HEMOSENSE INC
Form 424B3
December 20, 2005
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Registration No. 333-130099

PROSPECTUS

2,222,223 Shares

Common Stock

This prospectus relates to the public offering, which is not being underwritten, of up to 2,222,223 shares of our common stock under this prospectus by the selling stockholders identified in this prospectus. The selling stockholders may sell these shares from time to time on or off the American Stock Exchange in regular brokerage transactions, in transactions directly with market makers or in privately negotiated transactions. We issued these shares of our common stock to the selling stockholders in certain privately negotiated transactions.

For additional information on the methods of sale that may be used by the selling stockholders, see the section entitled Plan of Distribution on page 71. We will not receive any of the proceeds from the sale of these shares. We will bear the costs relating to the registration of these shares.

Our common stock is listed on the American Stock Exchange, or Amex, under the symbol HEM. On November 28, 2005, the last sale price of our common stock was $8.10 per share. Our principal executive office is located at 651 River Oaks Parkway San Jose, California 95134. Our telephone number is (408) 719-1393.

This offering involves certain material risks. See Risk Factors beginning on page 1.

The Securities and Exchange Commission may take the view that, under certain circumstances, the selling stockholders and any broker-dealers or agents that participate with the selling stockholder in the distribution of the shares may be deemed to be underwriters

within the meaning of the Securities Act of 1933, as amended. Commissions, discounts or concessions received by any such broker-dealer or agent may be deemed to be underwriting commissions under the Securities Act.

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

The date of this prospectus is December 19, 2005

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

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RISK FACTORS

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

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.

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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;
- 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 U.S. and foreign reimbursement decisions.

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

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

The INRatio System is our only product. Sales of this product will account for substantially all of our revenue for the foreseeable future. We cannot be sure that we will be successful in convincing patients and healthcare professionals to use our product. Certain competitors have

products that are established in our target markets, and we may not be able to convince users of those products to switch to the INRatio System. Healthcare professionals may be hesitant to recommend our product to their patients given our short operating history and the fact that we are a relatively small company. If our product fails to gain acceptance in the point-of-care and patient self-testing markets, our business will be harmed.

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

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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 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

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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 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.

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

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

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

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

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

Although many other insurance providers follow Medicare coverage determinations, Medicare coverage does not and will not guarantee widespread coverage by other insurance providers. These organizations are not required to offer the same level of coverage as Medicare, or any coverage at all, and their coverage policies are determined on a regional basis, carrier-by-carrier, so that obtaining nationwide

coverage from all the major insurance providers will be a time-consuming process. We cannot assure you that adequate coverage, if any, will be obtained. Further, coverage decisions for individual patients may be made on a case-by-case basis and may require the patient to seek and obtain prior authorization before being provided access to our product. Future legislation, regulation or reimbursement policies of insurance providers may adversely affect the demand for our product or our ability to sell our product on a profitable basis. The lack of insurance coverage or the inadequacy of reimbursement could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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;

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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

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performance is not acceptable, we discard the entire lot after we have incurred substantially all the material and labor costs required to manufacture the test strips in the lot. In order to manufacture test strips that will produce PT/INR measurement results that are sufficiently calibrated to clinical laboratory equipment, we are dependent upon our suppliers to deliver various components in conformity with our specifications. We have in the past had to, and may in the future have to, discard lots because they fail to meet specifications, which increases our costs of operations and may delay shipment of product to customers.

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

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

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

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

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- significant lot-to-lot variation in our test strips could negatively affect the performance of our product or cause delays in shipment of our product;

- we may have difficulty locating and qualifying on a timely basis alternative suppliers for our single-sourced supplies;

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

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

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

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

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

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

In addition, we may be subject to claims even if the apparent injury is due to the actions of others. For example, we rely on the expertise of physicians to determine if a patient is capable of performing patient self-testing. We similarly rely on IDTFs and other medical personnel to properly train patients to test themselves using our device. If these professionals are not properly trained or are negligent, our product may be used improperly or the patient may suffer critical injury, which may subject us to liability. These liabilities could prevent or interfere with our product commercialization efforts. Defending a lawsuit, regardless of merit, could be costly, could divert management attention and might result in adverse publicity, which could result in the withdrawal of, or reduced acceptance of, our product in the market.

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

The FDA has the authority to require the recall of our product in the event of material deficiencies, defects in design, manufacture or labeling, or other product problems that could cause serious adverse health consequences or death. Comparable governmental entities in other countries have similar authority. Even

where product problems do not present a risk of serious adverse health consequences or death, we may need to conduct a voluntary recall, if our product presents a risk to health. A government mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors or design defects. Any recall would divert managerial and financial resources and harm our reputation with customers.

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

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

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

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

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

Our operations may be directly or indirectly affected by various broad state and federal healthcare fraud and abuse laws, including the federal Anti-Kickback Statute, which prohibit any person from knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, to induce or reward either the referral of an individual, or the 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.

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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 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.

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

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

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

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

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

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

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

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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.

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

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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.

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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 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.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

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USE OF PROCEEDS

We will not receive any proceeds from the sale of shares by the selling stockholders. All net proceeds from the sale of the common stock covered by this prospectus will go to the selling stockholders. If and when all of the warrants are exercised, we will, however, receive up to approximately $6,048,150. See Principal and Selling Stockholders and Plan of Distribution described below.

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.

MARKET PRICE INFORMATION

Our common stock has been quoted on the American Stock Exchange since June 28, 2005 under the symbol HEM. The following table shows the high and low sales prices for the Company s Common Stock for the periods indicated, as reported on the American Stock Exchange.

	Common Stock Price	
	High	Low
Fiscal Year Ended September 30, 2005		
Third Quarter (June 28, 2005 through June 30, 2005)	$ 5.60	$ 5.50
Fourth Quarter (July 1, 2005 through September 30, 2005)	$ 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.

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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 prospectus. The statement of operations data for the years ended September 30, 2001 and 2002 and the balance sheet data at September 30, 2001, 2002 and 2003 are derived from our financial statements which are not included in this prospectus. The historical results are not necessary indicative of results expected for any future period. The following selected financial data should be read in conjunction with our financial statements and the related notes and Management s Discussion and Analysis of Financial Condition and Results of Operations appearing elsewhere in this prospectus. The selected financial data in this section is not intended to replace the financial statements.

	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)

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

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

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.

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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.

Results of Operations

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	Percent
	Amount	% of Sales	Amount	% of Sales	Increase (Decrease)	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.

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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 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.

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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.

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	Percent
	Amount	% of Sales	Amount	% of Sales	Increase (Decrease)	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.

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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.

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.

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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 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.

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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

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.

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

Critical Accounting Policies and Estimates

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

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.

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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.

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.

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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.

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.

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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.

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

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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BUSINESS

Overview

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

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

We have designed our INRatio System to address the needs of the emerging PT/INR patient self-testing and point-of-care markets. Our proprietary system requires one drop of blood from a patient s finger to quickly and reliably determine the rate at which their blood coagulates by measuring changes in the blood s electrical properties during the coagulation process. For ease of use, the INRatio System integrates into each disposable test strip clinical laboratory-like quality

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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.

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.

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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;

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however, these methods are inconvenient for the patient and the physician, and therefore not conducive to compliance. Clinical laboratory test results typically are not available until the following day, which could prevent a physician from properly advising a patient during their visit. In addition to being inconvenient for the patient, the delay in obtaining test results creates inefficiencies because the physician or nurse practitioner must perform patient call backs in order to advise patients of changes needed to their warfarin dosages.

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

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

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The Emergence of a Patient Self-Testing Market

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

Medicare reimburses for services provided to patients who perform PT/INR self-testing, similar to the Medicare reimbursement procedure for patients on pacemakers and Holter monitors. Our meters and test strips are distributed to Medicare patients without charge through a Medicare licensed facility known as an Independent Diagnostic Testing Facility, or IDTF, which may also monitor patient compliance and convey test results to the treating physician. Medicare provides a one-time reimbursement of $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.

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The HemoSense Solution

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

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

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

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

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

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

Our Strategy

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

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

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

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

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

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

Our Products

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

INRatio Meter

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

INRatio Disposable Test Strips

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

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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.

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

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been leaders in the adoption of patient self-testing. We intend to continue to enter into distribution agreements in other select countries where PT/INR patient self-testing and point-of-care testing are established medical practices. In emerging markets such as Asia, we intend to identify strategic partners as distributors of our product.

Sales and Marketing Organization

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

- creating awareness of the benefits of the INRatio System with distributors, physicians, nurse practitioners, educators and patients;
- providing strong educational and training programs to healthcare providers and patients to ensure the understanding of the ease of use, safety and effectiveness of the INRatio System;
- establishing a readily-accessible telephone and web-based technical and customer support infrastructure for our distribution partners, healthcare providers and patients; and
- building upon our network of leading distributors to sell our products to physician office laboratories and directly to the patients.

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;

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

We believe the principal competitive factors in our market include:

- reliability and ease of use;
- technological leadership and superiority;
- improved patient outcomes and reduced overall time to manage therapy; and
- effective marketing and distribution.

Emerging Oral Anticoagulation Therapies

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

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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 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.

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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

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510(k) clearances are not required for these modifications. If the FDA disagrees with our determination not to seek new 510(k) clearances, the FDA may require us to seek 510(k) clearance or premarket approval. The FDA also can require us to cease marketing and/or recall the modified device until 510(k) clearance or premarket approval is obtained. Also, in these circumstances, we may be subject to warning letters, significant regulatory fines or penalties, seizure or injunctive action, or criminal prosecution.

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

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resulted in the issuance of an FDA Form 483 containing two observations. First, the inspector observed that we failed to timely file Medical Device Reports, or MDRs, for six of seven complaints the inspector reviewed claiming that our INRatio device took inaccurate readings none of which resulted in a patient injury. MDRs are required to be filed, even if an injury has not occurred, if our device may have caused or contributed to a death or serious injury or if it may have malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur. We categorize as complaints instances reported to us in which our device takes a reading that is different from what the user expected. For example, discrepant results can be different readings obtained by the user on separate occasions using either the same or another testing device. In addition to potential device malfunction, discrepant PT/INR test results can arise from a number of factors, such as failure to follow our instructions for use, a patient s medication or diet between measurements, or variability in measurement results among different manufacturers instruments. Since we began selling our product, we have received complaints of discrepant test results representing approximately .01% of all test strips sold. At the time that we received the complaints reviewed by the FDA, our written procedure did not provide for the analysis of whether to file an MDR if the complaint solely involved discrepant results, without any resulting patient injury. In addressing the FDA s observation, we have revised our MDR reporting procedure to now determine when discrepancies between measurements taken with our device and those taken with a clinical laboratory device should be classified as a malfunction and result in an MDR filing. As a result of this revised procedure, we will be filing an increased number of MDRs. The FDA s second observation was that we had not properly defined and documented the procedures we employ to identify the statistical techniques for calibration of our test strips. This observation requires us to provide clarification of how our current strip calibration procedures are in conformity with standards applicable to PT/INR testing. We have filed a response to these observations that includes a description of and basis for our revised MDR reporting procedure, as well as the documentation of procedures employed to identify valid statistical techniques for our test strip calibration and our conformity to applicable standards. 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.

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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 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.

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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 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.

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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.

Facilities

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

Legal Proceedings

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

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MANAGEMENT

Executive Officers and Directors

The following table sets forth, as of November 15, 2005, information about our executive officers and directors:

Name	Age	Position
James D. Merselis	51	President, Chief Executive Officer and Director
Paul Balsara	62	Vice President, Finance and Chief Financial Officer
Maria C. Navarro	46	Executive Vice President, Operations and Research and Development
Timothy I. Still	40	Executive Vice President, Sales and Marketing
Edward F. Brennan, Ph.D. (1)(2)(3)	54	Chairman of the Board of Directors
Gregory M. Ayers, M.D., Ph.D.	43	Director
Richard P. Powers (1)	61	Director
Robert D. Ulrich, Ph.D. (1)(2)(3)	60	Director
Kurt C. Wheeler (2)	52	Director

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

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

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

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

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

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

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

Richard P. Powers has served as a member of our board of directors since September 2005. Since October 2001, Mr. Powers has been Vice President and Chief Financial Officer at Corgentech Inc., a biopharmaceutical company. From March 1999 to August 2000, Mr. Powers served as Executive Vice President and Chief Financial Officer of Eclipse Surgical Technologies, Inc., a medical device company. From February 1996 to March 1999, Mr. Powers served as Executive Vice President and Chief Financial Officer of CardioGenesis Corporation, a medical device company. From January 1981 to August 1995, Mr. Powers served as Senior Vice President and Chief Financial Officer of Syntex Corporation, a biopharmaceutical company. Mr. Powers also currently serves on the board of directors of Airlease Management Services, Inc. Mr. Powers holds a B.S. in Accounting from Canisius College and an M.B.A. from the University of Rochester, New York.

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

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

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Medical Advisory Board

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

- unmet needs and opportunities;
- clinical feedback on existing products;
- assessment of new technologies and their applications; and
- assessment of new clinical applications.

As of November 15, 2005, the following individuals are members of our Medical Advisory Board:

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

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

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Board of Directors

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

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

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

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

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

Board Committees

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

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

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

Compensation Committee Interlocks and Insider Participation

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

Director Compensation

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

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

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

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

Executive Compensation

The following table sets forth summary information concerning compensation earned for services rendered to us in all capacities by our chief executive officer and each of our executive officers whose total annual salary and bonus exceeded $100,000 as of the last fiscal year ended September 30, 2005. We refer to these persons as our named executive officers.

Summary 2005 Compensation Table

	Annual Compensation			Long Term Compensation
Name and Principal Positions	**Salary**	**Bonus**	**Other**	**Securities Underlying Options**
James D. Merselis President and Chief Executive Officer	$ 252,000	$ 92,921	$ 31,160(1)	113,750
Paul Balsara Vice President, Finance and Chief Executive Officer	185,062	60,141	10,068(2)	25,000
Maria C. Navarro Executive Vice President, Operations and Research and Development	204,365	49,641	10,061(2)	12,500
Timothy I. Still Executive Vice President, Sales and Marketing	214,457	55,241	10,042(2)	12,500

(1) Consists of $21,184 for temporary living expenses and $9,976 for insurance premiums.
(2) Consists of insurance premiums paid for such executive officer s benefit.

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2005 Option Grants

The following table sets forth information regarding stock option grants to the executive officers named in the summary compensation table during fiscal year 2005.

	Individual Grants				Potential Realizable Value at Assumed Annual Rates of Stock Appreciation for Option Term	
Name	Number of Securities Underlying Options Granted	Percent of Total Options Granted to Employees During Period	Exercise Price Per Share	Expiration Date	5%	10%
James D. Merselis	113,750	30.2%	$ 0.80	2/17/2015	$ 1,392,546	$ 2,206,057
Paul Balsara	25,000	6.6	0.80	2/17/2015	306,054	484,848
Maria C. Navarro	12,500	3.3	0.80	2/17/2015	153,027	242,424
Timothy I. Still	12,500	3.3	0.80	2/17/2015	153,027	242,424

These options were granted under our 1997 Stock Plan and vest at the rate of 25% after one year of service from the vesting commencement date of February, 17, 2005, and monthly thereafter in equal amounts over 36 additional months. However, the vesting of these options will fully accelerate upon the occurrence of a change of control or accelerate as to 12 months of vesting if such executive officer is terminated without cause or resigns for good reason. These options also immediately vested as to 20% of the shares underlying the option upon the closing of our initial public offering. Each of these options has a term of 10 years, but may terminate before its expiration date if such executive officer s status as an employee is terminated, or upon his or her death or disability. See Benefit Plans 1997 Stock Plan. The percent of the total options granted to each executive officer as set forth above is based on an aggregate of 377,000 options granted to our employees during fiscal year 2005. These options were granted at fair market value as determined by our board of directors on the date of grant.

With respect to the amount disclosed in the column captioned Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term, potential realizable value represents hypothetical gains that could be achieved for the option if exercised at the end of the option term assuming that the price of our common stock appreciates at 5% and 10% over the option term. The assumed 5% and 10% rates of stock price appreciation are provided in accordance with rules of the Securities and Exchange Commission and do not represent our estimate or projection of our future common stock price. The potential realizable value is calculated based on $8.25 per share, the per share price of our common stock as of September 30, 2005, and assume that the common stock appreciates at the indicated rate for the entire term of the option, and that the option is exercised at the exercise price and sold on the last day of the option term of the option at the appreciated price. Actual gains, if any, on stock option exercises are dependant on the future performance of our common stock and overall stock market conditions. The amounts reflected in the table may not necessarily be realized.

Aggregate Option Exercises and Option Values

The following table sets forth information concerning exercisable and unexercisable stock options held by the executive officers named in the summary compensation table as of September 30, 2005. No options were exercised by the named executive officers as of September 30, 2005. The amount described in the column captioned Value of Unexercised In-the-Money Options at September 30, 2005 represents the positive spread between the exercise price of stock options and the fair market value of the options, which is based upon on $8.25 per share, the per share

price of our common stock as of September 30, 2005, minus the actual exercise price per share. All options were granted under our 1997 Stock Plan.

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Name	Number of Securities Underlying Unexercised Options at September 30, 2005		Value of Unexercised In-the-Money Options at September 30, 2005	
	Exercisable	Unexercisable	Exercisable	Unexercisable
James D. Merselis	191,875	91,000	$ 1,429,469	$ 677,950
Paul Balsara	73,000	20,000	543,850	149,000
Maria C. Navarro	35,812	41,688	266,799	310,576
Timothy I. Still	35,812	41,688	266,799	310,576

Employment Agreement

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

Benefit Plans

1997 Stock Plan

Our board of directors adopted and our stockholders approved the 1997 Stock Plan in November 1997. No additional options under the plan will be granted under this plan. However, the plan will continue to govern the terms and conditions of the outstanding options previously granted under the plan. The plan will terminate when all the shares have been either exercised, cancelled or expire

A total of 1,137,500 shares of our common stock are authorized for issuance under the 1997 Stock Plan. As of November 15, 2005, options to acquire a total of 947,875 shares of our common stock were issued and outstanding, and a total of 138,087 shares of our common stock had been issued upon the exercise of options granted under the plan that had not been repurchased by us.

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

Generally, in the event of a change of control, the successor corporation will assume each outstanding option or replace such options with equivalent rights that preserve the spread between the strike price and fair market value associated with such option. If the outstanding options are not assumed, or if the successor corporation does not replace such options with equivalent rights, the outstanding options will become fully exercisable immediately prior to such change of control and will terminate upon the consummation of the change of control. Generally, if

options are assumed in connection with the change of control and an optionee s employment is terminated as the result of an involuntary termination within 12 months of the change of control, the options held by such optionee will immediately vest in full.

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2005 Equity Incentive Plan

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

As of November 15, 2005, a total of 581,534 shares of our common stock were reserved for issuance pursuant to the 2005 Equity Incentive Plan, of which options exercisable for 90,250 shares of our common stock were issued and outstanding as of that date. The shares reserved for issuance under our 2005 Equity Incentive Plan include (a) shares reserved but unissued under the 1997 Stock Plan as of the effective date of our initial public offering, (b) shares returned to the 1997 Stock Plan as the result of termination of options or the repurchase of shares issued under such plan, and (c) annual increases in the number of shares available for issuance on the first day of each fiscal year beginning with our 2006 fiscal year, equal to the least of:

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

1,250,000 shares; or

an amount our board may determine.

Our board of directors or a committee of our board administers our 2005 Equity Incentive Plan. In the case of options intended to qualify as performance-based compensation within the meaning of Section 162(m) of the Internal Revenue Code, the committee will consist of two or more outside directors within the meaning of Section 162(m) of the Code. The administrator has the power to determine the terms of the awards, including the exercise price, the number of shares subject to each such award, the exercisability of the awards and the form of consideration, if any, payable upon exercise. The administrator also has the authority to institute an exchange program by which outstanding awards may be surrendered in exchange for awards with a lower exercise price.

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

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

After termination of an employee, director or consultant, he or she may exercise his or her option for the period of time stated in the option agreement. Generally, if termination is due to death or disability, the option will remain exercisable for 12 months. In all other cases, the option

will generally remain exercisable for three months. However, an option generally may not be exercised later than the expiration of its term.

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

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

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

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

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

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

Our 2005 Equity Incentive Plan provides that in the event of our change of control the administrator will determine how awards granted thereunder will be treated, including without limitation that the successor corporation will assume or substitute an equivalent award for each award. If there is no assumption or substitution of outstanding awards, unless the administrator provides otherwise, all stock options and stock

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appreciation rights will become exercisable as to all shares subject to such awards, all restrictions on restricted stock and restricted stock units will lapse, and, with respect to performance shares and performance units, all performance goals or other vesting criteria will be deemed achieved at target levels and all other terms and conditions met. If awards are not assumed by the successor corporation, the award will terminate upon the expiration of such period as the administrator determines. With respect to awards granted to an outside director that are assumed or substituted for, if such outside director is terminated on or following a change in control, other than pursuant to a voluntary resignation, his or her awards will fully vest.

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

401(k) Plan

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

Severance Arrangements

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

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

For purposes of our agreements with these executive officers:

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

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

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

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RELATED PARTY TRANSACTIONS

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

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

Preferred Stock Issuances

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

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

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

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

(1) Kurt Wheeler, one of our directors, is an investment manager of MPM Asset Management II, LLC, the general partner of MPM Asset Management II, L.P., the general partner of the funds affiliated with MPM Capital which purchased these shares of our preferred stock.
(2) Robert Ulrich, one of our directors, is a member of Vanguard Venture Partners, LLC, the general partner of Vanguard V, L.P.

Each share of such preferred stock converted automatically into 0.25 shares of common stock immediately prior to our initial public offering. The purchasers of these shares of preferred stock are entitled to certain registration rights. See Description of Capital Stock Registration Rights.

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Debt Financing

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

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

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

The notes accrue interest at 6% annually and were repaid on July 1, 2005. We also issued to these investors warrants to purchase shares of our common stock. The warrants are exercisable for our common stock at $5.50 per share. The warrants will terminate five years from their date of issuance.

Relationships with Entities Affiliated with a Director

Innovative Medical Products GmbH, or IMed Pro, has provided us with consulting and distribution services in Germany pursuant to a consulting agreement entered into in May 2002 and a non-exclusive sales representative and services agreement entered into in November 2002. The consulting agreement provided for IMed Pro s assistance with running clinical trials involving our product. The sales representative and services agreement provided for IMed Pro to act as our non-exclusive sales representative in Germany. Dr. Gregory Ayers, one of our directors, is a general manager of IMed Pro. During the past three fiscal years, we made payments to IMed Pro of approximately $148,000 in 2005, and $560,000 in 2004 and $436,000 in 2003 for consulting and distribution services. The agreements between us and IMed Pro were terminated effective January 1, 2005. Since January 2005, I-Med-Partner GmbH has served as a distributor in Germany and purchased $416,000 of our product. IMed Pro is a shareholder of I-Med-Partner GmbH.

Consulting Agreements with Officers and Directors

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

Edward Brennan, Ph.D., one of our directors, has provided consulting services to us not directly related to his service as a board member. During the past three fiscal years, we made payments to Dr. Brennan of $23,000 in 2005, $58,750 in 2004 and $15,000 in 2003 for these consulting services.

Indemnification Agreements of Officers and Directors

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

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PRINCIPAL STOCKHOLDERS

The following table sets forth information known to us with respect to the beneficial ownership of our common stock as of November 15, 2005 and as adjusted to reflect the sale of common stock offered hereby by:

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

We have determined beneficial ownership in accordance with the rules of the Securities and Exchange Commission. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of common stock subject to options or warrants held by that person that are currently exercisable or exercisable within 60 days of November 15, 2005 are deemed outstanding, but are not deemed outstanding for computing the percentage ownership of any other person. This table is based upon information supplied by officers, directors and principal stockholders, and in Schedules 13F and 13G filed with the Securities and Exchange Commission. To our knowledge, except as set forth in the footnotes to this table and subject to applicable community property laws, each person named in the table has sole voting and investment power with respect to the shares set forth opposite such person s name. Except as otherwise indicated, the address of each of the persons in this table is c/o HemoSense, Inc., 651 River Oaks Parkway, San Jose, California 95134.

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Name and Address of Beneficial Owner	Beneficial Ownership: Shares	Beneficial Ownership: Options and Warrants Exercisable Within 60 Days	Percentage of Shares Outstanding (1)
Holders of More Than 5%			
Funds affiliated with MPM Capital 111 Huntington Ave., 31st Floor Boston, MA 02199	3,537,359(2)	42,225(2)	32.2%
Vanguard V, L.P. 1330 Post Oak Boulevard, Suite 1550 Houston, TX 77056	699,357(3)		6.3
W Capital Partners Ironworks, L.P. One East 52nd St., 5th Floor New York, NY 10022	694,407(4)	6,900(4)	6.3
Atlas Master Fund, Ltd. c/o Walker SPV Limited, Walker House P.O. Box 908 GT George Town, Grand Cayman Cayman Islands, British West Indies	570,070(5)		5.1
Named Executive Officers and Directors			
James D. Merselis		191,875	1.7
Paul Balsara		73,000	*
Maria C. Navarro		41,229	*
Timothy I. Still		41,229	*
Edward F. Brennan, Ph.D.		25,333	*
Gregory M. Ayers, M.D., Ph.D.	35,034(6)	47,500	*
Richard P. Powers			*
Robert D. Ulrich, Ph.D.	699,357(3)		6.3
Kurt C. Wheeler	3,537,359(2)	42,225(2)	32.2
All named executive officers and directors as a group (9 persons)	4,271,750	462,391	42.6

* Represents beneficial ownership of less than one percent (1%) of the outstanding shares of our common stock.

(1) Percentage of beneficial ownership is based upon 11,106,877 shares of our common stock outstanding as of November 15, 2005.

(2) Includes 838,354 shares held by MPM Bio Ventures GmbH & Co. Parallel-Beteiligungs KG, 262,825 shares held by MPM Bio Ventures II, L.P., 2,381,352 shares held by MPM Bio Ventures II-QP, L.P. and 54,828 shares held by MPM Asset Management Investors 2000 B LLC. Also includes 10,007, 3,137, 28,427 and 654 shares issuable upon the exercise of warrants held by MPM Bio Ventures GmbH & Co. Parallel-Beteiligungs KG, MPM Bio Ventures II, L.P., MPM Bio Ventures II-QP, L.P. and MPM Asset Management Investors 2000 B LLC, respectively. MPM Asset Management II, LLC is the general partner of MPM Asset Management II, L.P, the general partner of MPM Bio Ventures GmbH & Co. Parallel-Beteiligungs KG, MPM Bio Ventures II, L.P. and MPM Bio Ventures II-QP, L.P. Ansbert Gadicke, Michael Steinmetz, Luke Evnin, Nicholas Galakatos and Kurt Wheeler, as investment managers of MPM Asset Management II, LLC, the general partner of MPM Asset Management II, L.P., and MPM Asset Management Investors 2000 B LLC, share voting and investment power with respect to shares held by MPM Bio Ventures GmbH & Co. Parallel-Beteiligungs KG, MPM Bio Ventures II, L.P.,

MPM Bio Ventures II-QP, L.P. and MPM Asset Management Investors 2000 B LLC. Mr. Wheeler disclaims beneficial ownership of these shares, except to the extent of his pecuniary interest therein.

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

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

(5) Dimitry Balyasny as the sole managing member of the general partner of Balyasny Asset Management L.P., the sole managing member of Atlas Master Fund, Ltd., has sole voting and investment power with respect to these shares.

(6) Includes 28,784 shares held by Innovative Medical Product Consultants, GmbH, of which Dr. Ayers, along with Knut-Michael Scharnberger, are partners. Dr. Ayers and Mr. Scharnberger share investment power with respect to the shares held by Innovative Medical Product Consultants, GmbH. Dr. Ayers disclaims beneficial ownership of these securities, except to the extent of his pecuniary interest therein.

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SELLING STOCKHOLDERS

The 2,222,223 shares of common stock covered by this prospectus were acquired by the selling stockholders from us in a series of private placements consummated on November 4, 2005. We issued a total of 1,481,482 shares of common stock and warrants exercisable for five years to purchase up to an additional 740,741 shares of common stock with an exercise price of $8.165 per share. The following table sets forth certain information with respect to the beneficial ownership of our common stock as of November 15, 2005 for all of the selling stockholders.

Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of common stock subject to options or warrants held by that person that are currently exercisable or exercisable within 60 days of November 15, 2005 are deemed outstanding, but are not deemed outstanding for computing the percentage ownership of any other person. To our knowledge, except as set forth in the footnotes to this table and subject to applicable community property laws, each person named in the table has sole voting and investment power with respect to the shares set forth opposite such person s name.

	Shares Beneficially Owned Prior to Offering			Shares Beneficially Owned After Offering	
	Common Stock			Common Stock	
Name of Beneficial Owner	Shares (1)	% (1)	Shares Being Offered	Shares (1)	% (1)
Selling Stockholders:					
SF Capital Partners Limited 3600 South Lake Drive St. Francis, WI 53235			562,500(2)	(3)	
Atlas Master Fund Limited 650 Madison Ave., 19th Floor New York, NY 10022	199,700	2.1	555,555(4)	199,700(3)	1.8
UBS O Connor LLC FBO O Connor PIPES Corporate Strategies Master Limited One North Wacker Drive 32nd Floor Chicago, IL 60606			150,000(5)	(3)	
MPM Bioequities Master Fund LP 601 Gateway Blvd., Suite 350 South San Francisco, CA 94080	222,800	2.3	111,111(6)	222,800(3)	2.0
Crown Growth Partners, L.P. 60 E. 42nd Street, Suite 3405			97,500(7)	(3)	

New York, NY 10165		
J. Goldman + Co LP 152 W. 59th Street New York, NY 10019	78,888(8)	(3)
Iroquois Master Fund Limited 691 Lexington Avenue, 26th Floor New York, NY 10022	55,557(9)	(3)
The Jay Pritzker Foundation 2 N Riverside Plaza, Suite 720 Chicago, IL 60606	8,334(10)	(3)

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Name of Beneficial Owner	Shares Beneficially Owned Prior to Offering — Common Stock — Shares (1)	Shares Beneficially Owned Prior to Offering — Common Stock — % (1)	Shares Being Offered	Shares Beneficially Owned After Offering — Common Stock — Shares (1)	Shares Beneficially Owned After Offering — Common Stock — % (1)
CD Investment Partners Limited 2 N Riverside Plaza, Suite 720 Chicago, IL 60606			133,335(11)		(3)
EGI-NP Investment, LLC 2 N Riverside Plaza, Suite 720 Chicago, IL 60606			24,999(12)		(3)
Leonardo, L.P. 245 Park Avenue, 26th Floor New York, NY 10167			444,444(13)		(3)

(1) Unless otherwise indicated in the footnotes to this table and subject to community property laws, where applicable, we believe that each stockholder named in this table has sole voting and investment power with respect to the shares indicated as beneficially owned. The number and percentage of shares beneficially owned prior to this offering are based on an aggregate of 11,106,877 shares of our common stock outstanding as of November 15, 2005, less 1,481,482 shares of common stock that were acquired by the selling stockholders from us in a series of private placement transactions consummated on November 4, 2005 and are determined under rules promulgated by the Securities and Exchange Commission. The number and percentage of shares beneficially owned after this offering are based on an aggregate of 11,106,877 shares of our common stock outstanding, which excludes the shares of common stock issuable upon exercise of warrants acquired by the selling stockholders in our 2005 private placement since such warrants are not yet exercisable. This information is not necessarily indicative of beneficial ownership for any other purpose. Under the rules promulgated by the Securities and Exchange Commission, beneficial ownership includes any shares as to which the individual has sole or shared voting power or investment power and also any shares which the individual has the right to acquire within 60 days of November 15, 2005 through the exercise of any stock option or other right.

(2) Includes 375,000 shares and 187,500 shares issuable upon the exercise of warrants. Michael A. Roth and Brian J. Stark possess voting and dispositive power over all of the shares owned by SF Capital Partners Ltd.

(3) Assumes that selling stockholder sells all shares registered under this registration statement. However, to our knowledge, there are no agreements, arrangements or understandings with respect to the sale of any of our common stock, and selling stockholder may decide not to sell its shares that are registered under this registration statement. This registration statement also shall cover any additional shares of common stock that become issuable in connection with the shares registered for sale hereby by reason of any stock dividend, stock split, recapitalization or other similar transaction effected without the receipt of consideration that results in an increase in the number of our outstanding shares of common stock.

(4) Includes 370,370 shares and 185,185 shares issuable upon the exercise of warrants. Balyasny Asset Management L.P. is the investment manager of Atlas Master Fund Limited.

(5) Includes 100,000 shares and 50,000 shares issuable upon the exercise of warrants. UBS O Connor LLC fbo O Connor PIPES Corporate Strategies Master Limited is a wholly owned subsidiary of UBS AG.

(6) Includes 74,074 shares and 37,037 shares issuable upon the exercise of warrants.

(7) Includes 65,000 shares and 32,500 shares issuable upon the exercise of warrants.

(8) Includes 52,592 shares and 26,296 shares issuable upon the exercise of warrants. J. Goldman Capital LP LLC is the general partner of J. Goldman + Co LP. Jay G. Goldman is the managing member of J. Goldman Capital LP LLC.

(9) Includes 37,038 shares and 18,519 shares issuable upon the exercise of warrants. Joshua Silverman has voting and investment control over the shares held by Iroquois Master Fund Limited. Mr. Silverman disclaims beneficial ownership of these shares.

(10)

Includes 5,556 shares and 2,778 shares issuable upon the exercise of warrants. CD Capital Management LLC, as the investment manager for The Jay Pritzker Foundation, and John D. Ziegelman, as President of CD Capital Management LLC, each may be deemed to have beneficial ownership of the shares held by The Jay Pritzker Foundation.

(11) Includes 88,890 shares and 44,445 shares issuable upon the exercise of warrants. CD Capital Management LLC, as the investment manager for CD Investment Partners, Ltd., and John D. Ziegelman, as President of CD Capital Management LLC, each may be deemed to have beneficial ownership of the shares held by CD Investments Partners, Ltd.

(12) Includes 16,666 shares and 8,333 shares issuable upon the exercise of warrants. CD Capital Management LLC, as the investment manager for EGI-NP Investments, LLC, and John D. Ziegelman, as President of CD Capital Management LLC, each may be deemed to have beneficial ownership of the shares held by CD Investments Partners, Ltd.

(13) Includes 296,296 shares and 148,148 shares issuable upon the exercise of warrants. Leonardo Capital Management, Inc., or LCMI, is the sole general partner of Leonardo, L.P. Angelo Gordon & Co., L.P., or Angelo Gordon, is the sole director of LCMI. John M. Angelo and Michael L. Gordon are the principal executive officers of Angelo Gordon. Each of Angelo Gordon and Messrs. Angelo and Gordon disclaim beneficial ownership of the shares held by Leonardo, L.P.

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DESCRIPTION OF CAPITAL STOCK

As of the date of this prospectus, our authorized capital stock consists of 50 million shares of common stock, $0.001 par value, and 10 million shares of preferred stock, $0.001 par value. The following description summarizes the most important terms of our capital stock. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description you should refer to our certificate of incorporation and bylaws, copies of which have been filed as exhibits to the registration statement of which the prospectus is a part.

Common Stock

As of November 15, 2005, there were 11,106,877 shares of common stock issued and outstanding.

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

Our common stock is listed on the American Stock Exchange under the symbol HEM. The transfer agent and registrar for our common stock is Computershare Trust Company, Inc.

Preferred Stock

The board of directors has the authority, without further action by the stockholders, to issue up to 10 million shares of preferred stock from time to time in one or more series and to fix the number of shares, designations, preferences, powers, and relative, participating, optional or other special rights and the qualifications or restrictions thereof. The preferences, powers, rights and restrictions of different series of preferred stock may differ with respect to dividend rates, amounts payable on liquidation, voting rights, conversion rights, redemption provisions, sinking fund provisions, and purchase funds and other matters. The issuance of preferred stock could decrease the amount of earnings and assets available for distribution to holders of common stock or adversely affect the rights and powers, including voting rights, of the holders of common stock, and may have the effect of delaying, deferring or preventing a change in control of our company.

Warrants

As of November 15, 2005, the following warrants were outstanding:

Warrants to purchase an aggregate of 126,977 shares of common stock at an exercise price of $6.32 per share. These warrants may be exercised at any time prior to the earlier of July 21, 2010 as to 8,307 shares and March 5, 2011 as to 118,670 shares, or our merger or acquisition with or into another company.

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Warrants to purchase an aggregate of 54,542 shares of common stock at an exercise price of $5.50 per share. These warrants may be exercised at any time prior to April 25, 2010.

Warrants to purchase an aggregate of 740,741 shares of common stock at an exercise price of $8.165 per share. These warrants are exercisable for 740,741 of the shares of common stock offered under this prospectus. These warrants may be exercised from 180 days from November 4, 2005 to November 4, 2010.

Registration Rights

In addition, the holders of shares of 5,489,045 shares of common stock and warrants exercisable for an aggregate of 126,977 shares of common stock will be entitled to rights to cause us to register the sale of such shares under the Securities Act. These shares are referred to as registrable securities. Specifically, commencing 180 days after June 27, 2005, a holder or holders of at least 30% of the registrable securities may require us to prepare and file a registration statement under the Securities Act at our expense covering registrable securities, provided that the shares to be included in such registration will generate anticipated aggregate net proceeds of at least $250,000. Under these demand registration rights, we are required to use our best efforts to cause the shares requested to be included in the registration statement, subject to customary conditions and limitations. We are not obligated to effect more than two of these stockholder-initiated registrations. Once we become eligible to file a registration statement on Form S-3, the holders of registrable securities may require us to register all or a portion of their securities on a registration statement on Form S-3 and may participate in a Form S-3 registration by us, subject to specific conditions and limitations. Registration rights terminate no later than five years after June 27, 2005. Registration of these shares under the Securities Act would result in these shares, other than shares purchased by our affiliates, becoming freely tradable without restriction under the Securities Act.

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

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

acquisition of us by means of a tender offer;

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

removal of our incumbent officers and directors.

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

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

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

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

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

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

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

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

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

Limitations of Liability and Indemnification Matters

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

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

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

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

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

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

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

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

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PLAN OF DISTRIBUTION

The selling stockholders, which as used herein include donees, pledgees, transferees or other successors-in-interest selling shares of our common stock received after the date of this prospectus from a selling stockholder as a gift, pledge, partnership distribution or other transfer, may, from time to time, sell, transfer or otherwise dispose of any or all of their shares of common stock or interests in shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at negotiated prices.

The selling stockholders may use any one or more of the following methods when disposing of shares or interests therein:

- on the American Stock Exchange (or any other exchange on which the shares may be listed);
- on the over-the-counter market;
- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent, but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- short sales;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

The selling stockholders may, from time to time, pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock, from time to time, under this prospectus, or under an amendment to this prospectus under Rule 424(b) or under any applicable provision of the Securities Act amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus. The selling stockholders also may transfer the shares of common stock in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus. To the extent required, this prospectus may be amended or supplemented from time to time to describe a specific plan of distribution.

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In connection with the sale of our common stock or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may, in turn, engage in short sales of the common stock in the course of hedging the positions they assume. The selling stockholders may also sell shares of our common stock short and deliver these securities to close out their short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The aggregate proceeds to the selling stockholders from the sale of the common stock offered by them will be the purchase price of the common stock less discounts or commissions, if any. Each of the selling stockholders reserves the right to accept and, together with their agents from time to time, to reject, in whole or in part, any proposed purchase of common stock to be made directly or through agents. We will not receive any of the proceeds from this offering.

The selling stockholders also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act, provided that they meet the criteria and conform to the requirements of that rule.

The selling stockholders and any underwriters, broker-dealers or agents that participate in the sale of the common stock or interests therein may be underwriters within the meaning of Section 2(11) of the Securities Act. Any discounts, commissions, concessions or profit they earn on any resale of the shares may be underwriting discounts and commissions under the Securities Act. Selling stockholders who are underwriters within the meaning of Section 2(11) of the Securities Act will be subject to the prospectus delivery requirements of the Securities Act. The selling stockholders may indemnify any broker-dealer that participates in transactions involving the sale of the shares against certain liabilities, including liabilities arising under the Securities Act.

We have borne and will bear substantially all of the costs, expenses and fees in connection with the registration of the shares, other than any commissions, discounts or other fees payable to broker-dealers in connection with any sale of shares, which will be borne by the selling stockholder selling such shares of common stock. We have agreed to indemnify the selling stockholders against certain liabilities, including liabilities under the Securities Act and state securities laws, relating to the registration of the shares offered by this prospectus.

In order to comply with the securities laws of some states, if applicable, the common stock may be sold in these jurisdictions only through registered or licensed brokers or dealers. In addition, in some states the common stock may not be sold unless it has been registered or qualified for sale or an exemption from registration or qualification requirements is available and is complied with.

The selling stockholders may be subject to the anti-manipulation rules of Regulation M, which may limit the timing of purchases and sales of shares of our common stock by such selling stockholders.

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We will make copies of this prospectus (as it may be supplemented or amended from time to time) available to the selling stockholders for the purpose of satisfying the prospectus delivery requirements of the Securities Act.

We have agreed with each selling stockholder to keep the registration statement, of which this prospectus constitutes a part, effective with respect to its shares until the earlier of (1) the second anniversary of our issuance of shares and warrants to such selling stockholder, (2) the date on which all shares purchased from us by such selling stockholder may be sold pursuant to Rule 144 of the Securities Act without volume limitations and (3) such time as all of such selling stockholder s shares covered by this prospectus have been disposed of pursuant to and in accordance with the registration statement.

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LEGAL MATTERS

The validity of the shares of common stock offered hereby has been passed upon for us by Wilson Sonsini Goodrich & Rosati, P.C., Palo Alto, California. An investment partnership comprised of current and former members of and persons associated with Wilson Sonsini Goodrich & Rosati, as well as one current member of Wilson Sonsini Goodrich & Rosati, own interests representing in the aggregate approximately 0.2% of the shares of our common stock.

EXPERTS

The financial statements as of September 30, 2005 and 2004 and for each of the three years in the period ended September 30, 2005 included in this Prospectus have been so included in reliance on the report of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed a registration statement on Form S-1 with the SEC for the stock offered pursuant to this prospectus. This prospectus does not include all of the information contained in the registration statement and its exhibits. We have included all material terms of the registration statement and the related exhibits and schedules that are referred to in this prospectus. You should refer to the registration statement and its exhibits for additional information. We are also required to file annual, quarterly and special reports, proxy statements and other information with the SEC.

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.

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HEMOSENSE, INC.

INDEX TO FINANCIAL STATEMENTS

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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 accompanying balance sheets and the related statements of operations, of stockholders equity (deficit) and of cash flows 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 year 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 appearing under Item 16(b) on page II-6 presents fairly, in all material respects, the information set forth therein when read in conjunction with the related financial statements. These financial statements and the 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	37	38
Borrowings, current portion	2,000	529
Total current liabilities	4,225	1,797
Capital lease, net of current portion	52	91
Borrowings, net of current portion	4,714	2,855
Total liabilities	8,991	4,743
Commitments (Note 9)		
Redeemable convertible preferred stock, $0.001 par value Authorized: 25,749,840 shares at September 30, 2004 and 10,000,000 at September 30, 2005; Issued and outstanding: 23,635,791 shares at September 30, 2004 and none at September 30, 2005		36,679
Stockholders equity (deficit):		
Common stock, $0.001 par value Authorized: 50,000,000 shares; Issued and outstanding 9,604,989 and 337,347 at September 30, 2005 and September 30, 2004, respectively	10	
Additional paid-in capital	57,191	220
Accumulated other comprehensive loss	(3)	

Accumulated deficit	(47,186)	(35,440)
Total stockholders equity (deficit)	10,012	(35,220)
Total liabilities, redeemable convertible preferred stock and stockholders equity (deficit)	$ 19,003	$ 6,202

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

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HEMOSENSE, INC.

STATEMENTS OF OPERATIONS

(In thousands, except per share data)

	Years Ended September 30,		
	2005	**2004**	**2003**
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
Sales and marketing	6,733	5,206	3,186
General and administrative	1,962	1,499	912
Total operating expenses	9,954	8,103	5,779
Loss from operations	(10,557)	(9,918)	(6,871)
Interest income	130	16	39
Interest expense	(1,314)	(318)	(67)
Other expense, net	(5)	(41)	(11)
Net loss	$ (11,746)	$ (10,261)	$ (6,910)
Net loss per common share:			
Basic and diluted	$ (4.26)	$ (30.45)	$ (20.69)
Shares used to compute net loss per common share:			
Basic and diluted	2,758	337	334

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

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HEMOSENSE, INC.

STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY (DEFICIT)

(In thousands)

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Shareholders
	Shares	Amount	Capital	Loss	Deficit	Deficit
Balance at September 30, 2002	332	$	$ 95	$	$ (18,269)	$ (18,174)
Exercise of stock options	1					
Conversion of preferred stock into common stock	5		96			96
Common stock warrants for services			12			12
Issuance of non-employee common stock options for services			17			17
Net loss					(6,910)	(6,910)
Balance at September 30, 2003	338		220		(25,179)	(24,959)
Net loss					(10,261)	(10,261)
Balance at September 30, 2004	338		220		(35,440)	(35,220)
Exercise of stock options	35		35			35
Issue of common stock warrants in connection with borrowings			264			264
Conversion of preferred stock into common stock	5,679	6	40,003			40,009
Exercise of stock warrants	41		10			10
Issuance of common stock	3,512	4	16,659			16,663
Change in unrealized loss on short term investments				(3)		(3)
Net loss					(11,746)	(11,746)
Balance at September 30, 2005	9,605	$ 10	$ 57,191	$ (3)	$ (47,186)	$ 10,012

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

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HEMOSENSE, INC.

STATEMENTS OF CASH FLOWS

(In thousands)

	Years Ended September 30,		
	2005	**2004**	**2003**
Cash Flows From Operating Activities:			
Net loss	$ (11,746)	$ (10,261)	$ (6,910)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,292	793	240
Amortization of debt issuance costs	329	64	1
Provision/write-off of inventories	138	109	89
Provision for doubtful accounts	71		
Stock-based compensation expenses			29
Amortization of prepaid royalties	348	58	
Accrued interest on note payable	96	18	
Changes in assets and liabilities:			
Accounts receivable	(1,251)	(773)	(134)
Prepaid expenses and other assets	(506)	119	(55)
Inventories	(1,583)	(319)	(146)
Accounts payable	490	352	71
Accrued expenses and other liabilities	468	322	134
Net cash used in operating activities	(11,854)	(9,518)	(6,681)
Cash flows from investing activities			
Proceeds from sale of short term investments	1,000		
Purchases of short term investments	(8,943)		
Acquisition of property and equipment	(270)	(429)	(397)
Net cash used in investing activities	(8,213)	(429)	(397)
Cash flows from financing activities			
Proceeds from issuance of common stock	16,663		
Proceeds from exercise of warrants and options	45		
Proceeds from issuance of preferred stock, net of issuance costs	3,330	3,008	6,395
Principal payments on capital lease obligation	(40)	(44)	(34)
Proceeds from borrowings	6,093	2,907	991
Repayment of borrowings	(2,859)	(936)	(105)
Net cash provided by financing activities	23,232	4,935	7,247
Net increase (decrease) in cash and cash equivalents	3,165	(5,012)	169
Cash and cash equivalents at beginning of year	433	5,445	5,276
Cash and cash equivalents at end of year	$ 3,598	$ 433	$ 5,445

Supplemental disclosure of cash flow information			
Cash paid during the period for interest	$ 1,314	$ 318	$ 68
Non-cash investing activities:			
Property and equipment acquired under capital leases	$	$	$ 99
Non-cash financing activities:			
Issuance of preferred stock in exchange for supply and license agreement and prepaid royalties	$	$ 565	$ 1,245
Issuance of warrants in connection with debt	$ 264	$ 354	$ 24
Conversion of preferred stock to common stock	$ 40,009	$	$ 95

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

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HEMOSENSE, INC.

NOTES TO FINANCIAL STATEMENTS

1. Formation and Business of the Company

Description of the Company

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

Liquidity

The Company has incurred significant losses and negative cash flows from operations since its inception. At September 30, 2005, the Company had an accumulated deficit of $47.2 million. Management intends to raise additional funds through sales of the Company s products and external financings and to eventually achieve positive cash flows. Although management continues to pursue these plans, there is no assurance that they will be successful. As is further discussed in note 17, on November 5, 2005 the Company closed a private equity offering of $9.3 million. Management believes that existing cash and short-term investments, as augmented by the proceeds received from the private placement will provide sufficient capital through at least September 2006.

If at any time sufficient capital is not available, either through existing capital resources or through raising additional funds, the Company may be required to delay, reduce the scope of, eliminate or divest one or more of its sales and marketing programs, research and development programs or its entire business. The company 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 the Company when needed on acceptable terms or at all. Therefore, the Company may raise additional capital from time to time when market conditions are favorable, or if strategic considerations require the Company to do so, even if it has sufficient funds for planned operations.

2. Summary of Significant Accounting Policies

Use of estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and

liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. These estimates and assumptions include reserves and write-downs related to accounts receivables and inventories, the recoverability of long-lived assets, deferred tax assets and related valuation allowances and valuation of equity instruments.

Certain risks and uncertainties

Any future products developed by the Company will require approval from the United States Food and Drug Administration (FDA) or foreign regulatory agencies prior to commercial sales and are subject to continued regulations once approved. There can be no assurance that the Company s future products will receive the necessary approvals. If the Company is denied such approvals or such approvals are delayed, it could have a material adverse effect on the Company.

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A portion of the Company s sales occur outside of the United States, principally in Europe. As a result, the Company must comply with a wide variety of foreign laws and regulations. In particular, the Company may be materially adversely affected by changes in the political, social and economic conditions in these countries, and by changes in government policies with respect to such matters as laws and regulations, method to address inflation, currency conversion and restrictions and rate and method of taxation.

The Company currently has three single source suppliers which produce reagents used in test strip manufacturing and meters. Because of the custom nature of the components and the FDA requirements for validation and verification of significant changes, any interruption or delay in the supply of these materials could impair the Company s ability to meet the demand of customers and could have a material adverse effect on the Company, including the need to obtain additional regulatory approval.

Cash and cash equivalents

The Company considers all highly liquid investments with maturities of three months or less at the date of purchase to be cash equivalents.

Short-term investments

All marketable securities as of September 30, 2005 are considered to be available-for-sale short term investments and are carried at fair value. Available-for-sale securities are classified as current assets when they have scheduled maturities of less than one year. Available-for-sale securities are classified as non current assets when they have scheduled maturities of more than one year. Unrealized holding gains or losses on such securities are reported as a separate component of stockholders equity (deficit) until realized. Realized gains and losses on sales of all such securities are reported in interest and other income and are computed using the specific identification cost method.

Fair value of financial instruments

The carrying amount of the Company s financial instruments, including cash and cash equivalents, accounts payable and accrued liabilities approximate fair values due to their short maturities. Based on the borrowing rates currently available to the Company for loans with similar terms, the carrying value of the loan, debt payable and capital lease obligations approximate their fair values.

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.

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Significant revenue concentrations are as follows (in thousands):

	Years Ended September 30,					
	2005		2004		2003	
	Revenue	Percent of Total Revenue	Revenue	Percent of Total Revenue	Revenue	Percent of Total Revenue
Customer A	$ 2,100	24%	$ 1,008	31%	$ 178	42%
Customer B	$ 1,654	19%	$ 860	26%		
Customer C	$ 1,105	13%	$			

Significant accounts receivable concentrations are as follows (in thousands):

	Years Ended September 30,			
	2005		2004	
	Receivable Balance	Percent of Total Receivables	Receivable Balance	Percent of Total Receivables
Customer A	$ 747	36%	$ 279	31%
Customer B	*	*	229	25%
Customer C	*	*	126	14%

* Accounts receivable at year end was less than 10% of total receivables.

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. For the years ended September 30, 2005, 2004 and 2003, the Company increased its inventory reserve by $0, $284,000 and $223,000, respectively, for the cost of the test strips, which is recorded as a component of cost of goods sold.

Property and equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Property and equipment are depreciated on a straight-line basis over their estimated useful lives, which is generally three to five years. Amortization of leasehold improvements is computed using the straight-line method over the shorter of the useful life or remaining lease terms. Upon sale or retirement, the asset s cost and related accumulated depreciation and amortization are removed from the accounts and any related gain or loss is reflected in statements of operations. Repairs and maintenance costs are charged to expenses as incurred.

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.

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

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable are recorded at the invoiced amount and do not bear interest. 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. Account balances are charged off against the allowance when it is probable that the receivable will not be recovered.

Research and development

Research and development costs are charged to operations as incurred and consist primarily of personnel costs, consultants and supplies.

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

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ability to reasonably estimate warranty expenses, unforeseen changes in factors impacting the estimate for warranty could occur and such changes could cause a material change in the Company s warranty accrual estimate. Such a change would be recorded in the period in which the change was identified. Changes in the Company s product warranty liability during the fiscal year ended September 30, 2005, 2004 and 2003 were as follows (in thousands):

Balance, October 1, 2002	$
Accruals for warranties issued during the year	2
Balance, September 30, 2003	2
Accruals for warranties issued during the year	11
Settlement made in kind during this year	(7)
Balance, September 30, 2004	6
Accruals for warranties issued during the period	118
Settlement made in kind during this year	(65)
Balance, September 30, 2005	$ 59

Advertising Expense

Advertising costs, included in sales and marketing expenses, are expensed as incurred. Advertising cost were $404,000, $290,000 and $186,000 for the years ended September 30, 2005, 2004 and 2003, respectively.

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.

Net loss per common share

Basic net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted average number of common shares outstanding during the period. Diluted net loss per common share is computed by giving effect to all potential dilutive common shares, including options, warrants and redeemable convertible preferred stock.

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

	Years Ended September 30,		
	2005	2004	2003
Redeemable convertible preferred stock (as if converted)		5,909	5,337
Options to purchase common stock	1,028	817	596
Warrants to purchase redeemable convertible preferred stock		98	8
Warrants to purchase common stock	182	45	45

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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.

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

	Years Ended September 30,		
	2005	2004	2003
Net loss as reported	$ (11,746)	$ (10,261)	$ (6,910)
Less: total stock-based employee compensation expenses, determined under fair value based method for all awards	(51)	(56)	(46)
Adjusted net loss	$ (11,797)	$ (10,317)	$ (6,956)
Net loss per common share, basic and diluted:			
As reported	$ (4.26)	$ (30.45)	$ (20.69)
As adjusted	$ (4.28)	$ (30.61)	$ (20.83)

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

	Years Ended September 30,		
	2005	2004	2003
Expected volatility	62%	0%	0%
Risk-free interest rate	3.96%	4.89%	2.36%
Dividend yield	0%	0%	0%
Expected life (in years)	5	5	5

Weighted average fair value of options granted	$ 1.52	$ 0.28	$ 0.28

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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Comprehensive loss

Comprehensive loss is comprised of net loss and changes in unrealized losses on short term investments. There were no material differences between net loss and comprehensive loss for the year ended September 30, 2005. There were no comprehensive losses for the years ended September 30, 2004 and 2003.

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. (SAB) 107, *Share-Based Payment* . 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

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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.

3. Short Term Investments

The cost and fair market value of available-for-sale securities at September 30, 2005 are as follows (in thousands):

	Cost	Unrealized (Loss)	Fair Value	Maturity Date
Short-term marketable securities				
Commercial paper	$ 5,965	$ (2)	$ 5,963	October 2005 January 2006
Government agency	1,981	(1)	1,980	December 2005 January 2006
	$ 7,946	$ (3)	$ 7,943	

4. Inventories

Inventories consist of the following (in thousands)

	September 30,	
	2005	2004
Raw materials	$ 881	$ 773
Work-in-progress	1,138	292
Finished goods	725	234
	$ 2,744	$ 1,299

5. Plant Property and Equipment, net

Property and equipment consist of the following (in thousands),:

	September 30,	
	2005	2004
Lab equipment	$ 326	$ 326
Manufacturing equipment	2,112	1,881
Computer equipment	357	263
Furniture and equipment	217	210
Leasehold improvements	2	
Equipment in progress		66
	3,014	2,746
Less accumulated depreciation and amortization	(2,502)	(1,633)
	$ 512	$ 1,113

Included in property and equipment at September 30, 2005 and 2004 is equipment acquired under capital leases totaling $240,000 and related accumulated amortization of $229,000 and $177,000, respectively.

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Depreciation expense for the years ended September 30, 2005, 2004 and 2003 was $871,000, $546,000 and $239,000, respectively.

6. Accrued Liabilities

Accrued liabilities consist of the following (in thousands)

	September 30,	
	2005	2004
Payroll and related expenses	$ 619	$ 424
Consulting	119	25
Accrued inventory payables	244	
Other liabilities	177	242
	$ 1,159	$ 691

7. Technology Licenses and Prepaid Royalties

Technology licenses consist of the following (in thousands):

	September 30,	
	2005	2004
Dade Behring License	$ 1,245	$ 1,245
Inverness License	122	122
	1,367	1,367
Less: Accumulated amortization	(685)	(247)
	$ 682	$ 1,120

The licenses are amortized over their contractual lives of approximately 3-4 years. Amortization expense was $438,000, $247,000 and $0 for the years ended September 30, 2005, 2004 and 2003, respectively.

Estimated amortization of the technology licenses are $438,000, $196,000, $23,000 and $25,000 for the years ending September 30, 2006, 2007, 2008 and 2009, respectively.

Prepaid royalties related to technology licenses consist of the following (in thousands):

	September 30,	
	2005	2004
Dade Behring License	$ 260	$ 534
Inverness License	237	310
Total	$ 497	$ 844

In May 2003, the Company extended an existing non-exclusive Supply and License Agreement with Dade Behring Inc. (the Dade Behring License) in exchange for 787,919 shares of the Company s Series C-1 preferred stock valued at $1.58 per share (Note 11). The Dade Behring License also provides for quarterly payment of royalties based on net revenue on certain product sales and expires in March 2007, unless extended.

In June 2004, the Company received a credit for prepayment of $1.0 million for future royalties under the Dade Behring License in exchange for 357,570 shares of the Company s Series C-2 preferred stock valued at $565,000. The value of the preferred stock was capitalized as a royalty prepayment and will be amortized as revenues are generated, subject to the terms of the royalty agreement.

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On April 29, 2003, Inverness Medical Switzerland GmbH (Inverness) filed a complaint in the United States District Court for the District of Massachusetts, alleging that disposable test strips for the Company s INRatio System infringes certain issued patents. Inverness sought monetary damages and injunctive relief. On July 16, 2004, a settlement and mutual release agreement was signed between the Company and Inverness whereby the Company received a fully paid up license to the Inverness patent (the Inverness License), subject to a royalty to be accrued commencing July 16, 2006 and issued to Inverness a secured subordinated note in the amount of $1.0 million as payment in lieu of any alleged past damages, costs, expenses and legal fees.

The total value of the note payable was estimated to be $459,000 (Note 8). Of this amount, $337,000 was accounted for as prepaid royalties to be amortized over the initial free period in the Inverness agreement. The remaining portion of $122,000 was accounted for as a technology license to be amortized over the remaining life of the patent which ends in November 2009.

8. Borrowings

The Company s borrowings consist of the following (in thousands):

	September 30,	
	2005	2004
Lighthouse Capital loan payable	$ 6,141	$ 2,907
Inverness note payable net of unamortized discount of $427	573	477
Total	$ 6,714	$ 3,384

Lighthouse Capital Loan Payable

In March 2004, the Company obtained a secured loan commitment of $7.5 million from partnerships of Lighthouse Capital. The Company was entitled to draw against the loan commitment through March 1, 2005. During the drawdown period interest was paid monthly a rate equal to prime plus 7.5% which was 12.0% at September 30, 2004. Beginning March 1, 2005, principal and interest payments are made over a 36 month period at a rate equal to 3.1% of the total amounts borrowed, based on prime of 4.0%, subject to adjustment as of this date due to changes in prime. A final payment, equal to 12.5% of the amounts borrowed is due March 1, 2008. The effective interest rate during the repayment period is 16.4%. In addition, the Company will also pay a facility fee of 1.0% per annum, quarterly, on the average unused portion of the loan through March 1, 2005. During 2005, the Company had drawn down the entire $7.5 million and repaid $1.4 million during the year. Future minimum payments under the secured loan are as follows (in thousands):

For the years ending September 30,	
2006	$ 2,000
2007	2,353
2008	1,788

Total	$ 6,141

The Company is permitted to prepay the amounts borrowed for a fee of 2.0% to 3.0% of the outstanding loan balance.

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In connection with the secured loan commitment, the Company issued warrants to purchase shares of the Company s Series C-2 Preferred Stock at an exercise price of $1.58 per share, which were subsequently exchanged for Series C-3 Preferred Stock. On July 1, 2005 the warrants to purchase preferred stock were converted to warrants to purchase common stock of the Company. The number of shares underlying these warrants are based on the total amount drawn under the loan commitment. The warrants are immediately exercisable. As the Company drew against the loan commitment, the fair value of the warrants were recorded as an asset and amortized to interest expense over the life of the loan using the effective interest method. As of September 30, 2005, the warrants were exercisable into 118,670 shares.

The fair value of the warrants granted was estimated on the date of the grant using the following assumptions:

Risk-free interest rate	3.49% - 4.68%
Volatility	60%
Expected life	7 years
Dividend yield	0%

Inverness Note Payable

The note payable in the amount of $1.0 million to Inverness issued in conjunction with the litigation settlement was recorded at its estimated net present value of $459,000 based on an 18.5% estimated incremental borrowing rate. This amount is being accreted up to the amount due on July 16, 2009. The accretion is recorded as interest expense in the statement of operations. The note accrues interest at 5% per annum. However, no interest accrues or is due prior to July 16, 2006. The Company may at any time, prepay all or any portion of the principal amount and accrued interest, if any. Of the total value of the note payable, $337,000 was recorded as prepaid royalties and the remaining amount of $122,000 was capitalized as a license.

9. Commitments

Capital Leases

The Company leases certain equipment under capital leases which expire through March 2008.

Future minimum lease payments under capital lease agreements are as follows (in thousands):

For the years ending September 30,	
2006	$ 46
2007	40
2008	17
Total minimum lease payments	103
Less: Amount representing interest	(14)

Present value of minimum lease payments	89
Less: Current portion of capital lease obligation	(37)
Long-term portion of capital lease obligation	$ 52

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Operating Leases

The Company rents its facility under a non-cancelable operating lease, which expires in April 2009, unless extended. Future minimum lease payments under the non-cancelable operating lease agreement are as follows (in thousands):

For the years ending September 30,	
2006	$ 143
2007	153
2008	162
2009	90
	$ 548

Rent expense for the years ended September 30, 2005, 2004 and 2003 was $143,000, $189,000 and $190,000, respectively.

The Company rents office equipment under a non-cancelable operating lease which expires in September 8008 unless extended. Future minimum payments under the non-cancelable operating lease agreement are as follows (in thousands):

For the years ending September 30,	
2006	$ 8
2007	8
2008	7
	$ 23

Purchase Commitments

In 2005, the Company entered into purchase commitments containing cancelable and non-cancelable components. At September 30, 2005 the Company has $2.7 million of cancelable commitments and $504,000 of non-cancelable commitments.

Indemnifications

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company s exposure under these agreements is unknown because it involves future claims that may be made against the Company in the future, but have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations, and accordingly, the Company has not accrued any amounts for such indemnification

obligations. However, the Company may record charges in the future as a result of these indemnification obligations.

10. Redeemable Convertible Preferred Stock

Under the Company s Certificate of Incorporation, as amended, the Company is authorized to issue preferred stock in series. The Company s Board of Directors is authorized to determine the rights, preferences and terms of each series. On July 1, 2005 in conjunction with our initial public offering the Company converted all 21,956,251 shares of preferred stock into 5,489,045 shares of common stock. On February 7, 2005 the Company converted 3,803,758 shares of preferred stock into 190,185 shares of common stock. As of September 30, 2005 there is no preferred stock outstanding.

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As of September 30, 2004, the redeemable convertible preferred stock consisted of the following (in thousands, except per share data):

	Number of Shares Designated and Authorized	Number of Shares Issued and Outstanding	Proceeds of Preferred Stock, net/fair value of warrants	Redemption Value per Share	Liquidation Value	Common Stock Reserved for Conversion
Series A-2	1,430	1,430	$ 1,403	$ 1.00	$ 1,430	357
Series B-2	3,813	3,813	6,008	$ 1.58	6,025	953
Series C-2	20,507	18,393	28,890	$ 1.58	58,122	4,598
Preferred stock warrants		392	378	$		98
	25,750	24,028	$ 36,679		$ 65,577	6,006

In February 2005, the Company raised approximately $3.4 million by issuing 2,124,218 shares of Series C-3 preferred stock at $1.58 per share. As a result, participating holders of the Series A-2, B-2 and C-2 preferred stock converted to Series A-3, B-3 and C-3 preferred stock, respectively. 3,803,758 shares of non-participating preferred stock converted into 190,185 shares of common stock.

11. Stockholders Equity (Deficit)

Preferred stock

The Company is authorized to issue 10,000,000 shares of preferred stock. The board of directors has authority to issue the preferred stock in one or more series and to fix the price, rights preferences, privileges and restrictions thereof, including the dividend rights, dividend rates, conversion rights, voting rights terms of redemption, redemption prices, liquidation preferences and the number of shares constituting a series or the designation of such series, without any further vote or action by the Company s stockholders. In accordance with the Company s stockholder rights plan, 25,000 shares of the preferred stock have been designated as Series A participating preferred stock. None of the shares of Series A participating preferred stock were issued and outstanding as of September 30, 2005.

Initial Public Offering

The Company registered the initial public offering of its common stock, par value $0.001 per share, on a Registration Statement on Form S-1 (Registration No. 333-123705), which was declared effective on June 28, 2005. On July 1, 2005 the Company closed the initial public offering of the Company s 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. Upon the closing of the IPO, all of the outstanding shares of the Company s redeemable convertible preferred stock converted into 5,489,045 shares of the Company s common stock. Also, warrants issued to purchase 507,912 shares of the Company s redeemable convertible preferred stock were converted into warrants to purchase 126,977 shares of the Company s common stock.

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Common Stock

Each share of common stock is entitled to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the Board of Directors, subject to the prior rights of holders of all classes of stock outstanding. To date, no dividends have been declared.

Reverse Stock Split

On May 4, 2005, the Company effected a one-for-four reverse stock split of the Company s common stock and as a result the conversion ratio of the Company s preferred stock automatically adjusted to one-for-four. All share and per share amounts contained in the financial statements are retroactively adjusted accordingly.

Common Stock Warrants

Common stock warrants outstanding as of September 30, 2005 are as follows:

	Date of Issuance	Number of Warrants Issued	Exercise Price	Expiration Date	Fair Value
Notes Payable	April 2005	54,542	$ 5.50	April 2010	$ 149,000
Loan agreement	March 2004	118,670	$ 6.32	March 2011	$ 470,000
Equipment Financing agreement	July 2003	8,307	$ 6.32	July 2010	$ 24,000
Total		181,519			

As of September 30, 2005, all of these warrants were vested and none have been exercised. The fair values of these warrants were determined using Black-Scholes model and they have been recorded as an expense over the life of the loan.

12. Stock Option Plans

1997 Stock Option Plan

In 1997, the Company adopted the 1997 Stock Option Plan (the 1997 Plan), as amended, under which 1.1 million shares of the Company s common stock have been reserved for issuance to employees, directors and consultants. Options granted under the 1997 Plan may be incentive stock options or non-statutory stock options. Stock purchase rights may also be granted under the 1997 Plan. Incentive stock options may only be granted to employees. Options granted or stock purchased under the 1997 Plan must become exercisable or the Company s right to repurchase lapse no less than 20% after one year and ratably over 4 years thereafter. In addition, there were 463,375 options granted under the 1997 plan to certain employees in which the vesting will fully accelerate upon the occurrence of a change in control. Included in these options are 527,500 options granted to certain employees of which 20% became vested on an accelerated basis on the IPO effective date. The exercise price of incentive stock options and non-statutory stock options shall be no less than 100% and 85%, respectively, of the fair value per share of the Company s common stock on the grant date, as determined by the Board of Directors. The term of the options is ten years. Since the implementation of the 2005 Equity Incentive Plan, no additional options will be granted from this plan and the plan will terminate when all the shares have been either exercised, cancelled or expire.

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2005 Equity Incentive Plan

In March 2005, the Company s board of directors and stockholders approved the 2005 Equity Incentive Plan (the 2005 Plan), which became effective upon completion of its initial public offering on July 1, 2005. The Company has reserved a total of 50,000 shares of its common stock for issuance under the 2005 Plan, all of which are available for future grant. In addition, any unused shares in or any unvested shares under the 1997 Plan as of the effective date of an initial public offering has been added to the 2005 Plan.

Activity under both plans is as follows (in thousands except weighted average exercise price):

		Outstanding Options	
	Shares Available for Grant	Number of Shares	Weighted Average Exercise Price
Balance, September 30, 2002	119	487	$ 0.96
Options granted	(112)	112	$ 0.80
Options exercised		(1)	$ 0.80
Options cancelled	2	(2)	$ 2.13
Balance, September 30, 2003	9	596	$ 0.93
Additional shares authorized	262		
Options granted	(313)	313	$ 0.80
Options cancelled	92	(92)	$ 0.83
Balance, September 30, 2004	50	817	$ 0.89
Additional shares authorized	238		
Options granted	(377)	377	$ 2.30
Options exercised		(35)	$ 1.00
Options cancelled	131	(131)	$ 1.14
Balance, September 30, 2005	42	1,028	$ 1.37

The options outstanding and exercisable by exercise price at September 30, 2005 are as follows (in thousands, except per share amounts):

Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Number Exercisable	Weighted Average Exercisable Price
$0.10 - $0.70	34	2.23	34	$ 0.62
$0.70 - $0.80	896	7.87	559	$ 0.80

$0.80 - $2.00	2	3.97	2	$	2.00
$2.00 - $3.00	11	4.12	11	$	2.80
$3.00 - $7.00	27	9.65		$	0.00
$7.01 - $8.00	39	9.83		$	0.00
$8.00 - $9.00	19	9.85		$	0.00
	1,028		606	$	$0.83

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At September 30, 2004 there were 817,000 options outstanding at the weighted average exercise price of $0.95 per share. There were no stock options granted to employees with exercise prices below estimated fair market value on the date of grant.

13. Employee 401(k) Plan

In January 2001, the Company adopted a defined contribution retirement plan (the 401k Plan), which qualifies under Section 401(k) of the Internal Revenue Code of 1996. The 401k Plan covers all employees in the United States with a minimum of three months of service. The Company has made no contributions to date.

14. Income Taxes

A reconciliation of income taxes at the statutory federal income tax rate to income tax expense in the statement of operations is as follows (in thousands):

	2005	2004	2003
Pretax loss	$ (11,746)	$ (10,261)	$ (6,910)
Benefit at federal statutory rate	(3,993)	(3,489)	(2,350)
State, net of federal benefit	(697)	(428)	(349)
Meals and entertainment	18	13	8
Non-cash interest expense			18
Research and development credit	(92)	17	(286)
Other	(153)	(258)	289
Valuation allowance	4,917	4,145	2,670
Provision for taxes	$	$	$

At September 30, 2005, the Company had net operating loss carryforwards of approximately $45.5 million and $40.4 million available to reduce future taxable income, if any, for both federal and California state income tax purposes, respectively. The net operating loss carryforwards will begin to expire in 2007 and will completely expire in 2025.

The Company also has research and development tax credit carryforwards of approximately $789,000 and $756,000 for federal and state income tax purposes, respectively. If not utilized, the federal carryforwards expire in 2025. The state tax credits can be carried forward indefinitely.

Under the Tax Reform Act of 1986, the amounts of and benefits from net operating loss carryforwards may be impaired or limited in certain circumstances. Events which cause limitations in the amounts of net operating losses that the Company may utilize in any one year include, but are not limited to, a cumulative ownership change of more than 50%, as defined, over a three year period.

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The tax effects of temporary differences and carryforwards that give rise to significant portions of the deferred tax assets are as follows (in thousands):

	Year Ended September 30,	
	2005	2004
Deferred tax assets		
Fixed assets	$ 280	$ 214
Reserves and accruals	582	341
Net operating loss carryforwards	17,812	13,294
Research and development credits	1,288	1,196
	19,962	15,045
Less: Valuation allowance	(19,962)	(15,045)
	$	$

The Company has established a 100% valuation allowance against its deferred tax assets due to the uncertainty surrounding the realization of such assets. Annually, management evaluates the recoverability of the deferred tax assets and the amount of the required valuation allowance. At such time as it is determined that it is more likely than not that deferred tax assets are realizable the valuation allowance will be reduced.

15. Related Party Transactions

During the year ended September 30, 2003, the Company paid Innovative Medical Products GmbH (IMed Pro), a services company in Germany affiliated with Gregory Ayers, a Board member, $436,000 for clinical trials consulting and distribution services. During the year ended September 30, 2004, the Company paid IMed Pro for distribution services of $560,000. The agreements between the Company and IMed Pro were terminated effective January 1, 2005. Since January 2005 I-Med-Partner GmbH (IMedPartner) has served as a distributor in Germany and purchased $416,000 of product. IMed Pro is a shareholder of IMedPartner.

Edward Brennan, Ph.D., one of the Company s directors, has provided consulting services to the Company not directly related to his service as a board member. During the past three fiscal years, payments were made to Dr. Brennan of $23,000 in 2005, $58,750 in 2004 and $15,000 in 2003 for these consulting services.

The Company paid Dade Behring Inc., a stockholder which had a representative on the Company s Board of Directors, $8,000 and $102,000 of license royalties for the years ended September 30, 2003 and 2004, respectively. Also, as discussed in Note 7, in May 2003 the Company issued 787,919 shares of preferred stock valued at $1,245,000 to Dade Behring Inc. to extend the Dade Behring License, and in June 2004, the Company issued 357,570 shares of preferred stock valued at $565,000 to Dade Behring Inc. for the prepayment of $1.0 million of future license royalties.

16. Segment Information

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

	Years Ended September 30,		
	2005	2004	2003
United States	$ 6,473	$ 2,556	$ 323
Germany	1,227	556	93
Spain	564		
Other	504	138	11
	$ 8,768	$ 3,250	$ 427

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17. Subsequent Event

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 and issued warrants to purchase 740,741 shares of the Company s common stock at $8.165 per share. Gross proceeds from the offering were $10.0 million. Total expenses from the offering were approximately $850,000 which included underwriting discounts and commissions of $600,000.

18. Quarterly Financial Data (unaudited)

	Quarter Ended							
	Sept. 30, 2005	Jun. 30, 2005	Mar. 31, 2005	Dec. 31, 2004	Sept. 30, 2004	Jun. 30, 2004	Mar. 31, 2004	Dec. 31, 2003
	(in thousands, except share data)							
	(unaudited)							
Revenue	$ 2,897	$ 2,454	$ 1,800	$ 1,617	$ 1,094	$ 889	733	$ 534
Gross profit (loss)	352	(33)	(539)	(383)	(551)	(622)	(355)	(287)
Loss from operations	(2,598)	(2,425)	(2,898)	(2,636)	(2,663)	(2,824)	(2,459)	(1,972)
Net loss	$ (2,834)	$ (2,947)	$ (3,119)	$ (2,846)	$ (2,812)	$ (2,951)	$ (2,513)	$ (1,985)
Net loss per common share, basic and diluted	$ (0.30)	$ (5.29)	$ (7.15)	$ (8.35)	$ (8.34)	$ (8.76)	$ (7.46)	$ (5.89)