HEMOSENSE INC
Form 424B4
June 29, 2005
Table of Contents

Filed pursuant to Rule 424(b)(4)
Registration No. 333-123705

3,500,000 Shares

Common Stock

This is an initial public offering of shares of common stock by HemoSense, Inc. We are offering 3,500,000 shares of our common stock. The initial public offering price is $5.50 per share.

Our common stock has been approved for listing on the American Stock Exchange, or Amex, under the symbol HEM.

Investing in our common stock involves certain risks. See Risk Factors beginning on page 6.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Share	Total
Initial Public Offering Price	$ 5.50	$ 19,250,000
Underwriting Discount	$ 0.385	$ 1,347,500
Proceeds, Before Expenses, to HemoSense, Inc.	$ 5.115	$ 17,902,500

The underwriters have a 30-day option to purchase up to 525,000 additional shares of common stock from us to cover over-allotments, if any.

Lazard Capital Markets **WR Hambrecht + Co**

Roth Capital Partners

The date of this prospectus is June 28, 2005

Table of Contents

INSIDE FRONT COVER

[Picture of hand holding INRatio System meter with test strip inserted]

[Text on INRatio System meter screen with illustrative reading of data, including date, time, INR value, PT value and quality control check]

Actual size

Table of Contents

TABLE OF CONTENTS

You should rely only on the information contained in this prospectus. We have not, and the underwriters have not, authorized any other person to provide you with different information. This prospectus is not an offer to sell, nor is it seeking an offer to buy, these securities in any state where the offer or sale is not permitted. The information in this prospectus is complete and accurate as of the date on the front cover, but the information may have changed since that date.

Table of Contents

PROSPECTUS SUMMARY

The items in the following summary should be read together with the more detailed information regarding our company and the common stock being sold in this offering. This summary provides an overview of selected information and does not contain all of the information you should consider before investing in our common stock. Please read the entire prospectus carefully.

Business of HemoSense

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. Warfarin is an oral anticoagulation, or blood thinning, drug given to patients to prevent potentially lethal blood clots. Our product, the INRatio System, consists of a small, portable meter and disposable test strips and provides a quick and accurate measurement of a patient s blood clotting time, known as a PT/INR value. The accurate measurement of the PT/INR value is critical to ensuring the safety and effectiveness of warfarin in maintaining a patient s blood coagulation level IN-Ratio, or within a therapeutic range. We commercially launched the INRatio System in March 2003 in the United States and certain European markets. Tests performed using our INRatio System in the point-of-care setting are currently reimbursed by Medicare for all patients on warfarin as is self-testing by mechanical heart valve patients on warfarin. To date, we have sold more than 5,000 INRatio meters and more than one million INRatio test strips worldwide for professional use at the point-of-care and patient self-testing at home. We have established distribution agreements with several national and regional distributors of medical products, giving us access to over 1,000 U.S. sales representatives for the sale of the INRatio System. In addition, we have established international distribution agreements with 12 distribution partners covering 16 countries outside the United States. For the year ended September 30, 2004, our total revenue was $3.3 million.

Background and Market

Warfarin has been prescribed since the 1950s and is regarded as safe and effective when it is dosed correctly. It is the most widely prescribed oral anticoagulant besides aspirin. There are approximately three million people in the United States who take Warfarin daily. In 2003, there were over 20 million prescriptions for warfarin written in the United States, either in generic form, or under its brand name Coumadin. Based upon Medicare claims data, there were 18.3 million PT/INR tests conducted on U.S. Medicare patients in 2003, comprised of approximately 13.4 million clinical laboratory tests and 4.9 million point-of-care or patient self-tests. By contrast, there were 13.8 million tests performed in 2000, consisting of 12.1 million clinical laboratory tests, and 1.7 million point-of-care tests. The total number of PT/INR tests increased by more than 30% over this three-year period, with 11% growth in the laboratory testing market, as compared with 190% growth in the point-of-care and patient self-testing markets. We believe that similar trends have occurred with private insurance payors and in countries outside of the United States. In Germany, where reimbursement was established in 1996, more than 100,000 patients are performing PT/INR self-testing.

The U.S. Centers for Medicare & Medicaid Services, or CMS, has observed that monthly PT/INR testing is inadequate for the majority of patients on chronic warfarin therapy. More frequent testing helps maintain patients within their therapeutic range and may minimize adverse events, such as dangerous blood clots or serious bleeding, associated with insufficient or excessive anticoagulation. Numerous studies reviewed by CMS showed that frequent self-testing through the use of a home PT/INR monitor improves a patient s time in therapeutic range. CMS approved Medicare coverage for weekly home PT/INR monitoring of patients with mechanical heart valves on warfarin in 2002. Similar to the shift that has occurred in the standard of care for management of diabetes and blood glucose monitoring, we believe that the Medicare coverage decision and growing physician

1

Table of Contents

and patient awareness of the benefits of weekly PT/INR patient self-testing signal a shift in the standard of care for PT/INR testing from the clinical laboratory to point-of-care testing and, ultimately, patient self-testing.

The HemoSense Solution

We believe that the INRatio System represents a new generation of PT/INR testing devices designed specifically for use both in patient self-testing and by healthcare professionals at the point-of-care. We believe that physicians generally will not prescribe patient self-testing unless the physician is confident that the patient will be able to comply with the testing requirements. Many patients on warfarin are Medicare patients, some of whom may have limited manual dexterity and may be challenged by complex test instructions and training. We believe that we offer a unique combination of factors that make our INRatio System a simple and straightforward patient self-testing PT/INR measurement device. These features also enable busy healthcare professionals to quickly train their patients in the use of our system as a tool for monitoring their warfarin therapy. Specifically, these features include:

- patient-friendly, fast and easy-to-use meter and disposable test strips;
- integrated quality control tests;
- straightforward patient training;
- test strips that may be stored up to one year at room temperature; and
- proprietary, reliable electrochemical technology.

Our Strategy

Our objective is to become the leading provider of PT/INR patient self-testing and point-of-care testing systems for the monitoring of patients on warfarin. We seek to improve therapeutic outcomes while dramatically reducing the need for inconvenient visits by patients to healthcare professionals for routine testing. To achieve these objectives, we are pursuing the following strategies:

- increasing awareness among physicians and patients of the advantages of the INRatio System and the benefits of weekly PT/INR testing;
- leveraging our established and growing network of distributors worldwide;
- utilizing and expanding reimbursement opportunities;

pursuing reimbursement for new and additional indications for PT/INR patient self-testing; and

developing product improvements.

Risks Affecting Us

Our business is subject to numerous risks, as more fully described in the section entitled Risk Factors immediately following this prospectus summary.

We recently underwent an inspection of our facilities by the FDA, which resulted in the issuance of an FDA Form 483 containing two observations. First, the inspector observed that we failed to timely file Medical Device Reports, or MDRs, for six of seven complaints the inspector reviewed claiming that our INRatio device took inaccurate readings, none of which resulted in a patient injury. MDRs are required to be filed even if an injury

Table of Contents

has not occurred, if our device may have malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur. In addition to potential device malfunction, discrepant PT/INR test results can arise from a number of factors, such as failure to follow our instructions for use, a patient s medication or diet between measurements, or variability in measurement results among different manufacturers instruments. We are addressing this observation by revising our MDR reporting procedure to assess when discrepancies between measurements taken with our device and those taken with a clinical laboratory device should be classified as a malfunction and result in an MDR filing. As a result of this revised procedure, we will be filing an increased number of MDRs. Since we began selling our product, we have received complaints of discrepant test results representing approximately .01% of all test strips sold. The second observation was that we had not properly defined and documented the procedures we employ to identify the statistical techniques for calibration of our test strips. We have filed a response to these observations that includes a description of and basis for our revised MDR reporting procedure, as well as an explanation of the valid statistical techniques we utilize in our test strip calibration procedure. It is possible that the FDA will issue a Warning Letter related to one or both of the observations. A Warning Letter would require that we promptly submit a further response, advising the FDA of the corrective actions that we have taken or will take to address the identified regulatory violation, in order to avoid more serious FDA enforcement action.

We have a limited operating history and may be unable to accurately predict our future performance. We are dependent on the success of a single product, our INRatio System, and our product may not be accepted by the market. From our inception through March 31, 2005 we generated total revenue of $7.1 million and as of March 31, 2005 had an accumulated deficit of $41.4 million and may never achieve profitability. We believe that the net proceeds of this offering will be sufficient to fund our operations as currently conducted and as proposed to be conducted for at least the next 12 months. We expect that we will have to raise additional funds in the future to support our operations. Our future success depends upon the growth of the emerging PT/INR patient self-testing market and on favorable future reimbursement decisions both in the United States and internationally. Compared to our current competitors, we have far less brand recognition, as well as less experience and resources in manufacturing, sales and marketing, and research and development.

Corporate Information

We were incorporated in Delaware in March 1997 as CardioSense, Inc. We changed our name to HemoSense, Inc. in January 1998. Our principal executive offices are located at 651 River Oaks Parkway, San Jose, California 95134. Our telephone number is (408) 719-1393. Our website is located at www.hemosense.com. The information contained on our website is not a part of this prospectus.

HemoSense® and INRatio® are registered trademarks of our company. Other service marks, trademarks and trade names referred to in this prospectus, such as Coumadin and Exanta, are the property of their respective owners.

Table of Contents

The Offering

Common stock we are offering	3,500,000 shares
Common stock to be outstanding immediately after this offering	9,533,764 shares
Use of proceeds	We intend to use the net proceeds of this offering as follows: approximately $12.0 million for sales and marketing initiatives, $1.7 million for research and development activities, $1.5 million for loan repayment and the remainder for working capital and general corporate purposes. See Use of Proceeds.
American Stock Exchange symbol	HEM
Principal stockholder purchases	In this offering, funds affiliated with MPM Capital and W Capital Ironworks, L.P. will purchase 727,272 and 125,454 shares of our common stock, respectively.
Risk factors	See Risk Factors and other information included in this prospectus for a discussion of factors you should consider carefully before deciding to invest in our common stock.

The number of shares of common stock that will be outstanding immediately after this offering is based upon 6,033,764 shares outstanding as of March 31, 2005. The number of shares to be outstanding immediately after this offering excludes:

- 45,000 shares of common stock issuable upon the exercise of outstanding warrants at an exercise price of $0.80 per share;
- 126,977 shares of common stock issuable upon the exercise of outstanding warrants for Series C-3 preferred stock at an exercise price of $6.32 per share;
- 998,750 shares of common stock issuable upon the exercise of options outstanding under our 1997 Stock Plan at a weighted average exercise price of approximately $0.82 per share;
- 54,542 shares of common stock issuable upon the exercise of outstanding warrants at an exercise price of $5.50 per share, the initial public offering price;
- 38,799 shares of common stock reserved for future issuance upon exercise of options available for grant under our 1997 Stock Plan; and
- 50,000 shares of common stock reserved for future issuance upon the exercise of options available for grant under our 2005 Equity Incentive Plan.

Unless otherwise indicated, all information in this prospectus reflects a 1-for-4 reverse split of our common stock which was effectuated on May 4, 2005 and assumes:

- the conversion, in accordance with our certificate of incorporation, of all our outstanding shares of preferred stock into 5,489,045 shares of our common stock;
- the underwriters do not exercise their over-allotment option; and
- the filing of our amended and restated certificate of incorporation and bylaws.

Table of Contents

Summary Financial Data

The summary financial data set forth below should be read in conjunction with our financial statements and the related notes and Management s Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this prospectus.

	Fiscal years ended September 30,			Six months ended March 31,	
	2002	2003	2004	2004	2005
			(restated)		
	(in thousands, except per share data)				
Statement of operations data:					
Revenue	$	$ 427	$ 3,250	$ 1,267	$ 3,417
Cost of goods sold		(1,519)	(5,065)	(1,909)	(4,339)
Gross profit (loss)		(1,092)	(1,815)	(642)	(922)
Operating expenses:					
Research and development	3,354	1,681	1,398	708	540
Sales and marketing	745	3,186	5,206	2,266	3,200
General and administrative	711	912	1,499	815	872
Total operating expenses	4,810	5,779	8,103	3,789	4,612
Loss from operations	(4,810)	(6,871)	(9,918)	(4,431)	(5,534)
Interest income	142	39	16	10	10
Interest and other expense	(40)	(78)	(359)	(77)	(441)
Net loss	$ (4,708)	$ (6,910)	$ (10,261)	$ (4,498)	$ (5,965)
Net loss per share:					
Basic and diluted	$ (14.27)	$ (20.69)	$ (30.45)	$ (13.35)	$ (14.76)
Pro forma basic and diluted			$ (1.75)		$ (0.96)
Shares used in computing net loss per share:					
Basic and diluted	330	334	337	337	404
Pro forma basic and diluted			5,850		6,190

The following table presents a summary of our balance sheet as of September 30, 2002, 2003 and 2004. In addition, it presents a summary of our balance sheet as of March 31, 2005:

- on an actual basis;
- on a pro forma basis to give effect to the automatic conversion of all our outstanding preferred stock into 5,489,045 shares of our common stock upon completion of this offering; and

on a pro forma as adjusted basis to give effect to the sale of shares of common stock by us in this offering at the initial public offering price of $5.50 per share, after deducting underwriting discounts and commissions and estimated offering expenses to be paid by us.

	As of September 30,			As of March 31, 2005		
	2002	2003	2004	Actual	Pro Forma	Pro Forma As Adjusted
			(restated)			
			(in thousands)			
Balance sheet data:						
Cash and cash equivalents	$ 5,276	$ 5,445	$ 433	$ 2,094	$ 2,094	$ 18,697
Working capital	5,909	5,800	1,072	1,973	1,973	18,576
Total assets	7,518	9,458	6,202	8,846	8,846	25,449
Long term liabilities	83	736	2,946	5,775	5,775	5,775
Redeemable convertible preferred stock	25,183	32,751	36,679	34,116		
Accumulated deficit	(18,269)	(25,179)	(35,440)	(41,405)	(41,405)	(41,405)
Total stockholders equity (deficit)	(18,174)	(24,959)	(35,220)	(35,158)	(1,042)	15,561

Table of Contents

RISK FACTORS

An investment in our common stock offered by this prospectus involves a substantial risk of loss. You should carefully consider these risk factors, together with all of the other information included in this prospectus, before you decide to purchase shares of our common stock. The occurrence of any of the following risks could harm our business. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment.

Risks Related to Our Business

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

We have a limited history of operations and have incurred net losses in each year since our inception. We received regulatory clearance to market our INRatio System in 2002 and began commercial sales in early 2003. During the past five fiscal years, we incurred net losses of $4.7 million in 2000, $4.0 million in 2001, $4.7 million in 2002, $6.9 million in 2003 and $10.3 million in 2004. As of March 31, 2005, we had an accumulated deficit of $41.4 million. We expect that following this proposed initial public offering our operating expenses will increase as we expand our business, devote additional resources to our sales and marketing efforts and incur the costs of being a public company.

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

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

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

As a public company, we will be asked to predict future operating performance and our stock price will be based, in part, upon those predictions. It will 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;

new product introductions by our competitors; and

the timing and uncertainty of U.S. and foreign reimbursement decisions.

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

Table of Contents

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.

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.

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

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

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

- fines, injunctions and civil penalties;
- recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;

delays in clearance or approval, or failure to obtain approval of our products or product modifications;

Table of Contents

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.

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

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

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

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

greater experience in conducting research and development, manufacturing and marketing activities; and

greater financial and human resources for product development, sales and marketing and patent litigation.

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

Table of Contents

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

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

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

Advances in the treatment of underlying conditions could also affect the use of warfarin. For example, improvements in replacement tissue heart valves have reduced, and may in the future further reduce, the use of mechanical heart valves, one of the leading indications for chronic warfarin use. Additionally, several companies are pursuing new surgical procedures to 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. However, Medicare currently only reimburses PT/INR self-testing for the approximately 400,000 mechanical heart valve patients on warfarin, which represents approximately 15% of three million U.S. patients taking warfarin on a daily basis. Whether Medicare expands reimbursement for PT/INR patient self-testing for other indications, such as atrial fibrillation, will be partially dependent on the outcome of ongoing and future clinical studies that we do not participate in or have any direct control over. Coverage and reimbursement determinations are subject to change over time and we cannot assure you that Medicare will not reduce or change coverage and reimbursement policies.

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

Reimbursement and healthcare payment systems in international markets vary significantly by country and include both government-sponsored healthcare and private insurance. Obtaining international approvals is a lengthy process, and reimbursement policies may limit the marketability

of our product in certain countries. International reimbursement approvals may not be obtained in a timely manner, if at all, or may provide for

inadequate reimbursement levels. Our failure to receive international reimbursement approvals could have a material adverse effect on market acceptance of our product in the markets in which those approvals are sought.

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

We have limited experience as a company in the sale, marketing and distribution of our INRatio System. We maintain a relatively small sales and marketing team which is currently comprised of 28 people 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 five national and three regional distributors in the United States. We also have agreements with 12 international distributors of our product. Two of our distributors, Quality Assured Services and Cardinal Health, accounted for approximately 31% and 26%, respectively, of our total revenue in fiscal 2004. Our success is dependent upon developing and maintaining current and future distribution relationships. We have only recently entered into most of our distribution relationships, which makes it difficult for us to predict their future success. Some of our distribution agreements allow either party to terminate the relationship on short notice and without fault. Additionally, we may be unable to renew a distribution agreement upon its expiration on favorable terms, or at all. Distribution partners may fail to commit the necessary resources to market and sell our product to the level of our expectations. In particular, several of our distribution partners also distribute the products of our competitors, and as a result, we compete for the attention of these distributors against the experienced and well funded efforts of our competitors. If in the future our distribution partners elect to focus on selling the products of our competitors rather than our products, our sales efforts will be seriously compromised. If we are unable to establish and maintain adequate sales, marketing and distribution capabilities, independently or with others, we may not be able to generate product revenue and may not become profitable. If our current or future partners do not perform adequately, or we are unable to locate or retain partners, as needed, in particular geographic areas or in particular markets, our ability to achieve our expected revenue growth rate will be harmed.

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

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

- convince prescribing physicians of the benefit of weekly PT/INR testing;
- ensure patient compliance; and
- provide timely, quality customer service to patients and physicians.

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

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

The primary components of the INRatio System are the INRatio meter and INRatio disposable test strips. We manufacture INRatio test strips at our facility, and we contract with an electronic manufacturing services supplier to manufacture the INRatio meter. Our cost to manufacture our test strips currently exceeds the price at

Table of Contents

which we can sell them. To be successful, we must manufacture our test strips in substantial quantities and at acceptable costs. We currently have limited experience manufacturing our test strips, and no experience manufacturing in the quantities that we anticipate we will need in the foreseeable future. There are technical challenges to increasing our manufacturing capacity in a significant manner, including:

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

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

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

We manufacture our test strips in large lots that must be tested with blood from warfarin patients in order to determine if our product has acceptable performance. There are many elements to manufacturing each lot of strips that can cause variability in PT/INR measurement beyond acceptable limits. Variability is not detected until the entire lot is complete and selected strips are tested with patient blood samples. If the performance is not acceptable, we discard the entire lot after we have incurred substantially all the material and labor costs required to manufacture the test strips in the lot. In order to manufacture test strips that will produce PT/INR measurement results that are sufficiently calibrated to clinical laboratory equipment, we are dependent upon our suppliers to deliver various components in conformity with our specifications. We have in the past had to, and may in the future have to, discard lots because they fail to meet specifications, which increases our costs of operations and may delay shipment of product to customers. Costs relating to discarded lots were $740,000 in 2004 and $166,000 for the six months ended March 31, 2005.

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.

Table of Contents

Additionally, in the point-of-care setting, practitioners familiar with competitors products that function differently may fail to follow our directions and misuse our product. For example, we are aware of a few situations in which practitioners have applied blood drawn from a vein using a syringe rather than capillary blood using a finger stick, which caused inaccurate readings. Warfarin management is complex, and there are many drugs, diseases and other factors that may affect warfarin metabolism and the ability of our test to perform as intended in the presence of these factors. Additionally, there may be biologic variations and clinical conditions that exist in some patients that may have an adverse effect on the performance of our product. We have in the past taken, and may in the future take, corrective action in our manufacturing procedure in order to respond to complaints that our test strips were producing inaccurate results. If our product is misused or otherwise produces an incorrect reading, a patient could be either underdosed or overdosed with warfarin, which could lead to serious injury or death and expose us to potential liability.

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

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

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

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

- we may not be able to obtain an adequate supply of quality raw materials or component parts in a timely manner or on commercially reasonable terms;
- suppliers may make errors in manufacturing components that could negatively affect the performance of our product, cause delays in shipment of our product or lead to returns;
- significant lot-to-lot variation in our test strips could negatively affect the performance of our product or cause delays in shipment of our product;
- we may have difficulty locating and qualifying on a timely basis alternative suppliers for our single-sourced supplies;

switching components may require product redesign and new submissions to the FDA, either of which could significantly delay production;

our suppliers manufacture products for a range of customers, and fluctuations in demand for the products these suppliers manufacture for others may affect their ability to deliver components to us in a timely manner; and

Table of Contents

our suppliers may encounter financial hardships either related or unrelated to our demand for components, which could inhibit their ability to fulfill our orders and meet our requirements.

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

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

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

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

Table of Contents

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 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.

As discussed in Note 2 to our financial statements, we have had to restate our financial results for the fiscal year ended September 30, 2004 to reflect certain adjustments. The restatement arose, in part, to defer the recognition of revenue on certain shipments made prior to fiscal year end for which title transfer to the customer did not occur until the subsequent period, as well as to correct the accounting for a significant license and settlement agreement. Certain other accounting adjustments were also identified and made. As a result of these errors, we have determined that our internal controls over financial reporting were not effective as of September 30, 2004. In connection with the restatement of our financial statements our independent auditors identified a material weakness in our internal controls and procedures related to inadequate resources in the finance function. As a public company, we will require greater financial resources than we have had as a private company. We only recently hired a member of our finance department, a controller, with SEC reporting

14

Table of Contents

experience. We cannot provide you with assurance that our finance department has or will maintain adequate resources to ensure that we will not have any future material weakness in our system of internal controls. The effectiveness of our controls and procedures may in the future be limited by a variety of factors including:

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

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

Our ability to continue as a going concern is dependent on our ability to raise additional capital, including from this offering.

We believe that the net proceeds of this offering will be sufficient to fund our operations as currently conducted and as proposed to be conducted over at least the next 12 months. As disclosed in Note 1 to our financial statements, we do not currently have sufficient capital to fund our operations through 2005. The opinion we have received from our independent auditors regarding our 2004 financial statements contains an explanatory paragraph as to our ability to continue as a going concern. If the proceeds from this offering are inadequate to fund our operations through 2006, we may also receive a going concern qualification on our 2005 financial statements. If doubts are raised about our ability to continue as a going concern following this offering, our stock price could drop and our ability to raise additional funds, to obtain credit on commercially reasonable terms, or to remain in compliance with covenants that we have in place with current lenders may be adversely affected. Additionally, potential customers may not buy our product if they believe that we may not have a viable business. Any of these outcomes would be detrimental to our operations.

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

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

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

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

Table of Contents

operations regardless of the final outcome of such litigation. In the event of an adverse judgment, a court could hold that some or all of our asserted intellectual property rights are not infringed, invalid or unenforceable, and could award attorney fees to these third parties.

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

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

Third parties have in the past asserted, and could in the future assert, infringement or misappropriation claims against us with respect to our current or future products. Whether a product infringes a patent involves complex legal and factual issues, the determination of which is often uncertain. Therefore, we cannot be certain that we have not infringed the intellectual property rights of others. Our competitors may assert that our product or the methods we employ in the use or manufacture of our product are covered by U.S. or foreign patents held by them. This risk is exacerbated by the fact that there are numerous issued patents and pending patent applications related to our business that are held by others. For example, in April 2003, Inverness Medical Innovations filed suit against us, alleging that disposable test strips for our INRatio System infringed certain of its patent rights. Inverness sought monetary damages and injunctive relief. In July 2004, we entered into a settlement and mutual release agreement with Inverness pursuant to which we received a license to the patent rights in exchange for a product royalty and a lump sum payment. Additionally, on June 22, 2005, we received a letter from Beckman Coulter claiming that our test strip includes intellectual property covered by one of their patents, U.S. Patent 5,418,141, and that we could require a license to the patent. We do not believe that their patent covers our test strip or that we need to obtain a license from them.

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

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

Table of Contents

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 this offering to improve our compliance efforts. We could be held liable for damages, penalties and costs of investigation and remedial actions in connection with violations of environmental, health and safety laws or permits. We are also subject to potential liability for the investigation and clean up of any contamination at properties that we currently or formerly owned, operated or leased and off-site locations where we disposed of or arranged for disposal of hazardous materials. Liability for any such contamination can be joint, strict and several without regard to comparative fault under certain environmental laws. We may also be subject to related claims by private parties alleging property damage and/or personal injury due to exposure to hazardous materials at or in the vicinity of such properties. These expenses or this liability could have a significant negative impact on our financial condition. We may violate or have liability under environmental, health and safety laws in the future as a result of human error, equipment failure, or other causes.

Environmental laws or permit conditions could become more stringent over time, imposing greater compliance costs, including capital investments, and increasing risks and penalties associated with violations. For example, the European Parliament has recently finalized the Waste Electrical and Electronic Equipment Directive, or WEEE Directive, which makes producers of electrical goods financially responsible for specified collection, recycling, treatment and disposal of past and future covered products. As a producer of electronic equipment, we will incur financial responsibility for the collection, recycling, treatment or disposal of products covered under the WEEE Directive. We expect to incur increased costs to comply with future legislation which implements this Directive and potentially other related Directives, but we cannot currently estimate the extent of such increased costs. However, to the extent that such cost increases or delays are substantial, our operating results could be materially adversely affected. In addition, similar legislation may be enacted in other countries, including the United States. We

are also subject to potentially conflicting and changing regulatory agendas of

Table of Contents

political, business, and environmental groups. Changes to or restrictions on permitting requirements or processes, hazardous or biological material storage or handling might require us to make an unplanned capital investment or relocation.

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

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

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.

Risks Related to this Offering

Our common stock has not been publicly traded, and we expect that the price of our common stock will fluctuate substantially.

Prior to this offering, there has been no public market for shares of our common stock. An active public trading market may not develop following completion of this offering or, if developed, may not be sustained. We will determine the initial public offering price of the shares of common stock sold in this offering with the underwriters. This price may not be the price at which the common stock will trade after the offering. The market price for our common stock following this offering will be affected by a number of factors, including:

- our quarterly operating performance;
- changes in earnings estimates or recommendations by securities analysts;
- changes in the availability of reimbursement in the United States or other countries;
- the announcement of new products or product enhancements by us or our competitors;

announcements of technological or medical innovations in PT/INR monitoring or anticoagulation treatment;

our ability to develop, obtain regulatory clearance for, and market, new and enhanced products on a timely basis;

product liability claims or other litigation;

changes in governmental regulations or in our approvals or applications; and

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

Table of Contents

A large number of shares may be sold in the market following this offering which may cause the price of our common stock to decline.

After this offering, we will have approximately 9,533,764 shares of common stock outstanding, or 10,058,764 shares if the underwriters over-allotment is exercised in full. The 3,500,000 shares sold in this offering, or 4,025,000 shares if the underwriters over-allotment is exercised in full, will be freely tradable without restriction or further registration under the federal securities laws unless purchased by our affiliates. The remaining 6,033,764 shares of common stock outstanding after this offering and 1,225,269 shares issuable upon exercise of outstanding options and warrants to purchase shares of common stock, will be available for sale in the public market as follows:

Number of Shares	Date of Availability for Sale
0	Immediately after the date of this prospectus
6,673,440	180 days after the effective date of the registration statement containing this prospectus, subject to extension, and in some cases, volume and other limitations as further described in Underwriting
585,593	At various times after 180 days following the effective date of the registration statement containing this prospectus

The above table assumes the effectiveness of the lock-up agreements with the underwriters under which holders of substantially all of our common stock have agreed not to sell or otherwise dispose of their shares of common stock and assumes the exercise of warrants for 54,542 shares of common stock at an exercise price of $5.50 per share, the initial public offering price. Approximately 6.3 million of the shares that will be available for sale after the expiration of the lock-up period will be subject to volume restrictions because they are held by our affiliates or have been held for less than two years. In addition, the underwriters of our offering may waive these lock-up restrictions prior to the expiration of the lock-up period without prior notice.

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

Purchasers in this offering will experience immediate and substantial dilution.

We expect the initial public offering price of our shares to be substantially higher than the net tangible book value per share of the outstanding common stock. Accordingly, investors purchasing shares of common stock in this offering will pay a price per share that substantially exceeds the value of our assets after subtracting liabilities. The resulting per share dilution is further described in Dilution. To the extent outstanding stock options or warrants are exercised, there will be further dilution to new investors.

Table of Contents

Our principal stockholder will own a significant percentage of our stock, and as a result, can take actions that may be adverse to your interests.

MPM Capital and its affiliates will own approximately 45% of our common stock following this offering. 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 you.

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

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

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

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

Table of Contents

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements, principally in the sections entitled Summary, Risk Factors, Management s Discussion and Analysis of Financial Condition and Results of Operations and Business. Generally, you can identify these statements because they include words and phrases like expect, estimate, anticipate, predict, believe, plan, will, should, intend and similar expressions and variati statements are only predictions. Although we do not make forward-looking statements unless we believe we have a reasonable basis for doing so, we cannot guarantee their accuracy, and actual results may differ materially from those we anticipated due to a number of uncertainties, many of which cannot be foreseen. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this prospectus. Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including, among others, the risks we face that are described in the previous section entitled Risk Factors and elsewhere in this prospectus.

We believe it is important to communicate our expectations to our investors. There may be events in the future, however, that we are unable to predict accurately or over which we have no control. The risk factors listed on the previous pages, as well as any cautionary language in this prospectus, provide examples of risks, uncertainties and events that may cause our actual results to differ materially from the expectations we describe in our forward-looking statements. Before you invest in our common stock, you should be aware that the occurrence of the events described in the previous risk factors and elsewhere in this prospectus could negatively affect our business, operating results, financial condition and stock price.

Table of Contents

USE OF PROCEEDS

We estimate that the net proceeds we will receive from the sale of 3,500,000 shares of our common stock in this offering will be approximately $16.6 million, or approximately $19.3 million if the underwriters fully exercise their over-allotment option, in each case based on the initial public offering price of $5.50 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

Of the net proceeds we will receive in this offering, we expect to use approximately:

- $12.0 million of the net proceeds for sales and marketing initiatives to support the ongoing commercialization of our INRatio System;
- $1.7 million for research and development activities, including support of product development, regulatory and clinical study initiatives; and
- $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. These promissory notes will become due and payable in October 2005, though we intend to prepay the promissory notes upon the closing of the initial public offering. The proceeds from the promissory notes are being used for working capital and general corporate purposes. See Related Party Transactions.

We intend to use the remainder of our net proceeds for working capital and general corporate purposes. We believe that the net proceeds of this offering will be sufficient to fund our operations as currently conducted and as proposed to be conducted over at least the next 12 months. The amounts and timing of our actual expenditures may vary significantly depending upon numerous factors, including the progress of our research, development and commercialization efforts, and our operating costs and capital expenditures. Accordingly, we will retain broad discretion in the allocation of the net proceeds of this offering, and we reserve the right to change the specific allocation of use of these proceeds within the categories described above as a result of contingencies such as the progress and results of our research and development activities, the results of our commercialization efforts, competitive developments and our manufacturing requirements. Pending use of the net proceeds from this offering, we intend to invest the net proceeds of this offering in short-term, interest-bearing, investment-grade securities.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock, and we do not currently intend to pay any cash dividends on our common stock in the foreseeable future. We expect to retain future earnings, if any, to fund the development and growth of our business. The declaration of dividends is subject to the discretion of our board of directors and will depend on various factors, including our results of operations, financial condition, future prospects and any other factors deemed relevant by our board of directors. In addition, the terms of any current or future debt or credit facility may preclude us from paying dividends on our common stock.

Table of Contents

CAPITALIZATION

The following table sets forth our capitalization as of March 31, 2005:

- on an actual basis;
- on a pro forma basis to give effect to the automatic conversion of all outstanding shares of our preferred stock into 5,489,045 shares of common stock; and
- on a pro forma as adjusted basis to give further effect to the sale by us of 3,500,000 shares of common stock at the initial public offering price of $5.50 per share, less the underwriting discounts and commissions and estimated offering expenses to be paid by us.

You should read this table together with the section of this prospectus under the heading Management s Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and the related notes appearing elsewhere in this prospectus.

	Actual (unaudited)	Pro Forma (unaudited)	Pro Forma As Adjusted (unaudited)
	(in thousands, except share data)		
Long term liabilities	$ 5,775	$ 5,775	$ 5,775
Redeemable convertible preferred stock, $0.001 par value; 53,385,560 shares authorized, 21,956,251 shares issued and outstanding, actual; no shares issued and outstanding, pro forma and pro forma as adjusted	34,116		
Stockholders deficit:			
Common stock, $0.001 par value; 9,500,000 shares authorized, actual, pro forma and pro forma as adjusted; and 544,719 shares issued and outstanding, actual; 6,033,764 shares issued and outstanding, pro forma; and 9,533,764 shares issued and outstanding pro forma as adjusted	1	6	10
Additional paid-in capital	6,246	40,357	56,956
Accumulated deficit	(41,405)	(41,405)	(41,405)
Total stockholders equity (deficit)	(35,158)	(1,042)	15,561
Total capitalization	$ 4,733	$ 4,733	$ 21,336

The table above excludes, as of March 31, 2005:

- 45,000 shares of common stock issuable upon the exercise of outstanding warrants at $0.80 per share;

126,977 shares of common stock issuable upon the exercise of outstanding warrants for Series C-3 preferred stock at an exercise price of $6.32 per share;

998,750 shares of common stock issuable upon the exercise of options outstanding under our 1997 Stock Plan at a weighted average exercise price of approximately $0.82 per share;

54,542 shares of common stock issuable upon the exercise of outstanding warrants at an exercise price of $5.50 per share, the initial public offering price;

38,799 shares of common stock reserved for issuance upon the exercise of options available for grant under our 1997 Stock Plan; and

50,000 shares of common stock reserved for issuance upon the exercise of options available for grant under our 2005 Equity Incentive Plan.

Table of Contents

DILUTION

If you invest in our common stock, your interest will be diluted immediately to the extent of the difference between the initial public offering price of $5.50 per share of our common stock, and the pro forma as adjusted net tangible book value per share of our common stock after this offering. Our net tangible book value as of March 31, 2005 was approximately $(36.1) million or $(66.20) per share of common stock. Pro forma net tangible book value as of March 31, 2005 was approximately $(1.9) million or $(0.32) per share of common stock. Pro forma net tangible book value gives effect to the conversion of all of our outstanding redeemable convertible preferred stock into 5,489,045 shares of our common stock, immediately prior to the closing of this offering.

Dilution per share to new investors represents the difference between the amount per share paid by new investors who purchase shares of common stock in this offering and the pro forma as adjusted net tangible book value per share of common stock immediately after the completion of this offering. Giving effect to the sale of shares of our common stock offered by us at the initial public offering price of $5.50 per share, and after deducting the underwriting discounts and commissions and estimated offering expenses, our pro forma as adjusted net tangible book value as of March 31, 2005 would have been approximately $14.7 million. This amount represents an immediate increase in pro forma net tangible book value of $1.86 per share to our existing stockholders, and an immediate dilution in pro forma as adjusted net tangible book value of $3.96 per share to new investors purchasing shares of our common stock in this offering. The following table illustrates this dilution:

Assumed Initial public offering price per share		$ 5.50
Net tangible book value per share as of March 31, 2005	$ (66.20)	
Increase per share due to conversion of all shares of preferred stock	65.88	
Pro forma net tangible book value per share as of March 31, 2005	(0.32)	
Increase per share to existing investors	1.86	
Pro forma as adjusted net tangible book value per share after the offering		1.54
Dilution per share to new investors		$ 3.96

The following table sets forth, on a pro forma as adjusted basis, as of March 31, 2005, the differences between the number of shares of common stock purchased from us, the total consideration paid, and the average price per share paid by existing stockholders and new investors purchasing shares of our common stock in this offering, before deducting underwriting discounts and commissions and estimated expenses at the initial public offering price of $5.50 per share.

	Shares Purchased		Total Consideration		
	Number	Percent	Amount	Percent	Average Price Per Share
Existing stockholders	6,033,764	63%	$ 40,024,091	68%	$ 6.63
New investors	3,500,000	37%	19,250,000	32%	$ 5.50
Total	9,533,764	100%	$ 59,274,091	100%	

Assuming the exercise in full of all options and warrants outstanding as of March 31, 2005, the number of shares purchased by existing stockholders would be increased by 1,170,727 shares to 7,204,491 shares, total consideration paid by them would be increased by approximately $1,659,901 to $41,683,992 and the average price per share paid by them would be decreased by $0.84 per share to $5.79 per share.

Table of Contents

If the underwriters exercise their over-allotment option in full, the percentage of shares of common stock held by existing stockholders will decrease to approximately 60% of the total number of shares of our common stock outstanding after this offering, and the number of shares held by new investors will be increased to 4,025,000, or approximately 40% of the total number of shares of our common stock outstanding after this offering.

The tables above exclude, as of March 31, 2005:

- 45,000 shares of common stock issuable upon the exercise of outstanding warrants at $0.80 per share;
- 126,977 shares of common stock issuable upon the exercise of outstanding warrants for Series C-3 preferred stock at an exercise price of $6.32 per share;
- 998,750 shares of common stock issuable upon the exercise of options outstanding under our 1997 Stock Plan at a weighted average exercise price of approximately $0.82 per share;
- 54,542 shares of common stock issuable upon the exercise of outstanding warrants at an exercise price of $5.50 per share, the initial public offering price;
- 38,799 shares of common stock reserved for issuance upon the exercise of options available for grant under our 1997 Stock Plan; and
- 50,000 shares of common stock reserved for issuance upon the exercise of options available for grant under our 2005 Equity Incentive Plan.

The exercise of options and warrants, all of which have an exercise price less than the initial public offering price, would increase the dilution to new investors an additional $0.02 per share, to $3.98 per share.

Table of Contents

SELECTED FINANCIAL DATA

The selected financial data set forth below are derived from our financial statements. The statement of operations data for the years ended September 30, 2002, 2003 and 2004 and the balance sheet data at September 30, 2003 and 2004 are derived from our audited financial statements which are included elsewhere in this prospectus. The statement of operations data for the years ended September 30, 2000 and 2001 and the balance sheet data at September 30, 2000, 2001 and 2002 are derived from our financial statements which are not included in this prospectus. The selected financial data at March 31, 2005 and for the six months ended March 31, 2004 and 2005 are derived from our unaudited financial statements appearing elsewhere in this prospectus. The unaudited selected financial data include, in the opinion of management, all adjustments, consisting of only normal recurring adjustments that are necessary for a fair presentation of the financial position and the results of operations for the interim unaudited periods. Historical results are not necessarily indicative of future results. The following selected financial data should be read in conjunction with our financial statements and the related notes and Management s Discussion and Analysis of Financial Condition and Results of Operations appearing elsewhere in this prospectus. The selected financial data in this section is not intended to replace the financial statements. As discussed in Note 2 to the financial statements, the results as of September 30, 2004 and for the year then ended have been restated.

	Fiscal years ended September 30,					Six months ended March 31,	
	2000	2001	2002	2003	2004	2004	2005
					(restated)		
	(in thousands, except per share data)						
Statement of operations data:							
Revenue	$	$	$	$ 427	$ 3,250	$ 1,267	$ 3,417
Cost of goods sold				(1,519)	(5,065)	(1,909)	(4,339)
Gross profit (loss)				(1,092)	(1,815)	(642)	(922)
Operating expenses:							
Research and development	3,223	3,008	3,354	1,681	1,398	708	540
Sales and marketing	416	762	745	3,186	5,206	2,266	3,200
General and administrative	958	739	711	912	1,499	815	872
Total operating expenses	4,597	4,509	4,810	5,779	8,103	3,789	4,612
Loss from operations	(4,597)	(4,509)	(4,810)	(6,871)	(9,918)	(4,431)	(5,534)
Interest income	62	605	142	39	16	10	10
Interest and other expense	(122)	(46)	(40)	(78)	(359)	(77)	(441)
Net loss	$ (4,657)	$ (3,950)	$ (4,708)	$ (6,910)	$ (10,261)	$ (4,498)	$ (5,965)
Net loss per share:							
Basic and diluted	$ (13.16)	$ (11.52)	$ (14.27)	$ (20.69)	$ (30.45)	$ (13.35)	$ (14.76)
Pro forma basic and diluted					$ (1.75)		$ (0.96)
Shares used in computing net loss per share:							
Basic and diluted	354	343	330	334	337	337	404
Pro forma basic and diluted					5,850		6,190

	As of September 30,	As of March 31, 2005

	2000	2001	2002	2003	2004	
					(restated)	
			(in thousands)			
Balance sheet data:						
Cash and cash equivalents	$ 1,295	$ 10,414	$ 5,276	$ 5,445	$ 433	$ 2,094
Working capital	(3,050)	10,427	5,909	5,800	1,072	1,973
Total assets	2,570	12,180	7,518	9,458	6,202	8,846
Long term liabilities	160	120	83	736	2,946	5,775
Redeemable convertible preferred stock	7,508	25,183	25,183	32,751	36,679	34,116
Accumulated deficit	(9,611)	(13,561)	(18,269)	(25,179)	(35,440)	(41,405)
Total stockholders deficit	(9,573)	(13,498)	(18,174)	(24,959)	(35,220)	(35,158)

Table of Contents

MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial conditions and results of operations should be read in conjunction with our financial statements and the notes to those financial statements appearing elsewhere in this prospectus. This discussion contains forward-looking statements that involve significant risks and uncertainties. As a result of many factors, such as those set forth under Risk Factors and elsewhere in this prospectus, our actual results may differ materially from those anticipated in these forward-looking statements. As discussed in Note 2 to the financial statements the results as of September 30, 2004 and for the year then ended have been restated.

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 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. From our product launch in March 2003 through March 2005, we sold over 5,000 meters and one million disposable test strips on a worldwide basis.

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

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

the continual improvement of our technology.

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

Our cost of goods sold represents the cost of manufacturing our products. Our meters are manufactured for us by an electronics manufacturing service company, and we incur direct labor costs to assemble meters into packaged kits at our facility. Our cost of goods sold for the meter also includes an allowance for product

Table of Contents

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. While this royalty does not become payable until July 2006, we capitalized a portion of the settlement amount as prepaid royalties and are expensing that amount through 2009, the term of the royalty, as a cost of goods sold and do not believe that our obligation to pay royalties in 2006 will have an adverse effect on our results of operations.

While we have a positive margin on meters, until higher production volume is realized in test strip manufacturing to absorb the manufacturing overhead, the manufacturing cost per test strip will be high and in excess of our worldwide average selling price. For the year ended September 30, 2004 and the six months ended March 31, 2005, the gross profit on meters and accessories was 51% and 57%, respectively, while we experienced a negative gross margin on test strips of 161% and 102%, respectively. The manufacturing cost structure for our test strips currently includes a large component of fixed costs which is being spread over production that has not been maximized. Increases in production volume will be a significant factor for cost reduction for our test strips. We anticipate that this, along with other cost reduction efforts under way, will generate positive gross margins.

Results of Operations

Six months ended March 31, 2005 as compared to six months ended March 31, 2004

Revenue. Our revenue is derived from sales of our INRatio System. Revenue increased by $2.1 million, or 170%, from $1.3 million in the six months ended March 31, 2004 to $3.4 million in the six months ended March 31, 2005. Approximately 68% of the growth in revenue was derived from the United States and approximately 32% from outside the United States. Revenue for meters and accessories increased by $1.1 million, or 203%, from $531,000 in the six months ended March 31, 2004 to $1.6 million in the six months ended March 31, 2005. Revenue for test strips increased by $1.1 million, or 146%, from $736,000 in the six months ended March 31, 2004 to $1.8 million in the six months ended March 31, 2005. The increase in U.S. revenue was primarily attributable to the addition of two national distributors and increased field personnel. The increase in international revenue was primarily attributable to the addition of five distributors. We expect our revenue to increase as we continue to add distributors, expand our sales force and penetrate the market worldwide.

Cost of goods sold. Our cost of goods sold represents the cost of manufacturing our products. Cost of goods sold increased by $2.4 million, or 127%, from $1.9 million in the six months ended March 31, 2004 to $4.3 million in the six months ended March 31, 2005. Cost of goods sold for meters and accessories increased by $455,000, or 197%, from $231,000 in the six months ended March 31, 2004 to $685,000 in the six months ended March 31, 2005. Cost of goods sold for test strips increased by $1.9 million, or 118%, from $1.7 million in the six months ended March 31, 2004 to $3.6 million in the six months ended March 31, 2005. The aggregate increase of $2.4 million was primarily due to the increase in number of meters and test strips sold. Also, royalties and amortization of technology licenses increased by $257,000, from $92,000 in the six months ended March 31, 2004 to $349,000 in the six months ended March 31, 2005, due to the increase in strip sales and two technology licenses obtained in 2004. As a percentage of revenue, cost of goods sold decreased from 151% of sales in the six months ended March 31, 2004 to 127% in the same period in 2005. We expect cost of goods sold to continue to decrease as a percentage of revenue as we implement cost reduction initiatives, including manufacturing process improvements, and benefit from economies of scale.

Research and development expenses. Our research and development costs consist of expenses incurred for company-sponsored research and development activities. Research and development expenses decreased by $168,000, or 24%, from $708,000 in the six months ended March 31, 2004 to $540,000 in the six months ended March 31, 2005. The decrease was primarily attributable to the reduction in payroll costs and consultant expenses as certain personnel and other resources in research and development in 2004 were transferred to manufacturing in 2005. As a percentage of revenue, research and development expenses were 16% in the six months ended

28

March 31, 2005 compared to 56% in the same period in 2004. In future periods, we expect research and development expenses to grow in absolute terms but decrease as a percentage of revenue.

Sales and marketing expenses. Sales and marketing expenses consist primarily of sales and marketing personnel compensation, marketing consultant expenses, travel, and marketing programs. Sales and marketing expenses increased by $934,000, or 41%, from $2.3 million in the six months ended March 31, 2004 to $3.2 million in the six months ended March 31, 2005. The increase was primarily attributable to $693,000 of payroll and travel expenses for additional personnel, $80,000 for demonstration meters and $144,000 for promotion programs. As a percentage of revenue, sales and marketing expenses were 94% in the six months ended March 31, 2005 compared to 179% in the same period in 2004. In future periods, we expect sales and marketing expenses to grow in absolute terms but decrease as a percentage of revenue as we continue to leverage our expanding distribution network.

General and administrative expenses. Our general and administrative expenses consist of personnel and consultant expenses for corporate administration functions, professional fees and travel. General and administrative expenses increased by $57,000, or 7%, from $815,000 in the six months ended March 31, 2004 to $872,000 in the six months ended March 31, 2005. The increase was primarily attributable to $236,000 in expenses for administrative personnel and $189,000 in independent accountants fees for review and audit expenses in conjunction with the filing of this registration statement, offset by a decrease in legal expenses of $265,000 related to the settlement of an intellectual property infringement action. As a percentage of revenue, general and administrative expenses were 26% in the six months ended March 31, 2005 compared to 64% in the same period in 2004. In the short term, we expect general and administrative expenses to grow in absolute terms as a result of expenses associated with becoming and being a public company.

Interest and other expense, net. We recognized interest expense of $450,000 for the six months ended March 31, 2005, an increase of $376,000 from $74,000 for the same period in 2004. The increase was attributable to interest expense on amounts drawn down against a debt line of $7.5 million which was put in place in March 2004, as well as interest expense related to a note payable.

Year ended September 30, 2004 as compared to year ended September 30, 2003

Revenue. Revenue increased by $2.8 million, or 661%, from $427,000 in 2003 to $3.3 million in 2004. Approximately 76% of the growth in revenue was derived from the United States and approximately 24% from outside the United States. Revenue for meters and accessories increased by $1.3 million, or 453%, from $292,000 in 2003 to $1.6 million in 2004. Revenue for test strips increased by $1.6 million, or 1,114%, from $135,000 in 2003 to $1.7 million in 2004. We started selling our products in March 2003. The increase in U.S. revenue was primarily attributable to the addition of two national distributors and increased field personnel. The increase in international revenue was primarily attributable to the addition of nine distributors.

Cost of goods sold. Cost of goods sold increased by $3.5 million, or 233%, from $1.6 million in 2003 to $5.1 million in 2004. Cost of goods sold for meters and accessories increased by $649,000, or 446%, from $145,000 in 2003 to $794,000 in 2004. Cost of goods sold for test strips increased by $2.9 million, or 211%, from $1.4 million in 2003 to $4.3 million in 2004. The increase of $2.1 million was primarily due to the increase in number of meters and test strips sold. In addition, due to manufacturing scale up problems, several test strip lots and subassemblies with a manufacturing cost of $1.0 million were rejected and written-off in 2004. Also, royalties and amortization of technology licenses increased by $369,000, from $8,000 in 2003 to $377,000 in 2004 due to the increase in test strip sales and two technology licenses obtained in 2004. As a percentage of revenue, cost of goods sold decreased from 356% of sales in the year ended September 30, 2003 to 156% in the same period in 2004.

Research and development expenses. Research and development expenses decreased by $283,000, or 17%, from $1.7 million in 2003 to $1.4 million in 2004. The decrease was primarily attributable to the full year impact

in 2004 of resources in research and development that were transferred to manufacturing in the middle of 2003. As a percentage of revenue, research and development expenses were 43% in the year ended September 30, 2004 compared to 394% in the same period in 2003.

Sales and marketing expenses. Sales and marketing expenses increased by $2.0 million, or 63%, from $3.2 million in 2003 to $5.2 million in 2004. The increase was primarily attributable to $1.7 million of payroll and travel expenses for additional personnel, $256,000 for marketing consultants and $110,000 for promotion programs. As a percentage of revenue, sales and marketing expenses were 160% in the year ended September 30, 2004 compared to 746% in the same period in 2003.

General and administrative expenses. General and administrative expenses increased by $587,000, or 64%, from $912,000 in 2003 to $1.5 million in 2004. The increase of $319,000 was primarily attributable to increased administrative personnel and consultants, legal expenses of $125,000 related to an intellectual property infringement action, and $83,000 for increased coverages for liability and business insurance. As a percentage of revenues, general and administrative expenses were 46% in the year ended September 30, 2004 compared to 214% in the same period in 2003.

Interest and other expense, net. We recognized interest expense of $318,000 for the year ended September 30, 2004, an increase of $251,000 from $67,000 for the same period in 2003. The increase was attributable to interest expense on amounts drawn down against a debt line of $7.5 million which was put in place in March 2004, as well as interest expense related to a note payable.

Year ended September 30, 2003 as compared to year ended September 30, 2002

Revenue. Revenue for the year ended September 30, 2003 was $427,000 consisting of $292,000 for meters and accessories and $135,000 for test strips. There was no revenue for the year ended September 30, 2002, as we did not begin selling our product until March 2003. Product sales in the United States accounted for approximately 75% of revenue in fiscal year 2003.

Cost of goods sold. Cost of goods sold for the year ended September 30, 2003 was $1.5 million consisting of $145,000 for meters and accessories and $1.4 million for test strips. There was no cost of goods sold for the year ended September 30, 2002 since there were no product sales. In addition to $1.3 million for the cost to manufacture meters and test strips, cost of goods sold included approximately $223,000 in lower of cost or market adjustments for test strips due to average selling price being lower than manufacturing cost. As a percentage of revenue, cost of goods sold was 356% of sales for the year ended September 30, 2003.

Research and development expenses. Research and development expenses decreased by $1.7 million, or 50%, from $3.4 million in 2002 to $1.7 million in 2003. The decrease was primarily attributable to research and development resources in 2002 which were transferred to manufacturing in 2003. As a percentage of revenue, research and development expenses were 394% in the year ended September 30, 2003.

Sales and marketing expenses. Sales and marketing expenses increased by $2.4 million, or 328%, from $745,000 in 2002 to $3.2 million in 2003. The increase was primarily attributable to $1.3 million of payroll and travel expenses for additional personnel, $214,000 for marketing consultants and $312,000 for promotion programs. As a percentage of revenue, sales and marketing expenses were 746% in the year ended September 30, 2003.

General and administrative expenses. General and administrative expenses increased by $201,000, or 28%, from $711,000 in 2002 to $912,000 in 2003. The increase was primarily attributable to a $225,000 increase due to additional administrative personnel and legal expenses of $67,000 related to an intellectual property infringement action. As a percentage of revenues, general and administrative expenses were 214% for the year ended September 30, 2003.

Table of Contents

Interest and other expense, net. We recognized interest expense of $67,000 for the year ended September 30, 2003, an increase of $48,000 from $19,000 for the same period in 2002. The increase was attributable to interest expense on amounts drawn down against a bank equipment financing credit line of $1.75 million in fiscal 2003.

Liquidity and Capital Resources

Since our inception, our operations have been primarily financed through private equity capital, bank equipment financing loans, debt capital and capital leases. As of March 31, 2005, our cash and cash equivalents were $2.1 million. All of our cash equivalents have original maturities of three months or less.

During the six months ended March 31, 2005, our operating activities used cash of approximately $5.7 million, compared to approximately $4.6 million for the six months ended March 31, 2004, an increase of $1.1 million. The increase in cash used was due primarily to an increase in the net loss by approximately $1.5 million offset by $307,000 in adjustments for non-cash items and $121,000 in changes in assets and liabilities. The major components of the changes in assets and liabilities were in inventories and accounts receivable. The change in inventories was $864,000 for the six months ended March 31, 2005, an increase of $165,000 from $699,000 for the same period in 2004, which was due to an increase in our sales. The change in accounts receivable was $80,000 for the six months ended March 31, 2005, a decrease of $295,000 from $375,000 for the same period in 2004, which was due to September 30, 2004 accounts receivable being high as a result of a new distribution agreement being signed in September 2004, with a large initial order included in accounts receivable. We expect future increases in revenue to result in increases in the need for working capital due to increases of accounts receivable and inventories.

Our investing activities used cash of approximately $108,000 during the six months ended March 31, 2005 compared to $293,000 for the six months ended March 31, 2004. Investing activities in 2004 and 2003 comprised of acquisition of equipment.

Cash provided by financing activities was approximately $7.4 million for the six months ended March 31, 2005 compared to $51,000 used in financing activities for the six months ended March 31, 2004. The increase in cash provided was primarily due to $4.6 million of proceeds from draw downs against a debt line facility and $3.3 million in preferred stock proceeds during the six months ended March 31, 2005.

For the year ended September 30, 2004, our operating activities used cash of approximately $9.5 million. This was an increase of $2.8 million from the cash used in operating activities of $6.7 million for the year ended September 30, 2003. This change was primarily due to a loss of $10.3 million in the year ended September 30, 2004 compared to a loss of $6.9 million in 2003. Offsetting the loss were adjustments for non-cash items which reduced cash used in operations in the year ended September 30, 2004 by $915,000 compared to $270,000 in 2003. The change in accounts receivable was $773,000 for the year ended September 30, 2004, an increase of $639,000 from $134,000 for the same period in 2003, which was related to an increase in our sales. The change in inventories was $319,000 for the year ended September 30, 2004, an increase of $173,000 from $146,000 for the same period in 2003, which was due to an increase in our sales. During fiscal year 2003 we did not purchase any meters as we had a sufficient number in inventory. We did not commence purchasing meters again until the second quarter of fiscal year 2004.

For the year ended September 30, 2004, our investing activities used cash of approximately $429,000. This was an increase of $32,000 from cash used in investing activities of $397,000 for the year ended September 30, 2003 due to acquisitions of equipment.

For the year ended September 30, 2004, our financing activities provided $4.9 million. This was a decrease of $2.3 million from cash provided by financing activities of $7.2 million for the year ended September 30, 2003. The decrease was primarily due to proceeds from equity financing of $3.0 million for the year ended September

Table of Contents

30, 2004 compared to $6.4 million for the year ended September 30, 2003. This decrease was offset by loan proceeds of $2.0 million, net of repayment of previous loans outstanding, for the year ended September 30, 2004 compared to $886,000 for the year ended September 30, 2003. In March 2004, we obtained a debt line from Lighthouse Capital Partners in the amount of $7.5 million to be drawn down over a 12-month period. During the draw down period interest-only payments were required to be made monthly on amounts drawn down and a usage fee was payable quarterly on unused amounts. As of March 1, 2005, we had drawn down the full amount of $7.5 million which is being amortized monthly over 36 months with a final payment of $937,500 due at the end of the term. In conjunction with the loan, we issued warrants to purchase Series C-3 preferred stock, which upon completion of this offering, will be exercisable for 118,670 shares of common stock at an exercise price of $6.32 per share. Upon receiving this credit line, we used the first draw down of $907,000 in March 2004 to repay the amount outstanding on the loans payable to Silicon Valley Bank. The Silicon Valley Bank loans were drawn down under a $1.75 million equipment financing line of credit obtained by us in July 2003. The Silicon Valley Bank loans amortized over a 36-month term and also included warrants to purchase Series C-3 preferred stock, which upon completion of this offering, will be exercisable for 8,307 shares of common stock at an exercise price of $6.32 per share.

As of September 30, 2004, we had a long-term loan, a long-term note payable, capital lease obligations, commitments under a facility operating lease, and non-cancellable purchase commitments. We had no other off-balance sheet items or commitments. Future payments under these obligations are included in the table below for each of the fiscal years ending September 30 (in thousands):

	2005	2006	2007	2008	2009	Total
Loan payable	$ 732	$ 1,097	$ 1,097	$ 729	$	$ 3,655
Note payable					1,150	1,150
Capital leases	51	46	40	17		154
Facility lease	123	143	153	162	90	671
Non-cancellable purchase commitments	442					442
Total	$ 1,348	$ 1,286	$ 1,290	$ 908	$ 1,240	$ 6,072

In addition, as of September 30, 2004, we had cancellable purchase commitments totaling $1.3 million.

As of March 31, 2005, we had drawn down an additional $4.6 million on the loan payable. These draw downs resulted in us fully utilizing the debt line of $7.5 million that was available. In addition, in April 2005, we received $1.5 million in unsecured debt financing from certain preferred stockholders and in connection with that transaction issued to those stockholders warrants exercisable for shares of our common stock.

Our cash as of March 31, 2005 combined with our April 2005 $1.5 million note financing is expected to be used by July 2005. We believe that the estimated proceeds from this offering, $16.6 million, along with our existing cash and cash equivalents and cash generated from product sales, will be sufficient to meet our anticipated cash requirements for at least the next 12 months. Our future capital requirements are difficult to forecast and will depend on many factors, including:

- success of our product sales and related collections;
- future expenses to expand and support our sales and marketing activities;

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;

Table of Contents

costs of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights; and

our need or decision to acquire or license complementary products, technologies or businesses.

If at any time sufficient capital is not available, either through existing capital resources or through raising additional funds, we may be required to delay, reduce the scope of, eliminate or divest one or more of our research and development programs, sales and marketing 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 and Estimates

We prepare our financial statements in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. Our critical accounting policies are as follows:

Revenue Recognition. We recognize revenue from product sales when there is persuasive evidence that an arrangement exists, title has transferred to our customers, the price is fixed and determinable and collection is reasonably assured. Provisions for discounts to customers, returns or other adjustments are recorded as a reduction of revenue and provided for in the same period that the related product sales are recorded based upon analysis of historical discounts and returns. When terms of sale are Freight on Board, or FOB, shipping point, revenue is recognized at time of shipment and when the terms of sale are FOB receiving point, revenue is recognized when the products have reached the destination point and other criteria for revenue recognition have been met. Shipping and handling charges are invoiced to customers based on the amount of products sold. Shipping and handling fees are recorded as revenue and the related expense as cost of goods sold.

We offer an early payment discount to certain customers. We provide certain customers product return rights in limited circumstances. To date, we have experienced no product returns and have determined that a reserve for product returns is not necessary. Future changes in our experience with product returns may cause us to make changes in our reserve for product returns. Our inability to accurately estimate product returns in the future may cause us to defer recognition of revenue. We will, from time to time, provide free products to customers. The cost of these free products are charged to cost of goods sold.

Allowance for Doubtful Accounts. While we have not had material bad debts written-off in the past, we analyze the collectibility of our accounts receivable, historical bad debts, customer concentrations, customer credit-worthiness, current economic trends, and changes in customer payment terms in evaluating whether an allowance needs to be made during the period.

Valuation of Inventory. Inventories are stated at the lower of cost or market, cost being determined under a standard cost method, which approximates first-in, first-out basis. The manufacturing cost of test strips currently exceeds their selling price. As a result, we record a charge to cost of goods sold for test strips equal to the amount by which the manufacturing cost exceeds the average market selling price.

Our inventories are evaluated and any non-usable inventory is written-off. In addition, we reserve for any inventory that may be potentially non-usable. Charges for such write-offs and reserves are recorded as a

component of cost of goods sold. We have had write-offs and reserves of $1.0 million in the year ended September 30, 2004 for rejected subassemblies and test strip lots. Changes in demand in the future could cause us to have additional write-offs and reserves.

Product Warranty. We record an accrual for estimated warranty costs when revenue is recognized. Warranty covers replacement costs of defective meters and related test strips. The warranty period for meters is one year. We have processes in place to estimate accruals for meter warranty exposure based upon estimated failure rates and replacement costs. Although we believe we have the ability to reasonably estimate warranty expenses, unforeseen changes in factors affecting the estimate for warranty could occur and such changes could cause a material change in our warranty accrual estimate. Such a change would be recorded in the period in which the change was identified.

Impairment of Long-lived Assets. We review long-lived assets, including property and equipment and intangibles, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition is less than its carrying amount. Impairment, if any, is measured as the amount by which the carrying amount of a long-lived asset exceeds its fair value. We consider various valuation factors, principally discounted cash flows, to assess the fair values of long-lived assets. To date, we have not recorded any impairment losses.

Intangible Assets. Intangible assets are comprised of licensed technologies, carried at cost less accumulated amortization. Amortization is computed using a straight-line method over the shorter of the estimated useful lives or the term of the license agreements.

Accounting for Income Taxes. Significant management judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowances recorded against our net deferred tax assets. We have historically had net losses and not been required to provide for income tax liabilities. We have established a valuation allowance with respect to all of our deferred tax assets. Changes in our estimates of future taxable income may cause us to reduce the valuation allowance and require us to report income tax expense in amounts approximating the statutory rates.

Stock-Based Compensation. We account for stock-based compensation using the intrinsic value method prescribed in Accounting Principles Board, or APB, Opinion No. 25, *Accounting for Stock Issued to Employees.* Our policy is to grant options with an exercise price equal to the estimated fair value of our stock on the grant date as determined by our board of directors. In the preparation of our financial statements, our management is responsible for determining the fair value of our common stock. Based on a review of a variety of factors including: sales of our preferred stock, preferences granted to our preferred stockholders, our current liquidity and capital needs and a valuation performed by an independent valuation specialist firm in February 2005, management has determined that the value of our common stock was equal to the valuation determined by our Board of Directors. Accordingly, no compensation expense has been recognized in our statement of operations for employee stock options. We provide additional pro forma disclosures as required under Statement of Financial Accounting Standard, or, SFAS, No. 123 *Accounting for Stock-Based Compensation, as amended.*

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

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

measurement of stock-based compensation is subject to periodic adjustment as the underlying equity instruments vest.

Table of Contents

Under generally accepted accounting principles, companies are permitted to use an alternative method of valuing stock options which is based on the fair value of the stock option on the date of grant. This method generally results in the recording of a greater expense related to stock options. Recent changes to the accounting rules require all companies to use a fair value method to record compensation expense related to stock options. We are required to adopt this change in the fourth quarter of fiscal 2005.

As of March 31, 2005, the value of outstanding employee stock options, based on the initial public offering price of $5.50 was as follows:

Vested	$ 2,043,000
Unvested	2,629,000
	$ 4,672,000

Recent Accounting Pronouncements

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

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

Quantitative and Qualitative Disclosures About Market Risk

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.

35

Table of Contents

BUSINESS

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. Warfarin is an oral anticoagulation, or blood thinning, drug given to patients to prevent potentially lethal blood clots. Our product, the INRatio System, consists of a small, portable meter and disposable test strips and provides a quick and accurate measurement of a patient s blood clotting time, known as a PT/INR value. The accurate measurement of the PT/INR value is critical to ensuring the safety and effectiveness of warfarin in maintaining a patient s blood coagulation level within a therapeutic range. The INRatio System represents an alternative to the current laboratory-based standard of care, which generally involves monthly or less frequent testing and delayed results. The U.S. Centers for Medicare & Medicaid Services, or CMS, has observed that monthly testing is inadequate for the majority of patients on chronic warfarin therapy. More frequent testing helps maintain patients within their therapeutic range and may minimize adverse events, such as dangerous blood clots or serious bleeding, associated with insufficient or excessive anticoagulation. Numerous studies reviewed by CMS showed that frequent self-testing through the use of a home PT/INR monitor improves a patient s time in therapeutic range. CMS approved Medicare coverage for weekly home PT/INR monitoring of patients with mechanical heart valves on warfarin. This decision went into effect in 2002 and, in the latter half of 2003, reimbursement payments began to reach service providers. Similar to the shift that has occurred in the standard of care for management of diabetes and blood glucose monitoring, we believe that the Medicare coverage decision and growing physician and patient awareness of the benefits of weekly PT/INR patient self-testing signal a shift in the standard of care for PT/INR testing from the clinical laboratory to point-of-care testing and, ultimately, patient self-testing.

Warfarin has been prescribed since the 1950s and is regarded as safe and effective when it is dosed correctly. It is the most widely prescribed oral anticoagulant besides aspirin. There are approximately three million people in the United States who take warfarin daily. In 2003, there were over 20 million prescriptions for warfarin written in the United States, either in generic form, or under its brand name Coumadin. Based upon Medicare claims data, there were 18.3 million PT/INR tests conducted on U.S. Medicare patients in 2003, comprised of approximately 13.4 million clinical laboratory tests and 4.9 million point-of-care or patient self-tests. By contrast, there were 13.8 million tests performed in 2000, consisting of 12.1 million clinical laboratory tests, and 1.7 million point-of-care tests. The total number of PT/INR tests increased by more than 30% over this three-year period, with 11% growth in the laboratory testing market, as compared with 190% growth in the point-of-care and patient self-test markets. We believe that similar trends have occurred with private insurance payors and in countries outside of the United States. In Germany, where reimbursement was established in 1996, more than 100,000 patients are performing PT/INR self-testing. As the global population ages and develops disorders requiring management of blood coagulation, and as weekly patient self-testing gains wider acceptance, we expect these trends in PT/INR testing to accelerate. We believe our INRatio System is well positioned to gain a meaningful share of the global market for PT/INR patient self-testing and point-of-care testing.

We have designed our INRatio System to address the needs of the emerging PT/INR patient self-testing and point-of-care markets. Our proprietary system requires one drop of blood from a patient s finger to quickly and reliably determine the rate at which their blood coagulates by measuring changes in the blood s electrical properties during the coagulation process. For ease of use, the INRatio System integrates into each disposable test strip clinical laboratory-like quality controls designed to ensure test-by-test accuracy. These controls are designed to verify the accuracy of each PT/INR test without the need for additional costly and time consuming steps requiring separate chemicals and test strips. Unlike test strips offered by competitors, our test strips can be stored for up to one year at room temperature rather than requiring refrigeration for long-term storage.

After receiving U.S. and European regulatory clearances in 2002, we commercially launched the INRatio System in March 2003 in the U.S. and certain European markets. Tests performed using our INRatio System in the point-of-care setting are currently reimbursed by Medicare for all patients on warfarin as is self-testing by

Table of Contents

mechanical heart valve patients on warfarin. To date, we have sold more than 5,000 INRatio meters and more than one million INRatio test strips worldwide for professional use at the point-of-care and patient self-testing at home. We have established distribution agreements with several national and regional distributors of medical products, giving us access to over 1,000 U.S. sales representatives for the sale of the INRatio System. We are dependent upon these distributors for a substantial portion of our revenue, and the loss of any key distributors would have a material adverse effect on our business. Our distributors Quality Assured Services and Cardinal Health accounted for approximately 31% and 26%, respectively, of our total revenue in fiscal 2004. In addition, we have established international distribution agreements with 12 distribution partners covering 16 countries outside the United States. We own five issued U.S. patents, one issued European patent, and one pending European application. Three of the issued U.S. patents cover, and the pending European application relates to, the INRatio System and its method of measuring blood coagulation by monitoring changes in the electrical properties of the blood sample as it clots.

Background and Market

Blood Clotting Disorders

The formation of a blood clot, or thrombus, is a desirable and essential response to a wound, preventing a simple injury from becoming a potentially fatal bleeding event. However, blood clots can have unwanted effects when they block normal blood flow in the body. Both heart attacks and strokes occur when a vessel that supplies blood is blocked by a blood clot. Heart disease is the leading cause of death in the United States today with heart attacks as the most publicized outcome. Stroke is the third-leading cause and the leading cause of serious, long-term disability.

There are two types of patients requiring medication for potential blood clots; those with acute conditions requiring short-term therapy and those with chronic conditions requiring long-term therapy, often for life. Acute risks of blood clots can result from accidents or from certain surgical procedures, like knee or hip replacements. Typically, these patients are initially treated at a hospital with combinations of intravenous drugs that dissolve blood clots and blood thinning drugs. Often, these patients will continue treatment with an oral anticoagulant, such as warfarin, for several weeks following a hospital stay, until the blood clot risk has diminished. Long-term risks of blood clots result from chronic conditions and are typically treated with oral anticoagulation medications, including warfarin and aspirin. The most common chronic uses of warfarin are for patients with mechanical heart valves and patients with atrial fibrillation.

Mechanical Heart Valves. A faulty heart valve can be surgically replaced with a mechanical valve. Mechanical heart valves are designed to last for the life of the patient, but they can lead to blood clots as a reaction to the presence of this foreign body. According to CMS, there are approximately 400,000 patients in the United States with mechanical heart valves, all of whom require warfarin. The American Heart Association, or AHA, indicates that there were approximately 93,000 heart valve replacement surgeries in the United States during 2002, which we believe included more than 25,000 mechanical valve implants.

Atrial Fibrillation. Atrial fibrillation is an irregular, fluttering heartbeat that may cause blood to pool within the upper chambers of the heart, leading to blood clots that can cause a heart attack or stroke. According to the AHA s *Heart Disease and Stroke Statistics 2005 Update*, there are approximately 2.2 million patients in the United States with atrial fibrillation. The *2005 Update* estimates that atrial fibrillation is responsible for approximately 105,000 to 140,000 strokes, or 15% to 20% of all strokes in the United States annually. According to a 2004 publication in *Clinical Cardiology*, research to date shows that warfarin provides a major potential benefit to patients with atrial fibrillation, reducing the risk of stroke by approximately 68%. However, fewer than 50% of eligible patients are treated because of fear of brain hemorrhage. To reduce this risk, careful monitoring of warfarin dosage is critical.

Table of Contents

While our INRatio System is primarily marketed to physicians treating and patients suffering from these two chronic conditions, it is also sold to physicians for the management of warfarin dosage in patients with an acute need for the medication.

Importance of Monitoring and Managing Warfarin Dosage

The safety and effectiveness of warfarin depends on maintaining the blood s ability to coagulate within a narrow therapeutic range, which can be challenging if not actively managed. If there is too much warfarin in a patient s bloodstream, there is a risk of hemorrhage, or uncontrolled internal or external bleeding, which can be fatal. If there is too little warfarin in the bloodstream, it will be ineffective in reducing the risks associated with blood clots from the underlying condition, such as a stroke or heart attack.

A patient s warfarin dosage typically is managed by first giving a small starting dose and measuring the patient s blood clotting time, adjusting the dose and measuring again, and so on, until the patient s proper therapeutic dosage is achieved. When the correct dosage has been achieved, the anticoagulation effect of the drug will be within a safe and effective therapeutic range. The effectiveness of warfarin can vary between patients and within the same patient, depending upon a number of factors. Changes in diet, alcohol consumption, interaction with other drugs, a patient s overall health and environmental factors can all affect the degree of anticoagulation caused by warfarin. These factors make it important for patients on warfarin to measure their blood clotting ability frequently to provide their physicians with the information necessary to maintain an appropriate level of warfarin. Prothrombin time, or PT, is an expression of the time it takes for blood to clot and reflects the anticoagulation effect of warfarin. The internationally recognized measurement standard for clotting time is known as PT/INR. INR is the International Normalized Ratio, which expresses PT in a common scale established by the World Health Organization. Higher PT/INR values indicate the blood will take more time to clot, whereas lower values indicate the blood will clot more quickly.

Clinical Laboratory and Point-of-Care PT/INR Testing and their Limitations

Clinical Laboratory Testing. PT/INR measurements have traditionally been and are mostly still performed and analyzed in a clinical laboratory using sophisticated and costly high-volume screening equipment. Clinical laboratory tests accounted for 73% of all PT/INR tests performed in 2003 on Medicare patients. Clinical laboratory testing methods for PT/INR measurement are precise; however, these methods are inconvenient for the patient and the physician, and therefore not conducive to compliance. Clinical laboratory test results typically are not available until the following day, which could prevent a physician from properly advising a patient during their visit. In addition to being inconvenient for the patient, the delay in obtaining test results creates inefficiencies because the physician or nurse practitioner must perform patient call backs in order to advise patients of changes needed to their warfarin dosages.

Point-of-Care Testing. Handheld devices for PT/INR point-of-care measurement have existed since 1987. However, we believe that physician adoption of these devices was limited due to mixed clinical results regarding their precision and accuracy. In contrast to PT/INR tests performed in a clinical laboratory, point-of-care PT/INR tests can use capillary blood from a finger stick and produce quick results because tests are performed using a real time PT/INR measurement device directly at the patient point-of-care, such as at a physician s office, anticoagulation clinic or nursing home. The ability to obtain a quick PT/INR test result is valuable because it allows the healthcare professional to adjust warfarin dosage and suggest lifestyle changes with the patient during the same office visit. In addition, point-of-care PT/INR testing reduces time required and costs associated with the use of clinical laboratories that are not in close proximity to the physicians and patients. These costs include sample collection and processing steps, transportation costs, and the time spent by a physician or nurse practitioner performing patient call backs.

CMS reimburses both clinical laboratory and point-of-care PT/INR tests. However, as CMS has observed in its September 2001 National Coverage Decision Memorandum regarding PT/INR self-testing, clinical laboratory tests are generally performed only once every four to six weeks, due in large part to practical constraints of

Table of Contents

access and labor-intensiveness. In the Decision Memorandum, CMS indicated that monthly testing is inadequate for the majority of patients on chronic warfarin therapy, because the medication is highly individualized and affected by common variables like diet. More frequent testing helps to improve the time that patients spend within their therapeutic PT/INR range, which may minimize adverse events, such as dangerous blood clots or serious bleeding, associated with inadequate or excessive anticoagulation. CMS evaluated 11 clinical studies published in peer-reviewed journal articles, all of which found patients using home PT/INR monitors performed favorably compared to control groups treated at a medical facility. Seven of the eight studies that measured statistical significance showed statistically significant better time in therapeutic range, or TTR, for the patient self-testing group than for the group that received either usual care from a hospital or commercial laboratory, or point-of-care testing, regardless of testing frequency.

CMS Decision Memorandum Observations

	Usual Care	Point-of-Care	Patient Self-Testing
General observations			
Current site of patient testing	< 80%	20%	< 5%
Testing intervals	4-6 weeks	2-3 weeks	Weekly
Adverse event rates	> 15%	< 8%	Lowest
Observations based on specific studies			
Time in therapeutic range, TTR	32-68%	32-68%	56-92%

The studies described by CMS consistently showed that the more frequently a patient was tested the more time that patient spent in their therapeutic range, leading CMS to observe in order to achieve time in therapeutic range of greater than 90%, a patient most likely needs to be tested once a week. CMS went on to note that increased TTR leads to improved clinical outcomes, with reductions in thromboembolic and hemorrhagic events.

The Emergence of a Patient Self-Testing Market

The confluence of improved technology, approval of reimbursement coverage and increased physician and patient awareness has led to the emergence of a patient self-testing market for warfarin users. By early 2000, the FDA had cleared three monitors for patient self-testing, but each instrument had limitations. Studies have demonstrated that the accuracy and reliability of newer devices for patient self-testing compared well with clinical laboratory testing. The patient self-testing market has emerged as government and private payors have begun to provide reimbursement. Medicare reimbursement for up to weekly PT/INR monitoring of anticoagulation management for warfarin patients with mechanical heart valves went into effect in 2002 following publication of the CMS Decision Memorandum. Several European countries have also implemented national reimbursement coverage of home PT/INR testing for chronic warfarin patients, including Germany, the United Kingdom, Denmark and the Netherlands.

Medicare reimburses for services provided to patients who perform PT/INR self-testing, similar to the Medicare reimbursement procedure for patients on pacemakers and Holter monitors. Our meters and test strips are distributed to Medicare patients without charge through a Medicare

licensed facility known as an Independent Diagnostic Testing Facility, or IDTF, which may also monitor patient compliance and convey test results to the treating physician. Medicare provides a one-time reimbursement of $252 per patient for the cost associated with training patients in the proper use of our INRatio System. Medicare also provides for an annual total of over $2,000 per patient for physician review, monitoring service and the testing device. If all of the approximately 400,000 U.S. mechanical heart valve patients on warfarin performed weekly PT/INR self-testing, Medicare reimbursement for this population would be in excess of $800 million annually.

Table of Contents

The Department of Veterans Affairs has sponsored a clinical study known as The Home INR Study, or THINRS, to evaluate weekly PT/INR patient self-testing for patients with atrial fibrillation or a mechanical heart valve. THINRS is a randomized, open-label, active control outcome study designed to compare weekly patient self-testing with conventional monthly monitoring in the clinic. This study commenced in 2003 and is expected to be completed in 2006. It is anticipated that 3,200 patients will be enrolled at 32 sites. The study participants must have atrial fibrillation or mechanical heart valves and be scheduled to receive warfarin for at least two years. Participants are assigned into either a weekly patient self-testing group or monthly conventional monitoring group. The study evaluates adverse event rates, time to first adverse event, time in therapeutic range for anticoagulation intensity, and total healthcare cost and utilization. We expect that results from this study will be influential in Medicare s decision regarding reimbursement for PT/INR patient self-testing in atrial fibrillation. If Medicare were to commence reimbursement for PT/INR patient self-testing for the approximately 1.2 million atrial fibrillation patients currently on chronic warfarin, this will significantly increase the PT/INR patient self-testing market.

As more physicians, insurance providers and patients become aware of the healthcare benefits derived from more frequent PT/INR testing and the availability of simple and convenient PT/INR testing devices designed specifically for the patient self-testing market, we expect the PT/INR patient self-testing market to grow significantly.

The HemoSense Solution

We believe that the INRatio System represents a new generation of PT/INR testing devices designed specifically for use in both patient self-testing and by healthcare professionals at the point-of-care. We believe that physicians generally will not prescribe patient self-testing unless the physician is confident that the patient will be able to comply with the testing requirements. Many patients needing warfarin are Medicare patients, some of whom may have limited manual dexterity and may be challenged by complex test instructions and training. We believe that we offer a unique combination of factors that make our INRatio System a simple and straightforward patient self-testing PT/INR measurement device. These features also enable busy healthcare professionals to quickly train their patients in the use of our system as a tool for monitoring their warfarin therapy. Specifically, these features include:

Patient-friendly, fast and easy-to-use meter and test strips. Our INRatio System weighs less than a pound, is handheld, battery-operated and provides test results generally in two minutes or less. Results are displayed on an easy to read screen and stored in memory. A typical test requires a finger stick to provide one drop of blood, which is then deposited onto a disposable test strip that has been inserted into the INRatio meter.

Integrated quality control tests. Our INRatio System s fully integrated, on-board quality controls are designed to ensure the accuracy of each test and to help simplify patient self- testing by eliminating the need to perform separate quality control tests. Each time a PT/INR test is conducted, the INRatio System automatically performs two laboratory-like quality control tests within the same single disposable test strip. The integrated quality controls and self-tests built into the meter serve as additional safeguards against misuse. These tests are designed to confirm that the test strip has not been damaged, that the patient is using the system correctly and that the meter is performing as intended. In some competing PT/INR testing systems, the quality control tests are not fully integrated and must be performed manually using additional test strips and separate containers of control solution.

Straightforward patient training. Our INRatio System s features result in a clear-cut training procedure that we believe is easy for a patient to understand and remember and that we believe will encourage more patients to self-test. Unlike some competing products, our training is so simple that it can be done by phone or online, rather than in person. With the INRatio System s simple user interface, the meter guides the patient through a few intuitive steps. Error messages appear on the screen in the event that proper

Table of Contents

procedures are not followed. There is no need to learn how to use quality controls that require additional test strips, special handling and precise timing steps.

Test strips that may be stored up to one year at room temperature. Our INRatio System s disposable test strips do not require refrigeration, which provides additional convenience to patients and significant storage and handling cost savings to distributors and resellers. The test strips can be stored at room temperature for up to one year, compared to only 30 to 60 days for test strips used in other currently available PT/INR devices. Refrigerated test strips must be warmed by a patient to room temperature prior to use, requiring patients and healthcare professionals to plan ahead in order to allow time for acclimation to occur.

Proprietary, reliable electrochemical technology. The INRatio System is the only PT/INR testing device that utilizes electrochemical technology to determine a patient s PT/INR value. Our proprietary electrochemical technology generates rapid results and does not rely on mechanical moving parts. The sensors used in our system are small and allow us to measure a patient s PT/INR value and two levels of quality control with a single drop of blood.

The ability of patients to home test with our INRatio System reduces the time and inconvenience required to manage warfarin by reducing or eliminating trips to the laboratory or doctor s office for testing, both for the patient and, often, for the caregiver. In addition, the INRatio System s patient-friendly design and functionality helps minimize the burden of PT/INR self-testing for patients. With PT/INR patient self-testing, patients play an active role in management of their warfarin dosage, which we believe encourages optimal patient compliance.

Our Strategy

Our objective is to become the leading provider of PT/INR patient self-testing and point-of-care testing systems and related products for the monitoring of patients on warfarin. We seek to improve therapeutic outcomes while dramatically reducing the need for inconvenient visits by patients to healthcare professionals for routine testing. To achieve these objectives, we are pursuing the following strategies:

Increase awareness among physicians and patients of the advantages of the INRatio System and the benefits of weekly PT/INR testing. Our goal is to establish the INRatio System as the leading ease of use PT/INR testing device and the new standard of care. We continue to create awareness among patients and healthcare professionals of the advantages of the INRatio System for weekly patient self-testing and point-of-care testing. Because the INRatio System is easy to use, we intend to establish the INRatio System as the standard of care for PT/INR testing by patients in their homes and by healthcare professionals and caregivers in clinics, physicians offices, hospitals and long-term care facilities.

Leverage our established and growing network of distributors worldwide. Our target market can be broken down into several key segments, including anticoagulation clinics, physician office practices, hospitals, long-term care facilities, home healthcare and patient self-testing. We are establishing relationships with nationally recognized partners to optimize our distribution to each of these market segments. Our sales force assists our distributors in developing and maintaining relationships with leading medical professionals in order to facilitate the adoption of the INRatio System. We intend to expand our distribution internationally in order to gain access to new markets, such as Asia, and to bolster our presence in Europe.

Utilize and expand reimbursement opportunities. Clinical studies are currently underway to evaluate weekly PT/INR patient self-testing specifically for patients with atrial fibrillation. As data from these studies becomes available, we plan to campaign actively, both independently and in conjunction with our competitors as well as various healthcare professional associations, for reimbursement coverage of weekly PT/INR self-testing for patients with atrial fibrillation in both the United States and Europe. In

Table of Contents

addition, we plan to participate in efforts and discussions that support reimbursement for weekly patient self-testing and point-of-care testing for other indications.

Pursue reimbursement for new and additional indications for PT/INR patient self-testing. Our focus initially is on increasing the use of the INRatio System in the monitoring of patients on long-term warfarin, such as patients with implanted mechanical heart valves or those with atrial fibrillation. We also intend to address the PT/INR testing needs of patients on short-term warfarin therapy, such as patients at risk of blood clots resulting from accidents or surgeries.

Develop product improvements. We intend to develop improvements to our INRatio System with a focus on assuring that our products continue to be easy to use and convenient for our end-users.

Our Products

Our INRatio System is an easy-to-use testing system designed specifically for patient self-testing that provides PT/INR test results using one small drop of blood from the patient s finger. The INRatio System consists of a small, handheld meter and disposable test strips with integrated, laboratory-like quality control tests that are designed to assure the accuracy of PT/INR test results. We shipped our first commercial INRatio System in March 2003.

INRatio Meter

The INRatio meter contains a heater, digital user interface, and electronic components that measure the changes in resistance or impedance in a blood sample during the coagulation process. To ensure the proper functioning of its components, the INRatio meter performs a series of self-diagnostic tests every time the device is turned on. The meter has three buttons that control all of its functions and has a prominent, easy to read screen on which instructions and results are clearly displayed. The meter has the ability to store up to 60 PT/INR test results and contains a data port for interfacing with an optional printer. The meter is powered by four AA batteries and has an optional external A/C adapter. The user can choose to display messages in any of ten languages programmed into the meter.

INRatio Disposable Test Strips

The INRatio disposable test strips use our proprietary electrochemical technology to measure a patient s PT/INR value and perform two laboratory-like quality control tests on a single test strip with a single drop, or approximately 15 microliters, of blood. The two quality control tests confirm standard PT/INR readings for the normal lower range, or low control, and the therapeutic upper range, or high control. This helps ensure that the meter and test strip are functioning properly and that the patient s PT/INR test result will be accurate. The meter and a single test strip automatically perform all three tests each time a patient s blood sample is applied to a test strip that has been inserted into the meter. When the INRatio meter detects an unacceptable quality control test result, it does not display a potentially incorrect PT/INR test result, but rather alerts the user to the error. We designed our proprietary test strips with on-board quality control tests and our meter with built-in electronic diagnostic tests to help ensure the accuracy of test results and to simplify the process by eliminating the need to use specialized control test liquids and additional test strips to obtain quality control test measurements. Our test strips do not require refrigeration and can be shipped and stored at room temperature for one year, which provides distribution advantages and improves patient convenience. INRatio test strips can only be used with the INRatio meter.

INRatio Accessories

We include all accessories needed for the use of the INRatio System in the patient self-testing and point-of-care environments, such as lancets.

Table of Contents

Our Technology Platform

The INRatio System utilizes an electrochemical sensor to detect and measure changes in electrical impedance of a blood sample as it coagulates. The change is then recorded by the meter and converted to a PT/INR reading. When the meter is turned on, it performs an electronic diagnostic check, the first of a number of quality control tests performed by the INRatio System. Once the test strip is inserted into the meter, it is warmed to normal body temperature, and the meter alerts the user to apply the blood sample. After a drop of blood is applied to the sample well on the test strip, it is drawn by capillary action across the surface of the test strip and into the test area where it mixes with reagents that cause coagulation. The blood sample contacts separate electrodes which measure changes in impedance that occur during coagulation. As the reaction progresses, the electrical impedance increases and then gradually drops as the clotting process is completed. The elapsed time, in seconds, until the endpoint is reached is the raw PT time, which is then used to calculate the INR of the sample. The meter displays the patient s PT/INR results generally within two minutes or less after the blood sample is applied.

Sales and Marketing

The market for the INRatio System includes patient self-testing, physician office practices, anticoagulation clinics, hospitals, long-term care facilities, nursing homes and home healthcare providers. We currently sell our INRatio meter and disposable test strips through distribution agreements in the United States and internationally. In the United States, our distribution agreements provide us with access to more than 1,000 sales representatives.

U.S. Distribution

We have agreements with five national medical device distribution companies: Quality Assured Services, Cardinal Health, Raytel, Medline and McKesson Medical. We also have agreements with four companies which provide regional distribution.

Quality Assured Services. We entered into a distribution agreement with QAS in March 2003. QAS is a specialized healthcare sales, service, marketing and distribution company that focuses on new and evolving, easy-to-use medical diagnostics and related products for patient home care and professional office use. We believe that QAS is unique in the market due to its combination of medical diagnostics distribution, telehealth services, disease management, health insurance adjudication, training, and market development services. The term of our agreement with QAS runs through February 2007 and will be automatically renewed for one-year periods unless terminated by either party in the 60-day period preceding the end of any term. We are obligated to indemnify QAS in certain circumstances, including claims against us for malfeasance.

Cardinal Health. We entered into a distribution agreement with Cardinal Health in December 2003. Cardinal Health is one of the largest medical supply companies in the United States and has over 500 sales and service specialists that focus on marketing to physician office practices and hospitals. Our agreement with Cardinal Health provides us with broad geographic coverage of the physician and hospital market segments. The term of our agreement with Cardinal Health runs through April 2007 and may be renewed for successive one-year terms. Either party may terminate the agreement without cause upon 90 days written notice.

Raytel. We entered into a distribution agreement with Raytel in April 2004. Raytel is the market leader in contracted services for pacemaker and Holter monitoring, and employs a U.S. field sales force of 25 sales representatives. Our agreement with Raytel is focused on the PT/INR patient self-testing market and provides us with exposure to the patient base of St. Jude Medical, the largest manufacturer of mechanical heart valves. Raytel is the exclusive IDTF for St. Jude Medical s marketing of PT/INR patient self-testing

in conjunction with its mechanical heart valve product. As an IDTF, Raytel focuses on managing and monitoring these patients and has significant resources to handle claims processing and the logistics of

product supply. The term of our agreement with Raytel runs through April 2006 and will be automatically renewed for one-year periods unless terminated by either party in the 90-day period preceding the end of any term.

Medline. We entered into a distribution agreement with Medline in June 2004. Medline is the largest privately-held national manufacturer and distributor of medical supplies in the United States and has over 700 dedicated sales representatives nationwide, and 29 distribution centers in North America. Our distribution agreement with Medline provides access to the long-term care, nursing home and home healthcare market segments and is exclusive to Medline in those areas. The initial term of our agreement with Medline runs through December 2007 and may be renewed for additional one year periods. The agreement may be terminated by either party within 90 days following an uncured material breach. We are obligated to indemnify Medline in certain circumstances, including for intellectual property infringement claims, breaches of the agreement or our negligence.

McKesson Medical-Surgical. We entered into a distribution agreement with McKesson Medical-Surgical in May 2005. McKesson Medical, a subsidiary of McKesson, the world s leading healthcare services company, is a leading distributor of medical supplies and equipment to physician practices, surgery centers, hospitals, home care and extended care facilities. Under our agreement, McKesson Medical will act as a non-exclusive distributor of our products to medical clinics, hospitals, physician groups and other medical sites, excluding long-term care facilities and home health care. The term of our agreement runs through May 2010 and continues automatically for successive five year terms. Either party may terminate the agreement without cause upon 90 days written notice or with cause upon 10 days written notice.

International Distribution

We currently have 12 distribution agreements covering 16 countries internationally. These agreements generally provide that each distributor can sell into the professional and home-use markets within a country. Germany, as an exception, has two distributors covering the country. Our distribution agreements internationally include those with MicroMedical and InaBattke KG in Germany; as well as agreements with distributors covering Australia, Austria, Belgium, Denmark, Finland, Holland, Israel, Luxembourg, Norway, Spain, Sweden, Switzerland and the United Kingdom. Germany is a particularly important international market for us because its medical and patient communities have been leaders in the adoption of patient self-testing. We intend to continue to enter into distribution agreements in other select countries where PT/INR patient self-testing and point-of-care testing are established medical practices. In emerging markets such as Asia, we intend to identify strategic partners as distributors of our product.

Sales and Marketing Organization

We intend to use a variety of marketing tools to build market awareness, drive product adoption, ensure continued usage and establish brand loyalty for the INRatio System by:

creating awareness of the benefits of the INRatio System with distributors, physicians, nurse practitioners, educators and patients;

providing strong educational and training programs to healthcare providers and patients to ensure the understanding of the ease of use, safety and effectiveness of the INRatio System;

establishing a readily-accessible telephone and web-based technical and customer support infrastructure for our distribution partners, healthcare providers and patients; and

building upon our network of leading distributors to sell our products to physician office laboratories and directly to the patients.

Table of Contents

We currently employ 28 people in sales and marketing. Fifteen salespeople are located in key locations throughout the United States working with distribution partners and healthcare providers. We employ five product specialists in the field that focus on training and product troubleshooting for large accounts. The seven remaining employees are located in the corporate office, including four within marketing and three in customer and technical service. We also employ a director of international business development in Europe to support our international distribution partners and healthcare providers.

Competition

The market for PT/INR patient self-testing and point-of-care diagnostics is intensely competitive, subject to rapid changes and new product introductions. We believe that two companies, Roche Diagnostics and International Technidyne Corporation, a division of Thoratec, currently account for over 90% of the worldwide sales of PT/INR point-of-care and patient self-testing devices. Both of these competitors use a meter and disposable strips or cartridges, to test blood obtained by lancing the finger or drawing blood from a vein. Both of these competitors are focused on expanding their presence in the patient self-testing market.

In addition to our current competitors, we expect to encounter new entrants to the market, particularly if increased reimbursement drives the adoption of patient self-testing and increased testing volume. Specifically, Inverness Medical Innovations has announced that it plans to introduce its own warfarin anticoagulation monitoring device later this year.

Our competitors enjoy several competitive advantages, including:

- significantly greater name recognition;
- established relationships with healthcare professionals, patients and third-party payors;
- established distribution networks;
- additional product lines and the ability to offer rebates or bundle products to offer higher discounts or incentives to gain a competitive advantage;
- greater experience in conducting research and development, manufacturing, obtaining regulatory approval for products and marketing; and
- greater financial and human resources for product development, sales and marketing and patent litigation.

We believe the principal competitive factors in our market include:

- reliability and ease of use;

technological leadership and superiority;

improved patient outcomes and reduced overall time to manage therapy; and

effective marketing and distribution.

Emerging Oral Anticoagulation Therapies

A number of pharmaceutical companies are working on the development of a new class of oral direct thrombin inhibitors, or DTIs, to replace older anticoagulants such as warfarin. In theory, these new oral DTIs should have very few drug/non-drug interactions and should not require the same level of monitoring that warfarin requires. One goal of current research in this area is the elimination of the need for PT/INR testing,

Table of Contents

which if successful could render our device obsolete. One oral DTI, AstraZeneca s Exanta, is approved in Europe for preventing blood clots in connection with knee and hip replacements. However, in the fourth quarter of 2004, the FDA did not grant approval based on Exanta s dangerous side effects to patients livers. As of yet, it is unknown whether oral DTIs will be approved in the United States or perform as well as warfarin, especially for the chronic user.

Manufacturing

The primary components of the INRatio System are the INRatio meter and the INRatio disposable test strips. We manufacture the INRatio test strips at our California headquarters and we contract with an electronic manufacturing services supplier to manufacture the INRatio meter. We offer other accessories as part of the INRatio System such as lancets, blood collection devices, power supplies, and printers. These supplies and accessories are manufactured by third parties and are not customized for the INRatio System.

Both the INRatio meter and test strips are manufactured using components and assemblies that have been supplied by outside vendors. The test strip manufacturing process includes reagent dispensing and drying steps, mechanical assembly, packaging and calibration. Plastic film substrates are purchased from outside vendors that perform printing, die cutting and laminating operations according to specifications we have established. These printed and cut films are shipped to our manufacturing facility where we perform an incoming quality control check prior to test strip assembly. The meter is manufactured by an electronic manufacturing services company that is responsible for procuring materials, assembly, and testing of the device according to our specifications. The meters are shipped to our manufacturing facility where we perform calibration, packaging and labeling.

We use contract manufacturing relationships to minimize our capital investment, help control costs, and take advantage of the expertise these third parties have in the production of these assemblies. We also purchase certain components and materials from single sources due to constraints resulting from intellectual property requirements, quality or cost reasons. Currently, those single sources are Dade Behring, which produces a reagent used in our test strips, Haematologic Technologies, which produces the control reagents and Plexus, which manufactures our meters. We have supply agreements in place with these single source suppliers that provide for notification and termination periods; however, because of the custom nature of the components and the FDA requirements for validation and verification of significant changes, a supply interruption from any of these suppliers would limit our ability to produce our systems and could have a material adverse effect on our business. Our agreement with Dade Behring is terminable upon 90 days notice. Prior to the expiration of the agreement in March 2007, we have the option to extend the term until January 2015, the date of the last expiring patent covered by the agreement, by making a payment of $2.5 million, if made prior to March 2006, or $2.75 million, if made prior to March 2007. Our agreement with Haematalogic Technologies is terminable upon 18 months notice and our agreement with Plexus is terminable upon 180 days notice.

Research and Development

We are at the concept development stage for a new version of the INRatio meter that we believe would make our system even more attractive for the PT/INR patient self-testing market. The system design of the new version plans for a device that is smaller in size than our current INRatio meter. We expect this new product to utilize the current architecture of the INRatio disposable test strip and deliver the same patient-friendly feature set as the current INRatio meter. We believe that our next generation INRatio System could potentially be attractive for patients who are only on warfarin for a short period of time.

In addition, based on our initial specifications, we expect the new version could reduce our per-unit manufacturing costs at comparable volumes, using the same manufacturing technologies as the current INRatio System. Beyond investing in the design of a future version, we intend to

continue developing a number of product enhancements for the current INRatio System. We are also developing an integrated communications capability for use in the professional setting that will provide an automated means to interface the INRatio meter to a data management system. Product development efforts related to the current INRatio System are focused on

Table of Contents

manufacturing process enhancements aimed at cost reduction and quality improvements, as well as functional enhancements. Specifically, we are designing process development and automation projects for our disposable test strip production line that we believe will significantly increase manufacturing capacity and reduce our costs.

We believe that our electrochemical technology has applications in other tests beyond the measurement of PT/INR values for patients on warfarin. We plan to conduct feasibility studies for additional coagulation parameters including APTT, or activated partial thromboplastin time, and ACT, or activated clotting time.

We have had research and development expenses of $3.4 million, $1.7 million and $1.4 million in fiscal 2002, 2003 and 2004, respectively.

Intellectual Property

Protection of our intellectual property is a priority for us. We plan to pursue and maintain patent protection in both the United States and Europe. We rely on a combination of patents, copyrights, trade secrets and nondisclosure agreements to protect our proprietary rights. Currently, we have five issued U.S. patents and one issued European patent, which has been validated in certain member states of the European Patent Convention, including Germany and Austria. In addition, we have one pending European patent application. Three of the issued U.S. patents cover the INRatio System and its method of measuring blood coagulation. They expire in 2017. Similarly, the pending European application contains claims that would cover our INRatio System and its method of measuring blood coagulation if it were to issue in its present form. The pending European application, if issued, would expire in 2018.

The medical device industry is characterized by the existence of a large number of patents and frequent litigation based on assertions of patent infringement. On June 22, 2005, we received a letter from Beckman Coulter claiming that our test strip includes intellectual property covered by one of their patents, U.S. Patent 5,418,141, and that we could require a license to the patent. We do not believe that their patent covers our test strip or that we need to obtain a license from them. Together, our patents, patent application and licenses of patents protect aspects of our technologies. We believe that our patent and license position will provide us with sufficient rights to develop, sell and protect our product.

We also rely on trade secrets, technical know-how and continuing innovation to develop and maintain our competitive position. We seek to protect our proprietary information and other intellectual property by generally requiring our employees, consultants, contractors, outside scientific collaborators and other advisors to execute non-disclosure agreements on commencement of their employment or engagement.

In April 2003, Inverness Medical Innovations filed suit against us, alleging that disposable test strips for our INRatio System infringed certain patents held by Inverness. In July 2004, we entered into a settlement and mutual release agreement with Inverness pursuant to which we received a non-exclusive, perpetual, non-transferable worldwide license to the patent rights in exchange for a product royalty of 1.5% of net sales, which is subject to a cap on aggregate royalties payable of $5.0 million, which begins to accrue in July 2006 and the issuance to Inverness of a $1.0 million secured subordinated promissory note.

Government Regulation

Our products are medical devices subject to extensive regulation by the FDA and other regulatory bodies. FDA regulations govern, among other things, the following activities that we perform and will continue to perform to ensure that medical products distributed domestically and exported internationally are safe and effective for their intended uses:

- product design and development;
- product testing;
- product manufacturing;

Table of Contents

product safety;

product labeling;

product storage;

recordkeeping;

premarket clearance or approval;

advertising and promotion; and

product sales and distribution.

FDA s Premarket Clearance and Approval Requirements

Unless an exemption applies, each medical device we wish to commercially distribute in the United States will require either prior 510(k) clearance or prior premarket approval from the FDA. The FDA classifies medical devices into one of three classes. Devices deemed to pose lower risk to the patient are placed in either class I or II, which requires the manufacturer to submit a premarket notification requesting permission for commercial distribution. This process is known as 510(k) clearance. Most class I devices are exempted from this requirement. Devices deemed by FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) device or a pre-amendment class III device for which premarket approval applications, or PMAs, have not been required by the FDA, are placed in class III, requiring premarket approval. All of our current products are class II devices.

510(k) Clearance Pathway. To obtain 510(k) clearance, we must submit a premarket notification demonstrating that the proposed device is substantially equivalent to a previously cleared 510(k) device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of PMAs. By statute and regulation, the FDA is required to clear, deny, or request additional information on a 510(k) premarket notification within 90 days of submission of the application. As a practical matter, 510(k) clearance often takes significantly longer. The FDA may require further information, including clinical data, to make a determination regarding substantial equivalence.

We received 510(k) clearance for our INRatio System for professional use in May 2002, and for use in patient self-testing in October 2002. The components of our system include the meter, test strips, blood lancets, blood collection device and power supplies. A printer, manufactured by a third-party, is available as an accessory.

Product Modifications

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require a premarket approval. The FDA requires each manufacturer to make this determination initially, but the FDA can review any of these decisions. We have modified various aspects of our INRatio System since receiving regulatory clearance, but we believe that new 510(k) clearances are not required for these modifications. If the FDA disagrees with our determination not to seek new 510(k) clearances, the FDA may require us to seek 510(k) clearance or premarket approval. The FDA also can require us to cease marketing and/or recall the modified device until 510(k) clearance or premarket approval is obtained. Also, in these circumstances, we may be subject to warning letters, significant regulatory fines or penalties, seizure or injunctive action, or criminal prosecution.

Premarket Approval Pathway. If the FDA denies 510(k) clearance for one of our products or if one of our products is not eligible for 510(k) clearance, we must follow the premarket approval pathway for that product before marketing commences. A PMA requires reasonable assurance of the safety and effectiveness of the device

Table of Contents

to the FDA s satisfaction. A PMA must provide extensive pre-clinical and clinical trial data and also information about the device and its components, including, among other things, device design, manufacturing and labeling. After approval of a PMA, a new premarket approval or premarket approval supplement is required in the event of a significant modification to the device, its labeling or its manufacturing process. The premarket approval pathway is much more costly, lengthy and uncertain than 510(k) clearance. It generally takes from one to three years or even longer from submission of a complete application to PMA approval.

No device that we have developed has required premarket approval, nor do we currently expect that any future device or indication will require premarket approval.

Pervasive and Continuing FDA Regulation

After a device is placed on the market, numerous regulatory requirements apply. These include:

- quality system regulations, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations, which prohibit the promotion of products for uncleared, unapproved or off-label uses;
- medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur;
- correction and removal regulations, which require that manufacturers report to the FDA any corrections to, or removals of, distributed devices that are made to reduce a risk to health; and
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

We will need to continue to invest significant time and other resources to ensure ongoing compliance with FDA quality system regulations and other postmarket regulatory requirements.

The FDA enforces the quality system regulations, or QSRs, through scheduled and through unannounced inspections. We recently underwent an inspection of our facilities by the FDA, which resulted in the issuance of an FDA Form 483 containing two observations. First, the inspector observed that we failed to timely file Medical Device Reports, or MDRs, for six of seven complaints the inspector reviewed claiming that our INRatio device took inaccurate readings none of which resulted in a patient injury. MDRs are required to be filed, even if an injury has not occurred, if our device may have caused or contributed to a death or serious injury or if it may have malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur. We categorize as complaints instances reported to us in which our device takes a reading that is different from what the user expected. For example, discrepant results can be different readings obtained by the user on separate occasions using either the same or another testing device. In addition to potential device malfunction, discrepant PT/INR test results can arise from a number of factors, such as failure to follow our instructions for use, a patient s medication or diet between measurements, or variability in measurement results among different manufacturers instruments. Since we began selling our product, we have received complaints of discrepant

test results representing approximately .01% of all test strips sold. At the time that we received the complaints reviewed by the FDA, our written procedure did not provide for the analysis of whether to file an MDR if the complaint solely involved discrepant results, without any resulting patient injury. In addressing the FDA s observation, we have revised our MDR reporting procedure to now determine when discrepancies between measurements taken with our device and those taken with a clinical laboratory device should be classified as a malfunction and result in an MDR filing. As a result of this revised procedure, we will be filing an increased

number of MDRs. The FDA s second observation was that we had not properly defined and documented the procedures we employ to identify the statistical techniques for calibration of our test strips. This observation requires us to provide clarification of how our current strip calibration procedures are in conformity with standards applicable to PT/INR testing. We have filed a response to these observations that includes a description of and basis for our revised MDR reporting procedure, as well as the documentation of procedures employed to identify valid statistical techniques for our test strip calibration and our conformity to applicable standards. It is possible that the FDA will issue a Warning Letter related to one or both of the observations. A Warning Letter would require that we promptly submit a further response, advising the FDA of the corrective actions that we have taken or will take to address the identified regulatory violation, in order to avoid more serious FDA enforcement action. Our failure to comply with applicable regulatory requirements, or our failure to timely and adequately respond to inspectional observations or Warning Letter issued as a result of inspectional observations, could result in enforcement action by the FDA, which may include the following sanctions:

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

We are subject to unannounced inspections by the FDA and the Food and Drug Branch of the California Department of Health Services, and these inspections may include the manufacturing facilities of our subcontractors. Our most recent inspections by these agencies resulted in no observations.

CLIA waiver. The Clinical Laboratory Improvement Amendments, or CLIA, is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel qualifications, administration, participation in proficiency testing, patient test management, quality control, quality assurance and inspections. The regulations promulgated under CLIA establish three levels of diagnostic tests: waiver, moderately complex and highly complex, and the standards applicable to a clinical laboratory depend on the level of tests it performs. A CLIA waiver is available to clinical laboratory test systems if they meet certain requirements established by the statute. Waived tests are exempt from quality standards and are defined as simple tests having an insignificant risk of an erroneous result. Following the 510(k) clearance of our self-testing submission, we applied for a CLIA waiver for professional use of our INRatio System and received that waiver in December 2002. For patient self-testing, the INRatio System was waived under a CLIA provision that provides that tests approved by the FDA for home use automatically qualify for CLIA waiver.

International

International sales of medical devices are subject to foreign government regulations, which vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA approval, and the requirements may differ.

The primary regulatory environment in Europe is that of the European Union, which consists of 25 countries encompassing most of the major countries in Europe. Other countries, such as Switzerland, have voluntarily adopted laws and regulations that mirror those of the European Union with respect to medical devices. The European Union has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling, and adverse event reporting for medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear CE conformity marking, indicating that the device conforms with the

Table of Contents

essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout Europe. The method of assessing conformity varies depending on the class of the product, but normally involves a combination of self-assessment by the manufacturer and a third-party assessment by a Notified Body. This third-party assessment may consist of an audit of the manufacturer s quality system and specific testing of the manufacturer s product. An assessment by a Notified Body in one country within the European Union is required in order for a manufacturer to commercially distribute the product throughout the European Union. In November 2002, our INRatio System was certified by TÜV Rhineland Product Safety of Cologne, Germany, a Notified Body, under the European Union In-Vitro Diagnostic Directive allowing the CE conformity marking to be applied and marketing to commence throughout the European Union.

Third Party Reimbursement

Healthcare providers that purchase medical devices, such as the INRatio System, generally rely on third party payors, including Medicare and Medicaid programs and private payors, such as indemnity insurers, employer group health insurance programs and managed care plans, to reimburse all or part of the cost of the products and services they provide to patients. The INRatio System will be sold principally to independent diagnostic testing facilities, or IDTFs, anticoagulation clinics, and physician practices that receive reimbursement from these third parties. As a result, demand for the INRatio System is dependent in part on the coverage and reimbursement policies of these payors.

Medicare Coverage and Reimbursement for Anticoagulation Self-Testing

Medicare published a National Coverage Decision, or NCD, memorandum in May 2002, which provided certain coverage for Medicare beneficiaries with mechanical heart valves. This determination covered anticoagulation self-testing as a diagnostic testing service paid under the Physician Fee Schedule through IDTF and physician services.

To qualify for coverage under Medicare, the NCD requires patients with mechanical heart valves to have been on anticoagulation therapy for a minimum of three months, to undergo training on anticoagulation management and on the use of the self-monitoring device, and to perform tests according to the prescribing physician s order, but no more frequently than once a week.

For eligible beneficiaries, Medicare provides reimbursement for training the beneficiary on anticoagulation management and proper use of the self-testing device, physician review of the test results and the equipment and supplies required to perform the test.

Medicare Point-of-Care Reimbursement

Reimbursement for testing in a physician s office has been covered as outpatient services and reimbursed under Current Procedural Terminology codes. These codes cover all in-vitro diagnostic tests regardless of how the test is performed. Additionally, the physician can bill for an office visit in conjunction with performing the test.

Government reimbursement encourages point-of-care over central laboratory testing by paying for patient evaluation and management when done in the physician office or an anticoagulation clinic under the supervision of a physician. Evaluation and management services include

reviewing the patient history, examining the patient, reading and interpreting the test results, determining if dosage change is necessary, and counseling the patient. In contrast, if the physician s staff or anticoagulation clinic does a venous draw, sends the sample to the lab and calls the patient with the results and advice, no evaluation and management reimbursement is allowed.

Private Payors

Many third party private payors, including indemnity insurers, employer group health insurance programs and managed care plans, presently provide coverage for the patient s purchase or health professional s use of

Table of Contents

medical equipment which may include our INRatio System. The scope of coverage and payment policies varies among third party payors and may vary by region for certain private payors. To date, only a few of these payors have issued a coverage decision for any warfarin monitoring indication. Despite this, many private payors have been reimbursing individual patients on warfarin based on the medical necessity when provided by their physician. The possibility exists that coverage policies of individual third party payors may change unpredictably over time.

International

Point-of-care testing and reimbursement in the international marketplace is in various stages of approval and penetration. Point-of-care reimbursement outside the United States differs country by country, with the most advanced coverage of home testing established in 1996 for the German market. In Germany, both meters and test strips are provided to the patients through mechanical heart valve patient training centers or pharmacies. The Nordic region and the Netherlands work similar modes through thrombosis centers, while the UK government only covers the supplies and not the meter.

Employees

As of March 31, 2005, we had 73 full-time equivalent employees, including 37 engaged in manufacturing operations and quality assurance, three in research and development, 28 in sales and marketing and five in general and administrative functions. None of our employees is represented by a labor union or is covered by a collective bargaining agreement. We have never experienced any employment-related work stoppages and consider our employee relations to be good.

Facilities

We maintain our headquarters in San Jose, California in a 15,250 square foot facility, which includes manufacturing, research and development, marketing and general administrative functions. The lease for this facility expires in April 2009. We have the option to extend this lease for an additional five years, and a right of first offer for an adjacent facility as space becomes available in that facility. We believe our existing facility is adequate to meet our needs through the initial lease term, and that suitable additional space will be available in the future on commercially reasonable terms.

Legal Proceedings

We are not party to any material pending or threatened litigation.

Table of Contents

MANAGEMENT

Executive Officers and Directors

The following table sets forth, as of April 30, 2005, information about our executive officers and directors:

Name	Age	Position
James D. Merselis	51	President, Chief Executive Officer and Director
Paul Balsara	61	Vice President, Finance and Chief Financial Officer
Michael R. Acosta	46	Vice President, Quality Assurance and Regulatory Affairs
Maria C. Navarro	46	Executive Vice President, Operations and Research and Development
Timothy I. Still	39	Executive Vice President, Sales and Marketing
Edward F. Brennan, Ph.D.[(1)(2)(3)]	53	Chairman of the Board of Directors
Gregory M. Ayers, M.D., Ph.D.[(1)]	43	Director
Robert D. Ulrich, Ph.D.[(1)(2)(3)]	59	Director
Kurt C. Wheeler[(2)]	52	Director

(1) Member of the Audit Committee.
(2) Member of the Compensation Committee.
(3) Member of the Nominating and Governance Committee.

James D. Merselis has served as our President, Chief Executive Officer and a member of our board of directors since June 2002. From June 1998 to March 2002, Mr. Merselis served as President and Chief Executive Officer at Micronics, a provider of custom lab card design, development and production services on behalf of clients worldwide. Mr. Merselis began his career in marketing and sales at Boehringer Mannheim, now Roche Diagnostics, where over the course of 22 years he held several senior management positions, including Senior Vice President, General Manager, and member of the board of directors. Mr. Merselis holds a B.S. in Biology from Nebraska Wesleyan University and completed the Advanced Management Program at Harvard Business School.

Paul Balsara has served as our Vice President, Finance and Chief Financial Officer since April 2004. From November 1999 to March 2004, Mr. Balsara served as a part-time Chief Financial Officer and financial consultant for several privately-held companies, including serving as our part-time Vice President of Finance and Chief Financial Officer from April 2000 to April 2001 and financial consultant from May 2001 to March 2004. Mr. Balsara has more than 25 years of experience in various accounting and financial management positions for healthcare companies. Mr. Balsara holds a Bachelor of Commerce degree in Accounting from the University of Calcutta, India and is a Certified Public Accountant licensed in California.

Michael R. Acosta has served as our Vice President, Quality Assurance and Regulatory Affairs since March 1999. From December 1996 to March 1999, Mr. Acosta served as Director, Quality Assurance, Quality Control and Regulatory Affairs at Aerogen, formerly Fluid Propulsion Technologies, a manufacturer of medical devices for drug delivery. From May 1995 to December 1996, Mr. Acosta served as Director, Quality Assurance and Quality Control at Orquest, a developer of biologically-based implants for orthopedics and spine surgery. Mr. Acosta holds a B.S. degree in Microbiology from the California State University, Long Beach.

Maria C. Navarro has served as our Executive Vice President, Operations since June 2004 and was appointed our Executive Vice President, Operations and Research and Development in April 2005. From January 2004 to June 2004, Ms. Navarro served as a principal consultant at SayAgain Corp., a healthcare and technology consulting firm, and currently serves as a member of its board of directors. From January 1999 to January 2004, Ms. Navarro served as a principal consultant at MCNavarro Consulting, a healthcare consulting firm. From 1988 to 1999, Ms. Navarro held the position of Site Manager and Head of Operations for the California-based coagulation business unit of Roche Diagnostics. Ms. Navarro holds a B.S. in Chemistry from the University of Southern California and a M.S. in Chemical Engineering from the Massachusetts Institute of Technology.

Table of Contents

Timothy I. Still has served as our Executive Vice President, Sales and Marketing since June 2004. From October 1999 to May 2004, Mr. Still served as Vice President of Sales and Marketing at Cholestech, a manufacturer of point-of-care in vitro diagnostic equipment. Mr. Still joined Cholestech as Senior Director of Marketing in December 1997. Mr. Still was a Director of Global Marketing and Business Development for Boehringer Mannheim, now Roche Diagnostics, from 1992 to 1997. Mr. Still holds a B.S. in Biological Sciences from the University of California, Davis and an M.B.A. from the University of Southern California.

Gregory M. Ayers, M.D., Ph.D. has served as a member of our board of directors since October 2000 and served as our interim Chief Executive Officer from April 2001 to July 2002 while a venture partner at MPM Capital. Since April 2001, Dr. Ayers has served as a general manager of Innovative Medical Products GmbH, a consulting firm. In August 2000, Dr. Ayers founded CryoCor, a manufacturer of medical products for the treatment of cardiac rhythm disorders and since that time has served as a member of its board and as its President and Chief Executive Officer. From June 2000 to July 2002, Dr. Ayers was a venture partner at MPM Capital, a venture capital firm specializing in investing in healthcare related companies. Dr. Ayers is a member-manager of Ayers Medical Consulting, a medical device consulting firm, which he founded in January 2000. Dr. Ayers holds a B.S. and Ph.D. in Biomedical Engineering from Purdue University and an M.D. from Indiana University and currently serves on several university advisory committees.

Edward F. Brennan, Ph.D. has served as a member of our board of directors since October 2000 and has been Chairman of our board of directors since October 2003. From January 2001 to June 2002, Dr. Brennan served as our interim Executive Vice President, Regulatory and Quality Affairs. Since January 2005, Dr. Brennan has served as the Chief Operating Officer of CryoCor. From January 2001 to December 2003, Dr. Brennan was a managing director at Perennial Ventures, a venture capital firm. From January 2000 to December 2001, Dr. Brennan was a managing director at Tredegar Investments, an investment subsidiary of Tredegar Corporation, a manufacturer of plastic films and aluminum extrusions. Dr. Brennan currently serves on the board of a publicly-held company, Kilroy Realty Corporation, a real estate investment trust, as well as on the boards of several privately-held companies. Dr. Brennan holds a B.A. in Biology and Chemistry and a Ph.D. in Biology from the University of California, Santa Cruz.

Robert D. Ulrich, Ph.D. has served as a member of our board of directors since November 1997. Since October 1995, Dr. Ulrich has been a general partner at Vanguard Ventures, a venture capital firm. Dr. Ulrich currently serves on the boards of several privately-held companies. Dr. Ulrich holds a B.A. in Physics from Claremont Men s College, now Claremont McKenna College, and an M.S. and a Ph.D. in Polymer Science and Engineering from the University of Massachusetts.

Kurt C. Wheeler has served as a member of our board of directors since January 2002. Since February 2000, Mr. Wheeler has been a general partner at MPM Capital. Mr. Wheeler currently serves on the boards of several privately-held medical device and biotechnology companies. Mr. Wheeler holds a B.A. in Economics from Brigham Young University and an M.B.A. from Northwestern University, where he currently serves on the Kellogg Alumni Advisory Board.

Medical Advisory Board

The members of our medical advisory board, none of whom are our officers or employees, consult with us to provide advice, assistance and consultation in the field of blood coagulation testing and hemostasis. We consider our advisory board members to be opinion leaders in their respective fields, and they offer us advice and feedback regarding the following:

- unmet needs and opportunities;

clinical feedback on existing products;

Table of Contents

assessment of new technologies and their applications; and

assessment of new clinical applications.

As of April 30, 2005, the following individuals are members of our Medical Advisory Board:

Name	Position and Affiliation
Jack E. Ansell, M.D.	Vice Chairman of Clinical Affairs and Director of Anticoagulation Services, Boston University Medical Center; Professor of Medicine, Boston University School of Medicine
Henry Bussey, Pharm.D.	Professor of Pharmacy, University of Texas Health Science Center at San Antonio, Texas
Alan Jacobson, M.D.	Director, Anticoagulation Clinic, Veterans Affairs Medical Center, Loma Linda, California
Douglas Triplett, M.D.	Professor of Pathology and Assistant Dean, Indiana University School of Medicine; Director, Midwest Hemostasis and Thrombosis Laboratories, Muncie, Indiana; Director of Hematology, Indiana School of Medicine
Ann K. Wittkowsky, Pharm.D., CACP, FASHP	Director, Anticoagulation Services, University of Washington Medical Center; Clinical Professor, Department of Pharmacy, University of Washington School of Pharmacy
Franz-Josef Wittstamm, M.D.	Doctor of Cardiology, Kliniken Essen-Mitte

We have entered into a consulting agreement with each member of our medical advisory board. Our advisory board members are reimbursed for certain of their out-of-pocket expenses, including expenses incurred in connection with attending medical advisory board meetings. We pay $1,500 to each advisory board member for each medical advisory board meeting attended, with the exception of Dr. Wittstamm whom we pay $3,000 per meeting. In 2000 we granted to four of our advisory board members for their services stock options to purchase 1,250 shares of our common stock.

Board of Directors

We currently have six authorized directorships. In accordance with the terms of our amended and restated certificate of incorporation, the terms of office of the directors are divided into three classes:

Class I, whose term will expire at the annual meeting of stockholders to be held in 2006;

Class II, whose term will expire at the annual meeting of stockholders to be held in 2007; and

Class III, whose term will expire at the annual meeting of stockholders to be held in 2008.

The Class I directors are Dr. Ulrich and Mr. Wheeler, the Class II directors are Dr. Ayers and Dr. Brennan and the Class III director is Mr. Merselis. At each annual meeting of stockholders, or special meeting in lieu thereof, after the initial classification of the board of directors, the successors to directors whose terms will then expire will be elected to serve from the time of election and qualification until the third annual meeting following election or special meeting held in lieu thereof. The authorized number of directors may be changed only by resolution of the board of directors or a vote by the holders of at least 66 2/3% of our then outstanding common stock. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. This

Table of Contents

classification of the board of directors may have the effect of delaying or preventing changes in control or management.

Board Committees

Our audit committee consists of Drs. Ayers, Brennan and Ulrich. The audit committee reviews and monitors our financial statements and internal accounting procedures, makes recommendations to our board of directors regarding the selection of independent accountants and consults with and reviews the services provided by our independent accountants.

Our compensation committee consists of Dr. Brennan, Dr. Ulrich and Mr. Wheeler. The compensation committee reviews and recommends to the board of directors the compensation and benefits of our executive officers and administers our stock plans and employee benefit plans.

Our nominating and governance committee is comprised of Drs. Brennan and Ulrich. The function of the nominating and governance committee is to assist the board of directors with membership selection, evaluation of overall effectiveness of the board of directors and the review of developments in corporate governance practices.

Compensation Committee Interlocks and Insider Participation

Prior to establishing the compensation committee, the board of directors as a whole performed the functions delegated to the compensation committee. No member of the board of directors or the compensation committee serves as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our board of directors or compensation committee.

Director Compensation

We reimburse our non-employee directors for their expenses incurred in connection with attending board and committee meetings but do not compensate them for their services as board or committee members. We have in the past granted non-employee directors options to purchase our common stock pursuant to the terms of our 1997 Stock Plan, and our board continues to have the discretion to grant options to new and continuing non-employee directors.

In March 2005, our stockholders approved our 2005 Equity Incentive Plan, the terms of which include the automatic grant of stock options to directors who are not our officers or employees. The 2005 Equity Incentive Plan provides that such directors will automatically receive:

- one-time option grants of 11,250 shares vesting annually over three years from the date of joining the board which are to be granted on such date at an exercise price equal to the fair market value of our common stock on the date of grant; and

annual option grants of 3,750 shares vested in full on the third anniversary of the date of grant which are to be granted on the date of each annual stockholder meeting following the closing of this offering at an exercise price equal to the fair market value of our common stock on the date of grant, provided that such grant will only be made to non-employee directors that have been members of the board for at least six months at the time of such annual stockholder meeting.

Table of Contents

Executive Compensation

The following table sets forth summary information concerning compensation earned for services rendered to us in all capacities by our chief executive officer and each of our other four most highly compensated executive officers whose total annual salary and bonus exceeded $100,000 as of the last fiscal year ended September 30, 2004. We refer to these persons as our named executive officers.

Summary 2004 Compensation Table

	Annual Compensation			Long Term Compensation
Name and Principal Positions	**Salary**	**Bonus**	**Other**	**Securities Underlying Options (#)**
James D. Merselis President and Chief Executive Officer	$ 233,909	$ 55,000	$ 38,869[1]	
Paul Balsara Vice President, Finance and Chief Executive Officer	171,048[2]	13,449		65,000
Gary E. Hewett Former Executive Vice President, Research and Development[3]	187,188	36,188		
Dale Clendon Former Vice President, Sales[4]	179,566	28,028		
Michael R. Acosta Vice President, Quality Assurance and Regulatory Affairs	148,617	12,700		

(1) Consists of $29,495 for temporary living expenses and $9,374 for insurance premiums.
(2) Mr. Balsara s employment with us began in April 2004 at an annual salary of $180,000. Prior to that time, Mr. Balsara was our financial consultant. Includes $81,048 in consulting fees paid to Mr. Balsara prior to April 2004.
(3) Mr. Hewett resigned in March 2005.
(4) Mr. Clendon resigned in October 2004.

2004 Option Grants

The following table sets forth information concerning the stock option grant to Mr. Balsara during fiscal year 2004. No other grants of stock options were made to any of the other executive officers named in the summary compensation table during fiscal year 2004.

Name	Individual Grants				Potential Realizable Value at Assumed Annual Rates of Stock Appreciation for Option Term ($)	
	Number of Securities Underlying Options Granted	Percent of Total Options Granted to Employees During Period (%)	Exercise Price Per Share ($)	Expiration Date	5%	10%
James D. Merselis						
Paul Balsara	65,000	20.7%	$ 0.80	3/30/2014	$ 516,465	$ 833,114
Gary E. Hewett						
Dale Clendon						
Michael R. Acosta						

The option granted to Mr. Balsara was granted under the 1997 Stock Plan. This option vests at the rate of 25% after one year of service from the vesting commencement date of April 1, 2002, and monthly thereafter in equal amounts over 36 additional months. However, the vesting of this option will fully accelerate upon the

Table of Contents

occurrence of a change of control or accelerate as to 12 months of vesting if Mr. Balsara is terminated without cause or resigns for good reason. This option will also immediately vest as to 20% of the shares underlying the option upon the closing of this offering. This option has a term of 10 years, but may terminate before its expiration date if Mr. Balsara s status as our employee is terminated, or upon his death or disability. See Benefit Plans 1997 Stock Plan. The percent of the total options granted to Mr. Balsara as set forth above is based on an aggregate of 313,500 options granted to our employees during fiscal year 2004. This option was granted at fair market value as determined by our board of directors on the date of grant.

With respect to the amount disclosed in the column captioned Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term, potential realizable value represents hypothetical gains that could be achieved for the option if exercised at the end of the option term assuming that the initial public offering price of our common stock appreciates at 5% and 10% over the option term. The assumed 5% and 10% rates of stock price appreciation are provided in accordance with rules of the Securities and Exchange Commission and do not represent our estimate or projection of our future common stock price. The potential realizable value is calculated based on the initial public offering price of $5.50 per share, and assume that the common stock appreciates at the indicated rate for the entire term of the option, and that the option is exercised at the exercise price and sold on the last day of the option term of the option at the appreciated price. Actual gains, if any, on stock option exercises are dependant on the future performance of our common stock and overall stock market conditions. The amounts reflected in the table may not necessarily be realized.

Aggregate Option Exercises and Option Values

The following table sets forth information concerning exercisable and unexercisable stock options held by the executive officers named in the summary compensation table as of September 30, 2004. No options were exercised by the named executive officers as of September 30, 2004. The amount described in the column captioned Value of Unexercised In-the-Money Options at September 30, 2004 represents the positive spread between the exercise price of stock options and the fair market value of the options, which is based upon on the initial offering price of $5.50 per share, minus the actual exercise price per share. All options were granted under our 1997 Stock Plan.

	Number of Securities Underlying Unexercised Options at September 30, 2004 (#)		Value of Unexercised In-the-Money Options at September 30, 2004 ($)	
Name	**Exercisable**	**Unexercisable**	**Exercisable**	**Unexercisable**
James D. Merselis	114,750	54,375	$ 539,325	$ 255,563
Paul Balsara.	41,645	26,355	195,732	123,869
Gary E. Hewett.	58,150	14,350	273,305	67,445
Dale Clendon[1]	52,265	20,235	205,646	95,105
Michael R. Acosta	20,062	188	93,591	884

(1) Following Mr. Clendon s resignation in October 2004, these options were subsequently returned to our 1997 Stock Plan and are no longer exercisable.

Employment Agreement

We have entered into an employment agreement with James Merselis, our President and Chief Executive Officer. That agreement provides that in the event that Mr. Merselis is terminated without cause or constructively terminated he will receive salary continuation and payment of group healthcare premiums for a period of nine months. In the event that he is terminated without cause or constructively terminated prior to a change of control, he will also receive accelerated vesting of all then unvested shares subject to outstanding stock options. In the event that he is terminated without cause or constructively terminated following a change of control, he will receive accelerated vesting as to 50% of any then unvested shares subject to outstanding options.

Table of Contents

Benefit Plans

1997 Stock Plan

Our board of directors adopted and our stockholders approved the 1997 Stock Plan in November 1997. Our board of directors will not grant any additional options under the plan following the effective date of this offering. However, the plan will continue to govern the terms and conditions of the outstanding options previously granted under the plan.

A total of 1,137,500 shares of our common stock are authorized for issuance under the 1997 Stock Plan. As of March 31, 2005, options to acquire a total of 998,750 shares of our common stock were issued and outstanding, and a total of 99,947 shares of our common stock had been issued upon the exercise of options granted under the plan that had not been repurchased by us.

The plan provides for the grant of nonstatutory stock options to our employees and consultants, and for the grant of incentive stock options within the meaning of Section 422 of the Internal Revenue Code to our employees. Our board of directors administers the 1997 Stock Plan. The administrator has the authority to determine the terms and conditions of the options granted under the plan.

Generally, in the event of a change of control, the successor corporation will assume each outstanding option or replace such options with equivalent rights that preserve the spread between the strike price and fair market value associated with such option. If the outstanding options are not assumed, or if the successor corporation does not replace such options with equivalent rights, the outstanding options will become fully exercisable immediately prior to such change of control and will terminate upon the consummation of the change of control. Generally, if options are assumed in connection with the change of control and an optionee s employment is terminated as the result of an involuntary termination within 12 months of the change of control, the options held by such optionee will immediately vest in full.

2005 Equity Incentive Plan

Our board of directors and our stockholders adopted our 2005 Equity Incentive Plan in March 2005. Our 2005 Equity Incentive Plan provides for the grant of incentive stock options, within the meaning of Section 422 of the Internal Revenue Code, to our employees and our parent and subsidiary corporations employees, and for the grant of nonstatutory stock options, stock purchase rights, restricted stock, restricted stock units, performance units and performance shares to our employees, directors and consultants and our parent and subsidiary corporations employees and consultants.

As of March 2005, a total of 50,000 shares of our common stock were reserved for issuance pursuant to the 2005 Equity Incentive Plan, of which no options were issued and outstanding as of that date. The 2005 Equity Incentive Plan will become effective on the day prior to the completion of this offering. In addition, the shares reserved for issuance under our 2005 Equity Incentive Plan include (a) shares reserved but unissued under the 1997 Stock Plan as of the effective date of this offering, (b) shares returned to the 1997 Stock Plan as the result of termination of options or the repurchase of shares issued under such plan, and (c) annual increases in the number of shares available for issuance on the first day of each fiscal year beginning with our 2006 fiscal year, equal to the least of:

5% of the outstanding shares of common stock on the first day of our fiscal year;

1,250,000 shares; or

an amount our board may determine.

Our board of directors or a committee of our board administers our 2005 Equity Incentive Plan. In the case of options intended to qualify as performance-based compensation within the meaning of Section 162(m) of

the Internal Revenue Code, the committee will consist of two or more outside directors within the meaning of Section 162(m) of the Code. The administrator has the power to determine the terms of the awards, including the exercise price, the number of shares subject to each such award, the exercisability of the awards and the form of consideration, if any, payable upon exercise. The administrator also has the authority to institute an exchange program by which outstanding awards may be surrendered in exchange for awards with a lower exercise price.

The administrator determines the exercise price of options granted under our 2005 Equity Incentive Plan, but with respect to nonstatutory stock options and stock appreciation rights intended to qualify as performance-based compensation within the meaning of Section 162(m) of the Code and all incentive stock options, the exercise price must at least be equal to the fair market value of our common stock on the date of grant. The term of an incentive stock option may not exceed ten years, except that with respect to any participant who owns 10% of the voting power of all classes of our outstanding stock, the term must not exceed five years and the exercise price must equal at least 110% of the fair market value on the grant date. The administrator determines the term of all other options.

No participant may be granted an option to purchase more than 187,500 shares in any fiscal year. However, in connection with his or her initial service, a participant may be granted an additional option to purchase up to 312,500 shares.

After termination of an employee, director or consultant, he or she may exercise his or her option for the period of time stated in the option agreement. Generally, if termination is due to death or disability, the option will remain exercisable for 12 months. In all other cases, the option will generally remain exercisable for three months. However, an option generally may not be exercised later than the expiration of its term.

Stock appreciation rights may be granted under our 2005 Equity Incentive Plan. Stock appreciation rights allow the recipient to receive the appreciation in the fair market value of our common stock between the exercise date and the date of grant. The administrator determines the terms of stock appreciation rights, including when such rights become exercisable and whether to pay the increased appreciation in cash or with shares of our common stock, or a combination thereof.

Restricted stock may be granted under our 2005 Equity Incentive Plan. Restricted stock awards are shares of our common stock that vest in accordance with terms and conditions established by the administrator. The administrator will determine the number of shares of restricted stock granted to any participant. The administrator may impose whatever conditions to vesting it determines to be appropriate. For example, the administrator may set restrictions based on the achievement of specific performance goals. Shares of restricted stock that do not vest are subject to our right of repurchase or forfeiture.

Restricted stock units may be granted under the 2005 Equity Incentive Plan. Restricted stock units will vest in accordance with terms and conditions established by the administrator. Restricted stock units may be granted at the sole discretion of the administrator. The administrator may impose whatever conditions to vesting it determines to be appropriate including the participant s continued employment with us and the achievement of company-wide, business unit or other individual goals. Earned restricted stock units may be paid out in cash, shares of common stock or any combination hereof at the sole discretion of the administrator.

Performance units and performance shares may be granted under our 2005 Equity Incentive Plan. Performance units and performance shares are awards that will result in a payment to a participant generally only if performance goals established by the administrator are achieved or the awards otherwise vest. The administrator will establish organizational or individual performance goals in its discretion, which, depending on the extent to which they are met, will determine the number and/or the value of performance units and performance shares to be paid out to participants. Performance units shall have an initial dollar value established by the administrator prior to the grant date. Performance shares shall have an initial value equal to the fair market value of our common stock on the grant date.

60

Table of Contents

Our 2005 Equity Incentive Plan also provides for the automatic grant of options to our non-employee directors. Each non-employee director appointed or elected to the board after the completion of this offering will receive an initial option to purchase 11,250 shares upon such appointment or election, except for those directors who become non-employee directors by ceasing to be employee directors. In addition, beginning in 2006, non-employee directors who have been directors for at least six months will receive a subsequent option to purchase 3,750 shares following each annual meeting of our stockholders. All options granted under the automatic grant provisions have a term of ten years and an exercise price equal to fair market value on the date of grant. Each initial option becomes exercisable as to one-third of the shares subject to such option on each anniversary of the date of grant, provided the non-employee director remains a service provider on such dates. Each subsequent option becomes exercisable as to all of the shares subject to such option on the third anniversary of the date of grant, provided the non-employee director remains a service provider through such date.

Our 2005 Equity Incentive Plan generally does not allow for the transfer of awards and generally only the recipient of an award may exercise an award during his or her lifetime.

Our 2005 Equity Incentive Plan provides that in the event of our change of control the administrator will determine how awards granted thereunder will be treated, including without limitation that the successor corporation will assume or substitute an equivalent award for each award. If there is no assumption or substitution of outstanding awards, unless the administrator provides otherwise, all stock options and stock appreciation rights will become exercisable as to all shares subject to such awards, all restrictions on restricted stock and restricted stock units will lapse, and, with respect to performance shares and performance units, all performance goals or other vesting criteria will be deemed achieved at target levels and all other terms and conditions met. If awards are not assumed by the successor corporation, the award will terminate upon the expiration of such period as the administrator determines. With respect to awards granted to an outside director that are assumed or substituted for, if such outside director is terminated on or following a change in control, other than pursuant to a voluntary resignation, his or her awards will fully vest.

Our 2005 Equity Incentive Plan will automatically terminate in 2015, unless we terminate it sooner. In addition, our board of directors has the authority to amend, suspend or terminate the 2005 Equity Incentive Plan provided such action does not impair the rights of any participant.

401(k) Plan

Effective January 1, 2001, we adopted a Retirement Savings and Investment Plan, the 401(k) Plan, covering our employees located in the United States who have a minimum of three months of service. The 401(k) Plan is intended to qualify under Section 401(k) of the Internal Revenue Code, so that contributions to the 401(k) Plan by employees or by us, and the investment earnings thereon, are not taxable to the employees until withdrawn. If our 401(k) Plan qualifies under Section 401(k) of the Internal Revenue Code, our contributions will be deductible by us when made. Our employees may elect to reduce their current compensation by up to the statutorily prescribed annual limit of $14,000 if under 50 years old and $18,000 if over 50 years old in 2005 and to have those funds contributed to the 401(k) Plan.

Severance Arrangements

Employment with us is at-will. However, we have entered into agreements with Mr. Balsara, Ms. Navarro and Mr. Still pursuant to which each of them will receive a lump-sum cash severance payment equal to 50% of their annual base salary in the event they are terminated without cause or resign for good reason within 12 months of a change of control transaction. In the event of a change of control, these executive officers will receive accelerated vesting of all then unvested shares subject to their outstanding options.

In addition, these executive officers will receive 12 months of accelerated vesting of shares subject to their outstanding stock options and salary continuation and payment of group term healthcare premiums for a period of six months in the event they are terminated without cause or resign for good reason.

Table of Contents

For purposes of our agreements with these executive officers:

- change of control includes our merger or combination with or into a third party or the sale or disposition of all or substantially all of our assets;

- termination without cause means a termination for reasons other than an act of material dishonesty in performing the officer s duties, a felony conviction, gross misconduct or a willful failure to substantially perform the officer s duties; and

- resignation for good reason means a reduction in the officer s base compensation, a material reduction in responsibilities, perquisites or benefits or a relocation to more than 50 miles from our current facility.

Table of Contents

RELATED PARTY TRANSACTIONS

We describe below transactions and series of similar transactions, that have occurred this year or during our last three fiscal years, to which we were a party or will be a party, in which:

- the amounts involved exceeded or will exceed $60,000; and
- a director, executive officer, holder of more than 5% of our common stock or any member of their immediate family had or will have a direct or indirect material interest.

Preferred Stock Issuances

Over the past three years, we sold shares of our preferred stock in private financings at a price of $1.58 per share as follows:

- 4,903,526 shares of Series C-1 preferred stock in May 2003;
- 2,286,267 shares of Series C-2 preferred stock in June 2004; and
- 2,124,218 shares of Series C-3 preferred stock in February 2005.

The investors in these financings included the following directors and holders of more than 5% of our securities and their affiliated entities:

Investor	Series C-1	Series C-2	Series C-3
Funds affiliated with MPM Capital[1]	2,653,456	1,265,823	1,368,930
Vanguard V, L.P.[2]	523,406	237,530	270,646
W Capital Partners Ironworks, L.P.	519,701	235,849	268,730
GC Technology Fund L.P. and MGVF III, Ltd.	221,520		

(1) Kurt Wheeler, one of our directors, is an investment manager of MPM Asset Management II, LLC, the general partner of MPM Asset Management II, L.P., the general partner of the funds affiliated with MPM Capital which purchased these shares of our preferred stock.

(2) Robert Ulrich, one of our directors, is a member of Vanguard Venture Partners, LLC, the general partner of Vanguard V, L.P.

Each share of preferred stock will convert automatically into 0.25 shares of common stock immediately prior to the closing of this offering. The purchasers of these shares of preferred stock are entitled to certain registration rights. See Description of Capital Stock Registration Rights.

Debt Financing

In April 2005, we issued unsecured promissory notes to the following directors and holders of more than 5% of our securities and their affiliated entities:

Investor	Note Principal Amount	Warrant Shares[2]
Funds affiliated with MPM Capital[1]	$ 1,161,248	42,225
W Capital Partners Ironworks, L.P.	189,762	6,900

(1) Kurt Wheeler, one of our directors, is an investment manager of MPM Asset Management II, LLC, the general partner of MPM Asset Management II, L.P., the general partner of the funds affiliated with MPM Capital which purchased these notes.
(2) The number of shares issuable upon exercise of the warrant is calculated based on the initial public offering price of $5.50 per share.

Table of Contents

The notes accrue interest at 6% annually and are to be repaid on the earlier of October 31, 2005 or upon the occurrence of a liquidation event. A liquidation event is defined to mean our liquidation, dissolution or winding up or a merger, acquisition or sale of voting control or substantially all of our assets. The notes can be prepaid at any time following our initial public offering and we intend to prepay the notes upon the closing of the offering. We also issued to these investors warrants to purchase shares of our common stock. The number of shares issuable upon exercise of the warrants is calculated by dividing 20% of the principal amount of the notes by the warrant exercise price per share. The warrant exercise price per share will be set at the price per share paid by the investors in our next equity financing, whether public or private. The warrants will terminate five years from their date of issuance.

Management Retention Plan

We have a management retention plan that provides that in the event that we are acquired or sell substantially all of our assets in a transaction in which the net proceeds exceed a specified threshold, a portion of the proceeds will be reserved for distribution to our employees. The determination as to the allocation of such distributions will be made by our board of directors. Our executive officers are likely to be recipients of such distributions. Our management retention plan will automatically terminate upon the completion of this offering with no payment required to be made thereunder.

Relationships with Entities Affiliated with a Director

Innovative Medical Products GmbH, or IMed Pro, has provided us with consulting and distribution services in Germany pursuant to a consulting agreement entered into in May 2002 and a non-exclusive sales representative and services agreement entered into in November 2002. The consulting agreement provided for IMed Pro s assistance with running clinical trials involving our product. The sales representative and services agreement provided for IMed Pro to act as our non-exclusive sales representative in Germany. Dr. Gregory Ayers, one of our directors, is a general manager of IMed Pro. During the past three fiscal years, we made payments to IMed Pro of approximately $156,000 in 2002, $436,000 in 2003 and $560,000 in 2004 for consulting and distribution services. The agreements between us and IMed Pro were terminated effective January 1, 2005. Since January 2005, I-Med-Partner GmbH has served as a distributor in Germany and purchased $185,000 of our product. IMed Pro is a shareholder of I-Med-Partner GmbH.

Consulting Agreements with Officers and Directors

Prior to becoming our Vice President, Finance and Chief Financial Officer in April 2004, Paul Balsara provided financial consulting services to us. During the past three fiscal years, we made payments to Mr. Balsara of $76,365 in 2002, $111,200 in 2003 and $81,048 in 2004 for these consulting services.

Edward Brennan, Ph.D., one of our directors, has provided consulting services to us not directly related to his service as a board member. During the past three fiscal years, we made payments to Dr. Brennan of $15,000 in 2003 and $58,750 in 2004 for these consulting services.

Indemnification Agreements of Officers and Directors

Our amended and restated certificate of incorporation and bylaws provide that we will indemnify each of our directors and officers to the fullest extent permitted by the Delaware General Corporation Law. Further, we have entered into indemnification agreements with each of our directors and officers. For further information, see Description of Capital Stock Limitations of Liability and Indemnification Matters.

Table of Contents

PRINCIPAL STOCKHOLDERS

The following table sets forth information known to us with respect to the beneficial ownership of our common stock as of March 31, 2005 and as adjusted to reflect the sale of common stock offered hereby by:

- each stockholder known by us to own beneficially more than five percent of our common stock;
- each of the named executive officers listed in the Summary Compensation Table on page 57;
- each of our directors; and
- all of our directors and the named executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of common stock subject to options or warrants held by that person that are currently exercisable or exercisable within 60 days of March 31, 2005 are deemed outstanding, but are not deemed outstanding for computing the percentage ownership of any other person. To our knowledge, except as set forth in the footnotes to this table and subject to applicable community property laws, each person named in the table has sole voting and investment power with respect to the shares set forth opposite such person s name. Except as otherwise indicated, the address of each of the persons in this table is c/o HemoSense, Inc., 651 River Oaks Parkway, San Jose, California 95134.

	Beneficial Ownership (#)		Percentage of Shares Outstanding (%)	
Name and Address of Beneficial Owner	Shares	Options and Warrants Exercisable Within 60 Days	Before the Offering[1]	After the Offering
Holders of More Than 5%				
Funds affiliated with MPM Capital 111 Huntington Ave., 31st Floor Boston, MA 02199	3,537,359[2]		58.6	44.7[3]
Vanguard V, L.P. 1330 Post Oak Boulevard, Suite 1550 Houston, TX 77056	699,357[4]		11.6	7.3
W Capital Partners Ironworks, L.P. One East 52nd St., 5th Floor New York, NY 10022	694,407[5]		11.5	8.6[6]

GC Technology Fund L.P. and MGVF III, Ltd. 777 Post Oak Blvd., Suite 250 Houston, TX 77056	403,762[7]	6.7	4.2
Named Executive Officers and Directors			
James D. Merselis	187,214	3.0	1.9
Paul Balsara	71,104	1.2	*

Table of Contents

Name and Address of Beneficial Owner	Beneficial Ownership (#)		Percentage of Shares Outstanding (%)	
	Shares	Options and Warrants Exercisable Within 60 Days	Before the Offering[1]	After the Offering
Gary E. Hewett		68,776	1.1	*
Dale Clendon[8]				
Michael R. Acosta		20,250	*	*
Edward F. Brennan, Ph.D.		21,999	*	*
Gregory M. Ayers, M.D., Ph.D.		92,152[9]	1.5	1.0
Robert D. Ulrich, Ph.D.	699,357[4]		11.6	7.3
Kurt C. Wheeler	3,537,359[2]		58.6	44.7[3]
All named executive officers and directors as a group (9 persons)	4,236,716	461,495	72.3	54.3

* Represents beneficial ownership of less than one percent (1%) of the outstanding shares of our common stock, after giving effect to the conversion of all of our preferred stock into shares of our common stock.

(1) Percentage of beneficial ownership is based upon 6,033,764 shares of our common stock outstanding as of March 31, 2005, after giving effect to the conversion of all of our preferred stock into shares of our common stock.

(2) Includes 838,354 shares held by MPM Bio Ventures GmbH & Co. Parallel-Beteiligungs KG, 262,825 shares held by MPM Bio Ventures II, L.P., 2,381,352 shares held by MPM Bio Ventures II-QP, L.P. and 54,828 shares held by MPM Asset Management Investors 2000 B LLC. MPM Asset Management II, LLC is the general partner of MPM Asset Management II, L.P, the general partner of MPM Bio Ventures GmbH & Co. Parallel-Beteiligungs KG, MPM Bio Ventures II, L.P. and MPM Bio Ventures II-QP, L.P. Ansbert Gadicke, Michael Steinmetz, Luke Evnin, Nicholas Galakatos and Kurt Wheeler, as investment managers of MPM Asset Management II, LLC, the general partner of MPM Asset Management II, L.P., and MPM Asset Management Investors 2000 B LLC, share voting and investment power with respect to shares held by MPM Bio Ventures GmbH & Co. Parallel-Beteiligungs KG, MPM Bio Ventures II, L.P., MPM Bio Ventures II-QP, L.P. and MPM Asset Management Investors 2000 B LLC. Mr. Wheeler disclaims beneficial ownership of these shares, except to the extent of his pecuniary interest therein.

(3) Includes 727,272 shares purchased in this offering.

(4) Includes 699,357 shares held by Vanguard V, L.P. Dr. Ulrich is a member of Vanguard V Venture Partners, LLC, the general partner of Vanguard V, L.P., and shares voting and investment power with respect to shares held by Vanguard V, L.P. with Jack M. Gill, Clifford H. Higgerson and Curtis K. Myers, the other members of Vanguard V Venture Partners, LLC. Dr. Ulrich disclaims beneficial ownership of these shares, except to the extent of his pecuniary interest therein.

(5) WCP I, L.L.C. is the general partner of W Capital Partners Ironworks, L.P. David S. Wachter, Stephen Wertheimer and Robert J. Migliorino, as managing members of WCP I, L.L.C., share voting and investment power with respect to shares held by W Capital Partners Ironworks, L.P.

(6) Includes 125,454 shares purchased in this offering.

(7) Includes 261,079 shares held by GC Technology Fund L.P. and 142,683 shares held by MGVF III, Ltd. Shares held by GC Technology Fund L.P. and MGVF III, Ltd. are being aggregated for purposes of determining beneficial ownership of 5% or more of our common stock because Marc Geller is both a general partner of GCV Management LLC, the general partner of GC Technology Fund L.P., and a managing director of MGVF III, Ltd. Mr. Geller shares voting and investment power with Marc Cellier, the other general partner of GCV Management LLC, with respect to shares held by GC Technology Fund L.P. Mr. Geller has sole voting and dispositive power over shares held by MGVF III, Ltd.

(8) Mr. Clendon resigned in October 2004 and as such, does not hold any stock options which become exercisable within 60 days of March 31, 2005.

(9) Includes 45,000 shares issuable upon the exercise of outstanding warrants held by Innovative Medical Product Consultants, GmbH, of which Dr. Ayers, along with Knut-Michael Scharnberger, are partners. Dr. Ayers and Mr. Scharnberger share investment power with respect to the warrants held by Innovative Medical Product Consultants, GmbH. Dr. Ayers disclaims beneficial ownership of these securities, except to the extent of his pecuniary interest therein.

Table of Contents

DESCRIPTION OF CAPITAL STOCK

Upon the closing of this offering, our authorized capital stock, after giving effect to the conversion of all outstanding preferred stock into common stock and the amendment of our certificate of incorporation, will consist of 50 million shares of common stock, $0.001 par value, and 10 million shares of preferred stock, $0.001 par value. The following description summarizes the most important terms of our capital stock. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description you should refer to our certificate of incorporation and bylaws, effective upon completion of this offering, copies of which have been filed as exhibits to the registration statement of which the prospectus is a part.

Common Stock

As of March 31, 2005, there were 6,033,764 shares of common stock outstanding held by 33 stockholders of record, assuming the automatic conversion of each outstanding share of preferred stock into 0.25 shares of common stock immediately prior to the closing of this offering. After this offering, there will be 9,533,764 shares of our common stock outstanding, or 10,058,764 shares if the underwriters exercise their over-allotment option in full.

The holders of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders, including the election of directors, and do not have cumulative voting rights. Accordingly, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they so choose. Subject to preferences that may be applicable to any then outstanding preferred stock, holders of common stock are entitled to receive ratably those dividends, if any, as may be declared by the board of directors out of legally available funds. Upon our liquidation, dissolution or winding up, the holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities of our company, subject to the prior rights of any preferred stock then outstanding. Holders of common stock have no preemptive or conversion rights or other subscription rights and there are no redemption or sinking funds provisions applicable to the common stock. All outstanding shares of common stock are, and the common stock to be outstanding upon completion of this offering will be, fully paid and nonassessable.

Preferred Stock

As of March 31, 2005, there were 21,956,251 shares of preferred stock outstanding held by 16 stockholders of record. Immediately prior to the closing of this offering, each outstanding share of preferred stock will be converted into 0.25 shares of common stock, and shareholders will receive cash instead of fractional shares. Following the conversion, our certificate of incorporation will be amended and restated to delete all references to the prior series of preferred stock, and 10 million shares of undesignated preferred stock will be authorized.

The board of directors will have the authority, without further action by the stockholders, to issue from time to time the preferred stock in one or more series and to fix the number of shares, designations, preferences, powers, and relative, participating, optional or other special rights and the qualifications or restrictions thereof. The preferences, powers, rights and restrictions of different series of preferred stock may differ with respect to dividend rates, amounts payable on liquidation, voting rights, conversion rights, redemption provisions, sinking fund provisions, and purchase funds and other matters. The issuance of preferred stock could decrease the amount of earnings and assets available for distribution to holders of common stock or adversely affect the rights and powers, including voting rights, of the holders of common stock, and may have the effect of delaying, deferring or preventing a change in control of our company.

67

Table of Contents

Warrants

As of March 31, 2005, the following warrants were outstanding:

Warrants to purchase an aggregate of 45,000 shares of common stock at an exercise price of $0.80 per share. These warrants may be exercised at any time prior to the earlier of May 17, 2005 as to 12,500 shares, May 21, 2007 as to 16,250 shares and September 12, 2007 as to 16,250 shares, or our merger or acquisition with or into another company.

Warrants to purchase an aggregate of 507,912 shares of Series C-3 preferred stock at an exercise price of $1.58 per share. These warrants may be exercised at any time prior to the earlier of July 21, 2010 as to 33,228 shares and March 5, 2011 as to 474,684 shares, or our merger or acquisition with or into another company. Assuming conversion of all of our preferred stock into common stock immediately prior to the closing of this offering, these warrants to purchase Series C-3 preferred stock will be exercisable for 8,307 and 118,670 shares, respectively, of common stock at $6.32 per share.

Registration Rights

In addition, after this offering, the holders of shares of preferred stock convertible into 5,489,045 shares of common stock and warrants exercisable for an aggregate of 126,977 shares of common stock will be entitled to rights to cause us to register the sale of such shares under the Securities Act. These shares are referred to as registrable securities. Specifically, commencing 180 days after the effective date of the registration statement of which this prospectus is a part, a holder or holders of at least 30% of the registrable securities may require us to prepare and file a registration statement under the Securities Act at our expense covering registrable securities, provided that the shares to be included in such registration will generate anticipated aggregate net proceeds of at least $250,000. Under these demand registration rights, we are required to use our best efforts to cause the shares requested to be included in the registration statement, subject to customary conditions and limitations. We are not obligated to effect more than two of these stockholder-initiated registrations. Once we become eligible to file a registration statement on Form S-3, the holders of registrable securities may require us to register all or a portion of their securities on a registration statement on Form S-3 and may participate in a Form S-3 registration by us, subject to specific conditions and limitations. Registration rights terminate no later than five years after this offering. Registration of these shares under the Securities Act would result in these shares, other than shares purchased by our affiliates, becoming freely tradable without restriction under the Securities Act.

Anti-Takeover Effects of Provisions of our Amended and Restated Certificate of Incorporation and Bylaws and Delaware Law

Some provisions of Delaware law and our amended and restated certificate of incorporation and bylaws contain provisions that could make the following transactions more difficult:

acquisition of us by means of a tender offer;

acquisition of us by means of a proxy contest or otherwise; or

removal of our incumbent officers and directors.

These provisions, summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging such proposals because negotiation of such proposals could result in an improvement of their terms.

Table of Contents

Undesignated Preferred Stock. The ability to authorize undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of our company.

Stockholder Meetings. Our charter documents provide that a special meeting of stockholders may be called only by our board of directors, chairman of the board, chief executive officer or president (in the absence of a chief executive officer).

Requirements for Advance Notification of Stockholder Nominations and Proposals. Our bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

Elimination of Stockholder Action by Written Consent. Our certificate of incorporation eliminates the right of stockholders to act by written consent without a meeting.

Election and Removal of Directors. Our board of directors is divided into three classes. The directors in each class will serve for a three-year term, one class being elected each year by our stockholders. For more information on the classified board, see the section entitled Management Board of Directors. This system of electing and removing directors may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us because it generally makes it more difficult for stockholders to replace a majority of the directors.

Delaware Anti-Takeover Statute. We are subject to Section 203 of the Delaware General Corporation Law which prohibits persons deemed interested stockholders from engaging in a business combination with a Delaware corporation for three years following the date these persons become interested stockholders. Generally, an interested stockholder is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation s voting stock. Generally, a business combination includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors.

Amendment of Charter Provisions. The amendment of any of the above charter provisions would require approval by holders of at least 66 2/3% of our then outstanding common stock.

The provisions of Delaware law and our amended and restated certificate of incorporation and bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. Such provisions may also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions which stockholders may otherwise deem to be in their best interests.

Limitations of Liability and Indemnification Matters

We have adopted provisions in our amended and restated certificate of incorporation that limit the liability of our directors for monetary damages for breaches of their fiduciary duties, except for liability that cannot be eliminated under the Delaware General Corporation Law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for breaches of their fiduciary duties as directors, except liability for any of the following:

any breach of their duty of loyalty to the corporation or the stockholder;

acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;

Table of Contents

unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or

any transaction from which the director derived an improper personal benefit.

This limitation of liability does not apply to liabilities arising under the federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our amended and restated certificate of incorporation and bylaws also provide that we shall indemnify our directors and executive officers and may indemnify our other officers and employees and other agents to the fullest extent permitted by law. We believe that indemnification under our bylaws covers at least negligence and gross negligence on the part of indemnified parties. Our bylaws also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in such capacity, regardless of whether our bylaws would permit indemnification.

We have entered into separate indemnification agreements with our directors and executive officers, in addition to indemnification provided for in our charter documents. These agreements among other things, will provide for indemnification of our directors and executive officers for expenses, judgments, fines and settlement amounts incurred by any such person in any action or proceeding arising out of such person s services as a director or executive officer or at our request. We believe that these provisions and agreements are necessary to attract and retain qualified persons as directors and executive officers.

American Stock Exchange Listing

Our common stock has been approved for listing on the American Stock Exchange under the symbol HEM.

Transfer Agent and Registrar

The transfer agent and registrar for the common stock is Computershare Trust Company, Inc.

Table of Contents

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering there has been no public market for our common stock, and no predictions can be made regarding the effect, if any, that market sales of shares or the availability of shares for sale will have on the market price prevailing from time to time. As described below, only a limited number of shares will be available for sale shortly after this offering due to contractual and legal restrictions on resale. Nevertheless, sales of our common stock in the public market after the restrictions lapse, or the perception that such sales may occur, could adversely affect the prevailing market price.

Sale of Restricted Shares and Lock-Up Agreements

Upon completion of this offering, we will have an aggregate of 9,533,764 outstanding shares of common stock, or 10,058,764 shares if the underwriters exercise the over-allotment option in full. As of March 31, 2005, we had:

- outstanding stock options held by employees, consultants and directors for the purchase of an aggregate of 998,750 shares of common stock;
- outstanding warrants to purchase 45,000 shares of common stock; and
- outstanding warrants to purchase 126,977 shares of Series C-3 preferred stock which will automatically convert into warrants to purchase an equal number of shares of common stock immediately prior to the completion of this offering.

The 3,500,000 shares of common stock being sold in this offering will be freely tradable without restriction or further registration under the Securities Act, unless the shares are purchased by affiliates of our company, as that term is defined in Rule 144 of the Securities Act. All remaining shares were issued and sold by us in private transactions and are eligible for public sale if registered under the Securities Act or sold in accordance with Rule 144 or Rule 701 thereunder.

Eligibility of Restricted Shares for Sale in the Public Market

All of our officers and directors and substantially all of our stockholders have signed lock-up agreements under which they will agree not to transfer or dispose of, directly or indirectly, any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock, for a period of 180 days after the date of this prospectus. Transfers or dispositions can be made sooner with the prior written consent of Lazard Capital Markets LLC and WR Hambrecht + Co, LLC, as representatives of the underwriters.

Based on shares outstanding as of March 31, 2005 and following the expiration of the lock-up period, the shares of our common stock, including shares issuable upon the exercise of outstanding options and warrants, that will be available for sale in the public market subject to compliance with Rule 144, Rule 144(k) or Rule 701 are as follows:

958,297 shares will be immediately eligible for sale without restriction pursuant to Rule 144(k); and

6,246,194 shares will be eligible for sale under Rule 144 or Rule 701, subject to volume, manner of sale, and other limitations under those rules.

Rule 144

In general, under Rule 144, a person or persons whose shares are aggregated who has beneficially owned restricted securities for at least one year, including the holding period of any holder who is not an affiliate, and

Table of Contents

who files a Form 144 with respect to such sale, is entitled to sell within any three-month period commencing 90 days after the date of this prospectus a number of shares of common stock that does not exceed the greater of:

1% of the then outstanding shares of our common stock, or approximately 95,000 shares immediately after this offering; or

the average weekly trading volume during the four calendar weeks preceding such sale.

Sales under Rule 144 are also subject to restrictions relating to manner of sale, notice and the availability of current public information about us. We cannot estimate the number of shares that will be sold under Rule 144, as this will depend on the market price for our common stock, the personal circumstances of the sellers and other factors. Prior to this offering, there has been no public market for our common stock, and a significant public market for our common stock may never develop or be sustained after this offering. Any future sale of substantial amounts of our common stock in the open market may adversely affect the market price of our common stock.

Rule 144(k)

A person who is not deemed to have been our affiliate at any time during the three months immediately preceding a sale and who has beneficially owned his or her shares for at least two years, including the holding period of any prior owner who is not an affiliate, is entitled to sell these shares of common stock pursuant to Rule 144(k) without regard to the volume limitations, manner of sale provisions, public information or notice requirements of Rule 144. Affiliates must always sell pursuant to Rule 144, even after the applicable holding periods have been satisfied.

Rule 701

Rule 701 may be relied upon with respect to the resale of securities originally purchased from us by our employees, directors, officers, consultants or advisers prior to the closing of this offering and pursuant to written compensatory benefit plans or written contracts relating to the compensation of such persons. In addition, the SEC has indicated that Rule 701 will apply to stock options granted by us before this offering, along with the shares acquired upon exercise of such options. Securities issued in reliance on Rule 701 are deemed to be restricted securities and, beginning 90 days after the date of this prospectus, may be sold by persons other than affiliates subject only to the manner of sale provisions of Rule 144 and by affiliates under Rule 144 without compliance with the holding period requirements. As of March 31, 2005, 99,947 of our outstanding shares of common stock had been issued in reliance on Rule 701 as a result of exercise of stock options, and all of these shares are subject to 180-day lock-up agreements.

Stock Options

We intend to file a registration statement on Form S-8 under the Securities Act for shares of our common stock subject to options outstanding or reserved for issuance under our 1997 Stock Plan and 2005 Equity Incentive Plan. We expect to file this registration statement as soon as practicable after this offering. Shares registered under such registration statement will be available for sale in the open market, unless such shares are subject to vesting restrictions with us or are otherwise subject to the contractual restrictions described above.

Registration Rights

After this offering, the holders of 5,489,045 shares of common stock issued upon conversion of our preferred stock and 126,977 shares of common stock issued upon exercise of outstanding warrants, will be entitled to certain rights with respect to the registration of these shares under the Securities Act. These holders may demand that we register their shares under the Securities Act, or if we file another registration statement under the Securities Act may elect to include their registrable securities in that registration, subject to various conditions. For additional information, see Description of Capital Stock Registration Rights.

Table of Contents

UNDERWRITING

The underwriters named below, for whom Lazard Capital Markets LLC, WR Hambrecht + Co, LLC and Roth Capital Partners, LLC, are acting as representatives, have agreed to purchase, subject to the terms of an underwriting agreement, the number of shares listed opposite their names below. Lazard Capital Markets LLC and WR Hambrecht + Co, LLC are the joint book-running managers of this offering. The underwriters are committed to purchase and pay for all of the shares if any are purchased, other than those shares covered by the over-allotment option described below.

Underwriters	Number of Shares
Lazard Capital Markets LLC	1,400,000
WR Hambrecht + Co, LLC	1,400,000
Roth Capital Partners, LLC	700,000
Total	3,500,000

The underwriting agreement provides that the obligations of the several underwriters to purchase shares of our common stock are subject to the satisfaction of the conditions contained in the underwriting agreement, which include that:

- the registration statement of which this prospectus is a part has been declared effective;
- the representations and warranties made by us to the underwriters are true;
- there is no material adverse change in our business;
- the shares of our common stock to be sold in this offering have been approved for listing on the American Stock Exchange; and
- we deliver customary closing documents to the underwriters.

The underwriters have advised us that they propose to offer the shares initially to the public at $5.50 per share. The underwriters propose to offer the shares to certain dealers at the same price less a concession of not more than $0.19 per share. The underwriters may allow and the dealers may reallow a concession of not more than $0.10 per share on sales to certain other brokers and dealers. After this offering, these figures may be changed by the underwriters.

The offering of our shares of common stock is made for delivery when and if accepted by the underwriters and subject to prior sale and to withdrawal, cancellation, or modification of this offering without notice. The underwriters reserve the right to reject an order for the purchase of shares in whole or part.

Over-Allotment Option

We have granted to the underwriters an over-allotment option to purchase up to an additional 525,000 shares of our common stock from us at the same price as to the public, and with the same underwriting discount, as set forth on the front cover of this prospectus. The underwriters may exercise this option any time during the 30-day period after the date of this prospectus, but only to cover over-allotments, if any. To the extent the underwriters exercise the option, each underwriter will become obligated, subject to certain conditions, to purchase approximately the same percentage of the additional shares as it was obligated to purchase under the underwriting agreement.

Table of Contents

Discounts and Commissions

The following table shows the underwriting discounts and commissions to be paid to the underwriters in connection with this offering. These amounts are shown assuming both no exercise and full exercise of the over-allotment option.

	No Exercise	Full Exercise
Per share	$ 0.385	$ 0.385
Total to be paid by us	$ 1,347,500	$ 1,549,625

We estimate that the total expenses of this offering payable by us, excluding underwriting discounts and commissions, will be approximately $1.3 million. Expenses include the SEC and NASD filing fees, the American Stock Exchange listing fees, and printing, legal, accounting, transfer agent and registrar fees.

Lock-up Agreements

We have agreed not to offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale or otherwise dispose of any shares of common stock, or any options or warrants to purchase common stock other than the shares of common stock or options to acquire common stock issued under our stock incentive plans and shares of our common stock issued upon exercise of our outstanding warrants, for a period of 180 days after the date of this prospectus, except with the prior written consent of Lazard Capital Markets LLC and WR Hambrecht + Co, LLC. The holders of substantially all of our capital stock, warrants and options, including each of our directors and executive officers, have agreed to restrictions on their ability to sell, offer, contract or grant any option to sell, pledge, transfer or otherwise dispose of shares of our common stock for a period of 180 days after the date of this prospectus, without the prior written consent of Lazard Capital Markets LLC and WR Hambrecht + Co, LLC. The persons signing the lock-up agreements will be able to transfer their shares of common stock as a bona fide gift to immediate family members or to a trust or partnership or other business entity, or as a distribution without compensation to partners, members or shareholders of a business entity, subject to the transferees agreeing to enter into a lock-up agreement. In considering any request to release shares subject to a lock-up agreement, Lazard Capital Markets LLC and WR Hambrecht + Co, LLC will consider the possible impact of the release of the shares on the trading price of the stock sold in the offering.

The 180-day restricted period described in the preceding paragraph will be automatically extended if: (1) during the last 17 days of the period the company issues an earnings release or announce material news or a material event; or (2) prior to the expiration of the period, the company announces that it will release earnings results during the 16-day period beginning on the last day of the period, in which case the relevant restrictions described in the preceding paragraph will continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the announcement of the material news or material event.

Public Offering Price

Prior to this offering, there has been no established trading market for our common stock. The initial public offering price for the shares of our common stock offered by this prospectus will be negotiated between us and the underwriters immediately prior to this offering. Factors considered in determining the initial public offering price will include:

the history of, and the prospects for, the industry in which we compete;

our past and present operations;

our historical results of operations;

our prospects for future earnings;

Table of Contents

the recent market prices of securities of generally comparable companies; and

the general condition of the securities markets at the time of this offering and other relevant factors.

The initial public offering price of our common stock may not correspond to the price at which our common stock will trade in the public market subsequent to this offering, and an active public market for our common stock may never develop or, if it does develop, continue after this offering.

Stabilization, Short Positions and Penalty Bids

To facilitate this offering, the underwriters may engage in transactions that stabilize, maintain, or otherwise affect the price of our common stock during and after this offering. Specifically, the underwriters may over-allot or otherwise create a short position in our common stock for their own account by selling more shares of our common stock than have been sold to them by us. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in this offering. Covered short sales are sales made in an amount not greater than the underwriters option to purchase additional shares from us in this offering. The underwriters may close out any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option. Naked short sales are sales in excess of this option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in this offering.

In addition, the underwriters may stabilize or maintain the price of our common stock by bidding for or purchasing shares of our common stock in the open market and may impose penalty bids. If penalty bids are imposed, selling concessions allowed to syndicate members or other broker-dealers participating in this offering are reclaimed if shares of our common stock previously distributed in this offering are repurchased, whether in connection with stabilization transactions or otherwise. The effect of these transactions may be to stabilize or maintain the market price of our common stock at a level above that which mi