THERASENSE INC
Form 10-K405
March 20, 2002

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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, 2001

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]

Based on the closing sale price of the Common Stock on the NASDAQ National Market System on March 1, 2002, the aggregate market value of the registrant's Common Stock held by non-affiliates of the registrant was approximately $311,760,073.

There were 39,542,380 shares of the registrant's Common Stock $0.001 par value, issued and outstanding as of March 1, 2002.

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.

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PART I

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, FreeStyle, received FDA clearance in January 2000, and we began selling FreeStyle in the United States in June 2000. FreeStyle utilizes patented technologies that can accurately measure glucose concentrations from a tiny 0.3 microliter sample of blood, as opposed to competitive products that require from 1.0 to 10.0 microliters of blood. Our tiny sample size is easily obtained by lancing the forearm, thigh, calf, upper arm or hand and therefore avoids the pain associated with drawing a larger blood sample from the fingertip. These alternate sites are significantly less painful to lance than the traditional fingertip test site, which is more densely populated with highly sensitive nerve endings but yields the larger blood volumes required by competitive products. Nine out of ten people in our clinical studies found using FreeStyle less painful than their current finger-stick-based system. We 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 $3.5 billion worldwide in 2000. It is estimated that the worldwide blood glucose self-monitoring market will amount to $9.0 billion by 2005. We believe that FreeStyle and other products based on our proprietary technologies can expand this market by substantially reducing the pain associated with testing and thereby bring non-testers into the market and encourage under-testers to test more regularly.

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. Our contract sales force focuses on high volume pharmacies in the United States. We distribute and sell FreeStyle in the United States to the ten largest national retailers, including Walgreens, Wal-Mart and CVS, through wholesalers, including McKesson, Cardinal Health and Bergen Brunswig, and directly to end users over the telephone and through our website. In September 2000, we entered into an agreement with Disetronic Group for the exclusive distribution of FreeStyle in selected European countries. In March 2001, we obtained the CE Mark, which permits us to commercially distribute FreeStyle

throughout the European Union. Disetronic commenced sales in Germany and Sweden in May 2001, and since that time has commenced sales in Norway, Finland, Austria, The Netherlands and Denmark. 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 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 16 million people, about 6% of the population, have diabetes, although only approximately 10 million of these people have been diagnosed with the disease. The share of the United States population diagnosed with diabetes increased 33% between 1990 and 1998, primarily due to the aging of the population, inappropriate diets and increasingly sedentary lifestyles. The most rapid onset was in adults ages 30 through 39. It is also on the rise among a younger population base, including children and teenagers. Worldwide, approximately 175 million people, about 3% of the population, have been diagnosed with diabetes. The worldwide prevalence of diagnosed diabetics is expected to increase to 239 million by 2010.

Importance of Glucose Monitoring

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

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

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

Limitations of Existing Glucose Monitoring Products

Despite the proven benefits of frequent monitoring and intensive management of blood glucose levels, a significant number of people fail to test at their recommended frequency, or at all. The American Diabetes Association estimates that people with diabetes test, on average, slightly more than once per day. To obtain a sample with current glucose monitoring systems, users generally are required to prick one of their fingertips with a lancing device, which typically consists of a spring-loaded needle that penetrates a measured distance into the finger. Users must then draw a sample of blood from the finger, which often requires squeezing of the fingertips and may require another finger prick if a sufficient volume of blood is not obtained the first time. After drawing a

blood sample, users generally are required to drop the blood sample on a disposable test strip or place the test strip on the blood sample. We believe that under-testing is due to the limitations of existing products including:

- Pain. Although the fingertips are rich in capillary beds and provide a good site to obtain a blood sample, they are also more densely populated with highly sensitive nerve endings. This makes the lancing and subsequent manipulation of the finger painful. The pain and discomfort are compounded by the fact that fingers offer limited surface area, so tests are often performed on areas that are sore from prior tests. Users also suffer pain when the lance wound is disturbed during regular activities. A wound on the finger is also more susceptible to infection.

- Large Sample Size. Competitive blood glucose meters require users to draw a sample size from 1.0 to 10.0 microliters of blood to accurately measure blood glucose levels. These larger sample sizes are difficult or

impossible to obtain on sites other than the finger. Furthermore, the larger the blood sample required, the wider or deeper the lancing must be in order to reliably draw the sample. This leads to increased pain, greater likelihood of residual bleeding and longer healing time.

- Susceptibility to Interference. The accuracy of other electrochemical-based glucose monitoring systems can be compromised in the presence of many substances commonly found in blood, such as aspirin, acetaminophen, Vitamin C and uric acid. Accuracy can also be compromised by unusually high or low levels of red blood cells. These levels can be present in infants, pregnant women, patients on dialysis, athletes and those living at high altitudes.

- Lifestyle Disruption. The process of measuring blood glucose levels causes significant disruption in the daily lives of people with diabetes and their families. Lancing the fingertips on infants is traumatizing to both parent and child. Obtaining large blood samples is inconvenient and may cause embarrassment in social situations, particularly for young children who are often required to be removed from class or activities to test themselves in the nurse's office. Children may also avoid, or be prevented from, playing with their classmates following a test because of the fear that continued bleeding may cause contamination.

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

The TheraSense Solution

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

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

- Better Performance. FreeStyle's proprietary measurement technology is extremely accurate, operates over a broad temperature range and is unaffected by common interfering substances, such as aspirin, acetaminophen, Vitamin C and uric acid. It is also unaffected by unusually high or low levels of red blood cells. The tiny blood sample required by FreeStyle can be reliably obtained from sites other than the fingertip.

- Improved Quality of Life. The combination of a smaller sample size and off-fingertip testing enabled by FreeStyle significantly reduces residual bleeding. This reduces the embarrassment of testing felt by some people with diabetes and affords them more discretion in testing. The pain and awkwardness of publicly obtaining large blood samples 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 a sales force of more than 140 people. We believe an increased awareness of FreeStyle's less painful, more discreet and reliable process will lead many current testers to switch to FreeStyle. In addition, we believe we can expand the market to those people who have been diagnosed with diabetes but are currently not testing, as well as increase testing frequency for those who are under-testing.

- Maintain and enhance retail distribution. We currently have authorized shelf space with the ten largest chain drug stores, the three largest mass market retailers and the three largest supermarket retailers. These retailers represent over 20,000 pharmacy outlets in the United States. We plan to continue to expand FreeStyle's availability within these distribution channels through our national accounts sales representatives and a contract sales force dedicated to detailing pharmacies.

- Focus on our core competencies. We plan to continue to focus our internal resources on our core competencies--electrochemistry and sensor manufacturing technologies. Consequently, we have entered into strategic relationships to enhance speed to market and cost effectiveness for those business functions not included in our core competencies. For example, we have a strategic relationship with Flextronics International, which assisted us with the FreeStyle meter development and is currently manufacturing our meters and assembling our FreeStyle System kits. Through these relationships, we believe that we will be able to quickly and efficiently build infrastructure and services needed to meet anticipated market demand.

- Provide high quality customer service. We provide all of our customers with easy, comprehensive access to our products and services through the use of sophisticated software systems and an educated and caring customer service team. Our approach is to partner with a service organization while maintaining a small team of in-house service specialists to monitor quality. We offer customer service 24 hours per day, seven days per week with access to dedicated representatives via telephone or the Internet. In addition, we use the Internet to enable customers to purchase our products online, enhance awareness of our products, establish e-mail management, facilitate loyalty programs and provide product support and training.

- Expand International Distribution. We intend to expand our international sales of FreeStyle and enter new global markets through relationships with established health care companies that have developed distribution channels. The Disetronic Group is our exclusive distributor of FreeStyle in selected European countries. Disetronic has commenced sales in Germany, Sweden, Norway, Finland, Austria, The Netherlands and Denmark. In February 2002, Disetronic's territory was expanded to include 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 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 anticipate commencing sales of FreeStyle Tracker in 2002, subject to obtaining FDA clearance. We may also develop a lower priced glucose monitor or a glucose monitoring system that integrates lancing, sample acquisition and testing in a single device.

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. In December 2001, we received clearance for revised labeling which provided users with additional information regarding off-finger testing. The FreeStyle System kit includes a FreeStyle meter, an initial supply of 10 proprietary disposable FreeStyle test strips, a FreeStyle lancing device, an initial supply of 10 disposable FreeStyle lancets, FreeStyle control solution and instructional materials. We also sell additional supplies of disposable FreeStyle test strips in quantities of 50 and 100 and additional supplies of disposable FreeStyle lancets in quantities of 100.

- FreeStyle meter. The FreeStyle meter contains a large display screen to read test results, a slot where the test strip is inserted to get a blood glucose reading, and buttons to change the calibration code and review results in the system memory. It also contains a data port for interfacing with FreeStyle Connect data management software, which allows users to download information from the meter to personal computers and analyze glucose levels. The ergonomically designed meter fits easily in the hand and weighs 2.1 ounces. The meter displays blood glucose results in a range of 20 to 500 mg/dl. Once the sample is acquired, the meter takes about 15 seconds to display the result. The meter has the ability to store the last 250 blood glucose test results and to display a 14-day average blood glucose level.

- FreeStyle test strips. FreeStyle test strips are proprietary disposable sensors that are used with the FreeStyle meter to measure blood glucose levels. The test strips are clearly marked to indicate proper placement in the meter. Inserting the test strip into the meter activates the system and either side of the test strip can be used for measurement. The FreeStyle meter beeps one time when sufficient blood has been drawn into the test strip and beeps two times when the test is complete. Our proprietary FreeStyle test strips may only be used with our FreeStyle meter.

- FreeStyle lancing device and lancets. The FreeStyle lancing device is designed specifically to make blood sample acquisition reliable and convenient. It requires no mechanical or vacuum assistance to draw blood.

The lancing device offers five adjustable depth settings to allow for comfort and adequate sample size. Although FreeStyle lancets are available, other standard lancets are compatible with our system. It is recommended that a new, sterile lancet be inserted into the lancing device every time a test is administered. The reduction in pain from FreeStyle is attributable to the lancing site and the small sample size required, not the type of lancing device or lancet.

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

FreeStyle Connect. In May 2000, we received FDA clearance for FreeStyle Connect, a data management software product. FreeStyle Connect downloads data from FreeStyle to a personal computer and displays glucose values in eight different statistical reports, including the number of blood glucose values above, within, and below a given target range. The FreeStyle meter stores up to 250 glucose values each with time and date. This data allows 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;
- 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 whether glucose levels are rising, falling or remaining stable. The sensor system is designed to communicate to the wireless display unit within a 10-foot range, so it can be conveniently worn on a belt, carried in a purse or left on a bed stand at night.

We have completed two pilot clinical studies, and commenced a Phase I clinical trial of our Continuous Glucose Monitoring System in December 2001. Our Continuous Glucose Monitoring System will require premarket approval, which will require considerably more data and FDA review time than the 510(k) clearance process that was applicable to FreeStyle. The premarket approval process generally takes between one and three years from completion of an application or even longer. However, achieving a completed application is a process that may take numerous clinical trials and require filing 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.

FreeStyle Tracker. FreeStyle Tracker is a module and accompanying software for the Handspring Visor personal digital assistant that enables it to act as a glucose monitor and sophisticated diabetes management system. We anticipate commencing sales of FreeStyle Tracker in 2002, subject to obtaining FDA clearance.

Additional FreeStyle Products. We will continue to identify and develop products that fulfill unmet consumer needs and address strategic or competitive issues. We may develop a lower priced glucose monitoring system or a glucose monitoring system that integrates lancing, sample acquisition and testing in a single device.

Our Sensor Technologies

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

NanoSample Technology. NanoSample technology enables FreeStyle to measure glucose levels in blood samples of only 0.3 microliters, a fraction of the sample size required by competitive products. We have pioneered techniques to obtain accurate, reliable and fast responses when measuring glucose in sub-microliter sample sizes. This technology allows us to measure the total electrical charge generated by the reaction of all of the glucose in the sample, a process referred to as coulometry. In contrast, the most advanced competitive

products generally determine glucose levels by taking a measurement of the current generated by the sensor at a point in time, a process referred to as amperometry. Amperometry requires the use of a larger blood sample to achieve accurate results. Use of coulometry substantially eliminates some of the errors frequently associated with amperometry, such as dependence of sensor output on temperature and potential interference from commonly found substances in the blood, such as aspirin, acetaminophen, Vitamin C and uric acid, which can distort the glucose measurement.

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

Marketing and Sales

United States. Our marketing and sales program is intended to generate awareness of FreeStyle and penetrate and expand the glucose self-monitoring market. We currently have a national sales force comprised of more than 140 people. The sales force includes 120 sales 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 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 level. We believe that our strategy of selling through our own direct sales force is an important factor in achieving market penetration. In addition, we have a contract sales force of more than 50 people who promote FreeStyle and monitor stocking levels with retail outlets at the individual store level.

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, 2001:

Retailers	Wholesalers
Walgreens	McKesson
Wal-Mart	Cardinal Health
CVS	Bergen Brunswig

Eckerd	AmeriSource
Rite Aid	Bindley Western

International. We intend to expand our international sales efforts for FreeStyle and enter new global markets by establishing relationships with international partners who have established relationships with healthcare professionals and developed distribution channels. In March 2001, we obtained the CE Mark, which permits us to commercially distribute FreeStyle throughout the European Union. In September 2000, we entered into an agreement with Disetronic Group for the exclusive distribution of FreeStyle in Germany, Switzerland, Denmark, Austria, Sweden, Finland, Norway and the Netherlands. In 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. Disetronic is also entitled to market FreeStyle to Disetronic's pump users in North America. The initial term of the Disetronic agreement ends December 31, 2006. Disetronic commenced sales in Germany and Sweden in May 2001. Since that time they have commenced sales in Norway, Finland, Austria, The Netherlands and Denmark.

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 is five years, ending in April 2006. FreeStyle received regulatory approval for marketing in Japan in January 2002, and Nipro launched FreeStyle in Japan in February 2002.

Distribution. To establish a worldwide distribution capability for end users, health care professionals and retail customers, we have established relationships with expert distribution partners. For retail order management and shipping of our FreeStyle System kit and other products, we have entered into an exclusive services agreement with Livingston Healthcare Services, Inc., a division of UPS Global Logistics that specializes in providing outsourced distribution services for large pharmaceutical and medical device companies. The initial term of this agreement is three years, ending in March 2003. We may terminate this agreement prior to March 2003, subject to payment of a termination fee. Livingston has an extensive network of distribution centers and a sophisticated order management and product tracking system. Livingston also manages our billing process. Our relationship with Livingston allows us to meet shipment, delivery and billing expectations while minimizing our internal infrastructure requirements.

Customer Service. We provide customer service 24 hours per day, seven 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.

Manufacturing

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

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

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

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

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

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, 2002, we had 30 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, 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 useful in 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 applied to register FreeStyle in numerous jurisdictions including the U.S., Canada, Europe and Japan.

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 Unilever PLC. Each of these licenses grants us the right to use the licensed patents to make and sell diagnostic devices for diabetes monitoring that contain the licensed technology. We pay for these licenses through a combination of fixed payments and royalties on sales of covered products. Each of these licenses continues until expiration of the licensed patents.

Research and Development

Our research and development efforts are currently focused on developing further enhancements to FreeStyle as well as developing our Continuous Glucose Monitoring System. As of March 1, 2002, our research and development staff consists of 61 people, including 11 who hold Ph.D. degrees. Our research and development staff has extensive experience in the glucose monitoring industry and has been instrumental in technology development and commercialization of

glucose monitoring products. Research and development expenses, including clinical and regulatory expenses, were $7.7 million in 1999, $12.0 million in 2000 and $16.1 million in 2001. We expect research and development expenses to continue to increase as we seek to enhance our existing products and develop additional products.

We also fund biosensor 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 or, in some cases, the forearm. All of the competitive products require significantly larger blood samples than required by FreeStyle. One product approved for use on the finger and forearm offers a faster test time than FreeStyle, once the required sample has been obtained, and operates over a broader temperature range.

In addition, other companies are developing and/or marketing minimally invasive or noninvasive glucose monitoring devices and technologies that could compete with FreeStyle and our proposed Continuous Glucose Monitoring System. There are also a number of academic and other institutions involved in various phases of our industry's technology development. Many of these competitors have significantly greater financial and human resources than we do. At this time, there are two cleared products 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 MiniMed Inc., which was recently acquired by Medtronic, Inc., includes an implantable sensor that measures and stores glucose values every five minutes, for a period of two to three days. The MiniMed system is not a consumer product, rather, it is a physician product. The sensor is required to be implanted by a physician, and the results of the data aggregated by the MiniMed system can only be viewed by the physician, who must extract the sensor and download the results for viewing using customized software. The second cleared product for continuous glucose monitoring, developed by Cygnus Inc., is worn on the wrist like a

watch and can take glucose readings as frequently as every twenty minutes for up to twelve hours at a time. This product has only recently been cleared by the FDA for prescription to adults ages 18 and older who have diabetes.

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

- improved outcomes for people with diabetes through less painful and accurate testing methods;

- technological leadership and superiority;
- reliability and ease of use;
- customer focus and service;
- effective marketing and distribution;
- acceptance by health care professionals;
- speed to market; and
- exclusivity agreements between third-party payors and competitive brands.

Government Regulation

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

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

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 completed two pilot clinical studies, and a Phase I clinical trial was commenced in December 2001. A premarket approval application may never be submitted, or if submitted, approval may not be obtained for this device in a timely fashion, or at all.

Clinical Trials. A clinical trial is almost always required to support a premarket approval application and is sometimes required for a 510(k) premarket notification. These trials generally require submission of an application for

an investigational device exemption to the FDA. The investigational device exemption application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The investigational device exemption application must be approved in advance by the FDA for a specified number of patients, unless the product is deemed a non-significant risk device and eligible for more abbreviated investigational device exemption requirements. Clinical trials for a significant risk device may begin once the investigational device exemption

application is approved by the FDA and the appropriate institutional review boards at the clinical trial sites. Future clinical trials of our Continuous Glucose Monitoring System may require that we obtain an investigational device exemption from the FDA prior to commencing clinical trials. Our clinical trials must be conducted in accordance with FDA regulations. The results of clinical testing may not be sufficient to obtain approval 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. In May 2001, the FDA conducted an inspection of our facility in Alameda, California. The FDA issued a Form 483 that noted five observations. One observation was corrected and verified during the audit. In June 2001, we submitted a corrective action

plan to the FDA addressing the remaining four observations. In November 2001, we were audited by the Food and Drug Branch of the California Department of Health Services and no observations were noted.

International

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

The primary regulatory environment in Europe is that of the European Union, which consists of 15 countries encompassing most of the major countries in Europe. Other countries, such as Switzerland, have voluntarily adopted laws and regulations that mirror those of the European Union with respect to medical devices. The European Union has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling, and adverse event reporting for medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear CE conformity marking, indicating that the device conforms with the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout

Europe. CE is an abbreviation for European Compliance. The method of assessing conformity varies depending on the class of the product, but normally involves a combination of self-assessment by the manufacturer and a third-party assessment by a "Notified Body." This third-party assessment may consist of an audit of the manufacturer's quality system and specific testing of the manufacturer's product. An assessment by a Notified Body in one country within the European Union is required in order for a manufacturer to commercially distribute the product throughout the European Union. In March 2001, our quality system was certified by TUV Product Service, a Notified Body, under the European Union In-Vitro Diagnostic Directive allowing the CE conformity marking to be applied. In December 2001, we underwent a surveillance audit by TUV Product Service, our Notified Body. This audit also included an assessment of Flextronics International, our meter manufacturer and system kit assembler. In January 2002, TUV Product Service conducted an audit of our supplier of control solution. At the successful conclusion of these audits, TUV 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 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.

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, 2002, we had 376 full-time employees, including 146 in sales, nine in marketing, 57 in operations and manufacturing, 61 in research and development, 12 in customer service and 91 in general and administrative functions. None of our employees is represented by a collective bargaining agreement and we have never experienced any work stoppage. We believe that our employee relations are good.

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 in April 2009. We are also leasing 17,000 square feet of office space in an adjacent building at 1350 South Loop Road under a lease expiring in May 2004. An additional 3,000 square feet of office space at 1320 South Loop Road is subject to a lease which expires in October 2002. We are in the planning stages of an approximately 60,000 square foot expansion of the manufacturing, warehouse and office areas at our main building at 1360 South Loop Road. We are also in the planning stages of the construction of a new 33,000 square foot office building on a parcel of land adjacent to 1360 South Loop Road. We believe that our current facilities and the planned expansion 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, 2001.

PART II

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

(a) 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 (through 3/01/02).....	$23.39	$19.22

The closing sale price of our Common Stock on the Nasdaq National Stock Market on March 1, 2002 was $20.18.

(b) Holders

As of March 1, 2002, we had approximately 187 stockholders of record.

(c) 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

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. Our managing underwriters for the offering were U.S. Bancorp Piper Jaffray Inc., SG Cowen Securities Corporation and Thomas Weisel Partners LLC. Of the $131,100,000 in gross proceeds raised in connection with the offering, (i) $9,177,000 was paid to the managing underwriters in connection with underwriting discounts and commissions, and (ii) approximately $1,024,000 was paid by us in connection with expenses, including legal, printing and filing fees, in connection with the offering. There were no direct or indirect payments to our directors or officers or to any person or entity. 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 investments, such as commercial paper and U.S. Government obligations, with an average maturity of twelve months or less.

ITEM 6. SELECTED FINANCIAL DATA

The selected financial data set forth below are derived from our financial statements. The statement of operations data for the years ended December 31, 1997 and 1998, and the balance sheet data as of December 31, 1997, 1998 and 1999 are derived from our audited financial statements not included in this

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

	Years Ended December 31,			
	1997	1998	1999	2000
	(in thousands, except per share			
Statement of Operations Data:				
Product sales	$ --	$ --	$ 25	$ 5,000
License income	--	--	--	500
Research grant revenue	--	60	60	3
Total revenues	--	60	85	5,503
Cost of revenues	--	--	--	11,948
Gross profit (loss)	--	60	85	(6,445
Operating expenses:				
Research and development	977	3,056	7,672	12,019
Selling, general and administrative	703	1,810	5,557	25,460
Total operating expenses	1,680	4,866	13,229	37,4790
Loss from operations	(1680)	(4,806)	(13,144)	(43,924
Interest income, net	163	142	86	332
Net loss	(1,517)	(4,664)	(13,058)	(43,592
Deemed dividends related to beneficial conversion feature of preferred stock	--	--	--	(14,773
Net loss attributable to common stockholders	$(1,517)	$(4,664)	$(13,058)	$(58,365
Net loss per common share, basic and diluted	$ (1.66)	$ (2.31)	$ (4.32)	$ (14.69
Weighted-average shares used in computing net loss per common share, basic and diluted	914	2,015	3,024	3,973

	As of December 31,			
	1997	1998	1999	2000
	(in thousands)			
Balance Sheet Data:				
Cash and cash equivalents	$ 4,088	$11,438	$ 2,322	$ 12,532
Working capital	3,595	10,956	792	4,240
Total assets	4,680	12,379	8,026	37,565
Deferred revenue	72	11	511	8,687
Long-term obligations, less current portion	--	520	3,321	7,994
Convertible preferred stock	5,526	17,361	20,472	62,883
Deferred stock-based compensation, net	--	--	(1,244)	(11,263

Accumulated deficit	(1,410)	(6,074)	(19,132)	(62,724
Total stockholders' equity (deficit)	(1,387)	(6,047)	(18,159)	(59,848

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-looking 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 limited operating experience and history of losses; (2) limited manufacturing experience; (3) our dependence on FreeStyle for future revenues; (4) substantial competition; (5) risks related to failure to protect our intellectual property and litigation in which we may become involved; (6) our limited sales and marketing experience; (7) risks related to noncompliance with FDA regulations; (8) our dependence on single source suppliers and manufacturers for our FreeStyle products; 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 report as "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, 2001, are not necessarily indicative of the results that may be expected for any future period.

Overview and Critical Accounting Policies

We develop, manufacture and sell easy to use glucose self-monitoring systems that dramatically reduce the pain of testing for people with diabetes. Our first product, FreeStyle, received FDA clearance in January 2000, and we commenced commercial shipments in the United States in June 2000. We sell FreeStyle in the United States through national retailers and wholesalers, and directly to consumers over the telephone and through our website. In March 2001, we obtained the CE Mark for FreeStyle, and our European distributor commenced sales of FreeStyle in Germany and Sweden in May 2001 and commenced sales of FreeStyle in Finland, Austria, Norway, the Netherlands and Denmark 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 incurred significant operating losses and negative cash flows from operations in each full fiscal year since inception. We incurred net losses of $13.1 million in 1999, $43.6 million in 2000 and $52.9 million in 2001. As of December 31, 2001 we had an accumulated deficit of $115.6 million. We expect to incur significant additional losses as we expand our sales and marketing

efforts and continue to develop new products.

Revenues are generated from sales of our FreeStyle System kit and from the recurring sales of disposable FreeStyle test strips and lancets. Our return policy allows end users in the United States 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. As a result of these rights of return and the current unavailability of historical trends in sales and product returns, we defer recognition of revenue on sales of FreeStyle test strips until resold by the retailers and wholesalers to end users, and we defer recognition of revenue on FreeStyle System kits until 30 days after purchase by the end user. Because we lack a sufficient historical basis from which we could estimate return rates, we are required to rely on data estimates provided to us by third-party data providers in order to recognize revenue from sales to end users by retailers and wholesalers. These data estimates may cause imprecise revenue recognition, as these third-party data providers

may not provide consistent, reliable data. We do not know how long we will be required to rely on these estimates. However, we believe that we will have a sufficient historical basis from which we can estimate return rates beginning with the quarter ending September 30, 2002. For the first quarter in which we use our own estimates for return rates, we anticipate that our deferred revenue from product sales will decrease and we will experience a corresponding increase in our recognized revenue from product sales. This one-time event could cause a significant increase in our net revenues for the applicable period.

Domestic sales to durable medical equipment suppliers do not have a return right so we recognize revenue from these sales upon shipment. Similarly, products distributed internationally, with the exception of shipments to Canada, have no right of return, and we recognize revenue on these products upon shipment. We recognize revenue on direct product sales over the telephone or through our website to end users upon shipment for FreeStyle test strips and lancets and 30 days after purchase on sales of FreeStyle System kits. Our current sales terms to retailers and wholesalers provide for customer payment within 60 days of shipment on initial orders and payment within 30 days for subsequent orders. We perform ongoing credit evaluations of our customers' financial condition and, generally, require no collateral from our customers. We believe our terms to retailers, wholesalers and end users, including their rights to return, are similar to our competitors' terms.

Manufacturers typically sell their glucose monitoring devices at substantial discounts to list prices, offer customer rebates or provide free product samples to expand their installed base of monitoring devices and thus increase the market for their disposable test strips and lancets. We have been offering and expect to continue to offer similar discounts and rebates on, and free samples of, our FreeStyle System kits to establish an installed base of systems from which we expect to generate recurring revenues from our disposable FreeStyle test strips and lancets. Due to the recent commencement of our sales, we do not have significant historical trends in rebates claimed by end users. As a result, we record an allowance for 100% of the allowable rebate as a reduction of revenues reported. As we accumulate trend data in rebates claimed, we are likely to change the percentage of the allowable rebate.

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

Cost of revenues consists primarily of:

. payments to our manufacturing and distribution partners;

. expenses relating to our disposable test strip manufacturing;

. expenses relating to our internal operations;

. expenses relating to our five-year warranty on our FreeStyle meter;

. amortization of deferred stock-based compensation;

. royalties payable under technology licenses; and

. adjustment of FreeStyle System kit inventories to estimated net realizable value.

We provide for the estimated cost of product warranties at the time revenue is recognized. While we engage in extensive product quality programs and processes, including actively monitoring and evaluating the quality of our components suppliers, our warranty obligation is affected by product failure rates, material usage, and service delivery costs incurred in correcting a product failure. We also make estimates to reduce our FreeStyle System kit inventories to estimated fair net realizable value. In doing so, the historical costs of our FreeStyle System kit inventories are compared to realized product revenues, reduced by rebates and estimated direct selling costs.

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

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

. salaries and related personnel expenses;

. fees paid to outside service providers;

. expenditures for purchases of laboratory supplies and clinical trials;

. amortization of deferred stock-based compensation; and

. overhead allocated to product development.

At the time we commenced commercial shipments in June 2000, we transitioned

the recording of manufacturing-related costs from research and development expense to cost of revenues. All research and development costs are expensed as incurred. Our research and development efforts are periodically subject to significant non-recurring costs and fees that can cause significant variability in our quarterly research and development expenses.

Selling, general and administrative expenses primarily consist of:

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

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

. legal and regulatory expenses;

. amortization of deferred stock-based compensation; and

. general corporate expenses.

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.

We have recorded deferred stock-based compensation in connection with stock option grants and sales of stock to employees at exercise or sales prices below the deemed fair market value of our common stock. Deferred stock-based compensation for options granted to non-employees has been determined as the fair value of the equity instruments issued. Deferred stock-based compensation for options granted to non-employees is periodically remeasured as the underlying options vest. As of December 31, 2001 we have recorded aggregate deferred stock-based compensation of $28.5 million, of which $21.0 million will be amortized to expense on a straight line basis through 2005. This amount is being amortized over the respective vesting periods of these equity instruments, which is typically four years. Stock-based compensation expense has been allocated according to employees and their respective departments and by function for non-employees.

In September 2000, we entered into a five-year exclusive distribution agreement with Disetronic Group relating to the distribution of FreeStyle in Germany, Switzerland, Denmark, Austria, Sweden, Finland, Norway and the Netherlands. In February 2002, this agreement was amended to, among other things, extend the term through December 31, 2006 and to add France, Italy and Belgium to Disetronic's distribution territory.

Disetronic commenced sales in Germany and Sweden in May 2001 and since that time has commenced sales in Norway, Finland, Austria, The Netherlands and Denmark. In connection with this agreement, we received an advance payment on a purchase order from Disetronic of $1.5 million, which we recognized in the second quarter of 2001 as we shipped products.

In April 2001, we entered into a five-year exclusive distribution agreement with Nipro Corporation relating to the distribution of FreeStyle in Japan. Nipro launched FreeStyle in Japan in February, 2002. In connection with this agreement, we received a $5.0 million payment from Nipro, which is being recognized as revenue ratably over the term of the agreement commencing in April 2001.

Results of Operations

Years Ended December 31, 1999, 2000 and 2001

Revenues. Revenues in 1999 principally related to research grants and the sale of clinical evaluation units. Revenues recognized in 2000 totaled $5.5 million, principally consisting of product sales of FreeStyle System kits and FreeStyle test strips, which commenced in June 2000. 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 System kits and FreeStyle test strips. 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.

Cost of revenues. There was no cost of revenues recorded in 1999. Cost of revenues in 2000 was $11.9 million and was comprised of internal manufacturing costs, purchase costs for FreeStyle System kits and FreeStyle lancets from our contract manufacturing partners, costs of product warranties, royalties payable under technology licenses, start-up production costs and a $3.5 million charge to reduce FreeStyle System kit inventories to estimated net realizable value. Amortization of 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. 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.

Research and development expenses. Research and development expenses increased from $7.7 million in 1999 to $12.0 million in 2000 and to $16.1 million in 2001. The increase from 1999 to 2000 was primarily attributable to increases of $1.6 million for materials and supplies used in product development efforts, $1.1 million from hiring of additional personnel, a $0.5 million payment for the purchase of technology and license rights from E. Heller & Co., which owns more than five percent of our stock, $0.4 million for overhead costs associated with our new facility and $0.2 million for payments to outside service providers. The technology and license rights purchased from E. Heller & Co. concern the measurement of biochemicals other than glucose. This technology is at an early stage of development, and it is currently uncertain whether it will have commercial application. Amortization of deferred stock-based compensation was $0.6 million for the year ended December 31, 2000. Stock-based compensation expense for the corresponding period in 1999 was insignificant.

The increase from 2000 to 2001 was primarily attributable to $1.6 million from hiring additional personnel, $0.4 million spent on clinical trials and $2.7 million from increased spending on product development efforts. Prior to commencing commercial shipments of FreeStyle in June 2000, costs associated with start-up manufacturing activities were reported as research and development expenses. These expenses, which occurred in the first half of 2000, totaled $1.2 million, partially offsetting the increase in research and development expenses for the year ended December 31, 2001 over research and development expenses for the year ended December 31, 2000. Amortization of deferred stock-based compensation was $1.3 million for the year ended December 31, 2001 as compared to $0.6 million in the prior year. We expect research and development spending to increase over the next several years as we increase clinical trials for our Continuous Glucose Monitoring System and expand our research and development activities to support our current and future products.

Selling, general and administrative expenses. Selling, general and administrative expenses increased from $5.6 million in 1999 to $25.5 million in 2000 and to $60.5 million in 2001. The increase from 1999 to 2000 was primarily attributable to increases of $6.2 million for personnel costs, largely related to recruiting and hiring our U.S. direct sales force, as well as expanding marketing and business support functions, $4.6 million for advertising, marketing activities and other spending associated with the launch of FreeStyle, $2.8 million spent on the cost of product sampling, $1.5 million spent on establishing customer service and support operations, $1.1 million for overhead costs, $1.0 million for travel costs, largely related to our new sales force, $0.9 million spent on professional fees relating to a proposed public offering withdrawn in December 2000 and $0.5 million for legal fees for both patent and general corporate matters. Amortization of deferred stock-based compensation was $1.2 million for the year ended December 31, 2000. Stock-based compensation expense for the corresponding period in 1999 was insignificant. The increase from 2000 to 2001 was primarily attributable to increases of $8.3 million spent on product sampling, $10.1 million for marketing activities and other spending associated with expanding distribution and developing consumer awareness of FreeStyle, $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. Amortization of deferred stock-based compensation was $3.8 million for the year ended December 31, 2001, as compared to $1.2 million in the prior year. We expect our selling, general and administrative expenses to increase as we increase product sampling, expand our sales force, increase our marketing and promotional activities, and operate as a public company.

Interest income, net. Net interest income increased from $0.1 million in 1999, to $0.3 million in 2000 and to $1.0 million in 2001. Interest income in 2000 from 1999 increased due to higher average cash and cash equivalents balances, resulting from the net proceeds of a private equity offering completed in February 2000. Interest expense for the same period increased to a lesser extent, reflecting additional borrowings under available lines of credit, amortization of debt issuance costs associated with warrants issued in connection with lines of credit and capital lease obligations arising under a particular sale and leaseback transaction. Interest income in 2001 from 2000 increased 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 expense in 2001 remained comparable with 2000.

Provision for income taxes. We incurred net operating losses for the years ended December 31, 1999, 2000 and 2001 and, accordingly, we did not pay any federal or state income taxes. As of December 31, 2001, we had accumulated

approximately $65.6 million and $43.8 million in federal and state net operating loss carryforwards, respectively, to reduce future taxable income. If not utilized, the federal carryforward will expire in various amounts beginning in 2012, and the state carryforward will expire in 2005. Our net operating loss carryforwards are subject to annual limitation under Internal Revenue Code Section 382 due to substantial changes in ownership. Changes have already occurred on April 21, 1997 and February 23, 1999 as a result of our preferred stock financings. We are currently evaluating whether our October 2001 initial public offering resulted in a substantial change of ownership within the meaning of Section 382. The annual limitations do not result in the expiration of net operating losses prior to utilization. We have not recorded a benefit from our net operating loss carryforwards because we believe that it is uncertain that we will have sufficient income from future

operations to realize the carryforwards prior to their expiration. Accordingly, we have established a valuation allowance against the deferred tax asset arising from the carryforwards.

We also had federal and state research and development tax credit carryforwards as of December 31, 2001 of approximately $0.8 million and $0.6 million, respectively. If not utilized, the federal research credit will expire in various amounts beginning in 2012. The state research credit can be carried forward indefinitely.

Dividends related to beneficial conversion feature of preferred stock. Dividends relating to beneficial conversion of our preferred stock of $14.8 million were recorded in the year ended December 31, 2000. These dividends arose due to the issuance of 8,490,159 shares of Series C preferred stock in February 2000 for net proceeds of $42.4 million. 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 operations data for each of the seven quarters indicated below. This information is derived from our unaudited financial statements, which have been prepared by us on a basis consistent with our audited financial statements and, in management's opinion, include all adjustments necessary, consisting only of normal recurring adjustments, for a fair presentation of this information. These quarterly results of operations are not necessarily indicative of results of operations in any future period.

	Quarter Ended					
	June 30, 2000	September 30, 2000	December 31, 2000	March 31, 2001	June 30, 2001	September 30, 2001
	(in thousands) (unaudited)					
Revenues	$ 11	$ 1,280	$ 3,712	$ 7,677	$ 17,847	$ 19,858
Cost of revenues	306	6,768	4,874	6,225	13,443	12,938

Gross profit (loss).....	(295)	(5,488)	(1,162)	1,452	4,404	6,920
Operating expenses:						
Research and development.....	2,633	3,543	2,634	2,798	3,534	4,671
Selling, general and administrative.....	5,443	5,573	10,112	11,033	15,810	15,250
Total operating expenses..	8,076	9,116	12,746	13,831	19,344	19,921
Loss from operations.....	(8,371)	(14,604)	(13,908)	(12,379)	(14,940)	(13,001)
Interest income (expense), net.....	218	11	(32)	199	187	76
Net loss.....	$(8,153)	$(14,593)	$(13,940)	$(12,180)	$(14,753)	$(12,925)

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

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

Operating expenses. Prior to commencing commercial shipments of FreeStyle in June 2000, costs associated with start-up manufacturing activities were reported as research and development expenses. These

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

Liquidity and Capital Resources

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 $8.2 million in principal outstanding at December 31, 2001. Our current principal debt arrangements include both a $5.0 million subordinated debt agreement at an effective interest rate of 22.3% per annum and a $2.5 million equipment line of credit at effective interest rates between 8.5% and

9.5% per annum with Comdisco Ventures, a $3.0 million equipment line of credit at an effective rate of 7.3% with GE Healthcare Financial Services, and a $2.0 million senior loan and security agreement at an effective interest rate of 13.1% per annum with Phoenix Capital. These effective annual interest rates include the amortization of the fair value of warrants issued to Comdisco Ventures and Phoenix Capital. As of December 31, 2001, we had cash and cash equivalents of $143.2 million.

Cash used in operations. Net cash used in operating activities was approximately $11.8 million, $36.8 million, and $36.6 million for the years ended December 31, 1999, 2000, and 2001, respectively. For these periods, net cash used in operating activities resulted primarily from net losses. For the year ended December 31, 2000, increases in accounts receivable and inventories, which reflect commencement of commercial product shipments in June 2000, were partially offset by increases in deferred revenue, accounts payable, and accrued liabilities. For the year ended December 31, 2001, increases in deferred revenues, accounts payable, and accrued liabilities exceeded the increases in accounts receivable and inventories, reducing the net cash used in operating activities in 2001.

Cash provided by or used in investing activities. Net cash used in investing activities was approximately $3.3 million and $8.0 million for the years ended December 31, 1999 and 2001, respectively. For these periods, investing activities consisted of capital expenditures and in 2001 purchases of investments. 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.

Cash provided by financing activities. Net cash provided by financing activities was approximately $6.0 million, $46.4 million, and $175.2 million for the years ended December 31, 1999, 2000 and 2001, 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.

We expect to have negative cash flows from operations for the next 12 months. We also expect increased sales and marketing expenses related to the promotion of FreeStyle, increased research and development expenses, as well as expenses for additional personnel and product enhancement efforts. Our future capital requirements will depend on a number of factors, including market acceptance of FreeStyle, the resources we devote to developing and supporting our products, continued progress of our research and development of potential products, the need to acquire licenses to technology and the availability of other financing. Our capital expenditures for the year ended December 31, 2001 were $3.7 million, and we believe that our capital requirements for the next 12 months will increase as a result of expanding our facilities and our test strip manufacturing capacity. We believe that our current cash, cash equivalents and investment balances, together

with the revenue to be derived from sales of FreeStyle, will be sufficient to fund our operations for at least the next 18 months. To the extent our capital resources are insufficient to meet our future capital requirements, we will need to raise additional capital or incur additional indebtedness to fund our operations. Additional equity or debt financing, if required, may not be available on acceptable terms, or at all. If we are unable to obtain additional capital, we may be required to reduce our selling and marketing activities for FreeStyle, delay, reduce the scope of or eliminate our research and development programs, or relinquish rights to technologies or products that we might

otherwise seek to develop or commercialize. In the event that we do raise additional equity financing, 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.

Inflation

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

Recently Issued Accounting Pronouncements

In July 2001, the FASB issued SFAS No. 141 "Business Combinations" ("SFAS No. 141") which establishes financial accounting and reporting for business combinations and supersedes APB Opinion No. 16, "Business Combinations," and FASB Statement No. 38, "Accounting for Preacquisition Contingencies of Purchased Enterprises". SFAS No. 141 requires that all business combinations be accounted for using one method, the purchase method. The provisions of SFAS No. 141 apply to all business combinations initiated after June 30, 2001. Our adoption of SFAS No. 141 did not have any impact on our financial statements.

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

In June 2001, the FASB issued Statement of Financial Accounting Standards 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 except 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.

FACTORS AFFECTING OPERATIONS AND FUTURE RESULTS

We have limited operating experience and a history of net losses and may never achieve or maintain profitability.

We have a limited history of operations and have focused primarily on research and development, product engineering, clinical trials and seeking FDA regulatory clearance to market our products. We received FDA clearance for FreeStyle, our first commercial product, in January 2000, and we commenced commercial shipments in June 2000. We have generated only limited revenues from the sale of our products to date and have incurred losses every year since 1997. We incurred losses of $13.1 million in 1999, $43.6 million in 2000 and $52.9 million in 2001. As of December 31, 2001, we had an accumulated deficit of approximately $115.6 million. It is possible that we will never generate sufficient revenues from product sales to achieve profitability. Even if we do achieve significant revenues from our product sales, we expect that increased operating expenses will result in significant operating losses over the next several quarters as we, among other things:

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

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

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

To be successful, we must manufacture our FreeStyle test strips in substantial quantities at acceptable costs. If we do not succeed in manufacturing sufficient quantities of our test strips to meet customer demand, we could lose customers and fail to acquire new customers, if they choose a competitor's product because our product is not available. We currently manufacture our FreeStyle test strips using a process with which we have limited experience. Increasing demand since the launch of FreeStyle has necessitated an increase in our test strip manufacturing capacity. In response, we are now implementing a second manufacturing line at our facilities in Alameda, California. The delay in receiving certain specialized equipment has extended the date when we will be able to begin operations on the second line. If we are unable to implement our second manufacturing line in a timely manner, we would be unable to meet customer demand for our FreeStyle test strips, which would adversely affect our financial results and could restrict our sales growth sufficiently so that we do not achieve profitability. If demand for FreeStyle increases further, we may need to purchase additional specialized equipment with substantial lead times and obtain additional raw materials in order to increase the output volume of our test strips.

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

Currently, the primary products we market are the FreeStyle System kit, FreeStyle lancets and FreeStyle test strips, all of which we commercially introduced in June 2000. Our FreeStyle products are expected to account for substantially all of our revenues for at least the next several years. Accordingly, our success depends upon the acceptance by people with diabetes, as well as health care providers and third-party payors of FreeStyle as a

preferred blood glucose self-monitoring device. As a relatively new company in the area of glucose self-monitoring, we may have difficulty raising the brand awareness necessary to generate interest in FreeStyle.

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

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

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

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

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

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

- significantly greater name recognition;

- established relations with health care professionals, customers and third-party payors;

- additional lines of products, and the ability to offer rebates or bundle products to offer higher discounts or incentives to gain a competitive advantage;

- established distribution networks and relationships with retailers; and

- greater resources for product development, sales and marketing and patent litigation.

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

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

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

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

Third parties may claim we are using their patented inventions and may go to court to stop us from engaging in our normal operations and activities. These lawsuits are expensive to defend and conduct and would also consume and divert the time and attention of our management. A court may decide that we are infringing a third party's patents and may order us to cease the infringing activity. The court could also order us to pay damages for the infringement. These damages could be substantial and could harm our business, financial condition and operating results. 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 have made contact with the licensee to discuss a possible sublicense.

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 or otherwise harm our business.

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

We rely on licenses to use various technologies that are material to our business. We do not own the patents that underlie these licenses. The licenses from Asulab, SA and Unilever PLC grant us the right under specific patents to make and sell diagnostic devices for diabetes monitoring that contain the inventions claimed in the

licensed patents. Our rights to use these technologies and employ the inventions claimed in the licensed patents are subject to our licensors abiding by the terms of those licenses. In addition, we do not control the prosecution of the patents to which we hold licenses, and we do not control the strategy for determining when any patents to which we hold licenses should be enforced. Instead, we rely upon our licensors to determine the appropriate strategy for prosecuting and enforcing those patents.

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

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

We are currently developing additional enhancements for FreeStyle, 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. Development of these products will require additional research

and development expenditures. We may not be successful in developing, marketing or manufacturing these new products. In addition, several of our competitors are in various stages of development of products similar to our Continuous Glucose Monitoring System, and the FDA has approved two of these products. If any of our competitors succeeds in developing a commercially viable product for continuous glucose monitoring and obtains government approval or successfully commercializes its FDA-approved product, this could negatively affect our future revenues.

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

We currently have limited experience in marketing and selling our products. We received regulatory clearance for our initial product in January 2000 and commenced commercial shipments in June 2000. We currently sell our products in the United States directly, using a sales organization that we assembled following regulatory clearance. Our products require a complex marketing and sales effort targeted at health care professionals, diabetes educators, people with diabetes, pharmacists and national retailers. We significantly expanded our sales and marketing teams in 2001, and we are continuing this expansion in 2002. We will face significant challenges and risks in training, managing and retaining these teams, including managing geographically dispersed efforts and adequately training our people in the use and benefits of our products. We may not be able to hire sufficient additional personnel to increase demand for our products. In addition, we have distribution arrangements for the sale of our products internationally and are dependent upon the sales and marketing efforts of our third-party distributors. These distributors may not commit the necessary resources to effectively market and sell our products. Further, they may not be successful in selling our products. Our financial condition would be harmed if our marketing and sales efforts were unsuccessful.

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

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

devices until these clearances are obtained.

Any modification to an FDA cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new FDA 510(k) clearance or possibly premarket approval. The FDA requires every manufacturer to make this determination in the first instance, but the FDA can review any such decision. We have modified aspects of FreeStyle since receiving regulatory approval, but we believe that new 510(k) clearances are not required. 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 line for our FreeStyle meters at Flextronics International USA Inc. has not been inspected to date. If we or one of our suppliers fail a Quality System Regulation inspection, our operations could be disrupted and our manufacturing delayed. If we fail to take adequate corrective action in response to any FDA observations, we could face various enforcement actions, which could include a shut-down of our manufacturing operations and a recall of our products, which would cause our product sales and profitability to suffer. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements.

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

The FDA and similar governmental authorities in other countries have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. A government mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors or design defects. Any recall of product would 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. Our FreeStyle test strips, which we manufacture ourselves, are comprised of several components obtained from single-source suppliers. In the event we are unable, for whatever reason, to obtain components from suppliers, or if our contract manufacturers are unable to meet our manufacturing requirements, we may not be able to obtain components from alternate suppliers or engage an additional manufacturer in a timely manner. Any disruption or delay in shipments of FreeStyle meters, test strips, lancing devices or lancets could result in the loss of customers or the failure to acquire new customers, if they choose a competitor's product because our product is not available. Such a disruption or delay would negatively affect our revenues.

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

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

Any adverse changes in reimbursement procedures by Medicare or other third-party payors may limit our ability to market and sell our products.

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

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

We may have difficulty managing our growth.

We expect to continue to experience significant growth in the scope of our operations and the number of our employees. This growth may continue to place a significant strain on our management and operations. Our ability to manage this

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

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

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

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

Our return policy allows end users in the United States 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. If we experience significant returns from retailers, wholesalers or end users, this could seriously harm our business and results of operations. As a result of these rights to return and the unavailability of historical return rates, we defer revenue recognition on sales of test strips until resold by the retailers and wholesalers to end users, and we defer revenue recognition on FreeStyle System kits until 30 days after purchase by the end user.

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

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

Our ability to provide superior customer service to our customers, health care professionals and educators is critical. To effectively compete, we must build strong brand awareness among our customers, much of which is based upon personal referrals. In order to gain these referrals, we must provide customer service representatives who are able and available to provide our customers

with answers to questions regarding our products. This will require us to continue to build and maintain customer service operations, for which we currently rely on a single third-party provider. We will require increased staff at our third-party provider to further support growth in new customers. Any failures or disruption to our customer services operations, or the termination of our contract with our only third-party provider, could cause us to lose customers.

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

In September 2000, we entered into an agreement for the exclusive marketing and sale of FreeStyle in several European countries, subject to regulatory approval. In May 2001, our third-party distributor commercially introduced FreeStyle in Germany and Sweden and has commercially introduced FreeStyle in Finland, Austria, Norway, The Netherlands and Denmark since that time. In February 2002, this agreement was expanded to include France, Italy and Belgium. In April 2001, we entered into an agreement for the exclusive marketing and sale of FreeStyle in Japan, subject to regulatory approval. In February 2002, FreeStyle was launched in Japan. We will be dependent on these distributors in those markets, and we will need to attract additional distributors in

other markets. If our current or future third-party distributors do not succeed, we may never realize significant international revenues.

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

International sales of our products are subject to strict regulatory requirements. The review process varies from country to country, is typically lengthy and expensive, and approval is never certain. We have the required regulatory approvals to market FreeStyle in Europe, Japan, Canada and certain countries in the Middle East. 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 complimentary businesses, products or technologies instead of developing them ourselves, we may be unable to complete these acquisitions or to successfully integrate an acquired business or technology in a cost-effective and non-disruptive manner.

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

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.

We are subject to additional risks associated with international operations.

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

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

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

. revenues generated by sales of FreeStyle and our future products, if any;

. expenses we incur in developing and selling our products;

. the commercial success of our research and development efforts; and

. the emergence of competing technological developments.

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

We may have warranty claims that exceed our reserves.

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

All of our operations are currently conducted at a single location, and a

disaster at this facility is possible and could result in a prolonged interruption of our business.

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

Power outages in California may adversely affect us.

We conduct all of our scientific, test strip manufacturing and management activities in California and rely on a continuous power supply to conduct operations. Our sole-source supplier of FreeStyle meters is currently manufacturing our meters in a single facility that is also in California. California has previously implemented, and may in the future have to implement, rolling blackouts throughout the state. If blackouts interrupt our power supply, we may be temporarily unable to continue operations at our facilities, which includes the manufacture and production of our FreeStyle test strips. Interruptions in our ability to continue operations at our facilities could delay our shipments of FreeStyle test strips, delay the development of our products, and disrupt communications with our customers, suppliers and third-party manufacturing operations. Future interruptions could result in lost revenue and damage our reputation, either of which could harm our business and results of operations. Furthermore, past shortages in wholesale electricity supplies have caused power prices to increase. If similar shortages occur in the future, our operating expenses will likely increase, which will have a negative effect on our operating results.

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

Our research and development and clinical processes involve the use of potentially harmful biological materials as well as hazardous materials. We are subject to federal, state and local laws and regulations governing the use, handling, storage and disposal of hazardous and biological materials and we incur expenses relating to compliance with these laws and regulations. If violations of environmental, health, and safety laws

occur, we could be held liable for damages, penalties and costs of remedial actions. These expenses or this liability could have a significant negative impact on our financial condition. We may violate environmental, health and safety laws in the future as a result of human error, equipment failure, or other causes. Environmental laws could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. We are subject to potentially conflicting and changing regulatory agendas of political, business, and environmental groups. Changes to or restrictions on permitting requirements or processes, hazardous or

biological material storage or handling might require an unplanned capital investment and/or relocation. Compliance with new laws or regulations could harm our business, financial condition and results of operations.

Our common stock has 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 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, including shares that will become eligible for sale in the near future, may adversely affect the market price for our common stock

Sales of a 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, 2002, we had 39,542,380 shares of common stock outstanding. The 6,900,000 shares of our common stock sold in our October 2001 initial public offering are freely tradable. The remaining 32,642,380 of these shares are subject to a lock-up agreement under which the holders of these shares have agreed not to sell or otherwise dispose of their shares of common stock until after April 10, 2002. 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. All of these shares will be available for sale after April 10, 2002. In addition, U.S. Bancorp Piper Jaffray Inc., the lead underwriter of our October 2001 initial public offering, may waive these lock-up restrictions prior to the expiration of the lock-up period without prior notice.

In addition, the holders of approximately 23.5 million shares of common stock have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in

registration statements that we may file for ourselves or other stockholders. Furthermore, if we were to include in a company-initiated registration statement shares held by those holders pursuant to the exercise of their registration rights, those sales could impair our ability to raise needed capital by depressing the price at which we could sell our common stock.

Our principal stockholders, executive officers, directors and director nominees 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, directors, director nominees and entities affiliated with them beneficially own, in the aggregate, approximately 43.7% of our common stock as of March 1, 2002. This significant concentration of share ownership may adversely affect the trading price for our common stock because investors often perceive disadvantages in owning stock in companies with controlling stockholders. These stockholders, acting together, will have the ability to exert substantial influence over all matters requiring approval by our stockholders, including the election and removal of directors and any proposed merger, consolidation or sale of all or substantially all of our assets. In addition, they could dictate the management of our business and affairs. This concentration of ownership could have the effect of delaying, deferring or preventing a change in control, or impeding a merger or consolidation, takeover or other business combination that could be favorable to our investors.

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

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

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

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

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.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our invested cash without significantly increasing risk of loss. As of December 31, 2001, our cash and cash equivalents consisted primarily of money market funds maintained at one major U.S. financial institution. The recorded carrying amounts of cash and cash equivalents approximate fair value due to their short-term maturities. We do not believe that an increase in market rates would have any significant negative impact on the realized value of our investments, but an increase in market rates could negatively impact the interest expense associated with a portion of our long-term debt. Substantially all of our long-term debt obligations have a fixed rate of interest.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The Financial Statements and Supplementary Data required by this Item are set forth at the pages indicated in Item 14 of this report.

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

Not applicable.

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 entitled "Proposal No. 1: Election of Directors " and "Management " contained in our definitive Proxy Statement with respect to our 2002 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 entitled "Section 16(a) Beneficial Ownership Reporting Compliance" contained in our Proxy Statement.

ITEM 11. EXECUTIVE COMPENSATION

Information concerning executive compensation is incorporated by reference to the sections entitled "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 Proxy Statement referred to in Item 10 above.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

Information concerning the security ownership of certain beneficial owners and management is incorporated by reference to the section entitled "Common Stock Ownership of Certain Beneficial Owners and Management" 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 entitled "Related-Party Transactions" contained in our definitive Proxy Statement referred to in Item 10 above.

PART IV

ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K

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

(1) Financial Statements

Report of Independent Accountants.....
Balance Sheets as of December 31, 2001 and 2000.....
Statements of Operations for each of the three years in the year ended December 31, 2001.....
Statements of Stockholders' Equity (Deficit) for each of the three years in the year ended Decemb
2001.....
Statements of Cash Flows for each of the three years in the year ended December 31, 2001.....
Notes to Financial Statements.....

(2) Financial Statement Schedules

The following financial statement schedule of TheraSense for the years ended December 31, 2001, 2000 and 1999 is filed as part of this Annual Report and should be read in conjunction with the financial statements of TheraSense:

Schedule II--Valuation and Qualifying Accounts.....

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
***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 Octobe 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 2001
*10.8	Standard Industrial/Commercial Single-Tenant Lease between TheraSense, Inc. and PlyProp Partnership, dated as of February 26, 1999, and addendum thereto
+*10.9	Master Purchase Agreement between TheraSense and Flextronics International USA, Inc., d of November 3, 1999

Exhibit Number	Description of Document
+ *10.10	Assignment of Patent Rights and Technology by and among Board of Regents of the Univer Texas System, an agency of the State of Texas, Dr. Adam Heller, E. Heller & Company an TheraSense Inc. dated August 1, 1991
+*10.11	First Amendment, dated March 19, 1998, to the Agreement entitled Assignment of Patent and Technology by and among Board of Regents of the University of Texas System, an age the State of Texas, Dr. Adam Heller, E. Heller & Company and TheraSense Inc. dated Aug 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 Ser

Inc., dated March 15, 2000

+*10.14 International Distributor Agreement between TheraSense, Inc. and Nipro Corporation, da April 1, 2001

+*10.15 International Distributor Agreement between TheraSense, Inc. and Disetronic Handels AG September 13, 2000

++10.15(a) Amendment No. 1 to International Distributor Agreement between TheraSense, Inc. and Di Handels AG, dated February 8, 2002

+*10.16 Management Services Agreement between TheraSense, Inc. and ICT Group, Inc., dated Janu 2000

+*10.17 License Agreement between TheraSense, Inc. and Unilever PLC dated February 10, 2000

*10.18 Promissory Note dated March 5, 1999 for the principal aggregate amount of $72,495 issu W. Mark Lortz to TheraSense

*10.19 Promissory Note dated July 30, 1998 for the principal aggregate amount of $17,500 issu Charles T. Liamos to TheraSense

*10.20 Promissory Note dated March 5, 1999 for the principal aggregate amount of $15,187.50 i Charles T. Liamos to TheraSense

10.20(a) Amendment to Promissory Note dated March 5, 1999 for the principal aggregate amount of $15,187.50 issued by Charles T. Liamos to TheraSense, Inc.

*10.21 Promissory Note dated September 1, 1999 for the principal aggregate amount of $61,250 Charles T. Liamos to TheraSense

*10.22 Promissory Note dated December 1, 1997 for the principal aggregate amount of $62,650 i W. Mark Lortz to TheraSense, Inc.

10.22(a) Amendment to Promissory Note dated December 1, 1997 for the principal aggregate amount $62,650 issued by W. Mark Lortz to TheraSense, Inc.

*10.23 Amended and Restated Investors Rights Agreement by and among holders of TheraSense Pre Stock and TheraSense, Inc., dated January 23, 2001, as amended

*10.24 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 University of Texas System on behalf of the University of Texas at Austin

*10.25 Form of Change of Control Agreement between TheraSense, Inc. and each Vice President o TheraSense, Inc.

21.1 List of subsidiaries of TheraSense, Inc.

23.1 Consent of PricewaterhouseCoopers LLP, independent accountants

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* 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 Exhibit 3.1(b) 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 Exhibit 3.2(b) filed with our Registration Statement on Form S-1 (Registration No. 333-64456), which was declared effective on October 11, 2001.
+ 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.

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 19, 2002.

THERASENSE, INC.

/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 W. Mark Lortz	Chairman of the Board, President, Chief Executive Officer(Principal Executive Officer)	March 19, 2002
/s/ CHARLES T. LIAMOS Charles T. Liamos	Chief Operating Officer and Chief Financial Officer(Principal Financial and Accounting Officer)	March 19, 2002
/s/ ANNETTE J. CAMPBELL-WHITE Annette J. Campbell-White	Director	March 19, 2002

/s/ MARK J. GAINOR Mark J. Gainor	Director	March 19, 2002
/s/ EPHRAIM HELLER Ephraim Heller	Director	March 19, 2002
/s/ ROSS A. JAFFE, M.D. Ross A. Jaffe, M.D.	Director	March 19, 2002
/s/ MICHAEL M. MCNAMARA Michael M. McNamara	Director	March 19, 2002
/s/ ROBERT R. MOMSEN Robert R. Momsen	Director	March 19, 2002
/s/ RICHARD P. THOMPSON Richard P. Thompson	Director	March 19, 2002

THERASENSE, INC.

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Statements of Operations for each of the three years in the year ended December 31, 2001.....

Statements of Stockholders' Equity (Deficit) for each of the three years in the year ended Decemb

Statements of Cash Flows for each of the three years in the year ended December 31, 2001.....

Notes to Financial Statements.....

REPORT OF INDEPENDENT ACCOUNTANTS

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

In our opinion, the financial statements listed in the accompanying index present fairly, in all material respects, the financial position of TheraSense,

Inc. (the "Company") at December 31, 2000 and 2001 and the results of its operations and its cash flows for each of the three years in the year ended December 31, 2001 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule appearing under Item 14(a)(2) on page 40 presents fairly, in all material respects, the information set forth therein when read in conjunction with the related financial statements. These financial statements and financial statement schedule are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits. We conducted our audits of these statements in accordance with auditing standards generally accepted in the United States of America, which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PRICEWATERHOUSECOOPERS LLP

San Jose, California
February 1, 2002

THERASENSE, INC.

BALANCE SHEETS

	Decemb
	2000
ASSETS	
Current assets:	
Cash and cash equivalents	$ 12,532,474
Accounts receivable, net of allowance for doubtful accounts of $150,000 in 2000 and $704,296 in 2001	6,174,697
Inventories	3,493,777
Deferred cost of products sold	7,396,547
Prepaid expenses and other current assets	1,178,435
Total current assets	30,775,930
Investments	--
Property and equipment, net	4,838,682
Other assets	1,950,303
Total assets	$ 37,564,915
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)	
Current liabilities:	
Accounts payable	$ 10,624,731
Accrued liabilities	4,421,512

Deferred revenue	8,686,547
Current portion of capital lease obligations	844,394
Current portion of borrowings under lines of credit	1,958,958
Total current liabilities	26,536,142
Deferred revenue	--
Capital lease obligations, less current portion	2,037,140
Borrowings under lines of credit, less current portion	3,457,345
Convertible promissory note	2,500,000
Other liabilities	--
Total liabilities	34,530,627
Commitments and contingencies (Note 7)	
Convertible preferred stock, $0.001 par value:	
Authorized: 28,609,647 shares; Issued and outstanding: 20,078,780 shares in 2000 and none in 2001 (Liquidation preference: $63,025,778 in 2000 and none in 2001)	62,882,739
Stockholders' equity (deficit):	
Preferred stock: $0.001 par value; Authorized: 5,000,000 shares; none issued or outstanding	--
Common stock: $0.001 par value:	
Authorized: 200,000,000 shares; Issued and outstanding: 5,139,392 shares in 2000 and 39,534,209 shares in 2001	5,140
Additional paid-in capital	14,427,351
Notes receivable from stockholders	(294,750)
Deferred stock-based compensation, net	(11,262,561)
Accumulated deficit	(62,723,631)
Total stockholders' equity (deficit)	(59,848,451)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 37,564,915

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

THERASENSE, INC.

STATEMENTS OF OPERATIONS

	Years Ended December 31,		
	1999	2000	200
Revenues:			
Product sales	$ 25,000	$ 5,000,250	$ 71,10
License income	--	500,000	75
Research grant revenue	60,296	3,000	
Total revenues	85,296	5,503,250	71,85

Cost of revenues	--	11,948,283	49,14
Gross profit (loss)	85,296	(6,445,033)	22,70
Operating expenses:			
Research and development	7,672,517	12,019,110	16,10
Selling, general and administrative	5,556,708	25,460,349	60,45
Total operating expenses	13,229,225	37,479,459	76,56
Loss from operations	(13,143,929)	(43,924,492)	(53,85
Interest income	295,307	1,488,049	2,17
Interest and other expense, net	(209,100)	(1,155,394)	(1,19
Net loss	(13,057,722)	(43,591,837)	(52,86
Deemed dividends related to beneficial conversion feature of preferred stock	--	(14,772,878)	(26,78
Net loss attributable to common stockholders	$(13,057,722)	$(58,364,715)	$(79,64
Net loss per common share, basic and diluted	$ (4.32)	$ (14.69)	$
Weighted-average shares used in computing net loss per common share, basic and diluted	3,023,636	3,973,250	11,89

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

THERASENSE, INC.

STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

For the Years Ended December 31, 1999, 2000 and 2001

	Common Stock		Additional Paid-In	Notes Receivable from	Deferred
	Shares	Amounts	Capital	Stockholders	Stock-base Compensati
Balances, January 1, 1999	4,582,750	$ 4,583	$ 160,923	$(138,425)	$
Exercise of stock options for cash and in exchange for notes receivable from stockholders	394,182	394	198,566	(192,770)	
Issuance of warrants to purchase Series B preferred stock	--	--	819,760	--	
Deferred stock-based compensation	--	--	1,364,609	--	(1,364,6
Amortization of deferred stock-based compensation	--	--	--	--	120,1
Net loss	--	--	--	--	
Balances, December 31, 1999	4,976,932	4,977	2,543,858	(331,195)	(1,244,4
Exercise of stock options for cash and in exchange for notes receivable from stockholders	213,671	214	86,435	(6,068)	

Repurchase of shares and cancellation of stockholder note receivable.....	(51,211)	(51)	(14,333)	14,384	
Repayment of notes receivable from stockholders.....	--	--	--	28,129	
Deferred stock-based compensation.....	--	--	11,811,391	--	(11,811,3
Amortization of deferred stock-based compensation.....	--	--	--	--	1,793,2
Beneficial conversion feature related to issuance of Series C convertible preferred stock.....	--	--	14,772,878	--	
Deemed dividend related to beneficial conversion feature of Series C convertible preferred stock.....	--	--	(14,772,878)	--	
Net loss.....	--	--	--	--	
Balances, December 31, 2000.....	5,139,392	5,140	14,427,351	(294,750)	(11,262,5
Exercise of stock options for cash....	300,918	301	523,243	--	
Beneficial conversion feature related to issuance of Series D convertible preferred stock.....	--	--	26,782,911	--	
Deemed dividend related to beneficial conversion feature of Series D convertible preferred stock.....	--	--	(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	--	
Issuance of common stock upon exercise of warrants.....	471,748	472	(472)	--	
Conversion of convertible preferred stock into common stock.....	26,722,151	26,722	119,219,103	--	
Repayment of notes receivable from stockholders.....	--	--	--	2,699	
Deferred stock-based compensation, net of cancellations.....	--	--	15,314,446	--	(15,314,4
Amortization of deferred stock-based compensation.....	--	--	--	--	5,581,5
Net loss.....	--	--	--	--	
Balances, December 31, 2001.....	39,534,209	$39,535	$270,376,138	$(292,051)	$(20,995,4

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

THERASENSE, INC.

STATEMENTS OF CASH FLOW

	Years
	1999
Cash flows from operating activities:	
Net loss.....	$(13,057,722)
Adjustments to reconcile net loss to net cash used in operating activities:	

Depreciation and amortization	569,074
Provision for doubtful accounts	--
Amortization of debt issuance costs	74,268
Loss on disposal and sales of property and equipment	132
Amortization of deferred stock-based compensation	120,191
Changes in operating assets and liabilities:	
Accounts receivable	(25,000)
Inventories	--
Deferred cost of products sold	--
Prepaid expenses and other current assets	(773,699)
Other assets	(98,711)
Accounts payable	549,291
Accrued and other liabilities	350,766
Deferred revenue	500,000
Net cash used in operating activities	(11,791,410)
Cash flows from investing activities:	
Purchases of investments	--
Purchases of property and equipment	(3,323,407)
Proceeds from sale of property and equipment	--
Net cash provided by (used in) investing activities	(3,323,407)
Cash flows from financing activities:	
Proceeds from issuance of convertible preferred stock, net	3,110,471
Proceeds from issuance of common stock and exercise of stock options	6,190
Proceeds from lines of credit	3,090,953
Proceeds from convertible promissory note	--
Principal payments on capital lease obligations	(37,410)
Principal payments on lines of credit	(171,163)
Repayment of notes receivable from stockholders	--
Net cash provided by financing activities	5,999,041
Net increase (decrease) in cash and cash equivalents	(9,115,776)
Cash and cash equivalents, beginning of year	11,438,200
Cash and cash equivalents, end of year	$ 2,322,424
Noncash financing activities:	
Common stock issued for notes receivable from stockholders	$ 192,770
Repurchase of restricted common stock and cancellation of notes receivable	$ --
Issuance of warrants to purchase Series B preferred stock in connection with borrowings under lines of credit	$ 819,760
Conversion of promissory note into Series D preferred stock	$ --
Acquisition of property and equipment under capital lease	$ 366,133
Deferred stock-based compensation	$ 1,364,609
Supplemental disclosure of cash flow information:	
Cash paid for interest	$ 134,833

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

NOTES TO FINANCIAL STATEMENTS

NOTE 1--FORMATION AND BUSINESS OF THE COMPANY:

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

The Company develops and sells easy to use glucose self-monitoring systems that dramatically reduce the pain of testing for people with diabetes.

NOTE 2--SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

Use of estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America 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 securities and are recorded at market value using the specific identification method. 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 securities sold.

Fair value of financial instruments

For financial instruments consisting of cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities included in the Company's financial statements, the carrying amounts approximate fair value due to their short maturities. Investments are reported at market value. As of December 31, 2001, the carrying value of borrowings under lines of credit and capital lease obligations, including the current portion, was $8,244,763 and the estimated fair value was $8,415,382. The estimated fair value was determined based on borrowing rates currently available to the Company. As of December 31, 2000, the carrying value of these debt obligations approximated estimated fair value.

THERASENSE, INC.

NOTES TO FINANCIAL STATEMENTS--(Continued)

Inventories

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

Property and equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation is provided on a straight-line basis over the estimated useful lives of the assets, which is generally 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.

Concentration of credit risk and other risks and uncertainties

As of December 31, 2000 and 2001, the Company's accounts receivable derived from revenue earned from customers located in the United States of America was 100% and 82% of the total, respectively. 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.

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

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. Three customers accounted for 29%, 15% and 11% of total accounts receivable at 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. Two customers accounted for 14% and 10% of total accounts receivable at December 31, 2001.

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

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

The Company subcontracts the manufacturing of its FreeStyle meters through one subcontractor and subcontracts the manufacturing of the FreeStyle lancet devices through one subcontractor. The Company believes that there are a number of alternative contract manufacturers that could produce the Company's products, but in the event of a reduction or interruption of supply, it could take a significant period of time to qualify an alternative subcontractor and commence manufacturing. The effect of such reduction or interruption in supply on results of operations would be material.

Revenue recognition

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

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

North America. Under the terms of the agreement, the Company received a $1.5 million nonrefundable pre-payment, which was deferred and was credited as revenues were recognized. In April 2001, the Company entered into an agreement for the exclusive distribution of FreeStyle products in Japan through April 2006. Under the terms of the agreement, the Company received a $5.0 million noncreditable up-front payment, which 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 and lancets and 30 days after purchase on sales of FreeStyle System kits.

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

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

Research and development

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

Advertising costs

Advertising costs, included in selling, general and administrative expenses, are expensed as incurred. No expenses were incurred in 1999. Advertising expense in 2000 and 2001 was $1,878,396 and $4,903,023, 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, 2000 and 2001, all long-lived assets are maintained in the United States of America. All revenue was generated in the United States of America during the years ended December 31, 1999 and 2000. During 2001, 17% 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," and Financial Accounting Standards Board Interpretation No. 44 ("FIN 44") "Accounting for Certain Transactions Involving Stock Compensation, an Interpretation of APB No. 25," in accounting for its employee stock options, and presents disclosure of pro forma information required under SFAS No. 123, "Accounting for Stock-Based Compensation."

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

Net loss per common share

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

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,		
	1999	2000	200
Numerator:			
Net loss	$(13,057,722)	$(43,591,837)	$(52,86
Deemed dividends related to beneficial conversion feature of preferred stock	--	(14,772,878)	(26,78
Net loss attributable to common stockholders	$(13,057,722)	$(58,364,715)	$(79,64

Denominator:			
Weighted-average common stock outstanding	4,840,006	5,060,774	12,30
Less: Weighted-average shares subject to repurchase	(1,816,370)	(1,087,524)	(41
Weighted-average shares used in computing basic and diluted net loss per common share	3,023,636	3,973,250	11,89

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

	December 31,	
	1999	2000
Options to purchase common stock	1,644,468	4,201,599
Common stock subject to repurchase	1,562,751	612,297
Convertible preferred stock	11,588,621	20,078,780
Warrants	521,013	521,013
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 July 2001, the FASB issued SFAS No. 141 "Business Combinations" ("SFAS No. 141") which establishes financial accounting and reporting for business combinations and supersedes APB Opinion No. 16, "Business Combinations," and FASB Statement No. 38, "Accounting for Preacquisition Contingencies of Purchased Enterprises". SFAS No. 141 requires that all business combinations be accounted for using one method, the purchase method. The provisions of SFAS No. 141 apply to all business combinations initiated after June 30, 2001. The adoption of SFAS No. 141 had no impact on the Company's financial statements.

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

recognized in the financial statements. The provisions of SFAS No. 142 are effective for fiscal years beginning after December 15, 2001. The Company will adopt SFAS No. 142 during the first quarter of fiscal 2002, and the adoption of SFAS No. 142 is expected to have no material impact on financial reporting and related disclosures of the Company.

In June 2001, the FASB issued Statement of Financial Accounting Standards 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 except 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 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.

NOTE 3--CASH, CASH EQUIVALENTS AND INVESTMENTS:

Cash, cash equivalents and investments consisted of the following:

	December 31,	
	2000	2001
Cash and cash equivalents:		
Cash	$ 811,633	$ 912,721
Certificate of deposit	10,000	400,000
Money market funds	11,710,841	98,517,965
Commercial paper	--	12,036,270
Corporate bonds	--	9,000,000
Municipal securities	--	22,320,000
	$12,532,474	$143,186,956
Investments:		
Corporate bonds (maturity March 14, 2003)	$ --	$ 4,278,040
	$ --	$ 4,278,040

THERASENSE, INC.

NOTES TO FINANCIAL STATEMENTS--(Continued)

As of December 31, 2001, the market value of investments approximated cost. Accordingly, there was no unrealized gains or losses reported in accumulated other comprehensive income (loss).

NOTE 4--BALANCE SHEET ACCOUNTS:

Inventories consisted of the following:

	December 31,	
	2000	2001
Raw materials	$1,175,408	$2,089,705
Work-in-process	782,838	2,673,336
Finished goods	1,535,531	1,886,375
	$3,493,777	$6,649,416

Property and equipment consisted of the following:

	December 31,	
	2000	2001
Manufacturing equipment	$ 2,082,398	$ 4,391,255
Office equipment	580,017	772,901
Laboratory equipment	1,162,101	1,291,340
Computer equipment	1,294,610	1,758,393
Tooling	788,040	1,202,937
Leasehold improvements	1,051,983	1,209,359
	6,959,149	10,626,185
Less: Accumulated depreciation and amortization	(2,120,467)	(4,087,177)
	$ 4,838,682	$ 6,539,008

Other assets consisted of the following:

	December 31,

	2000	2001
Licenses, net	$ --	$1,720,833
Deposits	578,136	709,782
Debt issuance costs, net	477,003	208,511
Manufacturing equipment deposits	709,845	160,165
Other	185,319	30,557
	$1,950,303	$2,829,848

Accrued liabilities consisted of the following:

	December 31,	
	2000	2001
Salaries and related expense	$ 783,853	$ 5,630,741
Rebates	758,965	5,096,433
Marketing costs	182,917	3,782,602
Professional and other outside services	645,687	1,548,562
Royalties	383,651	1,508,334
Warranties	269,392	1,282,215
Distributor prepayment	1,343,147	--
Other liabilities	53,900	514,559
	$4,421,512	$19,363,446

NOTE 5--BORROWINGS UNDER LINES OF CREDIT:

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%.

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 $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 monthly equal payments. All borrowings under this agreement are collateralized by the equipment purchased. As of December 31, 2001, the funds for this agreement were held in escrow by a third party, the Company has included the $3,000,000 in prepaid expenses and other current assets.

As of December 31, 2001, aggregate future principal payments under the lines of credit are as follows:

2002	$ 2,902,106
2003	1,369,649
2004	593,252
2005	637,912
2006	685,933
	6,188,852
Less: Current portion	(2,902,106)
	$ 3,286,746

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, all of which was outstanding as of December 31, 2000. Upon the first closing of the Series D convertible preferred stock financing in January 2001, the note automatically converted into 294,118 shares of Series D convertible preferred stock. In accordance with the agreement, no interest was payable as the note was outstanding for less than one year.

NOTE 7--COMMITMENTS AND CONTINGENCIES:

Facility lease

The Company leases its facilities under various operating lease agreements which expire up through April 2009. The Company has the option to terminate one of the lease agreements in April 2006. 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. As of December 31, 2001, aggregate future minimum facility lease payments are as follows:

2002	$1,196,450
2003	1,128,120
2004	978,049
2005	864,972
2006	872,186
Thereafter	2,119,174
	$7,158,951

Rent expense for the years ended December 31, 1999, 2000 and 2001 was $619,766, $674,959 and $1,023,090, 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, 2001, aggregate future minimum lease payments are as follows:

2002	$325,988
2003	185,036
2004	12,768
2005	6,384
	$530,176

Capital lease obligations

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

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

forty-eight monthly installments through April 2004.

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

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

	December 31,	
	2000	2001
Manufacturing equipment	$1,099,009	$ 1,099,009
Leasehold improvements	863,891	863,891
Office equipment	400,750	437,521
Tooling	340,083	340,083
Computer equipment	332,610	332,610
Laboratory equipment	298,069	298,069
	3,334,412	3,371,183
Less: Accumulated amortization	(844,691)	(1,787,881)
	$2,489,721	$ 1,583,302

As of December 31, 2001, aggregate future minimum lease payments are as follows:

2002	$ 1,202,557
2003	812,935
2004	180,249
Minimum payments	2,195,741
Less: Amount representing interest	(139,830)
Principal amount of minimum payments	2,055,911
Less: Current portion	(1,087,850)
	$ 968,061

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, 2001, aggregate future minimum payments pursuant to these agreements are as follows:

2002	$1,045,000
2003	1,120,000
2004	1,120,000
2005	620,000
	$3,905,000

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 $2,800,000 in exchange for research and development services provided by Facet Technologies. For the years ended December 31, 1999, 2000 and 2001, none, $331,578 and $1,101,506 of royalties have been expensed to cost of revenues, respectively. As of December 31, 2000 and 2001, the Company has accrued $331,578 and $1,101,506, respectively, of royalties relating to this agreement.

As of December 31, 2000 and 2001, the Company has included $1,050,000 and $1,196,666, 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.

During 2001, the Company entered into two licensing agreements which provide fully paid-up licenses for use of certain technologies in current and future products. As of December 31, 2001, the cost of these licenses totaling $1,850,000 less accumulated amortization of $129,167 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:

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

As of December 31, 1999, 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
	12,109,647	11,588,621	$20,471,813		

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, 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. The warrants are exercisable at any

time and expire on December 31, 2001. During October 2001, 54,348 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. The warrants are exercisable at any time and expire in August 2008 or five years from the effective date of the Company's initial public offering, whichever is earlier. During November 2001, 47,619 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 warrants are exercisable at any time and expire in April 2007 or five years from the effective date of the Company's initial public offering, whichever is later. The fair value of the warrants calculated using the Black-Scholes pricing model, of $57,167, has been reflected as a debt issuance cost included in other assets and amortized as interest expense over the life of the line of credit. During October 2001, 34,285 warrants were exercised in a cashless transaction resulting in the issuance of 30,495 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 warrants are exercisable at any time and expire in October 2009 or five years from the effective date of the Company's initial public offering, whichever is earlier. The fair value of the warrants calculated using the Black-Scholes pricing model, of $762,593, has been reflected as a debt issuance cost included in other assets and amortized as interest expense over the life of the line of credit. During October 2001, 380,952 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.

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

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, commencing in 2002, by an amount equal to the lesser of (i) 2,500,000, (ii) 5.0% of the outstanding shares of common stock on the last day of the preceding fiscal year or (iii) an amount as determined by the Board of Directors.

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, commencing in 2002, 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 are authorized to enter into stock option agreements with selected individuals. The Board of Directors has the authority to determine to whom options will be granted, the number of shares, the term and exercise price (which cannot be less than estimated fair market value at date of grant for incentive stock options or 85% of estimated fair market value for nonqualified stock options). If an employee owns stock representing

more than 10% of the outstanding shares, the price of each share shall be at least 110% of estimated fair market value, as determined by the Board of Directors. Options granted under the Plan generally become exercisable 1/4 on the first anniversary of the vesting commencement date and an additional 1/48 of the total number of shares subject to the option shares shall become exercisable 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, 2000 and 2001, 405,461 and 175,924 shares of common stock were subject to the Company's repurchase rights, respectively. The options have a maximum term of ten years.

Activity under the Plans are as follows:

	Outstanding Options		
	Shares Available for Grant	Number of Shares	Weighted Average Exercise Price
Balances, December 31, 1998.....	548,123	502,094	$ 0.24
Additional shares reserved.....	1,500,000	--	--
Options granted.....	(1,568,245)	1,568,245	$ 0.77
Options exercised.....	--	(394,182)	$ 0.50
Options canceled.....	31,689	(31,689)	$ 0.33
Balances, December 31, 1999.....	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

The options outstanding and exercisable by exercise price range at December 31, 2001 are as follows:

Outstanding Options			Options Exercisable	
Range of Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Options Exercisable	Weighted Average Exercise Price
$ 0.00-$ 2.41	974,510	7.3	588,525	$ 0.66
$ 2.42-$ 4.82	1,558,307	8.3	662,752	$ 3.34
$ 4.83-$ 7.24	2,123,741	9.0	428,415	$ 5.27
$ 7.25-$ 9.65	1,035,623	9.6	76,882	$ 9.00
$ 9.65-$19.30	148,800	9.3	--	--
$19.31-$24.12	670,550	9.9	7,915	$24.02
	6,511,531	8.8	1,764,489	$ 3.26

THERASENSE, INC.

NOTES TO FINANCIAL STATEMENTS--(Continued)

Stock-based compensation

The Company has adopted the disclosure only provisions of SFAS No. 123. In accordance with the provisions of SFAS No. 123, the Company's filing of a registration statement with the Securities and Exchange Commission in October 2000 required that the fair value of all options granted after that date be calculated using the Black-Scholes option pricing model and contain an expected 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,		
	1999	2000	2001
Risk-free interest rate.....	5.55%	5.21%	5.47%
Expected life (in years).....	4	4	4
Dividend yield.....	--	--	--
Expected volatility.....	--	70%	70%

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 would have been as follows:

	Years Ended December 31,		
	1999	2000	2001
Net loss attributable to common stockholders--as reported.....	$(13,057,722)	$(58,364,715)	$(79,648,444)
Net loss attributable to common stockholders--pro forma.....	$(13,101,987)	$(59,150,002)	$(83,851,573)
Net loss per common share, basic and diluted--as reported.....	$ (4.32)	$ (14.69)	$ (6.70)
Net loss per common share, basic and diluted--pro forma.....	$ (4.33)	$ (14.89)	$ (7.05)

The weighted-average per share grant date fair value of options granted during the years ended December 31, 1999, 2000 and 2001 was $0.15, $0.76 and $3.66, respectively.

Deferred stock-based compensation

During 1999, 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, 1999, 2000, and 2001, the Company had recorded deferred stock-based compensation related to these options in the amounts of $1,118,400, $11,008,675 and $13,122,276, net of cancellations, respectively, of which $76,121, $1,501,948 and $4,700,211 had been amortized to expense during 1999, 2000, and 2001, respectively.

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, 1999, 2000 and 2001,

the Company granted options to purchase 73,000, 13,250 and 29,500 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,		
	1999	2000	2001
Risk-free interest rate.	6.05%	5.75%	5.42%
Expected life (in years)	10	10	10
Dividend yield.....	--	--	--
Expected volatility.....	70%	70%	70%

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 $246,209, $802,716 and $2,192,170 for the years ended December 31, 1999, 2000 and 2001, respectively, of which $44,070, $291,300 and $881,341 has been amortized to expense in 1999, 2000 and 2001, respectively.

Note receivable from stockholders

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

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, commencing in 2002, by an amount equal to the lesser of (i) 1,000,000, (ii) 1.5% of the outstanding shares of common stock on such date or (iii) an amount as determined by the Board of Directors.

The 2001 ESPP contains consecutive, overlapping twenty-four month offering periods. Each offering period includes four six-month purchase periods. The price of the common stock purchased shall be 85% of the lower of the fair market value of the common stock at the beginning of an offering period or at the end of a purchase period. The initial offering period commenced on October 11, 2001, the effective date of the Company's initial public offering.

NOTE 11--INCOME TAXES:

At December 31, 2001, the Company has approximately $65.6 million and $43.8 million in federal and state net operating loss carryforwards, respectively, to reduce future taxable income. The federal carryforwards have expiration dates beginning in 2012 and the state carryforwards will expire in 2005, in each case if not utilized.

At December 31, 2001, the Company had research credit carryforwards of approximately $803,000 and $643,000 for federal and state income tax purposes, respectively. If not utilized, the federal carryforwards will expire in various amounts beginning in 2012. The state research credit can be carried forward indefinitely.

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

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

	December 31,	
	2000	2001
Net operating loss carryforwards	$ 17,047,000	$ 26,846,000
Research and development tax credit carryforwards	1,228,000	1,439,000
Deferred revenue	3,456,000	10,743,000
Accruals and reserves not currently deductible for tax		

purposes	2,145,000	5,002,000
Capitalized start-up costs	348,000	209,000
Depreciation and amortization	189,000	123,000
	24,413,000	42,362,000
Valuation allowance	(24,413,000)	(42,362,000)
	$ --	$ --

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

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. During 1999, 2000 and 2001, the Company paid Dr. Heller $85,760, $110,141 and $121,196, respectively, in connection with this agreement. As of December 31, 2000 and 2001, the Company had no accrued liabilities relating to Dr. Heller's consulting services.

Pursuant to an agreement with Facet Technologies entered into in December 1998, Facet Technologies has provided development services for the FreeStyle lancing device and related products. In exchange for such services, the Company granted Facet Technologies the exclusive right to manufacture the FreeStyle lancing device for a period of seven years from the date of the agreement. A former principal of Facet Technologies is a member of the Company's Board of Directors. During 1999, 2000 and 2001, Facet Technologies provided development services of approximately $200,000, $300,000 and $900,000, respectively, and purchases from Facet Technologies totaled $4,675, $402,356 and $1,697,377, respectively. In addition, $27,799 and $111,477 is included in accounts payable as of December 31, 2000 and 2001, respectively, and $331,578 and $555,286 is included in accrued liabilities as of December 31, 2000 and 2001, respectively, in connection with this agreement.

In November 1999, the Company entered into an agreement with Flextronics International ("Flextronics") related to the manufacturing of the FreeStyle meter. The Company's contract with Flextronics expires in

November 2005, and is renewable annually thereafter. A member of the Company's Board of Directors is also President, Americas Operations of Flextronics. During 1999, 2000 and 2001, the Company purchased $261,195, $20,639,858 and $40,047,640 under this agreement, respectively. In addition, $4,045,179 and $5,252,134 are included in accounts payable as of December 31, 2000 and 2001, respectively, and $314,107 and $993,276 are included in accrued liabilities as of December 31, 2000 and 2001, respectively, relating to this agreement. As of December 31, 2000 and 2001, Flextronics owed the Company $545,200 and

$3,121,750, 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 is also a Vice President of the Company and a member of the Company's Board of Directors.

In September 2000, the Company entered into an International Distributor Agreement with Disetronic Handels A.G. relating to the distribution of FreeStyle in Germany, Switzerland, Denmark, Austria, Sweden, Finland, Norway and the Netherlands. In February 2002, the agreement was amended to, among other things, expand Disetronic's European territory to include France, Italy and Belgium. Under terms of the agreement, as amended, Disetronic will have exclusive responsibility for sales, marketing and customer service in its territory in Europe. In addition, Disetronic is also entitled to market FreeStyle to its pump users in North America. The initial term of the Disetronic agreement, as amended, ends on December 31, 2006. At the end of the initial term, the agreement will automatically renew for additional two-year terms unless one of the parties provides written notice of termination at least one year prior to the end of the then-current term. Under the terms of the agreement, the Company received a $1.5 million nonrefundable pre-payment, which was deferred and credited as revenues were recognized. Disetronic is required to meet specific minimum purchase requirements or the Company may terminate the agreement. Disetronic beneficially owns greater than 5% of the Company's outstanding shares of capital stock.

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--QUARTERLY FINANCIAL DATA (UNAUDITED):

	Quarter Ended					
March 31, 2000	June 30, 2000	September 30, 2000	December 31, 2000	March 31, 2001	J

Revenues	$ 500,000	$ 11,251	$ 1,279,879	$ 3,712,120	$ 7,677,456	$ 1
Cost of revenues	--	306,132	6,767,913	4,874,238	6,225,646	1
Gross profit (loss)	500,000	(294,881)	(5,488,034)	(1,162,118)	1,451,810	
Net loss	(6,905,768)	(8,153,065)	(14,593,274)	(13,939,730)	(12,180,463)	(1
Deemed dividends related to beneficial conversion of preferred stock	(14,772,878)	--	--	--	(23,302,349)	(
Net loss attributable to common stock holders	(21,678,646)	(8,153,065)	(14,593,274)	(13,939,730)	(35,482,812)	(1
Net loss per common share	$ (6.12)	$ (2.11)	$ (3.56)	$ (3.16)	$ (7.62)	$

	December 31, 2001
Revenues	$ 26,473,016
Cost of revenues	16,540,461
Gross profit (loss)	9,932,555
Net loss	(13,007,589)
Deemed dividends related to beneficial conversion of preferred stock	--
Net loss attributable to common stock holders	(13,007,589)
Net loss per common share	$ (0.40)

SCHEDULE II

THERASENSE, INC.

VALUATION AND QUALIFYING ACCOUNTS

FOR THE YEARS ENDED DECEMBER 31, 1999, 2000 AND 2001
(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 1999	$ --	--	--	$ --
Fiscal year ended 2000	$ --	150	--	$ 150
Fiscal year ended 2001	$ 150	576	(22)	$ 704
Allowance for inventories valuation:				
Fiscal year ended 1999	$ --	--	--	$ --
Fiscal year ended 2000	$ --	3,528	(657)	$2,871
Fiscal year ended 2001	$2,871	--	(1,603)	$1,268