THERASENSE INC
Form 10-K
March 27, 2003
**Table of Contents**

# UNITED STATES

# SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, D.C. 20549**

# FORM 10-K

(Mark One)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

**For the fiscal year ended December 31, 2002**

**OR**

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

**For the transition period from to**

**Commission File Number 000-33139**

# THERASENSE, INC.

**(Exact name of registrant as specified in its charter)**

| **Delaware** | **94-3267373** |
|---|---|
| **(State of incorporation)** | **(IRS Employer Identification No.)** |

**1360 SOUTH LOOP ROAD, ALAMEDA, CA 94502**

**(510) 749-5400**

**(Address, including zip code, and telephone number, including area code, of Registrant s principal executive offices)**

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

None

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

Common Stock, $0.001 par value

---

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

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

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Securities Exchange Act of 1934): Yes x No ¨.

The aggregate market value of the 27,506,178 shares of voting stock held by non-affiliates of the registrant, computed by reference to the closing price, as reported on the Nasdaq National Market, as of the last business day of registrant s most recently completed second fiscal quarter (June 30, 2002), was approximately $508,039,108. Registrant has no non-voting common equity.

There were 40,867,629 shares of the registrant s Common Stock $0.001 par value, issued and outstanding as of March 1, 2003.

**DOCUMENTS INCORPORATED BY REFERENCE**

Certain information is incorporated by reference to the Proxy Statement for the registrant s 2002 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Form 10-K.

Table of Contents

**TABLE OF CONTENTS**

Table of Contents

**PART 1**

## ITEM 1. 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, the Freestyle® Blood Glucose Monitoring System, 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. Most of the competitive products require blood samples from 1.0 to 10.0 microliters. 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 most competitive products. Nine out of ten people in our clinical studies found using FreeStyle less painful than their current finger-stick-based system.

In June 2002, we received 510(k) clearance for and commenced sales of our FreeStyle Tracker System that incorporates the blood glucose monitoring technology from FreeStyle into a module for the Handspring Visor personal digital assistant. In July 2002, we launched our FreeStyle CoPilot System that enables people with diabetes and their health care providers to analyze and communicate glucose information using the Internet. 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.

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 $4.0 billion worldwide. 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.

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 the ten largest national retailers, including Walgreens, Wal-Mart and Rite Aid, through wholesalers, including Cardinal Health, McKesson, and AmerisourceBergen, 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, and since that time has commenced sales in Norway, Finland, Austria, The Netherlands, Denmark, Switzerland, France, Italy and Belgium. In April 2001, we entered into an agreement with Nipro Corporation for the exclusive distribution of FreeStyle in Japan. An application for approval to market FreeStyle in Japan was approved by the Japanese Ministry of Health in January 2002, and Nipro launched FreeStyle in Japan in February 2002. 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

Table of Contents

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 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 17 million people, about 6% of the population, have diabetes, although only approximately 11 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 diabetes. The worldwide prevalence of diabetes is expected to increase to approximately 370 million by 2030.

*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 $132 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, 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

Table of Contents

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 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. 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.

*Large Sample Size.* Most 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. One other blood glucose meter requires a 0.3 microliter sample size, but this sample must be obtained from the pain-sensitive fingertips.

*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. 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.

As a result, we believe a significant market opportunity exists for a glucose self-monitoring system that combines a very small sample size requirement with the ability to test on the fingertip and other body sites. The ability to test on other body sites spares the user the pain associated with testing on the fingertip. The small sample size means the sample can be reliably obtained from other body sites and spares the user the inconvenience and social embarrassment of drawing large blood samples.

**The TheraSense Solution**

FreeStyle is easy to use, accurate and competitively priced. It is the only blood glucose monitoring system that combines a 0.3 microliter sample size requirement with the ability to test on other body sites and the fingertip. 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 most other systems. The extremely small volume of blood required enables people using FreeStyle to obtain blood from their forearm, hand, thigh, upper arm or calf as well as from their fingertips as required by most other systems on the market today. 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.

*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,

Table of Contents

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 has deterred some people with diabetes from testing frequently enough to properly 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 distribution and our sales force. 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 the ten largest chain drug stores, the three largest mass market retailers and the three largest supermarket retailers in the United States. 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 that interact with the retailers at the corporate and district level and geographically dispersed sales representatives that call on health care professionals including pharmacists.

*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 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.

*Expand International Distribution*. We intend to expand our international sales of FreeStyle and enter new global markets primarily through relationships with established health care companies that have developed distribution channels. The Disetronic Group is our exclusive distributor of FreeStyle in selected European countries. Disetronic has commenced sales in Germany, Sweden, Norway, Finland, Austria, The Netherlands, Denmark, Switzerland, France, Italy and Belgium. In April 2001, we entered into an agreement with Nipro Corporation for the exclusive distribution of FreeStyle in Japan. Nipro launched FreeStyle in Japan in February 2002. Disetronic and Nipro are the leading suppliers of insulin

4

Table of Contents

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 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. FreeStyle Tracker is a module for the Handspring Visor personal digital assistant that enables it to act as a glucose monitor and sophisticated diabetes management system. We obtained FDA clearance for FreeStyle Tracker and commenced sales in June 2002.

**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 25, 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 transmitting information to our FreeStyle CoPilot web-based data management system and FreeStyle Connect data management software. 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 and FreeStyle Tracker System.

*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 Tracker Diabetes Management System.* We received FDA clearance for the FreeStyle Tracker System and commenced sales in June 2002. The FreeStyle Tracker System is a diabetes management system that combines the blood glucose monitoring technology of our FreeStyle Blood Glucose Monitoring System with the computing power of the HandSpring Visor personal digital assistant, or PDA. The FreeStyle Tracker System

5

Table of Contents

enables patients to test for glucose levels and get a read-out on the PDA screen, graph and chart the results over time, review food lists to track their carbohydrate intake and create reminders about testing or dietary choices. For doctors, the FreeStyle Tracker System provides a time-stamped progression of the patient s glucose levels as well as patient-entered events and data that affect their diabetic health to make better diagnoses and recommendations for the patient s diabetes care. Patients can use the Hotsync® synchronization function of the PDA to download information from the FreeStyle Tracker System to our FreeStyle CoPilot System and FreeStyle Connect Software.

*FreeStyle CoPilot Web-Based Data Management System.* We launched the FreeStyle CoPilot System in July 2002. The FreeStyle CoPilot System is a free web-based service that we offer to users of blood glucose monitoring products and their permitted health care providers. Users can upload their blood glucose test results and other health-related information from their FreeStyle meter (through a FreeStyle Connect data cable) or FreeStyle Tracker System to the FreeStyle CoPilot or users can manually enter this information into the FreeStyle CoPilot System. The information can then be transferred into personalized reports focusing on integrated issues of diabetes care, including glycemic control, hypertension, hyperlipidemia, and diet. Users can grant permission to their health care providers to access the users information on the FreeStyle CoPilot System.

*FreeStyle Connect Data Management Software.* We received FDA clearance for the FreeStyle Connect software in May 2000 and we launched the FreeStyle Connect software in December 2000. FreeStyle Connect is a data management software product that 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 FreeStyle customers and their health care providers to appropriately adjust customers 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 health care providers. 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, and display of trends;
- elimination of the anxiety of not knowing glucose levels between periodic measurements;
- minimally invasive insertion procedure;
- comfort 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 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 their blood glucose value and whether it is rising, falling or remaining stable. The sensor

Table of Contents

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 have commenced a home-use study to evaluate the safety and efficacy of our Continuous Glucose Monitoring System. Following completion of this study, we will submit a premarket approval application. The premarket approval process requires 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, but may take longer. However, achieving a completed application is a process that may take numerous clinical trials and require filing of amendments over time. Therefore, even if the Continuous Glucose Monitoring System is successfully developed, it may not be commercially available for a number of years.

**Our Sensor Technologies**

We have developed two proprietary miniaturized electrochemical sensor technologies. The first, NanoSample technology, is used in our FreeStyle System and FreeStyle Tracker 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 most 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 usually 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 insertion 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. The sales force includes sale representatives who promote 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, pharmacists and internal medicine physicians. The primary goal of our sales representatives 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. There are also members of our sales force dedicated to serving retail and managed care accounts at the corporate and district level. In addition, our sales force promotes FreeStyle and monitors stocking levels with retail outlets at the individual store level. We believe that our strategy of selling through our own direct sales force is an important factor in achieving market penetration.

7

Table of Contents

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 for the year ended December 31, 2002:

| Retailers | Wholesalers |
|---|---|
| Walgreens | Cardinal Health |
| Wal-Mart | McKesson |
| Rite Aid | AmeriSource Bergen |
| CVS | Peyton s Northern |
| Eckerd | QK Healthcare |

*International.* We intend to expand our international sales efforts for our FreeStyle blood glucose monitoring system 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 February 2002, this agreement was amended to add France, Italy and Belgium to Disetronic s exclusive distribution territory. 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.

Under the 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 or for any other reason upon prior written notice. Disetronic is also entitled to market FreeStyle to Disetronic s pump users in North America. The term of the Disetronic agreement ends in December 2006. Disetronic commenced sales in Germany and Sweden in May 2001. Since that time they have commenced sales in Norway, Finland, Austria, The Netherlands, Denmark, Switzerland, France, Italy and Belgium. In January 2003, we amended our agreement with the Disetronic Group. Pursuant to the amendment, Disetronic Injection Systems will take over distribution of our FreeStyle blood glucose monitoring system from Disetronic Medical Systems. We received $15.0 million pursuant to the amendment, and we will recognize the $15.0 million over the remaining term of the agreement, which expires in December 2006. Although Disetronic Injection Systems will be subject to reduced minimum purchase requirements, Disetronic Injection Systems has committed to increase the sales force currently selling the FreeStyle system in Europe by 50%.

Under the 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 ends in April 2006. FreeStyle received

8

Table of Contents

regulatory approval for marketing in Japan in January 2002, and Nipro launched FreeStyle in Japan in February 2002.

In addition to the countries covered by the distribution agreements with Disetronic Group and Nipro Corporation, as of March 1, 2003, FreeStyle products are sold in 20 other countries through local distributors.

*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 UPS Supply Chain Management, a division of UPS Global Logistics that specializes in providing outsourced distribution services for large pharmaceutical and medical device companies. The initial term of this agreement ends in March 2005. We may terminate this agreement prior to March 2005, subject to payment of a termination fee. UPS Supply Chain Management has an extensive network of distribution centers and a sophisticated order management and product tracking system. UPS Supply Chain Management also manages our billing process. Our relationship with UPS Supply Chain Management 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 days 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. We are currently negotiating an amendment with ICT to, among other things, extend the term of the contract.

**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. The primary components of the FreeStyle Tracker System kit are the FreeStyle Tracker module that is inserted into the HandSpring Visor PDA, 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 to the material used in credit cards.

Flextronics International assisted us in the design of our FreeStyle meter and FreeStyle Tracker module. Flextronics is responsible for manufacturing the FreeStyle meter in China and assembling the FreeStyle System kits in San Jose, California. Flextronics is also responsible for manufacturing the FreeStyle Tracker module and assembling the FreeStyle Tracker System kits in San Jose, California. Flextronics has over 13 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 in San Jose who is responsible for the day-to-day interface with Flextronics. Production release to

finished goods inventory is done through our

Table of Contents

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 our suppliers, such as 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.

**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 March 1, 2003, we had 37 issued U.S. patents and had numerous additional U.S. patent applications pending. We believe it will take up to five years, and possibly longer, for some of 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 October 2019. The issued patents cover, among other things:

- the designs of our FreeStyle meter and FreeStyle strip and FreeStyle lancing device products;
- lancing devices of the type sold with our FreeStyle blood glucose monitoring system;
- aspects of glucose measurement in small sample volumes using electrochemical sensors, such as those using coulometry, those having certain fill detection features, and those having certain sensor chemistries;
- our Wired Enzyme chemistry;
- a one-point calibration method useful in our Continuous Glucose Monitoring System;
- manufacturing processes for sensors useful in our Continuous Glucose Monitoring System;
- certain sensing and electronic components and methods of use for our Continuous Glucose Monitoring System;
- an electrochemical affinity assay system;
- a biological fuel cell; and

electrochemical methods for verifying amplification of nucleic acids.

We have obtained registrations for the trademark TheraSense in the U.S., Canada, Europe and Japan and have applied to register TheraSense in numerous other jurisdictions as well. We have obtained registrations for the trademark FreeStyle in the U.S. and Japan and have applied to register FreeStyle in numerous other jurisdictions including Canada and Europe.

In addition to developing our own technology, we have entered into several license agreements. We have acquired rights to 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 enzyme electrodes, and we are the licensee of resulting inventions. We have also obtained non-exclusive, worldwide licenses to specific patents owned by Asulab SA and Inverness Medical

Table of Contents

Innovations, Inc. 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 our FreeStyle products as well as developing our Continuous Glucose Monitoring System. 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 $12.0 million in 2000, $16.1 million in 2001 and $20.3 million in 2002. 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 and enzyme electrode 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.

**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 and, in some cases, other body sites. All of these competitive products require significantly larger blood samples than required by FreeStyle. Two products cleared for use on the finger and forearm offer a faster test time than FreeStyle, once the required sample has been obtained, and operate over a broader temperature range. Also, a new competitor has recently launched a blood glucose monitoring system that claims the same sample size requirement as the FreeStyle System. However, this product is only cleared for use on the fingertip.

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 our competitors have significantly greater financial and human resources than we do. At this time, there is one cleared and one approved product for continuous glucose monitoring, neither of which is presently approved as a substitute for current glucose self-monitoring devices. The continuous glucose monitoring system developed by Medtronic MiniMed that has been cleared by the FDA, includes an implantable sensor that measures and stores glucose values every five minutes, for a period of two to three days. The Medtronic 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 system can only be accessed by the physician, who must extract the sensor and download the results for viewing using customized software. The second product for continuous glucose monitoring that has been approved by the FDA, developed by Cygnus Inc., is worn on the wrist like a watch and can take glucose readings as frequently as every ten minutes for up to twelve hours at a time.

Table of Contents

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

- improved outcomes for people with diabetes through less painful, more accurate and more convenient testing methods;
- technological leadership in features and reliability;
- equivalent reimbursement from third-party payors among competitive brands;
- customer focus and service;
- effective marketing and distribution;
- acceptance by health care professionals; and
- speed to market.

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

*FDA s Premarket Clearance and Approval Requirements*

Unless an exemption applies, each medical device we wish to commercially distribute in the United States will require either prior 510(k) clearance or prior premarket approval from the FDA. The FDA classifies medical devices into one of three classes. Devices deemed to pose lower risk 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

Table of Contents

on the thigh, calf, upper arm, and hand, in addition to the fingers and forearm. In December 2001, we received 510(k) clearance for certain labeling changes that we made to FreeStyle. In June 2002, we received 510(k) clearance for our FreeStyle Tracker system, our system that incorporates the blood glucose monitoring technology of FreeStyle into a module for the HandSpring Visor handheld computer.

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.

*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 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.

Our Continuous Glucose Monitoring System will require premarket approval. We have commenced a home-use study to evaluate the safety and efficacy of our Continuous Glucose Monitoring System. Following completion of this study, we will submit a premarket approval application. The premarket approval process requires 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 of amendments over time. Therefore, even if the Continuous Glucose Monitoring System is successfully developed, it may not be commercially available for a number of years.

*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

13

Table of Contents

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 or clearance 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:

- 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. The FDA last conducted an inspection of our facility in Alameda, California in May 2001. We were last audited by the Food and Drug Branch of the California Department of Health Services in November 2001.

*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

Table of Contents

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, our quality system was certified by TÜV Product Service, a Notified Body, under the European Union In-Vitro Diagnostic Directive and Medical Device Directive allowing the CE conformity marking to be applied. In December 2002, we underwent a surveillance audit by TÜV Product Service, our Notified Body. At the successful conclusion of this audit, TÜV Product Service recommended continuation of our ability to apply CE conformity marking.

Nipro Corporation is our exclusive distributor in Japan. Nipro s application for approval to market FreeStyle in Japan submitted to the Ministry of Health, Labor and Welfare was approved in January 2002.

**Third-Party Reimbursement**

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

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

Table of Contents

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.

*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 Shamoon, 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. Shamoon 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 with us.

Currently the following persons comprise our educator advisory board:

*Jo Ann Ahern, APRN, MSN, CDE* is the Diabetes Clinical Nurse Specialist for Pediatric and Adult Type I patients at the Yale New Haven Hospital, New Haven, Connecticut. She presents and publishes extensively in diabetes-related matters and was involved in the landmark Diabetes Control and Complications Trial.

*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.

*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 childrens diabetes camps. Dr. Christensen publishes extensively on diabetes treatment and dietetics.

*Debbie Hinnen ARNP, CDE, BC-ADM* is the Manager, Diabetes Services at the Via Christi Regional Medical Center in Wichita, Kansas. She has held numerous national positions with diabetes professional organizations and publishes extensively on diabetes management.

*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.

*Kimberly J. Krapek, RN, MS, CDE* is the President and Owner of Diabetes Education and Consulting, an independent consulting business with an emphasis on direct diabetes care and education in collaboration with endocrinologists and primary care physicians. She has been actively involved in several diabetes medical research programs.

Table of Contents

*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.

*Jane Seley, RN, BSN, MPH, MSN, GNP, CDE, CHES* is Clinical Coordinator/Nurse Practitioner for Endocrine Associates at Mount Sinai Medical Center in New York, New York and the Diabetes Management Program Director at Beth Israel Medical Center Continuum Center for Health & Healing in New York, New York. She is also a Doctoral fellow in the Division of Nursing at New York University in New York City.

*Kris Swenson RN, CDE* is the Director of Clinical Services for Diabetes Management and Training Centers in Tempe, Arizona, an organization that trains people with diabetes and health care professionals how to effectively manage diabetes. She has been actively involved in diabetes management training and establishing training centers.

**Employees**

As of March 1, 2003, we had 456 full-time employees and one part-time employee. 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.

**Internet Information**

Copies of our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 are available free of charge through our website (www.therasense.com) as soon as reasonably practicable after we electronically file the material with, or furnish it to, the Securities and Exchange Commission.

**ITEM 2. PROPERTIES**

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 on or about March 31, 2013. 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 June 2003. We have completed construction of an approximately 65,000 square foot expansion of the manufacturing,

warehouse and office areas at our main building at 1360 South Loop Road. We also have the ability to construct additional space on a parcel of land adjacent to 1360 South Loop Road. We believe that our current facilities and ability to expand further will be sufficient for the next few years.

**ITEM 3. LEGAL PROCEEDINGS**

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

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

We did not submit any matters to a vote of security holders during the fourth quarter of the fiscal year ended December 31, 2002.

Table of Contents

## PART II

### ITEM 5. MARKET FOR THE REGISTRANT S COMMON STOCK AND RELATED STOCKHOLDER INFORMATION

**Market Information**

Our Common Stock is traded on the Nasdaq National Stock Market under the symbol THER . The following table shows the high and low closing sale prices of our Common Stock for each quarterly period since the date of our initial public offering in October 2001 as reported on the Nasdaq National Stock Market:

| | High | Low |
|---|---|---|
| **2001** | | |
| Fourth Quarter (10/12/01 through 12/31/01) | $ 26.12 | $ 22.26 |

| | High | Low |
|---|---|---|
| **2002** | | |
| First Quarter | $ 23.39 | $ 18.75 |
| Second Quarter | $ 25.21 | $ 16.87 |
| Third Quarter | $ 17.54 | $ 12.70 |
| Fourth Quarter | $ 13.65 | $ 5.16 |

The closing sale price of our Common Stock on the Nasdaq National Stock Market on March 3, 2003 was $8.40.

**Holders**

As of March 3, 2003, we had approximately 213 stockholders of record.

**Dividends**

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

**Use of Proceeds and Changes in Securities**

In October 2001, we closed our initial public offering of 6,900,000 shares of our common stock at a per share price of $19.00 pursuant to a Registration Statement on Form S-1 (Registration No. 333-64456), which was declared effective on October 11, 2001.

To date, we have spent a portion of the net proceeds as follows (i) approximately $6.0 million for the purchase of capital equipment, (ii) approximately $3.0 million to expand our facility in Alameda, California, (iii) approximately $18.0 million to sponsor free product samples and accelerate the hiring of additional sales representatives, (iv) approximately $4.0 million for research and development of enhanced FreeStyle products and our Continuous Glucose Monitoring System and (v) approximately $25.0 million for general working capital purposes. We are currently investing the remaining net proceeds from the offering for future use as additional working capital. Such remaining net proceeds have been invested in highly liquid instruments, such as commercial paper and U.S. Government obligations, with an average maturity of twelve months or less.

From January 1, 2002 through December 31, 2002, we did not issue any unregistered securities.

Table of Contents

**ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA**

The selected consolidated financial data set forth below are derived from our consolidated financial statements. The consolidated statement of operations data for the years ended December 31, 1998 and 1999, and the consolidated balance sheet data as of December 31, 1998, 1999 and 2000 are derived from our audited consolidated financial statements not included in this report. The consolidated statement of operations data for the years ended December 31, 2000, 2001 and 2002, and the consolidated balance sheet data as of December 31, 2001 and 2002 are derived from our audited consolidated financial statements included in this report. Historical results are not necessarily indicative of future results. The selected consolidated financial data set forth below should be read in conjunction with our consolidated financial statements, the related notes and Management s Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this report.

| | Years Ended December 31, | | | | |
|---|---|---|---|---|---|
| | 1998 | 1999 | 2000 | 2001 | 2002 |
| | (in thousands, except per share data) | | | | |
| **Consolidated Statement of Operations Data:** | | | | | |
| Product sales | $ | $ 25 | $ 5,000 | $ 71,105 | $ 176,708 |
| License income | | | 500 | 750 | 1,000 |
| Research grant revenue | 60 | 60 | 3 | | |
| Total revenues | 60 | 85 | 5,503 | 71,855 | 177,708 |
| Cost of revenues | | | 11,948 | 49,147 | 92,835 |
| Gross profit (loss) | 60 | 85 | (6,445) | 22,708 | 84,873 |
| Operating expenses: | | | | | |
| Research and development | 3,056 | 7,672 | 12,019 | 16,103 | 20,253 |
| Selling, general and administrative | 1,810 | 5,557 | 25,460 | 60,458 | 94,897 |
| Total operating expenses | 4,866 | 13,229 | 37,479 | 76,561 | 115,150 |
| Loss from operations | (4,806) | (13,144) | (43,924) | (53,853) | (30,277) |
| Interest income, net | 142 | 86 | 332 | 987 | 1,115 |
| Net loss | (4,664) | (13,058) | (43,592) | (52,866) | (29,162) |
| Deemed dividends related to beneficial conversion feature of preferred stock | | | (14,773) | (26,783) | |
| Net loss attributable to common stockholders | $ (4,664) | $ (13,058) | $ (58,365) | $ (79,649) | $ (29,162) |
| Net loss per common share, basic and diluted | $ (2.31) | $ (4.32) | $ (14.69) | $ (6.70) | $ (0.73) |
| Weighted-average shares used in computing net loss per common share, basic and diluted | 2,015 | 3,024 | 3,973 | 11,891 | 40,129 |

| | As of December 31, |
|---|---|

| | 1998 | 1999 | 2000 | 2001 | 2002 |
|---|---|---|---|---|---|
| | | | (in thousands) | | |
| **Consolidated Balance Sheet Data:** | | | | | |
| Cash, cash equivalents and investments | $ 11,438 | $ 2,322 | $ 12,532 | $ 147,465 | $ 77,910 |
| Working capital | 10,956 | 792 | 4,240 | 128,408 | 90,737 |
| Total assets | 12,379 | 8,026 | 37,565 | 206,576 | 160,803 |
| Deferred revenue | 11 | 511 | 8,687 | 26,970 | 3,261 |
| Long-term obligations, less current portion | 520 | 3,321 | 7,994 | 4,255 | 3,161 |
| Convertible preferred stock | 17,361 | 20,472 | 62,883 | | |
| Deferred stock-based compensation, net | | (1,244) | (11,263) | (20,995) | (11,642) |
| Accumulated deficit | (6,074) | (19,132) | (62,724) | (115,589) | (144,752) |
| Total stockholders equity (deficit) | (6,047) | (18,159) | (59,848) | 133,539 | 115,589 |

Table of Contents

**ITEM 7. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*This Management s Discussion and Analysis of Financial Condition and Results of Operations and other parts of this report contain forward-looking statements that involve risks and uncertainties. These statements typically may be identified by the use of forward-looking words or phrases such as believe, expect, intend, anticipate, should, planned, estimated, and potential, among others. All forward-l statements included in this document are based on our current expectations, and we assume no obligation to update any such forward-looking statements. The Private Securities Litigation Reform Act of 1995 provides a safe harbor for such forward-looking statements. In order to comply with the terms of the safe harbor, we note that a variety of factors could cause actual results and experience to differ materially from the anticipated results or other expectations expressed in such forward-looking statements. The risks and uncertainties that may affect the operations, performance, development, and results of our businesses include but are not limited to: (1) our history of losses and variable quarterly results; (2) our dependence on FreeStyle for future revenues; (3) our limited sales and marketing experience; (4) substantial competition; (5) risks related to failure to protect our intellectual property and litigation in which we may become involved; (6) risks relating to development of innovative products; (7) risks related to noncompliance with FDA regulations; (8) limited manufacturing experience and our reliance on single manufacturers and sole source suppliers; and (9) other factors that are described from time to time in our periodic filings with the Securities and Exchange Commission, including those set forth in this filing as Risk Factors Affecting Operations and Future Results .*

*All percentage amounts and ratios were calculated using the underlying data in thousands. Operating results for the year ended December 31, 2002, are not necessarily indicative of the results that may be expected for any future period.*

**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 and Canada 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 and commenced sales of FreeStyle in Finland, Austria, Norway, the Netherlands, Denmark, Switzerland, France, Italy and Belgium since that time. In January 2002, we obtained regulatory approval to market FreeStyle in Japan, and our Japanese distributor launched FreeStyle in Japan in February 2002. We also sell FreeStyle in the United Kingdom through retailers and wholesalers. Our sales of FreeStyle products in Canada and the United Kingdom are through a wholly-owned subsidiary in each country.

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 UPS Supply Chain Management f/d/b/a Livingston Health Care Systems Inc., a division of UPS Global Logistics.

Manufacturers typically sell their glucose monitoring system kits at 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 currently distribute the FreeStyle System kit at a financial loss due in part to samples, discounts and rebates to establish an installed base of systems from which we expect to generate recurring revenues from our disposable FreeStyle test strips and lancets. We have been offering and expect to continue to offer similar discounts and rebates on, and free samples of, our FreeStyle System kits. In

20

Table of Contents

the event we establish a large installed base of systems, we expect to generate an increasing portion of our revenues through recurring sales of our FreeStyle test strips.

Revenues are generated from sales of our FreeStyle System kit and from the recurring sales of disposable FreeStyle test strips and lancets. We recognize revenue on these products upon shipment. Generally, our 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. However, we have occasionally granted longer credit terms to match our competitors. 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 rights to return and payment terms, are similar to our competitors terms.

We have incurred significant operating losses and negative cash flows from operations since inception. We incurred net losses of $43.6 million in 2000, $52.9 million in 2001 and $29.2 million in 2002. As of December 31, 2002 we had an accumulated deficit of $144.8 million. We will need to continue to increase product revenues and reduce product costs to achieve profitability.

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;
- royalties payable under technology licenses; and
- amortization of deferred stock-based compensation.

Research and development expenses include costs associated with the design, development and testing of our products. All research and development costs are expensed as incurred. 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;

overhead allocated to product development; and

amortization of deferred stock-based compensation.

Selling, general and administrative expenses primarily consist of:

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

costs associated with advertising, product sampling, trade shows, promotional and other marketing activities;

general corporate expenses;

legal and regulatory expenses; and

amortization of deferred stock-based compensation.

We estimate the uncollectability of our accounts receivable. In doing so, we analyze historical bad debts, customer concentrations, customer credit-worthiness, current economic trends and changes in customer payment terms.

Table of Contents

We have recorded deferred stock-based compensation in connection with stock option grants and sales of restricted 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 December 31, 2002 we have recorded aggregate deferred stock-based compensation of $25.1 million, of which $11.6 million will be amortized to expense on a straight line basis through 2006. This amount is being amortized over the respective vesting periods of these equity instruments, which is typically four years. Stock-based compensation expense has been allocated according to employees and their respective departments and by function for non-employees.

**Critical Accounting Policies and Estimates**

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, including those related to investments, income taxes, litigation and other contingencies. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. Management has discussed each of the critical accounting policies and estimates described below with the audit committee of our board of directors.

*Revenue Recognition*

We believe the following allowances and reserves which are utilized to reduce gross sales to an amount which we recognize as revenue represent our more significant judgments and estimates used in the preparation of our consolidated financial statements. For proper matching of costs and revenues, these allowances and reserves are created in the period when the revenue is recognized based on anticipated future events. If there are unanticipated changes in future events, then a reserve or allowance may need to be adjusted to a revised level impacting the period in which the adjustment is taken and causing variability in our financial results.

*Allowances for sales returns.* Our return policy allows end users in the United States and Canada 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 and Canada can return these products to us up to six months beyond this expiration date. We use historical trends and experience to estimate future product returns and create an allowance for sales returns. For the year ended December 31, 2002, the allowance for sales returns was 1.6% of gross sales. In the years ended December 31, 2000 and 2001, we did not have sufficient historical trends to estimate an allowance for sales returns. As a result, we deferred the recognition of revenue on sales of FreeStyle test strips until resold by retailers and wholesalers to end users, and we deferred recognition of revenue on Freestyle System Kits until 30 days after purchase by the end user.

*Reserve for consumer rebates.* FreeStyle System kits sold through retailers and wholesalers generally include a $40 consumer rebate. Based on historical trends and experience we determine a reserve for consumer rebates by applying an estimate of future redemption rates to the base of FreeStyle System kits sold through retailers and wholesalers. For the year ended December 31, 2002, the reserve for consumer rebates was 0.3% of gross sales. In the years ended December 31, 2000 and 2001, we did not have sufficient historical experience to estimate a reserve for consumer rebates. As a result, we assumed a 100% redemption rate.

22

Table of Contents

*Reserve for sales coupons.* We utilize sales coupons to promote sales to end users in the United States of America. Historically, our coupon programs have primarily promoted the sale of our FreeStyle System kits. These coupons are distributed through retailer circulars, national print advertisings, and direct mail programs. They are also distributed to health care professionals through our direct sales force. Based on historical trends and experience, we determine a reserve for sales coupons by estimating a future redemption rate for each promotional program and applying it to the applicable base of outstanding coupons. This estimate is difficult because each promotional program has unique characteristics and there is a substantial lag between distribution of the coupon and its redemption. There is a time lag between when the coupon is distributed and when an end user takes it to a retailer. The retailer then waits until a number of coupons have been accumulated before sending them to our third-party processor. For the years ended December 31, 2000, 2001 and 2002, the reserves for sales coupons were 4.0%, 1.3% and 0.6% of gross sales, respectively. The decrease reflects increased sales of FreeStyle test strips versus FreeStyle System kits and increased revenue from international sales of our FreeStyle products as a percentage of our total revenues.

*Reserve for Warranties*

We believe the following reserve which is utilized to determine our cost of revenues represents one of our more significant judgments and estimates used in the preparation of our consolidated financial statements. Our FreeStyle meter is sold with a five-year warranty. Our reserve for warranties is estimated in the period that revenues are recognized and is determined based on historical trends and experience with warranty replacement and the cost of replacement. For the years ended December 31, 2000, 2001 and 2002, the reserves for warranties were 1.8%, 1.3% and 1.1% of gross sales, respectively. The decrease reflects historical experience with a lower number of warranty returns and lower cost of warranty replacement due to lower FreeStyle meter production costs.

*Inventory Reserves*

We believe the following reserves which are utilized to reduce the value of our inventory represent one of our more significant judgments and estimates used in the preparation of our consolidated financial statements. Our inventory reserves are primarily related to our inventory of FreeStyle System kits. We employ two types of inventory reserves net realizable value reserve, or NRV reserve, and excess and obsolete reserve, or E&O reserve. Both the NRV reserves and E&O reserves are based on management s analysis of inventory levels and sales forecasts.

*NRV Reserve*. When the market value of our inventory is less than the cost of the inventory, we establish a NRV reserve. The market value of our inventory is based on the average sales price of the product, less reserves for returns, rebates and coupons and estimated selling expenses. We have been offering and expect to continue to offer discounts and rebates on 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. The cost of our inventory is based on standard cost, which approximates actual cost on a first-in first-out basis. As of December 31, 2000 and 2001, our NRV reserve was approximately 65% and 33% of finished goods inventory, respectively. This decrease reflects the reduction of our FreeStyle System kit manufacturing costs. As of December 31, 2002, we did not have a NRV reserve as the market value for our FreeStyle System kits equaled or exceeded their costs.

*E&O Reserve.* We also establish an E&O reserve to adjust the carrying value of impaired inventories to salvage or recoverable value. Excess inventory is defined as the inventory in stock beyond the next twelve months of estimated demand. Obsolete inventory is defined as in stock inventory that either has not sold through within six months of taking title to the inventory or is no longer used in finished goods due to product changes. As of December 31, 2000, we did not have any E&O reserve as we commenced commercial sales of our FreeStyle products in the second half of the year. As of December 31, 2001, our E&O reserve was approximately 5% of total inventory resulting primarily from our transition to a lower cost FreeStyle System kit. As of

23

Table of Contents

December 31, 2002, we did not have any E&O reserve as none of our inventory fell within our E&O reserve policy.

*Allowance for Doubtful Accounts*

We believe the following allowances and reserves which are utilized to reduce our accounts receivable to an amount that we believe can be collected from our customers represent one of our more significant judgments and estimates used in the preparation of our consolidated financial statements. In estimating the uncollectability of our accounts receivable, we analyze historical bad debts, customer concentrations, customer credit-worthiness, current economic trends and changes in customer payment terms. In 2000, our four 10% or more customers accounted for 53% of our revenues. In 2001, our two 10% or more customers accounted for 27% of our revenues. In 2002, our two 10% or more customers accounted for 21% of our revenues. Generally, we do not require collateral from our domestic customers, and we do not require collateral from our two principal international distributors. For our other international customers, accounts receivable balances are generally collateralized by irrevocable letters of credit.

Our estimate for the allowance for doubtful accounts related to accounts receivable is based on two methods. The amounts calculated for each of these methods are combined to determine the total amount reserved. First, we evaluate specific accounts where we have information that the customer may have an inability to meet its financial obligations. In these cases, we use our judgment, based on the best available facts and circumstances, and record a specific reserve for that customer against amounts due to reduce the receivable to the amount that is expected to be collected. These specific reserves are reevaluated and adjusted as additional information is received that impacts the amount reserved. Second, a general reserve is established for all customers based on a percentage applied to the outstanding accounts receivable amount. This percentage is based on historical collection and write-off experience. As of December 31, 2000, 2001 and 2002, the allowance for doubtful accounts was 2.2%, 3.8% and 2.2% of accounts receivable, respectively. The increase in 2001 reflects an increase in our general reserve for sales to a new class of customers, and we decreased our 2002 general reserve to an amount in line with our 2000 reserve based on our historical experience with these customers. If circumstances change, such as higher than expected defaults or an unexpected material adverse change in a major customer s ability to meet its financial obligation to us, our allowance for doubtful accounts could be increased.

Table of Contents

**Results of Operations**

The following table sets forth, for the fiscal years indicated, the percentage of total revenues represented by certain items reflected in our consolidated statements of operations:

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2000 | 2001 | 2002 |
| **Revenues:** | | | |
| Product sales | 90.9% | 99.0% | 99.4% |
| License income | 9.1 | 1.0 | 0.6 |
| Research grant revenue | | | |
| Total revenues | 100.0 | 100.0 | 100.0 |
| Cost of revenues | 217.1 | 68.4 | 52.2 |
| Gross profit (loss) | (117.1) | 31.6 | 47.8 |
| **Operating expenses:** | | | |
| Research and development | 218.4 | 22.4 | 11.4 |
| Selling, general and administrative | 462.6 | 84.1 | 53.4 |
| Total operating expenses | 681.0 | 106.5 | 64.8 |
| Loss from operations | (798.1) | (74.9) | (17.0) |
| Interest income | 27.0 | 3.0 | 1.3 |
| Interest and other expense | (21.0) | (1.7) | (0.7) |
| Net loss | (792.1)% | (73.6)% | (16.4)% |

*Years Ended December 31, 2000, 2001 and 2002*

*Revenues.* 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. Revenues in 2000 also included $0.5 million from a specific non-refundable negotiation fee related to a potential distribution arrangement, which was never consummated. In 2000, four of our customers, CVS, Walgreens, Wal-Mart and McKesson, individually accounted for more than 10% and collectively accounted for approximately 53% of our product shipments for that year.

Revenues recognized in 2001 totaled $71.9 million, principally consisting of sales of FreeStyle test strips and FreeStyle System kits. The increase in revenues from 2000 to 2001 is primarily attributable to an increase in our installed base of end users resulting in increased sales of FreeStyle products to our customers and our expansion into international markets. In 2001, one of our customers, McKesson, and our European

distributor, Disetronic, individually accounted for more than 10% and collectively accounted for approximately 27% of our product shipments for that year. As of December 31, 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 $22.7 million. Revenues in 2001 also included $0.8 million related to the $5.0 million distribution agreement payment received from Nipro.

Revenues recognized in 2002 totaled $177.7 million, principally consisting of sales of FreeStyle test strips and FreeStyle System kits. This includes a $20.4 million contribution from achieving the ability to estimate product return rates for sales to retailers and wholesalers in the United States and Canada beginning with the quarter ended June 30, 2002. Prior to the quarter ended June 30, 2002 we deferred revenue recognition until product had been purchased by an end-user and all rights of return had lapsed. The increase in total revenues over the comparable period of 2001 was 119% before the $20.4 million contribution. The increase in revenues from 2001 to 2002 is primarily attributable to an increase in our installed base of end users resulting in increased sales of FreeStyle products to our customers and our expansion into international markets. We believe that revenues

Table of Contents

for 2003 will be greater than revenues for 2002 but the percentage increase will be substantially lower than the 119% increase in 2002 revenues compared to 2001 revenues. Due to the recognition of previously deferred revenues from product sales during the quarter ended June 30, 2002, there were no deferred revenues from product sales as of December 31, 2002. In 2002, one of our customers, Cardinal Health, and our European distributor, Disetronic, individually accounted for more than 10% and collectively accounted for approximately 21% of our product shipments for that year.

*Cost of revenues.* 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 deferred stock-based compensation 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 in 2000.

Cost of revenues in 2001 was $49.1 million, attributable to product sales, as there was no cost associated with the license fee income earned. The increase in cost of revenues from 2000 to 2001 is primarily attributable to increased purchases of FreeStyle System kits and FreeStyle lancets from our contract manufacturing partners. As a percentage of revenues, the cost of revenues in 2001 was 68.4% versus 217.1% in 2000. This decrease reflects increased sales of lower cost FreeStyle test strips versus FreeStyle System kits. Amortization of deferred stock-based compensation reported in cost of revenues for the year ended December 31, 2001 was $0.5 million, as compared to an insignificant amount in the prior year.

Cost of revenues in 2002 was $92.8 million and was attributable to product sales. The increase in cost of revenues from 2001 to 2002 is primarily attributable to increased purchases of FreeStyle System kits and FreeStyle lancets from our contract manufacturing partners. This increase includes a $16.2 million charge associated with the recognition of previously deferred revenues. The increase in cost of revenues over the comparable period of 2001 was 56% excluding the $16.2 million charge. This increase is due to higher total revenues, which grew by 119% compared with total revenues for the comparable period in 2001, before the $20.4 million contribution. As a percentage of revenues and after excluding the $20.4 million contribution to revenues and the $16.2 million charge, the cost of revenues in 2002 was 48.7% versus 68.4% in 2001. This decrease reflects increased sales of lower cost FreeStyle test strips versus FreeStyle System kits and manufacturing cost reductions for FreeStyle test strips and FreeStyle System kits. Amortization of deferred stock-based compensation reported in cost of revenues for the year ended December 31, 2002 was $0.6 million, as compared to $0.5 million in the prior year. We believe that, as a percentage of revenues, cost of revenues will be lower in 2003 than in 2002.

*Research and development expenses.* Research and development expenses increased from $12.0 million in 2000 to $16.1 million in 2001 to $20.3 million in 2002. The increase from 2000 to 2001 was primarily attributable to $2.7 million from increased spending on product development efforts, $1.6 million from hiring additional personnel and $0.4 million spent on clinical trials. 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 year ended December 31, 2001 over research and development expenses for the year ended December 31, 2000. As a percentage of revenues, research and development expenses in 2001 were 22.4% versus 218.4% in 2000. The increase from 2001 to 2002 was primarily attributable to $2.1 million from increased spending on product development efforts, $1.7 million from hiring additional personnel and $0.4 million spent on clinical trials. As a percentage of revenues, research and development expenses in 2002 were 11.4% versus 22.4% in 2001. Amortization of deferred stock-based compensation increased from $0.6 million in 2000 to $1.3 million in 2001 and remained at $1.3 million in 2002. We expect research and development spending to increase in absolute dollars 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 $22.5 million in 2000 to $60.5 million in 2001 and to $94.9 million in 2002. The increase from 2000 to 2001 was primarily attributable to increases of $18.4 million for marketing activities and other spending associated with expanding distribution and developing consumer awareness of FreeStyle, including product sampling, $8.0 million for personnel costs largely related to expanding our U.S. direct sales force as well as marketing and business support functions, $2.0 million spent for customer service and support operations, and $1.7 million for travel costs, largely related to our sales force. As a percentage of revenues, selling, general and administrative expenses in 2001 were 84.1% versus 462.6% in 2000. The increase from 2001 to 2002 was primarily attributable to increases of $12.7 million for our retail sales force and personnel costs related to expanding our U.S. and international sales force, $11.2 million spent on product sampling, advertising, trade shows, exhibits and meetings, $4.1 million for our international expansion, $3.0 million for sales data services and computer services, and $2.6 million for travel costs. As a percentage of revenues, selling, general and administrative expenses in 2002 were 53.4% versus 84.1% in 2001. Amortization of deferred stock-based compensation increased from $1.2 million in 2000 to $3.8 million in 2001 and to $4.2 million in 2002. We expect our selling, general and administrative expenses to increase in absolute dollars as we increase product sampling, expand our sales force, increase our marketing and promotional activities, and operate as a public company. As a percentage of revenues, we expect selling, general and administrative expenses to decrease in 2003.

*Interest income.* Interest income increased from $1.5 million in 2000, to $2.2 million in 2001 and to $2.3 million in 2002. Interest income increased in 2001 from 2000 due to higher average cash, cash equivalents and investments balances, resulting from the net proceeds of a private equity offering closed in April 2001 and from the net proceeds of our initial public offering in October 2001. Interest income in 2002 from 2001 increased slightly due to the full year effect of higher average cash, cash equivalents and investments balances, resulting from the net proceeds of our initial public offering in October 2001, offset by the cash consumed during 2002.

*Interest and other expense.* Interest and other expense has remained at approximately $1.2 million in 2000, 2001 and 2002. Interest expense reflects the interest on 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.

*Provision for income taxes.* We incurred net operating losses for the years ended December 31, 2000, 2001 and 2002 and, accordingly, we did not pay any federal or state income taxes. As of December 31, 2002, we had accumulated approximately $108.9 million and $49.2 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 2006. Our net operating loss carryforwards are subject to annual limitation under Internal Revenue Code Section 382 due to substantial changes in ownership. Ownership changes as defined by Internal Revenue Code Section 382 have already occurred as a result of certain of our equity financings. 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, 2002 of approximately $1.6 million and $1.4 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.

*Dividends related to beneficial conversion feature of preferred stock.* The difference between the preferred stock purchase price and the fair market value of our common stock on the preferred stock issuance date resulted in a beneficial conversion feature, which has been reflected as

preferred stock dividends. Dividends relating to

Table of Contents

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. Dividends relating to beneficial conversion of our preferred stock of $26.8 million were recorded in the year ended December 31, 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.

**Quarterly Results of Operations**

The following table sets forth selected quarterly statement of consolidated operations data for each of the eight quarters indicated below. This information is derived from our unaudited consolidated 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 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | March 31, 2001 | June 30, 2001 | September 30, 2001 | December 31, 2001 | March 31, 2002 | June 30, 2002 | September 30, 2002 | December 31, 2002 |
| | (Unaudited, in thousands) | | | | | | | |
| Revenues. | $ 7,677 | $ 17,847 | $ 19,858 | $ 26,473 | $ 33,279 | $ 59,227 | $ 39,029 | $ 46,172 |
| Cost of revenues | 6,225 | 13,443 | 12,938 | 16,541 | 18,408 | 34,428 | 18,362 | 21,650 |
| Gross profit | 1,452 | 4,404 | 6,920 | 9,932 | 14,871 | 24,799 | 20,667 | 24,522 |
| Operating expenses: | | | | | | | | |
| Research and development | 2,798 | 3,534 | 4,671 | 5,100 | 4,441 | 6,046 | 5,332 | 4,510 |
| Selling, general and administrative | 11,033 | 15,810 | 15,250 | 18,365 | 21,905 | 22,159 | 24,991 | 25,753 |
| Total operating expenses | 13,831 | 19,344 | 19,921 | 23,465 | 26,346 | 28,205 | 30,323 | 30,263 |
| Loss from operations | (12,379) | (14,940) | (13,001) | (13,533) | (11,475) | (3,406) | (9,656) | (5,741) |
| Interest income, net | 199 | 187 | 76 | 525 | 490 | 310 | 308 | 7 |
| Net loss | $ (12,180) | $ (14,753) | $ (12,925) | $ (13,008) | $ (10,985) | $ (3,096) | $ (9,348) | $ (5,734) |

*Revenues.* The increase in revenues reflects increased market acceptance of FreeStyle. The increase in revenue in the quarter ended June 30, 2002 includes a $20.4 million contribution from achieving the ability to estimate product return rates for sales to retailers and wholesalers in the United States and Canada. We believe that revenues for the first quarter of 2003 will be lower than revenues in the fourth quarter of 2002, as we balance and reduce inventory levels in our distribution channels.

*Gross profit.* Gross profit 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 sequential increase in gross profit resulted from higher sales volume and an increased percentage of FreeStyle test strip revenues versus FreeStyle System kit revenues. Also favorably influencing gross profit has been our ability during 2002 to reduce the manufacturing costs of both the FreeStyle System kit and FreeStyle test strips by 45% and 25%, respectively. The gross profit in the quarter ended June 30, 2002 includes a $4.2 million contribution from

achieving the ability to estimate product return rates for sales to retailers and wholesalers in the United States and Canada.

*Operating expenses.* The increase in cost of revenues for the quarter ended June 30, 2002 includes a $16.2 million charge associated with the recognition of previously deferred revenues. 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. Research and development expenses increased

Table of Contents

during 2001 and 2002 due to increased spending on product development efforts, hiring of additional personnel, and clinical trials. Selling, general and administrative expenses increased throughout 2001 and 2002, 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 related to increases in product sampling to stimulate consumer adoption of FreeStyle.

**Liquidity and Capital Resources**

On October 17, 2001 we consummated our initial public offering of common stock in which we received net proceeds of $120.9 million. Previously, 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 capital leases with $8.3 million in principal outstanding at December 31, 2002.

Our current principal debt arrangements include a $2.5 million equipment line of credit at effective interest rates between 8.5% and 9.5% per annum with a lending company, a $3.0 million equipment line of credit at an interest rate of 7.28% with a lending company and a $2.0 million senior loan and security agreement at an effective interest rate of 13.1% per annum with a lending company. These effective annual interest rates include the amortization of the fair value of warrants issued to one of the lending companies.

In March 2002, we entered into an arrangement to finance the purchase of certain equipment we use to manufacture our FreeStyle test strips with our supplier of test strip packaging vials. The purchase price of the equipment is approximately $1.6 million. The financed purchase price has an interest rate of 7.0% per year. We pay the equipment purchase price to the supplier through a portion of the purchase price for each packaging vial purchased from the supplier. As of December 31, 2002, we have paid to the supplier approximately $187,900, consisting of approximately $70,400 in principal and approximately $117,500 in interest, pursuant to the financing arrangement. We will take title to the equipment once the equipment purchase price has been paid in full. We must pay the equipment purchase price to the supplier by not later than June 2008. The supplier has financed the equipment pursuant to a loan arrangement with a bank. The supplier s loan obligations to the bank are collateralized by the equipment. If the supplier defaults on its loan obligations to the bank, we must assume and satisfy the supplier obligations to the bank in order to take title to the equipment.

In May 2002, we entered into a revolving line of credit agreement with a lending company, which was amended and restated in December 2002. Under the terms of the credit agreement, amounts we borrow from the lending company are repaid to the lending company directly by our accounts receivable debtors. Outstanding amounts owed to the lending company under the credit agreement are collateralized by all of our assets excluding our intellectual property assets. The maximum amount we may borrow from the lending company is based on our eligible accounts receivable and cannot exceed $15.0 million. All outstanding amounts bear interest at the prime rate plus 0.5%. As of December 31, 2002, $3.0 million in principal was outstanding under the credit agreement.

As of December 31, 2002, we had cash, cash equivalents and investments of $77.9 million. In the first quarter of 2003, we received a $15.0 million payment from Disetronic, our European distributor, pursuant to the amendment of our international distributor agreement. We will recognize this payment over the remaining term of the international distributor agreement, which will expire in December 2006.

*Cash used in operating activities.* Net cash used in operating activities was approximately $36.8 million, $36.6 million and $64.0 million for the years ended December 31, 2000, 2001, and 2002, respectively. For the year ended December 31, 2000, increases in accounts receivable and inventories were partially offset by increases in deferred revenue, accounts payable, and accrued liabilities, which reflect commencement of commercial product shipments in June 2000. For the year ended December 31, 2001, increases in deferred revenues in line with increased

revenues, accounts payable as our operations expanded, and accrued liabilities due to increasing reserves for rebates and marketing costs exceeded the increases in accounts receivable and

Table of Contents

inventories due to our expanding operations, reduced the net cash used in operating activities in 2001. For the year ended December 31, 2002, decreases in deferred revenues due to estimations based on historical trends, accounts payable due to controlled disbursements, and increases in accounts receivable and inventories as we expanded operations, increased the net cash used in operating activities in 2002.

*Cash provided by or used in investing activities.* Net cash used in investing activities was approximately $8.0 million and $52.0 million for the years ended December 31, 2001 and 2002, respectively. For these periods, investing activities consisted of capital expenditures of $3.7 million and $11.0 million, respectively, and purchases, net of maturities, of investments of $4.3 million and $44.0 million, respectively. 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 and $2.1 million in capital expenditures.

*Cash provided by financing activities*. Net cash provided by financing activities was approximately $46.4 million, $175.2 million, and $5.1 million for the years ended December 31, 2000, 2001 and 2002, respectively. The net cash provided by financing activities was primarily attributable to the proceeds from private placements of equity securities, proceeds from long-term borrowings, and proceeds from initial public offering in October 2001. During 2002, the Company entered into a credit agreement with a lending company and borrowed $14.6 million and had repaid $11.6 million by December 31, 2002. Part of these proceeds were used to pay down higher interest bearing lines of credit.

We expect to have negative cash flows from operations for most of 2003. 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 expenditure for the year ended December 31, 2002 was $11.0 million, and we believe that our capital expenditure for the next 12 months will remain in line with our 2002 expenditure. We believe that our current cash, cash equivalents and investment balances, together with the revenue to be derived from sales of FreeStyle, will be sufficient to fund our operations until we become profitable. To the extent our capital resources are insufficient to meet our future capital requirements, we would 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, investors 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.

Table of Contents

The table below sets forth our payment obligations for the periods indicated under certain of our current contracts. The amounts set forth below only reflect current contractual obligations and do not reflect management s expectations for total expenditures for the categories of expenditures described below during these periods. The timing or amount of payments under these contracts may be altered in accordance with the terms of the contracts if, for example:

a contract is terminated prior to its expiration date or extended beyond its original expiration date;

a party defaults on its obligations under a contract;

changes in the consumer price index result in increases in the amount of the obligation; or

royalties based on sales or sublicenses exceed minimum royalties.

| | Contractual Obligations | | | | | |
|---|---|---|---|---|---|---|
| | Capital lease obligations | Lines of credit | Facility leases | License arrangements | Office equipment leases | Total |
| **Payments due by period** | | | | | | |
| 2003 | $ 1,185,785 | $ 3,963,102 | $ 1,832,154 | $ 1,120,000 | $ 185,036 | $ 8,286,077 |
| 2004 | 358,563 | 592,467 | 1,903,745 | 1,120,000 | 12,768 | 3,987,543 |
| 2005 | 222,728 | 640,686 | 1,804,223 | 620,000 | 6,384 | 3,294,021 |
| 2006 | 198,586 | 645,209 | 1,884,214 | 620,000 | | 3,348,009 |
| 2007 | 242,452 | | 1,884,214 | 620,000 | | 2,746,666 |
| Thereafter | 259,924 | | 10,756,975 | 3,700,000 | | 14,716,899 |
| Total | $ 2,468,038 | $ 5,841,464 | $ 20,065,525 | $ 7,800,000 | $ 204,188 | $ 36,379,215 |

**Inflation**

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

**Recently Issued Accounting Pronouncements**

In June 2001, the Financial Accounting Standards Board ( FASB ) issued SFAS No. 143, Accounting for Asset Retirement Obligations, ( SFAS No. 143 ) which is effective for us beginning in fiscal 2003. SFAS No. 143 requires that the fair value of a liability for an asset retirement

obligation be recognized in the period in which it is incurred if a reasonable estimate of fair value can be made, with the associated asset retirement costs capitalized as part of the carrying amount of the long-lived asset. We do not expect the adoption of SFAS No. 143 to have a material impact on our financial position and results of operations.

In October 2001, the FASB issued SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets ( SFAS No. 144 ), which is effective for fiscal years beginning after December 15, 2001 and interim periods within those fiscal periods. SFAS No. 144 supersedes FASB Statement No. 121 Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of and parts of APB Opinion No. 30 Reporting and Results of Operations Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions relating to Extraordinary Items, ( Opinion 30 ), however, SFAS No. 144 retains the requirement of Opinion 30 to report discontinued operations separately from continuing operations and extends that reporting to a component of an entity that either has been disposed of (by sale, by abandonment, or in a distribution to owners) or is classified as held for sale. SFAS No. 144 addresses financial accounting and reporting for the impairment of certain long-lived assets and for long-lived assets to be disposed of. We do not expect the adoption of SFAS No. 144 to have a material impact on our financial position and results of operations.

In April 2002, the FASB issued SFAS No. 145, Rescission of FASB Statement No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections ( SFAS No. 145 ) which eliminates

Table of Contents

inconsistencies between the required accounting for sale-leaseback transactions and the required accounting for certain lease modifications that have economic effects that are similar to sale-leaseback transactions. SFAS No. 145 also amends other existing authoritative pronouncements to make various technical corrections, clarify meanings, or describe their applicability under changed conditions. The provisions of SFAS No. 145 are effective for fiscal years beginning after May 15, 2002 and for transactions occurring after May 15, 2002. We do not expect adoption of SFAS No. 145 to have a material impact on our financial position or on our results of operations.

In June 2002, the FASB issued SFAS No. 146, Accounting for Exit or Disposal Activities ( SFAS No. 146 ) which addresses the recognition, measurement, and reporting of costs that are associated with exit and disposal activities, including restructuring activities that are currently accounted for pursuant to the guidance that the EITF has set forth in EITF Issue No. 94-3, Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring) . SFAS No. 146 will be effective for exit or disposal activities that are initiated after December 31, 2002. We do not expect adoption of SFAS No. 146 to have a material impact on our financial position or on our results of operations.

In November 2002, the FASB issued FASB Interpretation No. 45 ( FIN 45 ), Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others. FIN 45 requires that a liability be recorded in the guarantor s balance sheet upon issuance of a guarantee. In addition, FIN 45 requires disclosures about the guarantees that an entity has issued, including a reconciliation of changes in the entity s product warranty liabilities. The initial recognition and initial measurement provisions of FIN 45 are applicable on a prospective basis to guarantees issued or modified after December 31, 2002, irrespective of the guarantor s fiscal year-end. The disclosure requirements of FIN 45 are effective for financial statements of interim or annual periods ending after December 15, 2002. We believe that the adoption of FIN 45 will have no material impact on our financial statements.

In November 2002, the Emerging Issues Task Force ( EITF ) reached a consensus on Issue No. 00-21 ( EITF 00-21 ), Revenue Arrangements with Multiple Deliverables. EITF 00-21 provides guidance on how to account for arrangements that involve the delivery or performance of multiple products, services and/or rights to use assets. The provisions of EITF Issue No. 00-21 will apply to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. We believe that the adoption of ETIF 00-21 will have no material impact on our financial statements.

In December 2002, the FASB issued SFAS No. 148, Accounting for Stock-Based Compensation Transition and Disclosure an amendment of FASB Statement No. 123. SFAS No. 148 provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. SFAS No. 148 also requires prominent disclosures of the pro forma effect of using the fair value method of accounting for stock-based employee compensation in both annual and interim financial statements. The transition and annual disclosure requirements of SFAS No. 148 are effective for fiscal years ending after December 15, 2002. The interim disclosure requirements are effective for interim periods beginning after December 15, 2002. The adoption of SFAS No. 148 did not have a material impact on our financial position or on our results of operations.

In January 2003, the FASB issued FASB Interpretation No. 46 ( FIN 46 ), Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51. FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 is effective immediately for all new variable interest entities created or acquired after January 31, 2003. For variable interest entities created or acquired prior to February 1, 2003, the provisions of FIN 46 must be applied for the first interim or annual period beginning after June 15, 2003. We do not have any ownership in any variable interest entities as of December 31, 2002. We do not expect adoption of FIN 46 to have a material impact on our financial position or on our results of operations.

Table of Contents

## RISK FACTORS AFFECTING OPERATIONS AND FUTURE RESULTS

**We have a history of net losses and variable quarterly results and may never achieve or maintain profitability.**

We have incurred losses every year since 1997. We incurred losses of $43.6 million in 2000, $52.9 million in 2001 and $29.2 million in 2002. As of December 31, 2002, we had an accumulated deficit of approximately $144.8 million. We will need to continue to increase product revenues and reduce product costs to achieve profitability. 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. As a relatively new entrant to the blood glucose monitoring market that has been experiencing rapid growth, revenues can vary from quarter to quarter due to various factors, including:

- changes in customer stocking and inventory levels;
- the timing of promotions and price changes by us or our competitors; and
- new product introductions or enhancements by us or our competitors.

We maintain a limited inventory of finished goods and typically ship products within a short period after orders are received. Historically, customer buying patterns and our revenue growth have caused a substantial portion of our revenues to occur in the last month of the quarter. Delays in the receipt of orders or the manufacture of product near the end of the quarter could cause quarterly revenues to fall short of anticipated levels. Because our operating expenses are based on anticipated revenue levels and a high percentage of our expenses are relatively fixed, less than anticipated revenues for a quarter could have a significant adverse impact on our operating results.

**We expect to derive substantially all of our future revenue from sales of FreeStyle and this product could fail to generate significant revenues.**

Currently, the primary products we market are the FreeStyle test strips, FreeStyle System kit and FreeStyle lancets, all of which we commercially introduced in June 2000. Our FreeStyle products are expected to account for substantially all of our revenues for 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. Relative to the overall size of the blood glucose monitoring market, a limited number of people have used FreeStyle, and people with diabetes or the medical community may not substantially endorse FreeStyle as a preferred blood glucose self-monitoring device. In addition, FreeStyle may not achieve significant market acceptance on a timely basis, if at all, due to:

- the significant influence of established glucose monitoring products with healthcare professionals, customers and third-party payors;
- the ability of some of our competitors to price products below a price at which we can competitively manufacture and sell our products;

the introduction or acceptance of competing products or technologies; and

cost constraints.

Furthermore, FreeStyle may not encourage significantly 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

Table of Contents

future, we will therefore have to rely on recurring revenue from the repeated purchase of our FreeStyle test strips. If FreeStyle does not gain sufficient market share to generate significant recurring revenue from the sale of our test strips, we may not achieve profitability.

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

We have limited experience in marketing and selling our products relative to other companies in the blood glucose self-monitoring market. We received regulatory clearance for our initial product in January 2000 and commenced commercial shipments in June 2000. Our products require a complex marketing and sales effort targeted at health care professionals, diabetes educators, people with diabetes, pharmacists and national retailers. We have significantly expanded our sales and marketing teams in 2001 and 2002. We face significant challenges and risks in training, managing and retaining these teams, including managing geographically dispersed efforts. In addition, we currently have only one distributor in most of Europe and one distributor in Japan. We are dependent upon the sales and marketing efforts of our third-party distributors in these large international markets. 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. Recently, the Disetronic Group, the parent company of our European distributor, announced that its insulin pump business will be acquired by Roche Diagnostics, one of our competitors. While Disetronic Injections Systems AG, our European distributor, will continue to distribute our products, we may not have the level of access to Disetronic s insulin pump user base after the Roche Diagnostics acquisition that we enjoyed before the acquisition, and this could translate into decreased sales of our products. In addition, the recent amendment to the international distributor agreement with Disetronic lowered Disetronic Injection Systems AG s annual minimum purchase obligations. Our financial condition would be harmed if our marketing and sales efforts are unsuccessful.

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

The market for blood glucose monitoring 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. In addition, Becton, Dickinson and Company recently launched a new blood glucose monitoring system. Each of these companies is either publicly traded or a division of a publicly-traded company, and they enjoy 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; and
- greater resources for product development, sales and marketing, and patent litigation.

These companies and others have developed and will continue to develop and acquire new products that compete directly with our products. In addition, our competitors spend significantly greater funds for the research, development, promotion and sale of new and existing products. These resources can allow them to respond more quickly to new or emerging technologies and changes in customer requirements. These resources also allow them to aggressively promote and discount their products, particularly system kits. For all the foregoing reasons, we may

not be able to compete successfully against our current and future competitors.

**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

Table of Contents

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.

In September 2001, we received a letter from the exclusive licensee of an issued patent alleging that FreeStyle infringes the patent and requesting that we contact the licensee regarding sublicense opportunities. We have evaluated the patent and we are discussing a possible sublicense with the licensee. In August 2002, we received a letter from the owner of an issued United States patent that states our FreeStyle Tracker System may infringe the patent. We are currently evaluating the patent owner s claims.

If we were unable to obtain, on reasonable commercial terms, 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 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 and 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 Inverness Medical Innovations, Inc. grant us the right under specific patents to make and sell diagnostic devices for diabetes monitoring that contain the inventions claimed in the licensed patents. Our rights to use these technologies and employ the inventions

Table of Contents

claimed in the licensed patents are subject to our licensors abiding by the terms of those licenses. In addition, we often do not control the prosecution of the patents to which we hold licenses or the strategy for determining when any patents to which we hold licenses should be enforced. As a result, we are largely dependent 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 or be more competitive with regard to product features. In addition, over $91 billion is spent annually on the treatment of diabetes and its complications 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, and we are developing new products such as our Continuous Glucose Monitoring System. Marketing of these products will require FDA and other regulatory clearances and approvals. We have experienced some delays in the clinical trials being conducted to support the approval of our Continuous Glucose Monitoring System due to problems with the electronics portion of the system. Development of the Continuous Glucose Monitoring System and other 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 for continuous glucose monitoring and obtains government approval or successfully commercializes its FDA-approved product, this could negatively affect our future revenues. Similarly, several of our competitors and some new market entrants are developing products that have small sample size requirements and the ability to test on the fingertip and other body sites. A new competitor, for instance, recently launched a blood glucose monitoring system that claims the same sample size requirement as the FreeStyle blood glucose monitoring system. The successful development and introduction of such products by competitors or new entrants would reduce the product benefits of our FreeStyle products versus the competition and could adversely impact future revenues.

**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. Therefore, even if a product is successfully developed, it may not be commercially available for a number of years. Our Continuous Glucose Monitoring System under development will require premarket approval. We have experienced some delays in the clinical trials being conducted to support the approval of our Continuous Glucose Monitoring System due to problems with the electronics portion of the system. We may not be able to obtain additional clearances or approvals for the Continuous Glucose Monitoring System or other products in a timely fashion, or at all. Delays in obtaining clearance or approval could adversely affect our revenues and profitability.

Table of Contents

**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. In the case of certain labeling changes for FreeStyle, the FDA required a new 510(k) clearance which was obtained in December 2001. 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 our suppliers or we fail to comply with the FDA s Quality System Regulation, our manufacturing operations could be delayed, and our product sales and profitability could suffer.**

Our manufacturing processes for our FreeStyle test strips, as well as the manufacturing processes utilized by our suppliers of FreeStyle meters, lancing devices, lancets and control solution, 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. The manufacturing lines for our FreeStyle meters at Flextronics International Ltd. in San Jose, California and China have not been inspected to date. If we or one of our suppliers fail a Quality System Regulation inspection, 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 harm our reputation and 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 or field corrective actions 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 or field corrective actions for our products in the event of material deficiencies or defects in design or manufacture. A government mandated or firm-initiated recall or field corrective action by us could occur as a result of component failures, manufacturing errors or design defects. We commenced a firm-initiated field corrective action due to software bugs associated with the diabetes management features of our FreeStyle Tracker diabetes management system shortly after its launch. Any recall of or material field corrective action for product may divert managerial and financial resources and harm our reputation with customers.

**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. We have previously experienced delays in the delivery of some sole sourced electronic components for our meters. 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 as scheduled, or if our contract manufacturers are unable to meet our

Table of Contents

manufacturing requirements, we may not be able to obtain components from alternate suppliers or engage an additional manufacturer in a timely manner. Any disruption or delay in shipments of FreeStyle meters, test strips, lancing devices or lancets could result in the loss of customers or the failure to acquire new customers, if they choose a competitor s product because our product is not available. Such a disruption or delay would negatively affect our revenues. In addition, the purchase of components from alternate suppliers or engaging an additional manufacturer in a timely manner could impose increased costs that could negatively impact our gross margins.

**If we are unable to meet customer demand, we may not improve our sales growth sufficiently to achieve profitability.**

To be successful, we must manufacture our FreeStyle test strips in substantial quantities at acceptable costs. If we do not succeed in manufacturing sufficient quantities of our test strips to meet customer demand, we could lose customers and fail to acquire new customers, if they choose a competitor s product because our product is not available. Increasing demand since the launch of FreeStyle has necessitated an increase in our test strip manufacturing capacity. In response, we have expanded our manufacturing capacity at our facilities in Alameda, California. We anticipate the need to continue expanding manufacturing capacity and have ordered certain specialized equipment. Delays in receiving certain specialized equipment extended the date when we were able to begin operations on our second test strip line. If we are unable to expand manufacturing capacity in a timely manner we could be unable to meet customer demand for FreeStyle test strips, which would adversely affect our financial results and restrict our sales growth.

**Significant product returns could harm our operating results.**

Our return policy allows end users in the United States and Canada 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. Retailers and wholesalers in the United States and Canada can return these products to us within six months after this expiration date. We have established reserves for the liability associated with product returns. However, unforeseen returns from retailers, wholesalers or end users could adversely affect our operating results.

**We may have warranty claims that exceed our reserves.**

FreeStyle meters carry a five-year warranty against defects in materials and workmanship. We have established reserves for the liability associated with product warranties. However, any unforeseen warranty exposure could adversely affect our operating results.

**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, the operation of our customer service function, and certain distribution and logistics functions. Since outsourcing leaves us without direct control over these business functions, interruptions in the services of our third-party providers may be difficult or impossible to remedy in a timely fashion. In addition, we may be unable to obtain the necessary resources from our third-party providers to meet realized growth in our business.

**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

Table of Contents

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

We believe that in the future, reimbursement may 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.

**We may have difficulty managing our growth.**

We have experienced significant growth in the scope of our operations and the number of our employees. We expect this growth to continue though at substantially reduced rates. 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.

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

Our ability to provide superior customer service to our customers, health care professionals and educators is critical. To effectively compete, we must build strong brand awareness among our customers, much of which is based upon personal referrals. In order to gain these referrals, we must provide customer service representatives who are able and available to provide our customers with answers to questions regarding our products. This will require us to continue to build and maintain customer service operations, for which we currently rely on a single third-party

provider. We will require increased staff at our third-party provider to further support 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.

Table of Contents

**Our meters are manufactured in China, and we are subject to risks of international manufacturing operations.**

Our FreeStyle meters are manufactured according to our specifications by a single third-party manufacturer at its facility in China. The geographical distance between our principal facility in Alameda, California and the manufacturing facility in China creates a number of logistical and communications challenges. These challenges include managing operations across multiple time zones, directing the manufacture and delivery of products across distances, coordinating procurement and delivery of components and raw materials and coordinating the activities and decisions of the core manufacturing team, which is based in China and California.

Governmental authorities in China exercise significant influence over many aspects of the economy, and their actions could have a significant effect on the manufacture of our FreeStyle meters. Risks of changes in economic and political conditions in China, include:

- labor unrest and difficulties in staffing;
- increases in duties and taxation levied on our FreeStyle meters;
- limitations on imports of FreeStyle meter components or exports of assembled FreeStyle meters, or other travel restrictions;
- expropriation of private enterprises;
- a potential reversal of current favorable policies encouraging foreign trade; and
- fluctuations in the value of local currency.

Any delay or disruption in the manufacture of our FreeStyle meters, including delays or disruptions relating to these logistical and communication challenges or changes in the economic or political conditions in China, could delay or disrupt shipments of FreeStyle meters to our customers. Shipment delays or disruptions could result in the loss of customers or the failure to acquire new customers, if they choose a competitor s product because our product is not available. Such a disruption or delay would negatively affect our revenues. In addition, engaging an additional manufacturer or commencing FreeStyle meter manufacturing obligations on an alternative line in a timely manner could impose increased costs that would negatively impact our gross margins.

**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.

**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. We have the required regulatory approvals to market FreeStyle in various countries outside the United States. Failure to maintain current foreign approvals or to receive and maintain approvals 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,

Table of Contents

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.

**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 $22.0 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.

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

We may seek additional funds from public and private stock offerings, borrowings under lease lines of credit or other sources. This additional financing may not be available on a timely basis on terms acceptable to us, or at all. This financing may be dilutive to stockholders or may require us to grant a lender a security interest in our assets. The amount of money we will need will depend on many factors, including:

- revenues generated by sales of FreeStyle and our future products;
- 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.

**Most 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 and test strip manufacturing and most of our 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. 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.

**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

Table of Contents

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

**Our common stock has been and will likely continue to be subject to substantial price and volume fluctuations, and the value of our stock could decline.**

The market prices and trading volumes for emerging growth medical device companies and our company in particular have been highly volatile and are likely to continue to be highly volatile in the future. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our stock:

- volume and timing of orders for our products;
- monthly variations in market data relative to our competitors;
- our ability to develop, obtain regulatory clearance for, and market, new and enhanced products on a timely basis;
- the announcement of new products or product enhancements by us or our competitors;
- announcements of technological or medical innovations in the monitoring or treatment of diabetes;
- product liability claims or other litigation;
- quarterly variations in our or our competitors results of operations;
- changes in governmental regulations or in the status of our regulatory approvals or applications;
- changes in the availability of third-party reimbursement in the United States or other countries;
- changes in earnings estimates or recommendations by securities analysts; and
- general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

**The sales of a substantial number of shares of our common stock may adversely affect the market price for our common stock**

Sales of a significant number of shares of our common stock in the public market or the market perception that these sales may occur, could negatively affect the market price for our common stock. As of March 1, 2003, we had 40,867,629 shares of common stock outstanding. All of these shares are available for sale. Also, many of our employees, consultants and directors may exercise their stock options in order to sell the stock underlying their options in the market under a registration statement we have filed with the SEC.

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

Our executive officers and directors and entities affiliated with them beneficially own, in the aggregate, approximately 20% of our common stock as of March 1, 2003. This significant concentration of share ownership

Table of Contents

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

**Our Stockholder Rights Plan, charter documents and Delaware law may inhibit a takeover that stockholders consider favorable and could also limit the market price of investors stock.**

In February 2003, our Board of Directors adopted a Stockholder Rights Plan. The Stockholder Rights Plan provides for a dividend distribution of one Preferred Shares Purchase Right on each outstanding share of our common stock. Each Right entitles stockholders to buy 1/1000th of a share of the company s Series A participating preferred stock at an exercise price of $100.00. The Rights will become exercisable after a person or group announces the acquisition of 15% or more of our common stock, or announces commencement of a tender offer, the consummation of which would result in ownership by the person or group of 15% or more of our common stock. We will be entitled to redeem the Rights at $0.001 per Right at any time on or before the tenth day following acquisition by a person or group of 15% or more of our common stock. The Stockholder Rights Plan could have the effect of delaying, deferring or preventing a change in control of TheraSense, including without limitation, discouraging a proxy contest or making more difficult the acquisition of a substantial block of our common stock

Our certificate of incorporation and bylaws contain provisions that could also delay or prevent a change in control of our company. Among these provisions are the following:

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

In addition, we are governed by the provisions of Section 203 of Delaware General Corporate Law. These provisions may prohibit stockholders owning 15% or more of our outstanding voting stock from merging or combining with us. Section 203 of Delaware General Corporate Law, our Stockholder Rights Plan 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.

**The liquidity of our common stock is uncertain since it has been publicly traded for a short period of time and may have a limited market.**

Prior to our initial public offering in October 2001, there was no public market for our common stock. We cannot predict the extent to which investor interest in our company will lead to the development of an active, liquid trading market. Active trading markets generally result in lower price volatility and more efficient execution of buy and sell orders for investors.

43

Table of Contents

**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Because we translate foreign currencies into United States dollars for reporting purposes, exchange rates can have an impact on our financial results, although this impact is generally immaterial. We believe that our exposure to currency exchange risk is low because our Canadian and United Kingdom subsidiaries satisfy their financial obligations almost exclusively in their local currencies. As of December 31, 2002, we did not engage in foreign currency hedging activities.

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 December 31, 2002, our cash, cash equivalents and available-for-sale securities consisted primarily of money market funds maintained at three major U.S. financial institutions. 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.

**ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

The consolidated financial statements and supplementary data required by this Item are set forth at the pages indicated in Item 15 of this report.

**ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

Not applicable.

Table of Contents

**PART III**

**ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT.**

Information concerning our directors and executive officers is incorporated by reference to the sections titled Proposal No. 1: Election of Directors and Management contained in our definitive Proxy Statement with respect to our 2003 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission not later than 120 days after the end of the fiscal year covered by this report. Information concerning compliance with Section 16(a) of the Securities Exchange Act of 1934 is incorporated by reference to the section titled Section 16(a) Beneficial Ownership Reporting Compliance contained in our definitive Proxy Statement.

**ITEM 11. EXECUTIVE COMPENSATION**

Information concerning executive compensation is incorporated by reference to the sections titled Proposal No. 1: Election of Directors Director Compensation, Compensation of Executive Officers Summary Compensation Table, Compensation of Executive Officers Option Grants in Last Fiscal Year, Compensation of Executive Officers Aggregated Option Exercises in Last Fiscal Year and Fiscal Year-End Option Values, and Compensation of Executive Officers Change of Control and Severance Agreements contained in our definitive Proxy Statement referred to in Item 10 above.

**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT; SECURITIES AUTHORIZED FOR ISSUANCE UNDER EQUITY COMPENSATION PLANS.**

Information concerning the security ownership of certain beneficial owners and management is incorporated by reference to the section titled Common Stock Ownership of Certain Beneficial Owners and Management and Securities Authorized for Issuance under Equity Compensation Plans contained in our definitive Proxy Statement referred to in Item 10 above.

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.**

Information concerning certain relationships is incorporated by reference to the section titled Related-Party Transactions contained in our definitive Proxy Statement referred to in Item 10 above.

**ITEM 14. CONTROLS AND PROCEDURES**

(a) *Evaluation of disclosure controls and procedures*. Our chief executive officer and our chief financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in the Securities Exchange Act of 1934 Rules 13a-14(c) and 15-d-14(c)) as of a date (the Evaluation Date ) within 90 days before the filing date of this report, have concluded that as of the Evaluation Date, our disclosure

controls and procedures were adequate and designed to ensure that material information relating to us and our consolidated subsidiaries would be made known to them by others within those entities.

(b) *Changes in internal controls*. There were no significant changes in our internal controls or to our knowledge, in other factors that could significantly affect our internal controls subsequent to the Evaluation Date.

Table of Contents

## PART IV

### ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K

(a) The following documents are filed as part of this report:

(1) **Financial Statements**



(2) **Financial Statement Schedules**

The following financial statement schedule of TheraSense for the years ended December 31, 2002, 2001 and 2000 is filed as part of this Annual Report and should be read in conjunction with the financial statements of TheraSense:



All other schedules are omitted because they are not applicable or the required information is shown in financial statements or notes thereto.

(3) **Exhibits**

| Exhibit Number | Description of Document |
|---|---|
| *3.1 | Certificate of Incorporation of TheraSense, Inc., a Delaware corporation, as currently in effect |
| *3.2 | Bylaws of TheraSense, Inc. as currently in effect |
| *4.1 | Specimen Common Stock Certificate |
| **10.1 | 1997 Stock Plan, as amended, and forms of agreements thereunder |
| *10.2 | 2001 Stock Plan and forms of agreements thereunder |
| *10.3 | 2001 Employee Stock Purchase Plan and forms of agreement thereunder |
| *10.4 | Form of Director and Executive Officer Indemnification Agreement |

| | |
|---|---|
| *10.5 | Employment Letter from TheraSense, Inc. to W. Mark Lortz, dated as of October 6, 1997 |
| *10.6 | Technology Purchase Agreement between TheraSense and E. Heller & Co. dated as of October 10, 2000 |
| *10.7 | Cooperative Development Agreement between TheraSense, Inc. and Facet Technologies LLC (f/k/a Gainor Medical North America LLC), dated as of December 1, 1998 |
| *10.7(a) | First Amendment to Cooperative Development Agreement between TheraSense, Inc. and Facet Technologies LLC (f/k/a Gainor Medical North America LLC), effective June 1, 2001 |
| *10.7(b) | Master Purchase Agreement between TheraSense, Inc. and Facet Technologies LLC effective June 1, 2001 |

Table of Contents

| Exhibit Number | Description of Document |
|---|---|
| *10.8 | Standard Industrial/Commercial Single-Tenant Lease between TheraSense, Inc. and PlyProperties, a Partnership, dated as of February 26, 1999, and addendum thereto |
| ***10.8(a) | Second Amendment to Standard Industrial/Commercial Single-Tenant Lease between TheraSense, Inc. and PlyProperties, a Partnership dated May 7, 2002 |
| *10.9 | Master Purchase Agreement between TheraSense and Flextronics International USA, Inc., dated as of November 3, 1999 |
| *10.10 | Assignment of Patent Rights and Technology by and among Board of Regents of the University of Texas System, an agency of the State of Texas, Dr. Adam Heller, E. Heller & Company and TheraSense Inc. dated August 1, 1991 |
| *10.11 | First Amendment, dated March 19, 1998, to the Agreement entitled Assignment of Patent Rights and Technology by and among Board of Regents of the University of Texas System, an agency of the State of Texas, Dr. Adam Heller, E. Heller & Company and TheraSense Inc. dated August 1, 1991 |
| *10.12 | License Agreement between TheraSense, Inc. and Asulab SA., dated February 23, 2000 |
| *10.13 | Warehouse Distribution Contract between TheraSense, Inc. and Livingston Healthcare Service, Inc., dated March 15, 2000 |
| ****10.13(a) | October 23, 2002 amendment to Warehouse Distribution Contract between TheraSense, Inc. and UPS Supply Chain Management f/d/b/a Livingston Healthcare Service, Inc., dated March 15, 2000 |
| *10.14 | International Distributor Agreement between TheraSense, Inc. and Nipro Corporation, dated April 1, 2001 |
| *10.15 | International Distributor Agreement between TheraSense, Inc. and Disetronic Handels AG, dated September 13, 2000 |
| **10.15(a) | Amendment No. 1 to International Distributor Agreement between TheraSense, Inc. and Disetronic Handels AG, dated February 8, 2002 |
| 10.15(b) | Amendment No. 2 to International Distributor Agreement between TheraSense, Inc. and Disetronic Handels AG, dated January 1, 2003 |
| *10.16 | Management Services Agreement between TheraSense, Inc. and ICT Group, Inc., dated January 31, 2000 |
| *10.17 | License Agreement between TheraSense, Inc. and Unilever PLC dated February 10, 2000 |
| *10.18 | Amended and Restated Investors Rights Agreement by and among holders of TheraSense Preferred Stock and TheraSense, Inc., dated January 23, 2001, as amended |
| *10.19 | First Amendment to the Agreement Entitled Sponsored Research Agreement No. UTA 98-0296 entered into as of October 10, 2000, by and between TheraSense, Inc. and the Board of Regents of the University of Texas System on behalf of the University of Texas at Austin |
| *10.20 | Form of Change of Control Agreement between TheraSense, Inc. and each Vice President of TheraSense, Inc. |
| *****10.21 | Rights Agreement dated as of March 7, 2003 between TheraSense, Inc. and Computershare Investor Services, as Rights Agent, which includes the Form of Certificate of Designation of Series A Participating Cumulative Preferred Stock as Exhibit A, the Summary of Terms of the Rights Agreement as Exhibit B and the Form of Right Certificate s Exhibit C. |
| 21.1 | List of subsidiaries of TheraSense, Inc. |

**Table of Contents**

| Exhibit Number | Description of Document |
|---|---|
| 23.1 | Consent of independent accountants |
| 99.1 | Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 |

* Incorporated by reference to the same exhibit filed with our Registration Statement on Form S-1 (Registration No. 333-64456), which was declared effective on October 11, 2001.
** Incorporated by reference to the same exhibit filed with our Form 10-K for the year ended December 31, 2001.
*** Incorporated by reference to the same exhibit filed with our Form 10-Q for the period ended June 30, 2002.
**** Incorporated by reference to the same exhibit filed with our Form 10-Q for the period ended September 30, 2002.
***** Incorporated by reference to the same exhibit filed with our Registration Statement on Form 8-A, which was declared effective on March 11, 2003.
Confidential treatment granted for portions of these exhibits.
Confidential treatment requested for portions of this exhibit.

(b) Reports on Forms 8-K.

TheraSense did not file any reports on Form 8-K during the period covered by this report.

Table of Contents

**THERASENSE, INC.**

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

Table of Contents

**REPORT OF INDEPENDENT ACCOUNTANTS**

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

In our opinion, the consolidated financial statements listed in the accompanying index present fairly, in all material respects, the financial position of TheraSense, Inc. and its subsidiaries (the Company ) at December 31, 2001 and 2002 and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2002 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company s management; our responsibility is to express an opinion on these financial statements 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

January 31, 2003

Table of Contents

**THERASENSE, INC.**

**CONSOLIDATED BALANCE SHEETS**

| | December 31 | |
|---|---|---|
| | **2001** | **2002** |
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 143,186,956 | $ 32,157,782 |
| Available-for-sale investments | | 34,134,885 |
| Accounts receivable, net of allowance for doubtful accounts of $704,296 in 2001 and $815,075 in 2002 | 18,495,204 | 36,319,094 |
| Inventories | 6,649,416 | 21,059,720 |
| Deferred cost of products sold | 16,359,490 | |
| Prepaid expenses and other current assets | 8,238,008 | 6,358,221 |
| Total current assets | 192,929,074 | 130,029,702 |
| Available-for-sale investments | 4,278,040 | 11,617,665 |
| Property and equipment, net | 6,539,008 | 14,339,985 |
| Other assets | 2,829,848 | 4,815,994 |
| Total assets | $ 206,575,970 | $ 160,803,346 |
| **LIABILITIES AND STOCKHOLDERS EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 20,223,406 | $ 17,033,723 |
| Accrued liabilities | 16,598,810 | 16,109,785 |
| Deferred revenue | 23,708,647 | 1,000,000 |
| Current portion of capital lease obligations | 1,087,850 | 1,185,785 |
| Current portion of borrowings under lines of credit | 2,902,106 | 3,963,102 |
| Total current liabilities | 64,520,819 | 39,292,395 |
| Deferred revenue | 3,261,341 | 2,261,341 |
| Capital lease obligations, less current portion | 968,061 | 1,282,253 |
| Borrowings under lines of credit, less current portion | 3,286,746 | 1,878,362 |
| Other liabilities | 1,000,000 | 500,000 |
| Total liabilities | 73,036,967 | 45,214,351 |
| Commitments and contingencies (Note 7) | | |
| Stockholders equity: | | |
| Preferred stock: $0.001 par value; | | |
| Authorized: 5,000,000 shares; no shares issued or outstanding | | |
| Common stock: $0.001 par value: | | |
| Authorized: 200,000,000 shares; | | |
| Issued and outstanding: 39,534,209 shares in 2001 and 40,807,155 shares in 2002 | 39,535 | 40,807 |
| Additional paid-in capital | 270,376,138 | 271,782,160 |
| Notes receivable from stockholders | (292,051) | (155,695) |
| Deferred stock-based compensation, net | (20,995,455) | (11,642,289) |

| | | |
|---|---|---|
| Accumulated other comprehensive income | | 315,733 |
| Accumulated deficit | (115,589,164) | (144,751,721) |
| Total stockholders equity | 133,539,003 | 115,588,995 |
| Total liabilities and stockholders equity | $ 206,575,970 | $ 160,803,346 |

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

Table of Contents

**THERASENSE, INC.**

**CONSOLIDATED STATEMENTS OF OPERATIONS**

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2000 | 2001 | 2002 |
| **Revenues:** | | | |
| Product sales | $ 5,000,250 | $ 71,105,322 | $ 176,707,891 |
| License income | 500,000 | 750,000 | 1,000,000 |
| Research grant revenue | 3,000 | | |
| Total revenues | 5,503,250 | 71,855,322 | 177,707,891 |
| Cost of revenues | 11,948,283 | 49,147,207 | 92,835,388 |
| Gross profit (loss) | (6,445,033) | 22,708,115 | 84,872,503 |
| **Operating expenses:** | | | |
| Research and development | 12,019,110 | 16,103,139 | 20,252,560 |
| Selling, general and administrative | 25,460,349 | 60,457,638 | 94,897,510 |
| Total operating expenses | 37,479,459 | 76,560,777 | 115,150,070 |
| Loss from operations | (43,924,492) | (53,852,662) | (30,277,567) |
| Interest income | 1,488,049 | 2,178,743 | 2,342,774 |
| Interest and other expense | (1,155,394) | (1,191,614) | (1,227,764) |
| Net loss | (43,591,837) | (52,865,533) | (29,162,557) |
| Deemed dividends related to beneficial conversion feature of preferred stock | (14,772,878) | (26,782,911) | |
| Net loss attributable to common stockholders | $ (58,364,715) | $ (79,648,444) | $ (29,162,557) |
| Net loss per common share, basic and diluted | $ (14.69) | $ (6.70) | $ (0.73) |
| Weighted-average shares used in computing net loss per common share, basic and diluted | 3,973,250 | 11,890,566 | 40,130,614 |

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

Table of Contents

**THERASENSE, INC.**

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)**

**For the Years Ended December 31, 2000, 2001 and 2002**

| | Common Stock | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Additional Paid-In Capital | Notes Receivable from Stockholders | Deferred Stock-based Compensation | Accumulated other comprehensive income (loss) | Accumulated Deficit | Total Stockholders Equity (Deficit) |
| **Balances, January 1, 2000** | 4,976,932 | $ 4,977 | $ 2,543,858 | $ (331,195) | $ (1,244,418) | $ | $ (19,131,794) | $ (18,158,572) |
| Exercise of stock options for cash and in exchange for notes receivable from stockholders | 213,671 | 214 | 86,435 | (6,068) | | | | 80,581 |
| Repurchase of shares and cancellation of stockholder note receivable | (51,211) | (51) | (14,333) | 14,384 | | | | |
| Repayment of notes receivable from stockholders | | | | 28,129 | | | | 28,129 |
| Deferred stock-based compensation | | | 11,811,391 | | (11,811,391) | | | |
| Amortization of deferred stock-based compensation | | | | | 1,793,248 | | | 1,793,248 |
| Beneficial conversion feature related to issuance of Series C convertible preferred stock | | | 14,772,878 | | | | | 14,772,878 |
| Deemed dividend related to beneficial conversion feature of Series C convertible preferred stock | | | (14,772,878) | | | | | (14,772,878) |
| Net loss | | | | | | | (43,591,837) | (43,591,837) |
| **Balances, December 31, 2000** | 5,139,392 | 5,140 | 14,427,351 | (294,750) | (11,262,561) | | (62,723,631) | (59,848,451) |
| Exercise of stock options for cash | 300,918 | 301 | 523,243 | | | | | 523,544 |
| Beneficial conversion feature related to issuance of Series D convertible preferred stock | | | 26,782,911 | | | | | 26,782,911 |
| Deemed dividend related to beneficial conversion feature of Series D convertible preferred stock | | | (26,782,911) | | | | | (26,782,911) |
| Issuance of common stock upon filing of initial public offering, net of issuance costs of $10,200,633 | 6,900,000 | 6,900 | 120,892,467 | | | | | 120,899,367 |
| Issuance of common stock upon net exercise of warrants | 471,748 | 472 | (472) | | | | | |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Conversion of convertible preferred stock into common stock | 26,722,151 | 26,722 | 119,219,103 | | | | | 119,245,825 |
| Repayment of notes receivable from stockholders | | | | 2,699 | | | | 2,699 |
| Deferred stock-based compensation | | | 15,314,446 | | (15,314,446) | | | |
| Amortization of deferred stock-based compensation | | | | | 5,581,552 | | | 5,581,552 |
| Net loss | | | | | | | (52,865,533) | (52,865,533) |
| **Balances, December 31, 2001** | 39,534,209 | 39,535 | 270,376,138 | (292,051) | (20,995,455) | | (115,589,164) | 133,539,003 |
| Exercise of stock options for cash | 1,073,883 | 1,074 | 2,956,582 | | | | | 2,957,655 |
| Issuance of common stock upon net exercise of warrants | 3,401 | 3 | (3) | | | | | |
| Issuance of common stock under employee stock purchase plan | 199,002 | 199 | 1,934,346 | | | | | 1,934,545 |
| Repurchase of shares and cancellation of stockholder note receivable | (3,340) | (3) | (1,347) | 1,350 | | | | |
| Repayment of notes receivable from stockholders | | | | 135,006 | | | | 135,006 |
| Reversal of deferred stock-based compensation | | | (3,110,677) | | 3,110,677 | | | |
| Amortization of deferred stock-based compensation | | | (228,892) | | 6,242,489 | | | 6,013,597 |
| Tax cost of stock option exercises | | | (143,987) | | | | | (143,987) |
| Components of comprehensive income (loss): | | | | | | | | |
| Net loss | | | | | | | (29,162,557) | (29,162,557) |
| Foreign currency translation adjustments | | | | | | (117,523) | | (117,523) |
| Unrealized gain on available-for-sale investments | | | | | | 433,256 | | 433,256 |
| Total comprehensive income | | | | | | | | (28,846,824) |
| **Balances, December 31, 2002** | 40,807,155 | $ 40,807 | $ 271,782,160 | $ (155,695) | $ (11,642,289) | $ 315,733 | $ (144,751,721) | $ 115,588,995 |

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

Table of Contents

**THERASENSE, INC.**

**CONSOLIDATED STATEMENTS OF CASH FLOW**

| | Years Ended December 31, | | |
|---|---|---|---|
| | **2000** | **2001** | **2002** |
| **Cash flows from operating activities:** | | | |
| Net loss | $ (43,591,837) | $ (52,865,533) | $ (29,162,557) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation and amortization | 1,546,556 | 2,001,254 | 3,192,862 |
| Provision for doubtful accounts | 150,000 | 576,431 | 110,779 |
| Amortization of debt issuance costs | 268,489 | 268,492 | 208,511 |
| Loss on disposal and sale of property and equipment | 5,637 | 13,605 | |
| Amortization of deferred stock-based compensation | 1,793,248 | 5,581,552 | 6,013,597 |
| Tax cost of stock option exercises | | | (143,987) |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable | (6,299,697) | (15,661,574) | (17,934,669) |
| Inventories | (3,493,777) | (3,155,639) | (14,410,304) |
| Deferred cost of products sold | (7,396,547) | (8,962,943) | 16,359,490 |
| Prepaid expenses and other current assets | (342,430) | (7,059,573) | 1,879,787 |
| Other assets | (1,374,589) | (1,148,037) | (2,194,657) |
| Accounts payable | 9,946,047 | 9,598,675 | (3,189,683) |
| Accrued and other liabilities | 3,836,352 | 15,941,934 | (989,025) |
| Deferred revenue | 8,175,206 | 18,283,441 | (23,708,646) |
| Net cash used in operating activities | (36,777,342) | (36,587,915) | (63,968,502) |
| **Cash flows from investing activities:** | | | |
| Maturities of investments | | | 179,195,395 |
| Purchases of investments | | (4,278,040) | (220,236,650) |
| Purchases of property and equipment | (2,088,594) | (3,684,414) | (10,993,839) |
| Proceeds from sale of property and equipment | 2,666,374 | 6,000 | |
| Net cash provided by (used in) investing activities | 577,780 | (7,956,454) | (52,035,094) |
| **Cash flows from financing activities:** | | | |
| Proceeds from issuance of convertible preferred stock, net | 42,410,926 | 53,863,086 | |
| Proceeds from issuance of common stock and exercise of stock options | 80,581 | 121,422,911 | 4,982,200 |
| Proceeds from lines of credit | 3,000,000 | 3,000,000 | 16,228,408 |
| Proceeds from convertible promissory note | 2,500,000 | | |
| Principal payments on capital lease obligations | (417,393) | (862,394) | (4,564,872) |
| Principal payments on lines of credit | (1,192,631) | (2,227,451) | (11,598,797) |
| Repayment of notes receivable from stockholders | 28,129 | 2,699 | 135,006 |
| Net cash provided by financing activities | 46,409,612 | 175,198,851 | 5,091,945 |
| Effect of foreign exchange rate changes on cash and cash equivalents | | | (117,523) |
| Net increase (decrease) in cash and cash equivalents | 10,210,050 | 130,654,482 | (111,029,174) |
| Cash and cash equivalents, beginning of year | 2,322,424 | 12,532,474 | 143,186,956 |
| Cash and cash equivalents, end of year | $ 12,532,474 | $ 143,186,956 | $ 32,157,782 |

| | | | |
|---|---|---|---|
| **Noncash financing activities:** | | | |
| Common stock issued for notes receivable from stockholders | $ 6,068 | $ | $ |
| Repurchase of restricted common stock and cancellation of notes receivable | $ 14,384 | $ | $ |
| Conversion of promissory note into Series D preferred stock | $ | $ 2,500,000 | $ |
| Acquisition of property and equipment under capital lease | $ 2,970,204 | $ 36,771 | $ |
| Deferred stock-based compensation | $ 11,811,391 | $ 15,314,446 | $ 1,570,445 |
| **Supplemental disclosure of cash flow information:** | | | |
| Cash paid for interest | $ 881,265 | $ 909,517 | $ 817,271 |

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

Table of Contents

**THERASENSE, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE 1 FORMATION AND BUSINESS OF THE COMPANY:**

TheraSense, Inc. (the Company ) was incorporated in the state of California on December 6, 1996. 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 consolidated 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.

**NOTE 2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:**

*Basis of consolidation and foreign currency translation*

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All material intercompany balances and transactions have been eliminated.

The Company s international subsidiaries use the local currency as their functional currency. Assets and liabilities are translated at exchange rates in effect at the balance sheet date and revenue and expense accounts at average exchange rates during the period. Resulting translation adjustments are recorded directly to a separate component of stockholders equity.

*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.

*Cash and cash equivalents*

The Company considers all highly liquid investments purchased with original maturities of three months or less to be cash equivalents.

*Investments*

Investments with maturities of less than one year are considered to be short-term. All investments are classified as available-for-sale and are recorded at market value. Unrealized gains and losses are reflected in accumulated other comprehensive income (loss). Realized gains and losses on investments are reported in earnings and are derived using the specific identification method for determining the cost of investments sold.

*Fair value of financial instruments*

For financial instruments consisting of cash and cash equivalents, investments, accounts receivable, accounts payable and accrued liabilities included in the Company s financial statements, the carrying amounts approximate

Table of Contents

**THERASENSE, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

fair value due to their short maturities. Investments are recorded at market value. As of December 31, 2002, the carrying value of borrowings under lines of credit and capital lease obligations, including the current portion, was $8,309,502 and the estimated fair value was approximately $8,465,700. The estimated fair value was determined based on borrowing rates currently available to the Company.

*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. Reserves for potentially excess and obsolete inventory are based on management s analysis of inventory levels and future sales forecasts.

*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 three 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 reviews long-lived assets for impairment, whenever events or changes in circumstances indicate that the carrying amount of an asset might not be recoverable. When such an event occurs, 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.

*Other comprehensive income (loss)*

Comprehensive income (loss) generally represents all changes in stockholders equity except those resulting from investments or contributions by stockholders. The Company s unrealized gains on available-for-sale investments and cumulative translation adjustment represent the components of comprehensive income (loss) that are excluded from the net loss. As these components are not significant, individually or in aggregate, no separate statement of comprehensive income (loss) has been presented.

Due to availability of net operating losses, there is no tax effect associated with any component of other comprehensive income (loss).

*Accrued product warranties*

The Company s consolidated financial statements include accruals for product warranty claims. The Company provides a five-year warranty on its products. For proper matching of these costs in the period that revenues are recognized, an estimated warranty expense accrual rate is determined based on historical experience. Such costs are accrued at the time revenue is recognized. At December 31, 2001, and 2002, accrued product warranties totaled $1,282,215 and $1,931,935, respectively, and are included in accrued liabilities in the accompanying consolidated balance sheets.

Table of Contents

**THERASENSE, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

A tabular reconciliation of the changes in the Company s product warranty liability for 2002 is as follows:

| | | |
|---|---|---|
| Balance at January 1, 2002 | $ | 1,282,215 |
| Accruals for warranties issued during the year | | 1,626,736 |
| Settlements made during the year | | (977,016) |
| Balance at December 31, 2002 | $ | 1,931,935 |

*Concentration of credit risk and other risks and uncertainties*

As of December 31, 2001 and 2002, the Company s accounts receivable derived from revenue earned from customers located in the United States of America was 82% and 76% of the total, respectively. The remaining amounts were from sales to the Company s distributors in Europe, Japan, Canada and the United Kingdom. Revenues earned from the Company s two principal international distributors are on an open account basis; whereas, the remaining international customers accounts receivable balances are collateralized by irrevocable letters of credit. The Company performs ongoing credit evaluations of its customers financial condition and, generally, requires no collateral from its domestic customers.

Revenues from four customers individually accounted for greater than 10% of gross revenues and accounted for 53% of gross revenues in aggregate for the year ended December 31, 2000. Revenues from two customers individually accounted for greater than 10% of gross revenues and accounted for 27% of gross revenues in aggregate for the year ended December 31, 2001. Revenues from two customers individually accounted for greater than 10% of gross revenues and accounted for 21% of gross revenues in aggregate for the year ended December 31, 2002. Two customers accounted for 14% and 10% of total accounts receivable at December 31, 2001. Two customers each accounted for 10% of total accounts receivable at December 31, 2002.

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 under development may not receive the necessary approvals. If the regulatory approvals for the Company s products under development are denied or delayed, it may have a material adverse impact on the Company. A loss of regulatory approval or clearance for FreeStyle would have a material adverse impact on the Company. In January 2000, the Company received FDA approval for its first product, FreeStyle. In May 2000, the Company received FDA clearance for the FreeStyle Connect software, a data management software product. In June 2002, the Company received 510(k) clearance for its FreeStyle Tracker System that incorporates the blood glucose monitoring technology from FreeStyle into a module for the Handspring Visor handheld computer.

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 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.

The Company is subject to risks and uncertainties that may affect is operations, performance and results. These risks include, but are not limited to: (1) the Company s history of losses and variable quarterly results; (2) the Company s dependence on FreeStyle for future revenues; (3) the Company s limited sales and marketing experience; (4) substantial competition; (5) risks related to failure to protect the Company s intellectual property and litigation in which it may become involved; (6) risks relating to development of innovative products; (7) risks related to noncompliance with FDA regulations; and (8) limited manufacturing experience and the Company s reliance on single manufacturers and sole source suppliers.

Table of Contents

**THERASENSE, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

*Revenue recognition*

The Company recognizes revenue in accordance with Staff Accounting Bulletin No. 101, Revenue Recognition in Financial Statements. Product revenues are generated primarily 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 and Canada 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 and Canada can return these products to the Company up to six months beyond this expiration date. Prior to the second quarter of 2002, the Company lacked sufficient historical experience in sales and product returns, and the Company therefore deferred recognition of revenue on sales of FreeStyle test strips and lancets until resold by the retailers and wholesalers through to end-users, and the Company deferred recognition of revenue on FreeStyle System kits until 30 days after purchase by the end-user.

Now that the Company has a sufficient historical basis to estimate return rates, sales to retailers and wholesalers in the United States of America and Canada beginning with the second quarter of 2002 are recognized upon shipment. As a result, there are no deferred revenues from product sales for the second quarter of 2002 onwards, and previously deferred revenues from product sales were recognized in the second quarter of 2002.

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 existing customers in North America. Under the terms of the agreement, the Company received a $1,500,000 nonrefundable pre-payment, which was deferred and was credited as revenues were recognized. The pre-payment was fully recognized during 2001. 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 $5,000,000 noncreditable up-front payment, which was 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, except for Canada, 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 website to end users upon shipment for FreeStyle test strips, lancets and 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.

Table of Contents

**THERASENSE, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

*Advertising costs*

Advertising costs, included in selling, general and administrative expenses, are expensed as incurred. Advertising expenses in 2000, 2001 and 2002 were $1,878,396, $4,903,023 and $6,685,295 respectively.

*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, 2001 and 2002, all long-lived assets are maintained in the United States of America. All revenue was generated in the United States of America during the year ended December 2000. During 2001 and 2002, 17% and 23%, respectively, of gross revenue was from international shipments.

*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 Statement of Financial Accounting Standards, or SFAS No. 148, Accounting for Stock-Based Compensation Transition and Disclosure an amendment of FASB Statement No. 123.

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS No. 123 Accounting for Stock-Based Compensation 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. Pro forma net loss information using the fair value method to determine compensation expense prescribed by

SFAS No. 123 is included in Note 10.

*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, convertible promissory notes 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.

Table of Contents

**THERASENSE, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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, | | |
|---|---|---|---|
| | 2000 | 2001 | 2002 |
| Numerator: | | | |
| Net loss | $ (43,591,837) | $ (52,865,533) | $ (29,162,557) |
| Deemed dividends related to beneficial conversion feature of preferred stock | (14,772,878) | (26,782,911) | |
| Net loss attributable to common stockholders | $ (58,364,715) | $ (79,648,444) | $ (29,162,557) |
| Denominator: | | | |
| Weighted-average common stock outstanding | 5,060,774 | 12,306,456 | 40,178,342 |
| Less: Weighted-average shares subject to repurchase | (1,087,524) | (415,890) | (47,728) |
| Weighted-average shares used in computing basic and diluted net loss per common share | 3,973,250 | 11,890,566 | 40,130,614 |

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

| | December 31, | | |
|---|---|---|---|
| | 2000 | 2001 | 2002 |
| Options to purchase common stock | 4,201,599 | 6,511,531 | 7,336,349 |
| Common stock subject to repurchase | 612,297 | 175,924 | |
| Convertible preferred stock | 20,078,780 | | |
| Warrants | 521,013 | 3,809 | |
| Convertible promissory notes | 294,118 | | |

*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*

In June 2001, the Financial Accounting Standards Board ( FASB ) issued SFAS No. 143, Accounting for Asset Retirement Obligations, ( SFAS No. 143 ) which is effective for the Company beginning in fiscal 2003. SFAS No. 143 requires that the fair value of a liability for an asset retirement obligation be recognized in the period in which it is incurred if a reasonable estimate of fair value can be made, with the associated asset retirement costs capitalized as part of the carrying amount of the long-lived asset. The Company does not expect the adoption of SFAS No. 143 to have a material impact on the Company s financial position and results of operations.

In October 2001, the FASB issued SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets ( SFAS No. 144 ), which is effective for fiscal years beginning after December 15, 2001 and

Table of Contents

**THERASENSE, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

interim periods within those fiscal periods. SFAS No. 144 supersedes FASB Statement No. 121 Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of and parts of APB Opinion No. 30 Reporting and Results of Operations Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions relating to Extraordinary Items, ( Opinion 30 ), however, SFAS No. 144 retains the requirement of Opinion 30 to report discontinued operations separately from continuing operations and extends that reporting to a component of an entity that either has been disposed of (by sale, by abandonment, or in a distribution to owners) or is classified as held for sale. SFAS No. 144 addresses financial accounting and reporting for the impairment of certain long-lived assets and for long-lived assets to be disposed of. The Company does not expect the adoption of SFAS No. 144 to have a material impact on the Company s financial position and results of operations.

In April 2002, the FASB issued SFAS No. 145, Rescission of FASB Statement No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections ( SFAS No. 145 ) which eliminates inconsistencies between the required accounting for sale-leaseback transactions and the required accounting for certain lease modifications that have economic effects that are similar to sale-leaseback transactions. SFAS No. 145 also amends other existing authoritative pronouncements to make various technical corrections, clarify meanings, or describe their applicability under changed conditions. The provisions of SFAS No. 145 are effective for fiscal years beginning after May 15, 2002 and for transactions occurring after May 15, 2002. The Company does not expect adoption of SFAS No. 145 to have a material impact on the Company s financial position or on its results of operations.

In June 2002, the FASB issued SFAS No. 146, Accounting for Exit or Disposal Activities ( SFAS No. 146 ) which addresses the recognition, measurement, and reporting of costs that are associated with exit and disposal activities, including restructuring activities that are currently accounted for pursuant to the guidance that the EITF has set forth in EITF Issue No. 94-3, Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring) . SFAS No. 146 will be effective for exit or disposal activities that are initiated after December 31, 2002. The Company does not expect adoption of SFAS No. 146 to have a material impact on its financial position or on its results of operations.

In November 2002, the FASB issued FASB Interpretation No. 45 ( FIN 45 ), Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others. FIN 45 requires that a liability be recorded in the guarantor s balance sheet upon issuance of a guarantee. In addition, FIN 45 requires disclosures about the guarantees that an entity has issued, including a reconciliation of changes in the entity s product warranty liabilities. The initial recognition and initial measurement provisions of FIN 45 are applicable on a prospective basis to guarantees issued or modified after December 31, 2002, irrespective of the guarantor s fiscal year-end. The disclosure requirements of FIN 45 are effective for financial statements of interim or annual periods ending after December 15, 2002. The adoption of FIN 45 did not have a material impact on the Company s financial position or results of operations.

In November 2002, the EITF reached a consensus on Issue No. 00-21 ( EITF 00-21 ), Revenue Arrangements with Multiple Deliverables. EITF 00-21 provides guidance on how to account for arrangements that involve the delivery or performance of multiple products, services and/or rights to use assets. The provisions of EITF 00-21 will apply to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The Company believes that the adoption of EITF 00-21 will have no material impact on its financial statements.

In December 2002, the FASB issued SFAS No. 148, Accounting for Stock-Based Compensation Transition and Disclosure an amendment of FASB Statement No. 123. SFAS No. 148 provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. SFAS No. 148 also requires prominent disclosures of the pro forma effect of using the fair value

Table of Contents

**THERASENSE, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

method of accounting for stock-based employee compensation in both annual and interim financial statements. The transition and annual disclosure requirements of SFAS No. 148 are effective for fiscal years ending after December 15, 2002. The interim disclosure requirements are effective for interim periods beginning after December 15, 2002. The adoption of SFAS No. 148 did not have a material impact on the Company s financial position or on its results of operations.

In January 2003, the FASB issued FASB Interpretation No. 46 ( FIN 46 ), Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51. FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 is effective immediately for all new variable interest entities created or acquired after January 31, 2003. For variable interest entities created or acquired prior to February 1, 2003, the provisions of FIN 46 must be applied for the first interim or annual period beginning after June 15, 2003. The Company does not have any ownership in any variable interest entities as of December 31, 2002. The Company does not expect adoption of FIN 46 to have a material impact on its financial position or on its results of operations.

**NOTE 3 CASH, CASH EQUIVALENTS AND INVESTMENTS:**

Cash, cash equivalents and investments consisted of the following:

| | December 31, | |
|---|---|---|
| | 2001 | 2002 |
| **Cash and cash equivalents:** | | |
| Cash | $ 912,721 | $ 15,295,434 |
| Certificate of deposit | 400,000 | |
| Money market funds | 98,517,965 | 5,512,348 |
| Commercial paper | 12,036,270 | 5,500,000 |
| Corporate bonds | 9,000,000 | |
| Municipal securities | 22,320,000 | 5,850,000 |
| | $ 143,186,956 | $ 32,157,782 |
| **Short-term Available-for-sale Investments:** | | |
| Corporate bonds | $ | $ 23,968,845 |
| Government bonds | | 10,166,040 |
| | $ | $ 34,134,885 |

| | | |
|---|---|---|
| **Long-term Available-for-sale Investments:** | | |
| Certificate of deposit | $ | $ 400,000 |
| Corporate bonds | | 1,041,230 |
| Government bonds | 4,278,040 | 10,176,435 |
| | $ 4,278,040 | $ 11,617,665 |

As of December 31, 2001, the market value of investments approximated cost. Accordingly, there was no unrealized gain or loss reported in accumulated other comprehensive income (loss). As of December 31, 2002, the market value of investments exceeded the cost. Accordingly, there is an unrealized gain reported in accumulated other comprehensive income (loss) of $433,256.

Table of Contents

**THERASENSE, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The following is a summary of cash, cash equivalents and investments as of December 31, 2002:

| | Amortized Cost | Unrealized Gain | Fair Value |
|---|---|---|---|
| **Cash and cash equivalents:** | | | |
| Cash | $ 15,295,434 | $ | $ 15,295,434 |
| Money market funds | 5,512,348 | | 5,512,348 |
| Commercial paper | 5,499,950 | 50 | 5,500,000 |
| Municipal securities | 5,850,000 | | 5,580,000 |
| | 32,157,732 | 50 | 32,157,782 |
| **Short-term available-for-sale investments:** | | | |
| Corporate bonds | 23,697,171 | 271,675 | 23,968,845 |
| Government bonds | 10,061,139 | 104,901 | 10,166,040 |
| | 33,758,310 | 375,576 | 34,134,885 |
| **Long-term available-for-sale investments:** | | | |
| Certificate of deposit | 400,000 | | 400,000 |
| Corporate bonds | 1,022,878 | 18,352 | 1,041,230 |
| Government bonds | 10,138,156 | 38,279 | 10,176,435 |
| | 11,561,034 | 56,630 | 11,617,665 |
| Total: | $ 77,477,076 | $ 433,256 | $ 77,910,332 |

Maturities of investment securities at December 31, 2002 were as follows:

| | Maturity in 1 to 2 years | Maturity in 2 to 5 years | Total |
|---|---|---|---|
| **Long-term available-for-sale investments:** | | | |
| Certificate of deposit | $ | $ 400,000 | $ 400,000 |
| Corporate bonds | 1,041,230 | | 1,041,230 |
| Government bonds | 10,176,435 | | 10,176,435 |

| | | | |
|---|---|---|---|
| Total: | $ 11,217,665 | $ 400,000 | $ 11,617,665 |

In December 2001, a $400,000 certificate of deposit was established to collateralize the $3,000,000 equipment line of credit and, as such, the investment is restricted in its availability.

**NOTE 4 BALANCE SHEET ACCOUNTS:**

Inventories consisted of the following:

| | December 31, | |
|---|---|---|
| | 2001 | 2002 |
| Raw materials | $ 2,089,705 | $ 5,058,774 |
| Work-in-process | 2,673,336 | 3,807,331 |
| Finished goods | 1,886,375 | 12,193,615 |
| | $ 6,649,416 | $ 21,059,720 |

Table of Contents

**THERASENSE, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Property and equipment consisted of the following:

| | December 31, | |
|---|---|---|
| | 2001 | 2002 |
| Manufacturing equipment | $ 4,391,255 | $ 7,083,657 |
| Office equipment | 772,901 | 840,744 |
| Laboratory equipment | 1,291,340 | 1,720,010 |
| Computer equipment | 1,758,393 | 2,271,951 |
| Tooling | 1,202,937 | 4,259,643 |
| Leasehold improvements | 1,209,359 | 1,209,359 |
| Construction-in-progress | | 4,235,199 |
| | 10,626,185 | 21,620,653 |
| Less: Accumulated depreciation and amortization | (4,087,177) | (7,280,578) |
| | $ 6,539,008 | $ 14,339,985 |

Other assets consisted of the following:

| | December 31, | |
|---|---|---|
| | 2001 | 2002 |
| Licenses, net | $ 1,720,833 | $ 4,127,333 |
| Deposits | 709,782 | 674,770 |
| Debt issuance costs, net | 208,511 | |
| Manufacturing equipment deposits | 160,165 | |
| Other | 30,557 | 13,891 |
| | $ 2,829,848 | $ 4,815,994 |

Accrued liabilities consisted of the following:

| | December 31, | |
|---|---|---|
| | 2001 | 2002 |
| Salaries and related expense | $ 5,630,741 | $ 5,526,502 |
| Rebates and coupons | 2,331,797 | 1,713,568 |
| Marketing costs | 3,782,602 | 1,740,237 |
| Professional and other outside services | 1,548,562 | 1,603,777 |
| Royalties | 1,508,334 | 2,477,529 |
| Warranties | 1,282,215 | 1,931,935 |
| Other liabilities | 514,559 | 1,116,237 |
| | $ 16,598,810 | $ 16,109,785 |

**NOTE 5 BORROWINGS UNDER LINES OF CREDIT:**

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

Table of Contents

**THERASENSE, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

$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 9).

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 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 9). The effective annual interest rate, including warrant amortization, is 22.3%. In May 2002, the Company repaid the $1,557,962 balance of this debt.

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 warrants to purchase 38,094 shares of Series B preferred stock (Note 9). The effective annual interest rate, including warrant amortization, is 13.1%.

During 2001, the Company entered into an equipment line of credit agreement to borrow up to $3,000,000 for equipment purchases. The line of credit accrues interest at an annual rate of 7.28% and both principal and interest are payable in sixty equal monthly payments. All borrowings under this agreement are collateralized by the equipment purchased and a $400,000 certificate of deposit.

During 2002, the Company entered into a revolving line of credit agreement with a lending company, which was amended and restated in December 2002. Under the terms of the credit agreement, amounts the Company borrows from the lending company are repaid to the lending company directly by the Company s accounts receivable debtors. Outstanding amounts owed to the lending company under the credit agreement are collateralized by all of the Company s assets excluding its intellectual property assets. The maximum amount the Company may borrow from the lending company is based on its eligible accounts receivable and cannot exceed $15,000,000. All outstanding amounts bear interest at the prime rate plus 0.5%, which was 4.75% at December 31, 2002. The credit agreement remains in full force and effect until terminated by either party under certain circumstances. As of December 31, 2002, $3,000,000 in principal was outstanding under the credit agreement.

As of December 31, 2002, aggregate future principal payments under the lines of credit are as follows:

| | |
|---|---|
| 2003 | $ 3,963,102 |
| 2004 | 592,467 |
| 2005 | 640,686 |
| 2006 | 645,209 |

| | |
|---|---|
| | 5,841,464 |
| Less: Current portion | (3,963,102) |
| | $ 1,878,362 |

Table of Contents

**THERASENSE, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**NOTE 6 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. 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.

**NOTE 7 COMMITMENTS AND CONTINGENCIES:**

*Facility lease*

The Company leases its facilities under various operating lease agreements which expire up through April 2013. Under the terms of one of the agreements, 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. The remaining lease agreements do not contain any provisions for future rental adjustments. At the expiration of one of the lease terms, the Company has the option to extend the facility lease for an additional five years. Under the terms of one of the lease agreements, the Company has a right of first offer to purchase the facility in the event the owner offers to sell the facility to a third party. As of December 31, 2002, aggregate future minimum facility lease payments are as follows:

| | |
|---|---|
| 2003 | $ 1,832,154 |
| 2004 | 1,903,745 |
| 2005 | 1,804,223 |
| 2006 | 1,884,214 |
| 2007 | 1,884,214 |
| Thereafter | 10,756,975 |
| | $ 20,065,525 |

Rent expense for the years ended December 31, 2000, 2001 and 2002 was $674,959, $1,023,090, and $1,267,208, respectively.

*Office equipment leases*

The Company leases certain computer and office equipment under operating lease agreements which expire through June 2005. As of December 31, 2002, aggregate future minimum lease payments are as follows:

| | |
|---|---|
| 2003 | $ 185,036 |
| 2004 | 12,768 |
| 2005 | 6,384 |
| | $ 204,188 |

*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.

Table of Contents

**THERASENSE, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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 an additional 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.

During 2002, the Company has entered into an arrangement to finance the purchase of certain equipment the Company uses to manufacture the FreeStyle test strips with its supplier of test strip packaging vials. The purchase price of the equipment is approximately $1,600,000. The financed purchase price has an interest rate of 7.0% per year. Under the terms of the agreement, Company pays the equipment purchase price to the supplier through a portion of the purchase price for each packaging vial purchased from the supplier. To date, the Company has paid to the supplier approximately $187,900, consisting of approximately $70,400 in principal and approximately $117,500 in interest, pursuant to the financing arrangements. The Company will take title to the equipment once the equipment purchase price has been paid in full. The Company must pay the equipment purchase price to the supplier by not later than June 2008. The supplier has financed the equipment pursuant to a loan arrangement with a bank. The supplier s loan obligations to the bank are collateralized by the equipment. If the supplier defaults on its loan obligations to the bank, the Company must assume and satisfy the supplier obligations to the bank in order to take title to the equipment.

Property and equipment acquired under capital leases consisted of the following:

| | December 31, | |
|---|---|---|
| | 2001 | 2002 |
| Manufacturing equipment | $ 1,099,009 | $ 2,669,454 |
| Leasehold improvements | 863,891 | 863,891 |
| Office equipment | 437,521 | 437,521 |
| Tooling | 340,083 | 340,083 |
| Computer equipment | 332,610 | 332,610 |
| Laboratory equipment | 298,069 | 298,069 |
| | 3,371,183 | 4,941,628 |
| Less: Accumulated amortization | (1,787,881) | (2,740,218) |
| | $ 1,583,302 | $ 2,201,410 |

Table of Contents

**THERASENSE, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

As of December 31, 2002, aggregate future minimum capital lease payments are as follows:

| | |
|---|---|
| 2003 | $ 1,319,533 |
| 2004 | 418,060 |
| 2005 | 269,850 |
| 2006 | 269,850 |
| 2007 | 269,850 |
| 2008 | 269,796 |
| Minimum payments | 2,816,938 |
| Less: Amount representing interest | (348,900) |
| Principal amount of minimum payments | 2,468,038 |
| Less: Current portion | (1,185,785) |
| | $ 1,282,253 |

*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, 2002, aggregate future minimum payments pursuant to these agreements are as follows:

| | |
|---|---|
| 2003 | $ 1,120,000 |
| 2004 | 1,120,000 |
| 2005 | 620,000 |
| 2006 | 620,000 |
| 2007 | 620,000 |
| Thereafter | 3,700,000 |
| | $ 7,800,000 |

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 payments 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 $2,975,000 in exchange for research and development services provided by Facet Technologies.

For the years ended December 31, 2000, 2001 and 2002, $407,281, $2,403,541 and $4,327,759 of royalties have been expensed to cost of revenues, respectively. As of December 31, 2001 and 2002, the Company has accrued $1,508,334, and $2,477,629, respectively, of royalties relating to these agreements.

As of December 31, 2001 and 2002, the Company has included $1,196,666 and $1,184,167, respectively, of an annual $2,000,000 paid-up licensing fee in prepaid expenses and other current assets. These license fee payments are 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.

Table of Contents

**THERASENSE, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

In November 2002, the Company and Health Hero Network, Inc. ( Health Hero ) entered into a Patent License Agreement pursuant to which Health Hero granted the Company a fully paid-up license to certain patents the Company utilizes in connection with certain products. The license is co-exclusive with Health Hero in the field of diabetes. If the Company sublicenses any of the Health Hero patents, the Company will be required to make additional payments to Health Hero. Health Hero will also perform some product development tasks and has issued to the Company warrants to purchase shares of Health Hero s Series D preferred stock. For accounting purposes, no value has been assigned to these warrants.

As of December 31, 2001 and 2002, the cost of these licenses totaling $1,850,000 and $4,880,000 less accumulated amortization of $129,167 and $752,667, respectively, is included in other assets and is being amortized ratably to cost of revenues over 5 years, the estimated useful lives of licensed technologies.

*Contingencies*

From time to time, the Company may become involved in litigation relating to claims arising from the ordinary course of business. Management is not currently aware of any matters that will have a material adverse affect on the financial position, results of operations or cash flows of the Company.

**NOTE 8 INITIAL PUBLIC OFFERING:**

On October 17, 2001, the Company closed its initial public offering in which it sold 6,900,000 shares of common stock at $19.00 per share for net proceeds of approximately $120,899,367, net of underwriting discounts, commissions and other offering costs. Immediately prior to the closing of the initial public offering, all the Company s convertible preferred stock automatically converted into 26,722,151 shares of common stock.

**NOTE 9 CONVERTIBLE PREFERRED STOCK:**

As of December 31, 2000, the convertible preferred stock consisted of the following:

| | Number of Shares Authorized | Number of Shares Issued and Outstanding | Proceeds, Net of Issuance Costs | Liquidation Preference Per Share | 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 December 31, 2001 and 2002, there was no convertible preferred stock outstanding. All preferred stock was converted to common stock upon the closing of the Company s initial public offering.

*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. During October 2001, the warrants were exercised in a cashless transaction resulting in the issuance of 49,084 shares of common stock.

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.

Table of Contents

**THERASENSE, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

During November 2001, the warrants were exercised in a cashless transaction resulting in the issuance of 43,540 shares of common stock.

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 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. During October 2001, 34,285 of the warrants were exercised in a cashless transaction resulting in the issuance of 30,495 shares of common stock. During April 2002, 3,809 of the warrants were exercised in a cashless transaction resulting in the issuance of 3,401 shares of common stock.

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 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. During October 2001, the warrants were exercised in a cashless transaction resulting in the issuance of 348,629 shares of common stock.

**NOTE 10 STOCKHOLDERS EQUITY (DEFICIT):**

*Preferred stock*

In October 2001, the Board of Directors approved an amendment to the Company s certificate of incorporation to authorize 5,000,000 shares of undesignated preferred stock, for which the Board of Directors is authorized to fix the designation, powers, preferences and rights and an increase in the authorized number of shares of common stock to 200,000,000 shares.

*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.

*2001 Employee Stock Purchase Plan*

In June 2001, the Board of Directors and stockholders adopted the 2001 Employee Stock Purchase Plan ( 2001 ESPP ), 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 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

Table of Contents

**THERASENSE, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

period. The initial offering period commenced on October 11, 2001, the effective date of the Company s initial public offering.

*Incentive Stock Plans*

***2001 Stock Plan***

In June 2001, the Board of Directors and stockholders adopted the 2001 Stock Plan ( 2001 Plan ). 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. 6,500,000 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 was 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 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. For the year ended December 31, 2002, the Board of Directors did not increase the number of shares available for issuance under the 2001 Plan.

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 the fair market value at date of grant for incentive stock options or 85% of the fair market value for nonqualified stock options). Options granted under the 2001 Plan generally become exercisable 1/4 on the first anniversary of the optionee s employment start date and an additional 1/48 of the total number of shares subject to the option shares shall become exercisable monthly thereafter until all of the shares have become exercisable. In certain cases unvested options may be exercised and the Company may retain a repurchase right upon termination of the holder s status as an employee or consultant.

Under the terms of the 2001 Plan, 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 each non-employee director will be granted a nonstatutory option to purchase 5,000 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.

*1997 Stock Plan*

In March 1997, the Company approved the 1997 Stock Option Plan (the Plan ) under which the officers of the Company entered into stock option agreements with selected individuals. In connection with the Company s October 2001 initial public offering, the Company stopped granting stock options under the Plan and instead grants stock options under the 2001 Plan. Options granted under the Plan generally become exercisable

1/4 on the first anniversary of the optionee s employment start date and an additional 1/48 of the total number of shares subject to the option shares shall become exercisable monthly thereafter until all of the shares have become exercisable. In certain cases unvested options have been exercised and the Company has retained a repurchase right upon termination of the holder s status as an employee or consultant. The repurchase right lapses over time in the same manner as the option would have become exercisable. At December 31, 2001 and 2002, 175,924 and no shares, respectively, of common stock were subject to the Company s repurchase rights, respectively. The options have a maximum term of ten years.

Table of Contents

**THERASENSE, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Activity under the Plans are as follows:

| | | Outstanding Options | |
|---|---|---|---|
| | Shares Available for Grant | Number of Shares | Weighted Average Exercise Price |
| Balances, January 1, 2000 | 511,567 | 1,644,468 | $ 0.68 |
| Additional shares reserved | 2,670,865 | | |
| Options granted | (2,922,596) | 2,922,596 | $ 4.01 |
| Options exercised | | (213,671) | $ 0.41 |
| Options canceled/shares repurchased | 203,004 | (151,794) | $ 1.55 |
| Balances, December 31, 2000 | 462,840 | 4,201,599 | $ 2.98 |
| Additional shares reserved | 8,500,000 | | |
| Options granted | (2,949,000) | 2,949,000 | $ 11.83 |
| Options exercised | | (300,918) | $ 1.74 |
| Options canceled | 338,150 | (338,150) | $ 2.87 |
| Balances, December 31, 2001 | 6,351,990 | 6,511,531 | $ 7.05 |
| Options granted | (2,423,051) | 2,423,051 | $ 16.87 |
| Options exercised | | (1,073,883) | $ 2.73 |
| Options canceled | 470,041 | (524,350) | $ 9.28 |
| Balances, December 31, 2002 | 4,398,980 | 7,336,349 | $ 10.78 |

The options outstanding and exercisable by exercise price range at December 31, 2002 are as follows:

| | Outstanding Options | | | Options Exercisable | |
|---|---|---|---|---|---|
| Range of exercise price | Number outstanding | Weighted average remaining contractual life (years) | Weighted Average Exercise Price | Options Exercisable | Weighted Average Exercise Price |
| $0.00-$1.41 | 385,250 | 6.2 | $0.71 | 309,724 | $ 0.67 |
| $1.42-$2.12 | 0 | 0.0 | $0.00 | 0 | $ 0.00 |
| $2.13-$3.18 | 717,321 | 7.2 | $3.00 | 491,249 | $ 3.00 |

| | | | | | | |
|---|---|---|---|---|---|---|
| $3.19-$4.76 | 526,772 | 7.6 | | $3.93 | 307,294 | $ 3.92 |
| $4.77-$7.15 | 1,773,492 | 8.3 | | $5.60 | 742,778 | $ 5.52 |
| $7.16-$10.72 | 1,478,479 | 8.8 | | $9.29 | 306,600 | $ 9.00 |
| $10.73-$16.08 | 151,000 | 9.6 | $ | 15.29 | 0 | $ 0.00 |
| $16.09-$24.12 | 2,304,035 | 9.1 | $ | 21.15 | 354,010 | $21.61 |
| | 7,336,349 | 8.5 | $ | 10.78 | 2,511,655 | $ 6.93 |

As of December 31, 2001, 1,764,489 options outstanding were exercisable.

*Stock-based compensation*

As permitted by Statement of Financial Accounting Standard (SFAS) No. 123, Accounting for Stock-Based Compensation, (SFAS 123) the Company accounts for employee stock-based compensation in accordance with Accounting Principles Board Opinion No. 25 (APB 25), Accounting for Stock Issued to Employees , and related interpretations in accounting for its stock-based compensation plans. Accordingly, compensation costs for

Table of Contents

**THERASENSE, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

stock options granted to employees and directors are measured as the excess, if any, of the deemed fair market value of the Company s stock on the date of the grant over the amount an employee must pay to acquire the stock. Stock based compensation arrangements to non-employees are accounted for in accordance with SFAS 123 and Emerging issues Task Force Issue No. 96-18 (EITF 96-18), Accounting for Equity Instruments That Are Issued to Other Employees for Acquiring, or in Conjunction with Selling, Goods or Services which requires that these equity instruments are recorded at their fair value on the measurement date. The measurement of stock-based compensation is subject to periodic adjustments as the underlying equity instruments vest.

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 volatility factor as an assumption. The Company previously calculated the fair value of each option on the date of grant using the minimum value method as prescribed by SFAS No. 123. The assumptions used are as follows:

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2000 | 2001 | 2002 |
| Risk-free interest rate | 5.21% | 5.47% | 4.60% |
| Expected life (in years) | 4 | 4 | 4 |
| Dividend yield | | | |
| Expected volatility | 70% | 70% | 95% |

Had compensation costs been determined based upon the fair value at the grant date, consistent with the methodology prescribed under SFAS No. 123, the Company s pro forma net loss and pro forma basic and diluted net loss per share under SFAS No. 123 as if the fair value method had been applied to all awards would have been as follows:

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2000 | 2001 | 2002 |
| Net loss, as reported | $ (58,364,715) | $ (79,648,444) | $ (29,162,557) |
| Add : Total stock based employee compensation determined under fair value based method for all awards | (785,287) | (4,203,129) | (9,158,691) |
| Pro forma net loss | $ (59,150,002) | $ (83,851,573) | $ (38,321,248) |
| Basic and diluted net loss per share | | | |
| As reported | $ (14.69) | $ (6.70) | $ (0.73) |
| Pro forma | $ (14.89) | $ (7.05) | $ (0.95) |

During 2000 and 2001, the Company issued options to certain employees under the Plan with exercise prices below the deemed fair market value of the Company s common stock at the date of grant. In accordance with the requirements of APB 25, the Company has recorded deferred stock-based compensation for the difference between the exercise price of the stock options and the deemed fair market value of the Company s stock at the date of grant. This deferred stock-based compensation is amortized to expense on a straight line basis over the period during which the Company s right to repurchase the stock lapses or the options become vested, generally four years. During the years ended December 31, 2000, 2001, and 2002, the Company had recorded deferred stock-based compensation related to these options in the amounts of $11,008,675, $13,122,276 and ($1,685,420), net of cancellations, respectively.

Table of Contents

**THERASENSE, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Stock compensation expenses relating to employees and amortized to expenses for the years ended December 31, 2000, 2001 and 2002 were as follows:

| | Cost of revenues | Research and development | Selling, general and administrative | Total |
|---|---|---|---|---|
| 2000 | $ 75,675 | $ 427,249 | $ 999,024 | $ 1,501,948 |
| 2001 | $ 484,426 | $ 1,097,441 | $ 3,118,344 | $ 4,700,211 |
| 2002 | $ 599,021 | $ 1,122,356 | $ 3,831,023 | $ 5,552,400 |

Stock-based compensation expense related to stock options granted to non-employees is recognized on a straight line basis, as the stock options are earned. During the years ended December 31, 2000, 2001 and 2002, the Company granted options to purchase 13,250, 29,500 and 31,200 shares of common stock to non-employees, respectively. The Company believes that the fair value of the stock options is more reliably measurable than the fair value of the services received. The fair value of the stock options granted is calculated at each reporting date using the Black-Scholes option pricing model as prescribed by SFAS No. 123 using the following assumptions:

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2000 | 2001 | 2002 |
| Risk-free interest rate | 5.75% | 5.42% | 4.60% |
| Expected life (in years) | 10 | 10 | 10 |
| Dividend yield | | | |
| Expected volatility | 70% | 70% | 95% |

The stock-based compensation expense will fluctuate as the fair market 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 $802,716, $2,192,170 and ($1,425,257), net of cancellations, for the years ended December 31, 2000, 2001 and 2002, respectively.

Stock compensation expenses relating to non-employees and amortized to expenses for the years ended December 31, 2000, 2001 and 2002 were as follows:

| | Cost of revenues | Research and development | Selling, general and administrative | Total |
|---|---|---|---|---|
| 2000 | $ | $ 137,597 | $ 153,703 | $ 291,300 |
| 2001 | $ | $ 179,983 | $ 701,358 | $ 881,341 |
| 2002 | $ | $ 134,405 | $ 326,792 | $ 461,197 |

*Note receivable from stockholders*

During 1999 and 2000, the Company sold common stock to certain of its stockholders 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.

**NOTE 11 INCOME TAXES:**

The geographic distribution of net loss is summarized below:

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2000 | 2001 | 2002 |
| United States loss before provision for taxes | $ 43,591,837 | $ 52,865,533 | $ 24,349,149 |
| Foreign loss before provision for taxes | | | 4,813,408 |
| Net loss before provision for taxes | $ 43,591,837 | $ 52,865,533 | $ 29,162,557 |

Table of Contents

**THERASENSE, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The components of the benefit for income taxes are as follows:

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2000 | 2001 | 2002 |
| Current: | | | |
| Foreign | $ | $ | $ |
| Federal | | | |
| State | | | |
| Net current | | | |
| Deferred: | | | |
| Foreign: | | | |
| Federal | 14,303,368 | 15,554,622 | 8,490,275 |
| State | 1,802,594 | 2,394,346 | 1,816,473 |
| Deferred: | 16,107,108 | 17,948,968 | 10,306,748 |
| Valuation allowance | (16,107,108) | (17,948,968) | (10,306,748) |
| Net Deferred | $ | $ | $ |

The tax provision (benefit) differs from the amounts obtained by applying the statutory U.S. federal income tax rate to loss before taxes as shown below:

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2000 | 2001 | 2002 |
| Tax at federal statutory rate | -34.00% | -34.00% | -34.00% |
| State, net of federal benefit | -5.83 | -5.83 | -5.83 |
| Tax credits | -1.92 | -1.04 | -3.45 |
| Stock based compensation | 2.93 | 4.21 | 8.21 |
| Other | 0.83 | 0.45 | 2.65 |
| Deferred tax assets not benefited | 38.01 | 36.22 | 32.42 |
| | 0.00% | 0.00% | 0.00% |

Deferred tax assets consists of the following:

| | December 31, | |
|---|---|---|
| | 2001 | 2002 |
| Depreciation and amortization | $ 122,423 | $ 2,378,359 |
| Deferred revenues | 10,743,333 | 1,294,618 |
| Accruals, reserves, and other | 5,002,194 | 6,063,436 |
| Tax credit carryforwards | 1,439,060 | 2,964,212 |
| Capitalized start-up costs | 208,997 | 69,666 |
| Net operating loss carryforwards | 24,846,303 | 39,898,768 |
| | 42,362,310 | 52,669,059 |
| Valuation allowance | (42,362,310) | (52,669,059) |
| Net deferred tax assets | $ | $ |

Table of Contents

**THERASENSE, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Based on the available objective evidence, management believes it is more likely than not that the net deferred tax assets will not be fully realized. Accordingly, the Company has provided a full valuation allowance against its net deferred tax assets at December 31, 2001 and 2002.

As of December 31, 2002, the Company has a net operating loss carryforward of approximately $108,900,000 and $49,200,000 for Federal and state tax purposes, respectively. If not utilized, these carryforwards will begin to expire in 2012 for federal and in 2006 for state purposes.

As of December 31, 2002, deferred tax assets of approximately $1,500,000 pertain to certain net operating loss carryforwards resulting from the exercise of employee stock options. When recognized, the tax benefit of these loss carryforwards will be accounted for as a credit to additional paid-in capital rather than a reduction of the income tax provision.

The Company has research credit carryforwards of approximately $1,579,000 and $1,401,000 for federal and state income tax purposes, respectively. If not utilized, the federal carryforward will expire in various amounts beginning in 2012. The state 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 as a result of the Company s preferred stock financings. In accordance with Internal Revenue Code Section 382, the Company s net operating loss carryforwards are subject to annual limitation.

**NOTE 12 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 until April 2002. During 2000, 2001 and 2002, the Company paid Dr. Heller $110,141, $121,196 and $110,292, respectively, in connection with this agreement. As of December 31, 2001 and 2002, 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 principal of Facet Technologies until

2001 is a member of the Company s Board of Directors. During 2000 and 2001, Facet Technologies provided development services of approximately $300,000 and $900,000, respectively, and purchases from Facet Technologies totaled $402,356 and $1,697,377, respectively. In addition, $111,477 is included in accounts payable as of December 31, 2001, and $555,286 is included in accrued liabilities as of December 31, 2001 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 2000, 2001 and 2002, the Company purchased $20,639,858, $40,047,640 and $66,372,222 under this agreement, respectively. In addition, $5,252,134 and

Table of Contents

**THERASENSE, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

$4,379,375 are included in accounts payable as of December 31, 2001 and 2002, respectively, and $993,276 and $1,603,777 are included in accrued liabilities as of December 31, 2001 and 2002, respectively, relating to this agreement. As of December 31, 2001 and 2002, Flextronics owed the Company $3,121,750 and $2,500,757, respectively, for raw materials purchased.

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 was also a Vice President of the Company and a member of the Company s Board of Directors until April 2002.

**NOTE 13 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.

**NOTE 14 SUBSEQUENT EVENTS**

In January 2003, the Company amended its distributor agreement with the Disetronic Group. The Company received $15,000,000 pursuant to the amendment, and the Company will recognize the $15,000,000 over the remaining term of the agreement, which expires in December 2006.

Table of Contents

**THERASENSE, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**NOTE 15 QUARTERLY FINANCIAL DATA (UNAUDITED):**

| | Quarter Ended | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | March 31, 2001 | June 30, 2001 | September 30, 2001 | December 31, 2001 | March 31, 2002 | June 30, 2002(1) | September 30, 2002 | December 31, 2002 |
| Revenues. | $ 7,677,456 | $ 17,846,317 | $ 19,858,533 | $ 26,473,016 | $ 33,279,327 | $ 59,226,593 | $ 39,029,550 | $ 46,172,421 |
| Cost of Revenues | 6,225,646 | 13,442,423 | 12,938,677 | 16,540,462 | 18,408,646 | 34,427,698 | 18,348,496 | 21,650,548 |
| Gross profit | 1,451,810 | 4,403,894 | 6,919,856 | 9,932,554 | 14,870,681 | 24,798,895 | 20,681,054 | 24,521,873 |
| Net loss | $ (12,180,463) | (14,752,966) | (12,924,515) | (13,007,567) | (10,984,820) | (3,096,078) | (9,347,338) | (5,734,321) |
| Deemed dividends related to beneficial conversion of preferred stock | (23,302,349) | (3,480,562) | | | | | | |
| Net loss attributable to common stock holders | $ (35,482,812) | $ (18,233,528) | $ (12,924,515) | $ (13,007,567) | $ (10,984,820) | $ (3,096,078) | $ (9,347,338) | $ (5,734,321) |
| Net loss per common share | $ (7.62) | $ (3.74) | $ (2.53) | $ (0.40) | $ (0.28) | $ (0.08) | $ (0.23) | $ (0.14) |

(1) The increase in revenues in the quarter ended June 30, 2002 includes a $20,400,000 contribution from achieving the ability to estimate product return rates for sales to retailers and wholesalers in the United States and Canada. The increase in cost of revenues for the quarter ended June 30, 2002 includes a $16,200,000 charge associated with the recognition of previously deferred revenues. The gross profit in the quarter ended June 30, 2002 includes a $4,200,000 contribution from achieving the ability to estimate product return rates for sales to retailers and wholesalers in the United States and Canada.

Table of Contents

**REPORT OF INDEPENDENT ACCOUNTANTS ON**

**FINANCIAL STATEMENT SCHEDULE**

To the Board of Directors

of TheraSense, Inc.:

Our audits of the consolidated financial statements referred to in our report dated January 31, 2003 appearing in this Annual Report on Form 10-K also included an audit of the financial statement schedule listed in Item 15(a)(2) of this Form 10-K. In our opinion, the financial statement schedule presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements.

/s/ PricewaterhouseCoopers LLP

San Jose, California

January 31, 2003

Table of Contents

**SCHEDULE II**

**THERASENSE, INC.**

**VALUATION AND QUALIFYING ACCOUNTS**

**FOR THE YEARS ENDED DECEMBER 31, 2000, 2001 AND 2002**

**(IN THOUSANDS)**

| Description | Balance at Beginning of Year | Charged to Costs and Expenses | Deductions | Balance at End of Year |
|---|---|---|---|---|
| **Allowance for doubtful accounts receivable:** | | | | |
| Fiscal year ended 2000 | $ | 150 | | $ 150 |
| Fiscal year ended 2001 | $ 150 | 576 | (22) | $ 704 |
| Fiscal year ended 2002 | $ 704 | 111 | | $ 815 |
| **Allowance for inventories valuation:** | | | | |
| Fiscal year ended 2000 | $ | 3,528 | (657) | $ 2,871 |
| Fiscal year ended 2001 | $ 2,871 | | (1,603) | $ 1,268 |
| Fiscal year ended 2002 | $ 1,268 | | (1,268) | $ |

Table of Contents

**SIGNATURES**

**Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 25, 2003.**

THERASENSE, INC.

By: /s/ W. MARK LORTZ

**W. Mark Lortz**
*Chairman of the Board, President*

*and Chief Executive Officer*

**POWER OF ATTORNEY**

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints W. Mark Lortz, Charles T. Liamos and Robert D. Brownell, and each of them individually, as his attorney-in-fact, each with full power of substitution, for him in any and all capacities, to sign any and all amendments to this Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that said attorney-in fact, or his substitutes, may do or cause to be done by virtue hereof.

**Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons in the capacities and on the date indicated.**

| Signature | Title | Date |
|---|---|---|
| /s/ W. MARK LORTZ<br>**W. Mark Lortz** | Chairman of the Board, President, Chief Executive Officer (Principal Executive Officer) | March 25, 2003 |
| /s/ CHARLES T. LIAMOS<br>**Charles T. Liamos** | Chief Operating Officer, Chief Financial Officer and Director (Principal Financial and Accounting Officer) | March 25, 2003 |
| /s/ ROD F. DAMMEYER<br>**Rod F. Dammeyer** | Director | March 25, 2003 |
| /s/ MARK J. GAINOR<br>**Mark J. Gainor** | Director | March 25, 2003 |

| | | |
|---|---|---|
| /s/ Ross A. Jaffe, M.D.<br>**Ross A. Jaffe, M.D.** | Director | March 25, 2003 |
| /s/ Michael M. McNamara<br>**Michael M. McNamara** | Director | March 25, 2003 |
| /s/ Robert R. Momsen<br>**Robert R. Momsen** | Director | March 25, 2003 |
| /s/ Richard P. Thompson<br>**Richard P. Thompson** | Director | March 25, 2003 |

Table of Contents

**CERTIFICATIONS**

I, W. Mark Lortz, certify that:

1. I have reviewed this annual report on Form 10-K of TheraSense, Inc., a Delaware corporation;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant s other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

   a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

   b) evaluated the effectiveness of the registrant s disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the Evaluation Date ); and

   c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant s other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant s auditors and the audit committee of registrant s board of directors (or persons performing the equivalent functions):

   a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant s ability to record, process, summarize and report financial data and have identified for the registrant s auditors any material weaknesses in internal controls; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant s internal controls; and

6. The registrant s other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 25, 2003

By: /s/ W. MARK LORTZ

**W. Mark Lortz**

**Chief Executive Officer**

**Table of Contents**

I, Charles T. Liamos, certify that:

1. I have reviewed this annual report on Form 10-K of TheraSense, Inc., a Delaware corporation;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant s other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

   d) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

   e) evaluated the effectiveness of the registrant s disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the Evaluation Date ); and

   f) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant s other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant s auditors and the audit committee of registrant s board of directors (or persons performing the equivalent functions):

   a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant s ability to record, process, summarize and report financial data and have identified for the registrant s auditors any material weaknesses in internal controls; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant s internal controls; and

6. The registrant s other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 25, 2003

By: /s/ Charles T. Liamos

**Charles T. Liamos**

**Chief Financial Officer**