HEMOSENSE INC
Form 10-Q
August 11, 2006
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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, 2006

¨ 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 x No ¨

Indicate by check mark whether the registrant is a Large accelerated filer, an accelerated filer or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated Filer ¨ Accelerated filer ¨ Non-accelerated filer x

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

As of August 4, 2006 11,204,233 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, 2006	September 30, 2005
Assets		
Current assets:		
Cash and cash equivalents	$ 1,694	$ 3,598
Short term investments	10,377	7,943
Accounts receivable	3,089	2,087
Prepaid expenses and other current assets	404	714
Inventories	2,188	2,744
Total current assets	17,752	17,086
Property and equipment, net	433	512
Technology licenses and prepaid royalties	359	1,179
Other assets	146	226
Total assets	$ 18,690	$ 19,003
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 333	$ 1,029
Accrued expenses and other liabilities	1,681	1,159
Capital lease, current portion	41	37
Borrowings, current portion	2,259	2,000
Total current liabilities	4,314	4,225
Capital lease, net of current portion	22	52
Borrowings, net of current portion	3,069	4,714
Other long term liabilities	204	
Total liabilities	7,609	8,991
Stockholders equity:		
Common stock, $0.001 par value; Authorized: 50,000,000 shares; Issued and outstanding: 11,204,233 and 9,604,989 at June 30, 2006 and September 30, 2005, respectively	11	10
Additional paid-in capital	66,635	57,191
Accumulated other comprehensive loss	(17)	(3)
Accumulated deficit	(55,548)	(47,186)
Total shareholders equity	11,081	10,012
Total liabilities and shareholders equity	$ 18,690	$ 19,003

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,	
	2006	2005	2006	2005
Revenue	$ 4,571	$ 2,454	$ 12,049	$ 5,871
Cost of goods sold	3,513	2,487	8,880	6,826
Gross profit (loss)	1,058	(33)	3,169	(955)
Operating expenses:				
Research and development	769	266	1,913	806
Sales and marketing	2,058	1,677	5,954	4,877
General and administrative	1,139	449	3,181	1,321
Total operating expenses	3,966	2,392	11,048	7,004
Loss from operations	(2,908)	(2,425)	(7,879)	(7,959)
Interest income	144	8	450	18
Interest & other expense, net	(287)	(530)	(933)	(971)
Net loss	$ (3,051)	$ (2,947)	$ (8,362)	$ (8,912)
Net loss per share:				
Basic and diluted	$ (0.27)	$ (5.29)	$ (0.76)	$ (19.59)
Shares used to compute net loss per share:				
Basic and diluted	11,197	557	10,971	455

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,	
	2006	**2005**
Cash flows from operating activities:		
Net loss	$ (8,362)	$ (8,912)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	578	952
Amortization of debt issuance costs	117	279
Provision/write-off of inventories	(6)	105
Amortization of prepaid royalties	695	229
Accrued interest on note payable	85	70
Stock compensation cost	199	
Changes in current assets and liabilities:		
Accounts receivable	(1,002)	(434)
Prepaid expenses and other assets	273	(255)
Inventories	575	(698)
Accounts payable	(696)	390
Accrued expenses and other liabilities	522	159
Net cash used in operating activities	(7,022)	(8,115)
Cash flows from investing activities:		
Proceeds from sale of short term investments	15,954	
Purchase of short term investments	(18,402)	
Acquisition of property and equipment	(170)	(216)
Net cash used in investing activities	(2,618)	(216)
Cash flows from financing activities:		
Proceeds from issuance of common stock and warrants	9,233	33
Proceeds from issuance of preferred stock, net of issuance cost		3,331
Principal payments on capital lease obligation	(26)	(29)
Proceeds from borrowing		6,093
Repayment of borrowings	(1,471)	(910)
Net cash provided by financing activities	7,736	8,518
Net increase (decrease) in cash and cash equivalents	(1,904)	187
Cash and cash equivalents at beginning of period	3,598	433
Cash and cash equivalents at end of period	$ 1,694	$ 620

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

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NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

1) Organization and Basis of Presentation

Description of the Company

HemoSense, Inc., (the Company) was incorporated in the state of Delaware on March 4, 1997 to develop, manufacture and sell easy-to-use, handheld blood coagulation monitoring systems for use by healthcare professionals and patients in the management of warfarin medication. The Company began selling its first product, the INRatio meter and related test strips, in March 2003. Prior to that date, the Company was in the development stage and had been primarily engaged in developing its product technology and raising capital.

Basis of Presentation

The accompanying unaudited condensed financial statements of 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. With the exception of Statement of Financial Accounting Standards, No. 123(R), which was adopted October 1, 2005, 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, 2005 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission. The results of operations for the three and nine month periods ended June 30, 2006 are not necessarily indicative of the results for the year ending September 30, 2006 or any future interim period.

2) Summary of Significant Accounting Policies

The Company s significant accounting policies are disclosed in its Annual Report on Form 10-K for the year ended September 30, 2005, which was filed with the Securities and Exchange Commission. With the exception of Statement of Financial Accounting Standards (SFAS) 123(R) (SFAS 123(R)) which was adopted October 1, 2005, the Company s significant accounting policies have not materially changed since September 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 generally 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 month periods ended June 30, 2006 and June 30, 2005, were as follows (in thousands):

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2006	2005	2006	2005

Balance, at the beginning of the period	$ 70	$ 10	$ 59	$ 6
Accruals and charges for warranty for the period	23	21	65	50
Cost of repairs and replacements	(27)	(18)	(58)	(43)
Balance, at the end of the period	66	$ 13	$ 66	$ 13

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Balance Sheet Data

Inventories

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

	June 30, 2006	September 30, 2005
Raw materials	$ 906	$ 881
Work-in-process	1,000	1,138
Finished goods	282	725
	$ 2,188	$ 2,744

3) Stock-Based Compensation

Stock Option Plans

1997 Stock Option Plan

In 1997, the Company adopted the 1997 Stock Option Plan (the 1997 Plan), as amended, under which 1.1 million shares of the Company s common stock were reserved for issuance to employees, directors and consultants. Options granted under the 1997 Plan may be designated as either incentive stock options or non-statutory stock options. Stock purchase rights could also be granted under the 1997 Plan. Incentive stock options could only be granted to employees. Options granted or stock purchased under the 1997 Plan must become exercisable or the Company s right to repurchase must lapse no less than 20% after one year and ratably over 4 years thereafter. In addition, as of June 30, 2006 there were 125,920 unvested shares underlying stock options granted under the 1997 Plan to certain employees and directors in which the vesting will fully accelerate upon the occurrence of a change in control. The exercise price of incentive stock options and non-statutory stock options shall be no less than 100% and 85%, respectively, of the fair value per share of the Company s common stock on the grant date, as determined by the Company s board of directors. The term of the options is ten years. Since the implementation of the 2005 Equity Incentive Plan, no additional options will be granted from the 1997 Plan and the 1997 Plan will terminate when all the shares have been either exercised, cancelled or expire.

2005 Equity Incentive Plan

In March 2005, the Company s board of directors and stockholders approved the 2005 Equity Incentive Plan (the 2005 Plan), which became effective upon completion of the Company s initial public offering on July 1, 2005. As of June 30, 2006 there were 154,898 unvested shares underlying stock options granted under the 2005 Plan to certain employees and directors in which the vesting will fully accelerate upon the occurrence of a change in control. The Company has reserved a total of 530,000 shares of its common stock for issuance under the 2005 Plan, 304,000 shares of which are available for future grant. In addition, any unused shares in or any unvested shares under the 1997 Plan as of the effective date of the Company s initial public offering were added to the 2005 Plan.

Stock-Based Compensation

Effective October 1, 2005, the Company adopted SFAS 123(R), using the modified prospective application transition method, which establishes accounting for stock-based awards exchanged for employee services. Accordingly, stock-based compensation cost is measured at the beginning of the requisite service period, based on the fair value of the award and is expensed over the requisite service period, which is generally the vesting period. The Company previously applied Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees* and related Interpretations, as permitted by SFAS No. 123, *Accounting for Stock-Based Compensation* (SFAS 123).

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Periods prior to the adoption of SFAS 123(R)

Prior to the adoption of SFAS 123(R), the Company provided the disclosures required under SFAS No. 123, *Accounting for Stock-Based Compensation,* as amended by SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosures.* The Company generally did not recognize employee stock-based compensation expense in its statement of operations for periods prior to the adoption of SFAS 123(R) as most options granted had an exercise price equal to the market value of the underlying common stock on the date of grant.

Proforma disclosure for the three and nine months ended June 30, 2005 is not presented to illustrate the effect on net loss and net loss per share as if the Company had applied the fair value recognition provisions of SFAS 123(R) to options granted under the Company s stock based compensation plans prior to the adoption because all stock options were granted prior to the Company s initial public offering, which was completed in July 2005 and were valued using the minimum value method.

Adoption of SFAS 123(R)

The effect of recording stock-based compensation for the three and nine month periods ended June 30, 2006 was as follows (in thousands, except per share data):

	Three Months Ended June 30, 2006	Nine Months Ended June 30, 2006
Research and development	$ 6	$ 14
Sales and marketing	15	45
General and administrative	43	111
Total operating expense	64	170
Cost of goods sold	17	29
Total compensation expense	$ 81	$ 199
Increase in basic and diluted net loss per share attributable to common stockholders	$ (0. 01)	$ (0. 02)

Total stock-based compensation costs capitalized was $12,000 as of June 30, 2006.

As required by SFAS 123(R), management has made an estimate of expected forfeitures and is recognizing compensation costs only for those equity awards expected to vest.

Stock Options: During the three and nine months ended June 30, 2006, the Company granted approximately 25,000 and 243,000 stock options, respectively, with an estimated total grant-date fair value of $147,000 and $1.5 million, respectively. The Company estimated that the stock-based compensation for the awards not expected to vest was $18,000 and $148,000 for the three and nine months ended June 30, 2006, respectively. During the three and nine months ended June 30, 2006, the Company recorded stock-based compensation related to stock options of $81,000 and $199,000, respectively, for unvested options granted prior to and after the adoption of SFAS 123(R).

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Valuation Assumptions

In connection with the adoption of SFAS 123(R), the Company estimated the fair value of stock options using a Black-Scholes valuation model. The fair value of each option grant is estimated on the date of grant using the Black-Scholes option valuation model and the straight-line attribution approach with the following weighted-average assumptions:

	Three Months Ended June 30, 2006	Nine Months Ended June 30, 2006
Expected volatility	59%	59%
Risk free interest rate	5.17%	4.57%
Dividend yield	0.0%	0.0%
Expected life	6.26 Years	6.20 Years

Proforma disclosure for the three and nine months ended June 30, 2005 is not presented to illustrate the effect on net loss and net loss per share as if the Company had applied the fair value recognition provisions of SFAS 123(R) to options granted under the Company s stock based compensation plans prior to the adoption because all stock options were granted prior to the Company s initial public offering, which was completed in July 2005 and were valued at the minimum value method.

Expected Term: Due to insufficient historical information, given consideration to the contractual terms of the stock-based awards, the Company adopted the simplified method for estimating the expected term pursuant to Staff Accounting Bulletin No. 107 (SAB 107) to represent the period that the Company s stock-based awards are expected to be outstanding.

Expected Volatility: The fair value of stock-based payments made through the quarter ended June 30, 2006 were valued using the Black-Scholes valuation method with a volatility factor based on the Company s historical stock prices and comparable companies.

Expected Dividend: The Black-Scholes valuation model calls for a single expected dividend yield as an input. The Company has never declared or paid any cash dividends on its capital stock, and the Company does not anticipate any dividend payments on its common stock in the foreseeable future.

Risk-Free Interest Rate: The Company bases the risk-free interest rate used in the Black-Scholes valuation method on the implied yield currently available on U.S. Treasury constant maturities with an approximate equivalent remaining term.

Estimated Pre-vesting Forfeitures: When estimating forfeitures, the Company considers voluntary termination behavior.

Stock Option Activity

The following is a summary of options activities (amount in thousands, except per share amounts):

	Options Outstanding		
	Shares Available for Grant	Number of Shares	Weighted Average Exercise Price
Balance as of September 30, 2005	42	1,028	$ 1.37
Increase in authorized shares	480		
Granted	(243)	243	6.20
Cancelled	24	(24)	5.02
Exercised		(117)	0.78
Expired	1	(1)	2.80
Balance as of June 30, 2006	304	1,129	$ 2.39

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The options outstanding and exercisable at June 30, 2006 were in the following exercise price ranges (amount in thousands, except per share amounts):

	Options Outstanding				Options Exercisable			
Range of Exercise Prices	Number of Outstanding Shares	Weighted Average Remaining Contractual Life (in Yrs)	Weighted Average Exercise Price	Aggregate Intrinsic Value	Number of Outstanding Shares	Weighted Average Remaining Contractual Life (in Yrs)	Weighted Average Exercise Price	Aggregate Intrinsic Value
$ 0.00 1.00	805	7.3	$ 0.80	$ 3,624	606	7.0	$ 0.80	$ 2,731
1.01 2.00	1	3.2	2.00	4	1	3.2	2.00	4
2.01 5.30	10	3.9	2.80	24	10	3.9	2.80	24
5.31 7.00	214	9.5	6.01		16	9.5	6.01	
7.01 - 9.00	99	9.2	7.51		5	9.2	7.51	
	1,129	7.9	$ 2.39	$ 3,652	638	7.0	$ 0.90	$ 2,759

The aggregate intrinsic value in the table above represents the total intrinsic value, based on the Company s ending stock price of $5.30 at June 30, 2006, which would have been received by the option holders had all option holders exercised their options at the period end. The total number of in-the-money options exercisable as of June 30, 2006 was 617,000 shares.

Information regarding the Company s stock options transactions for the three and nine months ended June 30, 2006 is presented below (in thousands, except for per options information):

	Three Months Ended June 30, 2006	Nine Months Ended June 30, 2006
Total fair value of shares vested	$ 19	$ 73
Total intrinsic value of options exercised	$ 96	$ 584
Total cash received from employees from exercises of options	$ 12	$ 92
Weighted average exercise price of options granted	$ 5.94	$ 6.20

In connection with the above exercises, there was no tax benefit realized by the Company due to the Company s current loss position. The Company issues new shares of common stock upon exercise of stock options.

A summary of the status of the Company s non-vested shares as of June 30, 2006 and changes during the nine month period ended June 30, 2006, is presented below (amount in thousands, except per share amounts):

	Number of Shares	Weighted Average Grant Date Fair Value
Non-vested at September 30, 2005	422	$ 2.14
Granted	243	$ 3.75
Vested	(150)	$ 0.47
Cancelled /forfeited	(24)	$ 3.22
Non-vested at June 30, 2006	491	$ 2.52

As of June 30, 2006, there was $951,000 of total unrecognized compensation cost related to non-vested stock-based compensation arrangements granted under both of the plans. The cost is expected to be recognized over a weighted average period of 2.5 years.

4) 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 shares outstanding during a period, if dilutive.

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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 and Nine Months Ended June 30,	
	2006	2005
Redeemable convertible preferred stock (as if converted)		5,489
Options to purchase common stock	1,129	1,000
Warrants to purchase redeemable convertible preferred stock (as if converted)		127
Warrants to purchase common stock	922	55

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, was as follows, (in thousands):

	Three Months Ended June 30,		Nine Months Ended June 30,	
Revenue by Geographic Area	**2006**	**2005**	**2006**	**2005**
United States	$ 3,734	$ 1,867	$ 9,845	$ 4,295
Germany	292	291	809	907
Other	545	296	1,395	669
Total revenue	$ 4,571	$ 2,454	$ 12,049	$ 5,871

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

The following discussion contains trend information and other forward-looking statements that involve a number of risks and uncertainties. Forward-looking statements include, but are not limited to, statements such as those regarding anticipated growth or expansion of our business, expansion of reimbursement, our ability to achieve cost reductions and increases in production volumes, increases in gross margin, increases in research and development and sales and marketing expenses over the course of the next fiscal year, decreases in general and administrative expenses over the course of the next fiscal year, and the sufficiency of our cash to fund our operations for the next twelve months. Our actual results could differ materially from our historical results and those discussed in the forward-looking statements. Factors that could cause actual results to differ materially include, but are not limited to, those identified Part II, Item 1A, Risk Factors. This discussion should be read in conjunction with the Consolidated Financial Statements and accompanying notes and with our Annual Report on Form 10-K for the year ended September 30, 2005.

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 U.S. Food and Drug Administration, or FDA, for use by healthcare professionals as well as for patient self-testing. Our system is also 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 the INRatio System with quality controls integrated into the test strip;
- the portability of the INRatio system, which utilizes non-refrigerated strips and a battery operated meter;
- 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 Prothrombin Time, international normalized ratio, or 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 additional 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 future 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.

In April 2006 we signed an agreement with J-PAC, a medical device assembly and packaging services company, to provide highly customized packaging services for our test strips. We believe that the expansion of our production capacity through this agreement will help us meet expected demand for test strips and move us towards our goal of profitability. As a result of the change to J-PAC, the cost of our test strip should decline over the remainder of the fiscal year.

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 fully maximized. We expect that increases in production volume will be a significant factor for cost reduction for our test strips. We achieved a positive gross margin for the first time during the quarter ended September 30, 2005 which has continued through the quarter ended June 30, 2006, where we achieved a 23% gross margin. We believe continuing volume increases and process improvements will sustain and enhance cost reductions for our products in the future.

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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,					
	2006		2005		Amount of Increase (Decrease)	Percent Increase (Decrease)
	Amount	% of Sales	Amount	% of Sales		
Revenue	$ 4,571	100%	$ 2,454	100%	$ 2,117	86%
Cost of goods sold	3,513	77	2,487	101	1,026	41
Gross profit (loss)	1,058	23	(33)	(1)	1,091	3,306
Operating expenses						
Research and development	769	17	266	11	503	189
Sales and marketing	2,058	45	1,677	68	381	23
General and administrative	1,139	25	449	18	690	154
Total operating expenses	3,966	87	2,392	97	1,574	66
Loss from operations	(2,908)	(64)	(2,425)	(98)	(483)	(20)
Interest income	144	3	8		136	1,700
Interest and other expense, net	(287)	(6)	(530)	(22)	243	46
Net loss	$ (3,051)	(67)%	$ (2,947)	(120)%	$ 104	(4) %

	Nine Months Ended June 30,					
	2006		2005		Amount of Increase (Decrease)	Percent Increase (Decrease)
	Amount	% of Sales	Amount	% of Sales		
Revenue	$ 12,049	100%	$ 5,871	100%	$ 6,178	105%
Cost of goods sold	8,880	74	6,826	116	2,054	30
Gross profit (loss)	3,169	26	(955)	(16)	4,124	432
Operating expenses						
Research and development	1,913	16	806	14	1,107	137
Sales and marketing	5,954	49	4,877	83	1,077	22
General and administrative	3,181	26	1,321	23	1,860	141
Total operating expenses	11,048	91	7,004	120	4,044	58
Loss from operations	(7,879)	(65)	(7,959)	(136)	80	1
Interest income	450	4	18		432	2,400
Interest and other expense, net	(933)	(8)	(971)	(17)	38	4
Net loss	$ (8,362)	(69)%	$ (8,912)	(153)%	$ 550	6%

Revenue. For the three months ended June 30, 2006, revenue increased $2.1 million, or 86%, to $4.6 million from $2.5 million for the three months ended June 30, 2005. The revenue increase, both in the United States and internationally, was attributed to an increase in sales by our distribution partners in the markets they serve. The increase in sales was due to the sale of test strips which increased $1.9 million, or 128%, from $1.5 million for the three months ended June 30, 2005 to $3.4 million for the three months ended June 30, 2006. Meters and accessories revenue increased $204,000, or 21%, to $1.2 million for the three months ended June 30, 2006 as compared to $960,000 for the three months ended June 30, 2005. We anticipate revenue for all products to increase over the balance of the current fiscal year as we continue to penetrate the worldwide markets for our products.

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For the nine months ended June 30, 2006, total revenue increased $6.1 million, or 105%, to $12.0 million from $5.9 million for the nine months ended June 30, 2005. The revenue increase, both in the United States and internationally, was attributed to an increase in sales by our distribution partners in the markets they serve. The increase in sales was due to the sale of test strips which increased $4.9 million, or 148%, from $3.3 million for the nine months ended June 30, 2005 to $8.2 million for the nine months ended June 30, 2006. Meters and accessories revenue increased $1.3 million, or 51%, to $3.9 million for the nine months ended June 30, 2006 as compared to $2.6 million for the nine months ended June 30, 2005.

Cost of Goods Sold. Cost of goods sold increased $1.0 million, or 41%, to $3.5 million for the three months ended June 30, 2006 from $2.5 million for the three months ended June 30, 2005. Most of the increase related to increased product revenue shipments for the three months ended June 30, 2006 compared to the same period last year. Gross profit was 23% for the three months ended June 30, 2006 compared to a gross loss of 1% of revenue for the three months ended June 30, 2005. The improvement in gross profit from a gross loss was attributed to increased production volume and process improvements for test strips. Additionally, factory direct labor and overhead decreased while strip production increased to support increased unit sales. The decrease in factory spending was attributed primarily to reduced depreciation expense for production equipment as the result of fully depreciated equipment as well as wages and related benefits. Gross profit was adversely affected by our placement program of INRatio meters in certain markets which resulted in a lower overall average selling price for INRatio meters.

For the nine months ended June 30, 2006, cost of goods sold increased $2.1 million, or 30%, to $8.9 million from $6.9 million for the nine months ended June 30, 2005. Most of the increase related to increased product revenue shipments for the nine months ended June 30, 2006 compared to the same period last year. Gross profit was 26% for the nine months ended June 30, 2006 compared to a gross loss of 16% of revenue for the nine months ended June 30, 2005. The improvement in gross profit from a gross loss was attributed primarily to increased production volume and process improvements for test strips. Also direct labor and overhead decreased by 11% while production increased to support increased unit sales. The decline in overhead costs related to reduced production equipment depreciation as the result of fully depreciated equipment. We expect the gross margin percent for the remainder of fiscal 2006 to increase slightly over the third quarter year to date percentage, due primarily to outsourcing test strip final assembly and packaging and continued improvements in the in house production process.

Research and Development Expenses. Research and development expenses increased $503,000, or 189%, to $769,000 for the three months ended June 30, 2006 from $266,000 for the three months ended June 30, 2005. The increase was primarily attributable to $367,000 increased costs for consultants relating to the design of a next generation of INRatio meter. Additionally, increased head count resulted in $143,000 of higher payroll costs. As a percent of total revenue, research and development expenses increased to 17% for the three months ended June 30, 2006 from 11% for the three months ended June 30, 2005 mainly due to the increased product development. Over the remainder of the fiscal year we expect research and development expenses to increase as new initiatives are continued. As a result, there may be an increase in overall research and development expenses but a reduction in the percentage of total revenue represented by such expenses when compared to the third fiscal quarter.

For the nine months ended June 30, 2006, research and development expenses increased $1.1 million, or 137%, to $1.9 million, from $806,000 for the nine months ended June 30, 2005. The increase was primarily attributable to $845,000 in expenses for consultants and intellectual property related legal services relating to the design of a next generation of INRatio meter and other development programs. Additionally, increased head count resulted in $292,000 higher payroll and related costs. As a percent of total revenue, research and development expenses increased to 16% for the nine months ended June 30, 2006 from 14% for the nine months ended June 30, 2005.

Sales and Marketing Expenses. Sales and marketing expenses increased $381,000, or 23%, to $2.1 million for the three months ended June 30, 2006 from $1.7 million for the three months ended June 30, 2005. The increase was primarily attributable to $313,000 for payroll and travel expenses for additional personnel used in both the field and support functions. Additionally, product marketing costs increased $88,000 as the efforts to promote our product expanded. As a percent of total revenue, sales and marketing expenses decreased to 45% for the three months ended June 30, 2006 from 68% for the three months ended June 30, 2005 primarily due to our increased revenue.

For the nine months ending June 30, 2006 sales and marketing expenses increased $1.1 million, or 22%, to $6.0 million from $4.9 million for the nine months ended June 30, 2005. The increase was primarily attributable to $1.0 million for payroll and travel expenses for additional personnel used in both the field and support functions. Product marketing cost increased $241,000 as the efforts to promote our product expanded. These costs were partially offset by a $251,000 reduction in consulting expenses, primarily due to the discontinuance of a European agency relationship in January 2005. As

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a percent of total revenue, sales and marketing expenses decreased to 49% for the nine months ended June 30, 2006 from 83% for the nine months ended June 30, 2005 primarily due to the increase in revenue. Over the balance of the fiscal year, we expect sales and marketing expenses to continue to increase, but slower than our expected growth in revenue.

General and Administrative Expenses. General and administrative expenses increased $690,000 to $1.1 million for the three months ended June 30, 2006 from $449,000 for the three months ended June 30, 2005. Consultants and outside professional services, including legal and accounting, increased $435,000 representing costs associated with being a public company. Payroll and other benefits increased $123,000 due to increased stock-based compensation, management bonuses and headcount. Insurance expense increased $127,000 due to increased premiums for directors and officer liability insurance as a result of being a public company. As a percent of total revenue, general and administrative expenses increased to 25% for the three months ended June 30, 2006 from 18% for the three months ended June 30, 2005.

For the nine months ended June 30, 2006 general and administrative expenses increased $1.9 million to $3.2 million from $1.3 million for the nine months ended June 30, 2005. Consultants and outside professional services, including legal and accounting, increased $921,000 representing costs associated with being a public company, including preliminary work for Sarbanes-Oxley Section 404 compliance. Payroll and other benefits increased $487,000 due to increased headcount, stock based compensation and payment of management recognition awards. Insurance expense increased $405,000 due to increased premiums for directors and officer liability insurance as a result of being a public company. As a percent of total revenue, general and administrative expenses increased to 26% for the nine months ended June 30, 2006 from 23% for the nine months ended June 30, 2005. Over the balance of the fiscal year, we expect a reduction in our general and administrative expenses in connection with the extension by at least one year of our required date for compliance with Sarbanes-Oxley Section 404, compared to the first nine months of fiscal 2006. As a result, expenses are expected to decrease as a percentage of total revenue.

Interest Income. Interest income increased by $136,000 from $8,000 for the three months ended June 30, 2005 to $144,000 for the three months ended June 30, 2006. The increase related to returns on short term investments purchased with a portion of the funds received from the initial public offering, in July 2005, and our private placement in November 2005.

Interest income increased by $432,000, from $18,000 for the nine months ended June 30, 2005 to $450,000 for the nine months ended June 30, 2006. The increase related to returns on short term investments purchased with a portion of the funds received from the initial public offering, in July 2005, and our private placement in November 2005.

Interest and Other Expense. Interest and other expense decreased $243,000, or 46%, to $287,000 for the three months ended June 30, 2006 from $530,000 for the three months ended June 30, 2005. The decrease relates to the lower level of debt outstanding compared to the prior year, primarily relating to short term borrowings which were paid with the proceeds from our initial public offering.

For the nine months ended June 30, 2006 interest and other expenses decreased $38,000, or 4% to $933,000 from $971,000 for the nine months ended June 30, 2005. The decrease was attributed to a lower level of debt over the same period last year.

Liquidity and Capital Resources

Cash flow information for the nine months ended June 30, 2006 and June 30, 2005 was as follows (in thousands):

	June 30, 2006	June 30, 2005
Cash, cash equivalents and short term investments	$ 12,071	$ 620
Net cash used in operating activities	$ (7,022)	$ (8,115)
Net cash used in investing activities	(2,618)	(216)
Net cash provided by financing activities	7,736	8,518
Net increase (decrease) in cash and cash equivalents	$ (1,904)	$ 187

Since our inception, our operations have been primarily financed through the sale of equity securities, both public and private, bank equipment financing loans, debt capital and capital leases. As of June 30, 2006, our cash, cash equivalents and short term investments were $12.1 million.

All of our cash equivalents and investments have original maturities of one year or less. On November 4, 2005 we closed a private equity offering of 1,481,482 shares of common stock at $6.75 per share and warrants to purchase 740,741 shares of our common stock. Gross proceeds from the offering were $10.0 million. Net proceeds were $9.2 million after offering expenses, including underwriting commissions.

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During the nine months ended June 30, 2006, our operating activities used cash of approximately $7.0 million, compared to approximately $8.1 million for the nine months ended June 30, 2005, a decrease of $1.1 million. This was comprised of $550,000 decrease in the net loss and $33,000 increases in non-cash adjustments. Net increase of non-cash current assets and liabilities was $510,000 primarily due to increases in accounts receivable and reduced accounts payable. The increase in accounts receivable related primarily to the increase in revenue for the nine months ended June 30, 2006 over the same period last year. The reduction in accounts payable related to the timing of inventory purchases. These uses of funds were partially offset by a decline in inventory during the nine months ended June 30, 2006 compared to an increase in the same period in the prior fiscal year.

Our investing activities used cash of approximately $2.6 million during the nine months ended June 30, 2006 compared to $216,000 for the nine months ended June 30, 2005. The increase in the use of funds was attributable to $2.4 million increase in net purchases of marketable securities with cash and cash equivalents available in excess of operational needs.

Cash provided by financing activities was $7.7 million for the nine months ended June 30, 2006 compared to $8.5 million provided by financing activities for the nine months ended June 30, 2005. The increase in cash provided for the nine months ended June 30, 2006 was due to $9.2 million of net proceeds from our private stock placement in November 2005. For the nine months ending June 30, 2005, the source of funds was $6.1 million increased borrowings and $3.3 million from the sale of common and preferred stock. For the nine months ending June 30, 2006, we reduced our debt and other obligations by $1.5 million compared to payments of $910,000 for the same period last year.

As of June 30, 2006, we had a long term loan payable, a long term note payable, capital lease obligations, commitments under facility and equipment operating leases, and 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):

	2006	2007	2008	2009	2010	2011	Total
Loan payable	$ 531	$ 2,353	$ 1,786	$	$	$	$ 4,670
Note payable				658			658
Capital leases	10	36	17				63
Facility lease	37	152	162	90			441
Equipment leases	6	23	23	15	15	4	86
Cancelable purchase commitments	1,959						1,959
Non-cancelable purchase commitments	1,169						1,169
Total	$ 3,712	$ 2,564	$ 1,988	$ 763	$ 15	$ 4	$ 9,046

We believe that 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

a decision to acquire or license complementary products, technologies or businesses.

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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

Our significant accounting policies are disclosed in our Annual Report on Form 10-K for the year ended September 30, 2005, which was filed with the Securities and Exchange Commission. With the exception of Statement of Financial Accounting Standards, No. 123(R) or, SFAS 123(R), which was adopted October 1, 2005, our significant accounting policies have not materially changed as of June 30, 2006.

Effective October 1, 2005, we adopted SFAS 123(R), using the modified prospective application transition method, which establishes accounting for stock-based awards exchanged for employee services. Accordingly, stock-based compensation cost is measured at the beginning of the requisite service period, based on the fair value of the award and is recognized over the requisite service period. The option pricing model requires the input of subjective estimates, including the option s expected life and the price volatility of the underlying stock. Prior to the adoption of SFAS 123(R), we accounted for stock-based compensation using the intrinsic value method as prescribed in Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*. The fair value of each stock option was 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. Accordingly, no compensation cost had been recognized in our statement of operations for employee stock options; however, we provided additional pro forma disclosures as required under SFAS 123, as amended by SFAS No 148, *Accounting for stock-based compensation, transition and disclosure.*

Recent Accounting Pronouncements

None.

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.

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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, and that such information is accumulated and communicated to management as appropriate to allow for timely decisions regarding required disclosure.

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.

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not party to any pending material litigation.

ITEM 1A. RISK FACTORS

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 $4.0 million in 2001, $4.7 million in 2002, $6.9 million in 2003, $10.3 million in 2004 and $11.7 million in 2005. As of June 30, 2006, we had an accumulated deficit of $55.5 million. We expect that our operating expenses will increase as we expand our business, devote additional resources to our research and development, increase sales and marketing efforts and incur the costs of being a public company.

We expect that the price of our common stock will fluctuate substantially.

The average daily trading volume of our stock is low, and our stock price may move significantly from the trading of relatively few shares. The market price for our common stock 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 for the use of our products 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 marketing approvals or applications from or with regulatory authorities; and

general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

Changes in the price of our common stock will be unpredictable and any of these factors could cause our stock price to fluctuate substantially.

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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 valve surgeries;
- new product introductions by our competitors; and
- the timing and uncertainty of United States and foreign reimbursement decisions with respect to the use of our products.

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.

We will be unable to achieve profitability unless we increase revenue and decrease 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.

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, accuracy 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 are subject to FDA inspection and possible enforcement action in the event of regulatory violations.

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,

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shipping and post market surveillance of our product. The FDA enforces the QSR through both scheduled and unannounced inspections. During May 2005, we underwent an inspection of our facilities by the FDA, which resulted in the issuance of an FDA Form 483 and, subsequently, a warning letter, because the FDA believed that our Form 483 response did not provide sufficient detail and documentation for the FDA to evaluate whether our corrective actions would be adequate to prevent recurrence of the inspection observations. The FDA has accepted our response to the warning letter. In addition, during May, June and July of 2006, we underwent another inspection of our facility by the FDA which resulted in the issuance of a FDA Form 483 identifying deficiencies in the same general area as those described in the 2005 warning letter. We submitted our response to the Form 483 in July, 2006. Although we believe that our response adequately addresses FDA concerns, we cannot assure that the FDA will accept our response as adequate or will not take enforcement action against us, which may include the following sanctions:

- warning letter;
- 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.

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 a medical device report, or MDR with the FDA. Our revised procedure requires us to file a medical device report, or 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 have used 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, in part, 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 competition in 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 in the near future. 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

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effectively 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 litigation.

Because of these competitive advantages, these companies may be able to engage in aggressive practices that may harm our business, without us being able to effectively respond. In 2005, following the issuance by the FDA of a warning letter, we experienced a brief impact on our overseas sales performance as a competitor attempted to use a warning letter issued by the FDA to disrupt our customer relationships. If a warning letter were to be issued in the future, we could experience a similar adverse effect on our sales. If we are not able to compete effectively against these companies or their products, 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. We are aware that pharmaceutical companies are researching and developing potential alternatives to warfarin. 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 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 reimbursement for PT/INR testing is available in the point-of-care environment for monitoring all uses of warfarin. 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 United States 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 neither participate in nor 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.

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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. After international reimbursement is established, it may be severely limited or eliminated in future years. 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 June 30, 2006 was comprised of 33 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 seven national and four regional distributors in the United States. We also have agreements with 15 international distributors of our product. Three of our distributors, Quality Assured Services, Medline and Cardinal Health, each accounted for between 9% to 20% and 49% in the aggregate, of our total revenue in fiscal 2006. 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.

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 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. 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

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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.

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 and labeling 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.

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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 Flextronics, 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.

Additionally, we may become involved in a contractual dispute with any one of these suppliers, or may be unable to negotiate the renewal of an expiring contract, either of which could mean an interruption or delay in the supplied component or material. 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.

Certain of our manufacturing operations are dependent upon a single source contract manufacturer, making us vulnerable to production disruption, which could harm our business.

In March 2006, we executed a Packaging Agreement with J-PAC, a third party manufacturer, to provide pouching and packaging services to support our production of INRatio test strips in support of the INRatio PT/INR Monitoring System product line. J-PAC may encounter problems carrying out these aspects of the manufacture of our products and carrying out its services to us due to a variety of reasons, including failure to follow our protocols and procedures, supply shortages or equipment malfunction, any of which could delay or impede their ability to meet our demand. Our reliance on J-PAC also subjects us to other risks that could harm our business, including:

J-PAC carries out manufacturing services for a range of customers, and fluctuations in demand for J-PAC s services for others may affect their ability to deliver finished goods to us in a timely manner;

Risk of damage or loss of our product while in transit between sites,

J-PAC may encounter financial hardship either related or unrelated to our demand, which could inhibit their ability to fulfill our orders and meet our requirements; and

we may have difficulty locating and qualifying on a timely basis an alternative for J-PAC s services.

Additionally, we may become involved in a contractual dispute with J-PAC, or may be unable to negotiate the renewal of our contract with J-PAC, either of which could mean an interruption or delay in the obtaining J-PAC s services. Any interruption or delay in J-PAC s services, or our inability to obtain the same finished goods or services 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.

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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 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 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

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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 which both the Audit Committee and management agreed. As a public company, we require greater financial resources than we had as a private company. During 2005, we hired a member of our finance department, a Corporate Controller, with SEC reporting experience; however, 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 American Stock Exchange, or AMEX, delisting, Securities and Exchange Commission, or SEC, investigation, and civil or criminal sanctions.

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.

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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, 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 United States 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, we have been in discussions with Beckman Coulter regarding coverage of our test strip by one or more of their patents. While we are still evaluating such patents, we currently do not believe that they cover our test strip or that we need to obtain a license under such patents.

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.

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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.

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 our initial public 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.

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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.

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.

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 rules from the SEC and AMEX, 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 determine we have a material weakness of our internal controls under the 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.

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 39% 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.

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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 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.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

We registered for 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 completed 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 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. Of the $16.7 million in net proceeds, through June 30, 2006, we have spent approximately, $7.8 million for sales and marketing initiatives to support the ongoing commercialization of our INRatio System, $2.4 million for research and development activities, including support of product development, regulatory and clinical study initiatives, $1.5 million for repayment of outstanding principal and interest due from promissory notes bearing interest at the rate of 6% annually held by affiliates, plus accrued interest, and $5.0 million for working capital and general corporate purposes.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

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

None

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit No.	Description
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.

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4.3**	Form of Securities Purchase Agreement dated November 1, 2005 by and between the Company and each of the investors in its 2005 private placement.
4.4**	Form of Warrant to Purchase Common Stock.
10.6.1	Amendment No. 2 to Distribution Agreement, Dated June 15, 2006, by and between the Company and Medline Industries Inc.
10.25	Manufacturing Services Agreement, Dated May 25, 2006, by and between the Company and Flextronics International USA, Inc.
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 pursuant to 18 U.S.C. 1350.

* Incorporated by reference from our Registration Statement on Form S-1 (Registration No. 333-123705), which was declared effective on June 28, 2005.

** Incorporated by reference from our Current Report on Form 8-K dated November 8, 2005.
Pursuant to a request for confidential treatment, portions of this exhibit has been redacted from the previously filed document and have been furnished separately to the Securities and Exchange Commission as required by Rule 24b-2 under the Securities Exchange Act of 1934.

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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.

Date: August 11, 2006

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

Date: August 11, 2006

/s/ Paul Balsara
Paul Balsara
Vice President of Finance and

Chief Financial Officer
(Principal Financial and Accounting Officer)

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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.
4.3**	Form of Securities Purchase Agreement dated November 1, 2005 by and between the Company and each of the investors in its 2005 private placement.
4.4**	Form of Warrant to Purchase Common Stock.
10.6.1	Amendment No. 2 to Distribution Agreement, Dated June 15, 2006, by and between the Company and Medline Industries Inc.
10.25	Manufacturing Services Agreement, Dated May 25, 2006, by and between the Company and Flextronics International USA, Inc.
31.1	Certification of Chief Executive Officer under Rule 13a-14(a).
31.2	Certification of Chief Financial Officer under Rule 13a-14(ba).
32.1	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S. C. 1350.

* Incorporated by reference from our Registration Statement on Form S-1 (Registration No. 333-123705), which was declared effective on June 28, 2005.

** Incorporated by reference from our Current Report on Form 8-K dated November 8, 2005.
Pursuant to a request for confidential treatment, portions of this exhibit has been redacted from the previously filed document and have been furnished separately to the Securities and Exchange Commission as required by Rule 24b-2 under the Securities Exchange Act of 1934.