HEMOSENSE INC
Form 10-K
December 02, 2005
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

x Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the fiscal year ended September 30, 2005

or

¨ Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the transition period from to

Commission File Number: 001-32541

HEMOSENSE, INC.

(Exact name of registrant as specified in its charter)

Delaware	**77-0452938**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
651 River Oaks Parkway San Jose, California	**94545**
(Address of principal executive offices)	**(Zip Code)**

Registrant s telephone number, including area code: (408) 719-1393

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, $0.001 par value

(Title of Class)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

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

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

The aggregate market value of the voting stock held by non-affiliates of the registrant, based upon the closing sale price of the Common Stock on September 30, 2005 (which is the last business day of registrant s most recently completed fourth fiscal quarter), as reported on the American Stock Exchange was approximately $38.5 million. The registrant was not a reporting company as of March 31, 2005. Shares of Common Stock held by each executive officer and director and by each person who owns 5% or more of the outstanding Common Stock have been excluded in that such persons may be deemed affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes. As of November 28, 2005, the registrant had outstanding 11,481,482 shares of common stock. The registrant does not have any non-voting common equity.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant has incorporated by reference into Part III of this Annual Report on Form 10-K portions of its definitive proxy statement to be filed with the Securities and Exchange Commission within 120 days after the close of the fiscal year covered by this Annual Report.

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FORM 10-K

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PART I

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

We were incorporated under the laws of the State of 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 and our telephone number at that location is (408) 719-1393. Information about our company is also available at our website at *www.HemoSense.com*, which includes links to reports we have filed with the Securities and Exchange Commission. The contents of our website are not incorporated by reference in this Annual Report on Form 10-K.

ITEM 1. 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

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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 mechanical heart valve patients on warfarin. 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, Medline and Cardinal Health accounted for approximately 24%, 19% and 13%, respectively, of our total revenue in fiscal 2005. In addition, we have established international distribution agreements with 14 distribution partners covering 20 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.

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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.

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

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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 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

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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 $251 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 $1,900 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.

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.

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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 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,

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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 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

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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.

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.

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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 2009 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 14 distribution agreements covering 20 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, IMed Partners and InaBattke KG in Germany; as well as agreements with distributors covering Australia, Austria, Belgium, China Denmark, Finland, Holland, Ireland, Israel, Italy, Lithuania, Luxembourg, New Zealand, Norway, Portugal, 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;

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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.

As of November 15, 2005, we employ 31 people in sales and marketing. Sixteen 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 nine remaining employees are located in the corporate office, including five within marketing and four 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 in 2006.

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

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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, 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 determining the feature set 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

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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 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 $1.3 million, $1.4 million and $1.7 million in fiscal 2005, 2004 and 2003, 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. After requesting more information from Beckman Coulter and performing an investigation on their assertion, we concluded that their patent does not cover our test strip and that we do not 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;

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product manufacturing;

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

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before marketing commences. A PMA requires reasonable assurance of the safety and effectiveness of the device 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

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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. The FDA subsequently issued a Warning Letter on October 5, 2005. The Warning Letter indicates that the FDA believes that our response did not provide sufficient detail and documentation for the FDA to evaluate whether our corrective actions would be adequate to prevent recurrence of the observations. We have submitted a further written response to the FDA, which we believe addresses this concern. The FDA has accepted our response, but there can be no assurance that the FDA will not in the future impose more serious enforcement actions, 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 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

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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 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

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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 November 15, 2005, we had 76 full-time equivalent employees, including 35 engaged in manufacturing operations and quality assurance, 5 in research and development, 31 in sales and marketing and 5 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.

Available Information

We are subject to the reporting requirements under the Securities Exchange Act of 1934. Consequently, we are required to file reports and information with the Securities and Exchange Commission (SEC), including reports on the following forms: annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. You can read our SEC filings, including the registration statement, over the Internet at the SEC s web site at *http://www.sec.gov.* You may also read and copy any document we file with the SEC at its public reference facilities at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Room of the SEC at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. Please call the SEC at (202) 551-8090 for further information on the operation of the public reference facilities.

You may also find on our website at *http://www.hemosense.com* electronic copies of our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. The contents of our website are not incorporated by reference in this Annual Report on Form 10-K. Our charter for our Audit, Compensation and Nominating Governance Committees and our Code of Ethics are available on our website. In the event that we grant a waiver under our Code of Ethics, to any of our officers and directors, we will publish it on our website.

ITEM 2: PROPERTIES

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.

ITEM 3: LEGAL PROCEEDINGS

We are not party to any material pending or threatened litigation

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

None.

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PART II

ITEM 5: MARKET FOR REGISTRANT S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our common stock began trading on June 28, 2005 and is quoted on the American Stock Exchange, AMEX, under the symbol HEM. The following table sets forth the quarterly high and low trading prices for our common stock as reported by the AMEX for the periods indicated.

	HIGH	LOW
FISCAL YEAR 2005		
Third Quarter	$ 5.60	$ 5.50
Fourth Quarter	$ 9.50	$ 5.50

As of November 28, 2005, the last reported sales price of our common stock on the American Stock Exchange was $8.10 per share, and the number of holders of record was approximately 60. We currently intend to retain any earnings to fund the development and growth of our business.

During fiscal 2005, we have issued and sold the following unregistered securities:

1. On February 7, 2005, we issued and sold to accredited investors an aggregate of 2,124,218 shares of our Series C-3 preferred stock at a purchase price of $1.58 per share for an aggregate purchase price of $3,356,264. In connection with this transaction, these investors also participated in the following stock exchanges:

- on February 15, 2005, we issued to existing stockholders an aggregate of 1,429,566 shares of our Series A-3 preferred stock in exchange for an aggregate of 1,429,566 shares of our Series A-2 preferred stock held by such stockholders;
- on February 15, 2005, we issued to existing stockholders an aggregate of 1,914,555 shares of our Series B-3 preferred stock in exchange for an aggregate of 1,914,555 shares of our Series B-2 preferred stock held by such stockholders; and
- on February 15, 2005, we issued to existing stockholders an aggregate of 16,487,912 shares of our Series C-3 preferred stock in exchange for an aggregate of 16,487,912 shares of our Series C-2 preferred stock held by such stockholders.

2. On February 16, 2005, we issued to an existing stockholder an aggregate of 94,936 and 95,249 shares of our common stock in connection with the conversion of 1,898,734 shares of our Series B-2 preferred stock and 1,905,024 shares of our Series C-2 preferred stock held by such stockholder, respectively, into shares of our common stock.

3. On March 1, 2005, we issued to an accredited investor warrants to purchase an additional 189,874 shares of our Series C-3 preferred stock at $1.58 per share for an aggregate exercise price of $300,001. As of November 15, 2005, none of these warrants had been exercised.

4. On April 25, 2005, we sold nonconvertible promissory notes in the aggregate principal amount of $1.5 million to existing stockholders. In consideration for the purchase of these notes we issued to these stockholders warrants to purchase an aggregate of 54,542 shares of our common stock at $5.50 per share.

The sales and issuances of securities in the transactions described in paragraphs 1 through 4 above were deemed to be exempt from registration under the Securities Act in reliance upon the following exemptions:

with respect to transactions described in paragraphs 1, 3, and 4, Section 4(2) of the Securities Act or Rule 506 of Regulation D promulgated thereunder, as transactions by an issuer not involving any public

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offering. The recipients of securities in each transaction represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in such transactions. The sale of these securities were made without general solicitation or advertising. All recipients were accredited investors and had adequate access, through their relationship with us, to information about us; and

with respect to the transactions described in paragraph 2, Section 3(a)(9) of the Securities Act, as transactions involving an exchange with existing security holders for no consideration.

During fiscal 2005, we granted options to purchase 319,000 shares of common stock to employees, directors and consultants under our 1997 Stock Plan at an exercise price of $0.80 to $7.00 per share for an aggregate exercise price of $425,700. These option grants were deemed to be exempt from registration under the Securities Act in reliance upon Rule 701 promulgated under Section 3(b) of the Securities Act, as transactions pursuant to a written compensation benefit plan and contracts relating to compensation as provided under Rule 701.

We registered for the initial public offering of our common stock, par value $0.001 per share, on a Registration Statement on Form S-1 (Registration No. 333-123705), which was declared effective on June 28, 2005. On July 1, 2005 we completed the initial public offering of our common stock by selling 3.5 million shares at $5.50 per share. Additionally on July 27, 2005, the underwriters exercised their over-allotment option to purchase 12,207 shares at $5.50 per share. Gross proceeds from the offering were $19.3 million. Total expenses from the offering were $2.6 million, which included underwriting discounts and commissions of $1.3 million, and $1.3 million in other offering-related expenses. Net offering proceeds, after deducting total expenses were $16.7 million. Of the $16.7 million in net proceeds, through September 30, 2005, we have spent approximately, $1.9 million for sales and marketing initiatives to support the ongoing commercialization of our INRatio System, $453,000 for research and development activities, including support of product development, regulatory and clinical study initiatives, $1.5 million for repayment of outstanding principal and interest due from promissory notes bearing interest at the rate of 6% annually held by affiliates, plus accrued interest, and $2.4 for working capital and general corporate purposes. In addition, we invested the proceeds from the offering in short-term, investment grade, interest-bearing instruments.

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.

Equity Compensation Plans

The information require by this item regarding equity compensation plans is incorporated by reference under the section entitled *Equity Compensation Plan Information* contained in our proxy statement for our 2006 meeting of stock holders

ITEM 6: 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, 2005, 2004 and 2003, and the balance sheet data as of September 30, 2005 and 2004 are derived from our audited financial statements included elsewhere in this Form 10-K. The historical results are not necessary indicative of results expected for any future period. The data presented below has been derived from financial statements that have been prepared in accordance with

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accounting principles generally accepted in the United States of America and should be read with our financial statements, including the accompanying Notes to the Financial Statements, and with Management s Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this Form 10-K.

	Years Ended September 30,				
	2005	2004	2003	2002	2001
	(in thousands, except per share data)				
Statement of Operations Data:					
Revenue	$ 8,768	$ 3,250	$ 427	$	$
Cost of goods sold	9,371	5,065	1,519		
Gross loss	(603)	(1,815)	(1,092)		
Operating expenses:					
Research and development	1,259	1,398	1,681	3,354	3,008
Sales and marketing	6,733	5,206	3,186	745	762
General and administrative	1,962	1,499	912	711	739
Total operating expenses	9,954	8,103	5,779	4,810	4,509
Loss from operations	(10,557)	(9,918)	(6,871)	(4,810)	(4,509)
Interest income	130	16	39	142	605
Interest expense	(1,314)	(318)	(67)	(21)	(36)
Other expense	(5)	(41)	(11)	(19)	(10)
Net loss	$ (11,746)	$ (10,261)	$ (6,910)	$ (4,708)	$ (3,950)
Net loss per share:					
Basic and diluted	$ (4.26)	$ (30.45)	$ (20.69)	$ (14.27)	$ (11.52)
Shares used to compute net loss per common share:					
Basic and diluted	2,758	337	334	330	343

	As of September 30,				
	2005	2004	2003	2002	2001
	(in thousands)				
Balance Sheet Data:					
Cash, cash equivalents and short term investments	$ 11,541	$ 433	$ 5,445	$ 5,276	$ 10,414
Working capital	12,861	1,072	5,800	5,909	10,427
Total assets	19,003	6,202	9,458	7,518	12,180
Long term liabilities	4,766	2,946	736	83	120
Redeemable convertible preferred stock		36,679	32,751	25,183	25,183
Accumulated deficit	(47,186)	(35,440)	(25,179)	(18,269)	(13,561)
Total stockholders equity (deficit)	10,012	(35,220)	(24,959)	(18,174)	(13,498)

ITEM 7: MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATION

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.

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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.

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

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

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

Our cost of goods sold represents the cost of manufacturing our products. Our meters are manufactured for us by an electronics manufacturing service company, and we incur direct labor costs to assemble meters into packaged kits at our facility. Our cost of goods sold for the meter also includes an allowance for product warranty obligations. Our disposable test strips are manufactured by us at our facility, and our cost of goods sold is comprised of cost of materials, direct labor, associated overhead, yield losses and lot rejects, royalties on sales, and license fee costs.

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

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. During the fourth quarter of fiscal 2005 we achieved a gross margin for the first time. We believe continuing volume increases and process improvements will sustain and enhance cost reductions for our products in the future.

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Comparison of Fiscal Years Ended September 30, 2005 and September 30, 2004

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

	Fiscal year Ended September 30,					
	2005		2004			
	Amount	% of Sales	Amount	% of Sales	Amount of Increase (Decrease)	Percent Increase (Decrease)
Revenue	$ 8,768	100%	$ 3,250	100%	$ 5,518	170%
Cost of goods sold	9,371	107	5,065	156	4,306	85
Gross loss	(603)	(7)	(1,815)	(56)	1,212	(67)
Operating expenses						
Research and development	1,259	14	1,398	43	(139)	(10)
Sales and marketing	6,733	77	5,206	160	1,527	29
General and administrative	1,962	22	1,499	46	463	31
Total operating expenses	9,954	113	8,103	249	1,851	23
Loss from operations	(10,557)	(120)	(9,918)	(305)	(639)	6
Interest income	130	1	16		114	713
Interest expense	(1,314)	15	(318)	10	(996)	(313)
Other expense	(5)		(41)	1	(36)	(88)
Net loss	$ (11,746)	(134)%	$ (10,261)	(316)%	$ (1,485)	(14)%

Revenue. Revenue increased by $5.5 million, or 170%, from $3.3 million in 2004 to $8.8 million in 2005. INRatio Meters and accessories increased by $2.2 million, or 136%, from $1.6 million in 2004 to $3.8 million in 2005. Test strips revenue increased by $3.3 million, or 203%, from $1.6 million in 2004 to $5.0 million in 2005. Approximately 72% of the growth in revenue was derived from the United States and approximately 28% from outside the United States. The increase in United States revenue was the result of increased market penetration primarily attributable to the addition of distributors and increased field personnel. The international revenue increase was primarily attributable to the expansion of the European market. For fiscal year 2006, we expect revenue for both domestic and international to significantly increase as we continue to penetrate the worldwide markets for our products.

Cost of goods sold. Cost of goods sold increased by $4.3 million, or 85%, from $5.1 million in 2004 to $9.4 million in 2005. As a percentage of revenue, cost of goods sold decreased from 156% of sales in the year ended September 30, 2004 to 107% in the same period in 2005. During our fourth quarter of fiscal 2005 we achieved a gross margin for the first time. This was due to volume increases over earlier periods and process improvements. We expect that as volume continues to increase, these cost reductions will continue to improve into the future. The $4.3 million increase in the cost of goods sold, was primarily due to the increase in number of meters and test strips sold. Included in cost of goods sold are royalties and amortization of technology licenses which increased by $409,000, from $377,000 in 2004 to $786,000 in 2005. The increase in

royalty payments was due to the increase in test strip sales and a full year of amortization in fiscal 2005 for two technology licenses obtained during fiscal year 2004. The increases were partially off set by improvements in statistical process control and other quality improvements which reduced the amount of material scrap. Additionally, in the latter portion of fiscal year 2005 process improvements reduced the cost of test strips to a point which allowed us to eliminate the need for a lower of cost or market provision. In fiscal 2004, our cost of goods sold included a lower of cost or market provision of $301,000.

Research and development expenses. Research and development expenses decreased by $139,000, or 10%, from $1.4 million in 2004 to $1.3 million in 2005. The decrease was completely attributable to the continuing

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transfer of resources from research and development to manufacturing during the first nine months of fiscal 2005. During the next fiscal year, we expect research and development expense will increase as new projects are initiated.

Sales and marketing expenses. Sales and marketing expenses increased by $1.5 million, or 29%, from $5.2 million in 2004 to $6.7 million in 2005. The increase was primarily attributable to $1.3 million of payroll and travel expenses for additional personnel, $474,000 for promotion programs and $71,000 in bad debt provisions. This was partially offset by $370,000 decrease in marketing consultants. As a percentage of revenue, sales and marketing expenses were 77% in the year ended September 30, 2005 compared to 160% in the same period in 2004. The decrease in sales and marketing expense as a percentage of revenue is due to the revenue increase relative to the marketing programs and efforts of the sales staff. We expect sales and marketing spending will increase in fiscal 2006 but to decrease as a percentage of revenue.

General and administrative expenses. General and administrative expenses increased by $463,000, or 31%, from $1.5 million in the fiscal year 2004 to $2.0 million in the fiscal year 2005. The increase was primarily attributable to payroll and other benefits increase of $330,000 primarily from increased head count. Additionally, professional services and insurance increase by $216,000 related to the cost of being a public company. The decreased need for other consultants resulted in a $99,000 decline as full-time personnel were hired. As a percentage of revenues, general and administrative expenses were 22% in the year ended September 30, 2005 compared to 46% in the same period in 2004. The decrease in general and administrative expenses as a percentage of revenue is due mainly to the rapid expansion of revenue which without the need for a proportional increase in staff. We expect general and administrative expenses will increase during fiscal year 2006 due the costs relating to being a public company for a full year which may include the use of more consultants and increased staff.

Interest Income. Interest income increased by $114,000, or 713%, from $16,000 in fiscal year 2004 to $130,000 in fiscal year 2005. The increase related to returns on short term investments purchased with a portion of the funds received from the initial public offering. Over the next year, we anticipate interest income will increase due to the increase short term investments purchased in July 2005 and the proceeds from the private placement in November 2005.

Interest expense. Interest expense increased by $1.0 million, or 313%, from $318,000 in fiscal 2004 to $1.3 million in fiscal 2005. The increase was attributable the full drawdown of a $7.5 million borrowings in January 2005, interest on $1.5 million short term notes payable which were repaid in July 2005 and accrued interest expense related to a note payable to Inverness Medical Innovations.

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Comparison of Fiscal Years Ended September 30, 2004 and September 30, 2003

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

	Fiscal year Ended September 30,					
	2004		2003			
	Amount	% of Sales	Amount	% of Sales	Amount of Increase (Decrease)	Percent Increase (Decrease)
Revenue	$ 3,250	100%	$ 427	100%	$ 2,823	661%
Cost of goods sold	5,065	156	1,519	356	3,546	233
Gross loss	(1,815)	(56)	(1,092)	(256)	(723)	66
Operating expenses						
Research and development	1,398	43	1,681	394	(283)	(17)
Sales and marketing	5,206	160	3,186	746	2,020	63
General and administrative	1,499	46	912	214	587	64
Total operating expenses	8,103	249	5,779	1,354	2,324	40
Loss from operations	(9,918)	(305)	(6,871)	(1,610)	(3,047)	44
Interest income	16		39	9	(23)	(59)
Interest expense	(318)	10	(67)	16	(251)	(375)
Other expense	(41)	1	(11)	1	(30)	(273)
Net loss	$ (10,261)	(316)%	$ (6,910)	(1,618)%	$ (3,351)	48%

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% was derived 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 United States 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. 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 due primarily to increased volume of test strip production without an equivalent increase in factory spending.

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 due primarily to the redirection of activities from development to manufacturing.

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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. This was primarily the result of leveraging distributors sales force to increase sales without a proportional increase in the Company s head count.

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 coverage 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.

Liquidity and Capital Resources

Since our inception, our operations have been primarily financed through the sale of equity securities, both public and private, bank equipment financing loans, debt capital and capital leases. As of September 30, 2005, our cash, cash equivalents and short term investments were $11.5 million. All of our cash equivalents and investments have original maturities of one year or less.

On November 5, 2005 the Company closed a private equity offering of 1,481,482 shares of the Company s common stock at $6.75 per share. Gross proceeds from the offering were $10.0 million. Net proceeds were $9.2 million after offering expenses included underwriting discounts and commissions.

During the fiscal year ended September 30, 2005, our operating activities used cash of approximately $11.9 million, compared to approximately $9.5 million for the fiscal year ended September 30, 2004, an increase of $2.3 million. Cash used in operating activities increased by $2.3 million due to our increased net loss and additional investment in accounts receivable and inventory. The net loss for the current year (less depreciation and other non-cash items) used $253,000 more cash than last year. An additional $2.3 million was used for changes in current assets and liabilities. Cash used for expanding inventories was $1.6 million for the fiscal year 2005, an increase of $1.2 million from fiscal year 2004, due to material purchased to meet our expected future sales. The change in accounts receivable was $1.3 million for the fiscal year 2005, an increase of $407,000 from $773,000 used for the same period in 2004 due to higher sales during the fourth quarter of the current year. We expect future increases in revenue to result in increases in the need for working capital due to increases in accounts receivable and inventories but at a lower rate than the current year increases.

Our investing activities used cash of approximately $8.2 million during fiscal year 2005 compared to $429,000 for fiscal year 2004. Investing activities during fiscal 2005 primarily consisted of the purchase of short term investments with the proceeds of our initial public offering.

Cash provided by financing activities was approximately $23.2 million for fiscal year 2005 compared to $4.9 million provided during fiscal year 2004. The increase in cash provided was primarily due to $16.7 million from the sale of common stock in our initial public offering. Additionally we incurred net borrowing of $3.2 million of proceeds from draw downs against a debt line facility and $3.3 million in preferred stock proceeds.

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

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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 $1.0 million 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 generated $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 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 our IPO, became 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 our IPO, became exercisable for 8,307 shares of common stock at an exercise price of $6.32 per share.

During the fiscal year ended September 30, 2003, our operating activities used cash of approximately $11.9 million. The use of cash was due to our net loss of $6.9 million, increased accounts receivable and inventories. The increase in receivables related to higher sales during fiscal year 2003 and the increase in inventory was to support the anticipated demand for products in the next fiscal year. Cash used in investing activities of $397,000 related to the purchase of capital asset.

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

	2006	2007	2008	2009	Total
Loan payable	$ 2,000	$ 2,353	$ 1,788	$	$ 6,141
Note payable				573	573
Capital leases	37	36	16		89
Facility lease	143	153	162	90	548
Equipment lease	8	8	7		23
Cancelable purchase commitments	504				504
Non-cancelable purchase commitments	2,656				2,656
Total	$ 5,348	$ 2,550	$ 1,973	$ 663	$ 10,534

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During fiscal year 2005, we had drawn down an additional $4.6 million on the loan payable to lighthouse Capital. These draw downs resulted in us fully utilizing the debt line of $7.5 million that was available. As of September 30, 2005 we have made principal payments of $1.4 million relating to loan payable. 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. This debt to preferred stockholders was repaid with interest in July 2005.

We believe that our existing cash and cash equivalents, proceeds from our private placement in November 2005 and cash generated from product sales, will be sufficient to meet our anticipated cash requirements for at least the next 12 months. Our future capital requirements are difficult to forecast and will depend on many factors, including:

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

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

Critical Accounting Policies 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

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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:

Concentration of Credit Risk

Financial instruments which potentially subject the Company to concentrations of risk consist principally of cash and cash equivalents and accounts receivable. The Company s cash is invested in deposits with one financial institution. At times, cash deposits may be in excess of insured limits. Management believes that the financial institution which holds the Company s cash and cash equivalents is financially sound and, minimal credit risk exists with respect to these investments.

Inventories

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 previously exceeded their selling price. As a result, the Company recorded a charge to cost of goods sold on test strips inventory equal to the amount by which the manufacturing cost exceeds the average market selling price. Inventories are evaluated and any non-usable inventory is written off. In addition, the Company reserves for any inventory that may be potentially on-usable. Charges for such write-offs and reserves are recorded as a component of cost of goods sold. Changes in demand in the future could cause the Company to have additional write-offs and reserves.

Impairment of long-lived assets

The Company reviews 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. The Company considers various valuation factors, principally discounted cash flows, to assess the fair values of long-lived assets. To date, the Company has 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.

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.

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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 is charged to cost of goods sold.

Allowance for Doubtful Accounts

While the Company has not had material bad debts written-off in the past, we analyze the collectibility of its 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.

Warranties

The Company records an accrual for estimated warranty costs when revenue is recognized. Warranty covers replacement costs of defective meters and related test strips. The warranty period is one year. The Company has processes in place to estimate accruals for warranty exposure. The processes include estimated failure rates and replacement costs, and known design changes. Although the Company believes it has the ability to reasonably estimate warranty expenses, unforeseen changes in factors impacting the estimate for warranty could occur and such changes could cause a material change in the Company s warranty accrual estimate. Such a change would be recorded in the period in which the change was identified.

Income taxes

The Company accounts for income taxes under the liability method. Under this method, deferred income tax assets and liabilities are computed for differences between the financial statement and tax bases of assets and liabilities that will result in taxable or deductible amounts in the future based on enacted tax laws and rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized.

Accounting for stock-based compensation

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

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

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

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Recent Accounting Pronouncements

In December 2004, the FASB issued SFAS No. 123R, *Share-Based Payment*, which will replace SFAS No. 123 and 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.

In March 2005, the SEC issued Staff Accounting Bulletin No. 107, *Share-Based Payment* (SAB 107). SAB 107 provides guidance on the initial implementation of SFAS 123R. In particular, the statement includes guidance related to share-based payment awards for non-employees, valuation methods and selecting underlying assumptions such as expected volatility and expected term. SAB 107 also gives guidance on the classification of compensation expense associated with such awards and accounting for the income tax effects of those awards upon the adoption of SFAS 123R. We are currently assessing the guidance provided in SAB 107 in connection with the implementation of SFAS 123R.

Adoption of this statement is expected to have a significant impact on our financial statements as we will be required to expense the fair value of our stock option grants rather than disclose the impact on our net loss within our footnotes, as is our current practice. The full impact of SFAS 123R on our financial statements and related disclosures is still being evaluated by management but is expected to be material to our results of operations. Our actual share-based compensation expense in 2006 will be dependent on a number of factors, including the amount of awards granted and the fair value of those awards at the time of grant.

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

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

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Factors Affecting Future Operating Results

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

We have a limited history of operations and have incurred net losses in each year since our inception. We received regulatory clearance to market our INRatio System in 2002 and began commercial sales in early 2003. During the past five fiscal years, we incurred net losses of $4.0 million in 2001, $4.7 million in 2002, $6.9 million in 2003, $10.3 million in 2004 and $11.7 million in 2005. As of September 30, 2005, we had an accumulated deficit of $47.2 million. We expect that our operating expenses will increase as we expand our business, devote additional resources to our research and development, sales and marketing efforts and incur the costs of being a public company.

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

Until June 2005, there was no public market for shares of our common stock. The market price for our common stock 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.

We have only been a public company for a short period of time. Changes in the price of our common stock will be unpredictable and any of these factors could cause our stock price to fluctuate substantially.

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

We will need to both significantly increase the revenue we receive from sales of our product and, to the extent possible, reduce our costs in order to achieve profitability. It is possible that we will never generate sufficient revenue to achieve profitability. Our failure to achieve and maintain profitability would negatively affect our business and financial condition and the trading price of our common stock.

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

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

demand for our product;

timing of orders and shipments;

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the performance of our distributors on our behalf;

our mix of sales between our distributors and our direct sales force;

foreign currency fluctuations;

seasonality, in Europe, relating to mechanical heart valve surgeries;

new product introductions by our competitors; and

the timing and uncertainty of United States and foreign reimbursement decisions.

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

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

The INRatio System is our only product. Sales of this product will account for substantially all of our revenue for the foreseeable future. We cannot be sure that we will be successful in convincing patients and healthcare professionals to use our product. Certain competitors have products that are established in our target markets, and we may not be able to convince users of those products to switch to the INRatio System. Healthcare professionals may be hesitant to recommend our product to their patients given our short operating history and the fact that we are a relatively small company. If our product fails to gain acceptance in the point-of-care and patient self-testing markets, our business will be harmed.

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

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

We recently completed an FDA inspection and received a Warning Letter, 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. The FDA subsequently issued a Warning Letter on October 5, 2005. The Warning Letter indicates that the FDA believes that our response did not provide sufficient detail and documentation for the FDA to

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evaluate whether our corrective actions would be adequate to prevent recurrence of the observations. We have submitted a further written response to the FDA, which we believe addresses this concern. The FDA has accepted our response, but there can be no assurance that the FDA will not in the future impose more serious enforcement actions, 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.

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

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

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

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

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

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

The market for point-of-care and patient self-testing PT/INR measurement systems is intensely competitive, subject to rapid change, new product introductions and other activities of industry participants. We currently compete directly against Roche Diagnostics, the largest diagnostic company in the world, and International Technidyne Corporation, a division of Thoratec. Together these two companies currently account for substantially all of the point-of-care and patient self-testing PT/INR measurement market. Several other companies, including Inverness Medical Innovations, have announced that they are developing new products that would compete directly against us, and we expect one or more new products to become available next 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

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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;
- access to material information about our business, which we are required to publicly disclose, while not having to disclose their own comparable information, because it is an immaterial part of their overall operations;
- greater experience in conducting research and development, manufacturing and marketing activities; and
- greater financial and human resources for product development, sales and marketing and patent litigation.

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

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

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

While warfarin is a widely prescribed drug, it is known to have certain deficiencies which cause many physicians to be reluctant to prescribe it regularly, or at all. Aspirin is a safer blood thinning drug than warfarin and it does not require monitoring. Aspirin has been shown to be an effective alternative to warfarin for certain chronic conditions, such as blocked brain arteries. Warfarin s narrow therapeutic range creates the need for frequent monitoring of patient blood coagulation levels. Warfarin is known to have adverse interactions with other drugs and is sensitive to changes in diet and other factors. We are aware that pharmaceutical companies are researching and developing potential alternatives to warfarin. For example, AstraZeneca has developed an anticoagulant called Exanta. While the United States 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. Currently reimbursement for PT/INR testing in the point-of-care environment is for all indications. However, Medicare currently only

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reimburses PT/INR self-testing for patients with mechanical heart valves, or approximately 400,000 mechanical heart valve patients on warfarin, which represents approximately 15% of three million United States patients taking warfarin on a daily basis. Whether Medicare expands reimbursement for PT/INR patient self-testing for other indications, such as atrial fibrillation, will be partially dependent on the outcome of ongoing and future clinical studies that we do not participate in or have any direct control over. Coverage and reimbursement determinations are subject to change over time and we cannot assure you that Medicare will not reduce or change coverage and reimbursement policies.

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

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

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

We have limited experience as a company in the sale, marketing and distribution of our INRatio System. We maintain a relatively small sales and marketing team which as of November 15, 2005 was comprised of 31 employees and expect to depend heavily on third parties to sell our product both in the United States and internationally for the foreseeable future. To achieve commercial success, we must further develop our sales and marketing capabilities and enter into and maintain successful arrangements with others to sell, market and distribute our product.

We currently have agreements with six national and four regional distributors in the United States. We also have agreements with 14 international distributors of our product. Three of our distributors, Quality Assured Services, Medline and Cardinal Health, accounted for approximately 24%, 19% and 13%, respectively, of our total revenue in fiscal 2005. 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.

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

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

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

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

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

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

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

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

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

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

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

Additionally, we may become involved in a contractual dispute with any one of these suppliers, or may be unable to negotiate the renewal of an expiring contract, either of which could mean an interruption or delay in the supplied component or material. Any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to cancel orders or switch to competitive products, which would harm our business.

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.

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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.

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

Reporting Experience; however, we cannot provide you with assurance that our finance department has or will

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maintain adequate resources to ensure that we will not have any future material weakness in our system of internal controls. The effectiveness of our controls and procedures may in the future be limited by a variety of factors including:

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

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

We may 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 United States or foreign application, may not issue as a patent or may issue as a patent in a form that may not be advantageous to us. Our issued patents, and those that may issue in the future, may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products.

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

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

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

Third parties have in the past asserted, and could in the future assert, infringement or misappropriation claims against us with respect to our current or future products. Whether a product infringes a patent involves

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complex legal and factual issues, the determination of which is often uncertain. Therefore, we cannot be certain that we have not infringed the intellectual property rights of others. Our competitors may assert that our product or the methods we employ in the use or manufacture of our product are covered by United States or foreign patents held by them. This risk is exacerbated by the fact that there are numerous issued patents and pending patent applications related to our business that are held by others. For example, in April 2003, Inverness Medical Innovations filed suit against us, alleging that disposable test strips for our INRatio System infringed certain of its patent rights. Inverness sought monetary damages and injunctive relief. In July 2004, we entered into a settlement and mutual release agreement with Inverness pursuant to which we received a license to the patent rights in exchange for a product royalty and a lump sum payment. Additionally, in June 2005, we received a letter from Beckman Coulter claiming that our test strip includes intellectual property covered by one of their patents, United States 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.

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

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

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

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

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

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

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

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.

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

As of November 15, 2005, we had approximately 11,106,877 shares of common stock outstanding. Certain shares of common stock and shares of common stock issuable upon exercise of outstanding options were subject to lock-up agreements executed in connection with our initial public offering. Lock-up agreements with certain of our stockholders were extended in connection with our November 2005 private placement. 6,077,423 shares of common stock and 1,129,394 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
2,162,276	December 26, 2005
4,458,948	February 2, 2006
585,593	February 7, 2006

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

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

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

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

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

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

In December 2004, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards (SFAS) No. 123(R), Share-Based Payment, pursuant to which we must measure all stock-based

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compensation awards, including grants of employee stock options, using a fair value-based method and record such expense in our financial statements. This requirement to expense stock-based compensation awards is to take effect for public companies for annual periods beginning after June 15, 2005, thus we are required to adopt this standard commencing October 1, 2005. Currently, we disclose such expenses on a pro forma basis in the notes to our financial statements, but we do not record a charge for employee stock option expense in the financial statements. The inclusion of employee stock-option expense in accordance with SFAS No. 123(R) will cause our reported loss to increase, which may affect our stock price.

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

MPM Capital and its affiliates own approximately 32% of our common stock. This significant concentration of share ownership may adversely affect the trading price for our common stock because investors often perceive disadvantages in owning stock in companies with controlling stockholders. This stockholder will have the ability to exert substantial influence over all matters requiring approval by our stockholders, including the election and removal of directors and any proposed merger, consolidation or sale of all or substantially all of our assets. In addition, it could dictate the management of our business and affairs. This concentration of ownership could have the effect of delaying, deferring or preventing a change in control, or impeding a merger or consolidation, takeover or other business combination that could be favorable to our other stockholders.

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

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

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

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

ITEM 7A: QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Quantitative Disclosures

While we invoice our international distributors in U.S. dollars, some contract prices are stated in the customer s local currency and converted to U.S. dollars at a quarterly average 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

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The following table presents the future principal cash flows or amount and related weighted average interest rates expected in fiscal 2006 for our existing cash and cash equivalents and short term investments.

	(in thousands)
Cash, cash equivalents	$ 3,598
Short-term investments	$ 7,943
Weighted average interest rate	3.02%

Qualitative Disclosures

Our primary interest rate risk exposures relate to:

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

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

We have the ability to hold a significant portion of the fixed income investments until maturity and therefore would not expect the operating results or cash flows to be affected to a significant degree by a sudden change in market interest rates on our short term marketable securities portfolio.

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and

Stockholders of HemoSense, Inc.

In our opinion, the financial statements listed in the accompanying index present fairly, in all material respects, the financial position of HemoSense, Inc. at September 30, 2005 and 2004, and the results of its operations and its cash flows for each of the three years in the period ended September 30, 2005 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the accompanying index present fairly, in all material respects, the information set forth therein when read in conjunction with the related financial statements. These financial statements and financial statement schedule are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PRICEWATERHOUSECOOPERS LLP

San Jose, California

December 1, 2005

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HEMOSENSE, INC.

BALANCE SHEETS

(In thousands, except share data)

	September 30, 2005	September 30, 2004
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,598	$ 433
Short term investments	7,943	
Accounts receivable, net of allowance for doubtful accounts of $71 in 2005 and $0 in 2004	2,087	907
Prepaid expenses and other current assets	714	230
Inventories	2,744	1,299
Total current assets	17,086	2,869
Property and equipment, net	512	1,113
Technology licenses and prepaid royalties	1,179	1,964
Other assets	226	256
Total assets	$ 19,003	$ 6,202
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 1,029	$ 539
Accrued expenses and other liabilities	1,159	691
Capital lease, current portion		