was mainly attributable to lower payroll and related benefit costs of $58,000, decrease of $10,000 for outside professional services and $33,000 decrease in supplies. The decrease relates to the shift of resources from development efforts to the manufacturing process. As a percent of total revenue, research and development expenses decreased to 11% for the three months ended June 30, 2005 from 40% for the three months ended June 30, 2004 mainly due to the significant increase in revenue. Over the balance of the fiscal year we expect research and development expenses to increase as new initiatives are undertaken. As a result, there will be an increase in expenses as a percentage of total revenue.

For the nine months ended June 30, 2005, research and development expenses decreased $258,000, or 24%, to $806,000 from $1.1 million for the nine months ended June 30, 2004. The decreased spending related primarily to the reduction in payroll cost and consultant expenses as certain personnel and other resources in research and development in 2004 continued to be transferred to manufacturing in 2005. As a percent of total revenue, research and development expenses decreased to 14% for the nine months ended June 30, 2005 from 49% for the nine months ended June 30, 2004.

Sales and Marketing Expenses. Sales and marketing expenses include salaries, commissions, bonuses, travel and expenses for outside services related to marketing programs. Sales and marketing expenses increased $208,000, or 14%, to $1.7 million for the three months ended June 30, 2005 from $1.5 million for the three months ended June 30, 2004. The increase was mainly attributable to payroll and related benefits costs which increased by $234,000, and travel costs which increased by $38,000 which were due to the addition of five personnel. Additionally, product marketing cost increased $75,000 as the efforts to promote our product expanded. These costs were offset by $195,000 decrease primarily due to the discontinuance of a European agency relationship. As a percent of total revenue, sales and marketing expenses decreased to 68% for the three months ended June 30, 2005 from 165% for the three months ended June 30, 2004 due to the increase in revenue for the same periods. Over the balance of the fiscal year, we expect sales and marketing expenses to continue to increase but decline as a percentage of total revenue.

For the nine months ended June 30, 2005, sales and marketing expenses increased $1.1 million, or 31%, to $4.9 million from $3.7 million for the nine months ended June 30, 2004. The increase was primarily attributable to $965,000 of payroll, benefits and travel expenses for additional personnel, $163,000 for demonstration meters, $198,000 for promotional expenses including the related freight and postage. This was partially offset by $227,000 reduction primarily due to the discontinuance of a European agency relationship. As a percent of total revenue, sales and marketing expenses decreased to 83% for the nine months ended June 30, 2005 and from 173% for the nine months ended June 30, 2004.

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General and Administrative Expenses. General and administrative expenses include compensation, benefits and expenses for outside professional services, including information services, legal and accounting. General and administrative expenses increased $72,000 to $449,000 for the three months ended June 30, 2005 from $377,000 for the three months ended June 30, 2004. Payroll and related costs increased $35,000 due to increased staffing. Additionally, outside professional services, including legal and accounting, increased $37,000 relating to registration of our initial public offering. As a percent of total revenue, general and administrative expenses decreased to 18% for the three months ended June 30, 2005 from 42% for the three months ended June 30, 2004. Over the balance of the fiscal year, we expect general and administrative expenses to increase as we begin to incur the expenses associated with being a public company and such expenses will increase as a percentage of total revenue.

For the nine months ended June 30, 2005, general and administrative expenses increased $129,000, or 11%, to $1.3 million from $1.2 million for the nine months ended June 30, 2004. The increase was primarily attributable to $271,000 in payroll and related costs and $214,000 in independent accountants fees. This was partially offset by $265,000 decrease in legal expenses related to the settlement of an intellectual property infringement action for which costs were incurred in the nine months ended June 30, 2004. As a percent of total revenue, general and administrative expenses decreased to 23% for the nine months ended June 30, 2005 from 55% for the nine months ended June 30, 2004.

Interest and Other Expense. Interest and other expense increased $401,000, or 311%, to $530,000 for the three months ended June 30, 2005 from $129,000 for the three months ended June 30, 2004. The increase relates to the higher level of debt the company has incurred over the past year. This increase was primary attributable to the Lighthouse Capital loan which was fully drawn as of June 30, 2005 whereas as of June 30, 2004 only $2.9 million of the $7.5 million commitment was drawn down.

For the nine months ended June 30, 2005 interest and other expense increased $765,000, or 371%, to $971,000 from $206,000 for the nine months ended June 30, 2004. The increase primarily related to borrowings from Lighthouse Capital for which the borrowing facility was put in place during March 2004.

Liquidity and Capital Resources

Cash flow information for the nine months ended June 30, 2005 and June 30, 2004 was as follows (in thousands):

	June 30, 2005	June 30, 2004
Cash and cash equivalents	$ 620	$ 3,045
Net cash used in operating activities	$ (8,115)	$ (7,026)
Net cash used in investing activities	(216)	(359)
Net cash provided by financing activities	8,518	4,985
Net increase (decrease) in cash and cash equivalents	$ 187	$ (2,400)

Since our inception, our operations have been primarily financed through the sale of public equity securities, private equity capital, bank equipment financing loans, debt capital and capital leases. From our inception to June 30, 2005, we have raised $40.5 million in net

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proceeds from equity financings. On July 1, 2005 the Company closed the initial public offering of 3.5 million shares of its common stock. On July 27, 2005 the overallotment of 12,207 shares were exercised. Total net proceeds of $16.7 million were received after underwriting discounts, commissions and offer related expenses. In addition to these amounts, we have loans, notes payable and capital leases as of June 30, 2005 in the amount of $8.7 million. Notes payable totaling $1.5 million will be paid from our public offering proceeds received in July 2005. The other borrowings will be repaid on their agreed schedules through July 2009.

During the nine months ended June 30, 2005, our operating activities used cash of approximately $8.1 million, compared to approximately $7.0 million for the nine months ended June 30, 2004, an increase of $1.1 million. This comprised of an increase in the net loss by approximately $1.5 million and offset by $928,000 change in adjustments for non-cash items. The major component of the changes in assets and liabilities was in inventories. The change in inventory resulted in the use of $698,000 in cash for the nine months ended June 30, 2005, an increase of $491,000 from $207,000 use of cash for the same period in 2004; this was due to building of inventory to meet the expected increasing demand.

Our investing activities used cash of approximately $216,000 during the nine months ended June 30, 2005 compared to $359,000 for the nine months ended June 30, 2004. Investing activities in 2005 and 2004 comprised of acquisition of equipment.

Cash provided by financing activities was $8.5 million for the nine months ended June 30, 2005 compared to $5.0 million provided by financing activities for the nine months ended June 30, 2004. The increase in cash provided was due to $4.6 million of proceeds from draw downs against a debt line facility, $3.3 million in preferred stock proceeds and $1.5 million from short term notes payable, during the nine months ended June 30, 2005. Principal payments on outstanding loans and capital leases were $910,000 during the nine months ended June 30, 2005. During the nine months ending June 30, 2004 cash provided was due to $3.0 million in preferred stock proceeds and $2.9 million from draw down against a debt line facility. Loans and capital leases principal payments were 936,000 during the nine months ended June 30, 2004. We received proceeds from our initial public offering, in the amount of $17.9 million, net of underwriter s commission on July 1, 2005

As of June 30, 2005, we had a long-term loan payable, a long-term note payable, certain short term notes payable, capital lease obligations, commitments under a facility operating lease, and non-cancelable purchase commitments. We had no other off-balance sheet items or commitments. Future payments under these obligations are included in the table below for each of the fiscal years ending September 30 (in thousands):

	2005	2006	2007	2008	2009	Total
Loan payable	$ 451	$ 2,000	$ 2,353	$ 1,786	$	$ 6,590
Note payable	1,498				548	2,046
Capital leases	10	37	36	17		100
Facility lease	35	143	152	162	90	582
Cancelable purchase commitments	1,988					1,988
Non-cancelable purchase commitments	617					617
Total	$ 4,599	$ 2,180	$ 2,541	$ 1,965	$ 638	$ 11,923

During the nine months ended June 30, 2005, we had drawn down an additional $4.6 million on the loan payable to Lighthouse Capital. These draw downs resulted in us fully

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utilizing the debt line of $7.5 million that was available. As of June 30, 2005, principal payments of $910,000 relating to the Lighthouse Capital loan payable has been made. In addition, in April 2005, we received $1.5 million in unsecured debt financing from certain preferred stockholders and in connection with that transaction issued to those stockholders warrants exercisable for shares of our common stock.

We believe that the proceeds from our initial public offering of $16.6 million, net of underwriting commissions and offering expenses, along with our existing cash and cash equivalents and cash generated from product sales, will be sufficient to meet our anticipated cash requirements for at least the next 12 months. Our future capital requirements are difficult to forecast and will depend on many factors, including:

- success of our product sales and related collections;
- future expenses to expand and support our sales and marketing activities;
- Entering into new, or maintaining existing, distribution relationships;
- maintaining and expanding our manufacturing capacity and capabilities;
- costs relating to changes in regulatory policies or laws that affect our operations;
- the level of investment in research and development to maintain and improve our competitive edge and our technology position as well as broaden our technology platform;
- costs of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights; and
- our need or decision to acquire or license complementary products, technologies or businesses.

If at any time sufficient capital is not available, either through existing capital resources or through raising additional funds, we may be required to delay, reduce the scope of, eliminate or divest one or more of our sales and marketing programs, research and development programs or our entire business. We may raise additional funds through public or private offerings, debt financings, capital leases, corporate collaborations or other means. Due to the uncertainty of financial markets, financing may not be available to us when we need it on acceptable terms or at all. Therefore, we may raise additional capital from time to time when market conditions are favorable, or if strategic considerations require us to do so, even if we have sufficient funds for planned operations.

Critical Accounting Policies

The Company s significant accounting policies are disclosed in our Registration Statement on Form S-1 for the year ended September 30, 2004 which was filed with the Securities and Exchange Commission. The Company s significant accounting policies have not materially changed as of June 30, 2005.

Recent Accounting Pronouncements

In November 2004, the Financial Accounting Standards Board, or FASB issued SFAS No. 151, *Inventory Costs*, an amendment of Accounting Research Bulletin, or ARB, No. 43, Chapter 4. SFAS No. 151 clarifies the accounting for abnormal amounts of idle facility

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expense, freight, handling costs and wasted material. SFAS No. 151 is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. We do not believe the adoption of SFAS No. 151 will have a material effect on our financial position, results of operations or cash flows.

In December 2004, the FASB issued SFAS No. 123R, *Share-Based Payment*, which will replace SFAS No. 123 and supersede APB 25. SFAS No. 123R addresses the accounting for share-based payment transactions in which a company receives employee services in exchange for either equity instruments of the company or liabilities that are based on the fair value of the company s equity instruments or that may be settled by the issuance of such equity instruments. Under SFAS No. 123R, companies will no longer be able to account for share-based compensation transactions using the intrinsic method in accordance with APB 25, but will be required to account for such transactions using a fair-value method and recognize the expense in the consolidated statement of earnings. SFAS No. 123R is effective at the beginning of fiscal 2006. We have not yet determined which fair-value method and transitional provision we will follow and have not yet determined the impact on our financial statements of SFAS No. 123R.

In June 2005, the FASB issued as final FSP No. FAS 105-5 Issuers Accounting under FASB Statement No. 150 for Freestanding Warrants and Other Similar Instruments on Shares that are Redeemable . The FSP clarifies that freestanding warrants and similar instruments on shares that are redeemable should be accounted for as liabilities under FASB Statement No. 150 Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity regardless of the timing of the redemption feature or price, even though the underlying shares may be classified as equity. The FSP is effective for the first reporting period beginning after June 30, 2005. Although the Company does have outstanding warrants, the shares issued upon exercise of the warrants are not redeemable; consequently, FSP No. FAS 150-5 has no impact on the Company s results of operations or financial condition.

On June 7, 2005, the FASB issued Statement No. 154, Accounting Changes and Error Corrections, a replacement of APB Opinion No. 20, Accounting Changes, and Statement No. 3, Reporting Accounting Changes in Interim Financial Statements . FAS No. 154 changes the requirements for the accounting for, and reporting of, a change in accounting principle. Previously, most voluntary changes in accounting principles were required to be recognized by way of a cumulative effect adjustment within net income during the period of the change. FAS 154 requires retrospective application to prior periods financial statements, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. FAS 154 is effective for accounting changes made in fiscal years beginning after December 15, 2005; however, the Statement does not change the transition provisions of any existing accounting pronouncements. We do not believe that the adoption of FAS 154 will have a material effect on the Company s financial position, results of operations or cash flows.

Factors Affecting Future Operating Results

We have limited operating experience and a history of net losses. Unless we are able to significantly increase our revenue and reduce our costs, we may never achieve or maintain profitability.

We have a limited history of operations and have incurred net losses in each year since our inception. We received regulatory clearance to market our INRatio System in 2002 and began commercial sales in early 2003. During the past five fiscal years, we incurred net losses of $4.7 million in 2000, $4.0 million in 2001, $4.7 million in 2002, $6.9 million in 2003 and $10.3 million in 2004. As of June 30, 2005, we had an accumulated deficit of $44.4 million. We expect that, our operating expenses will increase as we expand our business, devote additional resources to our research and development, sales and marketing efforts and incur the costs of being a public company.

We will be unable to achieve profitability unless we increase revenue and decrease the cost of manufacturing our test strips.

Currently, we are operating at a negative gross margin, primarily due to the cost of manufacturing our test strips. We will need to both significantly increase the revenue we receive from sales of our product and, to the extent possible, reduce our costs in order to achieve profitability. It is possible that we will never generate sufficient revenue to achieve profitability. Our failure to achieve and maintain profitability would negatively affect our business and financial condition and the trading price of our common stock.

We have limited capital resources and expect that we will need to raise additional funds if we want to carry out our planned operations, which we may not be able to do.

We intend to finance our operations primarily through our cash and cash equivalents, marketable securities, future financing and future revenues. As of July 31, 2005, we had cash

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and cash equivalents on hand of approximately $13.9 million and working capital of approximately $14.4 million, which we believe will be adequate to meet our current and planned operations for at least the next 12 months. We intend to engage in additional fundraising to support our longer term operations and initiatives. The timing of such fundraising will be dependent upon a number of factors including our stock price, operating performance, market conditions and investor interest. There can be no assurance that we will be successful in consummating any such transaction, or, if we do consummate such a transaction, that the terms and conditions of such financing will be favorable to us. Equity financing would require us to issue more shares of stock, which would dilute our current stockholders and could lead to a decline in our stock price.

We may be unable to accurately predict our future performance, which could harm our stock price.

We provide guidance regarding future operating performance and our stock price is based, in part, upon those predictions. Because we have only recently become a publicly-traded company, it may be difficult for us to accurately predict our operating performance each quarter, and we believe that our quarterly results will fluctuate as a result of many factors outside of our control, such as:

- demand for our product;
- timing of orders and shipments;
- the performance of our distributors on our behalf;
- our mix of sales between our distributors and our direct sales force;
- foreign currency fluctuations;
- seasonality, in Europe, relating to mechanical heart vale surgeries;
- new product introductions by our competitors; and
- the timing and uncertainty of U.S. and foreign reimbursement decisions.

We believe that our stock price would decline if we are unable to meet or exceed our predicted performance.

We depend upon a single product. If our INRatio® System fails to gain market acceptance our business will suffer.

The INRatio System is our only product. Sales of this product will account for substantially all of our revenue for the foreseeable future. We cannot be sure that we will be successful in convincing patients and healthcare professionals to use our product. Certain competitors have products that are established in our target markets, and we may not be able to convince users of those products to switch to the INRatio System.

Healthcare professionals may be hesitant to recommend our product to their patients given our short operating history and the fact that we are a relatively small company. If our product fails to gain acceptance in the point-of-care and patient self-testing markets, our business will be harmed.

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The performance of our product may not be perceived as being comparable with established laboratory methods, which may limit the market acceptance of our product.

The majority of PT/INR testing has historically been and continues to be performed by large hospital or commercial laboratories. Healthcare professionals responsible for managing patients on warfarin therapy have experience with and confidence in the results generated by these large laboratories. In addition, these professionals influence many treatment decisions, including aspects critical to our business such as how often testing is to be performed, who is to perform the testing, and where testing is to be performed. In some instances, these decision makers may determine that our INRatio System test results lack the clinical history and reliability of large laboratories. If we are unable to demonstrate to physicians satisfaction that the performance of our INRatio System closely matches the results produced by these laboratories, market acceptance of our product will be limited.

We recently completed an FDA inspection, which could lead to regulatory enforcement action.

Our product and facilities are subject to continual review and periodic inspections by the FDA and other regulatory bodies. In particular, we are required to comply with quality system regulations, or QSR, and other regulations, which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage, shipping and post market surveillance of our product. The FDA enforces the QSR through scheduled and through unannounced inspections. We recently underwent an inspection of our facilities by the FDA, which resulted in the issuance of an FDA Form 483 containing two observations. First, the inspector observed that we failed to timely file Medical Device Reports, or MDRs, for six of seven complaints the inspector reviewed claiming that our INRatio device took inaccurate readings. MDRs are required to be filed if our device malfunctions in a way that would likely cause or contribute to a death or serious injury if it were to recur. The second observation was that we had not properly defined and documented the procedures we employ to identify the statistical techniques for calibration of our test strips. We have filed a response to these observations. It is possible that the FDA will issue a Warning Letter related to one or both of the observations. A Warning Letter would require that we promptly submit a further response, advising the FDA of the corrective actions that we have taken or will take to address the identified regulatory violation, in order to avoid more serious FDA enforcement action. Our failure to comply with applicable regulatory requirements, or our failure to timely and adequately respond to inspectional observations or Warning Letter issued as a result of inspectional observations, could result in enforcement action by the FDA, which may include the following sanctions:

- fines, injunctions and civil penalties;
- recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- delays in clearance or approval, or failure to obtain approval of our products or product modifications;
- withdrawal of clearances or approvals; and
- criminal prosecution.

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If any of these actions were to occur, it would harm our reputation and cause our product sales and profitability to suffer. Responding to inspectional observations may be time consuming and costly.

We are filing an increasing number of MDRs, which could harm market adoption of our product.

In order to correct an FDA observation during our recent inspection, we have revised our written procedure that describes when to file an MDR. Our revised procedure requires us to file MDRs for device malfunctions, including all allegations of inaccurate readings by our device. As a result, we have been filing, and expect to continue to file, an increased number of MDRs. MDRs are publicly available, and competitors could use this information in an attempt to disrupt our customer and potential customer relationships, which could harm market adoption of our product.

The success of our business is largely dependent upon the growth of the PT/INR patient self-testing market. If that market fails to develop as we anticipate, our results will be adversely affected

Our business plan is targeted at the emerging PT/INR patient self-testing market and our product has been designed to address that market. We cannot be sure that this market will grow as we anticipate. Such growth will require greater advocacy of patient self-testing from both healthcare professionals and patients than currently exists. Future research and clinical data may not sufficiently support patient self-testing as a safe or effective alternative to clinical laboratory testing or point-of-care testing, which could inhibit adoption of patient self-testing. If healthcare professionals fail to advocate self-testing for their patients or if patients do not become comfortable with it, self-testing may fail to become the standard practice for PT/INR measurement. If patient self-testing fails to be adopted at the rate we expect, our anticipated growth will be adversely affected and our results will suffer.

We operate in a highly competitive market and face competition from large, well-established medical device manufacturers with significant resources. If we fail to compete effectively, our business will suffer.

The market for point-of-care and patient self-testing PT/INR measurement systems is intensely competitive, subject to rapid change, new product introductions and other activities of industry participants. We currently compete directly against Roche Diagnostics, the largest diagnostic company in the world, and International Technidyne Corporation, a division of Thoratec. Together these two companies currently account for substantially all of the point-of-care and patient self-testing PT/INR measurement market. Several other companies, including Inverness Medical Innovations, have announced that they are developing new products that would compete directly against us, and we expect one or more new products to become available this year. In addition, other companies, including Johnson & Johnson and Beckman Coulter, have developed or acquired directly competitive products for the PT/INR market in the past, and while they are not current competitors, they could re-enter the market at any time. Additionally, these and other potential competitors hold intellectual property rights that could allow them to develop or sell the right to develop new products that could compete effectively

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with our INRatio System. All of these companies are larger than us and enjoy several competitive advantages, including:

- significantly greater name recognition;
- established relationships with healthcare professionals, patients and insurance providers;
- large, direct sales forces and established independent distribution networks;
- additional product lines and the ability to offer rebates, bundled products, and higher discounts or incentives;
- access to material information about our business, which we are required to publicly disclose, while not having to disclose their own comparable information, because it is an immaterial part of their overall operations;
- greater experience in conducting research and development, manufacturing and marketing activities; and
- greater financial and human resources for product development, sales and marketing and patent litigation.

We may not be able to compete effectively against these companies or their products and, if we fail to do so, our business will be harmed.

If alternative drugs or other treatments reduce the need for warfarin, the market for our product will be limited.

Our INRatio System is used to measure the rate of blood coagulation in patients using warfarin. As a result, the size of our market is directly dependent upon the number of warfarin users. If a new drug or other anticoagulation treatment that does not require regular monitoring of PT/INR levels is successfully developed, approved and adopted, the size of the market for our product will be adversely affected.

While warfarin is a widely prescribed drug, it is known to have certain deficiencies which cause many physicians to be reluctant to prescribe it regularly, or at all. Aspirin is a safer blood thinning drug than warfarin and it does not require monitoring. Aspirin has been shown to be an effective alternative to warfarin for certain chronic conditions, such as blocked brain arteries. Warfarin s narrow therapeutic range creates the need for frequent monitoring of patient blood coagulation levels. Warfarin is known to have adverse interactions with other drugs and is sensitive to changes in diet and other factors. We are aware that pharmaceutical companies are researching and developing potential alternatives to warfarin. For example, AstraZeneca has developed an anticoagulant called Exanta. While the U.S. Food and Drug Administration, or FDA, did not grant approval for its use in the United States, some European countries have approved it for certain indications.

Advances in the treatment of underlying conditions could also affect the use of warfarin. For example, improvements in replacement tissue heart valves have reduced, and may in the future further reduce, the use of mechanical heart valves, one of the leading indications for chronic warfarin use. Additionally, several companies are pursuing new surgical procedures to

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treat atrial fibrillation, another leading indication for warfarin use and monitoring. Any development that renders warfarin obsolete or diminishes the need for PT/INR testing by patients in our target markets would negatively affect our business and prospects.

Our ability to successfully market and sell our product is dependent on the availability of adequate reimbursement from Medicare and other insurance providers.

In the United States, purchasers of medical devices, including our INRatio System, generally rely on Medicare and other insurance providers to cover all or part of the cost of the product. Currently reimburse PT/INR testing in the point-of-care environment for all indications. However, Medicare currently only reimburses PT/INR self-testing for patients with mechanical heart valves, or approximately 400,000 mechanical heart valve patients on warfarin, which represents approximately 15% of three million U.S. patients taking warfarin on a daily basis. Whether Medicare expands reimbursement for PT/INR patient self-testing for other indications, such as atrial fibrillation, will be partially dependent on the outcome of ongoing and future clinical studies that we do not participate in or have any direct control over. Coverage and reimbursement determinations are subject to change over time and we cannot assure you that Medicare will not reduce or change coverage and reimbursement policies.

Although many other insurance providers follow Medicare coverage determinations, Medicare coverage does not and will not guarantee widespread coverage by other insurance providers. These organizations are not required to offer the same level of coverage as Medicare, or any coverage at all, and their coverage policies are determined on a regional basis, carrier-by-carrier, so that obtaining nationwide coverage from all the major insurance providers will be a time-consuming process. We cannot assure you that adequate coverage, if any, will be obtained. Further, coverage decisions for individual patients may be made on a case-by-case basis and may require the patient to seek and obtain prior authorization before being provided access to our product. Future legislation, regulation or reimbursement policies of insurance providers may adversely affect the demand for our product or our ability to sell our product on a profitable basis. The lack of insurance coverage or the inadequacy of reimbursement could have a material adverse effect on our business, financial condition and results of operations.

Reimbursement and healthcare payment systems in international markets vary significantly by country and include both government-sponsored healthcare and private insurance. Obtaining international approvals is a lengthy process, and reimbursement policies may limit the marketability of our product in certain countries. International reimbursement approvals may not be obtained in a timely manner, if at all, or may provide for inadequate reimbursement levels. Our failure to receive international reimbursement approvals could have a material adverse effect on market acceptance of our product in the markets in which those approvals are sought.

If we are unable to establish sufficient sales and marketing capabilities or enter into and maintain appropriate arrangements with third parties to sell, market and distribute our product, our business will be harmed.

We have limited experience as a company in the sale, marketing and distribution of our INRatio System. We maintain a relatively small sales and marketing team which as of July 31,

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2005 was comprised of 26 employees and expect to depend heavily on third parties to sell our product both in the United States and internationally for the foreseeable future. To achieve commercial success, we must further develop our sales and marketing capabilities and enter into and maintain successful arrangements with others to sell, market and distribute our product.

We currently have agreements with six national and four regional distributors in the United States. We also have agreements with 12 international distributors of our product. Two of our distributors, Quality Assured Services and Cardinal Health, accounted for approximately 31% and 26%, respectively, of our total revenue in fiscal 2004. Our success is dependent upon developing and maintaining current and future distribution relationships. We have only recently entered into most of our distribution relationships, which makes it difficult for us to predict their future success. Some of our distribution agreements allow either party to terminate the relationship on short notice and without fault. Additionally, we may be unable to renew a distribution agreement upon its expiration on favorable terms, or at all. Distribution partners may fail to commit the necessary resources to market and sell our product to the level of our expectations. In particular, several of our distribution partners also distribute the products of our competitors, and as a result, we compete for the attention of these distributors against the experienced and well funded efforts of our competitors. If in the future our distribution partners elect to focus on selling the products of our competitors rather than our products, our sales efforts will be seriously compromised. If we are unable to establish and maintain adequate sales, marketing and distribution capabilities, independently or with others, we may not be able to generate product revenue and may not become profitable. If our current or future partners do not perform adequately, or we are unable to locate or retain partners, as needed, in particular geographic areas or in particular markets, our ability to achieve our expected revenue growth rate will be harmed.

If our commercial partners fail to provide customer service on our behalf, our business will be harmed.

In the United States, Independent Diagnostic Testing Facilities, or IDTFs, are intermediary parties that provide our INRatio meters and test strips to patients and are often responsible for communicating patient results back to the prescribing physician and for monitoring patient compliance with the prescribed testing plan. As such, our success is tied to how well our IDTF partners can:

convince prescribing physicians of the benefit of weekly PT/INR testing;

ensure patient compliance; and

provide timely, quality customer service to patients and physicians.

Since self-testing is relatively new, IDTFs will play a critical role in the acceptance of home testing among patients and physicians and the creation of awareness of our INRatio System. If our IDTF partners are not successful in performing their role, our business will be adversely affected.

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We have limited test strip manufacturing capabilities and personnel. If we cannot produce an adequate supply of test strips, our growth will be limited and our business will be harmed.

The primary components of the INRatio System are the INRatio meter and INRatio disposable test strips. We manufacture INRatio test strips at our facility, and we contract with an electronic manufacturing services supplier to manufacture the INRatio meter. Our cost to manufacture our test strips currently exceeds the price at which we can sell them. To be successful, we must manufacture our test strips in substantial quantities and at acceptable costs. We currently have limited experience manufacturing our test strips, and no experience manufacturing in the quantities that we anticipate we will need in the foreseeable future. There are technical challenges to increasing our manufacturing capacity in a significant manner, including:

- maintaining the consistency of our incoming raw materials;
- equipment design and automation;
- material procurement;
- production yields; and
- quality control and assurance.

Developing high volume manufacturing facilities will require us to invest substantial additional funds and to hire and retain additional management and technical personnel who have the necessary manufacturing qualifications and experience. We may not successfully complete any required increase in manufacturing capacity in a timely manner or at all. If we are unable to manufacture a sufficient supply of our product, maintain control over expenses or otherwise adapt to anticipated growth, or if we underestimate growth, we may not have the capability to satisfy market demand or improve our sales growth sufficiently to achieve profitability.

Because of our limited experience, we have in the past manufactured, and may in the future manufacture, defective test strips that have to be discarded, which increases our costs of operations and may delay shipment of product to customers.

We manufacture our test strips in large lots that must be tested with blood from warfarin patients in order to determine if our product has acceptable performance. There are many elements to manufacturing each lot of strips that can cause variability in PT/INR measurement beyond acceptable limits. Variability is not detected until the entire lot is complete and selected strips are tested with patient blood samples. If the performance is not acceptable, we discard the entire lot after we have incurred substantially all the material and labor costs required to manufacture the test strips in the lot. In order to manufacture test strips that will produce PT/INR measurement results that are sufficiently calibrated to clinical laboratory equipment, we are dependent upon our suppliers to deliver various components in conformity with our specifications. We have in the past had to, and may in the future have to, discard lots because they fail to meet specifications, which increases our costs of operations and may delay shipment of product to customers.

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We depend on clinical sites to assist us in verifying the calibration of our test strips, and if they fail in that role we may be unable to produce test strips in a timely manner.

We must calibrate each lot of test strips that we manufacture using blood samples from patients who are taking therapeutic levels of warfarin as well as from individuals who are not on anticoagulant therapy. We have contracts in place with clinical sites that give us access to their patients on a regular basis to permit us to perform the testing we need to complete our manufacturing process. If these clinical sites fail to enroll a sufficient number of patients for our calibration requirements or if they fail to ensure that the patients meet the inclusion criteria we specify in our protocols, our ability to properly calibrate our product may be compromised and we may be unable to produce our test strips in a timely manner.

Our product could be misused or produce inaccurate results, which could lead to injury to the patient and potential liability for us.

We expect our product to be used by patients without direct physician supervision. Many users will be elderly Medicare patients, who may have difficulty following the instructions for the use of our product. Additionally, in the point-of-care setting, practitioners familiar with competitors products that function differently may fail to follow our directions and misuse our product. For example, we are aware of a few situations in which practitioners have applied blood drawn from a vein using a syringe rather than capillary blood using a finger stick, which caused inaccurate readings. Warfarin management is complex, and there are many drugs, diseases and other factors that may affect warfarin metabolism and the ability of our test to perform as intended in the presence of these factors. Additionally, there may be biologic variations and clinical conditions that exist in some patients that may have an adverse effect on the performance of our product. We have in the past taken, and may in the future take, corrective action in our manufacturing procedure in order to respond to complaints that our test strips were producing inaccurate results. If our product is misused or otherwise produces an incorrect reading, a patient could be either underdosed or overdosed with warfarin, which could lead to serious injury or death and expose us to potential liability.

We are currently responding to an inquiry from a European regulatory agency into the accuracy of readings produced from our test strips. Our failure to adequately respond could lead to restrictions or withdrawal of our product from the U.K. market.

We are currently responding to an inquiry from the United Kingdom s Medicines and Healthcare products Regulatory Agency, or MHRA, regarding two reported instances where our test strips failed to produce accurate readings. We believe that these misreadings were the result of misuse of our test strips at the point-of-care, caused by the use of blood from a vein rather than blood from a finger stick; however, we cannot be certain that MHRA will agree with our assessment. MHRA may instead find that these misreadings resulted from failures within our manufacturing processes. While we completed a voluntary exchange of our test strips in April 2005, we have not yet received a response from MHRA closing the matter. MHRA may make observations to which we would be required to adequately respond. Lack of an adequate response by us could lead to restrictions or withdrawal of our product from the U.K. market.

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Our manufacturing operations are dependent upon several single source suppliers, making us vulnerable to supply disruption, which could harm our business.

Currently, we have three single source suppliers: Dade Behring, which produces a reagent used in our test strips, Haematologic Technologies, which produces our control reagents, and Plexus, which manufactures our meters. Our suppliers may encounter problems during manufacturing due to a variety of reasons, including failure to follow our protocols and procedures, failure to comply with applicable regulations, or equipment malfunction, any of which could delay or impede their ability to meet our demand. Our reliance on these outside suppliers also subjects us to other risks that could harm our business, including:

- we may not be able to obtain an adequate supply of quality raw materials or component parts in a timely manner or on commercially reasonable terms;
- suppliers may make errors in manufacturing components that could negatively affect the performance of our product, cause delays in shipment of our product or lead to returns;
- significant lot-to-lot variation in our test strips could negatively affect the performance of our product or cause delays in shipment of our product;
- we may have difficulty locating and qualifying on a timely basis alternative suppliers for our single-sourced supplies;
- switching components may require product redesign and new submissions to the FDA, either of which could significantly delay production;
- our suppliers manufacture products for a range of customers, and fluctuations in demand for the products these suppliers manufacture for others may affect their ability to deliver components to us in a timely manner; and
- our suppliers may encounter financial hardships either related or unrelated to our demand for components, which could inhibit their ability to fulfill our orders and meet our requirements.

Any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to cancel orders or switch to competitive products, which would harm our business.

We face the risk of product liability claims or recalls and may not be able to maintain or obtain insurance.

Our business exposes us to the risk of product liability claims that are inherent in the testing, manufacturing and marketing of medical devices, including those which may arise from the misuse or malfunction of, or design flaws in, our product. We may be subject to such claims if our product causes, or merely appears to have caused, an injury. Claims may be made by patients, healthcare providers or others selling our product.

In addition, we may be subject to claims even if the apparent injury is due to the actions of others. For example, we rely on the expertise of physicians to determine if a patient is capable of performing patient self-testing. We similarly rely on IDTFs and other medical

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personnel to properly train patients to test themselves using our device. If these professionals are not properly trained or are negligent, our product may be used improperly or the patient may suffer critical injury, which may subject us to liability. These liabilities could prevent or interfere with our product commercialization efforts. Defending a lawsuit, regardless of merit, could be costly, could divert management attention and might result in adverse publicity, which could result in the withdrawal of, or reduced acceptance of, our product in the market.

Although we have product liability insurance that we believe is adequate, this insurance is subject to deductibles and coverage limitations. If we are unable to obtain insurance at an acceptable cost or on acceptable terms with adequate coverage or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may harm our business. A product liability claim or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could result in significant costs and significant harm to our business.

The FDA has the authority to require the recall of our product in the event of material deficiencies, defects in design, manufacture or labeling, or other product problems that could cause serious adverse health consequences or death. Comparable governmental entities in other countries have similar authority. Even where product problems do not present a risk of serious adverse health consequences or death, we may need to conduct a voluntary recall, if our product presents a risk to health. A government mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors or design defects. Any recall would divert managerial and financial resources and harm our reputation with customers.

We face the risk that modifications to our device may require new 510(k) clearance which may not be obtained.

We may be forced to make modifications to our product as a result of:

- obsolescence of a key single-sourced component;
- termination of a key supplier relationship;
- identification of a critical product defect;
- intellectual property issues; or
- enforcement action by a regulatory agency.

The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance; however, the FDA can review a manufacturer s decision. Any modifications to an FDA-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use would require a new 510(k) clearance or possibly a premarket approval. We may not be able to obtain additional 510(k) clearances or premarket approvals for new products, product modifications, or new indications for our product in a timely fashion, or at all. Delays in obtaining required future clearances would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. We have made modifications to our INRatio System in the past and may make additional modifications in the future that we believe do not or will not require additional

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clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing the INRatio System as modified, which would harm our operating results and require us to redesign the INRatio System. In these circumstances, we may be subject to significant enforcement actions.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws and regulations and, if we are unable to or have not fully complied with such laws, could face substantial penalties.

Our operations may be directly or indirectly affected by various broad state and federal healthcare fraud and abuse laws, including the federal Anti-Kickback Statute, which prohibit any person from knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, to induce or reward either the referral of an individual, or the furnishing or arranging for an item or service, for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs. If our past or present operations, including, but not limited to, our consulting arrangements with physicians, or our promotional or discount programs, are found to be in violation of these laws, we or our officers may be subject to civil or criminal penalties, including large monetary penalties, damages, fines, imprisonment and exclusion from Medicare and Medicaid program participation.

We may be subject to false claims laws which could result in substantial penalties.

Because our customers will most likely file claims for reimbursement with government programs such as Medicare and Medicaid, we may be subject to the federal False Claims Act if we knowingly cause the filing of false claims. Violations of the Act may lead to government enforcement actions resulting in substantial civil penalties, including treble damages. The federal False Claims Act also contains provisions that allow private individuals to bring actions on behalf of the government alleging that the defendant has defrauded the government. Various states have enacted laws modeled after the federal False Claims Act. We are unable to predict whether we could be subject to actions under the federal False Claims Act, or the impact of such actions. However, the costs of defending claims under the False Claims Act, as well as sanctions imposed under the Act, could significantly harm our operations.

Our financial controls and procedures may not be sufficient to ensure timely and reliable reporting of financial information, which, as a public company, could materially harm our stock price and Amex listing.

In March 2005, we restated our financial results for the fiscal year ended September 30, 2004 to reflect certain adjustments. The restatement arose, in part, to defer the recognition of revenue on certain shipments made prior to fiscal year end for which title transfer to the customer did not occur until the subsequent period, as well as to correct the accounting for a significant license and settlement agreement. Certain other accounting adjustments were also identified and made. As a result of these errors, we have determined that our internal controls over financial reporting were not effective as of September 30, 2004. In connection with the restatement of our financial statements our independent auditors identified a material weakness in our internal controls and procedures related to inadequate resources in the finance function. As a public company, we require

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greater financial resources than we had as a private company. We only recently hired a member of our finance department, a Corporate Controller, with SEC reporting experience. We cannot provide you with assurance that our finance department has or will maintain adequate resources to ensure that we will not have any future material weakness in our system of internal controls. The effectiveness of our controls and procedures may in the future be limited by a variety of factors including:

- faulty human judgment and simple errors, omissions or mistakes;
- fraudulent action of an individual or collusion of two or more people;
- inappropriate management override of procedures; and
- the possibility that any enhancements to controls and procedures may still not be adequate to assure timely and accurate financial information.

If we fail to have effective controls and procedures for financial reporting in place, we could be unable to provide timely and accurate financial information and be subject to Amex delisting, Securities and Exchange Commission, or SEC, investigation, and civil or criminal sanctions.

We may receive a going concern qualification on our 2005 financial statements, which could harm our operations and our stock price.

The opinion we received from our independent auditors regarding our 2004 financial statements contained an explanatory paragraph as to our ability to continue as a going concern. If the proceeds from our initial public offering are not sufficient to fund our operations as currently conducted and as proposed to be conducted through December 31, 2006, we may also receive a going concern qualification on our financial statements issued for our September 30, 2005 year end financials. If doubts are raised about our ability to continue as a going concern, our stock price could drop and our ability to raise additional funds, to obtain credit on commercially reasonable terms, or to remain in compliance with covenants that we have in place with current lenders may be adversely affected. Additionally, potential customers may not buy our product if they believe that we may not have a viable business. Any of these outcomes would be detrimental to our operations.

We may have warranty claims that exceed our reserves, which could adversely affect our operating results.

The INRatio meter carries a product warranty against defects in materials and workmanship. We have established a warranty reserve based on anticipated failure and return rates for our product. Unforeseen changes in factors affecting our estimates could occur and adversely affect our operating results.

Our inability to adequately protect our intellectual property could allow our competitors and others to produce products based on our technology, which could substantially impair our ability to compete.

Our success and ability to compete is dependent, in part, upon our ability to protect the INRatio System through our intellectual property rights. We rely on a combination of patent,

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copyright and trademark law, trade secrets and nondisclosure agreements to protect our intellectual property. However, such methods may not be adequate to protect us or permit us to gain or maintain a competitive advantage. Our European patent application, or any future U.S. or foreign application, may not issue as a patent or may issue as a patent in a form that may not be advantageous to us. Our issued patents, and those that may issue in the future, may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products.

To protect our proprietary rights, we may in the future need to assert claims of infringement or misappropriation against third parties. The outcome of litigation to enforce our intellectual property rights in patents, copyrights, trade secrets or trademarks is highly unpredictable, could result in substantial costs and diversion of resources, and could have a material adverse effect on our financial condition and results of operations regardless of the final outcome of such litigation. In the event of an adverse judgment, a court could hold that some or all of our asserted intellectual property rights are not infringed, invalid or unenforceable, and could award attorney fees to these third parties.

Despite our efforts to safeguard our unpatented and unregistered intellectual property rights, we may not be successful in doing so or the steps taken by us in this regard may not be adequate to detect or deter misappropriation of our technology or to prevent an unauthorized third party from copying or otherwise obtaining and using our product, technology or other information that we regard as proprietary. Additionally, third parties may be able to design around our patents. Furthermore, the laws of foreign countries may not protect our proprietary rights to the same extent as the laws of the United States. Our inability to adequately protect our intellectual property could allow our competitors and others to produce products based on our technology, which could substantially impair our ability to compete.

We may become subject to claims of infringement or misappropriation of the intellectual property rights of others, which could be costly and harm our business.

Third parties have in the past asserted, and could in the future assert, infringement or misappropriation claims against us with respect to our current or future products. Whether a product infringes a patent involves complex legal and factual issues, the determination of which is often uncertain. Therefore, we cannot be certain that we have not infringed the intellectual property rights of others. Our competitors may assert that our product or the methods we employ in the use or manufacture of our product are covered by U.S. or foreign patents held by them. This risk is exacerbated by the fact that there are numerous issued patents and pending patent applications related to our business that are held by others. For example, in April 2003, Inverness Medical Innovations filed suit against us, alleging that disposable test strips for our INRatio System infringed certain of its patent rights. Inverness sought monetary damages and injunctive relief. In July 2004, we entered into a settlement and mutual release agreement with Inverness pursuant to which we received a license to the patent rights in exchange for a product royalty and a lump sum payment. Additionally, on June, 2005, we received a letter from Beckman Coulter claiming that our test strip includes intellectual property covered by one of their patents, U.S. Patent 5,418,141, and that we could require a license to the patent. We do not believe that their patent covers our test strip or that we need to obtain a license from them.

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Because patent applications may take years to issue, there may be applications now pending of which we are unaware that may later result in issued patents that our product infringes. There could also be existing patents of which we are unaware that one or more components of our system may inadvertently infringe. As the number of competitors in the market for point-of-care and patient self-testing systems grows, the possibility of inadvertent patent infringement by us, or a patent infringement claim against us, increases.

Any infringement or misappropriation claim, with or without merit, could cause us to strain our financial resources, divert management s attention from our business and harm our reputation. If a third party patent were upheld as valid and enforceable and we were found to infringe such patent, we could be prohibited from selling our product unless we could obtain a license to the patent or were able to design around the patent. We may be unable to obtain such a license on terms acceptable to us, if at all, and we may not be able to redesign our product to avoid infringement. A court could also order us to pay compensatory damages for such infringement, plus prejudgment interest and could, in addition, treble the compensatory damages and award attorney fees. These damages could be substantial and could harm our reputation, business, financial condition and operating results. A court also could enter orders that temporarily, preliminarily or permanently enjoin us and our customers from making, using, selling, offering to sell or importing our product, or could enter an order mandating that we undertake certain remedial activities. Depending on the nature of the relief ordered by the court, we could become liable for additional damages to third parties.

The prosecution and enforcement of patents licensed to us by third parties are not within our control, and without these technologies, our product may not be successful and our business would be harmed if the patents were infringed or misappropriated without action by such third parties.

We have obtained licenses from Dade Behring for a reagent and, as part of a settlement of an infringement claim, from Inverness Medical Innovations for a material used in our INRatio test strips. These licenses allow us to use these third parties technologies in our product. We do not control the maintenance, prosecution, enforcement or strategy for the licensed patents and as such are dependent on our licensors to maintain their viability. Without access to these technologies, our ability to conduct our business would be impaired significantly.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Many of our employees were previously employed at other diagnostic companies, including our competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hamper or prevent our ability to market existing or new products, which could severely harm our business.

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We have potential exposure to environmental liabilities, including liability for contamination or other harm caused by materials that we use, generate, dispose of, release or discharge.

Our research and development and clinical processes involve the use of potentially harmful biological materials as well as hazardous materials. We are subject to federal, state and local laws and regulations governing the use, handling, storage, labeling, discharge, release and disposal of hazardous and biological materials and we incur expenses relating to compliance with these laws and regulations. Certain of these laws require us to obtain and operate under permits and authorizations that are subject to periodic renewal or modification. We have evaluated our environmental health and safety practices to determine where deficiencies exist and plan to apply proceeds from this offering to improve our compliance efforts. We could be held liable for damages, penalties and costs of investigation and remedial actions in connection with violations of environmental, health and safety laws or permits. We are also subject to potential liability for the investigation and clean up of any contamination at properties that we currently or formerly owned, operated or leased and off-site locations where we disposed of or arranged for disposal of hazardous materials. Liability for any such contamination can be joint, strict and several without regard to comparative fault under certain environmental laws. We may also be subject to related claims by private parties alleging property damage and/or personal injury due to exposure to hazardous materials at or in the vicinity of such properties. These expenses or this liability could have a significant negative impact on our financial condition. We may violate or have liability under environmental, health and safety laws in the future as a result of human error, equipment failure, or other causes.

Environmental laws or permit conditions could become more stringent over time, imposing greater compliance costs, including capital investments, and increasing risks and penalties associated with violations. For example, the European Parliament has recently finalized the Waste Electrical and Electronic Equipment Directive, or WEEE Directive, which makes producers of electrical goods financially responsible for specified collection, recycling, treatment and disposal of past and future covered products. As a producer of electronic equipment, we will incur financial responsibility for the collection, recycling, treatment or disposal of products covered under the WEEE Directive. We expect to incur increased costs to comply with future legislation which implements this Directive and potentially other related Directives, but we cannot currently estimate the extent of such increased costs. However, to the extent that such cost increases or delays are substantial, our operating results could be materially adversely affected. In addition, similar legislation may be enacted in other countries, including the United States. We are also subject to potentially conflicting and changing regulatory agendas of political, business, and environmental groups. Changes to or restrictions on permitting requirements or processes, hazardous or biological material storage or handling might require us to make an unplanned capital investment or relocation.

All of our operations are conducted at a single location. Any disruption at our facility could adversely affect our operations and increase our expenses.

All of our operations are conducted at a single location in San Jose, California. We take precautions to safeguard our facility, including insurance, health and safety protocols. However, a natural disaster, such as a fire, flood or earthquake, could cause substantial delays in our operations, damage or destroy our manufacturing equipment or inventory, and cause us to incur additional expenses. The insurance we maintain against fires, floods, earthquakes and other natural disasters may not be adequate to cover our losses in any particular case.

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Our success will depend on our ability to attract and retain key personnel, particularly members of management and scientific staff.

We believe our future success will depend upon our ability to attract and retain employees including scientists, members of management and other highly skilled personnel. Our employees may terminate their employment with us at any time and are generally not subject to employment contracts. Hiring qualified scientific and management personnel will be difficult due to the limited number of qualified professionals and the fact that competition for these types of employees is intense. If we fail to attract and retain key personnel, we may not be able to execute our business plan.

Our common stock has been publicly traded for a short period of time, and we expect that the price of our common stock will fluctuate substantially.

Until June 2005, there was no public market for shares of our common stock. The market price for our common stock following this offering will be affected by a number of factors, including:

- our quarterly operating performance;
- changes in earnings estimates or recommendations by securities analysts;
- changes in the availability of reimbursement in the United States or other countries;
- the announcement of new products or product enhancements by us or our competitors;
- announcements of technological or medical innovations in PT/INR monitoring or anticoagulation treatment;
- our ability to develop, obtain regulatory clearance for, and market, new and enhanced products on a timely basis;
- product liability claims or other litigation;
- changes in governmental regulations or in our approvals or applications; and
- general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

A large number of shares issued privately, prior to our initial public offering, may be sold in the market following expiration or early release of lock-up agreements, which may cause the price of our common stock to decline.

As of July 1, 2005, we had approximately 9,577,423 shares of common stock outstanding including, the 3,500,000 shares sold in our initial public offering. The 6,077,423 shares of common

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stock and 1,181,972 shares issuable upon exercise of outstanding options and warrants to purchase shares of common stock, will be available for sale in the public market as follows:

Number of Shares	Date of Availability for Sale
6,673,802	December 26, 2005
585,593	At various times after December 26, 2005

Approximately 6.3 million of the shares that will be available for sale after the expiration of the lock-up period will be subject to volume restrictions because they are held by our affiliates or have been held for less than two years. In addition, the underwriters of our initial public offering may waive these lock-up restrictions prior to the expiration of the lock-up period without prior notice.

If our common stockholders sell substantial amounts of common stock in the public market, or the market perceives that these sales may occur, the market price of our common stock could fall. The holders of approximately 5,616,022 shares of common have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Furthermore, if we were to include in a company-initiated registration statement shares held by those holders pursuant to the exercise of their registration rights, those sales could impair our ability to raise needed capital by depressing the price at which we could sell our common stock.

The cost of public company compliance with the securities laws and regulations is substantial and recently enacted and proposed changes to these laws and regulations will further increase our general and administrative expenses.

The cost of complying with the reporting requirements under the Securities and Exchange Act of 1934 are substantial. In addition, the Sarbanes-Oxley Act of 2002, along with other recent and proposed rules from the SEC and Nasdaq, have required further legal and financial compliance costs, and made some corporate actions more difficult. For example, compliance with the internal control requirements of Sarbanes-Oxley Section 404 requires us to commit significant resources to document and review the adequacy of our internal controls. While we are expending significant resources in developing the required documentation and testing procedures required by Section 404, we can provide no assurance as to conclusions by us or our external auditors with respect to the effectiveness of our internal controls over financial reporting. If we are unable to comply with the requirements of Section 404, we will have to issue a report that our internal controls are not effective, which could cause the market price of our stock to decline.

In addition, the changes in securities laws and regulations may make it more difficult and more expensive for us to maintain directors and officers liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These developments also could make it more difficult for us to attract and retain qualified executive officers and members of our board of directors, particularly with regard to our audit committee.

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Recent changes in the required accounting treatment for stock options will have a material negative impact on our financial statements and may affect our stock price.

In December 2004, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards (SFAS) No. 123(R), Share-Based Payment, pursuant to which we must measure all stock-based compensation awards, including grants of employee stock options, using a fair value-based method and record such expense in our financial statements. This requirement to expense stock-based compensation awards is to take effect for public companies for annual periods beginning after June 15, 2005, thus we are required to adopt this standard commencing January 1, 2006. Currently, we disclose such expenses on a pro forma basis in the notes to our financial statements, but we do not record a charge for employee stock option expense in the financial statements. The inclusion of employee stock-option expense in accordance with SFAS No. 123(R) will cause our reported earnings to decrease, which may affect our stock price

Our principal stockholder owns a significant percentage of our stock, and as a result, can take actions that may be adverse to our other stockholders interests.

MPM Capital and its affiliates own approximately 45% of our common stock. This significant concentration of share ownership may adversely affect the trading price for our common stock because investors often perceive disadvantages in owning stock in companies with controlling stockholders. This stockholder will have the ability to exert substantial influence over all matters requiring approval by our stockholders, including the election and removal of directors and any proposed merger, consolidation or sale of all or substantially all of our assets. In addition, it could dictate the management of our business and affairs. This concentration of ownership could have the effect of delaying, deferring or preventing a change in control, or impeding a merger or consolidation, takeover or other business combination that could be favorable to our other stockholders.

Our charter documents and Delaware law may inhibit a takeover that stockholders consider favorable and could also limit the market price of your stock.

Our amended and restated certificate of incorporation and bylaws will contain provisions that could delay or prevent a change in control of our company. Some of these provisions:

- authorize the issuance of preferred stock which can be created and issued by the board of directors without prior stockholder approval, commonly referred to as blank check preferred stock, with rights senior to those of common stock;
- prohibit stockholder actions by written consent; and
- provide for a classified board of directors.

In addition, we are governed by the provisions of Section 203 of Delaware General Corporate Law. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us. These and other provisions in our amended and restated certificate of incorporation and bylaws and under Delaware law could reduce the price that investors might be willing to pay for shares of our common stock in the future and result in the market price being lower than it would be without these provisions.

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ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Quantitative Disclosures

While we invoice our international distributors in U.S. dollars, the selling prices are adjusted based on fluctuations in the local country currency exchange rate. As a result, we have foreign currency exposure with respect to our revenues from fluctuations in foreign currency exchange rates. We hold no derivative financial instruments and do not currently engage in hedging activities.

Our exposure to interest rate risk is related to the investment of our excess cash into highly liquid financial investments with original maturities of three months or less. We invest in marketable securities with the primary objectives to preserve principal, maintain proper liquidity to meet operating needs and maximize yields while meeting specific credit quality standards for our investments. Due to the short term nature of our investments, we have assessed that there is no material exposure to changes in interest rates

Qualitative Disclosures

Our primary interest rate risk exposures relate to:

the available for sale securities will fall in value if market interest rates increase; and

the impact of interest rate movements on our ability to obtain adequate debt financing to fund future operations.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures. Our management evaluated, with the participation of our Chief Executive Officer and our Chief Financial Officer, the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act of 1934, as amended) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective to ensure that information we are required to disclose in reports that we file or submit under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

Changes in Internal Control Over Financial Reporting. There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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*Sarbanes-Oxley Section 404 Compliance. S*ection 404 of the Sarbanes-Oxley Act of 2002 (the Act) will require our company to include an internal control report from management in its Annual Report on Form 10-K for the fiscal year ending September 30, 2006 and in subsequent Annual Reports thereafter. The internal control report must include the following: (1) a statement of management s responsibility for establishing and maintaining adequate internal control over financial reporting, (2) a statement identifying the framework used by management to conduct the required evaluation of the effectiveness of our internal control over financial reporting, (3) management s assessment of the effectiveness of our internal control over financial reporting as of September 30, 2006, including a statement as to whether or not internal control over financial reporting is effective, and (4) a statement that our independent auditors have issued an attestation report on management s assessment of internal control over financial reporting.

Management acknowledges its responsibility for establishing and maintaining internal controls over financial reporting and seeks to continually improve those controls. In this regard, we will dedicate internal resources, engage outside consultants and adopt a detailed work plan to: (i) assess and document the adequacy of internal control over financial reporting; (ii) take steps to improve control processes where required; (iii) validate through testing that controls are functioning as documented; and (iv) implement a continuous reporting and improvement process for internal control over financial reporting. We believe our process for documenting, evaluating and monitoring our internal control over financial reporting is consistent with the objectives of Section 404 of the Act.

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not presently party to any material litigation.

ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS

We registered the initial public offering of our common stock, par value $0.001 per share, on a Registration Statement on Form S-1 (Registration No. 333-123705), which was declared effective on June 28, 2005. On July 1, 2005 we closed the initial public offering of our common stock by selling 3.5 million shares at $5.50 per share. Additionally on July 27, 2005, the underwriters of the Company s initial public offering exercised their over-allotment option to purchase 12,207 shares at $5.50 per share. Gross proceeds from the offering were $19.3 million. Total expenses from the offering were $2.6 million, which included underwriting discounts and commissions of $1.3 million, and $1.3 million in other offering-related expenses. Net offering proceeds, after deducting total expenses were $16.7 million. The managing underwriters of the offering were Lazard Capital Markets, WR Hambrecht + Co and Roth Capital Partners.

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ITEM 6. EXHIBITS

3.2*	Form of Amended and Restated Certificate of Incorporation as currently in effect.
3.4*	Form of Amended and Restated Bylaws as currently in effect.
4.1*	Specimen Common Stock Certificate.
4.2*	Amended and Restated Investor Rights Agreement dated February 7, 2005 by and among the Company and certain of its stockholders.
10.1*	Form of Indemnification Agreement by and between the Company and each of its directors and officers.
10.2*	1997 Stock Plan, as amended.
10.3*	2005 Equity Incentive Plan.
10.4*	Lease by and between the Company and Montague Oaks Associates Phase I & II dated February 11, 2004.
10.5 *	Physician Plus Agreement dated August 15, 2004 by and between the Company and Cardinal Health 200, Inc., as amended.
10.6 *	Distribution Agreement dated June 30, 2004 by and between the Company and Medline Industries, Inc.
10.7 *	Amended and Restated Distribution Agreement dated March 1, 2005 by and between the Company and Quality Assured Services, Inc.
10.8 *	INR PST Supplier Agreement dated April 2, 2004 by and between the Company and Raytel Cardiac Services.
10.9 *	Manufacture and Supply Agreement dated March 7, 2005 by and between the Company and Haematologic Technologies, Inc.
10.10 *	Professional Service Agreement dated October 29, 2003 by and between the Company and Plexus Services Corp.
10.11 *	Supply and License Agreement dated March 5, 1999 by and between the Company and Dade Behring Inc., as amended.
10.12*	Loan and Security Agreement No. 3821 dated March 5, 2004 by and between the Company and Lighthouse Capital Partners V, L.P.
10.13*	Settlement Agreement and Mutual Release dated July 16, 2004 by and between the Company and Inverness Medical Switzerland GmbH.
10.14*	Consulting Agreement dated May 17, 2002 by and between the Company and Innovative Medical Product Consultants, GmbH.
10.15*	Non-Exclusive Sales Representative and Services Agreement dated November 12, 2002 by and between the Company and Innovative Medical Product Consultants, GmbH.
10.16 *	Distribution Agreement dated April 1, 2003 by and between the Company and Inamed KG.

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10.17*	Employment Agreement dated June 3, 2002 by and between the Company and James D. Merselis.
10.18*	Form of Change of Control Severance Agreement by and between the Company and its officers.
10.19*	Consulting Agreement dated May 6, 2003 by and between the Company and Edward F. Brennan.
10.20*	Amended and Restated Employment Agreement by and between the Company and James D. Merselis effective as of June 1, 2005.
10.21*	Amended and Restated Management Retention Plan.
10.22*	Form of Employment Agreement by and between the Company and its officers.
10.23 *	Letter Agreement by and between the Company and I-Med-Partner GmbH effective as of January 1, 2005.
31.1	Certification of Chief Executive Officer under Rule 13a-14(a)
31.2	Certification of Chief Financial Officer under Rule 13a-14(a)
32.1	Certifications of Chief Executive Officer and Chief Financial Officer under Rule 13a-14(b)

* Incorporated by reference from our Registration Statement on Form S-1 (Registration No. 333-123705), which was declared effective on June 28, 2005.
Portions of the exhibit have been omitted pursuant to a request for confidential treatment. The confidential portions have been filed with the SEC.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Company has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

HEMOSENSE, INC.

Date: August 12, 2005

/s/ James D. Merselis

James D. Merselis
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 12, 2005

/s/ Paul Balsara

Paul Balsara
Vice President of Finance and

Chief Financial Officer
(Principal Financial and Accounting Officer)

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INDEX TO EXHIBITS

Exhibit No.	Description
31.1	Certification of Chief Executive Officer under Rule 13a-14(a)
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32.1	Certifications of Chief Executive and Chief Financial Officer under Rule 13a-14(b)