THERASENSE INC
Form S-8
November 29, 2001

As filed with the Securities and Exchange Commission on November 29, 2001
Registration No. 333-

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SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM S-8/S-3
REGISTRATION STATEMENT
(Including registration of shares for resale by means of a Form S-3 Prospectus)
Under
The Securities Act of 1933

THERASENSE, INC.
(Exact name of Registrant as specified in its charter)

Delaware	94-3267373
(State of incorporation)	(I.R.S. Employer Identification Number)

1360 South Loop Road
Alameda, CA 94502
(Address of principal executive offices)

1997 STOCK PLAN
(Full title of the plan)

W. Mark Lortz
President and Chief Executive Officer
TheraSense, Inc.
1360 South Loop Road
Alameda, CA 94502
(510 749-5400
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copy to:
Karen A. Dempsey, Esq.
Wilson Sonsini Goodrich & Rosati
Professional Corporation
One Market, Spear Street Tower, Suite 3300
San Francisco, CA 94105
(415) 947-2000

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CALCULATION OF REGISTRATION FEE

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Title of Securities	Amount	Proposed Maximum Offering

To be Registered	To be Registered	Price Per Share
Common Stock, par value $0.001 per share Issued under the 1997 Stock Plan.....	1,657,172 shares	$39,457,265.32

(1) The estimated Proposed Maximum Offering Price Per Share was determined pursuant to Rule 457 1933, as amended, to be equal to the average between the ask and bid price reported in the Nasda 2001.

RESALE PROSPECTUS

THERASENSE, INC.

1,657,172 SHARES OF COMMON STOCK

This Registration Statement on Form S-8/S-3 is being filed pursuant to General Instruction C to Form S-8 for the purpose of registering the resale of 1,657,172 shares of common stock previously issued under our 1997 Stock Plan.

This resale prospectus relates to 1,657,172 shares of the common stock of TheraSense, Inc., which may be offered from time to time by the selling stockholders listed on page 16 of this prospectus. It is anticipated that the selling stockholders will offer the shares for sale at prevailing market prices on the date of sale. We will not receive any proceeds from the sale of these shares. The selling stockholders will bear the expense of all sales commissions and similar expenses. Any other expenses incurred by us in connection with this registration and offering, and not borne by the selling stockholders, will be borne by us.

The shares registered hereby were acquired by the selling stockholders under our 1997 Stock Plan.

Our common stock is quoted on the Nasdaq National Market under the symbol "THER". The last reported sale price for our common stock on the Nasdaq National Market was $23.85 per share on November 28, 2001.

CONSIDER CAREFULLY THE RISK FACTORS
BEGINNING ON PAGE 3 IN THIS PROSPECTUS.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR PASSED UPON THE ADEQUACY OR ACCURACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The date of this prospectus is November 29, 2001.

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Prospectus

You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with information different from that contained in this prospectus. The selling stockholders are offering to sell, and seeking offers to buy, shares of TheraSense common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of the shares.

In this prospectus, unless indicated otherwise, "TheraSense," the "Company," "we," "us" and "our" refer to TheraSense, Inc.

INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the section entitled "Risk Factors," may contain forward-looking statements. These statements relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by the forward-looking statements. These risks and other factors include those listed under "Risk Factors" and elsewhere in this prospectus. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "intends," "potential," "continue" or the negative of these terms or other comparable terminology. These statements are only predictions. Actual events or results may differ materially.

We believe that it is important to communicate our future expectations to investors. However, there may be events in the future that we are not able to accurately predict or control and that may cause our actual results to differ materially from the expectations we describe in our forward-looking statements. Investors are cautioned that all forward-looking statements involve risks and uncertainties, and actual results may differ materially from those discussed as a result of various factors, including those factors described in the "Risk Factors" section of this prospectus.

Potential investors should not place undue reliance on our forward-looking statements. Before you invest in our common stock, you should be aware that the occurrence of the events described in the "Risk Factors" section and elsewhere in this prospectus could harm our business, prospects, operating results and financial condition.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements.

WHERE TO FIND MORE INFORMATION ABOUT THERASENSE

We have filed a registration statement on Form S-8/S-3 with the SEC for the stock the selling stockholders are offering by 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 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 www.sec.gov. You may also read and copy any document we file with the SEC at its public reference facilities at 450 Fifth Street, N.W., Washington, D.C. 20549 and Citicorp Center, 500 West Madison Street, Suite 1400, Chicago, Illinois 60661-2511. You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the SEC at 450 Fifth Street, N.W., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities.

INFORMATION INCORPORATED BY REFERENCE

The SEC allows us to "incorporate by reference" the information we file with them, which means that we can disclose important information to you by referring you to those documents that we have previously filed with the SEC or documents that we will file with the SEC in the future. The information incorporated by reference is considered to be part of this prospectus, and later information that we file with the SEC will automatically update and supercede this information. We incorporate by reference the documents listed below, and any future filings made with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, until the selling stockholders sell all of the shares registered hereby. This prospectus is part of a Registration Statement we filed with the SEC. The documents we incorporate by reference are:.

(1) Our Registration Statement on Form S-1 (File No. 333-64456) filed pursuant to Rule 424(b) under the Securities Act of 1933, as amended, declared effective on October 11, 2001.

(2) Our Quarterly Report on Form 10-Q for the quarter ended September 30, 2001 filed on November 14, 2001.

(3) The description of our common stock contained in our Registration Statement on Form 8-A declared effective by the Commission on October 11, 2001 pursuant to Section 12(g) of the Securities Exchange Act of 1934, as amended, and any description of any of our securities contained in any registration statement filed after the date hereof under Section 12 of the Exchange Act, including any amendment or report filed for the purpose of updating any such description.

We also incorporate by reference all documents that we subsequently file pursuant to Sections 13(a), 13(c), 14 and 15(d) of the Exchange Act, prior to the filing of a post-effective amendment which indicates that all securities registered have been sold or which deregisters all securities then remaining unsold, and shall be deemed to be incorporated by reference in this registration statement and to be part hereof from the date of filing of such documents.

You may request a copy of these filings, at no cost, by writing or telephoning us at the following address: TheraSense, Inc., 1360 South Loop Road, Alameda, California; 94502, attention: Corporate Secretary; the telephone number is (510) 749-5400.

THERASENSE, INC.

Because this is only a summary, it does not contain all the information that may be important to you. You should read the entire prospectus, especially "Risk Factors" before deciding to invest in our common stock.

We develop, manufacture and sell easy to use glucose self-monitoring systems that dramatically reduce the pain of testing for people with diabetes. Our first product, FreeStyle, received FDA clearance in January 2000, and we began selling FreeStyle in the United States in June 2000. FreeStyle utilizes patented technologies that can accurately measure glucose concentrations from a tiny 0.3 microliter sample of blood, as opposed to competitive products that require from 1.0 to 10.0 microliters of blood. Our tiny sample size is easily obtained by lancing the forearm, thigh, calf, upper arm or hand and therefore avoids the pain associated with drawing a larger blood sample from the fingertip. These alternate sites are significantly less painful to lance than the traditional fingertip test site, which is more densely populated with highly sensitive nerve endings but yields the larger blood volumes required by competitive products. Nine out of ten people in our clinical studies found using FreeStyle less painful than their current finger-stick-based system.

We believe that FreeStyle is well positioned to capture a meaningful share of the blood glucose self-monitoring market. The blood glucose self-monitoring market is the largest self-test market for medical diagnostic products in the world, with a size of approximately $2.0 billion in the United States and $3.5 billion worldwide in 2000. It is estimated that the worldwide blood glucose self-monitoring market will amount to $9.0 billion by 2005. We believe that FreeStyle and other products based on our proprietary technologies can expand this market by substantially reducing the pain associated with testing and thereby bring non-testers into the market and encourage under-testers to test more regularly. We are also developing a Continuous Glucose Monitoring System that is intended to permit people with diabetes to accurately and discreetly measure their glucose levels on a continuous basis.

Our direct sales force promotes FreeStyle in the United States to health care professionals who advise patients on the monitoring and management of their diabetes. We distribute and sell FreeStyle in the United States to large national retailers, through wholesalers, and directly to end users over the telephone and through our website. In September 2000, we entered into an agreement with Disetronic Group for the exclusive distribution of FreeStyle in selected European countries. In March 2001, we obtained the CE Mark, which permits us to commercially distribute FreeStyle throughout the European Union. Disetronic commenced sales in Germany and Sweden in May 2001. In April 2001, we entered into an agreement with Nipro Corporation for the exclusive distribution of FreeStyle in Japan, and an application for approval to market FreeStyle in Japan was recently submitted. Disetronic and Nipro are the leading suppliers of insulin pumps in Europe and Japan, respectively. Insulin pump users are typically highly motivated insulin- dependent diabetes patients who frequently test their blood glucose levels.

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 risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our operations. 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 and may never achieve or maintain profitability.

We have a limited history of operations and have focused primarily on research and development, product engineering, clinical trials and seeking FDA regulatory clearance to market our products. We received FDA clearance for FreeStyle, our first commercial product, in January 2000, and we commenced commercial shipments in June 2000. We have generated only limited revenues from the sale of our products to date and have incurred losses every year since 1997. We incurred losses of $13.1 million in 1999, $43.6 million in 2000 and $39.9 million in the nine months ended September 30, 2001. As of September 30, 2001, we had an accumulated deficit of approximately $102.6 million. It is possible that we will never generate sufficient revenues from product sales to achieve profitability. Even if we do achieve significant revenues from our product sales, we expect that increased operating expenses will result in significant operating losses over the next several quarters as we, among other things:

- expand our domestic and international selling and marketing activities as we attempt to gain market share for FreeStyle;
- increase our research and development efforts to improve our existing products and develop new products such as our Continuous Glucose Monitoring System;
- perform clinical research and trials in an effort to obtain governmental clearance and approval for the commercial sale of our Continuous Glucose Monitoring System; and
- expand our facilities in Alameda, California, including an expansion of our test strip manufacturing capacity.

We will need to significantly increase the revenues we receive from sales of our products. We may be unable to do so, and therefore, may never achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

We have limited experience manufacturing our FreeStyle test strips in substantial quantities, and if we are unable to purchase additional equipment or are otherwise unable to meet customer demand, we may not improve our sales growth sufficiently to achieve profitability.

To be successful, we must manufacture our FreeStyle test strips in substantial quantities at acceptable costs. If we do not succeed in manufacturing sufficient quantities of our test strips to meet customer demand, we could lose customers and fail to acquire new customers, if they choose a competitor's product because our product is not available. We currently manufacture our FreeStyle test strips using a process with which we have limited experience. If demand for FreeStyle increases, we will need to purchase additional specialized equipment with substantial lead times and obtain additional raw materials in order to increase the output

volume of our test strips. If we are unable to obtain the necessary equipment or raw materials to effectively manufacture and meet customer demand for our FreeStyle test strips, we may not improve our sales growth sufficiently to achieve profitability.

We expect to derive substantially all of our future revenue from sales of FreeStyle, a product we recently introduced, and this product could fail to generate significant revenues and achieve market acceptance.

Currently, the primary products we market are the FreeStyle System kit, FreeStyle lancets and FreeStyle test strips, all of which we commercially introduced in June 2000. Our FreeStyle products are expected to account for substantially all of our revenues for at least the next several years. Accordingly, our success depends upon the acceptance by people with diabetes, as well as health care providers and third-party payors of FreeStyle as a preferred blood glucose self-monitoring device. As a relatively new company in the area of glucose self-monitoring, we may have difficulty raising the brand awareness necessary to generate interest in FreeStyle.

To date, only a limited number of people have used FreeStyle, and people with diabetes or the medical community may not endorse FreeStyle as a preferred blood glucose self-monitoring device. In addition, FreeStyle may not achieve market acceptance on a timely basis, if at all, due to:

- the significant influence of established glucose monitoring products;
- the ability of some of our competitors to price products below a price at which we can competitively manufacture and sell our products;
- cost constraints; and
- the introduction or acceptance of competing products or technologies.

Furthermore, FreeStyle may not encourage more active testing, and participants in the glucose self-monitoring market may gravitate toward more established brands. If we are unable to successfully market and sell our FreeStyle products, we may not be able to generate significant revenues or achieve profitability because we do not have alternative products.

In addition, to encourage market acceptance of our products, we currently distribute the FreeStyle System kit at a financial loss through samples, discounts and rebates. In order to generate sufficient revenues in the future, we will therefore have to rely on recurring revenue from the repeated purchase of our FreeStyle test strips. If FreeStyle does not gain sufficient market share to generate significant recurring revenue from the sale of our test strips, we may not achieve profitability.

We face competition from competitors with greater resources, which may make it more difficult for us to achieve significant market penetration.

The market for medical devices is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. We compete directly with Roche Diagnostics Corporation, LifeScan, Inc., a division of Johnson & Johnson, MediSense, a division of Abbott Laboratories, and Bayer AG, which currently account for approximately 90% of the worldwide sales of blood glucose self-monitoring systems. Each of these companies is either publicly traded or a division of a publicly-traded company, and enjoys several competitive advantages, including:

- significantly greater name recognition;
- established relations with health care professionals, customers and third-party payors;
- additional lines of products, and the ability to offer rebates or bundle products to offer higher discounts or incentives to gain a competitive advantage;
- established distribution networks and relationships with retailers; and
- greater resources for product development, sales and marketing and patent litigation.

These companies and others have developed and will continue to develop and acquire new products that compete directly with our products. In addition, our competitors spend significantly greater funds for the research, development, promotion and sale of new and existing products. These resources can allow them to respond more quickly to new or emerging technologies and changes in customer requirements. For all the foregoing reasons, we may not be able to compete successfully against our current and future competitors.

If we fail to obtain or maintain necessary FDA clearances or approvals for products, or if approvals are delayed, we will be unable to commercially distribute and market our products in the United States.

Our products are medical devices that are subject to extensive regulation in the United States and in foreign countries where we do business. Unless an exemption applies, each medical device that we wish to market in the United States must first receive either 510(k) clearance or premarket approval from the FDA. Either process can be lengthy and expensive. The FDA's 510(k) clearance process usually takes from four to twelve months from the date the application is complete, but may take longer. Although we have obtained 510(k) clearance for our initial product, FreeStyle, our 510(k) clearance can be revoked if safety or effectiveness problems develop. The premarket approval process is much more costly, lengthy and uncertain. It generally takes from one to three years from the date the application is complete or even longer. However, achieving a completed application is a process that may take numerous clinical trials and require the filing of amendments over time.

We expect that our Continuous Glucose Monitoring System under development will require premarket approval. Therefore, even if the product is successfully developed, it may not be commercially available for a number of years. We may not be able to obtain additional clearances or approvals in a timely fashion, or at all. Delays in obtaining clearance or approval could adversely affect our revenues and profitability.

Modification to our marketed devices may require new 510(k) clearances or premarket approvals or require us to cease marketing or recall the modified devices until these clearances are obtained.

Any modification to an FDA cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new FDA 510(k) clearance or possibly premarket approval. The FDA requires every manufacturer to make this determination in the first instance, but the FDA can review any such decision. We have modified aspects of FreeStyle since receiving regulatory approval, but we believe that new 510(k) clearances are not required. We may make additional modifications to FreeStyle and future products after they have received clearance or approval, and in appropriate circumstances, determine that new clearance or approval is

unnecessary. The FDA may not agree with any of our decisions not to seek new clearance or approval. If the FDA requires us to seek 510(k) clearance or premarket approval for any modifications to a previously cleared product, we may be required to cease marketing or recall the modified device until we obtain this clearance or approval. Also, in these circumstances, we may be subject to significant regulatory fines or penalties.

If the FDA does not clear our recent FreeStyle labeling changes, we may be required to include significantly more restrictive labeling, cease marketing FreeStyle under this labeling or recall FreeStyle.

In June 2001, we submitted additional information to the FDA in support of a labeling change we previously implemented. This labeling change sought to clarify the safe and effective use of FreeStyle in light of physiological differences between the finger and alternate blood glucose testing sites. The FDA has decided to review our submission as a 510(k). Because FreeStyle is currently being marketed with the revised more cautionary labeling, unless and until we obtain clearance of that 510(k), we are technically out of compliance with FDA regulations. In response, the FDA could require us to cease marketing FreeStyle with the more cautionary labeling, publish a public health notification disclosing warnings regarding the use of blood glucose monitoring systems that can be utilized with blood samples obtained from sites other than the fingertip or recall FreeStyle until we obtain 510(k) clearance. Also, in these circumstances, we may be subject to significant regulatory fines or penalties.

We will work closely with the FDA to address their questions and resolve any issues around our labeling. On October 19, 2001, we had an individual meeting with the FDA where we specifically discussed our pending FreeStyle 510(k). In addition, on October 29, 2001 we attended a scheduled meeting of the FDA's Clinical Chemistry and Clinical Toxicology Panel to provide advice and recommendations on the types of data and/or labeling needed in 510(k) submissions for blood glucose monitoring systems that can be utilized with blood samples obtained from sites other than the fingertip. However, the FDA may not accept our cautionary language as sufficient, and the FDA could require us to include significant restrictions on use in the labeling. In discussions with the FDA, we have been informed that, since the labeling changes are due to human physiology, all manufacturers of off-fingertip glucose self-monitoring products are being treated the same, and when such a manufacturer has submitted a labeling change similar to ours, the FDA has required a 510(k). If the FDA orders us to cease marketing FreeStyle with its current labeling, to recall such product, to pay fines or penalties, or to include significant restrictions on use in the FreeStyle labeling, our sales growth would be adversely impacted, and we may not reach profitability.

If our suppliers or we fail to comply with the FDA's Quality System Regulation, our manufacturing operations could be delayed, and our product sales and profitability could suffer.

Our manufacturing processes for our FreeStyle test strips, as well as the manufacturing processes utilized by our suppliers of FreeStyle meters, lancing devices and lancets, are required to comply with the FDA's Quality System Regulation, which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of our products. The FDA enforces the Quality System Regulation through unannounced inspections. We recently went through a Quality System Regulation inspection at our facilities in Alameda, California and have submitted a corrective action plan to the FDA addressing the observations noted in the audit. The manufacturing line for our FreeStyle meters at Flextronics

International USA Inc. has not been inspected to date. If we or one of our suppliers fail a Quality System Regulation inspection or if our corrective action plan is not sufficient, our operations could be disrupted and our manufacturing delayed. If we fail to take adequate corrective action in response to any FDA observations, we could face various enforcement actions, which could include a shut-down of our manufacturing operations and a recall of our products, which would cause our product sales and profitability to suffer. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements.

Our products are subject to product recalls even after receiving FDA clearance or approval, which would harm our reputation.

The FDA and similar governmental authorities in other countries have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. A government mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors or design defects, including our new labeling for FreeStyle. Any recall of product would divert managerial and financial resources and harm our reputation with customers.

Because the medical device industry is litigious, we may be sued for allegedly violating the intellectual property rights of others.

The medical technology industry has in the past been characterized by a substantial amount of litigation and related administrative proceedings regarding patents and intellectual property rights. In addition, major medical device companies have used litigation against emerging growth companies as a means of gaining a competitive advantage.

Should third parties file patent applications or be issued patents claiming technology also claimed by us in pending applications, we may be required to participate in interference proceedings in the U.S. Patent and Trademark Office to determine the relative priorities of our inventions and the third parties' inventions. We could also be required to participate in interference proceedings involving our issued patents and pending applications of another entity. An adverse outcome in an interference proceeding could require us to cease using the technology or to license rights from prevailing third parties.

Third parties may claim we are using their patented inventions and may go to court to stop us from engaging in our normal operations and activities. These lawsuits are expensive to defend and conduct and would also consume and divert the time and attention of our management. A court may decide that we are infringing a third party's patents and may order us to cease the infringing activity. The court could also order us to pay damages for the infringement. These damages could be substantial and could harm our business, financial condition and operating results. We have recently received a letter from the exclusive licensee of a recently issued patent alleging that FreeStyle infringes the patent and requesting that we contact the licensee regarding sublicense opportunities. We are evaluating the patent and have responded to the letter indicating that we would be willing to discuss potential sublicensing terms.

If we were unable to obtain any necessary license following a determination of infringement or an adverse determination in litigation or in interference or other administrative proceedings, we would have to redesign our products to avoid infringing a third party's patent and could temporarily or permanently have to discontinue manufacturing and selling some of our products. If this were to occur, it would negatively impact future sales.

If we fail to protect our intellectual property rights, our competitors may take advantage of our ideas and compete directly against us.

We rely on patent protection, as well as a combination of copyright, trade secret and trademark laws, and nondisclosure, confidentiality agreements and other contractual restrictions to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. For example, our patents may be challenged, invalidated or circumvented by third parties. Our patent applications, including those already allowed, may not be issued as patents in a form that will be advantageous to us. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by employees. Furthermore, the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States. Even if our intellectual property rights are adequately protected, litigation may be necessary

to enforce our intellectual property rights, which could result in substantial costs to us and result in a substantial diversion of management attention. If our intellectual property is not adequately protected, our competitors could use our intellectual property to enhance their products. This would harm our competitive position, decrease our market share or otherwise harm our business.

The prosecution and enforcement of patents licensed to us by third parties are not within our control, and without these technologies, our products may not be successful and our business would be harmed.

We rely on licenses to use various technologies that are material to our business. We do not own the patents that underlie these licenses. The licenses from Asulab, SA and Unilever PLC grant us the right under specific patents to make and sell diagnostic devices for diabetes monitoring that contain the inventions claimed in the licensed patents. Our rights to use these technologies and employ the inventions claimed in the licensed patents are subject to our licensors abiding by the terms of those licenses. In addition, we do not control the prosecution of the patents to which we hold licenses, and we do not control the strategy for determining when any patents to which we hold licenses should be enforced. Instead, we rely upon our licensors to determine the appropriate strategy for prosecuting and enforcing those patents.

If we are unable to continue to develop innovative products in the glucose monitoring market, our business would be harmed.

The glucose monitoring market is subject to rapid technological change and product innovations. Our products are based on our proprietary technology, but our competitors may succeed in developing or marketing products that will be technologically superior to ours. In addition, over $44 billion is spent annually on diabetes treatment and the National Institutes for Health and other supporters of diabetes research are continually seeking ways to prevent or cure diabetes. Therefore, our products may also be rendered obsolete by technological breakthroughs in diabetes prevention, monitoring or treatment.

We are currently developing additional enhancements for FreeStyle, as well as new products such as our Continuous Glucose Monitoring System. Marketing of these products will require FDA and other regulatory clearances and approvals. Development of these products will require additional research and development expenditures. We may not be successful in developing, marketing or manufacturing these new products. In addition, several of our competitors are in various stages of development of products similar to our Continuous Glucose Monitoring System, and the FDA has approved two of these products. If any of our

competitors succeeds in developing a commercially viable product and obtains government approval or successfully commercializes its FDA-approved product, this could negatively affect our future revenues.

We have limited sales and marketing experience and any failure to expand sales of FreeStyle will negatively impact future revenues.

We currently have limited experience in marketing and selling our products. We received regulatory clearance for our initial product in January 2000 and commenced commercial shipments in June 2000. We currently sell our products in the United States directly, using a sales organization that we assembled following regulatory clearance. Our products require a complex marketing and sales effort targeted at health care professionals, diabetes educators, people with diabetes, retail pharmacists and national retailers. We significantly expanded our sales and marketing teams in 2000, and we are continuing this expansion in 2001 and we expect this expansion to continue in 2002. We will face significant challenges and risks in training, managing and retaining these teams, including managing geographically dispersed efforts and adequately training our people in the use and benefits of our products. We may not be able to hire sufficient additional personnel to create increasing demand for our products. In addition, we have distribution arrangements for the

sale of our products internationally and are dependent upon the sales and marketing efforts of our third-party distributors. These distributors may not commit the necessary resources to effectively market and sell our products. Further, they may not be successful in selling our products. Our financial condition would be harmed if our marketing and sales efforts are unsuccessful.

We currently depend on single suppliers and manufacturers for our FreeStyle products, and the loss of any of these suppliers or manufacturers could harm our business.

Our FreeStyle meters, along with our FreeStyle lancing devices and lancets, are each currently manufactured according to our specifications by single third-party manufacturers. The meters, lancing devices and lancets are manufactured from components purchased from outside suppliers, and some of these components are currently single-sourced. Our FreeStyle test strips, which we manufacture ourselves, are comprised of several components obtained from single-source suppliers. In the event we are unable, for whatever reason, to obtain components from suppliers, or if our contract manufacturers are unable to meet our manufacturing requirements, we may not be able to obtain components from alternate suppliers or engage an additional manufacturer in a timely manner. Any disruption or delay in shipments of FreeStyle meters, test strips, lancing devices or lancets could result in the loss of customers or the failure to acquire new customers, if they choose a competitor's product because our product is not available. Such a disruption or delay would negatively affect our revenues.

We outsource several key parts of our operations and any interruption in the services provided could prevent us from expanding our business.

We currently outsource several aspects of our business, including the manufacture of FreeStyle meters, lancing devices and lancets, the functioning of our procurement systems and the operation of our customer service function. Since outsourcing leaves us without direct control over these business functions, interruptions in the services of our third-party providers may be difficult or impossible to remedy in a timely fashion. In addition, we may be unable to obtain the necessary resources from our third-party providers to meet realized growth in our business.

We may have difficulty managing our growth.

We expect to continue to experience significant growth in the scope of our operations and the number of our employees. This growth may continue to place a significant strain on our management and operations. Our ability to manage this growth will depend upon our ability to attract, hire and retain skilled employees. Our success will also depend on the ability of our officers and key employees to continue to implement and improve our operational and other systems, to manage multiple, concurrent development projects and to hire, train and manage our employees. Our future success is heavily dependent upon growth and acceptance of new products. If we cannot scale our business appropriately or otherwise adapt to anticipated growth and new product introduction, our business, financial condition and results of operations will be adversely affected.

Our success will depend on our ability to attract and retain key personnel and scientific staff.

We believe our future success will depend upon our ability to successfully manage our growth, including attracting and retaining scientists, engineers and other highly skilled personnel. Our employees may terminate their employment with us at any time and are not subject to employment contracts. Hiring qualified management and technical personnel will be difficult due to the limited number of qualified professionals. Competition for these types of employees is intense in the field of diabetes monitoring and management. We have in the past experienced difficulty in recruiting qualified personnel. If we fail to attract and retain

personnel, particularly management and technical personnel, we may not be able to execute on our business plan.

Our products carry return policies that do not permit us to recognize revenue from sales to retailers and wholesalers prior to resale to end users.

Our return policy allows end users in the United States to return FreeStyle System kits to us for any reason for a full refund within 30 days of purchase. In addition, our FreeStyle System kits and FreeStyle test strips currently have an 18 month shelf life, and retailers and wholesalers in the United States can return these products to us within six months after this expiration date. If we experience significant returns from retailers, wholesalers or end users, this could seriously harm our business and results of operations. As a result of these rights to return and the unavailability of historical return rates, we defer revenue recognition on sales of test strips until resold by the retailers and wholesalers to end users, and we defer revenue recognition on FreeStyle System kits until 30 days after purchase by the end user.

Because we lack a sufficient historical basis from which we could estimate return rates, we are required to rely on data estimates provided to us by third-party data providers in order to recognize revenue from sales to end users by retailers and wholesalers. These data estimates may cause imprecise revenue recognition, as these third-party data providers may not provide consistent, reliable data. Further, we do not know how long we will be required to rely on these estimates, although we believe that we will have a sufficient historical basis from which we can estimate return rates beginning with the quarter ending September 30, 2002.

If we do not provide quality customer service, we would lose customers and our operating results would suffer.

Our ability to provide superior customer service to our customers, health care professionals and educators is critical. To effectively compete, we must build strong brand awareness among our customers, much of which is based upon personal referrals. In order to gain these referrals, we must provide customer service representatives who are able and available to provide our customers with answers to questions regarding our products. This will require us to continue to build and maintain customer service operations, for which we currently rely on a single third-party provider. We will require increased staff at our third-party provider to further support a growth in new customers. Any failures or disruption to our customer services operations, or the termination of our contract with our only third-party provider, could cause us to lose customers.

We currently have only one distributor in Europe and one distributor in Japan, and if these distributors are not successful or we are unable to attract additional distributors, we may never realize significant international revenues.

In September 2000, we entered into an agreement for the exclusive marketing and sale of FreeStyle in several European countries, subject to regulatory approval. In May 2001, our third-party distributor commercially introduced FreeStyle in Germany and Sweden. In April 2001, we entered into an agreement for the exclusive marketing and sale of FreeStyle in Japan, subject to regulatory approval. We will be dependent on these distributors in those markets, and we will need to attract additional distributors in other markets. If our current or future third-party distributors do not succeed, we may never realize significant international revenues.

Complying with international regulatory requirements is an expensive, time-consuming process and approval is never certain.

International sales of our products are subject to strict regulatory requirements. The review process varies from country to country, is typically lengthy and expensive, and approval is never certain. Nipro Corporation, our exclusive distributor in Japan, submitted an application for approval to market FreeStyle in Japan with the Ministry of Health, Labor and Welfare. Failure to receive the approval in Japan or in other countries would prevent us from expanding international sales of FreeStyle, which would negatively impact our future revenues.

If we choose to acquire new and complementary businesses, products or technologies instead of developing them ourselves, we may be unable to complete these acquisitions or to successfully integrate an acquired business or technology in a cost-effective and non-disruptive manner.

Our success depends on our ability to continually enhance and broaden our product offerings in response to changing technologies, customer demands and competitive pressures. Accordingly, we may, in the future, acquire complementary businesses, products, or technologies instead of developing them ourselves. We do not know if we will be able to complete any acquisitions, or whether we will be able to successfully integrate any acquired business, operate it profitably or retain its key employees. Integrating any business, product or technology we acquire could be expensive and time consuming, disrupt our ongoing business and distract our management. If we are unable to integrate any acquired entities, products or technologies effectively, our business will suffer. In addition, any amortization of goodwill or other assets or charges resulting from the costs of acquisitions could harm our business and operating results.

Any adverse changes in reimbursement procedures by Medicare or other third-party

payors may limit our ability to market and sell our products.

In the United States, glucose self-monitoring devices and test strips are generally covered by Medicare and other third-party payors, which provide for reimbursement of all or part of the cost of the product. Medicare and other third-party payors are increasingly scrutinizing whether to cover new products and the level of reimbursement for covered products. FreeStyle is currently being reimbursed through Medicare, Medicaid, open formulary plans and certain preferred provider organizations.

International market acceptance of our products may depend, in part, upon the availability of reimbursement within prevailing health care payment systems. Reimbursement and health care payment systems in international markets vary significantly by country, and include both government sponsored health care and private insurance. We may not obtain international reimbursement approvals in a timely manner, if at all. Our failure to receive international reimbursement approvals may negatively impact market acceptance of our products in the international markets in which those approvals are sought.

We believe that in the future, reimbursement will be subject to increased restrictions both in the United States and in international markets. Third-party reimbursement and coverage may not be available or adequate in either the United States or international markets. Future legislation, regulation or reimbursement policies of third-party payors may adversely affect the demand for our existing products or our products currently under development or our ability to sell our products on a profitable basis. The lack of third-party payor coverage or the inadequacy of reimbursement could have a material adverse effect on our business, financial condition and results of operations.

If we become subject to product liability claims, we may be required to pay damages that exceed our insurance coverage.

Our business exposes us to potential product liability claims that are inherent in the testing, production, marketing and sale of human diagnostic products. While we believe that we are reasonably insured against these risks, we may not be able to obtain insurance in amounts or scope sufficient to provide us with adequate coverage against all potential liabilities. Currently, we maintain product liability insurance in the amount of $20.0 million. A product liability claim in excess of our insurance coverage would have to be paid out of cash reserves and would harm our reputation in the industry.

We are subject to additional risks associated with international operations.

We believe that a significant amount of our future revenues may come from international sales, and these sales are subject to a number of risks. For example, foreign regulatory agencies often establish requirements different from those in the United States. Fluctuations in exchange rates of the U.S. dollar against foreign currencies may affect demand for our products overseas. In addition, our international sales may be adversely affected by export license requirements, the imposition of governmental controls, political and economic instability, trade restrictions, changes in tariffs and difficulties in staffing and managing international operations.

If we require future capital, we may not be able to secure additional funding in order to expand our operations and develop new products.

We may seek additional funds from public and private stock offerings, borrowings under lease lines of credit or other sources. This additional financing may not be available on a timely basis on terms acceptable to us, or

at all. This financing may be dilutive to stockholders or may require us to grant a lender a security interest in our assets. The amount of money we will need will depend on many factors, including:

- revenues generated by sales of FreeStyle and our future products, if any;
- expenses we incur in developing and selling our products;
- the commercial success of our research and development efforts; and
- the emergence of competing technological developments.

If adequate funds are not available, we may have to delay development or commercialization of our products or license to third parties the rights to commercialize products or technologies that we would otherwise seek to commercialize. We also may have to reduce marketing, customer support or other resources devoted to our products. Any of these results would harm our financial condition.

We may have warranty claims that exceed our reserves.

FreeStyle meters carry a five-year warranty against defects in materials and workmanship. We will be responsible for all claims, actions, damages, liens, liabilities, costs and expenses for defects attributable to the FreeStyle meter. We have established reserves for the liability associated with product warranties. However, any unforeseen warranty exposure could adversely affect our operating results.

All of our operations are currently conducted at a single location, and a disaster at this facility is possible and could result in a prolonged interruption of our business.

We currently conduct all our scientific, test strip manufacturing and management activities at a single location in Alameda, California near known earthquake fault zones. In addition, our facilities were built on fill material dredged from the San Francisco Bay in the 1960s. Our sole supplier of FreeStyle meters also currently manufactures these devices at a single facility in San Jose, California near known earthquake fault zones. We have taken precautions to safeguard our facilities, including insurance, health and safety protocols, and off-site storage of computer data. However, a natural disaster, such as an earthquake, fire or flood, could cause substantial delays in our operations, damage or destroy our manufacturing equipment or inventory, and cause us to incur additional expenses. A disaster could seriously harm our business and adversely affect our reputation with customers. The insurance we maintain against fires, floods, and earthquakes may not be adequate to cover our losses in any particular case.

Power outages in California may adversely affect us.

We conduct all of our scientific, test strip manufacturing and management activities in California and rely on a continuous power supply to conduct operations. Our sole-source supplier of FreeStyle meters is currently manufacturing our meters in a single facility that is also in California. California's current energy crisis could substantially disrupt our operations and increase our expenses. California has recently implemented, and may in the future continue to implement, rolling blackouts throughout the state. If

blackouts interrupt our power supply, we may be temporarily unable to continue operations at our facilities, which includes the manufacture and production of our FreeStyle test strips. Interruptions in our ability to continue operations at our facilities could delay our shipments of FreeStyle test strips, delay the development of our products, and disrupt communications with our customers, suppliers and third-party manufacturing operations. Future interruptions could result in lost revenue and damage our reputation, either of which could harm our business and results of operations. Furthermore, shortages in wholesale electricity supplies have caused power prices to increase. If wholesale prices continue to increase, our operating expenses will likely increase, which will have a negative effect on our operating results.

We may be liable for contamination or other harm caused by materials that we use, and changes in environmental regulations could cause us to incur additional expense.

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 and disposal of hazardous and biological materials and we incur expenses relating to compliance with these laws and regulations. If violations of environmental, health, and safety laws occur, we could be held liable for damages, penalties and costs of remedial actions. These expenses or this liability could have a significant negative impact on our financial condition. We may violate environmental, health and safety laws in the future as a result of human error, equipment failure, or other causes. Environmental laws could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. We are 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 an unplanned capital investment and/or relocation. Compliance with new laws or regulations could harm our business, financial condition and results of operations.

Our common stock has recently become publicly traded, and we expect that the price of our common stock may fluctuate substantially.

We consummated the initial public offering of our common stock in October 2001. Accordingly, there has only been a public market for shares of our common stock since October 2001. An active public

trading market may not develop or, if developed, may not be sustained. Further, we expect that the market price of our common stock may fluctuate substantially. The market price for our common stock may be affected by a number of factors, including:

- volume and timing of orders for our products;
- our ability to develop, obtain regulatory clearance for, and market, new and enhanced products on a timely basis;
- the announcement of new products or product enhancements by us or our competitors;
- announcements of technological or medical innovations in the monitoring or treatment of diabetes;
- product liability claims or other litigation;

- quarterly variations in our or our competitors' results of operations;
- changes in governmental regulations or in the status of our regulatory approvals or applications;
- changes in the availability of third-party reimbursement in the United States or other countries;
- changes in earnings estimates or recommendations by securities analysts; and
- general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

The sales of a substantial number of shares of our common stock, including shares that will become eligible for sale in the near future, may adversely affect the market price for our common stock

Sales of a substantial number of shares of our common stock in the public market or the market perception that these sales may occur, could significantly and negatively affect the market price for our common stock. As of September 30, 2001, we had 39,052,222 shares of common stock outstanding after giving effect to the issuance of 6,900,000 shares of common stock in our October 2001 initial public offering and the automatic conversion of all of our outstanding shares of preferred stock into an equal number of shares of common stock immediately prior to the closing of our October 2001 initial public offering. The 6,900,000 shares of our common stock sold in our October 2001 initial public offering are freely tradable. The remaining 32,152,222 of these shares are subject to a lock-up agreement under which the holders of these shares have agreed not to sell or otherwise dispose of their shares of common stock until 180 days after the effective date of our October 2001 initial public offering. All of these shares will be available for sale after the expiration of the lock-up period on April 10, 2002, and approximately 16.0 million of these shares will be subject to volume restrictions because they are held by our affiliates. In addition, U.S. Bancorp Piper Jaffray Inc., the lead underwriter of our initial public offering, may waive these lock-up restrictions prior to the expiration of the lock-up period without prior notice.

In addition, the holders of approximately 27,243,164 shares of common stock and warrants exercisable for shares of common stock will have rights (after giving effect to the automatic conversion of all of our outstanding shares of preferred stock into an equal number of shares of common stock immediately

prior to the closing of our October 2001 initial public offering), 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.

Our principal stockholders, executive officers and directors own a significant percentage of our stock, and as a result, the trading price for our shares may be depressed and these stockholders can take actions that may be adverse to investors' interests.

Our executive officers and directors and entities affiliated with them beneficially own, in the aggregate, approximately 37.0% of our common stock as of September 30, 2001 after giving effect to the issuance of 6,900,000 shares of common stock in our October 2001 initial public offering and the automatic conversion of all of our outstanding shares of preferred stock into an equal number of shares of common stock immediately prior to the closing of our October 2001 initial public offering. This significant concentration of share ownership may adversely affect the trading price for our common stock because investors often perceive disadvantages in owning stock in companies with controlling stockholders. These stockholders, acting together, 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, they 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 investors.

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

USE OF PROCEEDS

We will not receive any of the proceeds from the sale of the shares of common stock pursuant to this prospectus. All proceeds from the sale of the shares will be for the account of the selling stockholders, as described below. See "Selling Stockholders" and "Plan of Distribution" described below.

SELLING STOCKHOLDERS

The following table shows the names of the selling stockholders and the number of shares of common stock to be sold by them pursuant to this prospectus. Except as indicated in the footnotes to this table and pursuant to applicable community property laws, each stockholder named in the table has sole voting and investment power with respect to the shares set forth opposite that stockholder's name.

Applicable percentage ownership of our common stock is based on 39,490,229

shares of common stock outstanding as of November 1, 2001.

Selling Stockholders	Common Stock Ownership Prior to Offering		Number of Shares of Common Stock Offered	
	Number	Percent		
Behrad Aria	13,327	*	13,327	
Debra Armstrong	750	*	750	
Robert Arnesen	1,166	*	1,166	
Jay Audett	13,801	*	13,801	
Nooshin Azimi	8,000	*	8,000	
Vijay Bahkta	2,478	*	2,478	
Apolinar B. Bordador III	702	*	702	
Deborah Briggs	10,349	*	10,349	
Robert D. Brownell(1)	52,855	*	40,000	
James Carpenter	34,375	*	34,375	
Michael Cloud	2,343	*	2,343	
Joel Colburn	30,809	*	25,809	
Frederic C. Colman	153,514	*	153,514	
Eve Conner(2)	105,999	*	105,999	
Steve Drucker	13,000	*	13,000	
The Drucker Irrevocable Trust dated August 5, 1992	2,800	*	800	
Robert Ewell	1,172	*	1,172	
Charmaine Haiss	500	*	500	
Claire D. Heiss TTEE for Claire D. Heiss 2001 Revocable Trust U/A Dtd 2-20-01(3)	78,424	*	68,424	
Michael Hollingsworth	656	*	656	
Norma Horn	500	*	500	
Brian Jellin	2,049	*	2,049	
Feng Jiang	4,166	*	4,166	
Robert Jin	18,680	*	18,680	
Dina L. Killian-Barnes	2,670	*	2,670	
Charles Liamos(4)	180,375	*	180,375	
Kelley Lipman	22,862	*	22,862	

Selling Stockholders	Common Stock Ownership Prior to Offering		Number of Shares of Common Stock Offered	
	Number	Percent		
W. Mark Lortz and Patrice Rae Lortz Revocable Living Trust(5)	592,490	1.50%	592,490	
William Matievich Jr	2,933	*	2,933	
Carolyn McCorkindale	525	*	525	
Geoff McGarraugh	100,000	*	100,000	
Michael McNamara(6)	43,344	*	43,344	
Said Mortazavi	12,500	*	12,500	
Richard Myer	1,342	*	1,342	

Michael Nevares.....	3,941	*	3,941
Kathleen O'Connor-Masse.....	11,205	*	11,205
Jonathan Pesco.....	2,486	*	2,486
Whitney Pieper.....	1,587	*	1,587
Philip Plante.....	83,800	*	73,800
Donald Preston.....	3,264	*	3,264
Chuck Ray.....	4,770	*	4,770
Travis Rowe.....	1,765	*	1,765
Teresa Saiers.....	97	*	97
Hennings Sakslund.....	40,446	*	2,946
James Say.....	78,770	*	3,770
Harry Shamoon.....	5,625	*	5,625
Richard Thompson(7).....	30,000	*	30,000
Nirmala Verma.....	885	*	885
Karen Wing.....	5,596	*	5,596
Duane Yamasaki.....	3,374	*	3,374
Norma Zippin.....	20,460	*	20,460

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* Less than 1%.

(1) Robert D. Brownell serves as our Vice President of Human Resources and General Counsel.

(2) Eve A. Conner serves as our Vice President of Quality Assurance and Regulatory Affairs.

(3) Claire D. Heiss is a Trustee of the Claire D. Heiss 2001 Revocable Trust under Agreement dated 02-20-01 and has voting and dispositive powers over the shares. Claire D. Heiss serves as our Vice President of Operations.

(4) Charles T. Liamos is our Chief Operating Officer and Chief Finance Officer.

(5) W. Mark Lortz is a Co-Trustee or Successor Trustee of the W. Mark Lortz and Patrice Rae Lortz Revocable Living Trust, under Agreement dated February 10, 1999, as community property and shares voting and dispositive powers over the shares. W. Mark Lortz serves as our Chairman of the Board, President and Chief Executive Officer.

(6) Michael M. McNamara is a member of our board of directors.

(7) Richard P. Thompson is a member of our board of directors.

PLAN OF DISTRIBUTION

We are registering the shares on behalf of the selling stockholders, including donees and pledges of shares received from a named selling stockholder after the date of this prospectus. All costs, expenses and fees in connection with the registration of the shares offered hereby will be borne by us, and all brokerage commissions and similar selling expenses attributable to the sale of the shares will be borne by the selling stockholders.

The selling stockholders may sell all or a portion of the shares offered hereby from time to time in the Nasdaq National Market and such sales may be made at prices prevailing in the Nasdaq National Market at the times of such sales. The selling stockholders may also make private sales directly or through a broker or brokers, who may act as agent or as principal. Further, the selling stockholders may choose to dispose of the shares offered hereby by gift to a third party or as a donation to a charitable or other non-profit entity. In connection with any sales, the selling stockholders and any brokers participating in such sales may be deemed to be underwriters within the meaning of the Securities Act.

Any broker-dealer participating in such transactions as agent may receive commissions from the selling stockholders (and, if such broker acts as agent for

the purchaser of such shares, from such purchaser). Usual and customary brokerage fees will be paid by the selling stockholders. Broker-dealers may agree with the selling stockholders to sell a specified number of shares at a stipulated price per share, and, to the extent the broker-dealer is unable to do so acting as agent for the selling stockholders, to purchase as principal any unsold shares at the price required to fulfill the broker-dealer commitment to the selling stockholders. Broker-dealers who acquire shares as principal may thereafter resell such shares from time to time in transactions (which may involve crosses and block transactions and which may involve sales to and through other broker-dealers, including transactions of the nature described above) in the over-the-counter market, in negotiated transactions or otherwise at market prices prevailing at the time of sale or at negotiated prices, and in connection with such resales may pay to or receive from the purchasers of such shares commissions computed as described above.

We have advised the selling stockholders that Regulation M promulgated under the Exchange Act may apply to sales in the market and have informed them of the possible need for delivery of copies of this prospectus. 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. Any commissions paid or any discounts or concessions allowed to any such broker-dealers, and, if any such broker-dealers purchase shares as principal, any profits received on the resale of such shares, may be deemed to be underwriting discounts and commissions under the Securities Act.

Upon our being notified by the selling stockholders that any material arrangement has been entered into with a broker-dealer for the sale of shares through a cross or block trade, a supplemental prospectus will be filed under Rule 424(c) of the Securities Act, setting forth the name of the participating broker-dealer(s), the number of shares involved, the price at which such shares were sold by the selling stockholders, the commissions paid or discounts or concessions allowed by the selling stockholders to such broker-dealer(s), and where applicable, that such broker-dealer(s) did not conduct any investigation to verify the information set out in this prospectus.

Any securities covered by this prospectus which qualify for sale pursuant to Rules 144 and 701 under the Securities Act may be sold under Rule 144 rather than pursuant to this prospectus. In general, under Rule 144 as currently in effect, a person (or persons whose shares are aggregated), including any person who may be deemed to be our "affiliate," is entitled to sell within any three month period "restricted shares" beneficially owned by him or her in an amount that does not exceed the greater of (i) 1% of the then

outstanding shares of common stock of the company or (ii) the average weekly reported trading volume in shares of our common stock during the four calendar weeks preceding such sale, provided that at least one year has elapsed since such shares were acquired from us or any of our affiliates. Sales are also subject to certain requirements as to the manner of sale, notice and availability of current public information regarding TheraSense. However, a person who has not been our "affiliate" at any time within three months prior to the sale is entitled to sell his or her shares without regard to the volume limitations or other requirements of Rule 144, provided that at least two years have elapsed since such shares were acquired from us or any of our affiliates. In general, under Rule 701 as currently in effect, any employee, consultant or advisor of ours who purchases shares from us in connection with a compensatory stock or option plan or other written agreement related to compensation is eligible to resell such shares in reliance on Rule 144, but without compliance with certain restrictions contained in Rule 144.

Furthermore, each selling stockholder is subject to a lock-up agreement under which the selling stockholder has agreed not to transfer or dispose of, directly or indirectly, certain shares of common stock (including all shares beneficially owned prior to our October 2001 initial public offering) or certain securities convertible into or exercisable or exchangeable for shares of common stock (including all options to purchase shares of our common stock), for a period of 180 days after the effective date of our October 2001 initial public offering. Transfers or dispositions can be made sooner, however, with the prior written consent of U.S. Bancorp Piper Jaffray Inc., one of the underwriters of our October 2001 initial public offering.

There can be no assurance that the selling stockholders will sell any or all of the shares of common stock offered hereunder.

EXPERTS

The financial statements as of December 31, 1999 and 2000, and for each of the three years in the period ended December 31, 2000 incorporated in this prospectus by reference to the Registration Statement on Form S-1 (No. 333-64456), have been so incorporated in reliance on the report of PricewaterhouseCoopers LLP, independent accountants, given on the authority of said firm as experts in auditing and accounting.

INDEMNIFICATION OF DIRECTORS AND OFFICERS

Section 145 of the Delaware General Corporation Law permits a corporation to include in its charter documents, and in agreements between the corporation and its directors and officers, provisions expanding the scope of indemnification beyond that specifically provided by the current law.

Article VIII of our amended and restated certificate of incorporation provides for the indemnification of directors to the fullest extent permissible under Delaware law.

Article VI of our amended and restated bylaws provides for the indemnification of officers, directors and third parties acting on our behalf if such person acted in good faith and in a manner reasonably believed to be in and not opposed to our best interest, and, with respect to any criminal action or proceeding, the indemnified party had no reason to believe his or her conduct was unlawful.

We have entered into indemnification agreements with our directors and executive officers, in addition to indemnification provided for in our charter documents, and we intend to enter into indemnification agreements with any new directors and executive officers in the future.

In October 2001, we purchased, and we intend to maintain insurance on behalf of any person who is or was (as of October 2001) a director or officer against any loss arising from any claim asserted against him or her and incurred by him or her in any such capacity, subject to certain exclusions.

THERASENSE

REGISTRATION STATEMENT ON FORM S-8

PART II

Item 3. Incorporation of Documents by Reference.

There are hereby incorporated by reference into this Registration Statement the following documents and information heretofore filed by TheraSense, Inc. (the "Registrant") with the Securities and Exchange Commission (the "Commission"):

(1) The Registrant's Registration Statement on Form S-1 (File No. 333-64456) filed pursuant to Rule 424(b) under the Securities Act of 1933, as amended, declared effective on October 11, 2001.

(2) The Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2001 filed on November 14, 2001.

(3) The description of the Registrant's common stock contained in the Registrant's Registration Statement on Form 8-A declared effective by the Commission on October 11, 2001 pursuant to Section 12(g) of the Securities Exchange Act of 1934, as amended, and any description of any of the Registrant's securities contained in any registration statement filed after the date hereof under Section 12 of the Exchange Act, including any amendment or report filed for the purpose of updating any such description.

The Registrant also incorporates by reference all documents subsequently filed by the Registrant pursuant to Sections 13(a), 13(c), 14 and 15(d) of the Exchange Act, prior to the filing of a post-effective amendment which indicates that all securities registered have been sold or which deregisters all securities then remaining unsold, and shall be deemed to be incorporated by reference in this registration statement and to be part hereof from the date of filing of such documents.

Item 4. Description of Securities.

The class of securities to be offered is registered under Section 12(g) of the Exchange Act.

Item 5. Interests of Named Experts and Counsel.

Not applicable.

Item 6. Indemnification of Directors and Officers.

Section 145 of the Delaware General Corporation Law permits a corporation to include in its charter documents, and in agreements between the corporation and its directors and officers, provisions expanding the scope of indemnification beyond that specifically provided by the current law.

Article VIII of the Registrant's amended and restated certificate of incorporation provides for the indemnification of directors to the fullest extent permissible under Delaware law.

Article VI of the Registrant's amended and restated bylaws provides for the indemnification of officers, directors and third parties acting on the Registrant's behalf if such person acted in good faith and in a

manner reasonably believed to be in and not opposed to the Registrant's best interest, and, with respect to any criminal action or proceeding, the indemnified party had no reason to believe his or her conduct was unlawful.

The Registrant has entered into indemnification agreements with our

directors and executive officers, in addition to indemnification provided for in the Registrant's charter documents, and the Registrant intends to enter into indemnification agreements with any new directors and executive officers in the future.

In October 2001, the Registrant purchased and intends to maintain insurance on behalf of any person who is or was (as of October 2001) a director or officer against any loss arising from any claim asserted against him or her and incurred by him or her in any such capacity, subject to certain exclusions.

Item 7. Exemption from Registration Claimed.

The issuance of the shares being offered by the Form S-3 resale prospectus were deemed to be exempt from registration under the Securities Act in reliance on Section 4(2) of the Securities Act or Rule 701 promulgated under Section 3(b) of the Securities Act, as transactions by an issuer not involving a public offering or transactions pursuant to compensatory benefit plans and contracts relating to compensation as provided under such Rule 701. The recipients of securities in each such transaction represented their intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the share certificates and instruments issued in such transactions. All recipients had adequate access, through their relationship with TheraSense, to information about TheraSense.

Item 8. Exhibits.

Exhibit Number	Description
3.1(b)*	Amended and Restated Certificate of Incorporation of Registrant.
3.2(b)*	Amended and Restated Bylaws of Registrant.
10.1*	1997 Stock Plan.
23.1	Consent of independent accountants.
24.1	Power of Attorney (see page II-4).

* Incorporated by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-64456), declared effective by the Securities and Exchange Commission on October 11, 2001.

Item 9. Undertakings.

(a) The Registrant hereby undertakes:

(i) To file, during any period which offers or sales are being made, a post-effective amendment to this registration statement to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

(ii) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(iii) To remove from registration by means of a post-effective

amendment any of the securities being registered which remain unsold at the termination of the offering.

(b) The Registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in the Registration Statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(c) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to law, the Registrant's Amended and Restated Certificate of Incorporation, Amended and Restated Bylaws, indemnification agreements, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in a successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered hereunder, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing this Registration Statement on Form S-8/S-3 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Alameda, State of California, on this 29th day of November, 2001.

THERASENSE, INC.

By: /s/ W. Mark Lortz

W. Mark Lortz
President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints W. Mark Lortz, Charles T. Liamos and Robert D. Brownell, and each of them, as his or her attorneys-in-fact, with full power of substitution in each, for him or her in any and all capacities to sign any amendments to this Registration Statement on Form S-8/S-3, and to file the same, with exhibits thereto and other documents in connection therewith, with

the Securities and Exchange Commission, hereby ratifying and confirming all that said attorneys-in-fact, or his substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title
/s/ W. Mark Lortz W. Mark Lortz	President and Chief Executive Officer (Principal Executive Officer)
/s/ Charles T. Liamos Charles T. Liamos	Chief Finance Officer (Principal Financial and Accounting Officer
/s/ Annette J. Campbell-White Annette J. Campbell-White	Director
/s/ Mark J. Gainor Mark J. Gainor	Director
/s/ Ross A. Jaffe, M.D. Ross A. Jaffe, M.D.	Director
/s/ Michael M. McNamara Michael M. McNamara	Director
/s/ Robert R. Momsen Robert R. Momsen	Director
/s/ Ephraim Heller Ephraim Heller	Director
_____ Richard P. Thompson	Director

INDEX TO EXHIBITS

Exhibit Number	Description
3.1(b)*	Amended and Restated Certificate of Incorporation of Registrant.
3.2(b)*	Amended and Restated Bylaws of Registrant.
10.1*	1997 Stock Plan.
23.1	Consent of independent accountants.

24.1 Power of Attorney (see page II-4).

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* Incorporated by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-64456), declared effective by the Securities and Exchange Commission on October 11, 2001.