HEMOSENSE INC
Form 424B3
March 09, 2007
Table of Contents

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Registration No. 333-140160

PROSPECTUS

1,772,151 Shares

Common Stock

This prospectus relates to the public offering, which is not being underwritten, of up to 1,772,151 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 22. 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 January 19, 2007, the last sale price of our common stock was $4.35 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 4.

The Securities and Exchange Commission, or SEC, 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 SEC 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 March 9, 2007

Table of Contents

TABLE OF CONTENTS

	Page
Prospectus Summary	1
Special Note Regarding Forward-Looking Statements	3
Risk Factors	4
Use of Proceeds	20
Selling Stockholders	21
Plan of Distribution	22
Legal Matters	25
Experts	25
Incorporation of Certain Information by Reference	26
Where You Can Find Additional Information	27

INFORMATION CONTAINED IN THIS PROSPECTUS

You should rely only on the information provided or incorporated by reference in this prospectus or any prospectus supplement. Neither we nor the selling stockholders have authorized anyone to provide you with additional or different information. The selling stockholders are not making an offer of these securities in any jurisdiction where the offer is not permitted. You should assume that the information in this prospectus and any prospectus supplement is accurate only as of the date on the front of the document and that information incorporated by reference in this prospectus or any prospectus supplement is accurate only as of the date of the document incorporated by reference. In this prospectus and any prospectus supplement, unless otherwise indicated, HemoSense, we, us and our refer to HemoSense, Inc. and do not refer to the selling stockholders.

Table of Contents

PROSPECTUS SUMMARY

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

HemoSense, Inc.

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 four million people in the United States who take warfarin daily. In 2005, there were over 30 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 21.4 million PT/INR tests conducted on U.S. Medicare patients in 2005, comprised of approximately 15.3 million clinical laboratory tests and 6.1 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 50% over this four-year period, with 24% growth in the laboratory testing market, as compared with 258% 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 120,000 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

Table of Contents

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

After receiving U.S. and European regulatory clearances in 2002, we commercially launched the INRatio System in March 2003 in the U.S. and certain European markets. Tests performed using our INRatio System in the point-of-care setting are currently reimbursed by Medicare for all patients on warfarin as is self-testing by mechanical heart valve patients on warfarin. We have established distribution agreements with several national and regional distributors of medical products, giving us access to over 2,000 U.S. sales representatives for the sale of the INRatio System. In addition, we have established international distribution agreements with 15 distribution partners covering 22 countries outside the United States.

Corporate Information

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

We own or have rights to use trademarks or trade names that we use in conjunction with the operation of our business. HemoSense® and INRatio® are registered trademarks of our company. Other service marks, trademarks and trade names referred to in this prospectus are the property of their respective owners.

The Offering

Common stock offered by the selling stockholders	1,772,151 shares
Use of proceeds	We will not receive any proceeds from the sale of the shares of our common stock by the selling stockholders.
American Stock Exchange symbol	HEM

Table of Contents

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

We have made forward-looking statements in this prospectus and in documents that we incorporate by reference into this prospectus. We base these forward-looking statements on our expectations, assumptions, estimates and projections about our business and the industry in which we operate as of the date of this prospectus. These forward-looking statements are subject to a number of risks and uncertainties that cannot be predicted, quantified or controlled and that could cause actual results to differ materially from those set forth in, contemplated by, or underlying the forward-looking statements. Statements in this prospectus, and in documents incorporated into this prospectus, including those set forth below in Risk Factors, describe factors, among others, that could contribute to or cause these differences. In light of these risks and uncertainties, there can be no assurance that the forward-looking statements contained in this prospectus will in fact transpire or prove to be accurate. We do not intend to update any of these forward-looking statements.

Table of Contents

RISK FACTORS

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

We have a limited history of operations and have incurred net losses in each year since our inception. We received regulatory clearance to market our INRatio System in 2002 and began commercial sales in early 2003. During the past five fiscal years, we incurred net losses of $4.7 million in 2002, $6.9 million in 2003, $10.3 million in 2004, $11.7 million in 2005 and $10.9 million in 2006. As of September 30, 2006, we had an accumulated deficit of $58.1 million. We expect that our operating expenses will increase nominally as we expand our business, devote additional resources to our research and development, increase sales and marketing efforts and bear the costs associated with being a public company.

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

The average daily trading volume of our stock is low, and our stock price may move significantly from the trading of relatively few shares. The market price for our common stock will be affected by a number of factors, including:

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

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

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 and have been in

Table of Contents

a commercial stage for a relatively short time, 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;
- the ability of our vendors to deliver materials in the time and in quantities we need;
- new product introductions by our competitors; and
- the timing and uncertainty of United States and foreign reimbursement decisions with respect to the use of our products.

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

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

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

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

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

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

The majority of PT/INR testing has historically been and continues to be performed by large hospital or commercial laboratories. Healthcare professionals responsible for managing patients on warfarin therapy

Table of Contents

have experience with and confidence in the results generated by these large laboratories. In addition, these professionals influence many treatment decisions, including aspects critical to our business such as how often testing is to be performed, who is to perform the testing, and where testing is to be performed. In some instances, these decision makers may determine that our INRatio System test results lack the clinical history, accuracy and reliability of large laboratories. If we are unable to demonstrate to physicians satisfaction that the performance of our INRatio System closely matches the results produced by these laboratories, market acceptance of our product will be limited.

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

Our product and facilities are subject to continual review and periodic inspections by the FDA and other regulatory bodies. In particular, we are required to comply with quality system regulations, or QSR, and other regulations, which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage, shipping and post market surveillance of our product. The FDA enforces the QSR through both scheduled and unannounced inspections. During May 2005, we underwent an inspection of our facilities by the FDA, which resulted in the issuance of an FDA Form 483 and, subsequently, a warning letter, because the FDA believed that our Form 483 response did not provide sufficient detail and documentation for the FDA to evaluate whether our corrective actions would be adequate to prevent recurrence of the inspection observations. In addition, during May, June and July of 2006, we underwent another inspection of our facility by the FDA which resulted in the issuance of a FDA Form 483 identifying deficiencies in the same general area as those described in the 2005 warning letter. We submitted our response to the Form 483 in July 2006. On November 29, 2006, the FDA issued us a warning letter as a follow-up to the Form 483. This warning letter indicates among other things that the FDA believes that our responses to its FDA Form 483 notice were insufficient because we did not include analysis of root cause and because our corrective and preventative actions to address the specific observations have not yet been completed. We are in the process of preparing a further written response to the FDA to address these concerns, but we cannot assure that the FDA will accept our response as adequate or will not take enforcement action against us, which may include the following sanctions:

warning letter;

fines, injunctions and civil penalties;

recall or seizure of our products;

operating restrictions, partial suspension or total shutdown of production;

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

withdrawal of clearances or approvals; and

criminal prosecution.

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

Table of Contents

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

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

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

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

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

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

Table of Contents

access to material information about our business, which we are required to publicly disclose, while not having to disclose their own comparable information, because it is an immaterial part of their overall operations;

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

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

Because of these competitive advantages, these companies may be able to engage in aggressive practices that may harm our business, without us being able to effectively respond. In 2005, following the issuance by the FDA of a warning letter, we experienced a brief impact on our overseas sales performance as a competitor attempted to use a warning letter issued by the FDA to disrupt our customer relationships. If a warning letter were to be issued in the future, we could experience a similar adverse effect on our sales. If we are not able to compete effectively against these companies or their products, our business will be harmed.

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

Our INRatio System is used to measure the rate of blood coagulation in patients using warfarin. As a result, the size of our market is directly dependent upon the number of warfarin users. If a new drug or other anticoagulation treatment that does not require regular monitoring of PT/INR levels is successfully developed, approved and adopted, the size of the market for our product will be adversely affected. We are aware that pharmaceutical companies are researching and developing potential alternatives to warfarin. Advances in the treatment of underlying conditions could also affect the use of warfarin. For example, improvements in replacement tissue heart valves have reduced, and may in the future further reduce the use of mechanical heart valves, one of the leading indications for chronic warfarin use. Additionally, several companies are pursuing new surgical procedures to treat atrial fibrillation, another leading indication for warfarin use and monitoring. Any development that renders warfarin obsolete or diminishes the need for PT/INR testing by patients in our target markets would negatively affect our business and prospects.

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

In the United States, purchasers of medical devices, including our INRatio System, generally rely on Medicare and other insurance providers to cover all or part of the cost of the product. Currently reimbursement for PT/INR testing is available in the point-of-care environment for monitoring all uses of warfarin. However, Medicare currently only reimburses PT/INR self-testing for patients with mechanical heart valves, or approximately 400,000 mechanical heart valve patients on warfarin, which represents approximately 10% of four million United States patients taking warfarin on a daily basis. Whether Medicare expands reimbursement for PT/INR patient self-testing for other indications, such as atrial fibrillation, will be partially dependent on the outcome of ongoing and future clinical studies that we neither participate in nor have any direct control over. Coverage and reimbursement determinations are subject to change over time and we cannot assure you that Medicare will not reduce or change coverage and reimbursement policies.

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

Table of Contents

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. After international reimbursement is established, it may be severely limited or eliminated in future years. Our failure to receive international reimbursement approvals could have a material adverse effect on market acceptance of our product in the markets in which those approvals are sought.

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

We have limited experience as a company in the sale, marketing and distribution of our INRatio System. We maintain a relatively small sales and marketing team which as of November 30, 2006 was comprised of 35 employees and expect to depend heavily on third parties to sell our product both in the United States and internationally for the foreseeable future. To achieve commercial success, we must further develop our sales and marketing capabilities and enter into and maintain successful arrangements with others to sell, market and distribute our product.

We currently have agreements with seven national and four regional distributors in the United States. We also have agreements with 15 international distributors of our product. Three of our distributors, Quality Assured Services, Medline and National Distribution & Contracting, Inc., each accounted for between 12% to 21% and 53% in the aggregate, of our total revenue in fiscal 2006. Our success is dependent upon developing and maintaining current and future distribution relationships. We have only recently entered into most of our distribution relationships, which makes it difficult for us to predict their future success. Some of our distribution agreements allow either party to terminate the relationship on short notice and without fault. Additionally, we may be unable to renew a distribution agreement upon its expiration on favorable terms, or at all. Distribution partners may fail to commit the necessary resources to market and sell our product to the level of our expectations. In particular, several of our distribution partners also distribute the products of our competitors, and as a result, we compete for the attention of these distributors against the experienced and well funded efforts of our competitors. If in the future our distribution partners elect to focus on selling the products of our competitors rather than our products, our sales efforts will be seriously compromised. If we are unable to establish and maintain adequate sales, marketing and distribution capabilities, independently or with others, we may not be able to generate product revenue and may not become profitable. If our current or future partners do not perform adequately, or we are unable to locate or retain partners, as needed, in particular geographic areas or in particular markets, our ability to achieve our expected revenue growth rate will be harmed.

Table of Contents

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

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

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

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

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

The components of the INRatio System are the INRatio meter and INRatio disposable test strips. We manufacture INRatio test strips at our facility, and we contract with an electronic manufacturing services supplier to manufacture the INRatio meter. To be successful, we must manufacture our test strips in substantial quantities and at acceptable costs. We currently have limited experience manufacturing our test strips, and no experience manufacturing in the quantities that we anticipate 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.

Table of Contents

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

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

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

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

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

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

If our product is misused or otherwise produces an incorrect reading, a patient could be either underdosed or overdosed with warfarin, which could lead to serious injury or death and expose us to potential liability.

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

Currently, we have three single source suppliers: Dade Behring, which produces a reagent used in our test strips, Haematologic Technologies, which produces our control reagents, and Flextronics, which

Table of Contents

manufactures our meters. Our suppliers may encounter problems during manufacturing due to a variety of reasons, including failure to follow our protocols and procedures, failure to comply with applicable regulations, or equipment malfunction, any of which could delay or impede their ability to meet our demand. Our reliance on these outside suppliers also subjects us to other risks that could harm our business, including:

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

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

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

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

- J-PAC carries out manufacturing services for a range of customers, and fluctuations in demand for J-PAC s services for others may affect their ability to deliver finished goods to us in a timely manner;
- Risk of damage or loss of our product while in transit between sites,

Table of Contents

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

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

Additionally, we may become involved in a contractual dispute with J-PAC, or may be unable to negotiate the renewal of our contract with J-PAC, either of which could mean an interruption or delay in the obtaining J-PAC s services. Any interruption or delay in J-PAC s services, or our inability to obtain the same finished goods or services from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to cancel orders or switch to competitive products, which would harm our business.

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;

Table of Contents

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.

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.

Table of Contents

However, the costs of defending claims under the False Claims Act, as well as sanctions imposed under the Act, could significantly harm our operations.

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

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

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

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

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

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

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

Our success and ability to compete is dependent, in part, upon our ability to protect the INRatio System through our intellectual property rights. We rely on a combination of patent, copyright and trademark law, trade secrets and nondisclosure agreements to protect our intellectual property. However, such methods may not be adequate to protect us or permit us to gain or maintain a competitive advantage. Our European patent application, or any future U.S. or foreign application, may not issue as a patent or may issue as a patent

Table of Contents

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

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

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

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

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

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

Any infringement or misappropriation claim, with or without merit, could cause us to strain our financial resources, divert management s attention from our business and harm our reputation. If a third party patent were upheld as valid and enforceable and we were found to infringe such patent, we could be prohibited from selling our product unless we could obtain a license to the patent or were able to design around the patent. We may be unable to obtain such a license on terms acceptable to us, if at all, and we may

Table of Contents

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 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

Table of Contents

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.

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 Exchange Act of 1934 are substantial. In addition, the Sarbanes-Oxley Act of 2002, along with other recent rules from the SEC and Amex, have required further legal and financial compliance costs, and made some corporate actions more difficult. For example, compliance with the internal control requirements of Sarbanes-Oxley Section 404 requires us to commit significant resources to document and review the adequacy of our internal controls.

Table of Contents

While we are expending significant resources in developing the required documentation and testing procedures required by Section 404, we can provide no assurance as to conclusions by us or our external auditors with respect to the effectiveness of our internal controls over financial reporting. If we determine we have a material weakness of our internal controls under the Section 404, we will have to issue a report that our internal controls are not effective, which could cause the market price of our stock to decline.

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

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

MPM Capital and its affiliates own approximately 38% 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 contain provisions that could delay or prevent a change in control of our company. Some of these provisions:

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

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

Table of Contents

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. See Selling Stockholders and Plan of Distribution described below.

Table of Contents

SELLING STOCKHOLDERS

The 1,772,151 shares of common stock covered by this prospectus were acquired by the selling stockholders from us in a private placement consummated on December 12, 2006. The shares covered by this prospectus represent shares that to our knowledge remain unsold. The following table sets forth certain information with respect to the beneficial ownership of our common stock as of January 22, 2007 for all of the selling stockholders. We agreed to file a registration statement with the SEC covering the resale of the shares issued in the foregoing transactions.

The number of shares beneficially held before and after this offering as reported in the following table has been prepared based on the information supplied to us by the selling stockholders in connection with the initial registration of the shares covered by this prospectus. However, the selling stockholders may have purchased, sold, transferred or otherwise disposed of all or a portion of their shares of common stock since the date on which they provided such information. None of the selling stockholders has held any position or office with, or has otherwise had a material relationship with us within the past three years.

We do not know when or in what amounts a selling stockholder may offer shares of common stock for sale. The selling stockholders may choose not to sell any of the shares offered by this prospectus. Because the selling stockholders may offer all, some, or none of their shares of common stock pursuant to this offering, we cannot estimate the number of shares of common stock that the selling stockholders will hold after completion of the offering. For purposes of the following table, we have assumed that the selling stockholders will sell all of the shares of common stock covered by this prospectus.

Name of Selling Stockholder	Number of Shares Beneficially Owned Prior to Offering	Number of Shares Being Offered	Number of Shares Beneficially Owned After Offering	Percentage of Shares Beneficially Owned After Offering
New Enterprise Associates 12, Limited Partnership		1,772,151(1)		

(1) NEA 12 GP, LLC is the sole general partner of NEA Partners 12, Limited Partnership, which is the sole general partner of New Enterprise Associates 12, Limited Partnership. Peter J. Barris, M. James Barrett, Charles W. Newhall III, Ryan D. Drant, Eugene A. Trainor III, C. Richard Kramlich, Mark W. Perry, Scott D. Sandell, Forest Baskett, Peter T. Morris, Charles M. Linehan, Krishna S. Kolluri and Patrick Kerins are the managers of NEA 12 GP, LLC. As a result, Messrs. Barris, Barrett, Newhall, Drant, Trainor, Kramlich, Perry, Sandell, Baskett, Morris, Linehan, Kolluri and Kerins may be considered beneficial owners of any shares deemed to be beneficially owned by New Enterprise Associates 12, Limited Partnership. Each of the aforementioned persons disclaims beneficial interest of these shares, except to the extent of his pecuniary interest therein.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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 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.

Table of Contents

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 after giving effect to the conversion of all of our preferred stock into shares of our common stock.

EXPERTS

The financial statements incorporated in this Prospectus by reference to the Annual Report on Form 10-K for the year ended September 30, 2006 have been so incorporated 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.

Table of Contents

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to incorporate by reference in this prospectus the information that we file with them. This means that we can disclose important information to you in this document by referring you to other filings we have made with the SEC. The information incorporated by reference is considered to be part of this prospectus, and later information we file with the SEC will update and supersede this information. We incorporate by reference the documents listed below and any future filings made with the SEC under Section 13(a), 13(c), 14, or 15(d) of the Exchange Act prior to the completion of the offering covered by this prospectus:

our Annual Report on Form 10-K for our fiscal year ended September 30, 2006;

our Quarterly Report on Form 10-Q for our fiscal quarter ended December 31, 2006;

our Current Report on Form 8-K as filed with the SEC on December 14, 2006 and on February 1, 2007;

our Definitive Proxy Statement on Schedule 14A as filed with the SEC on January 29, 2007; and

the description of our common stock contained in our Registration Statement on Form 8-A filed with the SEC on June 21, 2005.

This prospectus may contain information that updates, modifies or is contrary to information in one or more of the documents incorporated by reference in this prospectus. Reports we file with the SEC after the date of this prospectus may also contain information that updates, modifies or is contrary to information in this prospectus or in documents incorporated by reference in this prospectus. Investors should review these reports as they may disclose a change in our business, prospects, financial condition or other affairs after the date of this prospectus.

Upon your written or oral request, we will provide at no cost to you a copy of any and all of the information that is incorporated by reference in this prospectus.

Requests for such documents should be directed to:

Chief Financial Officer

HemoSense, Inc.

651 River Oaks Parkway

San Jose, California 95134

(408) 719-1393

Table of Contents

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed a registration statement on Form S-3 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 (800) SEC-0330 for further information on the operation of the public reference facilities.