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THERASENSE INC
Form 424B4
October 12, 2001

FILED PURSUANT TO RULE 424(b)(4)
REGISTRATION NO. 333-64456

6,000,000 Shares

THERASENSE, INC.

[LOGO OF THERASENSE, INC.]

Common Stock

\$19.00 per share

- . TheraSense, Inc. is offering 6,000,000 shares.
- . Trading symbol: Nasdaq National Market - THER
- . This is our initial public offering and no public market existed for our shares prior to this offering.

This investment involves risk. You should carefully consider the "Risk Factors" beginning on page 5.

| | Per Share | Total |
|---|-----------|---------------|
| | ----- | ----- |
| Public offering price..... | \$19.00 | \$114,000,000 |
| Underwriting discounts and commissions..... | \$ 1.33 | \$ 7,980,000 |
| Proceeds to TheraSense, Inc. | \$17.67 | \$106,020,000 |

The underwriters have a 30-day option to purchase up to 900,000 additional shares of common stock from us to cover over-allotments, if any.

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

U.S. Bancorp Piper Jaffray

SG Cowen

Thomas Weisel Partners LLC

The date of this prospectus is October 11, 2001.

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[Inside Front Cover]

DESCRIPTION OF GRAPHIC

Graphic depicting the important functions of FreeStyle.

Two-step graphic depicting FreeStyle's testing procedure. The first picture depicts a lanced forearm with FreeStyle pressed on top. The second picture depicts a blood sample applied to the FreeStyle test strip for testing.

Picture of a FreeStyle Blood Glucose Monitoring System.

Graphic depicting the sample sizes required by other meters along with the sample size required by FreeStyle, which is shown to be significantly smaller.

Picture depicting a fingertip being lanced by a traditional lancing device.

TEXT ACCOMPANYING THE GRAPHIC

"The FreeStyle Blood Glucose Monitoring System."

"Pain is one of the biggest barriers to frequent testing."

"FreeStyle lets people test on their forearm, thigh, calf, upper arm and hand where it's much less painful to test than their fingers."

"FreeStyle uses the world's smallest blood sample."

"FreeStyle is quick and easy to use."

"Most people said, 'FreeStyle is painless.' (During clinical studies, most people said testing on their forearms was painless.*)" "

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

SUMMARY

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" and the financial statements and notes to those statements appearing elsewhere in this prospectus, before deciding to invest in our common stock.

Our Business

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. The FDA is currently reviewing our recent FreeStyle labeling changes, which are subject to clearance. In March 2001, we obtained the CE Mark, which permits us to commercially distribute FreeStyle throughout the European Union. As of July 31, 2001, we have shipped over 390,000 meters and over 79 million test strips. For the quarter ended June 30, 2001, our total revenues were \$17.8 million. Meter and test strip shipments for the quarter ended June 30, 2001 increased 72% and 71%, respectively, compared to the preceding quarter. 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.

The Opportunity

The blood glucose self-monitoring market is the largest self-test market for

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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.

Government studies in the United States and the United Kingdom have shown that complications from diabetes can be significantly reduced through regular testing--four or more times per day for Type 1 diabetes and two or more times per day for Type 2 diabetes--and improved therapy. Self-monitoring of blood glucose has become a standard of care, and glucose self-monitoring devices and disposable test strips are typically covered by health insurance, including Medicare and Medicaid. Despite the ability to significantly reduce complications of diabetes through regular testing and treatment and the availability of reimbursement, many people with diabetes under-test or fail to test at all. A study prepared for us indicated that pain is a leading factor that discourages people with diabetes from testing as recommended.

Our Solution

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. Because our product is less painful to use, we believe FreeStyle will enable us to both penetrate and expand the glucose self-monitoring market.

Our FreeStyle System kit includes a FreeStyle meter, an initial supply of proprietary FreeStyle test strips, a FreeStyle lancing device, FreeStyle lancets and FreeStyle control solution. We believe FreeStyle provides the following significant advantages over competing systems:

- . reduction in pain;
- . better performance; and
- . improved quality of life.

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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 nine of the ten largest national retailers, including Walgreens, Wal-Mart and CVS, through wholesalers, including McKesson, Cardinal Health and Bergen Brunswig, and directly to end users over the telephone and through our website. FreeStyle is currently being sold in Germany and Sweden by Disetronic Group, our European distributor that has exclusive distribution rights to FreeStyle in selected European countries. 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.

We are also developing a Continuous Glucose Monitoring System that utilizes a disposable miniaturized sensor that can be inserted under the skin by the user

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and incorporates a wireless display unit that can be worn like a pager. This sensor system is intended to continuously measure and display a person's glucose levels in real time for up to three days. The ability of people with diabetes to adjust insulin dose, oral medication, diet and exercise according to the glucose readings obtained from the system should result in significantly improved health. We have recently commenced a pilot clinical study with people who have diabetes using our Continuous Glucose Monitoring System. We expect that this product will require premarket approval by the FDA. Therefore, even if the product is successfully developed, it will not be commercially available for a number of years.

Our Strategy

Our objective is to be a leading provider of innovative glucose monitoring products that reduce the pain of testing, are easy to use, accurate, cost effective and improve the lives of people with diabetes. To achieve this objective, we are pursuing the following business strategies:

- . establish FreeStyle as a leading blood glucose self-monitoring device;
- . maintain and enhance retail distribution of FreeStyle;
- . focus on our core competencies in electrochemistry and sensor manufacturing technologies, while outsourcing other aspects of our business;
- . provide high quality customer service;
- . establish an international presence for FreeStyle; and
- . leverage our proprietary technology platform.

Additional Information

We have a limited operating history and we have significant losses. As of June 30, 2001, our accumulated deficit was approximately \$89.7 million. We will continue to have substantial future capital requirements. We expect to continue to incur significant net losses for the foreseeable future. In addition, we expect substantially all of our revenue will be derived from sales of FreeStyle, our only commercial product. FreeStyle faces intense competition in a market where four companies control approximately 90% of worldwide sales. We are subject to extensive regulation by the FDA and foreign regulatory bodies, and a recent FreeStyle labeling change is being reviewed by the FDA as a 510(k) submission. For a discussion of the foregoing factors and other factors that could adversely affect us, you should read "Risk Factors."

We were incorporated in California in 1996 and reincorporated in Delaware in 2000. Our principal executive offices are located at 1360 South Loop Road, Alameda, California 94502. Our telephone number at this location is (510) 749-5400. Our Internet address is www.therasense.com. The information contained on our website is not a part of this prospectus.

TheraSense(R), FreeStyle(TM), The Technology of Caring(TM), NanoSample(TM) and Wired Enzyme(TM) are trademarks and service marks of ours. Other service marks, trademarks and trade names referred to in this prospectus are the property of their respective owners.

The Offering

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Common stock offered by us..... 6,000,000 shares

Common stock to be outstanding after this offering..... 38,089,847 shares

Use of proceeds..... We intend to use the net proceeds from this offering for additional sales and marketing efforts, research and development, expansion of our facilities, as well as for working capital and other general corporate purposes.

Nasdaq National Market symbol..... THER

The number of shares of common stock to be outstanding after this offering is based on 32,089,847 shares outstanding as of June 30, 2001, and excludes:

- . 521,013 shares issuable upon exercise of outstanding warrants at a weighted average exercise price of \$2.07 per share;
- . 4,882,303 shares issuable upon exercise of outstanding options under our 1997 Stock Plan at a weighted average exercise price of \$3.73 per share; and
- . a total of 9,053,832 shares available for future issuance under our equity incentive plans.

Except as otherwise noted, all information in this prospectus:

- . assumes the underwriters do not exercise their over-allotment option;
- . reflects the filing of our amended and restated certificate of incorporation; and
- . reflects the conversion of each share of preferred stock into one share of common stock immediately prior to the closing of this offering.

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Summary Financial Data (in thousands, except per share data)

The following table sets forth our summary financial data. This data has been derived from our financial statements for the years ended December 31, 1998, 1999 and 2000, the six month periods ended June 30, 2000 and 2001, and as of June 30, 2001 included elsewhere in this prospectus. You should read this information in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes included elsewhere in this prospectus.

| Years Ended December 31, | Six Months Ended June 30, |
|--------------------------|------------------------------|
| ----- | ----- |

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| | 1998 | 1999 | 2000 | 2000 | 2001 |
|--|------------|-------------|-------------|-------------|-------------|
| | ----- | ----- | ----- | ----- | ----- |
| | | | | (unaudited) | |
| Statement of Operations Data: | | | | | |
| Total revenues..... | \$ 60 | \$ 85 | \$ 5,503 | \$ 511 | \$ 25,524 |
| Cost of revenues..... | -- | -- | 11,948 | 296 | 19,668 |
| | ----- | ----- | ----- | ----- | ----- |
| Gross profit (loss)..... | 60 | 85 | (6,445) | 215 | 5,856 |
| Operating expenses: | | | | | |
| Research and development..... | 3,056 | 7,672 | 12,019 | 5,841 | 6,332 |
| Selling, general and administrative..... | 1,810 | 5,557 | 25,460 | 9,787 | 26,843 |
| | ----- | ----- | ----- | ----- | ----- |
| Total operating expenses.... | 4,866 | 13,229 | 37,479 | 15,628 | 33,175 |
| Loss from operations..... | (4,806) | (13,144) | (43,924) | (15,413) | (27,319) |
| Interest income, net..... | 142 | 86 | 332 | 354 | 386 |
| | ----- | ----- | ----- | ----- | ----- |
| Net loss..... | (4,664) | (13,058) | (43,592) | (15,059) | (26,933) |
| Deemed dividend related to beneficial conversion feature of preferred stock..... | -- | -- | (14,773) | (14,773) | (26,783) |
| | ----- | ----- | ----- | ----- | ----- |
| Net loss attributable to common stockholders..... | \$ (4,664) | \$ (13,058) | \$ (58,365) | \$ (29,832) | \$ (53,716) |
| | ===== | ===== | ===== | ===== | ===== |
| Net loss per common share, basic and diluted..... | \$ (2.31) | \$ (4.32) | \$ (14.69) | \$ (8.03) | \$ (11.35) |
| | ===== | ===== | ===== | ===== | ===== |
| Weighted-average shares used in computing net loss per common share, basic and diluted..... | 2,015 | 3,024 | 3,973 | 3,713 | 4,732 |
| | ===== | ===== | ===== | ===== | ===== |
| Pro forma net loss per common share, basic and diluted (unaudited)..... | | | \$ (2.06) | | \$ (0.92) |
| | | | ===== | | ===== |
| Weighted-average shares used in computing pro forma net loss per common share, basic and diluted (unaudited)..... | | | 21,129 | | 29,331 |
| | | | ===== | | ===== |

As of June 30, 2001

| | |
|-------------|-------------|
| ----- | ----- |
| Actual | As Adjusted |
| ----- | ----- |
| (unaudited) | |

| | | |
|--|-----------|-----------|
| Balance Sheet Data: | | |
| Cash and cash equivalents..... | \$ 45,152 | \$150,422 |
| Working capital..... | 34,806 | 140,076 |
| Total assets..... | 78,982 | 184,252 |
| Deferred revenue..... | 17,684 | 17,684 |
| Long-term obligations, less current portion..... | 3,685 | 3,685 |
| Convertible preferred stock..... | 119,246 | -- |
| Deferred stock-based compensation, net..... | (15,645) | (15,645) |
| Accumulated deficit..... | (89,657) | (89,657) |

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Total stockholders' equity (deficit)..... (84,319) 140,197

The as adjusted column of the balance sheet data reflects the conversion of all of our outstanding shares of convertible preferred stock into shares of common stock immediately prior to the closing of this offering and the sale of 6,000,000 shares of common stock offered by us at an initial public offering price of \$19.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

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RISK FACTORS

An investment in our common stock offered by this prospectus involves a substantial risk of loss. You should carefully consider these risk factors, together with all of the other information included in this prospectus, before you decide to purchase shares of our common stock. The 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.

Risks Related to Our Business

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 \$26.9 million in the six months ended June 30, 2001. As of June 30, 2001, we had an accumulated deficit of approximately \$89.7 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.

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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. 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.

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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

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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.

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These companies and others have developed and will continue to develop 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

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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.

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We will work closely with the FDA to address their questions and resolve any issues around our labeling. 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 we or our suppliers 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

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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

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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. 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. 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 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

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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.

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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 and we do not know how long we will be required to rely on these estimates. Further, these third parties may not provide consistent, reliable data.

If we do not provide quality customer service, we would lose customers and our

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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.

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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.

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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.

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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.

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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.

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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.

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Risks Related to this Offering

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

Prior to this offering, there has been no public market for shares of our common stock. An active public trading market may not develop following completion of this offering or, if developed, may not be sustained. The price of the shares of common stock sold in this offering was determined by negotiation between the underwriters and us. This price will not necessarily reflect the market price of the common stock following this offering. The market price for the common stock following this offering will 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

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- 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.

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

After this offering, we will have 38,089,847 shares of common stock outstanding, or 38,989,847 shares if the underwriters' over-allotment is exercised in full. The 6,000,000 shares sold in this offering, or 6,900,000 shares if the underwriters' over-allotment is exercised in full, will be freely tradable without restriction or further registration under the federal securities laws unless purchased by our affiliates. The remaining 32,089,847 shares of common stock outstanding after this offering, based upon shares outstanding as of June 30, 2001, assuming no exercise of outstanding options prior to completion of this offering, will be available for sale in the public market as follows:

| Number of Shares | Date of Availability for Sale |
|------------------|--|
| 0 | Immediately after the date of this prospectus |
| 32,089,847 | 180 days after the effective date of the registration statement containing this prospectus (subject in some cases to volume and other limitations) |

The above table assumes the effectiveness of the lock-up agreements under which holders of substantially all of our common stock have agreed not to sell or otherwise dispose of their shares of

common stock. Approximately 16.0 million of the shares that will be available for sale after the expiration of the lock-up period will be subject to volume restrictions because they are held by our affiliates. In addition, U.S. Bancorp Piper Jaffray Inc. may waive these lock-up restrictions prior to the expiration of the lock-up period without prior notice.

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If our common stockholders sell substantial amounts of common stock in the public market, or the market perceives that these sales may occur, the market price of our common stock could fall. After this offering, the holders of approximately 27,243,164 shares of common stock issued upon conversion of our preferred stock and upon exercise of outstanding warrants will have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Furthermore, if we were to include in a company-initiated registration statement shares held by those holders pursuant to the exercise of their registration rights, those sales could impair our ability to raise needed capital by depressing the price at which we could sell our common stock.

Purchasers in this offering will experience immediate and substantial dilution.

The initial public offering price of our shares is substantially higher than the net tangible book value per share of the outstanding common stock. Accordingly, investors purchasing shares of common stock in this offering will:

- . pay a price per share that substantially exceeds the value of our assets after subtracting liabilities; and
- . contribute 48.6% of the total amount invested to date to fund us, but will own only 15.8% of the shares of common stock outstanding. To the extent outstanding stock options or warrants are exercised, there will be further dilution to new investors.

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 your interests.

Our executive officers and directors and entities affiliated with them will, in the aggregate, beneficially own approximately 37.8% of our common stock following this offering. This significant concentration of share ownership may adversely affect the trading price for our common stock because investors often perceive disadvantages in owning stock in companies with controlling stockholders. 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 you.

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

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

- . authorize the issuance of preferred stock which can be created and issued by the board of directors without prior stockholder approval, commonly referred to as "blank check" preferred stock, with rights senior to those of common stock;

- . prohibit stockholder actions by written consent; and

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. 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.

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INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the sections entitled "Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business," 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. We believe that the section entitled "Risk Factors" includes all material risks that could harm our business. 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 our 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.

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USE OF PROCEEDS

We estimate that the net proceeds from the sale of the 6,000,000 shares of common stock that we are selling in this offering will be approximately \$105.3 million based on an initial public offering price of \$19.00 per share, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters' over-allotment option is

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exercised in full, we estimate that we will receive net proceeds of approximately \$121.2 million.

We currently estimate that we will use the net proceeds of this offering, together with our cash on hand, to fund our operations, including:

- . approximately \$50.0 million to fund continued sales and marketing efforts for FreeStyle, including increases in advertising and product sampling;
- . approximately \$10.0 million for research and development of enhanced FreeStyle products and our Continuous Glucose Monitoring System;
- . approximately \$10.0 million to expand our facility in Alameda, California, including an expansion of our test strip manufacturing capacity; and
- . the remainder for working capital and other general corporate purposes.

The amounts actually expended for these purposes may vary significantly and will depend on a number of factors, including the amount of our future revenues, expenses and the other factors described under "Risk Factors." In addition, we will retain broad discretion in the allocation of the net proceeds of this offering. Should we determine to employ cash resources for the acquisition of complementary businesses, products or technologies, the amounts available for the purposes cited above may be significantly reduced. Although we evaluate potential acquisitions in the ordinary course of business, we have no specific understandings, commitments or agreements with respect to any acquisition or investment at this time.

Until we use the net proceeds of this offering for the above purposes, we intend to invest the funds in short-term, investment grade, interest-bearing securities. We cannot predict whether the proceeds invested will yield a favorable return.

DIVIDEND POLICY

Since our incorporation, we have never declared or paid any dividends on our capital stock. We currently expect to retain our future earnings, if any, for use in the operation and expansion of our business and do not anticipate paying any dividends in the foreseeable future.

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CAPITALIZATION

The following table sets forth our actual capitalization as of June 30, 2001. Our capitalization is also presented:

- . on a pro forma basis to give effect to the conversion of all outstanding shares of convertible preferred stock into shares of common stock immediately prior to the completion of this offering; and
- . on a pro forma as adjusted basis to reflect the sale in this offering of 6,000,000 shares of common stock at an initial public offering price of \$19.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

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| | As of June 30, 2001 | | |
|---|--|-----------|--------------------------|
| | Actual | Pro Forma | Pro Forma As Adjusted |
| | (in thousands, except share data) (unaudited) | | |
| Long-term obligations, less current portion.... | \$ 3,685 | \$ 3,685 | \$ 3,685 |
| Convertible preferred stock, \$0.001 par value; 28,309,647 shares authorized, 26,722,151 shares issued and outstanding, actual; no shares authorized, issued and outstanding, pro forma and pro forma as adjusted..... | 119,246 | -- | -- |
| Stockholders' equity (deficit): | | | |
| Preferred stock, \$0.001 par value; no shares authorized, issued or outstanding, actual and pro forma; 5,000,000 shares authorized, no shares issued or outstanding, pro forma as adjusted..... | -- | -- | -- |
| Common stock, \$0.001 par value; 50,000,000 shares authorized, 5,367,696 shares issued and outstanding, actual; 32,089,847 shares issued and outstanding, pro forma; 200,000,000 shares authorized and 38,089,847 shares issued and outstanding, pro forma as adjusted..... | 5 | 32 | 38 |
| Additional paid-in capital..... | 21,272 | 140,491 | 245,755 |
| Notes receivable from stockholders..... | (294) | (294) | (294) |
| Deferred stock-based compensation, net..... | (15,645) | (15,645) | (15,645) |
| Accumulated deficit..... | (89,657) | (89,657) | (89,657) |
| Total stockholders' equity (deficit)..... | (84,319) | 34,927 | 140,197 |
| Total capitalization..... | \$ 38,612 | \$ 38,612 | \$143,882 |

In addition to the shares of common stock to be outstanding after the offering, we may issue additional shares of common stock under the following plans and arrangements:

- . 521,013 shares issuable upon exercise of outstanding warrants as of June 30, 2001 at a weighted average exercise price of \$2.07 per share;
- . 4,882,303 shares issuable upon exercise of outstanding options under our 1997 Stock Plan at a weighted average exercise price of \$3.73 per share as of June 30, 2001; and
- . a total of 9,053,832 shares available for future issuance under our equity incentive plans.

You should read the capitalization table together with the sections of this prospectus entitled "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and with the financial statements and related notes beginning on page F-1.

DILUTION

Our pro forma net tangible book value at June 30, 2001 was approximately \$34.9 million, or \$1.09 per share, after giving effect to the conversion of all outstanding shares of our convertible preferred stock into shares of common stock upon completion of this offering. Pro forma net tangible book value per share is equal to our total tangible assets less our total liabilities, divided by the total number of shares of our common stock outstanding. After giving effect to the sale of the 6,000,000 shares of our common stock offered in this offering at an initial public offering price of \$19.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value at June 30, 2001 would have been approximately \$140.2 million, or \$3.68 per share. This represents an immediate increase in net tangible book value of \$2.59 per share to existing stockholders and an immediate dilution of \$15.32 per share to new investors purchasing shares of our common stock in this offering.

The following table illustrates the per share dilution to the new investors:

| | |
|--|---------|
| Initial public offering price per share..... | \$19.00 |
| Pro forma net tangible book value per share at June 30, 2001.... | \$1.09 |
| Increase in pro forma net tangible book value per share attributable to this offering..... | 2.59 |
| | ----- |
| Pro forma net tangible book value per share as adjusted after this offering..... | 3.68 |
| | ----- |
| Dilution per share to new investors in this offering..... | \$15.32 |
| | ===== |

If the underwriters exercise their over-allotment option in full, there will be an increase in pro forma net tangible book value to \$4.00 per share to existing stockholders and an immediate dilution in pro forma net tangible book value of \$15.00 to new investors.

The following table summarizes, on a pro forma basis as of June 30, 2001, the total number of stockholders and new investors with respect to the number of shares of common stock purchased from us, the total consideration paid and the average price per share paid by the existing stockholders and by the new investors in this offering before deducting the underwriting discounts and commissions and estimated offering expenses payable by us:

| | Shares Purchased | | Total Consideration | | Average Price Per Share |
|----------------------------|------------------|---------|---------------------|---------|-------------------------|
| | Numbers | Percent | Amount | Percent | |
| Existing stockholders..... | 32,089,847 | 84.25% | \$120,396,078 | 51.36% | \$ 3.75 |
| New investors..... | 6,000,000 | 15.75% | 114,000,000 | 48.64% | \$19.00 |
| | ----- | ----- | ----- | ----- | ----- |
| Total..... | 38,089,847 | 100.00% | \$234,396,078 | 100.00% | |
| | ===== | ===== | ===== | ===== | |

If the underwriters exercise their over-allotment option in full, our existing

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stockholders would own 82.3% and our new investors would own 17.7% of the total number of shares of our common stock outstanding after this offering.

Assuming the exercise in full of all options and warrants outstanding and exercisable as of June 30, 2001, the average price per share paid by our existing stockholders would be reduced by \$0.02 per share to \$3.73 per share.

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The preceding discussion and tables assume no exercise of stock options or warrants outstanding as of June 30, 2001. As of June 30, 2001, there were:

- . 521,013 shares issuable upon exercise of outstanding warrants at a weighted average exercise price of \$2.07 per share;
- . 4,882,303 shares issuable upon exercise of outstanding options under our 1997 Stock Plan at a weighted average exercise price of \$3.73 per share; and
- . a total of 9,053,832 shares available for future issuance under our equity incentive plans.

After this offering and assuming the exercise in full of all options and warrants outstanding and exercisable as of June 30, 2001, our pro forma net tangible book value per share as of June 30, 2001 would be \$3.67 per share, representing an immediate increase in net tangible book value of \$2.58 per share to existing stockholders and an immediate dilution in net tangible book value of \$15.33 per share to new investors.

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SELECTED FINANCIAL DATA

The selected financial data set forth below are derived from our financial statements. The statement of operations data for the years ended December 31, 1996 and 1997, and the balance sheet data as of December 31, 1996, 1997 and 1998 are derived from our audited financial statements not included in this prospectus. The statement of operations data for the years ended December 31, 1998, 1999 and 2000, and the balance sheet data as of December 31, 1999 and 2000 are derived from our audited financial statements included in this prospectus. The statement of operations data for the six months ended June 30, 2000 and 2001 and the balance sheet data as of June 30, 2001 are derived from our unaudited financial statements included in this prospectus. Our unaudited financial statements have been prepared by us on a basis consistent with our audited financial statements and, in management's opinion, include all adjustments necessary, consisting only of normal recurring adjustments, for a fair presentation of this information. The results of operations for the six months ended June 30, 2001 are not necessarily indicative of the results to be expected for the entire year, for any other interim period or for any future year. The selected financial data set forth below should be read in conjunction with our financial statements, the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this prospectus.

| Period from April 3, 1996 (inception) to December 31, 1996 | Years Ended December 31, | | | | Six Months Ende June 30, | |
|---|--------------------------|------|------|------|-----------------------------|------|
| | 1997 | 1998 | 1999 | 2000 | 2000 | 2001 |

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| | (in thousands, except per share data) | | | | | | (unaudited) |
|--|---------------------------------------|-----------|-----------|------------|------------|------------|-------------|
| Statement of Operations Data: | | | | | | | |
| Research grant revenue.. | \$618 | \$ -- | \$ 60 | \$ 60 | \$ 3 | \$ 3 | \$ 25, |
| Product sales..... | -- | -- | -- | 25 | 5,000 | 8 | 25, |
| License income..... | -- | -- | -- | -- | 500 | 500 | -- |
| Total revenues..... | 618 | -- | 60 | 85 | 5,503 | 511 | 25, |
| Cost of revenues..... | -- | -- | -- | -- | 11,948 | 296 | 19, |
| Gross profit (loss)..... | 618 | -- | 60 | 85 | (6,445) | 215 | 5, |
| Operating expenses: | | | | | | | |
| Research and development..... | 228 | 977 | 3,056 | 7,672 | 12,019 | 5,841 | 6, |
| Selling, general and administrative..... | 199 | 703 | 1,810 | 5,557 | 25,460 | 9,787 | 26, |
| Total operating expenses..... | 427 | 1,680 | 4,866 | 13,229 | 37,479 | 15,628 | 33, |
| Income (loss) from operations..... | 191 | (1,680) | (4,806) | (13,144) | (43,924) | (15,413) | (27, |
| Interest income (expense), net..... | (9) | 163 | 142 | 86 | 332 | 354 | -- |
| Net income (loss)..... | 182 | (1,517) | (4,664) | (13,058) | (43,592) | (15,059) | (26, |
| Deemed dividend related to beneficial conversion feature of preferred stock..... | -- | -- | -- | -- | (14,773) | (14,773) | (26, |
| Net income (loss) attributable to common stockholders..... | \$182 | \$(1,517) | \$(4,664) | \$(13,058) | \$(58,365) | \$(29,832) | \$(53, |
| Net income (loss) per common share, basic and diluted..... | | \$ (1.66) | \$ (2.31) | \$ (4.32) | \$ (14.69) | \$ (8.03) | \$ (11.00) |
| Weighted-average shares used in computing net loss per common share, basic and diluted..... | | 914 | 2,015 | 3,024 | 3,973 | 3,713 | 4,000 |
| Pro forma net loss per common share, basic and diluted (unaudited).... | | | | | \$ (2.06) | | \$ (0.00) |
| Weighted-average shares used in computing pro forma net loss per common share, basic and diluted (unaudited).... | | | | | 21,129 | | 29,000 |

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| | As of December 31, | | | | | As of |
|---|--------------------|----------|----------|----------|-----------|------------------|
| | 1996 | 1997 | 1998 | 1999 | 2000 | June 30, 2001 |
| | (in thousands) | | | | | (unaudited) |
| Balance Sheet Data: | | | | | | |
| Cash and cash equivalents..... | \$ 122 | \$ 4,088 | \$11,438 | \$ 2,322 | \$ 12,532 | \$ 45,152 |
| Working capital..... | 121 | 3,595 | 10,956 | 792 | 4,240 | 34,806 |
| Total assets..... | 178 | 4,680 | 12,379 | 8,026 | 37,565 | 78,982 |
| Deferred revenue..... | -- | 72 | 11 | 511 | 8,687 | 17,684 |
| Long-term obligations, less current portion... | -- | -- | 520 | 3,321 | 7,994 | 3,685 |
| Convertible preferred stock..... | -- | 5,526 | 17,361 | 20,472 | 62,883 | 119,246 |
| Deferred stock-based compensation, net..... | -- | -- | -- | (1,244) | (11,263) | (15,645) |
| Retained earnings (accumulated deficit)... | 107 | (1,410) | (6,074) | (19,132) | (62,724) | (89,657) |
| Total stockholders' equity (deficit)..... | 129 | (1,387) | (6,047) | (18,159) | (59,848) | (84,319) |

See our financial statements and related notes for a description of the calculation of the historical and pro forma net loss per common share and the weighted-average number of shares used in computing the historical and pro forma per common share data.

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

The following discussion should be read in conjunction with our financial statements and related notes appearing elsewhere in this prospectus. This discussion may contain forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of selected factors, including those set forth under "Risk Factors" and elsewhere in this prospectus. We believe that the section entitled "Risk Factors" includes all material risks that could harm our business.

Overview

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 commenced commercial shipments in the United States in June 2000. We sell FreeStyle in the United States through national retailers and wholesalers, and directly to consumers over the telephone and through our website. In March 2001, we obtained the CE Mark for FreeStyle, and our European distributor commenced sales of FreeStyle in Germany and Sweden in May 2001.

We incurred significant operating losses and negative cash flows from operations in each full fiscal year since inception. We incurred net losses of

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\$4.7 million in 1998, \$13.1 million in 1999, \$43.6 million in 2000 and \$26.9 million for the six months ended June 30, 2001. As of June 30, 2001, we had an accumulated deficit of \$89.7 million. We expect to incur significant additional losses as we expand our sales and marketing efforts and continue to develop new products.

Revenues are generated from sales of our FreeStyle System kit and from the recurring sales of disposable FreeStyle test strips and lancets. Our return policy allows end users in the United States to return FreeStyle System kits to us for a full cash refund within 30 days of purchase. There are no end-user return rights on sales of FreeStyle test strips and lancets. In addition, our FreeStyle System kit 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 up to six months beyond this expiration date. As a result of these rights of return and the current unavailability of historical trends in sales and product returns, we defer recognition of revenue on sales of FreeStyle test strips until resold by the retailers and wholesalers to end users, and we defer recognition of revenue 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 and we do not know how long we will be required to rely on these estimates. Further, these third parties may not provide consistent, reliable data.

Our products distributed internationally have no right of return, and we recognize revenue on these products upon shipment. We recognize revenue on direct product sales over the telephone or through our website to end users upon shipment for FreeStyle test strips and lancets and 30 days after purchase on sales of FreeStyle System kits. Our current sales terms to retailers and wholesalers provide for customer payment within 60 days of shipment on initial orders and payment within 30 days for subsequent orders. We perform ongoing credit evaluations of our customers' financial condition and, generally, require no collateral from our customers. We believe our terms to retailers, wholesalers and end users, including their rights to return, are similar to our competitors' terms.

Manufacturers typically sell their glucose monitoring devices at substantial discounts to list prices, offer customer rebates or provide free product samples to expand their installed base of monitoring devices and thus increase the market for their disposable test strips and lancets. We have been offering and

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expect to continue to offer similar discounts and rebates on, and free samples of, our FreeStyle System kits to establish an installed base of systems from which we expect to generate recurring revenues from our disposable FreeStyle test strips and lancets. Due to the recent commencement of our sales, we do not have significant historical trends in rebates claimed by end users. As a result, we record an allowance for 100% of the allowable rebate as a reduction of revenues reported. As we accumulate trend data in rebates claimed, we are likely to change the percentage of the allowable rebate.

The initial product mix of FreeStyle System kits when compared to disposable FreeStyle test strips and lancets will negatively impact our gross margins until we have established a sufficiently large installed base of users, as we currently distribute the FreeStyle System kit at a financial loss due in part to samples, discounts and rebates. In the event we establish an installed base of systems, we expect to generate an increasing portion of our revenues through

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recurring sales of our FreeStyle test strips.

Cost of revenues consists primarily of:

- . payments to our manufacturing and distribution partners;
- . expenses relating to our disposable test strip manufacturing;
- . expenses relating to our internal operations;
- . expenses relating to our five-year warranty on our FreeStyle meter;
- . amortization of deferred stock-based compensation; and
- . royalties payable under technology licenses.

We manufacture our disposable test strips ourselves at our facility in Alameda, California. We outsource the manufacturing, packaging and testing of our FreeStyle meters to Flextronics International Ltd., an electronics contract manufacturer. Our FreeStyle lancing device and disposable lancets are manufactured by Facet Technologies LLC, a wholly-owned subsidiary of Matria Healthcare, Inc. Our distribution services are performed by Livingston Health Care Systems Inc., a division of UPS Global Logistics.

Research and development expenses include costs associated with the design, development, testing and enhancement of our products. These costs consist primarily of:

- . salaries and related personnel expenses;
- . fees paid to outside service providers;
- . expenditures for purchases of laboratory supplies and clinical trials;
- . amortization of deferred stock-based compensation; and
- . overhead allocated to product development.

At the time we commenced commercial shipments in June 2000, we transitioned the recording of manufacturing-related costs from research and development expense to cost of revenues. All research and development costs are expensed as incurred. Our research and development efforts are periodically subject to significant non-recurring costs and fees that can cause significant variability in our quarterly research and development expenses.

Selling, general and administrative expenses primarily consist of:

- . salaries, commissions and related expenses for personnel engaged in sales, marketing, customer service and administrative functions;

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- . costs associated with advertising, product sampling, trade shows, promotional and other marketing activities;
- . legal and regulatory expenses;
- . amortization of deferred stock-based compensation; and
- . general corporate expenses.

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Deferred stock-based compensation consists of amortization of deferred compensation in connection with stock option grants and sales of stock to employees at exercise or sales prices below the deemed fair market value of our common stock. Deferred stock-based compensation for options granted to non-employees has been determined as the fair value of the equity instruments issued. Deferred stock-based compensation for options granted to non-employees is periodically remeasured as the underlying options vest. As of June 30, 2001, we have recorded aggregate deferred stock-based compensation of \$19.6 million, of which \$15.6 million will be amortized to expense on a straight line basis through 2005. This amount is being amortized over the respective vesting periods of these equity instruments, which is typically four years. Deferred stock-based compensation expense has been allocated according to employees and their respective departments and by function for non-employees.

In September 2000, we entered into a five-year exclusive distribution agreement with Disetronic Group relating to the distribution of FreeStyle in Germany, Switzerland, Denmark, Austria, Sweden, Finland, Norway and the Netherlands. Disetronic commenced sales in Germany and Sweden in May 2001. In connection with this agreement, we received an advance payment on a purchase order from Disetronic of \$1.5 million, which we recognized in the second quarter of 2001 as we shipped products.

In April 2001, we entered into a five-year exclusive distribution agreement with Nipro Corporation relating to the distribution of FreeStyle in Japan. In connection with this agreement, we received a \$5.0 million payment from Nipro, which is being recognized as revenue ratably over the term of the agreement commencing in April 2001.

Results of Operations

Six Months Ended June 30, 2000 and June 30, 2001

Revenues. There were nominal product revenues for the six months ended June 30, 2000. However, we recognized revenue of \$0.5 million from a specific non-refundable negotiation fee related to a potential distribution arrangement, which was never consummated. We recognized revenues of \$25.5 million for the six months ended June 30, 2001, principally consisting of sales of FreeStyle System kits and FreeStyle test strips. Two of our customers, McKesson and Walgreens, and our European distributor, Disetronic, individually accounted for more than 10% and collectively accounted for approximately 40% of our revenues for the six months ended June 30, 2001. As of June 30, 2001, deferred revenue, awaiting sale through to end users and for the 30-day cash refund period on FreeStyle System kit sales to lapse, was approximately \$12.9 million. In addition, we recognized revenues of \$0.3 million for the six months ended June 30, 2001 related to the \$5.0 million distribution agreement payment received from Nipro.

Cost of revenues. Cost of revenues for the six months ended June 30, 2000 was \$0.3 million, and principally related to start-up production costs, as there was no cost associated with the nonrefundable negotiation fee income earned. Cost of revenues for the six months ended June 30, 2001 was \$19.7 million, attributable to product sales, as there was no cost associated with the license fee income earned. Amortization of stock-based compensation expense reported in cost of revenues for the six months ended June 30, 2001 was \$0.2 million, as compared to an insignificant amount in the same prior year period.

Research and development expenses. Research and development expenses increased from \$5.8 million for the six months ended June 30, 2000 to \$6.3 million for

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the six months ended June 30, 2001, representing an increase of \$0.5 million, or 8%. This increase was primarily attributable to \$0.5 million from hiring additional personnel, \$0.5 million spent on clinical trials and \$0.4 million from increased spending on product development efforts. Prior to commencing commercial shipments of FreeStyle in June 2000, costs associated with start-up manufacturing activities were reported as research and development expenses. These expenses, which occurred in the first half of 2000, totaled \$1.2 million, partially offsetting the increase in research and development expenses for the six months ended June 30, 2001 over research and development expenses for the six months ended June 30, 2000. Amortization of deferred stock-based compensation was \$0.5 million for the six months ended June 30, 2001 as compared to \$0.2 million in the same prior year period. We expect research and development spending to increase over the next several years as we increase clinical trials for our Continuous Glucose Monitoring System and expand our research and development activities to support our current and future products.

Selling, general and administrative expenses. Selling, general and administrative expenses increased from \$9.8 million for the six months ended June 30, 2000 to \$26.8 million for the six months ended June 30, 2001, representing an increase of \$17.0 million, or 174%. This increase was primarily attributable to increases of \$6.0 million spent on product sampling, \$4.0 million for marketing activities and other spending associated with expanding distribution and developing consumer awareness of FreeStyle, \$3.3 million for personnel costs largely related to expanding our U.S. direct sales force as well as marketing and business support functions, \$1.0 million spent for customer service and support operations, and \$0.5 million for travel costs, largely related to our sales force. Amortization of deferred stock-based compensation was \$1.3 million for the six months ended June 30, 2001, as compared to \$0.3 million in the same prior year period. We expect our selling, general and administrative expenses to increase as we increase product sampling, expand our sales force, increase our marketing and promotional activities, and operate as a public company.

Interest income, net. Net interest income remained relatively flat at \$0.4 million for the six months ended June 30, 2000 and 2001. Interest income results from our interest on cash and cash equivalents, while interest expense is associated with borrowings under lines of credit and capital lease obligations. Interest income for the six months ended June 30, 2001 increased due to higher average cash and cash equivalents balances, resulting from the net proceeds of a private equity offering initiated in January 2001. Interest expense for the six months ended June 30, 2000 increased to a lesser extent, as a result of additional borrowings under available lines of credit, amortization of debt issuance costs associated with warrants issued in connection with lines of credit and capital lease obligations arising under a particular sale and leaseback transaction.

Dividend related to beneficial conversion feature of preferred stock. Dividends relating to beneficial conversion of our preferred stock of \$26.8 million were recorded in the six months ended June 30, 2001. These dividends arose due to the issuance of 6,643,371 shares of Series D preferred stock in January, February and April 2001 for net proceeds of \$56.4 million.

Years Ended December 31, 1998, 1999 and 2000

Revenues. Revenues in 1998 and 1999 principally related to research grants and the sale of clinical evaluation units. Revenues recognized in 2000 totaled \$5.5 million, principally consisting of product sales of FreeStyle System kits and FreeStyle test strips which commenced in June 2000. Revenue in 2000 also included \$0.5 million from a specific non-refundable negotiation fee related to a potential distribution arrangement, which was never consummated. Four of our customers, CVS, Walgreens, Wal-Mart and McKesson, individually accounted for more than 10% and collectively accounted for approximately 53% of our revenues

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for the year ended December 31, 2000. As of December 31, 2000,

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deferred revenue, awaiting sale through to end users and for the 30-day cash refund period on FreeStyle System kit sales to lapse, was approximately \$8.7 million.

Cost of revenues. There was no cost of revenues recorded in fiscal years 1998 and 1999. Cost of revenues in 2000 was \$11.9 million and was comprised of internal manufacturing costs, purchase costs for FreeStyle System kits and FreeStyle lancets from our contract manufacturing partners, costs of product warranties, royalties payable under technology licenses, start-up production costs and a \$3.5 million charge to reduce FreeStyle System kit inventories to estimated net realizable value. Amortization of stock-based compensation expense reported in cost of revenues for 2000 was insignificant. Prior to commencing commercial shipments of FreeStyle in June 2000, costs associated with start-up manufacturing-related activities, including stock-based compensation expense, were reported as research and development expenses. There was no cost associated with the license fee income earned.

Research and development expenses. Research and development expenses increased from \$3.1 million in 1998 to \$7.7 million in 1999 and to \$12.0 million in 2000. The increase from 1998 to 1999 was principally due to \$2.2 million from hiring of additional personnel and increased spending of \$1.6 million associated with the development of FreeStyle. The increase from 1999 to 2000 was primarily attributable to increases of \$1.6 million for materials and supplies used in product development efforts, \$1.1 million from hiring of additional personnel, a \$0.5 million payment for the purchase of technology and license rights from E. Heller & Co., which owns more than five percent of our stock, \$0.4 million for overhead costs associated with our new facility and \$0.2 million for payments to outside service providers. The technology and license rights purchased from E. Heller & Co. concern the measurement of biochemicals other than glucose. This technology is at an early stage of development, and it is currently uncertain whether it will have commercial application. Amortization of deferred stock-based compensation was \$0.6 million for the year ended December 31, 2000. Stock-based compensation expense for the corresponding period in 1999 was insignificant.

Selling, general and administrative expenses. Selling, general and administrative expenses increased from \$1.8 million in 1998 to \$5.6 million in 1999 and to \$25.5 million in 2000. The increase from 1998 to 1999 was primarily attributable to increases of \$1.5 million in personnel costs, \$0.8 million in marketing expenses, \$0.7 million in costs associated with moving into our new facility in August 1999, \$0.3 million in legal and professional services and \$0.2 million in travel costs. The increase from 1999 to 2000 was primarily attributable to increases of \$6.2 million for personnel costs, largely related to recruiting and hiring our U.S. direct sales force, as well as expanding marketing and business support functions, \$4.6 million for advertising, marketing activities and other spending associated with the launch of FreeStyle, \$2.8 million spent on the cost of product sampling, \$1.5 million spent on establishing customer service and support operations, \$1.1 million for overhead costs, \$1.0 million for travel costs, largely related to our new sales force, \$0.9 million spent on professional fees relating to a proposed public offering withdrawn in December 2000 and \$0.5 million for legal fees for both patent and general corporate matters. Amortization of deferred stock-based compensation was \$1.2 million for the year ended December 31, 2000. Stock-based compensation expense for the corresponding period in 1999 was insignificant.

Interest income, net. Net interest income remained relatively flat at \$0.1 million in 1998 and 1999, and \$0.3 million in 2000. Interest income in 2000

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increased due to higher average cash and cash equivalents balances, resulting from the net proceeds of a private equity offering completed in February 2000. Interest expense for the same period increased to a lesser extent, reflecting additional borrowings under available lines of credit, amortization of debt issuance costs associated with warrants issued in connection with lines of credit and capital lease obligations arising under a particular sale and leaseback transaction.

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Provision for income taxes. We incurred net operating losses for the years ended December 31, 1998, 1999 and 2000 and, accordingly, we did not pay any federal or state income taxes. As of December 31, 2000, we had accumulated approximately \$44.8 million and \$31.2 million in federal and state net operating loss carryforwards, respectively, to reduce future taxable income. If not utilized, the federal carryforward will expire in various amounts beginning in 2012, and the state carryforward will expire in 2005. Our net operating loss carryforwards are subject to annual limitation under Internal Revenue Code Section 382 due to substantial changes in ownership. Changes have already occurred on April 21, 1997 and February 23, 1999 as a result of our preferred stock financings. An additional change may occur as a result of this offering. The annual limitations do not result in the expiration of net operating losses prior to utilization. We have not recorded a benefit from our net operating loss carryforwards because we believe that it is uncertain that we will have sufficient income from future operations to realize the carryforwards prior to their expiration. Accordingly, we have established a valuation allowance against the deferred tax asset arising from the carryforwards.

We also had federal and state research and development tax credit carryforwards as of December 31, 2000 of approximately \$0.7 million and \$0.6 million, respectively. If not utilized, the federal research credit will expire in various amounts beginning in 2012. The state research credit can be carried forward indefinitely.

Dividend related to beneficial conversion feature of preferred stock. Dividends relating to beneficial conversion of our preferred stock of \$14.8 million were recorded in the year ended December 31, 2000. These dividends arose due to the issuance of 8,490,159 shares of Series C preferred stock in February 2000 for net proceeds of \$42.4 million.

Quarterly Results of Operations

The following table sets forth selected quarterly statement of operations data for each of the five quarters indicated below. This information is derived from our unaudited financial statements, which have been prepared by us on a basis consistent with our audited financial statements and, in management's opinion, include all adjustments necessary, consisting only of normal recurring adjustments, for a fair presentation of this information. These quarterly results of operations are not necessarily indicative of results of operations in any future period.

| Quarter Ended | | | | |
|-------------------------------|-----------------------|----------------------|-------------------|------------------|
| June 30, 2000 | September 30, 2000 | December 31, 2000 | March 31, 2001 | June 30, 2001 |
| (in thousands) (unaudited) | | | | |

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| | | | | | |
|--|------------|-------------|-------------|-------------|-------------|
| Revenues..... | \$ 11 | \$ 1,280 | \$ 3,712 | \$ 7,677 | \$ 17,847 |
| Cost of revenues..... | 306 | 6,763 | 4,879 | 6,225 | 13,443 |
| | ----- | ----- | ----- | ----- | ----- |
| Gross profit (loss)..... | (295) | (5,483) | (1,167) | 1,452 | 4,404 |
| | ----- | ----- | ----- | ----- | ----- |
| Operating expenses: | | | | | |
| Research and development..... | 2,633 | 3,561 | 2,615 | 2,798 | 3,534 |
| Selling, general and administrative..... | 5,444 | 5,522 | 10,163 | 11,033 | 15,810 |
| | ----- | ----- | ----- | ----- | ----- |
| Total operating expenses..... | 8,077 | 9,083 | 12,778 | 13,831 | 19,344 |
| | ----- | ----- | ----- | ----- | ----- |
| Loss from operations.... | (8,372) | (14,566) | (13,945) | (12,379) | (14,940) |
| Interest income (expense), net..... | 218 | 11 | (32) | 199 | 187 |
| | ----- | ----- | ----- | ----- | ----- |
| Net loss..... | \$ (8,154) | \$ (14,555) | \$ (13,977) | \$ (12,180) | \$ (14,753) |
| | ===== | ===== | ===== | ===== | ===== |

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Revenues. The increase in revenues beginning with the quarter ended September 30, 2000 reflects increased market acceptance of FreeStyle since commercial shipments commenced in June 2000.

Gross profit (loss). Gross profit (loss) is influenced by both sales volume and the product mix between FreeStyle System kits and FreeStyle test strips, as we currently distribute the FreeStyle System kit at a financial loss due in part to samples, discounts and rebates. The gross loss for the quarter ended September 30, 2000 was negatively impacted by a \$3.5 million charge to reduce FreeStyle System kit inventories to estimated net realizable value. The gross profit for the two most recent quarters resulted from higher sales volume and an increased percentage of FreeStyle test strip revenues versus FreeStyle System kit revenues.

Operating expenses. Prior to commencing commercial shipments of FreeStyle in June 2000, costs associated with start-up manufacturing activities were reported as research and development expenses. These expenses, which occurred in the first half of 2000, totaled \$1.2 million. Research and development expenses for the third quarter of 2000 included an expense accrual in the amount \$1.2 million related to incorporating engineering modifications into FreeStyle. Selling, general and administrative expenses increased in absolute dollars throughout 2000 and the first half of 2001, reflecting increased personnel costs, including recruiting and hiring our U.S. direct sales force, advertising, marketing and other spending associated with the launch of FreeStyle. In addition, costs were incurred beginning in the fourth quarter of 2000 related to increases in product sampling to stimulate consumer adoption of FreeStyle.

Liquidity and Capital Resources

From our inception through June 30, 2001, we have financed our operations primarily through private placements of convertible preferred stock resulting in net proceeds of \$119.2 million. We have also financed our operations through equipment financing arrangements and other loans with \$6.9 million in principal outstanding at June 30, 2001. Our current principal debt arrangements include both a \$5.0 million subordinated debt agreement at an effective interest rate

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of 22.3% per annum and a \$2.5 million equipment line of credit at effective interest rates between 8.5% and 9.5% per annum with Comdisco Ventures, and a \$2.0 million senior loan and security agreement at an effective interest rate of 13.1% per annum with Phoenix Capital. These effective annual interest rates include the amortization of the fair value of warrants issued to each of these lenders. We may no longer borrow capital under these debt arrangements. As of June 30, 2001, we had cash and cash equivalents of \$45.2 million.

Cash used in operations. Net cash used in operating activities was approximately \$4.5 million, \$11.8 million, \$36.8 million and \$19.4 million for the years ended December 31, 1998, 1999, 2000 and for the six months ended June 30, 2001, respectively. For these periods, net cash used in operating activities resulted primarily from net losses. For the year ended December 31, 2000 and the six months ended June 30, 2001, increases in accounts receivable and inventories, which reflected commencement of commercial product shipments in June 2000, were partially offset by increases in deferred revenue and accrued liabilities.

Cash used in or provided by investing activities. Net cash used in investing activities was approximately \$0.6 million, \$3.3 million and \$0.9 million for the years ended December 31, 1998 and 1999 and for the six months ended June 30, 2001, respectively. These investing activities consisted of capital expenditures. The increase in 1999 resulted from purchases of machinery and equipment for manufacturing our FreeStyle test strips in addition to expenses associated with our move into a new facility in August 1999. For the year ended December 31, 2000, net cash provided by investing activities, totaling \$0.6 million, included \$2.7 million in proceeds from the sale of capital assets under sale and leaseback transactions.

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Cash provided by financing activities. Net cash provided by financing activities was approximately \$12.5 million, \$6.0 million, \$46.4 million and \$52.9 million for the years ended December 31, 1998, 1999, 2000 and the six months ended June 30, 2001, respectively. The net cash provided by financing activities was primarily attributable to the proceeds from private placements of equity securities and proceeds from long-term borrowings.

We expect to have negative cash flow from operations for at least the next 12 months. We also expect increased sales and marketing expenses related to the promotion of FreeStyle, increased research and development expenses, as well as expenses for additional personnel and product enhancement efforts. Our future capital requirements will depend on a number of factors, including market acceptance of FreeStyle, the resources we devote to developing and supporting our products, continued progress of our research and development of potential products, the need to acquire licenses to technology and the availability of other financing. Our capital expenditures for the year ended December 31, 2000 were \$2.1 million, and we believe that our capital requirements for the next 12 months will increase as a result of expanding our facilities and our test strip manufacturing capacity. We believe that our current cash balances, together with the net proceeds of this offering and revenue to be derived from sales of FreeStyle, will be sufficient to fund our operations for at least the next 18 months. To the extent our capital resources are insufficient to meet our future capital requirements, we will need to raise additional capital or incur additional indebtedness to fund our operations. Additional equity or debt financing, if required, may not be available on acceptable terms, or at all. If we are unable to obtain additional capital, we may be required to reduce our selling and marketing activities for FreeStyle, delay, reduce the scope of or eliminate our research and development programs, or relinquish rights to technologies or products that we might otherwise seek to develop or commercialize. In the event that we do raise additional equity financing,

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investors in this offering will be further diluted. In the event we incur additional indebtedness to fund our operations, we may have to grant the lender a security interest in our assets.

Quantitative and Qualitative Discussion of Market Risk

Although we transact our business in U.S. dollars, future fluctuations in the value of the U.S. dollar may affect the price competitiveness of our products. However, we do not believe that we currently have any significant direct foreign currency exchange rate risk and have not hedged exposures denominated in foreign currencies or any other derivative financial instruments.

The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our invested cash without significantly increasing risk of loss. As of June 30, 2001, our cash and cash equivalents consisted primarily of money market funds maintained at one major U.S. financial institution. The recorded carrying amounts of cash and cash equivalents approximate fair value due to their short-term maturities. We do not believe that an increase in market rates would have any significant negative impact on the realized value of our investments, but an increase in market rates could negatively impact the interest expense associated with a portion of our long-term debt. Substantially all of our long-term debt obligations have a fixed rate of interest.

Inflation

The impact of inflation on our business has not been material to date.

Recently Issued Accounting Pronouncements

Effective January 1, 2001, we adopted SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities." SFAS No. 133 establishes accounting and reporting standards for derivative instruments and hedging activities. It requires that an entity recognize all derivatives as either assets or liabilities in the statement of financial position and measure those instruments at fair value. To date, we

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have not engaged in derivative and hedging activities, and therefore the adoption had no impact on our financial statements.

In July 2001, the Financial Accounting Standards Board issued SFAS No. 141 "Business Combinations" which establishes financial accounting and reporting for business combinations and supersedes APB Opinion No. 16, Business Combinations, and FASB Statement No. 38, Accounting for Preacquisition Contingencies of Purchased Enterprises. SFAS No. 141 requires that all business combinations be accounted for using one method, the purchase method. The provisions of this statement apply to all business combinations initiated after June 30, 2001. We will adopt SFAS No. 141 during the first quarter of fiscal 2002, and this adoption is expected to have no impact on our financial reporting and related disclosures.

In July 2001, the Financial Accounting Standards Board issued SFAS No. 142 "Goodwill and Other Intangible Assets," which establishes financial accounting and reporting for acquired goodwill and other intangible assets and supersedes APB Opinion No. 17, Intangible Assets. SFAS No. 142 addresses how intangible assets that are acquired individually or with a group of other assets (but not those acquired in a business combination) should be accounted for in financial statements upon their acquisition, and after they have been initially recognized in the financial statements. The provisions of this statement are

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effective for fiscal years beginning after December 15, 2001. We will adopt SFAS No. 142 during the first quarter of fiscal 2002, and this adoption is expected to have no material impact on our financial reporting and related disclosures.

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BUSINESS

Overview

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 nine of the ten largest national retailers, including Walgreens, Wal-Mart and CVS, through wholesalers, including McKesson, Cardinal Health and Bergen Brunswig, 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.

Market Opportunity

Diabetes

Diabetes is a chronic, life-threatening disease for which there is no known

cure. Diabetes occurs when the body does not produce sufficient levels of, or fails to effectively utilize, insulin. Insulin is a hormone that regulates the storage and metabolism of glucose. Glucose levels in the blood must be maintained within a specific concentration range to ensure optimal cellular function and health. Under normal conditions, the body maintains proper blood glucose levels by releasing insulin in response to increases in blood sugar.

Diabetes is typically classified as Type 1 or Type 2. Type 1 diabetes is the most serious form of the disease and is characterized by a severe lack of insulin secretion by the body. Type 1 diabetes usually

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occurs during childhood or adolescence, but it can occur at any age. Individuals with Type 1 diabetes require daily insulin injections to survive. Type 2 diabetes is the most common form of the disease and is characterized by the body's inability to produce enough insulin or to properly utilize insulin. Type 2 diabetes typically occurs in adulthood. However, because of sedentary lifestyles and inappropriate diet, Type 2 diabetes is increasing in incidence among the younger population. Type 2 diabetes is initially managed with diet, exercise and oral medication. However, many people with Type 2 diabetes will eventually require daily insulin injections.

In the United States, approximately 16 million people, about 6% of the population, have diabetes, although only approximately 10 million of these people have been diagnosed with the disease. The share of the United States population diagnosed with diabetes increased 33% between 1990 and 1998, primarily due to the aging of the population, inappropriate diets and increasingly sedentary lifestyles. The most rapid onset was in adults ages 30 through 39. It is also on the rise among a younger population base, including children and teenagers. Worldwide, approximately 175 million people, about 3% of the population, have been diagnosed with diabetes. The worldwide prevalence of diagnosed diabetics is expected to increase to 239 million by 2010.

Importance of Glucose Monitoring

Diabetes is the sixth leading cause of death by disease in the United States, with one death due to diabetic complications occurring every three minutes. The failure to frequently monitor and control blood glucose levels leads to severe medical complications over time, including blindness, loss of kidney function, nerve degeneration and cardiovascular disease. Diabetes is estimated to cost the United States economy over \$98 billion annually, including indirect costs such as lost productivity.

The goal of glucose monitoring is to avoid the complications of diabetes by allowing patients and their health care providers to determine a treatment regimen, to monitor the effectiveness of the regimen, and to alter it as needed for better overall control of blood glucose levels. Every person's blood glucose level varies during the course of the day, depending upon factors such as diet, insulin availability, exercise, illness and stress. To successfully maintain blood glucose levels within the proper range, a person with diabetes must first measure his or her glucose level and then manage this level by adjusting insulin intake, oral medication, diet and exercise. Then the person must take additional blood glucose measurements to gauge his or her individual response to the adjustments. The more frequently people with diabetes test their blood glucose levels and track their activities and food intake, the better they will be able to understand and manage their diabetes.

Studies show that active monitoring and management of diabetes reduces the risk of associated diabetes complications. The landmark Diabetes Control and Complications Trial, or DCCT, showed that the onset and progression of eye,

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kidney and nerve disease in people with Type 1 diabetes can be slowed by intensive therapy to maintain blood glucose levels as close to normal as possible. The DCCT demonstrated that the risk of complications could be reduced by 76% for eye disease, 50% for kidney disease and 60% for nerve disease. Similar studies in the United Kingdom and Japan involving people with Type 2 diabetes support the conclusion of the DCCT study that actively managing blood glucose levels reduces the risk of complications associated with diabetes. People with Type 1 diabetes are encouraged to test four or more times per day, and those with Type 2 diabetes are typically expected to test two or more times per day.

Limitations of Existing Glucose Monitoring Products

Despite the proven benefits of frequent monitoring and intensive management of blood glucose levels, a significant number of people fail to test at their recommended frequency, or at all. The American Diabetes Association estimates that people with diabetes test, on average, slightly more than once per day. To obtain a sample with current glucose monitoring systems, users generally are required to prick

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one of their fingertips with a lancing device, which typically consists of a spring-loaded needle that penetrates a measured distance into the finger. Users must then draw a sample of blood from the finger, which often requires squeezing of the fingertips and may require another finger prick if a sufficient volume of blood is not obtained the first time. After drawing a blood sample, users generally are required to drop the blood sample on a disposable test strip or place the test strip on the blood sample. We believe that under-testing is due to the limitations of existing products including:

- . Pain. Although the fingertips are rich in capillary beds and provide a good site to obtain a blood sample, they are also more densely populated with highly sensitive nerve endings. This makes the lancing and subsequent manipulation of the finger painful. The pain and discomfort are compounded by the fact that fingers offer limited surface area, so tests are often performed on areas that are sore from prior tests. Users also suffer pain when the lance wound is disturbed during regular activities. A wound on the finger is also more susceptible to infection.
- . Large Sample Size. Competitive blood glucose meters require users to draw a sample size from 1.0 to 10.0 microliters of blood to accurately measure blood glucose levels. These larger sample sizes are difficult or impossible to obtain on sites other than the finger. Furthermore, the larger the blood sample required, the wider or deeper the lancing must be in order to reliably draw the sample. This leads to increased pain, greater likelihood of residual bleeding and longer healing time.
- . Susceptibility to Interference. The accuracy of other electrochemical-based glucose monitoring systems can be compromised in the presence of many substances commonly found in blood, such as aspirin, acetaminophen, Vitamin C and uric acid. Accuracy can also be compromised by unusually high or low levels of red blood cells. These levels can be present in infants, pregnant women, patients on dialysis, athletes and those living at high altitudes.
- . Lifestyle Disruption. The process of measuring blood glucose levels causes significant disruption in the daily lives of people with diabetes and their families. Children must be awakened in the middle

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of the night for a blood glucose test to avoid dangerous episodes of sleeping hypoglycemia, a condition in which glucose levels are too low. Lancing the fingertips on infants is traumatizing to both parent and child. Obtaining large blood samples is inconvenient and may cause embarrassment in social situations, particularly for young children who are often required to be removed from class or activities to test themselves in the nurse's office. Children may also avoid, or be prevented from, playing with their classmates following a test because of the fear that continued bleeding may cause contamination.

As a result, we believe a significant market opportunity exists for a glucose self-monitoring system that requires a sufficiently small sample of blood so users can avoid the pain, inconvenience and social embarrassment of drawing large blood samples from their fingertips.

The TheraSense Solution

FreeStyle is easy to use, accurate and competitively priced. We believe FreeStyle also offers the following significant advantages over existing blood glucose monitoring systems:

- . Reduction in Pain. FreeStyle requires a tiny blood sample of 0.3 microliters, just a fraction of the sample size required by other systems. The extremely small volume of blood required enables people using FreeStyle to obtain blood not only from their fingertips as required by most other systems on the market today, but alternatively from their forearm, hand, thigh, upper arm or calf. Ninety percent of people in our clinical studies found using FreeStyle less painful than their current finger-stick-based systems. FreeStyle also eliminates soreness from repeated testing on a small surface area.

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- . Better Performance. FreeStyle's proprietary measurement technology is extremely accurate, operates over a broad temperature range and is unaffected by common interfering substances, such as aspirin, acetaminophen, Vitamin C and uric acid. It is also unaffected by unusually high or low levels of red blood cells. The tiny blood sample required by FreeStyle can be reliably obtained from sites other than the fingertip.
- . Improved Quality of Life. The combination of a smaller sample size and off-fingertip testing enabled by FreeStyle significantly reduces residual bleeding. This reduces the embarrassment of testing felt by some people with diabetes and affords them more discretion in testing. The pain and awkwardness of publicly obtaining large blood samples have deterred people with diabetes from testing frequently enough to manage their disease.

Our Strategy

Our objective is to be a leading provider of innovative glucose self-monitoring products that reduce the pain of testing, are easy to use, accurate, cost effective and improve the lives of people with diabetes. To achieve this objective, we are pursuing the following business strategies:

- . Establish FreeStyle as a leading blood glucose self-monitoring device. We are creating awareness of the advantages of FreeStyle in the United States among health care professionals and people with diabetes. We do this through advertising, extensive retail

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distribution and a sales force of more than 80 people. We believe an increased awareness of FreeStyle's less painful, more discreet and reliable process will lead many current testers to switch to FreeStyle. In addition, we believe we can expand the market to those people who have been diagnosed with diabetes but are currently not testing, as well as increase testing frequency for those who are under-testing.

- . Maintain and enhance retail distribution. We currently have authorized shelf space with eight of the ten largest chain drug stores, the three largest mass market retailers and the three largest supermarket retailers. These retailers represent over 20,000 pharmacy outlets in the United States. We plan to continue to expand FreeStyle's availability within these distribution channels through our national accounts sales representatives.
- . Focus on our core competencies. We plan to continue to focus our internal resources on our core competencies--electrochemistry and sensor manufacturing technologies. Consequently, we have entered into strategic relationships to enhance speed to market and cost effectiveness for those business functions not included in our core competencies. For example, we have a strategic relationship with Flextronics International, which assisted us with the FreeStyle meter development and is currently manufacturing our meters and assembling our FreeStyle System kits. Through these relationships, we believe that we will be able to quickly and efficiently build infrastructure and services needed to meet anticipated market demand.
- . Provide high quality customer service. We provide all of our customers with easy, comprehensive access to our products and services through the use of sophisticated software systems and an educated and caring customer service team. Our approach is to partner with a service organization while maintaining a small team of in-house service specialists to monitor quality. We offer customer service 24 hours per day, seven days per week with access to dedicated representatives via telephone or the Internet. In addition, we use the Internet to enable customers to purchase our products online, enhance awareness of our products, establish e-mail management, facilitate loyalty programs and provide product support and training.
- . Establish an international presence for FreeStyle. We intend to expand our international sales of FreeStyle and enter new global markets through relationships with established health care companies that have developed distribution channels. The Disetronic Group is

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our exclusive distributor of FreeStyle in selected European countries. 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. We anticipate that Nipro will commence sales in 2002, subject to regulatory approval. 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.

- . Leverage our proprietary technology platform. We intend to leverage our proprietary electrochemical sensor technologies to develop new glucose monitoring products. We are currently developing a Continuous

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Glucose Monitoring System intended to continuously measure and display a person's glucose levels in real time for up to three days. We are also expanding our current FreeStyle product family by developing enhanced versions of FreeStyle and a module for the Handspring Visor personal digital assistant that would enable it to act as a glucose monitor and sophisticated diabetes management system. We may also develop a lower priced glucose monitor or a hospital version of FreeStyle for multiple users.

Our Products

FreeStyle Blood Glucose Monitoring System. Our initial product, the FreeStyle blood glucose monitoring system, received FDA clearance in January 2000 for use on the forearm and fingers. We began selling FreeStyle in the United States in June 2000. In December 2000, we received FDA clearance that permits FreeStyle to be used on the thigh, calf, upper arm and hand. This represents the broadest array of off-finger testing sites cleared by the FDA. The FreeStyle System kit includes a FreeStyle meter, an initial supply of 10 proprietary disposable FreeStyle test strips, a FreeStyle lancing device, an initial supply of 10 disposable FreeStyle lancets, FreeStyle control solution and instructional materials. We also sell additional supplies of disposable FreeStyle test strips in quantities of 50 and 100 and additional supplies of disposable FreeStyle lancets in quantities of 100.

- . FreeStyle meter. The FreeStyle meter contains a large display screen to read test results, a slot where the test strip is inserted to get a blood glucose reading, and buttons to change the calibration code and review results in the system memory. It also contains a data port for interfacing with FreeStyle Connect data management software, which allows users to download information from the meter to personal computers and analyze glucose levels. The ergonomically designed meter fits easily in the hand and weighs 2.1 ounces. The meter displays blood glucose results in a range of 20 to 500 mg/dl. Once the sample is acquired, the meter takes about 15 seconds to display the result. The meter has the ability to store the last 250 blood glucose test results and to display a 14-day average blood glucose level.
- . FreeStyle test strips. FreeStyle test strips are proprietary disposable sensors that are used with the FreeStyle meter to measure blood glucose levels. The test strips are clearly marked to indicate proper placement in the meter. Inserting the test strip into the meter activates the system and either side of the test strip can be used for measurement. The FreeStyle meter beeps one time when sufficient blood has been drawn into the test strip and beeps two times when the test is complete. Our proprietary FreeStyle test strips may only be used with our FreeStyle meter.
- . FreeStyle lancing device and lancets. The FreeStyle lancing device is designed specifically to make blood sample acquisition reliable and convenient. It requires no mechanical or vacuum assistance to draw blood. The lancing device offers five adjustable depth settings to allow for comfort and adequate sample size. Although FreeStyle lancets are available, other standard lancets are compatible with our system. It is recommended that a new, sterile lancet be inserted into the lancing device every time a test is administered. The

reduction in pain from FreeStyle is attributable to the lancing site and the small sample size required, not the type of lancing device or

lancet.

- . FreeStyle control solution. The FreeStyle control solution contains a fixed amount of glucose that may be used periodically to ensure the FreeStyle System is functioning correctly and users are following correct testing procedures.

FreeStyle Connect. In May 2000, we received FDA clearance for FreeStyle Connect, a data management software product. FreeStyle Connect downloads data from FreeStyle to a personal computer and displays glucose values in eight different statistical reports, including the number of blood glucose values above, within, and below a given target range. The FreeStyle meter stores up to 250 glucose values each with time and date. This data allows health care providers to help patients appropriately adjust their diet, exercise and medication to improve and maintain their health.

Products Under Development

Continuous Glucose Monitoring System. We are developing a continuous monitoring device that will utilize a disposable, miniaturized electrochemical sensor that can be inserted under the skin by the user utilizing a spring-loaded insertion device. This sensor system will enable users to continuously measure and display glucose levels and store the results for further analysis by the user or a physician. This product is intended to act as a substitute for current glucose self-monitoring devices. The increased number of glucose readings will allow people with diabetes to more effectively adjust insulin, oral medication, diet and exercise, which should result in significantly improved health outcomes for people with diabetes. The Continuous Glucose Monitoring System is being designed to offer people with diabetes the following benefits:

- . accurate and discreet measurement of glucose levels on a continuous basis;
- . elimination of the anxiety of not knowing glucose levels between periodic measurements;
- . minimally invasive insertion procedure;
- . comfortable to wear during use;
- . warnings against dangerously high or low glucose levels, even while sleeping; and
- . ability to improve health through intensively managed therapy from continuous glucose information.

We believe each sensor used with our system will provide up to three days of continuous glucose measurement. The accuracy and precision of our Continuous Glucose Monitoring System will be dependent on the initial calibration. Therefore, our system will have a built-in FreeStyle meter that will allow for accurate and convenient calibration using FreeStyle test strips. The integrated calibration will help eliminate the risk of human error during data entry. The display unit, which can be worn like a pager, will translate the sensor's information into a numerical value and periodically, or on demand, display the glucose level and trend. This information will allow users to determine whether glucose levels are rising, falling or remaining stable. The sensor system is designed to communicate to the wireless display unit within a 10-foot range, so it can be conveniently worn on a belt, carried in a purse or left on a bed stand at night.

We recently commenced two pilot clinical studies, one with people who do not

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have diabetes and one with people who have diabetes. We expect that our Continuous Glucose Monitoring System will require premarket approval, which will require considerably more data and FDA review time than the 510(k) clearance process that was applicable to FreeStyle. The premarket approval process generally takes between one and three years from completion of an application or even longer. However, achieving a completed application is a process that may take numerous clinical trials and require filing

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of amendments over time. Therefore, even if the product is successfully developed, it will not be commercially available for a number of years.

Additional FreeStyle Products. We are also expanding our current FreeStyle product family by developing enhanced versions of FreeStyle and a module for the Handspring Visor personal digital assistant that would enable it to act as a glucose monitor and sophisticated diabetes management system. We may also develop a lower priced glucose monitor or a hospital version of FreeStyle for multiple users. We will also continue to identify and develop products that fulfill unmet consumer needs and address strategic or competitive issues.

Our Sensor Technologies

We have developed two proprietary miniaturized electrochemical sensor technologies. The first, NanoSample technology, is used in our FreeStyle System. The second, Wired Enzyme chemistry, is used in our Continuous Glucose Monitoring System under development.

NanoSample Technology. NanoSample technology enables FreeStyle to measure glucose levels in blood samples of only 0.3 microliters, a fraction of the sample size required by competitive products. We have pioneered techniques to obtain accurate, reliable and fast responses when measuring glucose in sub-microliter sample sizes. This technology allows us to measure the total electrical charge generated by the reaction of all of the glucose in the sample, a process referred to as coulometry. In contrast, the most advanced competitive products generally determine glucose levels by taking a measurement of the current generated by the sensor at a point in time, a process referred to as amperometry. Amperometry requires the use of a larger blood sample to achieve accurate results. Use of coulometry substantially eliminates some of the errors frequently associated with amperometry, such as dependence of sensor output on temperature and potential interference from commonly found substances in the blood, such as aspirin, acetaminophen, Vitamin C and uric acid, which can distort the glucose measurement.

Wired Enzyme Chemistry. Our Wired Enzyme chemistry is allowing us to develop miniaturized, self-insertable, biocompatible, disposable sensors. We are currently using this technology to develop our Continuous Glucose Monitoring System. Our Continuous Glucose Monitoring System sensor, which will be inserted under the skin by the user, will react with the glucose near or at the implant site to produce an electrical signal that enables glucose concentration measurement. We believe our technology will successfully address the core technical issues that have limited the performance of other implantable glucose sensors, including oxygen dependence and interference from commonly found substances in blood, such as aspirin, acetaminophen, Vitamin C and uric acid. We also believe our system will be calibrated easily and accurately.

Marketing and Sales

United States. Our marketing and sales program is intended to generate awareness of FreeStyle and penetrate and expand the glucose self-monitoring market. We currently have a national sales force comprised of more than 80

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people. The sales force promotes FreeStyle to the health care professionals who strongly influence the health care decisions made by people with diabetes, a group which includes endocrinologists, certified diabetes educators and internal medicine physicians. In addition, our sales force promotes FreeStyle to retail outlets at the individual store level. The primary goal of our sales force is to educate and train health care professionals on the benefits of our products. We also provide these health care professionals with free samples of our products. We believe these efforts will ultimately result in recommendations and referrals for our products. There are also members of our sales force dedicated to serving retail and managed care accounts at the corporate level. We believe that our strategy of selling through our own direct sales force is an important factor in achieving market penetration.

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Our direct-to-consumer advertising campaign is aimed at health care professionals, people with diabetes and people who know people with diabetes. Our belief is that pain, reliability and quality of life issues are so important in glucose testing that they are recognized and understood not only by people with diabetes, but also by their co-workers, friends, and families, each of whom will be willing to tell others. To further generate awareness and penetrate the market, our sales and marketing organization provides a wide range of programs, support materials and events that support our national sales force. These include public relations efforts, product training, conference and trade show attendance, and educational and promotional literature.

We primarily sell our products through retail pharmacies. We sell our products directly to national retail pharmacies and supply other retail pharmacies through wholesalers. We also sell to durable medical equipment suppliers and directly to end users through phone orders and our website. Although there is substantial competition from existing products, the consolidation of the retail industry has allowed us to concentrate our sales efforts. The following is a list of our top five retailers and top five wholesalers, ranked by dollar volume of sales through July 31 , 2001:

Retailers

Walgreens
Wal-Mart
CVS
Eckerd
Rite Aid

Wholesalers

McKesson
Cardinal Health
Bergen Brunswig
Bindley Western
AmeriSource

International. We intend to expand our international sales efforts for FreeStyle and enter new global markets by establishing relationships with international partners who have established relationships with healthcare professionals and developed distribution channels. In March 2001, we obtained the CE Mark, which permits us to commercially distribute FreeStyle throughout the European Union. In September 2000, we entered into an agreement with Disetronic Group for the exclusive distribution of FreeStyle in Germany, Switzerland, Denmark, Austria, Sweden, Finland, Norway and the Netherlands. In April 2001, we entered into an agreement with Nipro Corporation for the exclusive distribution of FreeStyle in Japan. 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.

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Under terms of the Disetronic Group agreement, Disetronic has exclusive responsibility for sales, marketing and customer service in its territory in Europe. We may terminate the agreement if Disetronic does not meet specified minimum purchase requirements. Disetronic is also entitled to market FreeStyle to Disetronic's pump users in North America. The initial term of the Disetronic agreement is five years, ending in September 2005. Disetronic commenced sales in Germany and Sweden in May 2001.

Under terms of the Nipro Corporation agreement, Nipro will have exclusive responsibility for sales, marketing and customer service in Japan. We may terminate the agreement if Nipro does not meet specified minimum purchase requirements. The initial term of the Nipro agreement is five years, ending in April 2006. We anticipate that Nipro will commence sales of FreeStyle in Japan in 2002, subject to regulatory approval.

Distribution. To establish a worldwide distribution capability for end users, health care professionals and retail customers, we have established relationships with expert distribution partners. For retail order management and shipping of our FreeStyle System kit and other products, we have entered into an exclusive services agreement with Livingston Healthcare Services, Inc., a division of UPS Global Logistics that specializes in providing outsourced distribution services for large pharmaceutical and

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medical device companies. The initial term of this agreement is three years, ending in March 2003. We may terminate this agreement prior to March 2003, subject to payment of a termination fee. Livingston has an extensive network of distribution centers and a sophisticated order management and product tracking system. Livingston also manages our billing process. Our relationship with Livingston allows us to meet shipment, delivery and billing expectations while minimizing our internal infrastructure requirements.

Customer Service. We provide customer service 24 hours per day, seven day per week through ICT Group. This service is transparent to the caller and provides a standard of service expected in the industry. This relationship with ICT Group provides customer service, technical support, a help desk and order processing. ICT Group is an international telemarketing and e-support company, with a medical marketing division which has developed a special facility and dedicated customer care agents for us. ICT Group's agents have the systems capability to handle large volumes of our customer contacts at any time, both over the phone or through our web site. We select and train the ICT Group agents who work on our account, as well as maintain in-house customer service personnel that monitor quality. Our non-exclusive contract with ICT has an initial term of three years, ending in April 2003, although it can be terminated by either party without cause upon 120 days notice.

Manufacturing

The primary components of the FreeStyle System kit are the FreeStyle meter, FreeStyle disposable test strips, the FreeStyle lancing device, FreeStyle disposable lancets and FreeStyle control solution. We manufacture the FreeStyle test strips and contract with third parties for the manufacture of the other FreeStyle products. These contract manufacturing relationships minimize our capital investment, help control costs and allow us to compete with larger volume manufacturers of blood glucose self-monitoring systems.

We manufacture the FreeStyle test strips at our facility in Alameda, California. We have developed a manufacturing process for the test strips that we believe is robust, cost effective and scaleable to meet higher volumes. The test strip is composed of chemicals, adhesive and a printed polyester similar

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to the material used in credit cards.

Flextronics International assisted us in the design of our meter and is responsible for manufacturing the FreeStyle meter and assembling the FreeStyle System kits in San Jose, California. Flextronics has 12 years of experience building blood glucose meters, and has facilities in Asia, Europe and the Americas. Flextronics has demonstrated strong process control and knowledge of just-in-time and total quality management techniques and has software tools to handle product tracking. We have an on-site manager at Flextronics who is responsible for the day-to-day interface with Flextronics. Production release to finished goods inventory is done through our quality assurance department. Our contract with Flextronics expires in November 2004, and is renewable annually thereafter. Either party may terminate this contract for any reason upon one year's prior written notice to the other.

Facet Technologies LLC, a wholly-owned subsidiary of Matria Healthcare, assisted us in the design of the FreeStyle lancing device and we have agreed to purchase the FreeStyle lancing devices and lancets exclusively from Facet until June 1, 2007. Facet is a leading supplier of lancing devices and lancets, including our lancets. Our FreeStyle lancing device can also use conventional lancets, which are widely available.

Each of the production processes utilized in the manufacture of our products has been verified and validated, as required by the FDA's quality system regulations. As a medical device manufacturer, our manufacturing facility and the facilities of Flextronics and Facet Technologies are subject to periodic unannounced inspection by regulatory authorities and these operations may undergo compliance inspections conducted by the FDA and corresponding state agencies.

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Intellectual Property

We rely on a combination of copyright, patent, trademark, trade secret and other intellectual property laws, nondisclosure agreements and other measures to protect our proprietary rights. As of June 30, 2001, we had 21 issued U.S. patents, had received notices of allowance with respect to six U.S. patent applications, and had numerous additional U.S. patent applications pending. We believe it will take up to five years, and possibly longer, for these U.S. patent applications to result in issued patents. We have also filed foreign patent applications on our technology. Our issued patents expire between November 2010 and April 2018. The issued and allowed patents cover, among other things:

- . glucose measurement in a small sample volume using a coulometric measurement;
- . our Wired Enzyme chemistry;
- . one point calibration of the Continuous Glucose Monitoring System;
- . manufacturing processes for the Continuous Glucose Monitoring System sensor; and
- . the components of the Continuous Glucose Monitoring System.

We have obtained registrations for the trademark TheraSense in the U.S., Europe and Japan and have applied to register TheraSense in Canada, South Korea and Taiwan as well. We have applied to register FreeStyle in the U.S., Europe, Japan and South Korea.

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In addition to developing our own technology, we have entered into several license agreements. We have acquired patents from the University of Texas at Austin developed by Professor Adam Heller, a co-founder of our company, and his collaborators. We also fund ongoing research at the University of Texas at Austin in the field of biosensors, and we obtain some of the intellectual property rights to resulting inventions. We have also obtained non-exclusive, worldwide licenses to specific patents owned by Asulab SA and Unilever PLC. Each of these licenses grants us the right to use the licensed patents to make and sell diagnostic devices for diabetes monitoring that contain the licensed technology. We pay for these licenses through a combination of fixed payments and royalties on sales of covered products. Each of these licenses continues until expiration of the licensed patents.

Research and Development

Our research and development efforts are currently focused on developing further enhancements to FreeStyle as well as developing our Continuous Glucose Monitoring System. Our research and development staff consists of 51 people, including seven who hold Ph.D. degrees. Our research and development staff has extensive experience in the glucose monitoring industry and has been instrumental in technology development and commercialization of glucose monitoring products. Research and development expenses, including clinical and regulatory expenses, were \$3.1 million in 1998, \$7.7 million in 1999, \$12.0 million in 2000 and \$6.3 million for the six months ended June 30, 2001. We expect research and development expenses to continue to increase as we seek to enhance our existing products and develop additional products.

We also fund biosensor research under a Sponsored Research Agreement with the University of Texas at Austin. We have specific rights with regard to inventions resulting from the research. The research is currently under the direction of Professor Adam Heller and is focused on improvements to implantable glucose sensors and on extension of the Wired Enzyme technology for the measurement of other biochemicals. This agreement continues on a year-to-year basis unless otherwise agreed by the parties and so long as the University has received sponsored research funds from us in the prior six month period. We fund such research on a cost plus reasonable overhead basis.

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Competition

The medical device industry is subject to intense competition. Four companies, Roche Diagnostics, LifeScan, Inc., a division of Johnson & Johnson, Bayer Corporation and MediSense, a division of Abbott Laboratories, currently account for approximately 90% of the worldwide sales of blood glucose self-monitoring systems. All of these competitors' products use a meter and disposable test strips to test blood obtained by lancing the finger or, in some cases, the forearm. All of the competitive products require significantly larger blood samples than required by FreeStyle. One product approved for use on the finger and forearm offers a faster test time than FreeStyle, once the required sample has been obtained, and operates over a broader temperature range.

In addition, other companies are developing and/or marketing minimally invasive or noninvasive glucose monitoring devices and technologies that could compete with FreeStyle and our proposed Continuous Glucose Monitoring System. There are also a number of academic and other institutions involved in various phases of our industry's technology development. Many of these competitors have significantly greater financial and human resources than we do. At this time, there are two approved products for continuous glucose monitoring, neither of which is presently approved as a substitute for current glucose self-monitoring

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devices. The continuous glucose monitoring system developed by MiniMed Inc., which recently entered into an agreement to be acquired by Medtronic, Inc., includes an implantable sensor that measures and stores glucose values every five minutes, for a period of two to three days. The MiniMed system is not a consumer product, rather, it is a physician product. The sensor is required to be implanted by a physician, and the results of the data aggregated by the MiniMed system can only be viewed by the physician, who must extract the sensor and download the results for viewing using customized software. The second approved product for continuous glucose monitoring, developed by Cygnus Inc., is worn on the wrist like a watch and can take glucose readings as frequently as every twenty minutes for up to twelve hours at a time. This product has only recently been approved by the FDA for prescription to adults ages 18 and older who have diabetes.

We believe that the principal competitive factors in our market include:

- . improved outcomes for people with diabetes through less painful and accurate testing methods;
- . technological leadership and superiority;
- . reliability and ease of use;
- . customer focus and service;
- . effective marketing and distribution;
- . acceptance by health care professionals;
- . speed to market; and
- . exclusivity agreements between third-party payors and competitive brands.

Government Regulation

Our products are medical devices subject to extensive regulation by the FDA and other regulatory bodies. FDA regulations govern, among other things, the following activities that we or our partners perform and will continue to perform:

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

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- . product storage;
- . premarket clearance or approval;
- . advertising and promotion; and
- . product sales and distribution.

FDA's Premarket Clearance and Approval Requirements

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

510(k) Clearance Pathway. To obtain 510(k) clearance, we must submit a premarket notification demonstrating that the proposed device is substantially equivalent to a previously cleared 510(k) device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of premarket approval applications. The FDA's 510(k) clearance pathway usually takes from four to twelve months from the date the application is completed, but it can take significantly longer.

Blood glucose testing systems have generally qualified for clearance under 510(k) procedures. We received 510(k) clearance for FreeStyle in January 2000 for use on the fingers and forearm. In May 2000, we also obtained 510(k) clearance for FreeStyle Connect, our data management system that enables downloading of blood glucose data stored in a user's FreeStyle monitor to a personal computer for use by the user or his or her health care provider. In December 2000, we received 510(k) clearance allowing us to promote FreeStyle for use on the thigh, calf, upper arm, and hand, in addition to the fingers and forearm.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new 510(k) clearance or could require premarket approval. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or premarket approval is obtained. We have modified aspects of FreeStyle since receiving regulatory approval, but we believe that new 510(k) clearances are not required. 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. We have made and plan to continue to make additional product enhancements to our FreeStyle System that we believe do not require new 510(k) clearances.

Pending 510(k) for New FreeStyle Labeling. In our original 510(k) submission, the performance of FreeStyle was determined by the FDA to be substantially equivalent to other currently marketed blood glucose monitoring systems. Shortly after clearance to market FreeStyle, we initiated additional clinical studies to better understand off-fingertip testing of blood glucose levels. After reviewing the data from these post-clearance clinical studies we concluded that:

- . Due to human physiology, changes in blood glucose can be detected first on the finger, and changes can lag on the forearm.

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- . Vigorously rubbing the test site prior to lancing stimulates blood flow and minimizes the difference between readings on the forearm and the finger.
- . The faster the rate of change in blood glucose, the greater the difference in readings between the finger and the forearm.
- . There are significant differences from person to person with regard to lag time, and in some people, the lag between arm and finger is negligible.
- . The lag is most clinically significant when testing for low blood sugar (hypoglycemia).

These discoveries prompted us to implement more cautionary labeling to clarify the safe and effective use of FreeStyle. This labeling emphasized rubbing the test site before lancing and instructed both users and health care professionals that when they are testing because they think blood glucose is low (hypoglycemia), they may want to obtain a blood sample from the fingertip rather than alternative sites such as the forearm. In April 2001, we notified the FDA of these labeling changes. In May 2001, the FDA responded that, based on the information provided, they believed the labeling changes required submission and clearance of an additional 510(k). In June 2001, we submitted additional information to the FDA in support of our labeling changes and our belief that an additional 510(k) was not necessary. The FDA is reviewing that 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. As a result, the FDA could order 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 FreeStyle labeling. We continue to study off-fingertip testing in an effort to build greater knowledge around this new paradigm for blood glucose testing. We have studies underway examining whether less painful alternate site testing impacts test frequency and results in better diabetes management. We are also examining specific alternate sites, such as the thigh and hand, and specific user groups, such as children and women with gestational diabetes. All of this data will be made available to the FDA, and we will work closely with the FDA to address their questions and resolve any issues around our labeling. The FDA had scheduled a meeting of its Clinical Chemistry and Clinical Toxicology Panel for September 24, 2001 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. As a result of the national tragedies on September 11, 2001, the FDA canceled this Panel meeting and rescheduled the meeting for October 29, 2001. In addition, the FDA has agreed to an individual meeting with us, scheduled for October 19, 2001, to specifically discuss our pending FreeStyle 510(k).

Premarket Approval Pathway. A premarket approval application must be submitted if the device cannot be cleared through the 510(k) process. A premarket approval application must be supported by extensive data including, but not limited to, technical, preclinical, clinical trials, manufacturing and labeling to demonstrate to the FDA's satisfaction the safety and effectiveness of the device.

After a premarket approval application is complete, the FDA begins an in-depth review of the submitted information, which generally takes between one and three years, but may take significantly longer. During this review period, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside the FDA will be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In

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addition, the FDA will conduct a preapproval inspection of the manufacturing facility to ensure compliance with quality system regulations. New premarket approval applications or premarket approval application supplements are required for significant modifications to the manufacturing process, labeling and design of a device that is approved through the premarket approval process. Premarket approval supplements often require submission of the same type of information as a premarket approval application, except that the supplement is limited to information needed to support any changes from the device covered by the original premarket approval application, and may not require as extensive clinical data or the convening of an advisory panel.

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We expect that our Continuous Glucose Monitoring System will require premarket approval. We recently commenced two pilot clinical studies, one with people who do not have diabetes and one with people who have diabetes. A premarket approval application may never be submitted, or if submitted, approval may not be obtained for this device in a timely fashion, or at all.

Clinical Trials. A clinical trial is almost always required to support a premarket approval application and is sometimes required for a 510(k) premarket notification. These trials generally require submission of an application for an investigational device exemption to the FDA. The investigational device exemption application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The investigational device exemption application must be approved in advance by the FDA for a specified number of patients, unless the product is deemed a non-significant risk device and eligible for more abbreviated investigational device exemption requirements. Clinical trials for a significant risk device may begin once the investigational device exemption application is approved by the FDA and the appropriate institutional review boards at the clinical trial sites. Future clinical trials of our Continuous Glucose Monitoring System may require that we obtain an investigational device exemption from the FDA prior to commencing clinical trials. Our clinical trials must be conducted in accordance with FDA regulations. The results of clinical testing may not be sufficient to obtain approval of the product.

Pervasive and Continuing FDA Regulation

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

- . quality system regulation, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures during the manufacturing process;
- . labeling regulations, which prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labeling; and
- . medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

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- . fines, injunctions, and civil penalties;
- . recall or seizure of our products;
- . operating restrictions, partial suspension or total shutdown of production;
- . refusing our request for 510(k) clearance or premarket approval of new products;
- . withdrawing 510(k) clearance or premarket approvals that are already granted; and
- . criminal prosecution.

We are subject to unannounced inspections by the FDA and the Food and Drug Branch of the California Department of Health Services, and these inspections may include the manufacturing facilities of our subcontractors. In May 2001, the FDA conducted an inspection of our facility in Alameda, California. The FDA issued a Form 483 that noted five observations. One observation was corrected and verified during the audit. In June 2001, we submitted a corrective action plan to the FDA addressing the remaining four observations.

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International

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

The primary regulatory environment in Europe is that of the European Union, which consists of 15 countries encompassing most of the major countries in Europe. Other countries, such as Switzerland, have voluntarily adopted laws and regulations that mirror those of the European Union with respect to medical devices. The European Union has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling, and adverse event reporting for medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear CE conformity marking, indicating that the device conforms with the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout Europe. CE is an abbreviation for European Compliance. The method of assessing conformity varies depending on the class of the product, but normally involves a combination of self-assessment by the manufacturer and a third-party assessment by a "Notified Body." This third-party assessment may consist of an audit of the manufacturer's quality system and specific testing of the manufacturer's product. An assessment by a Notified Body in one country within the European Union is required in order for a manufacturer to commercially distribute the product throughout the European Union. In March 2001, FreeStyle was certified by TUV Product Service, a Notified Body, under the European Union In-Vitro Diagnostic Directive allowing the CE conformity marking to be applied.

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 this approval would prevent us from selling FreeStyle in Japan, which would negatively impact future revenues.

Third-Party Reimbursement

Self-monitoring of blood glucose is a standard of care in the United States and

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other developed countries. The costs associated with the purchase of blood glucose monitoring products such as meters and test strips by people with diabetes are generally reimbursed. FreeStyle is currently being reimbursed through Medicare, Medicaid, open formulary plans and certain preferred provider organizations in the United States. 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. Reimbursement has not yet been determined for our Continuous Glucose Monitoring System.

Advisory Boards

Medical Advisory Board

We have established a medical advisory board, consisting of individuals with recognized expertise in fields relating to diabetes treatment. Our members advise us concerning long-term product planning, research, development and marketing. Members of our medical advisory board meet formally and informally with us. Several of the members of our medical advisory board are employed by academic institutions and may have commitments to or agreements with other entities that may limit their availability to us. Members of our medical advisory board may also serve as consultants to other medical product companies. The members of our medical advisory board have agreed to maintain the confidentiality of all proprietary information we disclose to them, and each member has executed a confidentiality agreement with us.

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Currently, the following persons comprise our medical advisory board:

Richard Bergenstal, MD is an endocrinologist and is currently the Executive Director of the International Diabetes Center in Minneapolis, Minnesota. Dr. Bergenstal's focus has been the development of diabetes treatment algorithms and education of primary care physicians to improve the level of clinical care for people with diabetes. Dr. Bergenstal received the Charles H. Best Medal from the American Diabetes Association for distinguished service for his role as an investigator in the Diabetes Control and Complications Trial.

John Buse, MD, Ph.D. is an endocrinologist and is currently an Associate Professor, Division of Endocrinology, at the University of North Carolina Medical School, Chapel Hill, North Carolina. Dr. Buse has a large clinical practice as Director of the Diabetes Program and a significant research practice as Director of Endocrinology Clinics at UNC. Dr. Buse has published widely on diabetes and drug therapies and is a frequent presenter at professional conferences around the world.

Alan Moses, MD is an endocrinologist and is currently the Chief Medical Officer of the Joslin Clinic and Diabetes Center in Boston, Massachusetts. Dr. Moses is also an Associate Professor of Medicine at Harvard Medical School and participates in the administration and leadership of numerous diabetes related clinical and research initiatives. Dr. Moses' research is focused on severe insulin resistance and novel routes of drug delivery and therapies for diabetes. He is known as being a vocal advocate of issues involving children with diabetes.

Anne Peters, MD is an endocrinologist and is currently a Director of the University of Southern California Diabetes Program in Los Angeles, California. She has researched and published on diabetes drug therapies and clinical treatment of diabetes, and has a particular research interest in outcomes studies in diabetes.

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Philip Raskin, MD is an endocrinologist and is currently a Professor of Medicine for the Department of Internal Medicine at Southwestern Medical School, University of Texas Health Science Center in Dallas, Texas. Dr. Raskin was involved in the Diabetes Complications and Control Trial study and was recognized for achieving the best clinical results among all the clinical study sites.

Harry Shamon, MD is an endocrinologist and is currently a Professor for the Department of Medicine, Division of Endocrinology and Metabolism at the Albert Einstein College of Medicine in New York, New York. Dr. Shamon is a leading expert on hypoglycemia and diabetes and was involved as an investigator in the Diabetes Control and Complications Trial. He is on the National Board of Directors for the American Diabetes Association and the American Board of Endocrinology and Metabolism.

Educator Advisory Board

We have also established an educator advisory board of consultants with expertise in educating people with diabetes. The educator advisory board meets formally and informally and provides us advice on training materials, patient/product acceptance criteria and product marketing. The members of our educator advisory board have agreed to maintain the confidentiality of all proprietary information we disclose to them, and each member has executed a confidentiality agreement.

Currently the following persons comprise our educator advisory board:

Nancy Bristow, RN, BSN, CDE is the Clinical Nurse of the Diabetes and Endocrine Associates of Tarrant County in Fort Worth, Texas. She supports numerous people with diabetes as well as endocrinologists and has been involved in clinical studies with several local universities and major diabetes related companies.

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Nedra Christensen, RD, Ph.D. is an Assistant Professor at Utah State University, Logan, Utah. She has practiced diabetes clinical dietetics with the Joslin Clinic, Vanderbilt University and children's diabetes camps. Dr. Christensen publishes extensively on diabetes treatment and dietetics.

Carol Homko, RN, CDE, MS, Ph.D. is a Clinical Nurse Practitioner at the General Clinical Research Center at Temple University Hospital in Philadelphia, Pennsylvania. Her academic and clinical focus has been on diabetes and pregnancy.

Marsha McCleskey, RD, MS, CDE is the Clinical Dietician for the Diabetes and Endocrine Associates of Tarrant County in Fort Worth, Texas. She teaches people in a large clinical practice, consults and speaks extensively on diabetes care. She has a particular interest in diabetes data management.

Jim Pichert, Ph.D. is the Diabetes Education Program Director of the Diabetes Research and Training Center at the Vanderbilt University Medical Center in Nashville, Tennessee. He has researched and published extensively on educational methods that improve diabetes care. He has held numerous national positions in diabetes professional organizations and is a popular speaker on improved diabetes outcomes with innovative teaching methods.

Employees

As of June 30, 2001, we had 241 full-time employees, including 87 in sales and marketing, 63 in operations and manufacturing, 51 in research and development,

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15 in customer service and 25 in general and administrative functions. None of our employees is represented by a collective bargaining agreement and we have never experienced any work stoppage. We believe that our employee relations are good.

Facilities

We lease approximately 54,500 square feet of manufacturing, laboratory and office space at 1360 South Loop Road in Alameda, California under a lease expiring in April 2009. We are also leasing 17,000 square feet of office space in an adjacent building at 1350 South Loop Road under a lease expiring in May 2004. An additional 3,000 square feet of office space at 1320 South Loop Road is subject to a lease which expires in October 2002. We are in the planning stages of a 40,000 square foot expansion of the manufacturing and office areas at our main building at 1360 South Loop Road. We believe that our current facilities and the planned expansion will be sufficient for the next few years.

Legal Proceedings

We are not currently subject to any material pending or threatened legal proceedings.

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MANAGEMENT

Executive Officers and Directors

The following table sets forth, as of June 30, 2001, information about our executive officers, directors and Chief Scientific Advisor:

| Name ---- | Age --- | Position ----- |
|----------------------------------|------------|---|
| W. Mark Lortz..... | 49 | Chairman of the Board, Chief Executive Officer and President |
| Tae Andrews..... | 38 | Vice President of Marketing and Sales |
| W. Patrick Bengtsson..... | 44 | Vice President of Intellectual Property |
| Robert D. Brownell..... | 39 | Vice President of Human Resources, General Counsel and Secretary |
| Eve A. Conner, Ph.D. | 55 | Vice President of Quality Assurance and Regulatory Affairs |
| Timothy T. Goodnow, Ph.D. | 40 | Vice President of Research and Development |
| Claire D. Heiss..... | 54 | Vice President of Operations |
| Adam Heller, Ph.D. | 67 | Co-Founder and Chief Scientific Advisor |
| Ephraim Heller..... | 39 | Co-Founder, Vice President of Business Development and Director |
| Lawrence W. Huffman..... | 56 | Vice President of International Business Development |
| Holly D. Kulp..... | 43 | Vice President of Professional Relations and Customer Services |
| Charles T. Liamos..... | 42 | Vice President and Chief Financial Officer |
| Annette J. Campbell-White(/1/).. | 54 | Director |
| Mark J. Gainor..... | 45 | Director |
| Ross A. Jaffe, M.D.(/2/) | 42 | Director |
| Michael M. McNamara(/1/) | 44 | Director |
| Robert R. Momsen(/2/) | 54 | Director |

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Richard P. Thompson(/2/). 49 Director

(/1/)Member of Compensation Committee
(/2/)Member of Audit Committee

W. Mark Lortz has served as our President and Chief Executive Officer since December 1997 and as Chairman of the Board since October 1998. From July 1991 to October 1997, Mr. Lortz held several positions at LifeScan, Inc., a division of Johnson & Johnson, a diversified health care company, including Vice President, Operations and Group Vice President, Worldwide Business Operations and International Franchise Development. Mr. Lortz holds an M.B.A. in Management from Xavier University and a B.S. in Engineering Science from Iowa State University.

Tae Andrews has served as our Vice President of Marketing and Sales since May 1999. From January 1997 to May 1999, Mr. Andrews was the Vice President of Marketing for Enamelon, Inc., a start-up oral care technology company. From July 1994 to January 1997, Mr. Andrews was a Senior Product Manager for Kraft Foods, a consumer packaged foods company. Mr. Andrews holds an M.B.A. from Columbia University and a B.S. in Engineering and Political Science from the United States Naval Academy.

W. Patrick Bengtsson has served as our Vice President of Intellectual Property since January 2001. From August 1998 to January 2001, Mr. Bengtsson was a partner at Pillsbury Winthrop LLP, an international law firm, where he headed the San Francisco patent practice and was co-chairman of the national intellectual property practice. From January 1992 to August 1998, Mr. Bengtsson was a

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partner at Limbach & Limbach L.L.P., a law firm that specialized in the practice of intellectual property law. Mr. Bengtsson holds a J.D., cum laude, from the University of San Diego School of Law and a B.S. in Chemical Engineering from the University of California, Berkeley. Mr. Bengtsson is a registered patent attorney.

Robert D. Brownell has served as our Vice President and General Counsel since March 2001 and Vice President of Human Resources and Secretary since June 2001. From February 1996 to April 2000, Mr. Brownell was a member of Wilson Sonsini Goodrich & Rosati, P.C., a leading technology law firm. Prior to becoming a member, Mr. Brownell was an associate at Wilson Sonsini Goodrich & Rosati, P.C. Mr. Brownell holds a J.D. from the University of California, Los Angeles and a B.A. in Jurisprudence and Social Policy from the University of California, Berkeley.

Eve A. Conner, Ph.D. has served as our Vice President of Quality Assurance and Regulatory Affairs since January 1999. From June 1996 to December 1998 she served as Vice President, Clinical/Regulatory Affairs and Quality Assurance for Somnus Medical Technologies, Inc., a manufacturer of electrosurgical devices. From October 1991 to June 1996, Dr. Conner was Vice President, Regulatory/Clinical Affairs and Quality Assurance for Baxter Healthcare's Novacor Division, a manufacturer of implantable heart assist devices. Dr. Conner holds a Ph.D. in Pharmacology from the University of Minnesota and a B.A. in Biology from Keuka College.

Timothy T. Goodnow, Ph.D. has served as our Vice President of Research and Development since November 2000. From June 1999 to October 2000, Dr. Goodnow held the position of Vice President of Research and Development for Verax Biomedical Incorporated, a blood safety start-up company. From July 1998 to

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June 1999, Dr. Goodnow served in the capacity of Vice President of Research and Development for ZymeQuest, Inc., a start-up company specializing in the development of enzymic blood conversion processing systems for use in blood transfusion medicine. From January 1983 to July 1998, he served in various positions of increasing responsibility, including Vice President of Research and Development for Baxter Healthcare/Dade Behring, a global corporation providing products and support services to clinical laboratories. Dr. Goodnow holds a B.S. and Ph.D. in Chemistry from the University of Miami.

Claire D. Heiss has served as our Vice President of Operations since August 1999. From May 1994 to November 1997, Ms. Heiss served as the Vice President and General Manager of Cooking Products for AB Electrolux's Frigidaire Company, a producer of major appliances for the home. She took a brief retirement from November 1997 until August 1999. Ms. Heiss has over twenty five years of operations experience with General Electric and Motorola. Ms. Heiss holds a B.S. in Industrial Engineering from the University of Illinois and has served as an examiner for the Malcolm Baldrige National Quality Award, a management standards organization.

Adam Heller, Ph.D. co-founded TheraSense with Ephraim Heller in December 1996 and has served as our Chief Scientific Advisor since the founding. Since August 1988, Dr. Heller has been the Ernest Cockrell, Sr. Chair in Engineering at the University of Texas at Austin. He is a Member of the National Academy of Engineering of the United States of America. Dr. Heller was awarded an honorary doctorate by Sweden's Uppsala University and awards from the American Chemical Society, the Royal Society of Chemistry (U.K.) and The Electrochemical Society. Dr. Heller has a Ph.D. in Chemistry, and an M.Sc. in Chemistry and Physics from the Hebrew University in Jerusalem. He did postdoctoral research at the University of California, Berkeley and at Bell Laboratories, a research and development organization.

Ephraim Heller served as our President from our founding in December 1996 until October 1997, and currently serves as a director and as our Vice President of Business Development. Prior to co-founding TheraSense, from August 1991 to December 1996, Mr. Heller was the Founder and President of E. Heller & Company, a company involved in the development and commercialization of new technologies in materials science, which involves the study of the physical and chemical properties of

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different compounds. Mr. Heller holds an M.B.A. from Yale University and a B.A. in Physics from Harvard University.

Lawrence W. Huffman has served as our Vice President of International Business Development since December 2000. From March 1995 to December 2000, Mr. Huffman held various positions at MediSense Inc., a glucose monitoring company, and following its acquisition of MediSense, at Abbott Laboratories, a diversified health care company, including Vice President of International Sales and Marketing and Vice President of Business Development. Mr. Huffman holds an M.B.A. from the Wharton School of Business at the University of Pennsylvania and a B.S. in Economics from the University of Pennsylvania.

Holly D. Kulp has served as our Vice President of Professional Relations and Customer Service since January 1999. From October 1986 to December 1998, she held numerous positions at LifeScan, Inc., including the position of Vice President of Quality Assurance, Regulatory Affairs and Legal from April 1994 through December 1998. Ms. Kulp holds an M.Ed. in Medical Education from Vanderbilt University and a B.S. in Dietetics and Distributed Sciences from David Lipscomb University.

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Charles T. Lamos has served as our Vice President and Chief Financial Officer since July 1999 and as our Director of Purchasing and Finance from April 1998 to July 1999. From May 1995 to April 1998, Mr. Lamos was Director, Worldwide Sourcing at LifeScan, Inc. He holds a B.S. in Business Administration from the University of Vermont and is a graduate of the General Electric Financial Management Program.

Annette J. Campbell-White has served on our board of directors since April 1997. She has been the Managing Partner of MedVenture Associates I, II and III, which are venture partnerships investing primarily in early stage businesses in the health care field, since May 1986. Ms. Campbell-White currently serves on the board of directors of ArthroCare Corporation, a company that designs, manufactures and markets surgical instruments. Ms. Campbell-White holds a B.S. degree and an M.S. degree in Chemical Engineering, both from the University of Cape Town, South Africa.

Mark J. Gainor has served on our board of directors since January 2000. Mr. Gainor currently serves as President of Lucor Holdings, LLC, a private investment company investing primarily in health care technology companies. From January 1999 to August 2000, Mr. Gainor served as President of the diabetes management services subsidiary of Matria Healthcare, Inc., a leading provider of population-based disease management programs. From 1986 to January 1999, Mr. Gainor was President and Chief Executive Officer of Gainor Medical Management LLC, a multinational manufacturer and distributor of diabetes supplies, which was acquired by Matria Healthcare, Inc. in January 1999 and was recently renamed Facet Technologies LLC. Mr. Gainor has a degree in Business Administration and Commerce from the University of Alberta, Canada.

Ross A. Jaffe, M.D. has served on our board of directors since October 1998. Dr. Jaffe joined Brentwood Venture Capital, a private venture capital firm, in August 1990, and continues to serve as a Managing Member of Brentwood VIII Ventures LLC, the general partner of Brentwood Associates VIII, L.P. and Brentwood Affiliates Fund II, L.P. Dr. Jaffe is a Managing Director of Versant Ventures, a health care-focused venture capital firm that was formed in November 1999. Dr. Jaffe holds an M.D. from the Johns Hopkins University School of Medicine and completed his residency in internal medicine at the University of California, San Francisco. He received an M.B.A. from Stanford University and an A.B. in Policy Studies from Dartmouth College.

Michael M. McNamara has served on our board of directors since May 1997. He has served as President, Americas Operations of Flextronics International Ltd., an electronics manufacturing services provider, since April 1994. Mr. McNamara received a B.S. from the University of Cincinnati and an M.B.A. from Santa Clara University.

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Robert R. Momsen has served on our board of directors since October 1998. He has been a General Partner at InterWest Partners, a private venture capital firm, since September 1982. Mr. Momsen serves as a director of ArthroCare Corporation, a company that designs, manufactures and markets surgical instruments, and Corixa Corporation Inc., a developer of immunotherapeutic products. Mr. Momsen received a B.S. in engineering and an M.B.A. from Stanford University.

Richard P. Thompson has served on our board of directors since November 1998. He has been President, Chief Executive Officer and a director of Aradigm Corporation, a developer of pulmonary drug delivery systems, since 1994 and was Chief Financial Officer of Aradigm from April 1996 until December 1996. He was named Chairman of the Board of Aradigm in August 1999. From 1991 to 1994, Mr. Thompson was President of LifeScan, Inc. In 1981, Mr. Thompson founded

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LifeScan, Inc., which was sold to Johnson & Johnson in 1986. Mr. Thompson holds a B.S. in biological sciences from the University of California, Irvine and an M.B.A. from California Lutheran University.

Executive officers are appointed by our board of directors and serve until their successors have been duly elected and qualified. Ephraim Heller, our Vice President of Business Development and a director, is the son of Dr. Adam Heller, our Chief Scientific Advisor. There are no other family relationships among any of our directors, executive officers and advisors.

Board of Directors

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

- . Class I, whose term will expire at the annual meeting of stockholders to be held in 2002;
- . Class II, whose term will expire at the annual meeting of stockholders to be held in 2003; and
- . Class III, whose term will expire at the annual meeting of stockholders to be held in 2004.

The Class I directors are Mr. Ephraim Heller and Ms. Campbell-White, the Class II directors are Messrs. Lortz and Gainor and Dr. Jaffe and the Class III directors are Messrs. McNamara, Momsen and Thompson. At each annual meeting of stockholders, or special meeting in lieu thereof, after the initial classification of the board of directors, the successors to directors whose terms will then expire will be elected to serve from the time of election and qualification until the third annual meeting following election or special meeting held in lieu thereof. The authorized number of directors may be changed only by resolution of the board of directors or a super-majority vote of the stockholders. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. This classification of the board of directors may have the effect of delaying or preventing changes in control or management.

Board Committees

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

Our compensation committee consists of Ms. Campbell-White and Mr. McNamara. The compensation committee reviews and recommends to the board of directors the compensation and benefits of our executive officers and administers our stock plans and employee benefit plans.

Our option committee is comprised of Mr. Lortz. The function of the option committee is to determine stock option grants for employees and consultants who are not executive officers or directors.

Compensation Committee Interlocks and Insider Participation

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

Director Compensation

We reimburse our non-employee directors for their expenses incurred in connection with attending board and committee meetings, but do not compensate them for their services as board or committee members. In the past, we have granted non-employee directors options to purchase our common stock under our 1997 Stock Plan. Specifically, during 1997, the board granted Mr. McNamara an option to purchase 43,344 shares of our common stock with an exercise price of \$0.14 per share, and, during 1998, the board granted Mr. Thompson an option to purchase 30,000 shares of our common stock with an exercise price of \$0.28 per share. In September 2000, the board granted each of Messrs. Gainor, McNamara, Momsen, Thompson, Ms. Campbell-White and Dr. Jaffe an option to purchase 30,000 shares of our common stock with an exercise price of \$5.00 per share.

Our board will continue to have discretion to grant options to non-employee directors from time to time under our 2001 Stock Plan. Each non-employee director who joins our board following this offering will receive a nondiscretionary, automatic grant of options to purchase 30,000 shares of our common stock upon joining our board of directors. In addition, each of our non-employee directors will receive yearly nondiscretionary, automatic grants of options to purchase 5,000 shares of our common stock, pursuant to our 2001 Stock Plan.

Executive Compensation

The following table summarizes the compensation earned for services rendered to us in all capacities for the year ended December 31, 2000 by our chief executive officer and our four other most highly paid executive officers. These executives are referred to as the named executive officers elsewhere in this prospectus.

Summary Compensation Table

| Name and Principal Position ----- | 2000 Annual Compensation | | Long-Term Compensation ----- |
|---|-----------------------------|-------------------|---|
| | Salary | Bonus | Securities Underlying Options (/2/) |
| ----- | ----- | ----- | ----- |
| W. Mark Lortz..... Chief Executive Officer and President | \$250,000.00 | \$25,000.00 (/1/) | 525,000 |
| Tae Andrews..... Vice President of Marketing and Sales | \$170,523.48 | -- | 80,000 |
| Eve A. Conner, Ph.D..... Vice President of Quality Assurance and Regulatory Affairs | \$165,000.00 | -- | 88,500 |
| Holly D. Kulp..... Vice President of Professional Relations and Customer Service | \$163,750.00 | -- | 91,000 |
| Charles T. Liamos..... | \$159,999.96 | -- | 110,500 |

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Chief Financial Officer and Vice
President

(/1/Represents) a bonus earned in 2000 but paid in 2001.

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(/2/) On August 3, 2001, our board of directors granted the following options to purchase shares of our common stock to our named executive officers: W. Mark Lortz, our President, Chief Executive Officer and Chairman of the Board, was granted an option to purchase 250,000 shares; Charles T. Liamos, our Chief Financial Officer, was granted an option to purchase 37,400 shares; Tae Andrews, our Vice President of Marketing and Sales, was granted an option to purchase 15,000 shares; Eve A. Conner, our Vice President of Quality Assurance and Regulatory Affairs, was granted an option to purchase 30,000 shares; and Holly D. Kulp, our Vice President of Professional Relations and Customer Services, was granted an option to purchase 33,000 shares. Each option has an exercise price of \$9.00 per share and vests at a rate of 1/48th per month over a four year period, commencing August 1, 2001.

2000 Option Grants

The following table summarizes the stock options granted to each named executive officer during the year ended December 31, 2000, including the potential realizable value over the 10-year term of the options, based on assumed rates of stock appreciation of 5% and 10%, compounded annually. These assumed rates of appreciation comply with the rules of the Securities and Exchange Commission and do not represent our estimate of future stock price. Actual gains, if any, on stock option exercises will be dependent on the future performance of our common stock. The assumed 5% and 10% rates of stock appreciation are based on the initial public offering price of \$19.00 per share.

In the year ended December 31, 2000, we granted options to purchase up to an aggregate of 2,759,346 shares to employees. All options were granted under our 1997 Stock Plan at exercise prices at or above the fair market value of our common stock on the date of grant, as determined in good faith by our board of directors. Option shares generally vest over four years.

| Name | Individual Grants | | | | Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term | |
|--------------------|---|--|--------------------------------|--------------------|--|--------------|
| | Number of Securities Underlying Options Granted | Percent of Total Options Granted to Employees | Exercise Price Per Share | Expiration Date | 5% | 10% |
| W. Mark Lortz..... | 400,000 | 14.50% | \$3.00 | 3/17/10 | \$11,179,599 | \$18,512,443 |
| | 75,000 | 2.72% | \$4.00 | 7/31/10 | \$ 2,021,175 | \$ 3,396,083 |
| | 50,000 | 1.81% | \$5.00 | 9/29/10 | \$ 1,297,450 | \$ 2,214,055 |
| Tae Andrews..... | 18,000 | 0.65% | \$3.00 | 3/17/10 | \$ 503,082 | \$ 833,060 |
| | 42,000 | 1.52% | \$4.00 | 7/31/10 | \$ 1,131,858 | \$ 1,901,806 |
| | 20,000 | 0.72% | \$5.00 | 9/29/10 | \$ 518,980 | \$ 885,622 |

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| | | | | | | |
|--------------------------|--------|-------|--------|---------|--------------|--------------|
| Eve A. Conner, Ph.D. ... | 36,000 | 1.30% | \$3.00 | 3/17/10 | \$ 1,006,164 | \$ 1,666,120 |
| | 37,500 | 1.36% | \$4.00 | 7/31/10 | \$ 1,010,587 | \$ 1,698,042 |
| | 15,000 | 0.54% | \$5.00 | 9/29/10 | \$ 389,235 | \$ 664,217 |
| Holly D. Kulp..... | 32,000 | 1.16% | \$3.00 | 3/17/10 | \$ 894,368 | \$ 1,480,995 |
| | 39,000 | 1.41% | \$4.00 | 7/31/10 | \$ 1,051,011 | \$ 1,765,963 |
| | 20,000 | 0.72% | \$5.00 | 9/29/10 | \$ 518,980 | \$ 885,622 |
| Charles T. Liamos..... | 45,000 | 1.63% | \$3.00 | 3/17/10 | \$ 1,257,705 | \$ 2,082,650 |
| | 40,500 | 1.47% | \$4.00 | 7/31/10 | \$ 1,091,434 | \$ 1,833,885 |
| | 25,000 | 0.91% | \$5.00 | 9/29/10 | \$ 648,725 | \$ 1,107,028 |

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Aggregate Option Exercises and Option Values

The following table describes for the named executive officers their option exercises for the year ended December 31, 2000, and exercisable and unexercisable options held by them as of December 31, 2000.

The value realized and the value of unexercised in-the-money options at December 31, 2000 are based on the initial public offering price of \$19.00 per share, less the per share exercise price, multiplied by the number of shares issued or issuable, as the case may be, upon exercise of the option. All options were granted under our 1997 Stock Plan.

| Name | Number of Shares Acquired on Exercise | Value Realized | Number of Securities Underlying Unexercised Options at December 31, 2000 | | Value of Unexercised In-The-Money Options at December 31, 2000 | |
|--------------------------|---------------------------------------|----------------|--|---------------|--|---------------|
| | | | Exercisable | Unexercisable | Exercisable | Unexercisable |
| W. Mark Lortz..... | -- | -- | 104,166 | 420,834 | \$1,650,970 | \$6,574,030 |
| Tae Andrews..... | -- | -- | 68,750 | 161,250 | \$1,248,749 | \$2,694,251 |
| Eve A. Conner, Ph.D. ... | 68,500 | \$1,266,000 | 23,501 | 146,499 | \$ 411,874 | \$2,478,626 |
| Holly D. Kulp..... | -- | -- | 80,958 | 160,042 | \$1,479,781 | \$2,672,220 |
| Charles T. Liamos..... | -- | -- | 16,939 | 93,561 | \$ 262,776 | \$1,414,724 |

Change of Control and Severance Agreements

We have agreements with each of our executive officers that contain provisions that will be triggered in the event of a change of control. Upon a change of control, our executive officers will receive accelerated vesting on 75% of their then unvested shares and the remaining unvested shares will vest in the event their employment relationship is terminated under certain circumstances thereafter. In addition, Mr. Lortz is entitled to receive a severance payment equal to six months of his then current salary in the event he is terminated without cause.

Benefit Plans

1997 Stock Plan

Our 1997 Stock Plan was adopted by our board of directors in March 1997, and our stockholders initially approved the plan in April 1997. Our 1997 Stock Plan provides for the grant of incentive stock options, which may provide for

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preferential tax treatment to our employees, and for the grant of nonstatutory stock options to our employees, directors and consultants. As of June 30, 2001, we have reserved an aggregate of 7,607,032 shares of our common stock for issuance under this plan. As of June 30, 2001, 1,670,897 of our outstanding shares have been issued pursuant to the exercise of options, options to purchase 4,882,303 shares of common stock were outstanding, and 1,053,832 shares were available for future grant. In August 2001, we reserved an additional 500,000 shares of common stock for issuance under our 1997 Stock Plan that we had previously reserved under our 2001 Stock Plan. Following this offering, the 1997 Stock Plan will terminate, and we will not grant any additional stock options under our 1997 Stock Plan. Instead we will grant options under our 2001 Stock Plan. The 1997 Stock Plan provides that in the event of a change in control, each outstanding option will be assumed or an equivalent option will be granted in its place by the successor corporation. If the successor corporation refuses to assume or substitute for the options, the options will terminate as of the closing of the merger or sale of assets.

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2001 Stock Plan

In connection with this offering, our board of directors and stockholders approved the 2001 Stock Plan in June 2001. Our 2001 Stock Plan provides for the grant of incentive stock options to our employees, and for the grant of nonstatutory stock options and stock purchase rights to our employees, directors and consultants.

Number of Shares of Common Stock Available under the 2001 Stock Plan. As of June 30, 2001, we have reserved a total of 7,000,000 shares of our common stock for issuance pursuant to the 2001 Stock Plan plus (i) any shares which have been reserved but not issued under our 1997 Stock Plan and (ii) any shares returned to our 1997 Stock Plan as a result of termination of options. In August 2001, we decreased the number of shares reserved for issuance under the 2001 Stock Plan by 500,000 shares and instead reserved these shares under our 1997 Stock Plan. In addition, our 2001 Stock Plan provides for annual increases in the number of shares available for issuance under our 2001 Stock Plan on the first day of each fiscal year, beginning with our fiscal year 2002, equal to the lesser of:

- . 5% of the outstanding shares of common stock on the first day of our fiscal year;
- . 2,500,000 shares; or
- . a lesser amount as our board may determine.

Administration of the 2001 Stock Plan. Our board of directors or a committee of our board administers the 2001 Stock Plan. In the case of options intended to qualify as "performance-based compensation" within the meaning of Section 162(m) of the Internal Revenue Code of 1986, as amended, or the Code, the committee will consist of two or more "outside directors" within the meaning of Section 162(m) of the Code. The administrator has the power to determine the terms of the options or stock purchase rights granted, including the exercise price, the number of shares subject to each option or stock purchase right, the exercisability of the options and the form of consideration payable upon exercise.

Options. The administrator determines the exercise price of options granted under the 2001 Stock Plan, but with respect to nonstatutory stock options intended to qualify as "performance-based compensation" within the meaning of Section 162(m) of the Code and all incentive stock options, the exercise price

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must at least be equal to the fair market value of our common stock on the date of grant. The term of an incentive stock option generally may not exceed ten years and the administrator determines the term of all other options.

No optionee may be granted an option to purchase more than 1,000,000 shares in any fiscal year. In connection with his or her initial service, an optionee may be granted an additional option to purchase up to 1,000,000 shares.

After termination of one of our employees, directors or consultants, he or she may exercise his or her option to the extent it is vested for the period of time stated in the option agreement. Generally, if termination is due to death or disability, the option will remain exercisable for 12 months. In all other cases, the option will generally remain exercisable for one to three months. However, an option may never be exercised later than the expiration of its term.

Stock Purchase Rights. The administrator determines the exercise price of stock purchase rights granted under our 2001 Stock Plan. Unless the administrator determines otherwise, the restricted stock purchase agreement will grant us a repurchase option that we may exercise upon the voluntary or involuntary termination of the purchaser's service with us for any reason, including death or disability. The purchase price for shares we repurchase will generally be the original price paid by the purchaser and may be paid by cancellation of any indebtedness of the purchaser to us. The administrator determines the rate at which our repurchase option will lapse.

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Transferability of Options and Stock Purchase Rights. Our 2001 Stock Plan generally does not allow for the transfer of options or stock purchase rights and only the optionee may exercise an option and stock purchase right during his or her lifetime.

Automatic Option Grants to Non-Employee Directors. Our 2001 Stock Plan also provides for the automatic grant of 30,000 shares of common stock to a director who first becomes a non-employee director (except those directors who become non-employee directors by ceasing to be employee directors) on or after the date of this offering. This option will vest as to one-third of the shares subject to the option on each anniversary of the date of grant. Each non-employee director will automatically be granted an option to purchase 5,000 shares each year following the date of our annual stockholder's meeting (except after the first such annual meeting if it is held within six months of the date of this offering) if on such date, he or she will have served on our board of directors for at least the previous six months. This option will vest as to 100% of the shares subject to the option on each anniversary of the date of grant. All options automatically granted to non-employee directors will have a term of 10 years and the exercise price will be 100% of the fair market value per share of common stock on the date of grant.

Adjustments upon Merger or Asset Sale. Our 2001 Stock Plan provides that in the event of our merger with or into another corporation or a sale of substantially all of our assets, the successor corporation will assume or substitute an equivalent option or right for each outstanding option or stock purchase right. If there is no assumption or substitution of outstanding options or stock purchase rights, all such options and stock purchase rights shall immediately vest and the administrator will provide notice to the optionee that he or she has the right to exercise the option or stock purchase right as to all of the shares subject to the option or stock purchase right, including shares which would not otherwise be exercisable, for a period of 15 days from the date of the notice. The option or stock purchase right will terminate upon the expiration of the 15-day period.

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Amendment and Termination of our 2001 Stock Plan. Our 2001 Stock Plan will automatically terminate in 2011, unless we terminate it sooner. In addition, our board of directors has the authority to amend, suspend or terminate the 2001 Stock Plan provided it does not adversely affect any option previously granted under it.

2001 Employee Stock Purchase Plan

In connection with this offering, we established an Employee Stock Purchase Plan. Our board of directors and stockholders approved the 2001 Employee Stock Purchase Plan in June 2001.

Number of Shares of Common Stock Available under the Employee Stock Purchase Plan. A total of 1,000,000 shares of our common stock will be made available for sale. In addition, our Employee Stock Purchase Plan provides for annual increases in the number of shares available for issuance under the Employee Stock Purchase Plan on the first day of each fiscal year, beginning with our fiscal year 2002, equal to the lesser of:

- . 1.5% of the outstanding shares of our common stock on the first day of the fiscal year;
- . 1,000,000 shares; or
- . a lesser amount as our board may determine.

Administration of the Employee Stock Purchase Plan. Our board of directors or a committee of our board administers the Employee Stock Purchase Plan. Our board of directors or its committee has full and exclusive authority to interpret the terms of the Employee Stock Purchase Plan and determine eligibility.

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Eligibility to Participate. All of our employees are eligible to participate if they are customarily employed by us or any participating subsidiary for at least 20 hours per week and more than five months in any calendar year. However, an employee may not be granted an option to purchase stock if such employee:

- . immediately after grant owns stock possessing 5% or more of the total combined voting power or value of all classes of our capital stock; or
- . whose rights to purchase stock under all of our employee stock purchase plans accrues at a rate that exceeds \$25,000 worth of stock for each calendar year.

Offering Periods and Contributions. Our Employee Stock Purchase Plan is intended to qualify under Section 423 of the Code and contains consecutive, overlapping 24-month offering periods (provided that the first offering period will be a 25-month period). Each offering period includes four six-month purchase periods. The offering periods generally start on the first trading day on or after May 1 and November 1 of each year, except for the first such offering period which will commence on the first trading day on or after the effective date of this offering and will end on the last trading day on or before November 1, 2003.

Our Employee Stock Purchase Plan permits participants to purchase common stock through payroll deductions of up to 100% of their eligible compensation in 2001 and up to 15% of their eligible compensation thereafter. Eligible compensation

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includes only a participant's base salary, wages, commissions, shift premium and overtime. A participant may purchase a maximum of 10,000 shares during a six-month purchase period.

Purchase of Shares. Amounts deducted and accumulated by the participant are used to purchase shares of our common stock at the end of each six-month purchase period. The price is 85% of the lower of the fair market value of our common stock at the beginning of an offering period or at the end of the particular purchase period. If the fair market value at the end of a purchase period is less than the fair market value at the beginning of the offering period, participants will be withdrawn from the current offering period following their purchase of shares on the purchase date and will be automatically re-enrolled in a new offering period. Participants may end their participation at any time during an offering period, and will be paid their payroll deductions to date. Participation in the Employee Stock Purchase Plan ends up to three months after termination of employment with us.

Transferability of Rights. A participant may not transfer rights granted under the Employee Stock Purchase Plan other than by will, the laws of descent and distribution or as otherwise provided under the Purchase Plan.

Adjustments upon Merger or Change in Control. In the event of our merger with or into another corporation or change in control, a successor corporation may assume or substitute each outstanding option. If the successor corporation refuses to assume or substitute for the outstanding options, the offering period then in progress will be shortened, and a new exercise date will be set.

Amendment and Termination of the Employee Stock Purchase Plan. Our Employee Stock Purchase Plan will terminate in 2011. However, our board of directors has the authority to amend or terminate our Employee Stock Purchase Plan, except that, subject to certain exceptions described in the Employee Stock Purchase Plan, no such action may adversely affect any outstanding rights to purchase stock under our Employee Stock Purchase Plan.

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RELATED PARTY TRANSACTIONS

Common Stock Issuances

In March 1999, we issued W. Mark Lortz, our President, Chief Executive Officer and Chairman of the Board, 144,990 shares of our common stock at a price of \$0.50 per share. The shares issued to Mr. Lortz are subject to a restricted stock purchase agreement. The agreement provides that the shares are subject to a right of repurchase in our favor, which right lapses over a four year period. As of June 30, 2001, 81,556 of the shares are fully vested, and 63,434 of the shares remain subject to our right of repurchase.

In July 1998, we issued 62,500 shares of our common stock to Charles T. Liamos, our Chief Financial Officer, at a price of \$0.28 per share. In March 1999, we issued Mr. Liamos 30,375 shares of our common stock at a price of \$0.50 per share. In September 1999, we issued Mr. Liamos 87,500 shares of our common stock at a price of \$0.70 per share. The shares issued to Mr. Liamos are subject to restricted stock purchase agreements. The agreements each provide that the shares are subject to a right of repurchase in our favor, which right lapses over a four year period. As of June 30, 2001, an aggregate of 108,492 of the shares are fully vested and 71,883 of the shares remain subject to our right of repurchase.

Preferred Stock Issuances

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From October 1998 through April 2001, we sold shares of our preferred stock in private financings as follows:

- . 7,142,851 shares of Series B preferred stock at a price of \$2.10 per share in October 1998 and February 1999;
- . 8,490,159 shares of Series C preferred stock at a price of \$5.00 per share in February 2000; and
- . 6,643,371 shares of Series D preferred stock at a price of \$8.50 per share in January, February and April 2001.

Each share of preferred stock will convert automatically into one share of common stock upon the closing of this offering. The purchasers of these shares of preferred stock are entitled to certain registration rights. See "Description of Capital Stock--Registration Rights." The investors in these financings included the following executive officers, directors and holders of more than 5% of our securities and their affiliated entities:

| Investor ----- | Series B ----- | Series C ----- | Series D ----- |
|--|-------------------|-------------------|-------------------|
| Brentwood Venture Capital(/1/) | 3,123,236 | 400,000 | 117,647 |
| Delphi Ventures and affiliates | 238,095 | 800,000 | 470,588 |
| InterWest Partners(/2/) | 3,123,237 | 1,254,160 | 470,588 |
| Lehman Brothers and affiliates | -- | 1,999,999 | 294,117 |
| MedVentures Associates and affiliates(/3/) | 476,190 | 200,000 | 323,529 |
| MJG Partners, L.P.(/4/) | -- | 800,000 | 150,000 |
| Sequoia Capital and affiliates | -- | -- | 588,235 |
| Disetronic Holding AG | -- | -- | 2,352,941 |
| Robert D. Brownell | 3,571 | 4,300 | -- |
| Claire D. Heiss | -- | 10,000 | -- |
| Lawrence W. Huffman | -- | -- | 20,000 |
| Robert R. Momsen | -- | -- | 17,647 |

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- (/1/) Ross A. Jaffe, M.D., one of our directors, is a Managing Member of Brentwood VIII Ventures LLC, the General Partner of Brentwood Associates VIII, L.P. and Brentwood Affiliates Fund II, L.P. The Brentwood Venture Capital shares include shares purchased by Brentwood Associates VIII, L.P. and Brentwood Affiliates Fund II, L.P.
- (/2/) Robert R. Momsen, one of our directors, is a General Partner of InterWest Partners VI, L.P. and InterWest Investors VI, L.P. The InterWest Partners shares include shares purchased by InterWest Partners VII, L.P., InterWest Partners VI, L.P., InterWest Investors, VII, L.P., and InterWest Investors, VI, L.P.
- (/3/) Annette J. Campbell-White, one of our directors, is the Managing Partner of MedVentures Associates II and III.
- (/4/) Mark J. Gainor, one of our directors, is President of MJG Partners, L.P.

Indemnification Agreements of Officers and Directors

Our amended and restated certificate of incorporation and bylaws provide that we will indemnify each of our directors and officers to the fullest extent permitted by the Delaware General Corporation Law. Further, we have entered into indemnification agreements with each of our directors and officers. For

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further information, see "Description of Capital Stock--Limitation of Liability and Indemnification Matters."

Loans to Directors and Executive Officers

In December 1997 and March 1999, we loaned an aggregate of \$135,145 to W. Mark Lortz, our President, Chief Executive Officer and Chairman of the Board, in connection with his purchase of an aggregate of 592,490 shares of our restricted common stock. The loans were made pursuant to two full-recourse promissory notes in the amounts of \$62,650 and \$72,495. The notes do not bear interest and are secured by the shares of common stock purchased. The notes are payable upon the earlier of December 1, 2001 and March 5, 2003, respectively, or termination of Mr. Lortz's employment with or services to us.

In July 1998, March 1999 and September 1999, we loaned an aggregate of \$93,938 to Charles T. Liamos, our Chief Financial Officer, in connection with the purchase of an aggregate of 180,375 shares of our restricted common stock. The loans were made pursuant to three full-recourse promissory notes in the amounts of \$17,500, \$15,188 and \$61,250. The notes do not bear interest and are secured by the shares of common stock purchased. The notes are payable upon the earlier of April 6, 2002, March 5, 2003 and September 1, 2003, respectively, or termination of Mr. Liamos' employment with or services to us.

Agreement with Flextronics

In November 1999, we entered into an agreement with Flextronics International related to the manufacturing of the FreeStyle meter. Flextronics is exclusively responsible for building the FreeStyle meter and assembling the FreeStyle System kits. Our contract with Flextronics expires in November 2004, and is renewable annually thereafter. This agreement may be terminated by either party upon one year's prior written notice. In 1999 and 2000, we purchased \$261,195 and \$20.6 million under this agreement, respectively. Michael McNamara, a member of our board of directors, is President of Americas Operations of Flextronics.

Agreement with Facet Technologies

Pursuant to an agreement we entered into with Facet Technologies LLC in December 1998, as amended in July 2001, Facet has provided financial support for the development and design of the FreeStyle lancing device. Under the agreement, we are obligated to pay royalties, based upon a fixed fee per FreeStyle System kit shipped. Pursuant to an agreement we entered into with Facet in July 2001, we have agreed to purchase the FreeStyle lancing devices and lancets exclusively from Facet through June 1, 2007. In 1999 and 2000, we purchased \$4,675 and \$402,356 of lancing devices and lancets from Facet, respectively. Mark J. Gainor, a former principal of Facet Technologies LLC and a former director of Matria Healthcare, Inc., which wholly owns Facet Technologies LLC, is a member of our board of directors.

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Agreement with E. Heller & Co.

In October 2000, we entered into a Technology Purchase Agreement with E. Heller & Co., providing for the transfer and assignment of several licenses and rights to us in exchange for \$500,000. E. Heller & Co. is controlled by Ephraim Heller, a co-founder, Vice President of Business Development and member of our board of directors.

Agreement with Adam Heller

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Dr. Adam Heller, our Chief Scientific Advisor, has performed consulting services for us since April 1997. The terms of our consulting agreement with Dr. Heller provide that we pay Dr. Heller a consulting fee of \$1,200 per day of service, plus reimbursement for travel and business expenses. The agreement has a term of one year with automatic one year renewals. The agreement is terminable by either party upon 30 days written notice. In 1998, 1999 and 2000, we paid Dr. Heller \$55,260, \$85,760 and \$110,141, respectively, in connection with this agreement. Dr. Adam Heller is the father of Ephriam Heller, co-founder, Vice President of Business Development and director.

Agreement with Disetronic Group

In September 2000, we entered into an International Distributor Agreement with Disetronic Handels A.G. relating to the distribution of FreeStyle in Germany, Switzerland, Denmark, Austria, Sweden, Finland, Norway and the Netherlands. Under terms of the agreement, Disetronic will have exclusive responsibility for sales, marketing and customer service in its territory in Europe. In addition, Disetronic is also entitled to market FreeStyle to its pump users in North America. The initial term of the Disetronic agreement is five years, ending in September 2005. At the end of the initial term, the agreement will automatically renew for additional three year terms unless one of the parties provides written notice of termination at least one year prior to the end of the Agreement. Under the terms of the agreement, we received a \$1.5 million nonrefundable pre-payment which has been deferred and is being credited as revenues are recognized. Disetronic is required to meet specified minimum purchase requirements or we may terminate the agreement. Disetronic beneficially owns greater than 5% of our outstanding shares of capital stock.

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PRINCIPAL STOCKHOLDERS

The following table sets forth information about the beneficial ownership of our common stock on June 30, 2001, and as adjusted to reflect the sale of the shares of common stock in this offering, by:

- . each person known to us to be the beneficial owner of more than 5% of our common stock;
- . each named executive officer;
- . each of our directors; and
- . all of our executive officers and directors as a group.

Unless otherwise noted below, the address of each beneficial owner listed on the table is c/o TheraSense, Inc., 1360 South Loop Road, Alameda, California 94501. We have determined beneficial ownership in accordance with the rules of the Securities and Exchange Commission. Except as indicated by the footnotes below, we believe, based on the information furnished to us, that the persons and entities named in the tables below have sole voting and investment power with respect to all shares of common stock that they beneficially own, subject to applicable community property laws. We have based our calculation of the percentage of beneficial ownership on 32,089,847 shares of common stock outstanding on June 30, 2001 and 38,089,847 shares of common stock outstanding upon completion of this offering.

In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of that person, we deemed outstanding shares of common stock subject to options held by that person that are currently exercisable or exercisable within 60 days of June 30, 2001. We did

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not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person.

| Beneficial Owner | Number of Shares Owned | Number of Shares Underlying Options Exercisable Within 60 Days of June 30, 2001 | | Percentage of Shares Outstanding | |
|--|------------------------|---|--|----------------------------------|--------|
| | | | | Before | After |
| Five Percent Stockholders | | | | | |
| InterWest | | | | | |
| Partners (/1/) | 4,847,983 | -- | | 15.11% | 12.73% |
| Brentwood Venture | | | | | |
| Capital (/2/) | 3,640,883 | -- | | 11.35% | 9.56% |
| Delphi Ventures (/3/) | 3,302,941 | -- | | 10.29% | 8.67% |
| E. Heller & Co. | 3,129,375 | -- | | 9.75% | 8.22% |
| Sequoia Capital (/4/) | 2,382,492 | -- | | 7.42% | 6.25% |
| Disetronic Holding | | | | | |
| AG (/5/) | 2,352,941 | -- | | 7.33% | 6.18% |
| Lehman Brothers (/6/) | 2,294,116 | -- | | 7.15% | 6.02% |
| MedVentures | | | | | |
| Associates (/7/) | 1,797,167 | -- | | 5.60% | 4.72% |
| Directors and Named Executive Officers | | | | | |
| W. Mark Lortz (/8/) | 592,490 | 191,660 | | 2.43% | 2.05% |
| Tae Andrews | -- | 108,330 | | * | * |
| Eve A. Conner, Ph.D. | 68,500 | 63,245 | | * | * |
| Holly D. Kulp | -- | 122,371 | | * | * |
| Charles T. Liamos | 180,375 | 35,352 | | * | * |
| Ephraim Heller (/9/) | 3,129,375 | -- | | 9.75% | 8.22% |
| Annette J. Campbell- | | | | | |
| White (/7/) | 1,797,167 | 9,167 | | 5.63% | 4.74% |
| Mark J. Gainor (/10/) | 950,000 | 9,167 | | 2.99% | 2.52% |
| Ross A. Jaffe, | | | | | |
| M.D. (/2/) | 3,640,883 | 9,167 | | 11.37% | 9.58% |

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| Beneficial Owner | Number of Shares Owned | Number of Shares Underlying Options Exercisable Within 60 Days of June 30, 2001 | | Percentage of Shares Outstanding | |
|---|------------------------|---|--|----------------------------------|--------|
| | | | | Before | After |
| Michael M. McNamara | 43,344 | 9,167 | | * | * |
| Robert R. Momsen (/11/) | 3,347,152 | 9,167 | | 10.46% | 8.81% |
| Richard P. Thompson | 30,000 | 9,167 | | * | * |
| All directors and executive officers as a group (17 people) | | | | | |
| | 13,930,565 | 764,926 | | 44.73% | 37.82% |

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* Less than one percent

- (/1/) The InterWest Partners shares include 3,228,289 shares purchased by InterWest Partners VI, L.P., 1,449,082 shares purchased by InterWest Partners VII, L.P., 101,216 shares purchased by InterWest Investors, VI, L.P., and 69,396 shares purchased by InterWest Investors, VII, L.P. InterWest Partners VII, L.P. and InterWest Investors VII, L.P. are managed by InterWest Management Partners VII, LLC. InterWest Management Partners VII, LLC has sole voting and investment control over shares owned by InterWest Partners VII and InterWest Investors VII. The managing directors of InterWest Management Partners VII, LLC are Harvey B. Cash, Alan W. Crites, Philip T. Gianos, W. Scott Hedrick, W. Stephen Holmes, Gilbert H. Kliman, Thomas L. Rosch and Arnold L. Oronsky. Stephen C. Bowsher is a venture member. Managing Directors and Venture members share voting and investment control. InterWest Management Partners VI, LLC has sole voting and investment control over the shares held by InterWest Partners VI, L.P. and InterWest Investors VI, L.P. Managing Directors are Harvey B. Cash, Alan W. Crites, Philip T. Gianos, W. Scott Hedrick, W. Stephen Holmes, Robert R. Momsen and Arnold L. Oronsky. The sole Venture Member is Gilbert H. Kliman. Managing Directors and Venture Members share voting and investment control. The address of InterWest Partners is 3000 Sand Hill Road, Building 3, Suite 255, Menlo Park, California 94025.
- (/2/) The Brentwood Venture Capital shares include 3,495,247 shares purchased by Brentwood Associates VIII, L.P. and 145,636 shares purchased by Brentwood Affiliates Fund II, L.P. Brentwood VIII Ventures LLC, the general partner of Brentwood Associates VIII, L.P. and Brentwood Affiliates Fund II, L.P., has sole voting and dispositive power over these shares. The managing members of Brentwood VIII Ventures LLC, Dr. Ross A. Jaffe (one of our directors), Brian G. Atwood, Jeffrey C. Brody, G. Bradford Jones, William J. Link and John L. Walecka, share voting and investment control over the shares held by these funds, but none of them individually possesses voting or dispositive power over the shares. The managing members disclaim beneficial ownership of these shares except to the extent of their respective pecuniary interests therein. The address of each of the Brentwood entities referred to herein is 11150 Santa Monica Blvd., Suite 1200, Los Angeles, California 90025.
- (/3/) The Delphi Ventures shares include 2,389,337 shares purchased by Delphi Ventures III, L.P., 853,002 shares purchased by Delphi Ventures IV, L.P., 43,017 shares purchased by Delphi BioInvestments III, L.P. and 17,586 shares purchased by Delphi BioInvestments IV, L.P. The managing members of Delphi Management Partners III, L.L.C., which is the general partner of Delphi Ventures III, L.P. and Delphi BioInvestments III, L.P., disclaim beneficial ownership except to the extent of their pecuniary interest therein. The managing members of Delphi Management Partners III, L.P., all of whom share voting and dispositive power over these shares, are James J. Bochnowski, David L. Douglass and Donald J. Lothrop. The managing members of Delphi Management Partners IV, L.L.C., which is the general partner of Delphi Ventures IV, L.P. and Delphi BioInvestments IV, L.P., disclaim beneficial ownership except to the extent of their pecuniary interest therein. The managing members of Delphi Management Partners IV, L.P., all of whom share voting and dispositive power over these shares, are James J. Bochnowski, David L. Douglass and Donald J. Lothrop. The address of Delphi Ventures is 3000 Sand Hill Road, Building 1, Suite 135, Menlo Park, California 94025.
- (/4/) The Sequoia Capital shares include 1,618,421 shares purchased by Sequoia Capital VII, 78,947 shares purchased by Sequoia Technology Partners VII, 44,856 shares purchased by Sequoia International Partners, 52,033 shares purchased by Sequoia 1997, LLC, 517,647 shares purchased by Sequoia Capital Franchise Fund, and 70,588 shares purchased by Sequoia Capital Franchise Partners. The general partner of Sequoia Capital VII, Sequoia Technology Partners VII and Sequoia International Partners is SC VII Management-A, LLC., whose managing members are Douglas Leone, Michael Moritz, Thomas McMurray, Thomas Stephenson and Mark Stevens. These

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individuals also have signing power over Sequoia 1997, LLC. The general partner of Sequoia Capital Franchise Fund and Sequoia Capital Franchise Partners is SCFF Management, LLC, whose managing members are Michael Goguen, Douglas Leone, Michael Moritz, Thomas Stephenson and Mark Stevens. The managing members of the respective funds share voting and investment control over all shares held by those funds. The address of Sequoia Capital is 3000 Sand Hill Road, Building 4, Suite 280, Menlo Park, California 94025.

- (/5/)The address of Disetronic Holding AG is Brunnmattstrasse 6, Burgdorf, CH 3401 Switzerland.
- (/6/)The Lehman Brothers shares include 957,193 shares purchased by LB I Group, Inc., 832,235 shares purchased by Lehman Brothers Venture Partners, L.P., and 504,688 shares purchased by Lehman Brothers Venture Capital Partners I, L.P. The above-listed entities are controlled by subsidiaries of Lehman Brothers Holdings, Inc., a publicly held corporation. The address of Lehman Brothers is 3 World Financial Center, 8th Floor, New York, New York 10285-0800.

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- (/7/The)MedVentures Associates shares include 1,561,873 shares purchased by MedVentures Associates II, L.P., 225,694 shares purchased by MedVentures Associates III, L.P., and 9,600 shares purchased by MedVen Affiliates III, L.P. Ms. Campbell-White is a member of MedVentures Associates Management II Co., LLC, which is the general partner of MedVentures Associates II, and a member of MedVentures Associates Management III Co., LLC, which is the general partner of MedVentures Associates III, L.P. and MedVen Affiliates III, L.P. Ms. Campbell-White disclaims beneficial ownership of these shares except to the extent of her pecuniary interest therein. Annette Campbell-White and George Choi share voting and investment control in MedVentures Associates Management II Co., LLC, and MedVentures Associates Management II Co., LLC. The address of MedVentures Associates is 4 Orinda Way, Building D, Suite 150, Orinda, California 94563.
- (/8/Includes)592,490 shares held by the W. Mark Lortz And Patrice Rae Lortz, Co-Trustees or Successor Trustee, of the W. Mark Lortz and Patrice Rae Lortz Revocable Living Trust, under Agreement Dated February 10, 1999, as community property.
- (/9/Represents)3,129,375 shares owned by E. Heller & Co., of which Ephraim Heller is the controlling stockholder. Mr. Heller disclaims beneficial ownership of these shares except to the extent of his pecuniary interest therein.
- (/10/Represents)950,000 shares owned by MJG Partners, L.P., of which Mr. Gainor is president. Mr. Gainor disclaims beneficial ownership of these shares except to the extent of his pecuniary interest therein. The address of MJG Partners, L.P. is 40301 Fisher Island Drive, Fisher Island, Florida 33109.
- (/11/Includes)17,647 shares purchased by the Momsen Living Trust U/A/D 1/5/95, Robert Momsen Trustee and shares purchased by InterWest Partners, as follows: 3,228,289 shares purchased by InterWest Partners VI, L.P. and 101,216 shares purchased by InterWest Investors VI, L.P. Mr. Momsen is a general partner of InterWest Partners VI, L.P. and InterWest Investors VI, L.P., and a limited partner of InterWest Investors VI, L.P. Mr. Momsen disclaims beneficial ownership of these shares except to the extent of his pecuniary interest therein.

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DESCRIPTION OF CAPITAL STOCK

Upon the closing of this offering, our authorized capital stock, after giving effect to the conversion of all outstanding preferred stock into common stock

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and the amendment of our certificate of incorporation, will consist of 200,000,000 shares of common stock, \$0.001 par value, and 5,000,000 shares of preferred stock, \$0.001 par value. The following description summarizes the most important terms of our capital stock. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description you should refer to our certificate of incorporation and bylaws, effective upon completion of this offering, copies of which have been filed as exhibits to the registration statement of which the prospectus is a part.

Common Stock

As of June 30, 2001, there were 32,089,847 shares of common stock outstanding and held by approximately 166 stockholders of record, assuming the automatic conversion of each outstanding share of preferred stock upon the closing of this offering. After this offering, there will be 38,089,847 shares of our common stock outstanding, or 38,989,847 shares if the underwriters exercise their over-allotment option in full.

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

Preferred Stock

As of June 30, 2001, there were 26,722,151 shares of preferred stock outstanding. Upon the closing of this offering, each outstanding share of preferred stock will be converted into one share of common stock. Following the conversion, our certificate of incorporation will be amended and restated to delete all references to the prior series of preferred stock, and 5,000,000 shares of undesignated preferred stock will be authorized.

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

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Warrants

As of June 30, 2001, there were warrants outstanding to purchase 54,348 shares of Series A preferred stock and 466,665 shares of Series B preferred stock at a per share exercise price of \$1.84 and \$2.10, respectively. Upon completion of this offering, the warrants will be exercisable for an aggregate of 521,013 shares of common stock, at a per share weighted average exercise price of \$2.07. The warrant exercisable to purchase 54,348 shares of Series A preferred stock can be exercised at any time prior to December 31, 2001, at a per share exercise price of \$1.84. Warrants exercisable to purchase 380,952 and 47,619 shares of Series B preferred stock, respectively, can be exercised at any time prior to the earlier of five years after the effective date of this offering, or October 7, 2009 or August 24, 2008, respectively, at a per share exercise price of \$2.10. Warrants exercisable to purchase 3,809, 8,928 and 25,357 shares of Series B preferred stock, respectively, can be exercised at any time prior to the later of five years after the effective date of this offering, or April 1, 2007, at a per share exercise price of \$2.10.

Registration Rights

After this offering, the holders of 27,243,164 shares of common stock issued upon conversion of our preferred stock, and upon exercise of outstanding warrants, are entitled to rights with respect to the registration of these shares under the Securities Act of 1933, as amended. These shares are referred to as registrable securities. The registration rights provide that if we propose to register any of our securities under the Securities Act for our own account, holders of common stock issuable upon conversion of the Series A, Series B, Series C and Series D preferred stock, or issuable upon exercise of outstanding warrants, are entitled to notice of such registration and are entitled to include their registrable securities in that registration, subject to various conditions. The underwriters of any such offering have the right to limit the number of shares included in such registration. These registration rights have been waived with respect to this offering.

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

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

- . acquisition of us by means of a tender offer;
- . acquisition of us by means of a proxy contest or otherwise; or
- . removal of our incumbent officers and directors.

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

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

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management of our company.

Stockholder Meetings. Our charter documents provide that a special meeting of stockholders may be called only by the chairman of the board, the chief executive officer or the president of our company, or by a resolution adopted by a majority of our board of directors.

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

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

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

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

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

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

Limitations of Liability and Indemnification Matters

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

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damages for breach of their fiduciary duties as directors, except liability for any of the following:

- . any breach of their duty of loyalty to the corporation or the stockholder;
- . acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- . unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or
- . any transaction from which the director derived an improper personal benefit.

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

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

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

Transfer Agent And Registrar

The transfer agent and registrar for the common stock is Computershare Investor Services LLC.

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SHARES ELIGIBLE FOR FUTURE SALE

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

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Sale of Restricted Shares and Lock-Up Agreements

Upon completion of this offering, we will have an aggregate of 38,089,847 outstanding shares of common stock based upon shares outstanding as of June 30, 2001, assuming no exercise of the underwriters' over-allotment option and no exercise of outstanding options prior to completion of this offering. As of June 30, 2001, we had:

- . outstanding stock options held by employees, consultants and directors for the purchase of an aggregate of 4,882,303 shares of common stock; and
- . outstanding warrants to purchase 521,013 shares of preferred stock which will automatically convert into warrants to purchase an equal number of shares of common stock upon the completion of this offering.

The 6,000,000 shares of common stock being sold in this offering will be freely tradeable without restriction or further registration under the Securities Act, unless the shares are purchased by affiliates of our company, as that term is defined in Rule 144 of the Securities Act. All remaining shares were issued and sold by us in private transactions and are eligible for public sale if registered under the Securities Act or sold in accordance with Rule 144 or Rule 701 thereunder.

Eligibility of Restricted Shares for Sale in the Public Market

All of our officers and directors and substantially all of our stockholders are subject to lock-up agreements under which they will agree not to transfer or dispose of, directly or indirectly, any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock, for a period of 180 days after the date of this prospectus. Transfers or dispositions can be made sooner with the prior written consent of U.S. Bancorp Piper Jaffray Inc.

Following the expiration of the lock-up period, approximately 32,089,847 shares of common stock will be available for sale in the public market, subject in some instances to compliance with Rule 144, Rule 144(k) or Rule 701.

Rule 144

In general, under Rule 144, a person or persons whose shares are aggregated who has beneficially owned restricted securities for at least one year, including the holding period of any holder who is not an affiliate, and who files a Form 144 with respect to such sale, is entitled to sell within any three-month period commencing 90 days after the date of this prospectus a number of shares of common stock that does not exceed the greater of:

- . 1% of the then outstanding shares of our common stock, or approximately 380,000 shares immediately after this offering, or
- . the average weekly trading volume during the four calendar weeks preceding such sale.

Sales under Rule 144 are also subject to restrictions relating to manner of sale, notice and the availability of current public information about us.

We cannot estimate the number of shares that will be sold under Rule 144, as this will depend on the market price for our common stock, the personal

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circumstances of the sellers and other factors. Prior to this offering, there has been no public market for our common stock, and a significant public market for our common stock may never develop or be sustained after this offering. Any future sale of substantial amounts of our common stock in the open market may adversely affect the market price of our common stock.

Rule 144(k)

A person who is not deemed to have been our affiliate at any time during the 90 days immediately preceding a sale and who has beneficially owned his or her shares for at least two years, including the holding period of any prior owner who is not an affiliate, is entitled to sell these shares of common stock pursuant to Rule 144(k) without regard to the volume limitations, manner of sale provisions, public information or notice requirements of Rule 144. Affiliates must always sell pursuant to Rule 144, even after the applicable holding periods have been satisfied.

Rule 701

Rule 701 may be relied upon with respect to the resale of securities originally purchased from us by our employees, directors, officers, consultants or advisers prior to the closing of this offering and pursuant to written compensatory benefit plans or written contracts relating to the compensation of such persons. In addition, the SEC has indicated that Rule 701 will apply to stock options granted by us before this offering, along with the shares acquired upon exercise of such options. Securities issued in reliance on Rule 701 are deemed to be restricted shares and, beginning 90 days after the date of this prospectus, may be sold by persons other than affiliates subject only to the manner of sale provisions of Rule 144 and by affiliates under Rule 144 without compliance with the holding period requirements. As of June 30, 2001, 542,206 of our outstanding shares of common stock had been issued in reliance on Rule 701 as a result of exercise of stock options, and all of these shares are subject to 180 day lock-up agreements.

Stock Options

We intend to file registration statements under the Securities Act covering approximately 13,936,135 shares of common stock reserved for issuance under our 1997 Stock Plan, 2001 Stock Plan and 2001 Employee Stock Purchase Plan. These registration statements are expected to be filed soon after the date of this prospectus and will automatically become effective upon filing. In addition, within 90 days following the date of this prospectus, we intend to file a registration statement on Form S-8/S-3 under the Securities Act covering, as of June 30, 2001, approximately 1,655,997 shares of common stock issued to certain of our employees upon exercise of options granted in reliance on Rule 701, Section 4(2) of the Securities Act and applicable state securities laws. Accordingly, shares registered under such registration statements will be available for sale in the open market, unless such shares are subject to vesting restrictions with us or are otherwise subject the contractual restrictions described above.

Registration Rights

In addition, after this offering, the holders of shares of preferred stock convertible into 26,722,151 shares of common stock and warrants exercisable for an aggregate of 521,013 shares of common stock will be entitled to rights to cause us to register the sale of such shares under the Securities Act. These shares are referred to as registrable securities. Specifically, commencing 180 days after the effective date of the registration statement of which this prospectus is a part, a holder or holder of at least 50% of the registrable securities may require us to prepare and file a registration statement under the Securities Act at our expense covering at least 50% of the registrable

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securities, or any lesser amount if the shares to be included in such registration will generate anticipated aggregate net proceeds to TheraSense of at least \$15,000,000. Under these demand registration rights, we are

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required to use our best efforts to cause the shares requested to be included in the registration statement, subject to customary conditions and limitations. We are not obligated to effect more than two of these stockholder-initiated registrations. Once we become eligible to file a registration statement on Form S-3, the holders of registrable securities may require us to register all or a portion of their securities on a registration statement on Form S-3 and may participate in a Form S-3 registration by us, subject to specific conditions and limitations. Registration rights terminate no later than five years after this offering. Registration of these shares under the Securities Act would result in these shares, other than shares purchased by our affiliates, becoming freely tradable without restriction under the Securities Act.

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UNDERWRITING

The underwriters named below, for whom U.S. Bancorp Piper Jaffray Inc., SG Cowen Securities Corporation and Thomas Weisel Partners LLC are acting as representatives, have agreed to buy, subject to the terms of a purchase agreement, the number of shares listed opposite their names below. The underwriters are committed to purchase and pay for all of the shares if any are purchased, other than those shares covered by the over-allotment option described below.

| Underwriters ----- | Number of Shares ----- |
|---|------------------------------|
| U.S. Bancorp Piper Jaffray Inc. | 2,475,000 |
| SG Cowen Securities Corporation..... | 1,237,500 |
| Thomas Weisel Partners LLC..... | 1,237,500 |
| Banc of America Securities LLC..... | 100,000 |
| CIBC World Markets Corp..... | 100,000 |
| Credit Suisse First Boston Corporation..... | 100,000 |
| Dain Rauscher Incorporated..... | 100,000 |
| First Union Securities, Inc..... | 100,000 |
| Merrill Lynch, Pierce, Fenner & Smith Incorporated..... | 100,000 |
| J.P. Morgan Securities Inc..... | 100,000 |
| Salomon Smith Barney Inc..... | 100,000 |
| UBS Warburg LLC..... | 100,000 |
| William Blair & Company, L.L.C..... | 50,000 |
| McDonald Investments Inc., a KeyCorp Company..... | 50,000 |
| Raymond James & Associates, Inc..... | 50,000 |
| | ----- |
| Total..... | 6,000,000 ===== |

The underwriters have advised us that they propose to offer the shares initially to the public at \$19.00 per share. The underwriters propose to offer the shares to certain dealers at the same price less a concession of not more than \$0.80 per share. The underwriters may allow and the dealers may reallow a

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concession of not more than \$0.10 per share on sales to certain other brokers and dealers. After the offering, these figures may be changed by the underwriters.

At our request, the underwriters have reserved for sale at the initial public offering price up to 300,000 shares of common stock to directors, employees and persons having business relationships with or otherwise related to TheraSense. The number of shares of common stock available for sale to the general public will be reduced to the extent that such individuals purchase all or a portion of these reserved shares. Any reserved shares which are not purchased will be offered by the underwriters to the general public on the same basis as the shares of common stock offered hereby.

We have granted to the underwriters an option to purchase up to an additional 900,000 shares of common stock from us at the same price to the public, and with the same underwriting discount, as set forth on the cover page of this prospectus. The underwriters may exercise this option any time during the 30-day period after the date of this prospectus, but only to cover over-allotments, if any. To the extent the underwriters exercise the option, each underwriter will become obligated, subject to certain conditions, to purchase approximately the same percentage of the additional shares as it was obligated to purchase under the purchase agreement.

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

| | No Exercise | Full Exercise |
|----------------|----------------|------------------|
| | ----- | ----- |
| Per share..... | \$ 1.33 | \$ 1.33 |
| Total..... | \$7,980,000 | \$9,177,000 |

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We estimate that the total expenses of the offering payable by us, excluding underwriting discounts and commissions, will be approximately \$750,000.

We have agreed to indemnify the underwriters against certain liabilities, including civil liabilities under the Securities Act, or to contribute to payments that the underwriters may be required to make in respect of those liabilities.

The underwriters have informed us that neither they, nor any other underwriter participating in the distribution of the offering, will make sales of the common stock offered by this prospectus to accounts over which they exercise discretionary authority without the prior specific written approval of the customer.

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

We and each of our directors and executive officers and substantially all of our stockholders have agreed to certain restrictions on our ability to sell

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additional shares of our common stock for a period of 180 days after the date of this prospectus. We have agreed not to directly or indirectly, offer for sale, sell, contract to sell, grant any option for the sale of, pledge, transfer, establish an open "put equivalent position" within the meaning of Securities Act Rule 16A-1(h) or otherwise dispose of, any shares of common stock, options or warrants to acquire shares of common stock, or security or instrument related to common stock, subject to limited exceptions, without the prior written consent of U.S. Bancorp Piper Jaffray Inc.

Prior to the offering, there has been no established trading market for the common stock. The initial public offering price for the shares of common stock offered by this prospectus was negotiated by us and the underwriters. The factors considered in determining the initial public offering price included:

- . the history of and the prospects for the industry in which we compete;
- . our past and present operations;
- . our historical results of operations;
- . our prospects for future earnings;
- . the recent market prices of securities of generally comparable companies; and
- . the general condition of the securities markets at the time of the offering and other relevant factors.

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

To facilitate the offering, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the common stock during and after the offering. Specifically, the underwriters may over-allot or otherwise create a short position in the common stock for their own account by selling more shares of common stock than have been sold to them by us. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering. "Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares from the issuer in the offering. The underwriters may close out any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the

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open market as compared to the price at which they may purchase shares through the over-allotment option. "Naked" short sales are sales in excess of this option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in the offering.

In addition, the underwriters may stabilize or maintain the price of the common stock by bidding for or purchasing shares of common stock in the open market and may impose penalty bids. If penalty bids are imposed, selling concessions

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allowed to syndicate members or other broker-dealers participating in the offering are reclaimed if shares of common stock previously distributed in the offering are repurchased, whether in connection with stabilization transactions or otherwise. The effect of these transactions may be to stabilize or maintain the market price of the common stock at a level above that which might otherwise prevail in the open market. The imposition of a penalty bid may also effect the price of the common stock to the extent that it discourages resales of the common stock. The magnitude or effect of any stabilization or other transactions is uncertain. These transactions may be effected on The Nasdaq National Market or otherwise and, if commenced, may be discontinued at any time.

Due to the fact that Thomas Weisel Partners LLC, one of the underwriters, was organized within the last three years, we are providing you the following information. Thomas Weisel Partners LLC was organized and registered as a broker-dealer in December 1998. Since December 1998, Thomas Weisel Partners LLC has been named as a lead or co-manager of, or as a syndicate member in, numerous public offerings of equity securities. Thomas Weisel Partners LLC does not have any material relationship with us or any of our officers, directors or other controlling persons, except with respect to its contractual relationship with us pursuant to the purchase agreement entered into in connection with this offering.

One investment fund and three individuals affiliated with U.S. Bancorp Piper Jaffray Inc., one of the representatives, purchased an aggregate of 89,177 shares of Series D preferred stock at a purchase price of \$8.50 per share in our Series D financing in February and April, 2001. The NASD has determined that the difference between the public offering price of our common stock and the purchase price paid by this fund and individuals for the Series D preferred stock is underwriting compensation. As a result, each of the investment fund and the individuals has agreed that, for a period of one year from the effective date of this offering, it will not sell, transfer, assign, pledge or hypothecate any of its shares of Series D preferred stock (or shares of our common stock into which it may be converted in connection with this offering). In addition, the investment fund and two of these individuals also purchased an aggregate of 200,000 shares of Series C preferred stock at \$5.00 per share in our Series C financing in February 2000. Each of the investment fund and the individuals has agreed that, for a period of 90 days from the effective date of this offering, it will not sell, transfer, assign, pledge or hypothecate any of its shares of Series C preferred stock (or shares of our common stock into which it may be converted in connection with this offering).

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LEGAL MATTERS

Various legal matters with respect to the validity of the common stock offered by this prospectus will be passed upon for us by Wilson Sonsini Goodrich & Rosati, P.C., San Francisco, California. An investment partnership comprised of some current and former members of Wilson Sonsini Goodrich & Rosati and one current member of Wilson Sonsini Goodrich & Rosati, will beneficially own an aggregate of 34,153 shares of our common stock assuming conversion of all outstanding shares of preferred stock. These shares have an aggregate value of \$648,907, based on the initial public offering price of \$19.00 per share. Various legal matters relating to the offering will be passed upon for the underwriters by Brobeck, Phleger & Harrison LLP, San Diego, California.

EXPERTS

The financial statements of TheraSense, Inc. as of December 31, 1999 and 2000, and for each of the three years in the period ended December 31, 2000 included

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in this prospectus have been so included in reliance on the report of PricewaterhouseCoopers LLP, independent accountants, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed a registration statement on Form S-1 with the SEC for the stock we 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 and schedules that are referred to in this prospectus. You should refer to the registration statement and its exhibits for additional information. When we complete this offering, we will also be 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.

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THERASENSE, INC.

INDEX TO FINANCIAL STATEMENTS

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F-1

REPORT OF INDEPENDENT ACCOUNTANTS

To the Board of Directors and Stockholders
of TheraSense, Inc.

In our opinion, the financial statements listed in the accompanying index present fairly, in all material respects, the financial position of TheraSense, Inc. (the "Company") at December 31, 1999 and 2000 and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2000 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule appearing under Item 16(b) on page II-4 presents fairly, in all material respects, the information set forth therein when read in

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conjunction with the related financial statements. These financial statements and financial statement schedule are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits. We conducted our audits of these statements in accordance with auditing standards generally accepted in the United States of America, which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

San Jose, California
 June 21, 2001, except for the sixth paragraph of Note 6,
 as to which the date is June 27, 2001

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THERASENSE, INC.
 BALANCE SHEETS

| | December 31, | | June 30, | Pro Forma at June 30, 2001 (see Note 2) |
|---|--------------|---------------|---------------|--|
| | 1999 | 2000 | 2001 | |
| | ----- | | ----- | ----- |
| | | | (unaudited) | |
| Assets | | | | |
| Current assets: | | | | |
| Cash and cash equivalents..... | \$ 2,322,424 | \$ 12,532,474 | \$ 45,152,387 | |
| Accounts receivable, net of allowance for doubtful accounts of none in 1999, \$150,000 in 2000 and \$285,425 (unaudited) in 2001..... | 25,000 | 6,174,697 | 10,767,414 | |
| Inventories..... | -- | 3,493,777 | 3,951,874 | |
| Deferred cost of products sold..... | -- | 7,396,547 | 9,759,940 | |
| Prepaid expenses and other current assets..... | 836,005 | 1,178,435 | 1,783,514 | |
| | ----- | ----- | ----- | |
| Total current assets..... | 3,183,429 | 30,775,930 | 71,415,129 | |
| Property and equipment, net..... | 3,998,451 | 4,838,682 | 4,856,194 | |
| Other assets..... | 844,203 | 1,950,303 | 2,710,773 | |
| | ----- | ----- | ----- | |
| Total assets..... | \$ 8,026,083 | \$ 37,564,915 | \$ 78,982,096 | |
| | ===== | ===== | ===== | |
| Liabilities, Convertible | | | | |

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| | | | | |
|--|------------|---------------|---------------|-------|
| Preferred Stock and Stockholders' Equity (Deficit) | | | | |
| Current liabilities: | | | | |
| Accounts payable..... | \$ 678,684 | \$ 10,624,731 | \$ 10,317,865 | |
| Accrued liabilities.... | 585,160 | 4,421,512 | 9,151,079 | |
| Deferred revenue..... | 511,341 | 8,686,547 | 13,923,140 | |
| Current portion of capital lease obligations..... | 109,356 | 844,394 | 1,029,927 | |
| Current portion of borrowings under lines of credit..... | 507,276 | 1,958,958 | 2,187,394 | |
| | ----- | ----- | ----- | |
| Total current liabilities..... | 2,391,817 | 26,536,142 | 36,609,405 | |
| Deferred revenue..... | -- | -- | 3,761,341 | |
| Capital lease obligations, less current portion..... | 219,367 | 2,037,140 | 1,569,331 | |
| Borrowings under lines of credit, less current portion..... | 3,101,658 | 3,457,345 | 2,115,476 | |
| Convertible promissory note..... | -- | 2,500,000 | -- | |
| | ----- | ----- | ----- | |
| Total liabilities.... | 5,712,842 | 34,530,627 | 44,055,553 | |
| | ----- | ----- | ----- | |
| Commitments and contingencies (Note 6) | | | | |
| Convertible preferred stock, \$0.001 par value: | | | | |
| Authorized: 20,609,647 shares; Issued and outstanding: | | | | |
| 11,588,621 shares in 1999, 20,078,780 shares in 2000, 26,722,151 shares in 2001 (unaudited) and none pro forma (unaudited) (Liquidation preferences: \$20,574,983, \$63,025,778 and \$119,494,432 at December 31, 1999, 2000 and June 30, 2001 (unaudited), respectively..... | 20,471,813 | 62,882,739 | 119,245,825 | \$ -- |
| | ----- | ----- | ----- | ----- |
| Stockholders' equity (deficit): | | | | |
| Common stock: \$0.001 par value: | | | | |
| Authorized: 50,000,000 shares; Issued and outstanding: | | | | |

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| | | | | |
|---|--------------|---------------|---------------|---------------|
| 4,976,932 shares in 1999, 5,139,392 shares in 2000, 5,367,696 shares in 2001 (unaudited) and 32,089,847 shares pro forma (unaudited)..... | 4,977 | 5,140 | 5,368 | 32,090 |
| Additional paid-in capital..... | 2,543,858 | 14,427,351 | 21,271,769 | 140,490,872 |
| Notes receivable from stockholders..... | (331,195) | (294,750) | (294,750) | (294,750) |
| Deferred stock-based compensation, net..... | (1,244,418) | (11,262,561) | (15,644,609) | (15,644,609) |
| Accumulated deficit.... | (19,131,794) | (62,723,631) | (89,657,060) | (89,657,060) |
| | ----- | ----- | ----- | ----- |
| Total stockholders' equity (deficit).... | (18,158,572) | (59,848,451) | (84,319,282) | \$ 34,926,543 |
| | ----- | ----- | ----- | ===== |
| Total liabilities, convertible preferred stock and stockholders' equity (deficit)..... | \$ 8,026,083 | \$ 37,564,915 | \$ 78,982,096 | |
| | ===== | ===== | ===== | |

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

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THERASENSE, INC.
STATEMENTS OF OPERATIONS

| | Years Ended December 31, | | | Six Months Ended June 30, | |
|---|--------------------------|-----------|-------------|---------------------------|------------|
| | 1998 | 1999 | 2000 | 2000 | 2001 |
| | ----- | | | ----- | |
| | | | | (unaudited) | |
| Revenues: | | | | | |
| Research grant revenue..... | \$ 60,296 | \$ 60,296 | \$ 3,000 | \$ 3,000 | \$ -- |
| Product sales..... | -- | 25,000 | 5,000,250 | 8,251 | 25,273,773 |
| License income..... | -- | -- | 500,000 | 500,000 | 250,000 |
| | ----- | ----- | ----- | ----- | ----- |
| Total revenues..... | 60,296 | 85,296 | 5,503,250 | 511,251 | 25,523,773 |
| Cost of revenues..... | -- | -- | 11,948,283 | 296,020 | 19,668,068 |
| | ----- | ----- | ----- | ----- | ----- |
| Gross profit (loss).... | 60,296 | 85,296 | (6,445,033) | 215,231 | 5,855,705 |
| | ----- | ----- | ----- | ----- | ----- |
| Operating expenses: | | | | | |
| Research and development..... | 3,055,819 | 7,672,517 | 12,019,110 | 5,841,296 | 6,332,483 |
| Selling, general and administrative..... | 1,809,978 | 5,556,708 | 25,460,349 | 9,786,893 | 26,842,800 |

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| | | | | | |
|---|---------------|----------------|----------------|----------------|----------------|
| Total operating expenses..... | 4,865,797 | 13,229,225 | 37,479,459 | 15,628,189 | 33,175,283 |
| Loss from operations.... | (4,805,501) | (13,143,929) | (43,924,492) | (15,412,958) | (27,319,578) |
| Interest income..... | 167,312 | 295,307 | 1,488,049 | 811,986 | 1,049,100 |
| Interest and other expense, net..... | (25,762) | (209,100) | (1,155,394) | (457,861) | (662,951) |
| Net loss..... | (4,663,951) | (13,057,722) | (43,591,837) | (15,058,833) | (26,933,429) |
| Deemed dividend related to beneficial conversion feature of preferred stock..... | -- | -- | (14,772,878) | (14,772,878) | (26,782,911) |
| Net loss attributable to common stockholders.... | \$(4,663,951) | \$(13,057,722) | \$(58,364,715) | \$(29,831,711) | \$(53,716,340) |
| Net loss per common share, basic and diluted..... | \$ (2.31) | \$ (4.32) | \$ (14.69) | \$ (8.03) | \$ (11.35) |
| Weighted-average shares used in computing net loss per common share, basic and diluted..... | 2,015,032 | 3,023,636 | 3,973,250 | 3,712,999 | 4,732,091 |
| Pro forma net loss per common share, basic and diluted (unaudited) (see Note 10)..... | | | \$ (2.06) | | \$ (0.92) |
| Weighted-average shares used in computing pro forma net loss per common share, basic and diluted (unaudited) (see Note 10)..... | | | 21,129,193 | | 29,330,866 |

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

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THERASENSE, INC.

STATEMENTS OF STOCKHOLDERS' DEFICIT

FOR THE YEARS ENDED DECEMBER 31, 1998, 1999 AND 2000
AND THE SIX MONTHS ENDED JUNE 30, 2001

| Common Stock | | Additional Paid-In Capital | Notes Receivable from Stockholders | Deferred Stock-based Compensation | Accumulated Deficit |
|--------------|--------|----------------------------------|---|---|------------------------|
| Shares | Amount | | | | |
| ----- | ----- | ----- | ----- | ----- | ----- |

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| | | | | | | | |
|---|-----------|---------|--------------|-------------|--------------|--------------|----------------|
| Balances, January 1, 1998..... | 4,419,794 | \$4,420 | \$ 111,172 | \$ (91,993) | \$ | -- | \$ (1,410,121) |
| Repurchase and retirement of common stock..... | (53,203) | (53) | (3,353) | -- | -- | -- | -- |
| Exercise of stock options for cash and in exchange for notes receivable from stockholders..... | 216,159 | 216 | 53,104 | (52,500) | -- | -- | -- |
| Repayment of notes receivable from stockholders..... | -- | -- | -- | 6,068 | -- | -- | -- |
| Net loss..... | -- | -- | -- | -- | -- | -- | (4,663,951) |
| | ----- | ----- | ----- | ----- | ----- | ----- | ----- |
| Balances, December 31, 1998..... | 4,582,750 | 4,583 | 160,923 | (138,425) | -- | -- | (6,074,072) |
| Exercise of stock options for cash and in exchange for notes receivable from stockholders..... | 394,182 | 394 | 198,566 | (192,770) | -- | -- | -- |
| Issuance of warrants to purchase Series B preferred stock..... | -- | -- | 819,760 | -- | -- | -- | -- |
| Deferred stock-based compensation..... | -- | -- | 1,364,609 | -- | (1,364,609) | -- | -- |
| Amortization of deferred stock-based compensation..... | -- | -- | -- | -- | 120,191 | -- | -- |
| Net loss..... | -- | -- | -- | -- | -- | -- | (13,057,722) |
| | ----- | ----- | ----- | ----- | ----- | ----- | ----- |
| Balances, December 31, 1999..... | 4,976,932 | 4,977 | 2,543,858 | (331,195) | (1,244,418) | (19,131,794) | |
| Exercise of stock options for cash and in exchange for notes receivable from stockholders..... | 213,671 | 214 | 86,435 | (6,068) | -- | -- | -- |
| Repurchase of shares and cancellation of stockholder note receivable..... | (51,211) | (51) | (14,333) | 14,384 | -- | -- | -- |
| Repayment of notes receivable from stockholders..... | -- | -- | -- | 28,129 | -- | -- | -- |
| Deferred stock-based compensation..... | -- | -- | 11,811,391 | -- | (11,811,391) | -- | -- |
| Amortization of deferred stock-based compensation..... | -- | -- | -- | -- | 1,793,248 | -- | -- |
| Beneficial conversion feature related to issuance of Series C convertible preferred stock..... | -- | -- | 14,772,878 | -- | -- | -- | -- |
| Deemed dividend related to beneficial conversion feature of Series C convertible preferred stock..... | -- | -- | (14,772,878) | -- | -- | -- | -- |
| Net loss..... | -- | -- | -- | -- | -- | -- | (43,591,837) |

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| | | | | | | |
|-------------------------------------|-----------|-------|------------|-----------|--------------|--------------|
| Balances, December 31, 2000..... | 5,139,392 | 5,140 | 14,427,351 | (294,750) | (11,262,561) | (62,723,631) |
|-------------------------------------|-----------|-------|------------|-----------|--------------|--------------|

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

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THERASENSE, INC.

STATEMENTS OF STOCKHOLDERS' DEFICIT

FOR THE YEARS ENDED DECEMBER 31, 1998, 1999 AND 2000
AND THE SIX MONTHS ENDED JUNE 30, 2001
(CONTINUED)

| | Common Stock | | Additional | Notes | Deferred | Accumulated |
|--|--------------|---------|--------------------|------------------------------------|-----------------------------|-----------------|
| | Shares | Amount | Paid-In Capital | Receivable from Stockholders | Stock-based Compensation | Deficit |
| Balances, December 31, 2000..... | 5,139,392 | 5,140 | 14,427,351 | (294,750) | (11,262,561) | (62,723,631) |
| Exercise of common stock options for cash (unaudited)..... | 228,304 | 228 | 450,304 | -- | -- | -- |
| Deferred stock-based compensation (unaudited)..... | -- | -- | 6,394,114 | -- | (6,394,114) | -- |
| Amortization of deferred stock-based compensation (unaudited)..... | -- | -- | -- | -- | 2,012,066 | -- |
| Beneficial conversion feature related to issuance of Series D convertible preferred stock (unaudited)..... | -- | -- | 26,782,911 | -- | -- | -- |
| Deemed dividend related to beneficial conversion feature of Series D convertible preferred stock (unaudited)..... | -- | -- | (26,782,911) | -- | -- | -- |
| Net loss (unaudited)... | -- | -- | -- | -- | -- | (26,933,429) |
| Balances, June 30, 2001 (unaudited)..... | 5,367,696 | \$5,368 | \$ 21,271,769 | \$ (294,750) | \$ (15,644,609) | \$ (89,657,060) |

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

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THERASENSE, INC.
STATEMENTS OF CASH FLOWS

| | Years Ended December 31, | | | Six Months Ended June 30, | |
|------------------------|--------------------------|-----------------|-----------------|------------------------------|-----------------|
| | 1998 | 1999 | 2000 | 2000 | 2001 |
| | | | | | (unaudited) |
| Cash flows from | | | | | |
| operating activities: | | | | | |
| Net loss..... | \$ (4,663,951) | \$ (13,057,722) | \$ (43,591,837) | \$ (15,058,833) | \$ (26,933,429) |
| Adjustments to | | | | | |
| reconcile net loss to | | | | | |
| net cash used in | | | | | |
| operating activities: | | | | | |
| Depreciation and | | | | | |
| amortization..... | 253,700 | 569,074 | 1,546,556 | 618,665 | 873,770 |
| Provision for doubtful | | | | | |
| accounts..... | -- | -- | 150,000 | -- | 135,425 |
| Amortization of debt | | | | | |
| issuance costs..... | -- | 74,268 | 268,489 | 134,238 | 134,244 |
| Loss on disposal and | | | | | |
| sales of property and | | | | | |
| equipment..... | -- | 132 | 5,637 | 5,637 | -- |
| Amortization of | | | | | |
| deferred stock-based | | | | | |
| compensation..... | -- | 120,191 | 1,793,248 | 485,561 | 2,012,066 |
| Changes in operating | | | | | |
| assets and | | | | | |
| liabilities: | | | | | |
| Accounts receivable... | -- | (25,000) | (6,299,697) | (574,848) | (4,728,142) |
| Inventories..... | -- | -- | (3,493,777) | (5,771,598) | (458,097) |
| Deferred cost of | | | | | |
| products sold..... | -- | -- | (7,396,547) | (491,753) | (2,363,393) |
| Prepaid expenses and | | | | | |
| other current | | | | | |
| assets..... | (37,466) | (773,699) | (342,430) | (1,493,068) | (605,079) |
| Other assets..... | 70,089 | (98,711) | (1,374,589) | (2,219) | (894,714) |
| Accounts payable..... | (218,012) | 549,291 | 9,946,047 | 3,351,783 | (306,866) |
| Accrued liabilities... | 111,988 | 350,766 | 3,836,352 | 1,624,902 | 4,729,567 |
| Deferred revenue..... | (60,296) | 500,000 | 8,175,206 | 145,662 | 8,997,934 |
| | | | | | |
| Net cash used in | | | | | |
| operating | | | | | |
| activities..... | (4,543,948) | (11,791,410) | (36,777,342) | (17,025,871) | (19,406,714) |
| Cash flows from | | | | | |
| investing activities: | | | | | |
| Purchase of property | | | | | |
| and equipment..... | (634,309) | (3,323,407) | (2,088,594) | (1,364,944) | (854,511) |
| Proceeds from sale of | | | | | |
| property and | | | | | |
| equipment..... | -- | -- | 2,666,374 | 1,603,769 | -- |
| | | | | | |
| Net cash provided by | | | | | |
| (used in) investing | | | | | |
| activities..... | (634,309) | (3,323,407) | 577,780 | 238,825 | (854,511) |

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| | | | | | |
|-------------------------|--------------|--------------|---------------|---------------|---------------|
| Cash flows from | | | | | |
| financing activities: | | | | | |
| Proceeds from issuance | | | | | |
| of convertible | | | | | |
| preferred stock, net.. | 11,835,840 | 3,110,471 | 42,410,926 | 42,410,926 | 53,863,086 |
| Proceeds from issuance | | | | | |
| of common stock and | | | | | |
| exercise of stock | | | | | |
| options..... | 820 | 6,190 | 80,581 | 11,526 | 450,532 |
| Proceeds from lines of | | | | | |
| credit..... | 758,590 | 3,090,953 | 3,000,000 | 2,000,000 | -- |
| Proceeds from | | | | | |
| convertible promissory | | | | | |
| note..... | -- | -- | 2,500,000 | -- | -- |
| Repurchase and | | | | | |
| retirement of common | | | | | |
| stock..... | (3,406) | -- | -- | -- | -- |
| Principal payments on | | | | | |
| capital lease | | | | | |
| obligations..... | -- | (37,410) | (417,393) | (52,793) | (319,047) |
| Principal payments on | | | | | |
| lines of credit..... | (69,444) | (171,163) | (1,192,631) | (309,482) | (1,113,433) |
| Repayment of notes | | | | | |
| receivable from | | | | | |
| stockholders..... | 6,068 | -- | 28,129 | 28,129 | -- |
| | ----- | ----- | ----- | ----- | ----- |
| Net cash provided by | | | | | |
| financing | | | | | |
| activities..... | 12,528,468 | 5,999,041 | 46,409,612 | 44,088,306 | 52,881,138 |
| | ----- | ----- | ----- | ----- | ----- |
| Net increase (decrease) | | | | | |
| in cash and cash | | | | | |
| equivalents..... | 7,350,211 | (9,115,776) | 10,210,050 | 27,301,260 | 32,619,913 |
| Cash and cash | | | | | |
| equivalents, beginning | | | | | |
| of period..... | 4,087,989 | 11,438,200 | 2,322,424 | 2,322,424 | 12,532,474 |
| | ----- | ----- | ----- | ----- | ----- |
| Cash and cash | | | | | |
| equivalents, end of | | | | | |
| period..... | \$11,438,200 | \$ 2,322,424 | \$ 12,532,474 | \$ 29,623,684 | \$ 45,152,387 |
| | ===== | ===== | ===== | ===== | ===== |
| Noncash financing | | | | | |
| activities: | | | | | |
| Common stock issued for | | | | | |
| notes receivable from | | | | | |
| stockholders..... | \$ 52,500 | \$ 192,770 | \$ 6,068 | \$ 6,068 | \$ -- |
| Repurchase of | | | | | |
| restricted common | | | | | |
| stock and cancellation | | | | | |
| of notes receivable... | \$ -- | \$ -- | \$ 14,384 | \$ 14,384 | \$ -- |
| Issuance of warrants to | | | | | |
| purchase Series B | | | | | |
| preferred stock in | | | | | |
| connection with | | | | | |
| borrowings under lines | | | | | |
| of credit..... | \$ -- | \$ 819,760 | \$ -- | \$ -- | \$ -- |
| Conversion of | | | | | |
| promissory note into | | | | | |
| Series D preferred | | | | | |
| stock..... | \$ -- | \$ -- | \$ -- | \$ -- | \$ 2,500,000 |
| Acquisition of property | | | | | |

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| | | | | | | | | | | |
|---|----|--------|----|-----------|----|------------|----|-----------|----|-----------|
| and equipment under capital lease..... | \$ | -- | \$ | 366,133 | \$ | 2,970,204 | \$ | 1,757,348 | \$ | 36,771 |
| Deferred stock-based compensation..... | \$ | -- | \$ | 1,364,609 | \$ | 11,811,391 | \$ | 4,968,317 | \$ | 6,394,114 |
| Supplemental disclosure of cash flow information: | | | | | | | | | | |
| Cash paid for interest..... | \$ | 25,762 | \$ | 134,833 | \$ | 881,265 | \$ | 434,668 | \$ | 509,102 |

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

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THERASENSE, INC.

NOTES TO FINANCIAL STATEMENTS

NOTE 1--FORMATION AND BUSINESS OF THE COMPANY:

TheraSense, L.L.C. was formed in the state of California on April 3, 1996. TheraSense, Inc. was incorporated in the state of California on December 6, 1996. In April 1997, all assets and liabilities of TheraSense, L.L.C. were transferred to TheraSense, Inc. TheraSense, L.L.C. and TheraSense, Inc. are collectively referred to as the "Company." In September 2000, the Company's Board of Directors authorized the reincorporation of the Company in the state of Delaware, which was approved by the stockholders in October 2000. In conjunction with the reincorporation, the Company's Board of Directors approved a one-for-two reverse stock split of its common and convertible preferred stock, which was approved by the stockholders in October 2000. All convertible preferred and common stock data and common stock option plan information in these financial statements has been restated to reflect the split. In addition, the conversion prices of the Company's preferred stock have also been adjusted to reflect the effect of the split.

The Company develops and sells easy to use glucose self-monitoring systems that dramatically reduce the pain of testing for people with diabetes. In June 2000, the Company commenced commercial shipments of its products, its planned principal operations, and emerged from the development stage.

In June 2001, the Company's Board of Directors authorized management to file a registration statement with the Securities and Exchange Commission to permit the Company to sell its common stock to the public. Upon completion of the Company's initial public offering, all of the outstanding convertible preferred stock will be converted into shares of common stock.

NOTE 2--SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

Unaudited interim results

The accompanying balance sheet as of June 30, 2001, the statements of operations and of cash flows for the six months ended June 30, 2000 and 2001, and the statement of stockholders' deficit for the six months ended June 30, 2001 are unaudited. The unaudited interim financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to present fairly the Company's financial position and results of operations and cash flows for the six months ended June 30, 2000 and 2001. The financial data and other information disclosed in these notes to financial statements related to the six-month periods are

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unaudited. The results for the six months ended June 30, 2001 are not necessarily indicative of the results to be expected for the year ending December 31, 2001 or for any other interim period or for any future year.

Unaudited pro forma stockholders' equity

If the offering contemplated by this prospectus is consummated, all of the convertible preferred stock outstanding will automatically convert into 26,722,151 shares of common stock based on the shares of convertible preferred stock outstanding at June 30, 2001. Unaudited pro forma stockholders' equity, as adjusted for the assumed conversion of the preferred stock, is set forth on the balance sheet.

Use of estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America require management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

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THERASENSE, INC.

NOTES TO FINANCIAL STATEMENTS--(Continued)

Cash and cash equivalents

The Company considers all highly liquid investments purchased with original maturities of three months or less to be cash equivalents. Cash and cash equivalents include money market funds and various deposit accounts.

Inventories

Inventories are stated at the lower of cost (principally standard cost, which approximates actual cost on a first-in, first-out basis) or market value.

Property and equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation is provided on a straight-line basis over the estimated useful lives of the assets, which is generally two to five years. Amortization of leased assets and leasehold improvements is computed using the straight-line method over the shorter of the remaining lease term or the estimated useful life of the related assets, typically three to seven years. Upon sale or retirement of assets, the cost and related accumulated depreciation and amortization are removed from the balance sheet and the resulting gain or loss is reflected in operations.

Impairment of long-lived assets

The Company accounts for long-lived assets under Statement of Financial Accounting Standards ("SFAS") No. 121 ("SFAS No. 121"), "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of." SFAS No. 121 requires the Company to review for impairment of long-lived assets, whenever events or changes in circumstances indicate that the carrying amount of an asset might not be recoverable. When such an event occurs,

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management determines whether there has been an impairment by comparing the anticipated undiscounted future net cash flows to the related asset's carrying value. If an asset is considered impaired, the asset is written down to fair value, which is determined based either on discounted cash flows or appraised values, depending on the nature of the asset.

Concentration of credit risk and other risks and uncertainties

The Company's cash and cash equivalents are maintained with one major financial institution in the United States of America. Deposits in this institution may exceed the amount of insurance provided on such deposits.

For financial instruments consisting of cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities included in the Company's financial statements, the carrying amounts approximate fair value due to their short maturities. Based on borrowing rates currently available to the Company for loans with similar terms, the carrying value of notes payable and capital lease obligations approximate fair value.

As of December 31, 1999 and 2000, the Company's accounts receivable are derived from revenue earned from customers located in the United States of America. The Company performs ongoing credit evaluations of its customers' financial condition and, generally, requires no collateral from its customers.

For the year ended December 31, 1998, all revenues were generated from a research grant from one customer.

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THERASENSE, INC.

NOTES TO FINANCIAL STATEMENTS--(Continued)

Three customers individually accounted for greater than 10% of total revenues and accounted for 100% of total revenues in aggregate for the year ended December 31, 1999. All revenues were generated from research grants and clinical product shipments. One customer accounted for 100% of total accounts receivable at December 31, 1999.

Revenues from four customers individually accounted for greater than 10% of total revenues and accounted for 53% of total revenues in aggregate for the year ended December 31, 2000. Three customers accounted for 29%, 15% and 11% of total accounts receivable at December 31, 2000.

The Company's products require clearance or approval from the Food and Drug Administration ("FDA") and other international regulatory agencies prior to commercial sales. The Company's products may not receive the necessary approvals. If the regulatory approvals for the Company's products are denied or delayed, it may have a material adverse impact on the Company. In January 2000, the Company received FDA approval for its first product, FreeStyle.

The Company is subject to risks common to companies in the medical device industry. These risks include, but are not limited to, new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, uncertainty of market acceptance of products, product liability and the need to obtain additional financing.

The Company subcontracts the manufacturing of its FreeStyle meters through one subcontractor and subcontracts the manufacturing of the FreeStyle lancet devices through one subcontractor. The Company believes that there are a number

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of alternative contract manufacturers that could produce the Company's products, but in the event of a reduction or interruption of supply, it could take a significant period of time to qualify an alternative subcontractor and commence manufacturing. The effect of such reduction or interruption in supply on results of operations would be material.

Revenue recognition

The Company recognizes revenue in accordance with Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements." Product revenues are generated from sales of the Company's FreeStyle System kit and from the recurring sales of disposable FreeStyle test strips and lancets. The Company's return policy allows end users in the United States of America to return FreeStyle System kits to the Company for a full cash refund within 30 days of purchase. There are no end-user return rights on sales of disposable FreeStyle test strips and lancets. In addition, the Company's FreeStyle System kit and FreeStyle test strips currently have an 18 month shelf life, and retailers and wholesalers in the United States of America can return these products to the Company up to six months beyond this expiration date. As a result of these rights of return and the current unavailability of historical trends in sales and product returns, the Company defers recognition of revenues and the related cost of revenues on sales of FreeStyle test strips until resold by the retailers and wholesalers to end users, and the Company defers recognition of revenues and the related cost of revenues on FreeStyle System kits until 30 days after purchase by the end user. At that time, the Company recognizes revenues net of allowances for customer rebates and coupons. Because the Company lacks a sufficient historical basis from which to estimate return rates, the Company is required to rely on data estimates provided to the Company by third-party data providers in order to recognize revenue from sales to end users by retailers and wholesalers. In addition, due to the lack of significant historical trends in rebates claimed by end users, the Company is accruing 100% of the allowable rebate.

In September 2000, the Company entered into an agreement for the exclusive distribution of FreeStyle products in certain European countries and the nonexclusive distribution to certain of the distributor's

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THERASENSE, INC.

NOTES TO FINANCIAL STATEMENTS--(Continued)

existing customers in North America. Under the terms of the agreement, the Company received a \$1.5 million nonrefundable pre-payment, which has been deferred and is being credited as revenues are recognized. In April 2001, the Company entered into an agreement for the exclusive distribution of FreeStyle products in Japan through April 2006. Under the terms of the agreement, the Company received a \$5.0 million noncreditable up-front payment which has been deferred and is being recognized as revenue ratably over the term of the agreement. If the agreement is terminated prior to the expiration of its term, under limited circumstances, the Company would be obligated to a return of a portion of the up-front payment for each full-year remaining in the initial term. Products shipped to the Company's distributors do not have a right of return although end users in North America are allowed to return FreeStyle System kits within 30 days of purchase.

The Company's FreeStyle System kits and disposable FreeStyle test strips and lancets shipped internationally have no right of return, and the Company recognizes revenue on these products upon shipment. The Company recognizes revenue on direct product sales over the telephone or through the Company's

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website to end users upon shipment for FreeStyle test strips and lancets and 30 days after purchase on sales of FreeStyle System kits.

The Company recognizes license and other up-front fees on a ratable basis over the term of the respective agreement. Any amounts received in advance of performance are recorded as deferred revenue. All revenues recognized to date are not refundable.

Research and development grant agreements provide for periodic payments in support of the Company's research activities. Grant revenue is recognized as earned based on actual costs incurred or as milestones are achieved. All revenues recognized to date are not refundable if the relevant research effort is not successful.

Research and development

Research and development costs are charged to operations as incurred. Research grant revenue projects are funded under agreements with third parties and the costs related to these activities are included in research and development expense.

Advertising costs

Advertising costs, included in selling, general and administrative expenses, are expensed as incurred. No expenses were incurred in 1998 and 1999. Advertising expense in 2000 was \$1,878,396.

Income taxes

The Company accounts for income taxes under the liability method whereby deferred tax asset or liability account balances are calculated at the balance sheet date using current tax laws and rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

Segments

The Company operates in one business segment. As of December 31, 1999 and 2000, all long-lived assets are maintained in the United States of America. All revenue was generated in the United States of America during the years ended December 31, 1998, 1999 and 2000.

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THERASENSE, INC.

NOTES TO FINANCIAL STATEMENTS--(Continued)

Stock-based compensation

The Company uses the intrinsic value method of Accounting Principles Board Opinion No. 25 ("APB 25"), "Accounting for Stock Issued to Employees," in accounting for its employee stock options, and presents disclosure of pro forma information required under SFAS No. 123, "Accounting for Stock-Based Compensation." The Company adopted Financial Accounting Standards Board ("FASB") Interpretation No. 44 ("FIN No. 44"), effective July 1, 2000. The adoption of FIN No. 44 did not have a material impact on the Company's financial statements.

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

Net loss per common share

Basic net loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average number of vested common shares outstanding for the period. Diluted net loss per share is computed giving effect to all potential dilutive common stock, including options, warrants and convertible preferred stock. Options, warrants, common stock subject to repurchase and convertible preferred stock were not included in the computation of diluted net loss per share because the effect would be antidilutive.

A reconciliation of the numerator and denominator used in the calculation of basic and diluted net loss per common share follows:

| | Years Ended December 31, | | | Six Months Ended June 30, | |
|---|--------------------------|-----------------|-----------------|------------------------------|-----------------|
| | 1998 | 1999 | 2000 | 2000 | 2001 |
| | | | | | (unaudited) |
| Numerator: | | | | | |
| Net loss..... | \$ (4,663,951) | \$ (13,057,722) | \$ (43,591,837) | \$ (15,058,833) | \$ (26,933,429) |
| Deemed dividend related to beneficial conversion feature of preferred stock..... | -- | -- | (14,772,878) | (14,772,878) | (26,782,911) |
| Net loss attributable to common stockholders.... | \$ (4,663,951) | \$ (13,057,722) | \$ (58,364,715) | \$ (29,831,711) | \$ (53,716,340) |
| Denominator: | | | | | |
| Weighted-average common stock outstanding..... | 4,439,214 | 4,840,006 | 5,060,774 | 5,036,141 | 5,202,150 |
| Less: Weighted-average shares subject to repurchase..... | (2,424,182) | (1,816,370) | (1,087,524) | (1,323,142) | (470,059) |
| Weighted-average shares used in computing basic and diluted net loss per common share..... | 2,015,032 | 3,023,636 | 3,973,250 | 3,712,999 | 4,732,091 |

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THERASENSE, INC.

NOTES TO FINANCIAL STATEMENTS--(Continued)

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The following outstanding options, common stock subject to repurchase, convertible preferred stock and warrants were excluded from the computation of diluted net loss per share attributable to common stockholders as they had an antidilutive effect:

| | December 31, | | | Six Months Ended June 30, | |
|-------------------------|--------------|------------|------------|------------------------------|------------|
| | 1998 | 1999 | 2000 | 2000 | 2001 |
| | ----- | | | | |
| | (unaudited) | | | | |
| Options to purchase | | | | | |
| common stock..... | 502,094 | 1,644,468 | 4,201,599 | 2,672,948 | 4,882,303 |
| Common stock subject to | | | | | |
| repurchase..... | 2,073,503 | 1,562,751 | 612,297 | 1,040,190 | 327,822 |
| Convertible preferred | | | | | |
| stock..... | 10,104,060 | 11,588,621 | 20,078,780 | 20,078,780 | 26,722,151 |
| Warrants..... | 101,967 | 521,013 | 521,013 | 521,013 | 521,013 |

Reclassification

Certain amounts in the prior year financial statements have been reclassified to conform to the current year's presentation. The reclassification had no impact on the previously reported net loss.

Recent accounting pronouncements

On January 1, 2001, the Company adopted SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities," which establishes accounting and reporting standards for derivative instruments and hedging activities. It requires that an entity recognize all derivatives as either assets or liabilities in the statement of financial position and measure those instruments at fair value. The Company, to date, has not engaged in derivative and hedging activities and therefore, the adoption had no impact on the Company's financial statements.

In July 2001, the FASB issued SFAS No. 141 "Business Combinations" ("SFAS No. 141") which establishes financial accounting and reporting for business combinations and supersedes APB Opinion No. 16, "Business Combinations," and FASB Statement No. 38, "Accounting for Preacquisition Contingencies of Purchased Enterprises". SFAS No. 141 requires that all business combinations be accounted for using one method, the purchase method. The provisions of SFAS No. 141 apply to all business combinations initiated after June 30, 2001. The Company will adopt SFAS No. 141 during the first quarter of fiscal 2002, and the adoption of SFAS No. 141 is expected to have no material impact on financial reporting and related disclosures of the Company.

In July 2001, the FASB issued SFAS No. 142 "Goodwill and Other Intangible Assets," ("SFAS No. 142") which establishes financial accounting and reporting for acquired goodwill and other intangible assets and supersedes APB Opinion No. 17, "Intangible Assets". SFAS No. 142 addresses how intangible assets that are acquired individually or with a group of other assets (but not those acquired in a business combination) should be accounted for in financial statements upon their acquisition, and after they have been initially recognized in the financial statements. The provisions of SFAS No. 142 are effective for fiscal years beginning after December 15, 2001. The Company will adopt SFAS No. 142 during the first quarter of fiscal 2002, and the adoption of SFAS No. 142 is expected to have no material impact on financial reporting and

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related disclosures of the Company.

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THERASENSE, INC.

NOTES TO FINANCIAL STATEMENTS--(Continued)

NOTE 3--BALANCE SHEET ACCOUNTS:

At December 31, 1999, the Company held no inventory. At December 31, 2000 and June 30, 2001 (unaudited), inventories consisted of the following:

| | December 31, 2000 | June 30, 2001 |
|----------------------|----------------------|------------------|
| | ----- | ----- |
| | | (unaudited) |
| Raw materials..... | \$1,175,408 | \$ 2,113,679 |
| Work-in-process..... | 782,838 | 1,175,079 |
| Finished goods..... | 1,535,531 | 663,116 |
| | ----- | ----- |
| | \$3,493,777 | \$ 3,951,874 |
| | ===== | ===== |

Property and equipment consisted of the following:

| | December 31, | |
|--|--------------|--------------|
| | 1999 | 2000 |
| | ----- | ----- |
| Laboratory equipment..... | \$ 997,964 | \$ 1,162,101 |
| Leasehold improvements..... | 909,542 | 1,051,983 |
| Office equipment..... | 513,747 | 580,017 |
| Computer equipment..... | 895,779 | 1,294,610 |
| Tooling..... | 434,832 | 788,040 |
| Manufacturing equipment..... | 958,141 | 2,082,398 |
| | ----- | ----- |
| | 4,710,005 | 6,959,149 |
| Less: Accumulated depreciation and amortization... | (711,554) | (2,120,467) |
| | ----- | ----- |
| | \$3,998,451 | \$ 4,838,682 |
| | ===== | ===== |

Included in property and equipment are assets acquired under capital leases with a cost of \$366,133 and \$3,334,412, and accumulated amortization of \$50,852 and \$844,691 as of December 31, 1999 and 2000, respectively.

Other assets consisted of the following:

| | December 31, | |
|--|--------------|-------|
| | 1999 | 2000 |
| | ----- | ----- |

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| | | | | |
|---------------------------------------|----|---------|----|-----------|
| Manufacturing equipment deposits..... | \$ | -- | \$ | 709,845 |
| Facility deposits..... | | -- | | 578,136 |
| Debt issuance costs..... | | 745,492 | | 477,003 |
| Other..... | | 98,711 | | 185,319 |
| | | | | ----- |
| | \$ | 844,203 | \$ | 1,950,303 |
| | | ===== | | ===== |

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THERASENSE, INC.

NOTES TO FINANCIAL STATEMENTS--(Continued)

Accrued liabilities consisted of the following:

| | December 31, | | |
|--|--------------|---------|-------------|
| | 1999 | 2000 | |
| | ----- | ----- | |
| Distributor prepayments..... | \$ | -- | \$1,343,147 |
| Salaries and related expense..... | | 220,838 | 783,853 |
| Rebates..... | | -- | 758,965 |
| Professional and other outside services..... | | 137,468 | 645,687 |
| Royalties..... | | -- | 383,651 |
| Warranties..... | | -- | 269,392 |
| Other liabilities..... | | 226,854 | 236,817 |
| | | | ----- |
| | \$ | 585,160 | \$4,421,512 |
| | | ===== | ===== |

NOTE 4--NOTES PAYABLE:

During 1998, the Company entered into an equipment line of credit agreement with a financial institution under which the Company could borrow up to \$500,000 for equipment purchases prior to July 10, 1998. Borrowings under the equipment line of credit are collateralized by the equipment purchased, accrue interest at the rate of the prime rate plus 1.25% (10.75% at December 31, 2000) and are due in monthly installments through June 2001.

During 1998, the Company entered into an equipment line of credit agreement under which the Company could borrow up to \$2,500,000 for equipment purchases prior to December 31, 1999. During 1998, the Company executed two promissory notes under this agreement for \$184,711 and \$73,879 which accrue interest at the rate of 8.5% and 9.5%, respectively, and are due in forty-eight and thirty-six monthly installments, respectively. During 1999, the Company executed an additional two promissory notes under this agreement for \$35,833 and \$285,574 which accrue interest at the rate of 9.5% and 8.5%, respectively, and are due in thirty-six and forty-eight monthly installments, respectively. All borrowings under the equipment line of credit are collateralized by the equipment purchased. In connection with this agreement, the Company issued warrants to purchase 47,619 shares of Series B preferred stock (Note 7).

During 1999, the Company entered into a subordinated debt agreement with a lending company under which the Company could borrow up to \$5,000,000 for

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equipment purchases prior to July 7, 2000. In December 1999 and January and July 2000, the Company executed \$2,000,000, \$2,000,000 and \$1,000,000 promissory notes under this agreement, respectively. The notes accrue interest at an annual rate of 11.5% and are each due in thirty-six monthly installments. All borrowings under this agreement are collateralized by the equipment purchased. In connection with this agreement, the Company issued warrants to purchase 380,952 shares of Series B preferred stock (Note 7). The effective annual interest rate, including warrant amortization, is 22.3%.

During 1999, the Company entered into a senior loan and security agreement with a lending company to borrow up to \$2,000,000 for equipment purchases prior to December 31, 1999. The Company executed promissory notes under this agreement for \$253,864, \$253,055 and \$262,625. Principal and interest are payable in consecutive monthly installments, each of which are equal to 1.0% of the principal sum for months one through twelve and 3.075% of the principal sum for months thirteen through forty-eight, yielding an annual interest rate of 8.7%. All borrowings under this agreement are collateralized by the equipment purchased. In connection with this agreement, the Company issued

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THERASENSE, INC.

NOTES TO FINANCIAL STATEMENTS--(Continued)

warrants to purchase 38,094 shares of Series B preferred stock (Note 7). The effective annual interest rate, including warrant amortization, is 13.1%.

As of December 31, 2000, aggregate future principal payments under the lines of credit are as follows:

| | |
|----------------------------|--------------|
| 2001..... | \$ 1,958,958 |
| 2002..... | 2,500,952 |
| 2003..... | 956,393 |
| | ----- |
| | 5,416,303 |
| Less: Current portion..... | (1,958,958) |
| | ----- |
| | \$ 3,457,345 |
| | ===== |

NOTE 5--CONVERTIBLE PROMISSORY NOTE:

In September 2000, the Company entered into an agreement for the exclusive distribution of FreeStyle products in certain European countries and the nonexclusive distribution to certain of the distributor's customers in North America. In connection with the agreement, the Company received a \$2.5 million convertible promissory note, all of which was outstanding as of December 31, 2000. Upon the first closing of the Series D convertible preferred stock financing in January 2001, the note automatically converted into 294,118 shares of Series D convertible preferred stock. In accordance with the agreement, no interest was payable as the note was outstanding for less than one year. As of June 30, 2001, revenues of \$4,742,502 (unaudited) have been generated from this agreement.

NOTE 6--COMMITMENTS AND CONTINGENCIES:

Facility lease

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The Company leases its facilities under an operating lease agreement which expires in April 2009. The Company has the option to terminate the lease in April 2006. Under the terms of the agreement, the initial base monthly rent shall be adjusted as specified under the terms of the agreement and every two and one half years based on changes in the Consumer Price Index by amounts not to be less than 5.0%, nor to exceed 7.5%, over each two and one half year period. At the expiration of the lease term, the Company has the option to extend the facility lease for an additional five years. Future minimum facility lease payments are as follows:

| | | |
|-----------------|----|-------------|
| 2001..... | \$ | 791,098 |
| 2002..... | | 823,788 |
| 2003..... | | 823,788 |
| 2004..... | | 851,244 |
| 2005..... | | 864,972 |
| Thereafter..... | | 2,991,360 |
| | | ----- |
| | | \$7,146,250 |
| | | ===== |

Rent expense for the years ended December 31, 1998, 1999 and 2000 was \$223,892, \$619,766 and \$674,959, respectively.

In April 2001, the Company entered into a facility lease agreement expiring in October 2002. Total future minimum lease payments at the date of signing amounted to approximately \$123,000.

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THERASENSE, INC.

NOTES TO FINANCIAL STATEMENTS--(Continued)

In June 2001, the Company entered into facility lease agreement expiring in May 2004. Total future minimum lease payments at the date of signing amounted to \$883,295.

Office equipment lease

The Company leases certain office equipment under an operating lease agreement which expires in June 2005. As of December 31, 2000, future minimum lease payments are as follows:

| | |
|-----------|----------|
| 2001..... | \$12,768 |
| 2002..... | 12,768 |
| 2003..... | 12,768 |
| 2004..... | 12,768 |
| 2005..... | 6,384 |
| | ----- |
| | \$57,456 |
| | ===== |

In March 2001, the Company entered into an operating lease agreement for

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computer equipment expiring in March 2003. Total future minimum lease payments at the date of signing amounted to \$93,875.

In June 2001, the Company entered into an operating lease agreement for office equipment expiring in June 2003. Total future minimum lease payments at the date of signing amounted to \$285,938.

Capital lease obligations

During 1999 and 2000, the Company acquired office furniture under capital lease agreements. Payments, comprising both principal and interest, are due in thirty-six equal monthly installments through October 2003.

During February 2000, the Company entered into a sale and leaseback transaction whereby the Company sold and leased back under capital lease agreements, assets with a net book value of \$1,607,557 for total proceeds of \$1,603,769, recognizing a loss on the sale of \$3,788. In addition, the Company leased \$153,579 of computer equipment under a capital lease agreement. Payments, comprising both principal and interest, are due in thirty-six to forty-eight monthly installments through April 2004.

During April 2000, the Company entered into sale and leaseback transaction whereby the Company sold and leased back under capital lease agreements, assets with a net book value of \$1,062,605 for an equal amount of total proceeds. In addition, the Company financed \$126,756 of property and equipment purchases under capital lease agreements. Payments, comprising both principal and interest, are due in forty-eight equal monthly installments through March 2004.

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THERASENSE, INC.

NOTES TO FINANCIAL STATEMENTS--(Continued)

As of December 31, 2000, aggregate future minimum lease payments are as follows:

| | |
|---|-------------|
| 2001..... | \$1,052,771 |
| 2002..... | 1,202,557 |
| 2003..... | 812,935 |
| 2004..... | 180,249 |
| | ----- |
| Minimum payments..... | 3,248,512 |
| Less: Amount representing interest..... | (366,978) |
| | ----- |
| Principal amount of minimum payments..... | 2,881,534 |
| Less: Current portion..... | (844,394) |
| | ----- |
| | \$2,037,140 |
| | ===== |

Licensing agreements

The Company has entered into several licensing agreements with various universities, institutions and companies under which it obtained rights to certain patents, patent applications, and other technology. As of December 31, 2000, future minimum payments, which will be expensed to cost of revenues,

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pursuant to these agreements are as follows:

| | |
|-----------|-------------|
| 2001..... | \$ 420,000 |
| 2002..... | 620,000 |
| 2003..... | 620,000 |
| 2004..... | 620,000 |
| | ----- |
| | \$2,280,000 |
| | ===== |

In addition to the payments summarized above, the Company is required to make royalty payments based upon a percentage of net sales of any products developed from certain of the licensed technologies. These royalties, which are creditable against the minimum payment summarized above, are expensed to cost of revenues upon product shipment.

In December 1998, the Company entered into an agreement with Facet Technologies, LLC, formerly Gainor Medical North America LLC ("Facet Technologies"), whereby the Company is obligated to pay royalties, based upon a fixed fee per FreeStyle System kit shipped, to Facet Technologies of up to \$2,800,000 in exchange for research and development services provided by Facet Technologies. For the years ended December 31, 1998, 1999 and 2000, none, none and \$331,578 of royalties have been expensed to cost of revenues, respectively. As of December 31, 1999 and 2000, the Company has accrued none and \$331,578, respectively, of royalties relating to this agreement.

At December 31, 2000, the Company has included \$1.1 million of a \$2.0 million paid-up licensing fee in prepaid expenses and other current assets, which is being amortized ratably to cost of revenues over the annual term of the license. At the Company's option, the Company can extend this non-exclusive paid-up licensing agreement with future license payments.

Contingencies

From time to time, the Company may become involved in litigation relating to additional claims arising from the ordinary course of business. Management does not believe the final disposition of these matters will have a material adverse affect on the financial position, results of operations or cash flows of the Company.

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THERASENSE, INC.

NOTES TO FINANCIAL STATEMENTS--(Continued)

NOTE 7--CONVERTIBLE PREFERRED STOCK:

Under the Company's Certificate of Incorporation, as amended, the Company's convertible preferred stock is issuable in series.

As of December 31, 1998, the convertible preferred stock comprises:

| Number of | Number of | Proceeds, Net of | Annual |
|-----------|-----------|---------------------|--------|
|-----------|-----------|---------------------|--------|

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| | Shares Authorized | Shares Issued and Outstanding | Issuance Costs | Liquidation Preference | Dividends per Share |
|---------------|----------------------|----------------------------------|-------------------|---------------------------|------------------------|
| Series A..... | 4,500,123 | 4,445,770 | \$ 5,525,502 | \$1.254 | \$0.10 |
| Series B..... | 7,609,524 | 5,658,284 | 11,835,840 | \$2.100 | \$0.16 |
| | ----- | ----- | ----- | ----- | ----- |
| | 12,109,647 | 10,104,054 | \$17,361,342 | | |
| | ===== | ===== | ===== | | |

As of December 31, 1999, the convertible preferred stock comprises:

| | Number of Shares Authorized | Number of Shares Issued and Outstanding | Proceeds, Net of Issuance Costs | Liquidation Preference | Annual Dividends per Share |
|---------------|-----------------------------------|---|--|---------------------------|----------------------------------|
| Series A..... | 4,500,123 | 4,445,770 | \$ 5,525,502 | \$1.254 | \$0.10 |
| Series B..... | 7,609,524 | 7,142,851 | 14,946,311 | \$2.100 | \$0.16 |
| | ----- | ----- | ----- | ----- | ----- |
| | 12,109,647 | 11,588,621 | \$20,471,813 | | |
| | ===== | ===== | ===== | | |

As of December 31, 2000, the convertible preferred stock comprises:

| | Number of Shares Authorized | Number of Shares Issued and Outstanding | Proceeds, Net of Issuance Costs | Liquidation Preference | Annual Dividends per Share |
|---------------|-----------------------------------|---|--|---------------------------|----------------------------------|
| Series A..... | 4,500,123 | 4,445,770 | \$ 5,525,502 | \$1.254 | \$0.10 |
| Series B..... | 7,609,524 | 7,142,851 | 14,946,311 | \$2.100 | \$0.16 |
| Series C..... | 8,500,000 | 8,490,159 | 42,410,926 | \$5.000 | \$0.40 |
| | ----- | ----- | ----- | ----- | ----- |
| | 20,609,647 | 20,078,780 | \$62,882,739 | | |
| | ===== | ===== | ===== | | |

As of June 30, 2001, the convertible preferred stock comprises (unaudited):

| | Number of Shares Authorized | Number of Shares Issued and Outstanding | Proceeds, Net of Issuance Costs | Liquidation Preference | Annual Dividends per Share |
|---------------|-----------------------------------|---|--|---------------------------|----------------------------------|
| Series A..... | 4,500,123 | 4,445,770 | \$ 5,525,502 | \$1.254 | \$0.10 |
| Series B..... | 7,609,524 | 7,142,851 | 14,946,311 | \$2.100 | \$0.16 |
| Series C..... | 8,500,000 | 8,490,159 | 42,410,926 | \$5.000 | \$0.40 |
| Series D..... | 7,700,000 | 6,643,371 | 56,363,086 | \$8.500 | \$0.68 |
| | ----- | ----- | ----- | ----- | ----- |
| | 28,309,647 | 26,722,151 | \$119,245,825 | | |

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THERASENSE, INC.

NOTES TO FINANCIAL STATEMENTS--(Continued)

The Company's Board of Directors is authorized to determine the rights, preferences and terms of each series which are as follows:

Dividends

The holders of Series A, Series B, Series C and Series D convertible preferred stock are entitled to receive dividends, out of any assets legally available, prior and in preference to any declaration or payment of any dividend for the common stock, at the rate stated above per share per annum or, if greater (as determined on a per annum basis and on an as converted basis for the Series A, Series B, Series C and Series D preferred stock), an amount equal to that paid on any other outstanding stock of the Company. Such dividends are payable when, as and if declared by the Board of Directors, and are not cumulative. As of June 30, 2001, no dividends have been declared.

In February 2000, the Company issued 8,490,159 shares of Series C convertible preferred stock at \$5.00 per share for gross cash proceeds of \$42,450,800. The issuance resulted in a beneficial conversion feature of \$14,772,878, calculated in accordance with EITF No. 98-5, "Accounting for Convertible Securities with Beneficial Conversion Features." The beneficial conversion feature is reflected as a preferred stock deemed dividend in the Statement of Operations for the year ended December 31, 2000.

In January, February and April 2001 (all amounts unaudited), the Company issued 6,643,371 shares of Series D convertible preferred stock at \$8.50 per share for gross cash proceeds of \$56,468,654. The issuance resulted in a beneficial conversion feature of \$26,782,911, calculated in accordance with EITF No. 98-5. The beneficial conversion feature is reflected as a preferred stock deemed dividend in the Statement of Operations for the six months ended June 30, 2001.

Liquidation

In the event of any liquidation, dissolution or winding up for the Company, either voluntary or involuntary, the holders of Series A, Series B, Series C and Series D convertible preferred stock are entitled to receive, prior and in preference to any distribution of any of the assets of the Company to the holders of common stock by reason of their ownership, an amount per share equal to the liquidation preference per share stated in the table above, (as adjusted for any stock splits, combinations, reorganizations and the like) plus any declared but unpaid dividends on such shares.

After payment has been made to the holders of the convertible preferred stock, any remaining assets and funds are to be distributed among the holders of common stock pro rata based on the number of shares of common stock held by each stockholder.

A merger, reorganization or sale of all or substantially all of the assets of the Company in which the stockholders of the Company immediately prior to the transaction do not possess more than 50% of the voting power of the surviving entity (or its parent) immediately after the transaction shall be deemed to be a liquidation, dissolution or winding up.

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Voting

Except as otherwise required by law or as required by the Company's amended and restated Certificate of Incorporation, the holders common and convertible preferred stock vote together as a single class. The holders of the convertible preferred stock are entitled to the number of votes equal to the number of common stock into which the convertible preferred stock could be converted on the record date for the vote or written consent of stockholders.

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THERASENSE, INC.

NOTES TO FINANCIAL STATEMENTS--(Continued)

Conversion

Each Series A, Series B, Series C and Series D convertible preferred stock, at the option of the holder and at any time after the date of issuance, is convertible into common stock on a one-for-one basis.

Conversion is automatic at the conversion price (i) immediately upon the closing of a firm commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, in which the public offering price equals or exceeds \$10.00 per share (as adjusted for any stock dividends, stock splits or recapitalizations) and the aggregate proceeds raised equal or exceed \$25,000,000, or (ii) at the election of stockholders of a majority of the outstanding preferred shares.

Warrants

During April 1997, the Company issued warrants to purchase 54,348 shares of its Series A convertible preferred stock at \$1.84 per share in connection with the Series A preferred stock financing. The warrants are exercisable at any time and expire on December 31, 2001. The Company has reserved 54,348 shares of its Series A convertible preferred stock for issuance in the event of exercise.

During August 1998, the Company issued warrants to purchase 47,619 shares of its Series B convertible preferred stock at \$2.10 per share in connection with the execution of an equipment line of credit agreement. The warrants are exercisable at any time and expire in August 2008 or five years from the effective date of the Company's initial public offering, whichever is earlier. The Company has reserved 47,619 shares of Series B convertible preferred stock for issuance in the event of exercise.

The fair value of the above warrants was calculated using the Black-Scholes pricing model and deemed to be immaterial.

During April 1999, the Company issued warrants to purchase 38,094 shares of Series B convertible preferred stock at \$2.10 per share in connection with the execution of a senior loan and security agreement. The warrants are exercisable at any time and expire in April 2007 or five years from the effective date of the Company's initial public offering, whichever is later. The fair value of the warrants calculated using the Black-Scholes pricing model, of \$57,167, has been reflected as a debt issuance cost included in other assets and amortized as interest expense over the life of the line of credit. The Company has reserved 38,094 shares of Series B convertible preferred stock for issuance in the event of exercise.

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During October 1999, the Company issued warrants to purchase a total of 380,952 shares of Series B convertible preferred stock at \$2.10 per share in connection with the execution of a subordinated debt agreement. The warrants are exercisable at any time and expire in October 2009 or five years from the effective date of the Company's initial public offering, whichever is earlier. The fair value of the warrants calculated using the Black-Scholes pricing model, of \$762,593, has been reflected as a debt issuance cost included in other assets and amortized as interest expense over the life of the line of credit. The Company has reserved 380,952 shares of Series B convertible preferred stock for issuance in the event of exercise.

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THERASENSE, INC.

NOTES TO FINANCIAL STATEMENTS--(Continued)

NOTE 8--STOCKHOLDERS' EQUITY (DEFICIT):

Common stock

Each share of common stock is entitled to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the Board of Directors, subject to the prior rights of holders of all convertible preferred stock.

The Company has issued a total of 3,525,000 shares of common stock under restrictive stock purchase agreements, under which the Company has the option to repurchase unvested shares of stock upon the termination of employment or services to the Company. The number of shares subject to repurchase is generally reduced by 1/48th of the initial number subject to repurchase for each month that the holder continues to serve as a consultant, employee or director. As of December 31, 2000 and June 30, 2001, 206,836 and no (unaudited) shares of common stock are subject to repurchase, respectively.

Incentive Stock Plan

In March 1997, the Company approved the 1997 Stock Option Plan (the "Plan") under which the officers of the Company are authorized to enter into stock option agreements with selected individuals. The Board of Directors has the authority to determine to whom options will be granted, the number of shares, the term and exercise price (which cannot be less than estimated fair market value at date of grant for incentive stock options or 85% of estimated fair market value for nonqualified stock options). If an employee owns stock representing more than 10% of the outstanding shares, the price of each share shall be at least 110% of estimated fair market value, as determined by the Board of Directors. Options granted under the Plan generally become exercisable 1/4 on the first anniversary of the vesting commencement date and an additional 1/48 of the total number of shares subject to the option shares shall become exercisable on the last day of each calendar month thereafter until all of the shares have become exercisable. Unvested option exercises are subject to repurchase upon termination of the holder's status as an employee or consultant. At December 31, 2000 and June 30, 2001, 405,461 and 327,822 (unaudited) shares of common stock were subject to the Company's repurchase rights, respectively. The options have a maximum term of ten years.

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THERASENSE, INC.

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NOTES TO FINANCIAL STATEMENTS--(Continued)

Activity under the Plan is as follows:

| | Outstanding Options | | | |
|---|----------------------------|------------------|---------------------------------|-----------------|
| | Shares Available for Grant | Number of Shares | Weighted Average Exercise Price | Aggregate Price |
| Balances, January 1, 1998..... | 575,454 | 190,922 | \$0.14 | \$ 26,729 |
| Additional shares reserved..... | 500,000 | -- | -- | -- |
| Options granted..... | (532,700) | 532,700 | \$0.28 | 147,056 |
| Options exercised..... | -- | (216,159) | \$0.25 | (53,320) |
| Options canceled..... | 5,369 | (5,369) | \$0.15 | (822) |
| Balances, December 31, 1998..... | 548,123 | 502,094 | \$0.24 | 119,643 |
| Additional shares reserved..... | 1,500,000 | -- | -- | -- |
| Options granted..... | (1,568,245) | 1,568,245 | \$0.77 | 1,211,198 |
| Options exercised..... | -- | (394,182) | \$0.50 | (198,960) |
| Options canceled..... | 31,689 | (31,689) | \$0.33 | (10,361) |
| Balances, December 31, 1999..... | 511,567 | 1,644,468 | \$0.68 | 1,121,520 |
| Additional shares reserved..... | 2,670,865 | -- | -- | -- |
| Options granted..... | (2,922,596) | 2,922,596 | \$4.01 | 11,727,269 |
| Options exercised..... | -- | (213,671) | \$0.41 | (86,649) |
| Options canceled/shares repurchased..... | 203,004 | (151,794) | \$1.55 | (235,318) |
| Balances, December 31, 2000..... | 462,840 | 4,201,599 | \$2.98 | 12,526,822 |
| Additional shares reserved (unaudited)..... | 1,500,000 | -- | -- | -- |
| Options granted (unaudited).... | (1,066,450) | 1,066,450 | \$6.13 | 6,534,325 |
| Options exercised (unaudited)... | -- | (228,304) | \$1.97 | (450,532) |
| Options canceled (unaudited).... | 157,442 | (157,442) | \$2.45 | (385,684) |
| Balances, June 30, 2001 (unaudited)..... | 1,053,832 | 4,882,303 | \$3.73 | \$18,224,931 |

The options outstanding and exercisable by exercise price at December 31, 2000 are as follows:

| Outstanding Options | | | |
|---------------------|--------------------|---|---------------------|
| Exercise Price | Number Outstanding | Weighted Average Remaining Contractual Life (Years) | Options Exercisable |
| ----- | ----- | ----- | ----- |

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| | | | |
|--------|-----------|-----|---------|
| \$0.14 | 61,563 | 6.6 | 51,375 |
| 0.28 | 162,272 | 7.8 | 42,550 |
| 0.50 | 315,380 | 8.1 | 142,614 |
| 0.70 | 218,500 | 8.4 | 84,535 |
| 1.10 | 580,000 | 8.8 | 180,295 |
| 3.00 | 1,011,633 | 9.1 | 133,132 |
| 3.50 | 122,350 | 9.4 | 729 |
| 4.00 | 550,598 | 9.6 | 52,151 |
| 4.40 | 46,400 | 9.7 | 781 |
| 5.00 | 1,132,903 | 9.8 | 12,388 |
| | ----- | | ----- |
| | 4,201,599 | | 700,550 |
| | ===== | | ===== |

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THERASENSE, INC.

NOTES TO FINANCIAL STATEMENTS--(Continued)

The options outstanding and exercisable by exercise price at June 30, 2001 (unaudited) are as follows:

| Outstanding Options | | | |
|---------------------|--------------------|---|---------------------|
| Exercise Price | Number Outstanding | Weighted Average Remaining Contractual Life (Years) | Options Exercisable |
| ----- | ----- | ----- | ----- |
| \$0.14 | 59,063 | 6.1 | 55,856 |
| 0.28 | 145,710 | 7.3 | 66,102 |
| 0.50 | 254,553 | 7.6 | 141,488 |
| 0.70 | 216,250 | 7.9 | 110,723 |
| 1.10 | 406,079 | 8.3 | 128,821 |
| 3.00 | 976,915 | 8.5 | 311,581 |
| 3.50 | 109,135 | 8.9 | 34,198 |
| 4.00 | 530,398 | 9.1 | 117,708 |
| 4.40 | 46,400 | 9.2 | 2,343 |
| 5.00 | 1,124,753 | 9.3 | 36,509 |
| 5.50 | 568,090 | 9.6 | 24,578 |
| 7.00 | 444,957 | 9.9 | 82 |
| | ----- | | ----- |
| | 4,882,303 | | 1,029,989 |
| | ===== | | ===== |

Stock-based compensation

The Company has adopted the disclosure only provisions of SFAS No. 123. In accordance with the provisions of SFAS No. 123, the Company's filing of a registration statement with the Securities and Exchange Commission in October 2000 required that the fair value of all options granted after that date be calculated using the Black-Scholes option pricing model and contain an expected

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value of the common stock fluctuates. In connection with the grant of stock options to non-employees, the Company recorded deferred stock-based compensation of none, \$246,209, \$802,716 and \$385,886 (unaudited) for the years ended December 31, 1998, 1999, 2000 and for the six months ended June 30, 2001, respectively, of which none, \$44,070, \$291,300 and \$256,422 (unaudited) has been amortized to expense in 1998, 1999, 2000 and in the six months ended June 30, 2001, respectively.

Note receivable from stockholders

During 1998, 1999 and 2000, the Company sold common stock to certain of its officers in exchange for full recourse notes receivable. The notes are non-interest bearing, have due dates through September 2003, and are collateralized by the underlying shares of common stock.

2000 Stock Plan

In September 2000, the Board of Directors adopted the 2000 Stock Plan ("2000 Plan"). The 2000 Plan was approved by the stockholders in October 2000 and was to be effective upon the completion of an initial public offering of the Company's common stock. In June 2001, the Board of Directors terminated the 2000 Plan.

2001 Stock Plan

In June 2001, the Board of Directors adopted the 2001 Stock Plan ("2001 Plan"), subject to stockholder approval. The 2001 Plan, which will terminate no later than 2011, provides for the granting of incentive stock options to employees and nonstatutory stock options to employees, directors and consultants. 7,000,000 shares of common stock are reserved for issuance plus any shares which have been reserved but not issued under the 1997 Stock Plan, plus any shares returned thereafter. The 1997 Stock Plan will be cancelled upon the effectiveness of the 2001 Plan. In addition, the number of shares available for issuance will be increased on the first day of each fiscal year, commencing in 2002, by an amount equal to the lesser of (i) 2,500,000, (ii) 5.0% of the outstanding shares of common stock on the last day of the preceding fiscal year or (iii) an amount as determined by the Board of Directors.

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THERASENSE, INC.

NOTES TO FINANCIAL STATEMENTS--(Continued)

Under the terms of the 2001 Plan, on or after the effectiveness of an initial public offering of the Company's stock, each newly-elected non-employee director will be granted a nonstatutory option to purchase 30,000 shares of common stock which vests annually over a three year period. Thereafter, on an annual basis, on the date of the annual stockholder meeting, commencing in 2002, each non-employee director will be granted a nonstatutory option to purchase 10,000 shares of common stock which vests after one year. The exercise price of an option shall not be less than 100% of the fair market value of the common stock on the date of grant and the term shall not exceed 10 years.

2000 Employee Stock Purchase Plan

In September 2000, the Board of Directors adopted the 2000 Employee Stock Purchase Plan ("2000 ESPP"). The 2000 Plan was approved by the stockholders in October 2000 and was to be effective upon the completion of an initial public offering of the Company's common stock. In June 2001, the Board of Directors

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terminated the 2000 ESPP.

2001 Employee Stock Purchase Plan

In June 2001, the Board of Directors adopted the 2001 Employee Stock Purchase Plan ("2001 ESPP"), subject to stockholder approval, under which eligible employees are permitted to purchase common stock at a discount through payroll deductions. 1,000,000 shares of common stock are reserved for issuance and will be increased on the first day of each fiscal year, commencing in 2002, by an amount equal to the lesser of (i) 1,000,000, (ii) 1.5% of the outstanding shares of common stock on such date or (iii) an amount as determined by the Board of Directors.

The 2001 ESPP contains consecutive, overlapping twenty-four month offering periods. Each offering period includes four six-month purchase periods. The price of the common stock purchased shall be 85% of the lower of the fair market value of the common stock at the beginning of an offering period or at the end of a purchase period. The initial offering period will commence on the effective date of the Company's initial public offering.

NOTE 9--INCOME TAXES:

At December 31, 2000, the Company has approximately \$44.8 million and \$31.2 million in federal and state net operating loss carryforwards, respectively, to reduce future taxable income. These carryforwards have expiration dates from 2012 through 2020 for federal and in 2005 for state, if not utilized.

At December 31, 2000, the Company had research credit carryforwards of approximately \$718,000 and \$569,000 for federal and state income tax purposes, respectively. If not utilized, the federal carryforwards will expire in various amounts beginning in 2012. The state research credit can be carried forward indefinitely.

The Tax Reform Act of 1986 limits the use of net operating loss and tax credit carryforwards in the case of an "ownership change" of a corporation. Ownership changes, as defined, have already occurred on April 21, 1997 and February 23, 1999 as a result of the Company's preferred stock financings. In accordance with Internal Revenue Code Section 382, such losses are subject to annual limitation. The annual limitations did not result in the expiration of net operating losses prior to utilization.

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THERASENSE, INC.

NOTES TO FINANCIAL STATEMENTS--(Continued)

Temporary differences and carryforwards which gave rise to significant portions of deferred tax assets and liabilities are as follows:

| | December 31, | |
|---|--------------|---------------|
| | 1999 | 2000 |
| Net operating loss carryforwards..... | \$ 6,924,000 | \$ 17,047,000 |
| Research and development tax credit carryforwards..... | 645,000 | 1,228,000 |

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| | | |
|---|-------------|--------------|
| Deferred revenue..... | -- | 3,456,000 |
| Accruals and reserves not currently deductible for tax purposes..... | 23,000 | 2,145,000 |
| Capitalized start-up costs..... | 415,000 | 348,000 |
| Depreciation and amortization..... | (158,000) | 189,000 |
| Valuation allowance..... | (7,849,000) | (24,413,000) |
| | ----- | ----- |
| | \$ -- | \$ -- |
| | ===== | ===== |

The Company has established a valuation allowance against its deferred tax assets due to the uncertainty surrounding the realization of such assets.

NOTE 10--UNAUDITED PRO FORMA NET LOSS PER SHARE:

Pro forma basic and diluted net loss per share have been computed to give effect to convertible preferred stock that will convert to common stock upon the closing of the Company's initial public offering (using the as-if-converted method) for the year ended December 31, 2000 and the six months ended June 30, 2001. A reconciliation of the numerator and denominator used in the calculation of pro forma basic and diluted net loss per common share follows:

| | Year Ended December 31, 2000 | Six Months Ended June 30, 2001 |
|---|------------------------------------|---|
| | ----- | ----- |
| | (unaudited) | |
| Pro forma net loss per common share, basic and diluted: | | |
| Net loss attributable to common stockholders..... | \$ (58,364,715) | \$ (53,716,340) |
| Deemed dividend related to beneficial conversion feature of preferred stock..... | 14,772,878 | 26,782,911 |
| | ----- | ----- |
| Net loss..... | \$ (43,591,837) | \$ (26,933,429) |
| | ===== | ===== |
| Weighted-average shares used in computing net loss per common share, basic and diluted..... | 3,973,250 | 4,732,091 |
| Adjustments to reflect the effect of the assumed conversion of the preferred stock from the date of issuance..... | 17,155,943 | 24,598,775 |
| | ----- | ----- |
| Weighted-average shares used in computing pro forma net loss per common share, basic and diluted..... | 21,129,193 | 29,330,866 |
| | ===== | ===== |
| Pro forma net loss per common share, basic and diluted..... | \$ (2.06) | \$ (0.92) |
| | ===== | ===== |

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NOTE 11--RELATED PARTIES:

Since April 1997, Dr. Adam Heller, the Chief Scientific Advisor, has performed consulting services for the Company. The terms of the consulting agreement provide that the Company pay Dr. Heller a consulting fee of \$1,200 per day, plus reimbursement for travel and business expenses. The agreement has a term of one year with automatic one year renewals. The agreement is terminable by the Company or Dr. Heller upon thirty days written notice. Dr. Adam Heller is the father of Ephriam Heller, Co-Founder, Vice President of Business Development and Director. During 1998, 1999 and 2000, the Company paid Dr. Heller \$55,260, \$85,760 and \$110,141, respectively, in connection with these agreements. At December 31, 1999 and 2000, the Company had no accrued liabilities relating to Dr. Heller's consulting services.

Pursuant to an agreement with Facet Technologies entered into in December 1998, Facet Technologies has provided development services for the FreeStyle lancing device and related products. In exchange for such services, the Company granted Facet Technologies the exclusive right to manufacture the FreeStyle lancing device for a period of seven years from the date of the agreement. A former principal of Facet Technologies is a member of the Company's Board of Directors. During 1998, 1999 and 2000, Facet Technologies provided development services of approximately none, \$200,000 and \$300,000, respectively, and purchases from Facet Technologies totaled none, \$4,675 and \$402,356, respectively. In addition, none and \$27,799 is included in accounts payable at December 31, 1999 and 2000, respectively, and none and \$331,578 is included in accrued liabilities at December 31, 1999 and 2000, respectively, in connection with this agreement.

In November 1999, the Company entered into an agreement with Flextronics International ("Flextronics") related to the manufacturing of the FreeStyle meter. The Company's contract with Flextronics expires in November 2005, and is renewable annually thereafter. A member of the Company's Board of Directors is also President Americas Operations of Flextronics. During 1999 and 2000, the Company purchased \$261,195 and \$20,639,858 under this agreement, respectively. Approximately \$32,606 and \$4,045,179 are included in accounts payable at December 31, 1999 and 2000, respectively, and none and \$314,107 are included in accrued liabilities at December 31, 1999 and 2000, respectively, relating to this agreement.

In October 2000, the Company entered into a Technology Purchase Agreement with E. Heller & Co. The agreement includes a covenant not to compete for three years and provides for the transfer and assignment of several licenses and rights to the Company in exchange for \$500,000. The portion of the payment attributable to the covenant not to compete, of \$50,000, has been capitalized and is being amortized to research and development expense on a straight-line basis over the three-year term. Based upon the early stage of development and the uncertainty as to the feasibility of the technology and its alternative uses, the remaining acquisition cost was immediately expensed to research and development. E. Heller & Co. is controlled by one of the Company's founders, who is also a Vice President of the Company and a member of the Company's Board of Directors.

NOTE 12--EMPLOYEE BENEFIT PLAN:

In October 1997, the Company adopted a defined contribution retirement plan (the "Plan"), which qualifies under Section 401(k) of the Internal Revenue Code of 1996. The Plan covers essentially all employees. Eligible employees may make voluntary contributions to the Plan up to 15% of their annual compensation, subject to statutory annual limitations, and the employer is allowed to make discretionary contributions. The Company has made no contributions to date.

THERASENSE, INC.

NOTES TO FINANCIAL STATEMENTS--(Continued)

NOTE 13--SUBSEQUENT EVENTS (UNAUDITED):

Related Parties

In July 2001, the Company and Facet Technologies amended the December 1998 agreement and entered into a new agreement pursuant to which the Company agrees to purchase the FreeStyle lancing devices and lancets from Facet Technologies until June 1, 2007.

Option Grants

On August 3, 2001, the Company granted a total of 999,800 options to purchase shares of common stock under the 1997 Stock Option Plan to employees and non-employees at an exercise price of \$9.00 per share. The total deferred stock-based compensation related to these grants amounted to \$7,198,560 and will be amortized to expense over the vesting period.

Incentive Stock Plans

In August 2001, the Board of Directors authorized an additional 500,000 shares of common stock to be available for issuance under the 1997 Stock Option Plan from 7,607,032 to 8,107,032, and decreased the number of shares available for issuance under the 2001 Stock Plan by 500,000 from 7,000,000 to 6,500,000.

[INSIDE BACK COVER ART WORK]

DESCRIPTION OF GRAPHIC

Graphic depicts four primary components of our Continuous Glucose Monitoring System - the wireless display unit, the sensor, the spring-loaded insertion device, and the transmitter.

TEXT ACCOMPANYING THE GRAPHIC

"Continuous Glucose Monitoring System."

"Display Unit. Wireless display unit continuously displays glucose levels and trends and stores them for future use."

"Sensor. Disposable sensor provides up to three days of continuous glucose measurement."

"Insertion Device. Insertion device places the sensor beneath the skin."

"Transmitter. Transmitter adheres to the skin and broadcasts glucose readings to the display unit."

"Our Continuous Glucose Monitoring System is in the development stage and has been tested on humans on a very limited basis. Our Continuous Glucose Monitoring System will require further development and regulatory approval or registration

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before it can be marketed in the United States or internationally. Accordingly, the final design of our Continuous Glucose Monitoring System may differ from the conceptual design depicted above."

6,000,000 Shares

THERASENSE, INC.

Common Stock

[THERASENSE INC. LOGO]

PROSPECTUS

Until November 5, 2001, all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

U.S. Bancorp Piper Jaffray

SG Cowen

Thomas Weisel Partners LLC

October 11, 2001