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, con