THERASENSE INC
Form 10-K
March 12, 2004
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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, 2003

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	No. 94-3267373
(State or other jurisdiction incorporation or organization)	(I.R.S. Employer Identification No.)

1360 South Loop Road, Alameda, CA 94502

(Address of principal executive offices)

Registrant s telephone number, including area code: (510) 749-5400

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 registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

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

The aggregate market value of the 36,292,629 shares of voting stock held by non-affiliates of the registrant, computed by reference to the closing price, as reported on the Nasdaq National Market, as of the last business day of registrant s most recently completed second fiscal quarter (June 30, 2003), was approximately $362,926,290. Registrant has no non-voting common equity.

There were 42,566,797 shares of the registrant s Common Stock $0.001 par value, issued and outstanding as of March 1, 2004.

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THERASENSE, INC.

2003 ANNUAL REPORT ON 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, the Freestyle® blood glucose monitoring system, received FDA clearance in January 2000, and we began selling FreeStyle in the United States in June 2000. We began selling the FreeStyle Flash blood glucose monitoring system in October 2003. The FreeStyle systems utilize patented technologies that can accurately measure glucose concentrations from a tiny 0.3 microliter sample of blood. Most of the competitive products require blood samples from 1.0 to 10.0 microliters. Our tiny sample size is easily obtained by lancing the forearm, thigh, calf, upper arm or hand and therefore avoids the pain associated with drawing a larger blood sample from the fingertip. These alternate sites are significantly less painful to lance than the traditional fingertip test site, which is more densely populated with highly sensitive nerve endings but yields the larger blood volumes required by most competitive products. Nine out of ten people in our clinical studies found using FreeStyle systems on their forearm less painful than their current finger-stick-based system.

We are developing FreeStyle Navigator which is designed to permit users to accurately and discreetly monitor their glucose levels in real time for up to three days. We submitted our premarket approval application for FreeStyle Navigator in November 2003. We are also developing the CozMore insulin technology system with Deltec, Inc. The CozMore system combines Deltec s insulin pump and our FreeStyle blood glucose monitoring technology to allow users to test their glucose levels and administer insulin with one device. Our partner Deltec submitted the 510(k) clearance application in June 2003.

We believe that FreeStyle products are well positioned to capture a meaningful share of the blood glucose self-monitoring market. The blood glucose self-monitoring market is the largest self-test market for medical diagnostic products in the world, with a size of approximately $2.0 billion in the United States and $4.0 billion worldwide. It is estimated that the worldwide blood glucose self-monitoring market will amount to $9.0 billion by 2005. We believe that the FreeStyle products could potentially expand this market by substantially reducing the pain and inconvenience associated with testing glucose levels and managing diabetes. This could bring non-testers into the market and encourage under-testers to test more regularly.

Our direct sales force promotes FreeStyle in the United States to health care professionals who advise patients on the monitoring and management of their diabetes. We distribute and sell FreeStyle in the United States to the ten largest national retailers, including Walgreens, Wal-Mart and Rite Aid, through wholesalers, including Cardinal Health, McKesson, and AmeriSourceBergen, and directly to end users over the telephone and through our website.

FreeStyle products are distributed in various European countries through Ypsomed, formerly Disetronic Injection Systems. In Japan FreeStyle products are distributed by Nipro Corporation. The TheraSense headquarters and test strip manufacturing facility are located in Alameda, California.

On January 12, 2004, we entered into an Agreement and Plan of Merger with Abbott Laboratories and Corvette Acquisition Corp., a Delaware corporation and a wholly-owned subsidiary of Abbott, providing for the merger of Corvette Acquisition Corp., with and into TheraSense, with TheraSense continuing as the surviving corporation. Our Board of Directors has unanimously approved the merger and the merger agreement.

We have filed a notice of special meeting of stockholders and definitive proxy statement for the special meeting of stockholders to be held on April 5, 2004 pursuant to which we will ask our stockholders to adopt and approve the merger agreement and the merger contemplated thereby. For more information about the merger agreement and the merger, please see a copy of the definitive proxy statement filed with the SEC on March 1, 2004 that is available free of charge on our website at www.therasense.com.

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 17 million people, about 6% of the population, have diabetes, although only approximately 11 million of these people have been diagnosed with the disease. The share of the United States population diagnosed with diabetes increased 33% between 1990 and 1998, primarily due to the aging of the population, inappropriate

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diets and increasingly sedentary lifestyles. The most rapid onset was in adults ages 30 through 39. It is also on the rise among a younger population base, including children and teenagers. Worldwide, approximately 175 million people, about 3% of the population, have diabetes. The worldwide prevalence of diabetes is expected to increase to approximately 370 million by 2030.

Importance of Glucose Monitoring

Diabetes is the sixth leading cause of death by disease in the United States, with one death due to diabetic complications occurring every three minutes. The failure to frequently monitor and control blood glucose levels leads to severe medical complications over time, including blindness, loss of kidney function, nerve degeneration and cardiovascular disease. Diabetes is estimated to cost the United States economy over $132 billion annually, including indirect costs such as lost productivity.

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

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

Limitations of Existing Glucose Monitoring Products

Despite the proven benefits of frequent monitoring and intensive management of blood glucose levels, a significant number of people fail to test at their recommended frequency, or at all. The American Diabetes 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 may require squeezing of the fingertips. After drawing a blood sample, users generally are required to drop the blood sample on a disposable test strip or place the test strip on the blood sample. We believe that under-testing is due to the limitations of existing products including:

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

Large Sample Size. Most competitive blood glucose meters require users to draw a sample size from 1.0 to 10.0 microliters of blood to accurately measure blood glucose levels. These larger sample sizes are difficult or impossible to obtain on sites other than the finger. Furthermore, the larger the blood sample required, the wider or deeper the lancing must be in order to reliably draw the sample. This leads to increased pain, greater likelihood of residual bleeding and longer healing time. One other blood glucose meter requires a 0.3 microliter sample size, but this sample must be obtained from the pain-sensitive fingertips.

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

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Lifestyle Disruption. The process of measuring blood glucose levels causes significant disruption in the daily lives of people with diabetes and their families. Lancing the fingertips on infants is traumatizing to both parent and child. Obtaining large blood samples is inconvenient and may cause embarrassment in social situations, particularly for young children who are often required to be removed from class or activities to test themselves in the nurse s office.

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

The TheraSense Solution

FreeStyle blood glucose monitoring products are easy to use, accurate and competitively priced. They are the only blood glucose monitoring systems that combine a 0.3 microliter sample size requirement with the ability to test on other body sites and the fingertip. We believe FreeStyle blood glucose monitoring products also offer the following significant advantages over existing systems:

Reduction in Pain. FreeStyle products require a tiny blood sample of 0.3 microliters, just a fraction of the sample size required by most other systems. The extremely small volume of blood required enables people using FreeStyle products to obtain blood from their forearm, hand, thigh, upper arm or calf as well as from their fingertips as required by most other systems on the market today. Ninety percent of people in our clinical studies found using FreeStyle products on their forearm less painful than their current finger-stick-based systems. FreeStyle products can also eliminate soreness from repeated testing on a small surface area.

Better Performance. Our 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 products 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 products 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 brand for blood glucose self-monitoring. We are creating awareness of the advantages of FreeStyle blood glucose monitoring products in the United States among health care professionals and people with diabetes. We do this through advertising, extensive retail distribution and our sales force. We believe an increased awareness of FreeStyle s less painful, more discreet and reliable process will lead many current testers to switch to FreeStyle.

Maintain and enhance retail distribution. We currently have authorized shelf space with the ten largest chain drug stores, the three largest mass market retailers and the three largest supermarket retailers in the United States. These retailers represent over 20,000 pharmacy outlets in the United States. We plan to continue to expand FreeStyle s availability within these distribution channels through our national accounts sales representatives that interact with the retailers at the corporate and district level and geographically dispersed sales representatives that call on health care professionals including pharmacists.

Focus on our core competencies. We plan to continue to focus our internal resources on our core competencies electrochemistry and sensor manufacturing technologies. Consequently, we have entered into strategic relationships to enhance speed to market and cost effectiveness for those business functions not included in our

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core competencies. For example, we have a strategic relationship with Flextronics International, which is currently manufacturing our meters and assembling our FreeStyle System kits.

Provide high quality customer service. We provide 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.

Expand international distribution. We intend to expand our international sales of FreeStyle products and enter new global markets primarily through relationships with established health care companies that have developed distribution channels. FreeStyle products are distributed in various European countries through Ypsomed, formerly Disetronic Injection Systems. In Japan FreeStyle products are distributed by Nipro Corporation.

Leverage our proprietary technology platform. We intend to leverage our proprietary electrochemical sensor technologies to develop new glucose monitoring products. We are currently developing FreeStyle Navigator, our 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 developing the CozMore insulin technology system with our partner Deltec, Inc. The CozMore system combines Deltec s insulin pump and our FreeStyle blood glucose monitoring technology to allow users to test their glucose levels and administer insulin with one device.

Our Products

FreeStyle Blood Glucose Monitoring Systems. We began selling our initial product, the FreeStyle blood glucose monitoring system, in the United States in June 2000. In October 2003 we began selling our FreeStyle Flash blood glucose monitoring system in the United States. These FreeStyle systems can be used on the thigh, calf, upper arm and hand. This represents the broadest array of off-finger testing sites cleared by the FDA. The system kit for each of these FreeStyle products includes a meter, an initial supply of 10 proprietary disposable FreeStyle test strips, a lancing device, an initial supply of 10 disposable FreeStyle lancets, FreeStyle control solution and instructional materials. We also sell additional supplies of disposable FreeStyle test strips in quantities of 25, 50 and 100 and additional supplies of disposable FreeStyle lancets in quantities of 100.

FreeStyle meters. The FreeStyle meters include a 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. They also contain a data port for transmitting information to our FreeStyle CoPilot web-based data management system and FreeStyle Connect data management software. The FreeStyle Flash meter is smaller than our original meter and displays a test result in an average of 7 seconds. Our original FreeStyle meter displays a test result in an average of 15 seconds.

FreeStyle test strips. FreeStyle test strips are proprietary disposable sensors that are used with the original FreeStyle meter and the FreeStyle Flash 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 meters beep one time when sufficient blood has been drawn into the test strip and beep two times when the test is complete. Our proprietary FreeStyle test strips may only be used with our original FreeStyle meter, our FreeStyle Flash meter and our FreeStyle Tracker System.

FreeStyle lancing device and lancets. The FreeStyle lancing devices are designed specifically to make blood sample acquisition reliable and convenient. They require no mechanical or vacuum assistance to draw blood. The lancing devices offer adjustable depth settings to allow for comfort and adequate sample size. The FreeStyle Flash lancing device is smaller than our original FreeStyle lancing device. Although FreeStyle lancets are available, other standard lancets are compatible with our systems. 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 that our FreeStyle products are functioning correctly and users are following correct testing procedures.

FreeStyle Tracker Diabetes Management System. We received FDA clearance for the FreeStyle Tracker System and commenced sales in June 2002. The FreeStyle Tracker System is a diabetes management system that combines the blood

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

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

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

Products Under Development

FreeStyle Navigator 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 FreeStyle Navigator system is being designed to offer people with diabetes the following benefits:

- accurate and discreet measurement of glucose levels and trends 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 FreeStyle Navigator system will be dependent on the 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 also eliminate the risk of human error during data entry. The display unit, which can be worn like a pager, will translate the sensor s information into a numerical value and periodically, or on demand, display the glucose level and trend. This information will allow users to determine their blood glucose value and whether it is rising, falling or remaining stable. The sensor 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 submitted our premarket approval application for the FreeStyle Navigator system in November 2003. The premarket approval process requires considerably more data and FDA review time than the 510(k) clearance process that was applicable to our current FreeStyle systems. The premarket approval process generally takes between one and three years from completion of an application, but may take longer. However, achieving a completed application is a process that may take numerous clinical trials and require filing of amendments over time. Therefore, even if the Navigator System is successfully developed, it may not be commercially available for a number of years.

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CozMore Insulin Technology System. We are developing the CozMore Insulin Technology System with Deltec, Inc., a leading maker and marketer of insulin pumps including the Cozmo Insulin Pump. The CozMore system combines Deltec s Cozmo insulin pump with our FreeStyle blood glucose monitoring technology to allow users to test their glucose levels and administer insulin with one device. Our partner Deltec submitted the 510(k) clearance application for the CozMore Insulin Technology System in June 2003.

Our Sensor Technologies

We have developed two proprietary miniaturized electrochemical sensor technologies. The first, NanoSample technology, is used in our original FreeStyle System, our FreeStyle Flash System and the FreeStyle Tracker System. The second, Wired Enzyme chemistry, is used in our FreeStyle Navigator continuous glucose monitoring system under development.

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

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

Marketing and Sales

United States. Our marketing and sales program is intended to generate awareness of FreeStyle products and penetrate and expand the glucose self-monitoring market. The sales force includes sale representatives who promote FreeStyle products to the health care professionals who strongly influence the health care decisions made by people with diabetes, a group which includes endocrinologists, certified diabetes educators, pharmacists and internal medicine physicians. The primary goal of our sales representatives is to educate and train health care professionals on the benefits of our products. We also provide these health care professionals with free samples of our products. There are also members of our sales force dedicated to serving retail and managed care accounts at the corporate and district level. In addition, our sales force promotes FreeStyle products and monitors stocking levels with retail outlets at the individual store level. We believe that our strategy of selling through our own direct sales force is an important factor in achieving market penetration.

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, 2003:

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

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International. We intend to expand our international sales efforts for our FreeStyle products and enter new global markets by establishing relationships with international partners who have established relationships with healthcare professionals and developed distribution channels. FreeStyle products are distributed in various European countries through Ypsomed, formerly Disetronic Injection Systems. In Japan, FreeStyle products are distributed by Nipro Corporation.

Under the terms of the Ypsomed agreement, Ypsomed has exclusive responsibility for sales, marketing and customer service in its territory in Europe. We may terminate the agreement if Ypsomed does not meet specified minimum purchase requirements or for any other reason upon prior written notice. The term of the Ypsomed agreement ends in December 2006.

Under the terms of the Nipro Corporation agreement, Nipro has exclusive responsibility for sales, marketing and customer service in Japan. We may terminate the agreement if Nipro does not meet specified minimum purchase requirements. The initial term of the Nipro agreement ends in April 2006.

In addition to the countries covered by the distribution agreements with Ypsomed and Nipro Corporation, as of March 1, 2004, FreeStyle products are sold in more than 30 other countries through local distributors.

Distribution. To establish a worldwide distribution capability for end users, health care professionals and retail customers, we have established relationships with expert distribution partners. For retail order management and shipping of our FreeStyle System kit and other products, we have entered into an exclusive services agreement with UPS Supply Chain Management, a division of UPS Global Logistics that specializes in providing outsourced distribution services for large pharmaceutical and medical device companies. The initial term of this agreement ends in March 2005. We may terminate this agreement prior to March 2005, subject to payment of a termination fee. UPS Supply Chain Management has an extensive network of distribution centers and a sophisticated order management and product tracking system. UPS Supply Chain Management also manages our billing process. Our relationship with UPS Supply Chain Management allows us to meet shipment, delivery and billing expectations while minimizing our internal infrastructure requirements.

Customer Service. We provide customer service 24 hours per day, seven days per week through ICT Group. This service is transparent to the caller and provides a standard of service expected in the industry. This relationship with ICT Group provides customer service, technical support, a help desk and order processing. ICT Group is an international telemarketing and e-support company, with a medical marketing division which has developed a special facility and dedicated customer care agents for us. ICT Group s agents have the systems capability to handle large volumes of our customer contacts at any time, both over the phone or through our web site. We select and train the ICT Group agents who work on our account, as well as maintain in-house customer service personnel that monitor quality. Our non-exclusive contract with ICT expires in January 2005. We may terminate this agreement prior to January 2005, subject to payment of a termination fee.

Manufacturing

The primary components of our original FreeStyle System kit and the FreeStyle Flash System kit are the meter, FreeStyle disposable test strips, the lancing device, FreeStyle disposable lancets and FreeStyle control solution. The primary components of the FreeStyle Tracker System kit are the FreeStyle Tracker module that is inserted into the HandSpring Visor PDA, FreeStyle disposable test strips, the 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 components. These contract manufacturing relationships minimize our capital investment, help control costs and allow us to compete with larger volume manufacturers of blood glucose self-monitoring systems.

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

Flextronics International assisted us in the design of our FreeStyle meter and FreeStyle Tracker module. Flextronics is responsible for manufacturing our meters in China and assembling the FreeStyle system kits in California. Flextronics is also responsible for manufacturing the FreeStyle Tracker module and assembling the FreeStyle Tracker System kits in California. Flextronics has over 13 years of experience building blood glucose meters, and has facilities in Asia, Europe and the Americas.

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Flextronics has demonstrated strong process control and knowledge of just-in-time and total quality management techniques and has software tools to handle product tracking. We have an on-site manager at Flextronics in San Jose who is responsible for the day-to-day interface with Flextronics. Production release to finished goods inventory is done through our quality assurance department. Our contract with Flextronics expires in November 2005, and is renewable annually thereafter. Either party may terminate this contract for any reason upon one year s prior written notice to the other.

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

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

Intellectual Property

We rely on a combination of copyright, patent, trademark, trade secret and other intellectual property laws, nondisclosure agreements and other measures to protect our proprietary rights. As of March 1, 2004, we had 56 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. The issued patents cover, among other things:

- the designs of our FreeStyle meter and FreeStyle strip and FreeStyle lancing device products;
- lancing devices of the type sold with our FreeStyle blood glucose monitoring system;
- aspects of glucose measurement in small sample volumes using electrochemical sensors, such as those using coulometry, those having certain fill detection features, and those having certain sensor chemistries;
- our Wired Enzyme chemistry;
- a one-point calibration method useful in continuous glucose monitoring;
- manufacturing processes for sensors useful in our Navigator System;
- certain sensing and electronic components and methods of use for our Navigator 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 trademarks TheraSense and FreeStyle in the U.S., Europe and Japan. We have obtained registrations or applied to register these marks in numerous other jurisdictions as well.

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

Research and Development

Our research and development efforts are currently focused on developing further enhancements to our current FreeStyle systems as well as developing our FreeStyle Navigator System. Our research and development staff has extensive experience in

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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 $16.1 million in 2001, $20.3 million in 2002, and $21.6 million in 2003. We expect research and development expenses to continue to increase as we seek to enhance our existing products and develop additional products.

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

Competition

The medical device industry is subject to intense competition. Four companies, Roche Diagnostics, LifeScan, Inc., a division of Johnson & Johnson, Bayer Corporation and MediSense, a division of Abbott Laboratories, currently account for approximately 90% of the worldwide sales of blood glucose self-monitoring systems. All of these competitors products use a meter and disposable test strips to test blood obtained by lancing the finger and, in some cases, other body sites. Bayer recently launched a blood glucose monitoring system that claims a sample size requirement of less than one microliter and is cleared for testing on certain alternative sites. Two products cleared for use on the finger and forearm offer a faster test time than our original FreeStyle system, once the required sample has been obtained, and operate over a broader temperature range. Becton Dickinson launched a blood glucose monitoring system that claims the same sample size requirement as our FreeStyle systems. However, this product is only cleared for use on the fingertip. The Becton Dickinson system is capable of wirelessly communicating to an insulin pump manufactured by Medronic, Inc., the leading supplier of such pumps. This integration of a blood glucose monitor and insulin pump is competitive with the CozMore Insulin Technology System we are developing with Deltec, Inc.

In addition, other companies are developing and/or marketing minimally invasive or noninvasive glucose monitoring devices and technologies that could compete with our FreeStyle blood glucose monitoring systems and the FreeStyle Navigator our continuous glucose monitoring system under development. There are also a number of academic and other institutions involved in various phases of our industry s technology development. Many of our competitors have significantly greater financial and human resources than we do. At this time, there are three products approved by the FDA for continuous glucose monitoring, none of which is presently approved as a substitute for current glucose self-monitoring devices. Medtronic MiniMed has two continuous glucose monitoring products approved for sale. Each product includes an implantable sensor that measures and stores glucose values for a period of up to three days. One product is a physician product. The sensor is required to be implanted by a physician, and the results of the data aggregated by the system can only be accessed by the physician, who must extract the sensor and download the results to a personal computer for viewing using customized software. The other product is a consumer product which permits the user to download the results to a personal computer for viewing using customized software. This consumer product also provides an alarm if glucose levels fall out of a range set by the user or a physician. The third product for continuous glucose monitoring that has been approved by the FDA, developed by Cygnus Inc., is worn on the wrist like a watch and can take glucose readings as frequently as every ten minutes for up to thirteen hours at a time. It also provides an alarm if glucose levels are high, low or likely to be low within 20 minutes.

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

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

technological leadership in features and reliability;

equivalent reimbursement from third-party payors among competitive brands;

customer focus and service;

effective marketing and distribution;

acceptance by health care professionals; and

speed to market.

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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 and December 2003, we received 510(k) clearance for certain labeling changes that we made to FreeStyle. In June 2002, we received 510(k) clearance for our FreeStyle Tracker system, our system that incorporates

the blood glucose monitoring technology of FreeStyle into a module for the HandSpring Visor handheld computer.

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

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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.

We filed our premarket approval application for FreeStyle Navigator, our continuous glucose monitoring system, with the FDA in November 2003. The application has been accepted for filing and granted expedited review. The premarket approval process requires considerably more data and FDA review time than the 510(k) clearance process that was applicable to our current FreeStyle products. 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 Navigator System is successfully developed, it may not be commercially available for a number of years.

Clinical Trials. A clinical trial is almost always required to support a premarket approval application and is sometimes required for a 510(k) premarket notification. These trials generally require submission of an application for an investigational device exemption to the FDA. The investigational device exemption application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The investigational device exemption application must be approved in advance by the FDA for a specified number of patients, unless the product is deemed a non-significant risk device and eligible for more abbreviated investigational device exemption 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 FreeStyle Navigator 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.

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We are subject to unannounced inspections by the FDA and the Food and Drug Branch of the California Department of Health Services, and these inspections may include the manufacturing facilities of our subcontractors. The FDA last conducted an inspection of our facility in Alameda, California in November 2003. The FDA issued a Form 483 with two observations. One observation was corrected and verified during the audit. We submitted a corrective action plan to the FDA for the remaining observation in November 2003. We were last audited by the Food and Drug Branch of the California Department of Health Services in November 2001.

International

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

The primary regulatory environment in Europe is that of the European Union, which consists of 15 countries encompassing most of the major countries in Europe. Other countries, such as Switzerland, have voluntarily adopted laws and regulations that mirror those of the European Union with respect to medical devices. The European Union has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling, and adverse event reporting for medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear CE conformity marking, indicating that the device conforms with the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout Europe. CE is an abbreviation for European Compliance. The method of assessing conformity varies depending on the class of the product, but normally involves a combination of self-assessment by the manufacturer and a third-party assessment by a Notified Body. This third-party assessment may consist of an audit of the manufacturer s quality system and specific testing of the manufacturer s product. An assessment by a Notified Body in one country within the European Union is required in order for a manufacturer to commercially distribute the product throughout the European Union. In March 2001, our quality system was certified by TÜV Product Service, a Notified Body, under the European Union In-Vitro Diagnostic Directive and Medical Device Directive allowing the CE conformity marking to be applied. In December 2003, we underwent a surveillance audit by TÜV Product Service, our Notified Body. At the successful conclusion of this audit, TÜV Product Service recommended continuation of our ability to apply CE conformity marking.

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

Third-Party Reimbursement

Self-monitoring of blood glucose is a standard of care in the United States and other developed countries. The costs associated with the purchase of blood glucose monitoring products such as meters and test strips by people with diabetes are generally reimbursed. FreeStyle is currently being reimbursed through Medicare, Medicaid, open formulary plans and certain preferred provider organizations in the United States. International market acceptance of our products may depend, in part, upon the availability of reimbursement within prevailing health care payment systems. Reimbursement and health care payment systems in international markets vary significantly by country, and include both government-sponsored health care and private insurance. Reimbursement has not yet been determined for our Navigator System.

Employees

As of March 1, 2004, we had 512 full-time employees and one part-time employee. None of our employees is represented by a collective bargaining agreement and we have never experienced any work stoppage. We believe that our employee relations are good.

Internet Information

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

Item 2. ***Properties***

We lease approximately 120,000 square feet of manufacturing, laboratory and office space at 1360 South Loop Road in Alameda, California under a lease expiring on or about March 31, 2013. We are also leasing 17,000 square feet of office space in an adjacent building at 1350 South Loop Road under a lease expiring in May 2004. We are not currently utilizing the 1350 South Loop Road office space. We also have the ability to construct

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additional space on a parcel of land adjacent to 1360 South Loop Road. We believe that our current facilities and ability to expand further will be sufficient for our current business for the next few years.

Item 3. ***Legal Proceedings***

Litigation with Gem Edwards, Inc. dba GEMCO Medical

From November 2000 through November 2003, Gem Edwards, Inc. dba GEMCO Medical distributed our products pursuant to a series of distribution agreements. In November 2003, we terminated our then-current distribution agreement with GEMCO, and our distribution relationship with GEMCO ended at that time.

In January 2004, GEMCO filed a complaint in the Court of Common Pleas Summit County, Ohio against us and certain of our employees. The lawsuit alleged that we (and in some instances, the employee defendants) engaged in tortious acts that injured GEMCO. The complaint sought: (1) compensatory damages in excess of $6.0 million; (2) punitive damages in excess of $6.0 million; and (3) payment of GEMCO s reasonable legal fees and costs of its lawsuit. GEMCO voluntarily dismissed the complaint without prejudice on March 1, 2004.

On February 4, 2004, GEMCO filed a complaint in Alameda County Superior Court against us. The lawsuit, Gem Edwards, Inc. dba GEMCO Medical v. TheraSense, Inc., et al. (Case No. RG04139796), alleges that: (1) we breached our distribution agreements with GEMCO; (2) we (and, in some instances, certain unnamed Doe defendants) engaged in activity in violation of various sections of the California Business and Professions Code relating to unfair competition and trade practices; and (3) we interfered with GEMCO s current and potential contractual relationships with its customers. The complaint seeks certain legal and equitable relief, including: (1) compensatory and consequential damages according to proof; (2) doubling or trebling damages as allowed by statute according to proof; (3) equitable relief according to proof; (4) interest, payment of GEMCO s reasonable legal fees and costs of its lawsuit; and (5) such other and further relief as the court may deem proper.

The time for the defendants to respond to the complaint has not yet expired and, to date, no motions have been filed by any of the parties in this lawsuit. We believe that this lawsuit is without merit and intend to defend against it vigorously.

Litigation Relating to the Proposed Merger

On February 9, 2004, a purported stockholder class action lawsuit was filed in Alameda County Superior Court against us, our directors, certain of our officers and 25 unnamed Doe defendants. The lawsuit, Alaska U.F.C.W. Pension Trust v. TheraSense, Inc., et al. (Case No. RG04140525), alleges that the defendants breached their fiduciary duties to our stockholders in connection with our proposed merger with Abbott Laboratories by failing to institute procedures to maximize stockholder value and by advancing their individual interests at the expense of our stockholders. The complaint also alleges that our directors breached their fiduciary duties to act reasonably and establish a level playing field for all potential bidders for TheraSense. The complaint seeks certain declaratory and injunctive relief, including: (1) a declaration that the lawsuit is properly maintainable as a class action; (2) a declaration and decree that the merger agreement was entered into in breach of the defendants fiduciary duties and that it is therefore unlawful and unenforceable; (3) an injunction prohibiting TheraSense and the other defendants from proceeding with any merger until our Stockholder Rights Agreement is revoked; (4) an injunction prohibiting TheraSense and the other defendants from consummating the merger or a business combination with any third party unless a procedure or process is adopted to protect the interests of the our stockholders; (5) an order directing the individual defendants to exercise their fiduciary duties to obtain a transaction in the best interests of our stockholders; (6) an award of costs and disbursements, including attorneys and experts fees; and (7) such

other equitable relief as the court may deem appropriate.

The time for the defendants to respond to the complaint has not yet expired and, to date, no motions have been filed by any of the parties in this lawsuit. The plaintiff has served discovery requests on certain of the defendants and a third party. We believe that this lawsuit is without merit and intend to defend against it vigorously.

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, 2003.

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PART II

Item 5. ***Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities***

Market Information

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

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

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

	High	Low
2003		
First Quarter	$ 8.68	$ 5.75
Second Quarter	$ 12.18	$ 6.45
Third Quarter	$ 15.75	$ 10.00
Fourth Quarter	$ 20.18	$ 11.80

	High	Low
2004		
First Quarter (January 1, 2004 through March 1, 2004)	$ 26.88	$ 19.92

The closing sale price of our Common Stock on the Nasdaq National Stock Market on March 1, 2004 was $26.88.

Holders

As of March 1, 2004, we had approximately 147 stockholders of record.

Dividends

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

Use of Proceeds and Changes in Securities

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

To date, we have spent a portion of the net proceeds as follows (i) approximately $14.2 million for the purchase of capital equipment, (ii) approximately $3.6 million to expand our facility in Alameda, California, (iii) approximately $29.6 million to sponsor free product samples and accelerate the hiring of additional sales representatives, (iv) approximately $6.6 million for research and development of enhanced FreeStyle products and our Navigator System and (v) approximately $6.4 million for general working capital purposes. We are currently investing the remaining net proceeds from the offering for future use as additional working capital. Such remaining net proceeds have been invested in highly liquid instruments, such as commercial paper and U.S. Government obligations, with an average maturity of twelve months or less.

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From January 1, 2003 through December 31, 2003, we did not issue any unregistered securities.

Item 6. ***Selected Financial Data***

The selected consolidated financial data set forth below are derived from our consolidated financial statements. The consolidated statement of operations data for the years ended December 31, 1999 and 2000, and the consolidated balance sheet data as of December 31, 1999, 2000 and 2001 are derived from our audited consolidated financial statements not included in this report. The consolidated statement of operations data for the years ended December 31, 2001, 2002 and 2003, and the consolidated balance sheet data as of December 31, 2002 and 2003 are derived from our audited consolidated financial statements included in this report. Historical results are not necessarily indicative of future results. The selected consolidated financial data set forth below should be read in conjunction with our consolidated financial statements, the related notes and Management s Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this report.

	Years Ended December 31,				
	1999	2000	2001	2002	2003
	(in thousands, except per share data)				
Consolidated Statement of Operations Data:					
Product sales	$ 25	$ 5,000	$ 71,105	$ 176,708	$ 210,854
License income		500	750	1,000	1,000
Research grant revenue	60	3			
Total revenues	85	5,503	71,855	177,708	211,854
Cost of revenues		11,948	49,147	92,835	88,139
Gross profit (loss)	85	(6,445)	22,708	84,873	123,715
Operating expenses:					
Research and development	7,672	12,019	16,103	20,253	21,600
Selling, general and administrative	5,557	25,460	60,458	94,897	107,429
Total operating expenses	13,229	37,479	76,561	115,150	129,029
Loss from operations	(13,144)	(43,924)	(53,853)	(30,277)	(5,314)
Interest income, net	86	332	987	1,115	865
Provision for income taxes					325
Net loss	(13,058)	(43,592)	(52,866)	(29,162)	(4,774)
Deemed dividends related to beneficial conversion feature of preferred stock		(14,773)	(26,783)		
Net loss attributable to common stockholders	$ (13,058)	$ (58,365)	$ (79,649)	$ (29,162)	$ (4,774)
Net loss per common share, basic and diluted	$ (4.32)	$ (14.69)	$ (6.70)	$ (0.73)	$ (0.12)
Weighted-average shares used in computing net loss per common share, basic and diluted	3,024	3,973	11,891	40,131	41,255

	As of December 31,				
	1999	2000	2001	2002	2003
	(in thousands)				
Consolidated Balance Sheet Data:					
Cash, cash equivalents and investments	$ 2,322	$ 12,532	$ 147,465	$ 77,510	$ 89,551
Working capital	792	4,240	128,408	90,737	92,524
Total assets	8,026	37,565	206,576	160,803	164,443
Deferred revenue	511	8,687	26,970	3,261	14,809
Long-term obligations, less current portion	3,321	7,994	4,255	3,160	1,282
Convertible preferred stock	20,472	62,883			
Deferred stock-based compensation, net	(1,244)	(11,263)	(20,995)	(11,642)	(5,651)
Accumulated deficit	(19,132)	(62,724)	(115,589)	(144,752)	(149,526)
Total stockholders equity (deficit)	(18,159)	(59,848)	133,539	115,589	121,184

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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-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) failure to consummate our proposed merger with Abbott Laboratories; (2) our history of losses and variable quarterly results; (3) our dependence on FreeStyle for future revenues; (4) our limited sales and marketing experience; (5) risks related to managed care contracts and adverse changes in reimbursement procedures; (6) substantial competition; (7) risks related to failure to protect our intellectual property and litigation in which we may become involved; (8) risks relating to development of innovative products; (9) risks related to noncompliance with FDA regulations; (10) limited manufacturing experience and our reliance on single manufacturers and sole source suppliers; and (11) other factors that are described from time to time in our periodic filings with the Securities and Exchange Commission, including those set forth in this filing as Risk Factors Affecting Operations and Future Results .

All percentage amounts and ratios were calculated using the underlying data in thousands. Operating results for the year ended December 31, 2003, are not necessarily indicative of the results that may be expected for any future period.

Overview

We develop, manufacture and sell easy to use glucose self-monitoring systems that dramatically reduce the pain of testing for people with diabetes. Our first product, the FreeStyle blood glucose monitoring system, received FDA clearance in January 2000, and we commenced commercial shipments in the United States in June 2000. We began selling the FreeStyle Flash blood glucose monitoring system in October 2003. We sell the FreeStyle systems in the United States and Canada through national retailers and wholesalers, and directly to consumers over the telephone and through our website. FreeStyle products are distributed in various European countries through Ypsomed, formerly Disetronic Injection Systems. In Japan FreeStyle products are distributed by Nipro Corporation. Our sales of FreeStyle products in Canada and the United Kingdom are through a wholly-owned subsidiary in each country.

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

Manufacturers typically sell their glucose monitoring system kits at discounts to list prices, offer customer rebates or provide free product samples to expand their installed base of monitoring devices and thus increase the market for their disposable test strips and lancets. We currently distribute the FreeStyle System kit at a financial loss due in part to samples, discounts and rebates to establish an installed base of systems from which we expect to generate recurring revenues from our disposable FreeStyle test strips and lancets. We have been offering and expect to continue to offer similar discounts and rebates on, and free samples of, our FreeStyle system kits. In the event we establish a large installed base of systems, we expect to generate an increasing portion of our revenues through recurring sales of our FreeStyle test strips.

Revenues are generated from sales of our FreeStyle system kits and from the recurring sales of disposable FreeStyle test strips and lancets. We recognize revenue on these products upon shipment. Generally, our sales terms to retailers and wholesalers provide for customer payment within 60 days of shipment on initial orders and payment within 30 days for subsequent orders. However, we have occasionally granted longer credit terms to match our competitors. We perform ongoing credit evaluations of our customers financial condition and, generally, require no collateral from our customers. We believe our terms to retailers, wholesalers and end users, including rights to return and payment terms, are similar to our competitors terms.

We have incurred significant operating losses and negative cash flows from operations since inception to December 31, 2002 and positive cash flows from operations for four consecutive quarters during 2003. We incurred net losses of $52.9 million in 2001, $29.2 million in 2002 and $4.8 million in 2003. As of December 31, 2003 we had an accumulated deficit of

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$149.5 million. We will need to continue to increase product revenues and reduce product costs to achieve profitability on a sustained basis.

Cost of revenues consists primarily of:

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

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

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

Selling, general and administrative expenses primarily consist of:

- salaries, commissions and related expenses for personnel engaged in sales, marketing, customer service and administrative functions;
- costs associated with advertising, product sampling, trade shows, promotional and other marketing activities;

general corporate expenses;

legal and regulatory expenses; and

amortization of deferred stock-based compensation.

We have recorded deferred stock-based compensation in connection with stock option grants and sales of restricted stock to employees at exercise or sales prices below the deemed fair market value of our common stock. Deferred stock-based compensation for options granted to non-employees has been determined as the fair value of the equity instruments issued. Deferred stock-based compensation for options granted to non-employees is periodically remeasured as the underlying options vest. As of December 31, 2003 we have recorded aggregate deferred stock-based compensation of $24.6 million, of which $5.7 million will be amortized to expense on a straight line basis through 2006. This amount is being amortized over the respective vesting periods of these equity instruments, which is typically four years. Stock-based compensation expense has been allocated according to employees and their respective departments and by function for non-employees.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, including those related to investments, income taxes, litigation and other contingencies. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the

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circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. Management has discussed each of the critical accounting policies and estimates described below with the audit committee of our board of directors.

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

Allowances for sales returns. Our return policy allows end users in the United States and Canada to return FreeStyle System kits to us for a full cash refund within 30 days of purchase. There are no end user return rights on sales of FreeStyle test strips and lancets. In addition, our FreeStyle system kits and FreeStyle test strips currently have 18-month and 24-month shelf lives, respectively, and retailers and wholesalers in the United States and Canada can return these products to us up to six months beyond this expiration date. We use historical trends and experience to estimate future product returns and create an allowance for sales returns. For the years ended December 31, 2002 and 2003, the allowance for sales returns was 1.6% and 1.8% of gross sales, respectively. The increase reflects historical experience with an increasing level of sales returns. In the year ended December 31, 2001, we did not have sufficient historical trends to estimate an allowance for sales returns. As a result, we deferred the recognition of revenue on sales of FreeStyle test strips until resold by retailers and wholesalers to end users, and we deferred recognition of revenue on Freestyle system kits until 30 days after purchase by the end user.

Reserve for consumer rebates. FreeStyle system kits sold through retailers and wholesalers generally include a $40 consumer rebate. Based on historical trends and experience we determine a reserve for consumer rebates by applying an estimate of future redemption rates to the base of FreeStyle system kits sold through retailers and wholesalers. For the years ended December 31, 2002 and 2003, the reserve for consumer rebates was 0.3% and 0.6% of gross sales, respectively. This increased due to the launch of FreeStyle Flash in the fourth quarter of 2003 which increased system kit units shipped. In the year ended December 31, 2001, we did not have sufficient historical experience to estimate a reserve for consumer rebates. As a result, we assumed a 100% redemption rate.

Reserve for sales coupons. We utilize sales coupons to promote sales to end users in the United States. Historically, our coupon programs have primarily promoted the sale of FreeStyle system kits. These coupons are distributed through retailer circulars, national print advertisings, and direct mail programs. They are also distributed to health care professionals through our direct sales force. Based on historical trends and experience, we determine a reserve for sales coupons by estimating a future redemption rate for each promotional program and applying it to the applicable base of outstanding coupons. This estimate is difficult because each promotional program has unique characteristics and there is a substantial lag between distribution of the coupon and its redemption. There is a time lag between when the coupon is distributed and when an end user takes it to a retailer. The retailer then waits until a number of coupons have been accumulated before sending them to our third-party processor. For the years ended December 31, 2002 and 2003, the reserves for sales coupons were 0.6% and 0.6% of gross sales, respectively.

Reserve for Warranties. We believe the following reserve which is utilized to determine our cost of revenues represents one of our more significant judgments and estimates used in the preparation of our consolidated financial statements. Our meters are sold with a five-year warranty. Our reserve for warranties is estimated in the period that revenues are recognized and is determined based on historical trends and experience with warranty replacement and the cost of replacement. For the years ended December 31, 2002 and 2003, the reserves for warranties were 1.1% and 0.7% of gross sales, respectively. The decrease reflects historical experience with a lower number of warranty returns and lower cost of warranty replacement due to lower meter production costs.

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

NRV Reserve. When the market value of our inventory is less than the cost of the inventory, we establish a NRV reserve. The market value of our inventory is based on the average sales price of the product, less reserves for returns, rebates and coupons and estimated selling expenses. We have been offering and expect to continue to offer discounts and rebates on

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our FreeStyle system kits to establish an installed base of systems from which we expect to generate recurring revenues from our disposable FreeStyle test strips and lancets. The cost of our inventory is based on standard cost, which approximates actual cost on a first-in first-out basis. As of December 31, 2002, we did not have a NRV reserve as the market value for our FreeStyle system kits equaled or exceeded their costs. As of December 31, 2003, our NRV reserve was approximately 0.5% of total inventory as the market value for our FreeStyle Tracker system kits were below their costs.

E&O Reserve. We also establish an E&O reserve to adjust the carrying value of impaired inventories to salvage or recoverable value. Excess inventory is defined as the inventory in stock beyond the next twelve months of estimated demand. Obsolete inventory is defined as in stock inventory that either has not sold through within six months of taking title to the inventory or is no longer used in finished goods due to product changes. As of December 31, 2002, we did not have any E&O reserve as none of our inventory fell within our E&O reserve policy. As of December 31, 2003, our E&O reserve was approximately 9.8% of total inventory resulting primarily from slow-moving European system kits and FreeStyle Tracker system kits.

Allowance for Doubtful Accounts. In estimating the uncollectability of our accounts receivable, we analyze historical bad debts, customer concentrations, customer credit-worthiness, current economic trends and changes in customer payment terms. In 2002, our two 10% or more customers accounted for 21% of our product shipments . In 2003, no customers accounted for more than 10% of our product shipments for that year, but our four largest customers accounted for 39% of product shipments. Generally, we do not require collateral from our domestic customers, and we do not require collateral from our two principal international distributors. For our other international customers, accounts receivable balances are generally collateralized by irrevocable letters of credit. Our estimate for the allowance for doubtful accounts related to accounts receivable is based on two methods. The amounts calculated for each of these methods are combined to determine the total amount reserved. First, we evaluate specific accounts where we have information that the customer may have an inability to meet its financial obligations. In these cases, we use our judgment, based on the best available facts and circumstances, and record a specific reserve for that customer against amounts due to reduce the receivable to the amount that is expected to be collected. These specific reserves are reevaluated and adjusted as additional information is received that impacts the amount reserved. Second, a general reserve is established for all customers based on a percentage applied to the outstanding accounts receivable amount. This percentage is based on historical collection and write-off experience. As of December 31, 2002 and 2003, the allowance for doubtful accounts was 2.2% and 1.6% of accounts receivable, respectively. In 2002 and 2003 we decreased our general reserve based on our historical experience with these customers. If circumstances change, such as higher than expected defaults or an unexpected material adverse change in a major customer s ability to meet its financial obligation to us, our allowance for doubtful accounts could be increased.

Results of Operations

Set forth below are certain expectations concerning trends in 2004 with respect to a number of the line items discussed below. These expectations assume we will continue to operate as a stand-alone company and that the merger with Abbott Laboratories will not be completed.

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

	Years Ended December 31,		
	2001	2002	2003
Revenues:			

Product sales	99.0%	99.4%	99.5%
License income	1.0	0.6	0.5
Total revenues	100.0	100.0	100.0
Cost of revenues	68.4	52.2	41.6
Gross profit	31.6	47.8	58.4
Operating expenses:			
Research and development	22.4	11.4	10.2
Selling, general and administrative	84.1	53.4	50.7
Total operating expenses	106.5	64.8	60.9
Loss from operations	(74.9)	(17.0)	(2.5)
Interest income	3.0	1.3	0.8
Interest and other expense	(1.7)	(0.7)	(0.4)
Loss before income taxes	(73.6)	(16.4)	(2.1)
Provision for income taxes			0.2
Net loss	(73.6%)	(16.4%)	(2.3%)

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Years Ended December 31, 2001, 2002 and 2003

Non-GAAP financial information due to impact in 2002 of achieving ability to estimate product return rates. Prior to the quarter ending June 30, 2002 we did not have a sufficient historical basis from which we could estimate product return rates. Accordingly, we deferred recognition of revenue on products shipped to retailers and wholesalers until they were resold to end users and any rights of return had expired. We estimated end user purchases based on data provided to us by third-party data providers. Product shipments that were not recognized as revenue were recorded as deferred revenues on our condensed consolidated balance sheets. The associated cost of these deferred revenues were recorded as deferred cost of products sold on our balance sheets.

Commencing with the quarter ending June 30, 2002 we achieved the ability to estimate product return rates. This event caused a $20.4 million increase in total revenues for the second quarter of 2002 due to the recognition of previously deferred revenues. There was a corresponding $4.2 million increase to our gross profit for the second quarter of 2002 and our gross margin for the period was adversely impacted because the deferred revenues were comprised primarily of lower margin system kits rather than test strips. Similarly, our loss from operations was favorably impacted by the gross profit from the previously deferred revenue which mitigated the loss. The impact of this event is reflected in the condensed consolidated statement of operations data for the twelve months ended December 31, 2002 presented in this report.

Due to the significance of the financial impact from achieving the ability to estimate product return rates in the second quarter of 2002, we have provided the non-GAAP financial information set forth in the tables below. We believe this non-GAAP financial information is useful supplemental information which facilitates meaningful comparisons of operational performance for the fiscal 2002 periods that include this event, with prior and subsequent periods that do not include this event. These non-GAAP measures are not in accordance with, or an alternative for, GAAP and may be different from non-GAAP measures used for other companies.

The following table sets forth, for the twelve months ended December 31, 2002, condensed consolidated statement of operations data in accordance with generally accepted accounting principals (GAAP) and on a non-GAAP basis adjusted to exclude the impact from achieving the ability to estimate product return rates and recognizing previously deferred revenues, costs, and gross profit, in the second quarter of 2002. Set forth between the columns showing GAAP and non-GAAP results is a column indicating the reconciliation to the GAAP results.

	Year Ended December 31, 2002		
	GAAP	Reconciliation	Non-GAAP
	(in thousands, except per share amounts)		
Total revenues	$ 177,708	$ 20,387	$ 157,321
Cost of revenues	92,835	16,192	76,643
Gross profit	84,873	4,195	80,678
Operating expenses:			
Research and development	20,253		20,253
Selling, general and administrative	94,897		94,897
Total operating expenses	115,150		115,150
Income (loss) from operations	(30,277)	4,195	(34,472)

Interest income, net	1,115		1,115
Net income (loss)	$ (29,162)	$ 4,195	$ (33,357)
Net income (loss) per share, basic and diluted	$ (0.73)	$ 0.10	$ (0.83)
Weighted-average shares used in computing net income (loss) per share, basic and diluted	40,131	40,131	40,131

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The following table sets forth, for the years ended December 31, 2001, 2002 and 2003, the percentage of total revenues represented by certain items reflected in our condensed consolidated statement of operations in accordance with GAAP and, for the twelve months ended December 31, 2002 only, on a non-GAAP basis adjusted to exclude the impact from achieving the ability to estimate product return rates and recognizing previously deferred revenues, costs and gross profit.

	Years Ended December 31,			
	2001	2002		2003
	GAAP	GAAP	NON-GAAP	GAAP
Revenues:				
Total revenues	100.0%	100.0%	100.0%	100.0%
Cost of revenues	68.4	52.2	48.7	41.6
Gross profit	31.6	47.8	51.3	58.4
Operating expenses:				
Research and development	22.4	11.4	12.9	10.2
Selling, general and administrative	84.1	53.4	60.3	50.7
Total operating expenses	106.5	64.8	73.2	60.9
Loss from operations	(74.9)	(17.0)	(21.9)	(2.5)
Interest income, net	1.3	0.6	0.7	0.4
Provision for income tax				(0.2)
Net loss	(73.6%)	(16.4%)	(21.2%)	(2.3%)

Revenues. Revenues recognized in 2001 totaled $71.9 million, principally consisting of sales of FreeStyle test strips and FreeStyle System kits. In 2001, one of our customers, McKesson, and our European distributor 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 recognized in 2002 totaled $177.7 million, principally consisting of sales of FreeStyle test strips and FreeStyle system kits. This includes a $20.4 million contribution from achieving the ability to estimate product return rates for sales to retailers and wholesalers in the United States and Canada beginning with the quarter ended June 30, 2002. Prior to the quarter ended June 30, 2002 we deferred revenue recognition until product had been purchased by an end-user and all rights of return had lapsed. The increase in total revenues over the comparable period of 2001 was 119% before the $20.4 million contribution. The increase in revenues from 2001 to 2002 is primarily attributable to an increase in our installed base of end users resulting in increased sales of FreeStyle products to our customers and our expansion into international markets. Due to the recognition of previously deferred revenues from product sales during the quarter ended June 30, 2002, there were no deferred revenues from product sales as of December 31, 2002. In 2002, one of our customers, Cardinal Health, and our European distributor individually accounted for more than 10% and collectively accounted for approximately 21% of our product shipments for that year.

Revenues recognized in 2003 totaled $211.9 million, principally consisting of sales of FreeStyle test strips and FreeStyle System kits. This represents an increase of 35% over 2002 revenues before the $20.4 million contribution. The increase in revenues from 2002 to 2003 is primarily attributable to an increase in our installed base of end users resulting in increased sales of FreeStyle products to our customers. We believe that revenues for 2004 will be greater than revenues for 2003. In 2003, none of our customers individually accounted for more than 10% of our product shipments, but our four largest customers accounted for 39% of our product shipments

Cost of revenues. Cost of revenues in 2001 was $49.1 million and was attributable to product sales. Amortization of deferred stock-based compensation reported in cost of revenues for 2001 was $0.5 million.

Cost of revenues in 2002 was $92.8 million and was attributable to product sales. This increase includes a $16.2 million charge associated with the recognition of previously deferred revenues. The increase in cost of revenues over the comparable period of 2001 was 56% excluding the $16.2 million charge. This increase is due to higher total revenues, which grew by 119% compared with total revenues for the comparable period in 2001, before the $20.4 million contribution. As a percentage of revenues and after excluding the $20.4 million contribution to revenues and the $16.2 million charge, the cost of revenues in

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2002 was 48.7% versus 68.4% in 2001. This decrease reflects increased sales of FreeStyle test strips versus FreeStyle System kits and manufacturing cost reductions for FreeStyle test strips and FreeStyle system kits. Amortization of deferred stock-based compensation reported in cost of revenues for the year ended December 31, 2002 was $0.6 million, as compared to $0.5 million in 2001.

Cost of revenues in 2003 was $88.1 million and was attributable to product sales. This represents an increase of 15% over 2002, excluding the $16.2 million charge. This increase is due to higher total revenues, which grew by 35% over 2002 revenues, before the $20.4 million contribution. As a percentage or revenues the cost of revenues in 2003 was 41.6% versus 48.7% in 2002 after excluding the $20.4 million contribution to revenues and the $16.2 million charge. This decrease reflects increased sales of FreeStyle test strips which typically have higher gross margins, versus FreeStyle System kits, and manufacturing cost reductions for FreeStyle test strips and FreeStyle system kits. Amortization of deferred stock-based compensation reported in cost of revenues for 2003 was $0.5 million, as compared to $0.6 million in 2002. We believe that, as a percentage of revenues, cost of revenues will be lower in 2004 than in 2003.

Research and development expenses. Research and development expenses increased from $16.1 million in 2001, to $20.3 million in 2002 and $21.6 million in 2003. The increase from 2001 to 2002 was primarily attributable to $2.1 million from increased spending on product development efforts, $1.7 million from hiring additional personnel and $0.4 million spent on additional clinical trials. As a percentage of revenues and after excluding the $20.4 million contribution to revenues, research and development expenses in 2002 were 12.9% versus 22.4% in 2001. The increase from 2002 to 2003 was primarily attributable to an increase in spending on Navigator product development efforts. As a percentage of revenues, research and development expenses in 2003 were 10.2% versus 12.9% in 2002 after excluding the $20.4 million contribution to revenues. Amortization of deferred stock-based compensation was $1.3 million in 2001, $1.3 million in 2002, and $1.1 million in 2003. We expect research and development spending to increase in absolute dollars over the next several years as we increase clinical trials for our Navigator 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 $60.5 million in 2001, to $94.9 million in 2002 and to $107.4 million in 2003. The increase from 2001 to 2002 was primarily attributable to increases of $12.7 million for our retail sales force and personnel costs related to expanding our U.S. and international sales force, $11.2 million spent on product sampling, advertising, trade shows, exhibits and meetings, $4.1 million for our international expansion, $3.0 million for sales data services and computer services, and $2.6 million for travel costs. As a percentage of revenues and after excluding the $20.4 million contribution to revenues, selling, general and administrative expenses in 2002 were 60.3% versus 84.1% in 2001. The increase from 2002 to 2003 was primarily attributable to increases of $2.2 million for our retail sales force and personnel costs related to expanding our U.S. and international sales force, $9.3 million spent on product sampling, advertising, trade shows, exhibits and meetings, $2.9 million for our international expansion, while we reduced expenses by $1.2 million in sales data and computer services and travel costs. As a percentage of revenues, selling, general and administrative expenses in 2003 were 50.7% versus 60.3% in 2002 after excluding the $20.4 million contribution to revenues. Amortization of deferred stock-based compensation was $3.8 million in 2001, to $4.2 million in 2002 and to $3.8 million in 2003. We expect our selling, general and administrative expenses to increase in absolute dollars as we increase product sampling, expand our sales force, and increase our marketing and promotional activities. As a percentage of revenues, we expect selling, general and administrative expenses to decrease in 2004.

Interest income. Interest income increased from $2.2 million in 2001 to $2.3 million in 2002 and then decreased to $1.7 million in 2003. Interest income increased slightly from 2001 to 2002 due to the full year effect of higher average cash, cash equivalents and investments balances, resulting from the net proceeds of our initial public offering in October 2001, offset by the cash consumed during 2002. Interest income in 2003 decreased from 2002 primarily due to lower average cash, cash equivalents and investments balances as well as lower interest rates.

Interest and other expense. Interest and other expense remained at approximately $1.2 million in 2001 and 2002. Interest and other expense for 2003 was $0.8 million. Interest expense decreased as we paid off debt during 2003. Interest expense reflects the interest on borrowings under available lines of credit, amortization of debt issuance costs associated with warrants issued in connection with lines of credit and capital lease obligations arising under a particular sale and leaseback transaction.

Provision for income taxes. We incurred net operating losses in 2001, 2002, and 2003. We did not pay any federal or state income taxes in 2001 or 2002. For 2003 we provided for $0.3 million for anticipated taxes. As of December 31, 2003, we had accumulated approximately $112.3 million and $54.1 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 2007. Our net operating loss carryforwards are subject to annual limitations

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under Internal Revenue Code Section 382 due to substantial changes in ownership. Ownership changes as defined by Internal Revenue Code Section 382 have already occurred as a result of certain of our equity financings. We have not recorded a benefit from our net operating loss carryforwards because we believe that it is uncertain that we will have sufficient income from future operations to realize the carryforwards prior to their expiration. Accordingly, we have established a valuation allowance against the deferred tax asset arising from the carryforwards.

We also had federal and state research and development tax credit carryforwards as of December 31, 2003 of approximately $2.9 million and $2.8 million, respectively. If not utilized, the federal research credit will expire in various amounts beginning in 2012. The state research credit can be carried forward indefinitely.

Dividends related to beneficial conversion feature of preferred stock. The difference between the preferred stock purchase price and the fair market value of our common stock on the preferred stock issuance date resulted in a beneficial conversion feature, which has been reflected as preferred stock dividends. Dividends relating to beneficial conversion of our preferred stock of $26.8 million were recorded in 2001. These dividends arose due to the issuance of 6,643,371 shares of Series D preferred stock in January, February and April 2001 for net proceeds of $56.4 million.

Quarterly Results of Operations

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

	Quarter Ended							
	March 31, 2002	June 30, 2002 [1]	September 30, 2002	December 31, 2002	March 31, 2003	June 30, 2003	September 30, 2003	December 31, 2003
	(unaudited, in thousands)							
Revenues	$ 33,279	$ 59,227[1]	$ 39,029	$ 46,173	$ 40,904	$ 50,930	$ 58,230	$ 61,790
Cost of revenues	18,408	34,428[1]	18,362	21,651	19,114	22,495	22,918	23,612
Gross profit	14,871	24,799[1]	20,667	24,522	21,790	28,435	35,312	38,178
Operating expenses:								
Research and development	4,441	6,046	5,332	4,434	5,166	5,678	5,149	5,607
Selling, general and administrative	21,905	22,159	24,991	25,842	25,280	26,453	27,689	28,007
Total operating expenses	26,346	28,205	30,323	30,276	30,446	32,131	32,838	33,614
Income (loss) from operations	(11,475)	(3,406)[1]	(9,656)	(5,754)	(8,656)	(3,696)	2,474	4,564
Interest income, net	490	310	308	7	116	221	216	312

Income (loss) before income taxes	(10,985)	(3,096)[1]	(9,348)	(5,747)	(8,540)	(3,475)	2,690	4,876
Provision for income taxes								325
Net income (loss)	$ (10,985)	$ (3,096)[1]	$ (9,348)	$ (5,747)	$ (8,540)	$ (3,475)	$ 2,690	$ 4,551

(1) Includes the impact from achieving the ability to estimate product return rates and recognizing previously deferred revenues, costs and gross profit:

Revenues	$ 20,387
Cost of revenues	$ 16,192
Gross profit	$ 4,195
Income (loss) from operations	$ 4,195
Income (loss) before income taxes	$ 4,195

Revenues. The increase in revenues over time reflects increased market acceptance of FreeStyle products. The increase in revenue in the quarter ended June 30, 2002 includes a $20.4 million contribution from achieving the ability to estimate product return rates for sales to retailers and wholesalers in the United States and Canada. Revenues for the first quarter of

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2003 were lower than revenues in the fourth quarter of 2002, as we balanced and reduced inventory levels in our distribution channels.

Gross profit. Gross profit is influenced by both sales volume and the product mix between FreeStyle system kits and FreeStyle test strips, as we currently distribute FreeStyle system kits at a financial loss due in part to samples, discounts and rebates. The sequential increase in gross profit resulted from higher revenues and an increasing proportion of those revenues coming from FreeStyle test strips versus FreeStyle system kits. Also favorably influencing gross profit has been our ability to reduce the manufacturing costs of both FreeStyle system kits and FreeStyle test strips over time. The gross profit in the quarter ended June 30, 2002 includes a $4.2 million contribution from achieving the ability to estimate product return rates. Gross margin increased each quarter in 2003 from 53% to 56% to 61% to 62% as we increased sales of FreeStyle test strips versus FreeStyle system kits and benefited from manufacturing cost reductions for FreeStyle test strips and FreeStyle system kits.

Operating expenses. Our research and development efforts are periodically subject to significant non-recurring costs and fees that can cause significant variability in our quarterly research and development expenses. Research and development expenses increased in 2003 due to increased spending on product development efforts, hiring of additional personnel, and clinical trials. Selling, general and administrative expenses have increased over time, 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 products. In addition, costs were incurred related to increases in product sampling to stimulate consumer adoption of FreeStyle products.

Liquidity and Capital Resources

On October 17, 2001 we consummated our initial public offering of common stock in which we received net proceeds of $120.9 million. Previously, we have financed our operations primarily through private placements of convertible preferred stock resulting in net proceeds of $119.2 million. We have also financed our operations through equipment financing arrangements and capital leases with $8.3 million in principal outstanding at December 31, 2002. During the year ended December 31, 2003, these capital leases were fully paid off.

In May 2002, we entered into a revolving line of credit agreement with a lending company. Under the terms of the credit agreement as amended and currently in effect, amounts we borrow from the lending company are repaid to the lending company directly by our accounts receivable debtors. Outstanding amounts owed to the lending company under the credit agreement were collateralized by all of our assets excluding our intellectual property assets. The maximum amount we may borrow from the lending company is based on our eligible accounts receivable and cannot exceed $15.0 million. All outstanding amounts bear interest at the prime rate plus 0.5%. As of December 31, 2002, and 2003 principal of $3.0 million and none, respectively, was outstanding under the credit agreement.

In April 2003, we entered into an agreement with one of our lenders pursuant to which we paid approximately $844,000 to the lending company as a compromised and final payment of all amounts outstanding under this arrangement, and we took title to all of the equipment that had been leased pursuant to this arrangement.

In March 2002, we entered into an arrangement to finance the purchase of certain equipment we use to manufacture our FreeStyle test strips with our supplier of test strip packaging vials. The purchase price of the equipment was approximately $1.6 million. From March 2002 to March 2003, we paid down the equipment purchase price to the supplier through a portion of the purchase price for each packaging vial purchased from the supplier. In April 2003, we paid the remaining purchase price of approximately $1.5 million for the equipment to the supplier and took title to the equipment.

As of December 31, 2003, we owed $1.9 million on an equipment line of credit at an interest rate of 7.3% with a lending company.

As of December 31, 2003, we had cash, cash equivalents and investments of $89.6 million. In January 2003, we received a $15.0 million payment from our European distributor, pursuant to the amendment of their international distributor agreement. This is being recognized as revenue over the term of the international distributor agreement, which expires in December 2006, if not terminated earlier. In 2003, we recognized revenue of $2.4 million from this payment.

Cash provided by or used in operating activities. Net cash used in operating activities was approximately $36.6 million and $64.3 million for 2001, and 2002, respectively. For 2003, cash of $22.4 million was provided by operating activities. The increase in cash used in operating activities from 2001 to 2002 was largely due to decreases in deferred revenues due to the ability to estimate product returns, accounts payable due to controlled disbursements and increases in accounts receivable and inventories. For the year ended December 31, 2003, net cash provided by operating activities of $22.4 million was largely due to the $15.0 million payment from our European distributor in January 2003 pursuant to the amendment of our international distributor agreement in January 2003. In addition, decreases in inventories of $9.9 million and in prepaid expenses and other current assets of $3.8 million were offset by a reduction of accounts payable of $8.0 million. Inventories decreased due to lower per unit costs on both FreeStyle system kits and FreeStyle test strips plus continued improvements in management of raw materials, work-in-process and finished goods inventories. The decrease in accounts payable is due primarily to lower purchase prices we pay for our system kits and lower inventory levels.

Cash used in investing activities. Net cash used in investing activities was approximately $8.0 million, $52.0 million, and $10.0 million for 2001, 2002 and 2003, respectively. For these periods, investing activities consisted of capital expenditures of $3.7 million, $11.0 million, and $8.8 million, respectively, and purchases, net of maturities, of investments of $4.3 million, $40.0 million, and $1.3 million, respectively.

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Cash provided by or used in financing activities. Net cash provided by financing activities was approximately $175.2 million and $4.9 million for 2001 and 2002, respectively. Net cash of $1.3 million was used in financing activities as we paid down higher interest bearing lines of credit. During 2002, we entered into a credit agreement with a lending company and borrowed $14.6 million and had repaid $11.6 million by December 31, 2002. Part of these proceeds were used to pay down higher interest bearing lines of credit. During 2003 we made payments on lines of credit which totaled to $103.1 million and borrowings of $99.1 million largely consisting of advances and repayments under the revolving line of credit.

We had positive cash flows from operations for all four quarters of 2003. For 2004 we also expect increased sales and marketing expenses related to the promotion of FreeStyle products, 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 products, 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 2003 were $8.8 million.

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

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

a party defaults on its obligations under a contract;

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

royalties based on sales or sublicenses exceed minimum royalties.

Contractual Obligations (in thousands)

Payments due by period	Lines of credit	Facility leases	License agreements	Office equipment leases	Total
2004	$ 596	$ 1,904	$ 1,250	$ 13	$ 3,763
2005	641	1,804	620	6	3,071
2006	641	1,884	620		3,145
2007		1,884	620		2,504
2008		1,884	620		2,504
Thereafter		8,873	3,080		11,953
Total	$ 1,878	$ 18,233	$ 6,810	$ 19	$ 26,940

Inflation

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

Recently Issued Accounting Pronouncements

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

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In November 2002, the EITF reached a consensus on Issue No. 00-21, Revenue Arrangements with Multiple Deliverables. EITF Issue No. 00-21 provides guidance on how to account for arrangements that involve the delivery or performance of multiple products, services and/or rights to use assets. The provisions of EITF Issue No. 00-21 applied to revenue arrangements entered into in fiscal periods beginning after June 15, 2003, including interim periods. The adoption of EITF Issue No. 00-21 did not have a material impact on our financial position or our results of operations.

In January 2003, the FASB issued FASB Interpretation No. 46 (FIN 46), Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51. FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. During December 2003, the FASB issued FIN 46R, a revision to FIN 46. FIN 46R provides a broad deferral of the latest date by which all public entities must apply FIN 46 to certain variable interest entities, to the first reporting period ending after March 15, 2004. We do not expect the adoption of FIN 46 to have a material impact upon our financial position, or our results of operations.

In May 2003, the FASB issued SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity. SFAS No. 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. SFAS No. 150 requires that an issuer classify a financial instrument that is within its scope as a liability or an asset in some circumstances. Many of those instruments were previously classified as equity. SFAS No. 150 was effective for financial instruments entered into or modified after May 31, 2003, and otherwise was effective at the beginning of the first interim period beginning after June 15, 2003. SFAS No. 150 was to be implemented by reporting the cumulative effect of a change in an accounting principle for financial instruments created before the issuance date of SFAS No. 150 and still existing at the beginning of the interim period of adoption. The adoption of SFAS No. 150 did not have a material impact on our financial position or our results of operations.

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RISK FACTORS AFFECTING OPERATIONS AND FUTURE RESULTS

If our proposed merger with Abbott Laboratories is not consummated our stock price, business and operations could be harmed.

On January 12, 2004, we entered into an Agreement and Plan of Merger with Abbott Laboratories and Corvette Acquisition Corp., a Delaware corporation and a wholly-owned subsidiary of Abbott, providing for the merger of Corvette Acquisition Corp., with and into TheraSense, with TheraSense continuing as the surviving corporation. Our Board of Directors has unanimously approved the merger and the merger agreement, and we have scheduled a meeting of our stockholders to adopt and approve the merger and the merger agreement for April 5, 2004.

The obligations of the parties to effect the merger are subject to a number of conditions, including approval by our stockholders, and the merger may not occur. If the merger is not consummated for any reason, we may be subject to a number of material risks, including the following:

- we may be required to pay Abbott a termination fee of $44 million;
- the price of our common stock may decline to the extent that the current market price of our common stock reflects an assumption that the merger will be completed; and
- we must pay our accrued costs related to the merger, such as legal, accounting and certain financial advisory fees, even if the merger is not completed;

In addition, our customers may, in response to the announcement of the merger, delay or defer purchasing decisions. Any delay or deferral in purchasing decisions by our customers would have a material adverse effect on our business, regardless of whether or not the merger is ultimately completed.

Similarly, our current and prospective employees may experience uncertainty about their future role with Abbott until Abbott s strategies with regard to us are announced or executed. This uncertainty may adversely affect our ability to attract and retain key management, marketing, technical, manufacturing, administrative, sales and other personnel.

We have a history of net losses and variable quarterly results and may not maintain profitability in the future.

We have incurred losses every year since 1997. We incurred losses of $43.6 million in 2000, $52.9 million in 2001, $29.2 million in 2002 and $4.8 million in 2003. As of December 31, 2003, we had an accumulated deficit of approximately $149.5 million. The quarters ended September 30, 2003 and December 31, 2003 were the first two profitable quarters in our history. We will need to continue to increase product revenues and reduce product costs to sustain and increase our profitability each quarter. As a relatively new entrant to the blood glucose monitoring market that has been experiencing rapid growth, revenues and profitability can vary from quarter to quarter due to various factors, including:

changes in customer stocking and inventory levels;

the timing of promotions and price changes by us or our competitors; and

new product introductions or enhancements by us or our competitors.

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

We expect to derive substantially all of our revenue in the next several years from sales of FreeStyle blood glucose monitoring products and these products could fail to generate increased revenues.

Currently, the primary products we market are the FreeStyle test strips, FreeStyle system kits and FreeStyle lancets, all of which we commercially introduced in June 2000. In addition, in October 2003 we commercially introduced the FreeStyle Flash system kit. Our FreeStyle products are expected to account for substantially all of our revenues for the next several years. Accordingly, our success depends upon the acceptance by people with diabetes, as well as health care providers and third-party payors of our FreeStyle products as a preferred blood glucose self-monitoring devices. Relative to the overall size of the blood glucose monitoring market, a limited number of people have used our FreeStyle products, and people with diabetes or the medical community may not substantially endorse these products as a preferred blood glucose self-monitoring device. In addition, FreeStyle s market acceptance may not be sustained or may not increase on a timely basis, if at all, due to:

the significant influence of established glucose monitoring products with healthcare professionals, customers and third-party payors;

the ability of some of our competitors to price products below a price at which we can competitively manufacture and sell our products;

the introduction or acceptance of competing products or technologies; and

cost constraints.

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

In addition, to encourage market acceptance of our products, we currently distribute the FreeStyle system kit and the FreeStyle Flash 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 products do not gain and maintain sufficient market share to generate increased recurring revenue from the sale of our test strips, we may not achieve sustained profitability.

We have less sales and marketing experience relative to other companies in the blood glucose self-monitoring market and any failure to expand sales of FreeStyle products will negatively impact future revenues.

We have less experience in marketing and selling our products relative to other companies in the blood glucose self-monitoring market. We received regulatory clearance for our initial product in January 2000 and commenced commercial shipments in June 2000. Our products require a complex marketing and sales effort targeted at health care professionals,

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diabetes educators, people with diabetes, pharmacists, national retailers, independent distributors and managed care plans. We significantly expanded our sales and marketing teams in 2001, 2002 and 2003. We face significant challenges and risks in training, managing and retaining these teams, including managing geographically dispersed efforts. In addition, we currently have only one distributor in most of Europe and one distributor in Japan. We are dependent upon the sales and marketing efforts of our third-party distributors in these large international markets. These distributors may not commit the necessary resources to effectively market and sell our products. Further, they may not be successful in selling our products. The Disetronic Group, formerly the parent company of our European distributor, sold its insulin pump business to Roche Diagnostics, one of our competitors, in 2003. While our European distributor was not acquired by Roche Diagnostics and will continue to distribute our products, we may not have the level of access to Disetronic s (now Roche Diagnostics) insulin pump user base that we enjoyed before the acquisition, and this could translate into decreased sales of our products. In addition, the January 2003 amendment to the international distributor agreement with our European distributor lowered its annual minimum purchase obligations. Our financial condition would be harmed if our marketing and sales efforts are unsuccessful.

We may not be successful in securing additional managed care contracts or implementing and managing existing managed care contracts.

Many people with diabetes obtain reimbursement for their purchase of glucose self-monitoring devices and test strips through managed care organizations. Accordingly, entering into reimbursement arrangements with managed care organizations is important to our business. To date, we have entered into reimbursement arrangements with a limited number of managed care organizations, and we are actively seeking additional arrangements. Regarding our current managed care reimbursement arrangements, we have recently started the process of implementing these arrangements throughout the managed care organizations and managing the program, including processing reimbursement submissions. If we are not successful in securing reimbursement for our products from additional managed care organizations that cover a significant number of insured lives or we do not successfully implement and manage our existing or future reimbursement arrangements, we may have difficulty growing our business and retaining our customers. In order to obtain reimbursement arrangements, we often agree to a net sales price lower than the net sales price we charge in other sales channels. Accordingly, unit sales within this channel must increase at a more rapid rate than other channels in order to achieve the same revenue growth rate.

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

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

International market acceptance of our products will depend, in part, upon the availability of reimbursement within prevailing health care payment systems. Reimbursement and health care payment systems in international markets vary significantly by country, and include both government sponsored health care and private insurance. Failures to receive or maintain international reimbursement approvals may negatively impact market acceptance of our products in the applicable international markets.

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

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

The market for blood glucose monitoring devices is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. We compete directly with Roche Diagnostics Corporation, LifeScan, Inc., a division of Johnson & Johnson, MediSense, a division of Abbott Laboratories, and Bayer Corporation, which currently account for approximately 90% of the worldwide sales of blood glucose self-monitoring systems. In addition, Becton, Dickinson has launched a new blood glucose monitoring system. Each of these

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companies is either publicly traded or a division of a publicly-traded company, and they enjoy several competitive advantages, including:

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

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

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

The medical technology industry has in the past been characterized by a substantial amount of litigation and related administrative proceedings regarding patents and intellectual property rights. In addition, major medical device companies have used litigation against emerging growth companies as a means of gaining a competitive advantage. Medtronic, Inc., a large medical device company, has recently filed a lawsuit against Deltec, Inc., alleging that Deltec s Cozmo insulin pump infringes certain Medtronic patents. The CozMore Insulin Technology System is a product we are developing with Deltec that permits the electronic transmission of a blood glucose reading taken using our FreeStyle blood glucose monitoring technology to the Cozmo insulin pump. If Deltec were found to infringe the Medtronic patents, it would have to obtain a license or redesign its Cozmo insulin pump to avoid infringing Medtronic s patents, which could delay the launch of the CozMore system or possibly reduce its features.

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

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

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

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

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

We rely on patent protection, as well as a combination of copyright, trade secret and trademark laws, and nondisclosure, confidentiality agreements and other contractual restrictions to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. For example, our patents may be challenged, invalidated or circumvented by third parties. Our patent applications

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may not be issued as patents in a form that will be advantageous to us. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by employees. Furthermore, the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States. Even if our intellectual property rights are adequately protected, litigation may be necessary to enforce our intellectual property rights, which could result in substantial costs to us and result in a substantial diversion of management attention. If our intellectual property is not adequately protected, our competitors could use our intellectual property to enhance their products. This would harm our competitive position, decrease our market share and otherwise harm our business.

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

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

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

The glucose monitoring market is subject to rapid technological change and product innovations. Our products are based on our proprietary technology, but our competitors may succeed in developing or marketing products that will be technologically superior to ours or be more competitive with regard to product features. In addition, over $91 billion is spent annually on the treatment of diabetes and its complications and the National Institutes for Health and other supporters of diabetes research are continually seeking ways to prevent or cure diabetes. Therefore, our products may also be rendered obsolete by technological breakthroughs in diabetes prevention, monitoring or treatment.

We are currently developing additional enhancements for our FreeStyle products. We are also developing new products such as the CozMore Insulin Technology System, a product we are developing with Deltec, Inc. that permits the electronic transmission of a blood glucose reading taken using our FreeStyle blood glucose monitoring technology to Deltec s Cozmo insulin pump, and FreeStyle Navigator, our continuous glucose monitoring system. Marketing of these products will require FDA and other regulatory clearances and approvals. We experienced some delays in the clinical trials conducted to support the approval of Navigator due to problems with the electronics portion of the system. Development of Navigator and other products will require additional research and development expenditures. We may not be successful in developing, marketing or manufacturing these new products.

In addition, several of our competitors are in various stages of development of continuous glucose monitoring products continuous glucose monitoring similar to Navigator, and the FDA has approved three of these products for adjunctive use with *in vitro* blood glucose monitoring systems. If any of our competitors succeeds in developing a continuous glucose monitor that is approved for marketing as a replacement for *in vitro* blood glucose monitoring, this would negatively affect our future revenues.

Similarly, several of our competitors and some new market entrants are developing products that have small sample size requirements, the ability to test on the fingertip and other body sites, or the ability to communicate with an insulin pump. For instance, Bayer Corporation recently launched a blood glucose monitoring system that claims a sample size requirement of less than one microliter and is cleared for testing on certain alternative sites. In addition, Becton, Dickinson has launched a blood glucose monitoring system that claims the same sample size

requirement as FreeStyle and communicates with an insulin pump from Medtronic, Inc., the leading provider of such pumps. The successful development and introduction of such products by competitors or new entrants would reduce the product benefits of our FreeStyle products versus the competition and could adversely impact future revenues.

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

Our products are medical devices that are subject to extensive regulation in the United States and in foreign countries where we do business. Unless an exemption applies, each medical device that we wish to market in the United States must first receive either 510(k) clearance or premarket approval from the FDA. Either process can be lengthy and expensive. The FDA s

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510(k) clearance process usually takes from four to twelve months from the date the application is complete, but may take longer. Although we have obtained 510(k) clearance for our initial product, FreeStyle, our 510(k) clearance can be revoked if safety or effectiveness problems develop. The premarket approval process is much more costly, lengthy and uncertain. It generally takes from one to three years from the date the application is complete or even longer. However, achieving a completed application is a process that may take numerous clinical trials and require the filing of amendments over time. The FDA acknowledged receipt of our premarket approval submission in November 2003, and the FDA recently accepted the submission for filing. Therefore, even if a product is successfully developed, it may not be commercially available for a number of years. Navigator, our continuous glucose monitoring system under development, will require premarket approval. We experienced some delays in the clinical trials conducted to support the approval of Navigator due to problems with the electronics portion of the system. We may not be able to obtain additional clearances or approvals for Navigator or other products in a timely fashion, or at all. Delays in obtaining clearance or approval could adversely affect our revenues and profitability.

Modification to our marketed devices may require new 510(k) clearances or premarket approvals. Any modification to an FDA cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new FDA 510(k) clearance or possibly premarket approval. The FDA requires every manufacturer to make this determination in the first instance, but the FDA can review any such decision and potentially require us to cease marketing or recall the modified devices until these clearances are obtained.

Any modification to an FDA cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new FDA 510(k) clearance or possibly premarket approval. The FDA requires every manufacturer to make this determination in the first instance, but the FDA can review any such decision. We have modified certain aspects of FreeStyle since receiving regulatory approval, but we believe that new 510(k) clearances are not required. In the case of certain labeling changes for FreeStyle, the FDA required a new 510(k) clearance which was obtained in December 2001. We may make additional modifications to FreeStyle and future products after they have received clearance or approval, and in appropriate circumstances, determine that new clearance or approval is unnecessary. The FDA may not agree with any of our decisions not to seek new clearance or approval. If the FDA requires us to seek 510(k) clearance or premarket approval for any modifications to a previously cleared product, we may be required to cease marketing or recall the modified device until we obtain this clearance or approval. Also, in these circumstances, we may be subject to significant regulatory fines or penalties.

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

Our manufacturing processes for our FreeStyle test strips, as well as the manufacturing processes utilized by our suppliers of meters, lancing devices, lancets and control solution, are required to comply with the FDA s Quality System Regulation, which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of our products. The FDA enforces the Quality System Regulation through unannounced inspections. The manufacturing lines for our meters at Flextronics International Ltd. in China have not been inspected to date. If we or one of our suppliers fail a Quality System Regulation inspection, our operations could be disrupted and our manufacturing delayed. If we fail to take adequate corrective action in response to any FDA observations, we could face various enforcement actions, which could include a shut-down of our manufacturing operations and a recall of our products, which would harm our reputation and cause our product sales and profitability to suffer. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements.

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

The FDA and similar governmental authorities in other countries have the authority to require the recall of or field corrective actions for our products in the event of material deficiencies or defects in design or manufacture. A government mandated or firm-initiated recall or field corrective action by us could occur as a result of component failures, manufacturing errors or design defects. We commenced a firm-initiated field corrective action due to software bugs associated with the diabetes management features of our FreeStyle Tracker diabetes management system shortly after its launch. Any recall of or material field corrective action for product may divert managerial and financial resources and harm our reputation with customers.

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

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

If we are unable to meet customer demand, it would adversely impact our financial results and restrict our sales growth.

To be successful, we must manufacture our FreeStyle test strips in substantial quantities at acceptable costs. If we do not succeed in manufacturing sufficient quantities of our test strips to meet customer demand, we could lose customers and fail to acquire new customers, if they choose a competitor s product because our product is not available. Increasing demand since the launch of FreeStyle has necessitated an increase in our test strip manufacturing capacity. In response, we have expanded our manufacturing capacity at our facilities in Alameda, California. If we are unable to meet customer demand for FreeStyle test strips, it would adversely affect our financial results and restrict our sales growth.

We are subject to additional risks associated with international operations.

We believe that a significant amount of our future revenues may come from international sales, and these sales are subject to a number of risks. These risks include:

- foreign regulatory requirements different from those in the United States, which may require product or labeling changes;
- fluctuations in exchange rates of the U.S. dollar against foreign currencies, which may affect demand for our products overseas;
- export license requirements, the imposition of governmental controls, political and economic instability, trade restrictions, changes in tariffs and difficulties in staffing and managing international operations, any of which could adversely affect our international sales; and
- parallel importing by third parties, which supplants our product sales in certain higher-margin markets. Parallel importing occurs when we ship product to a foreign market for sale to end users in that market and a third party reships the product to another market where it can sell our products at a higher-margin than the designated market.

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

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

Significant product returns could harm our operating results.

Our return policy allows end users in the United States and Canada to return our system kits to us for any reason for a full refund within 30 days of purchase. In addition, our system kits currently have an 18 month shelf life. Our test strips currently sold in most markets, including the United States and Canada, have a 24 month shelf life. Retailers and wholesalers in the United States and Canada can return these products to us in accordance with our returned goods policy within six months after this expiration date. We have established reserves for the liability associated with product returns. However, unforeseen returns from retailers, wholesalers or end users could adversely affect our operating results.

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We may have warranty claims that exceed our reserves.

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

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

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

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

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

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

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

We may have difficulty managing our growth.

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

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

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

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

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

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

International sales of our products are subject to strict regulatory requirements. The review process varies from country to country, is typically lengthy and expensive, and approval is never certain. We have the required regulatory approvals to market FreeStyle products in various countries outside the United States. Failure to maintain current foreign approvals or to receive and maintain approvals in other countries would prevent us from expanding international sales of FreeStyle products, which would negatively impact our future revenues.

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

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

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

- labor unrest and difficulties in staffing;
- increases in duties and taxation levied on our meters;
- limitations on imports of meter components or exports of assembled meters;
- expropriation of private enterprises;
- a potential reversal of current favorable policies encouraging foreign trade; and

fluctuations in the value of local currency.

In addition, the outbreak of severe acute respiratory syndrome (SARS) may adversely impact our business and particularly Flextronics Freestyle meter manufacturing operations. The SARS outbreak has been most notable in Asia, in particular China. Flextronics manufacture of our meters in China could suffer if its employees contract SARS or otherwise are unable to fulfill their responsibilities. In addition, our business could also be harmed if travel to or from China and the United States is restricted or inadvisable.

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

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

Our business exposes us to potential product liability claims that are inherent in the testing, production, marketing and sale of human diagnostic products. While we believe that we are reasonably insured against these risks, we may not be able to

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obtain insurance in amounts or scope sufficient to provide us with adequate coverage against all potential liabilities. Currently, we maintain product liability insurance in the amount of $22.0 million. A product liability claim in excess of our insurance coverage would have to be paid out of cash reserves and would harm our financial position and reputation in the industry.

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

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

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

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

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

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

- volume and timing of orders for our products;
- monthly variations in market data relative to our competitors;

our ability to develop, obtain regulatory clearance for, and market, new and enhanced products on a timely basis;

the announcement of new products or product enhancements by us or our competitors;

announcements of technological or medical innovations in the monitoring or treatment of diabetes;

product liability claims or other litigation;

quarterly variations in our or our competitors results of operations;

changes in governmental regulations or in the status of our regulatory approvals or applications;

changes in the availability of third-party reimbursement in the United States or other countries;

changes in earnings estimates or recommendations by securities analysts; and

general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

On January 12, 2004, we entered into an Agreement and Plan of Merger with Abbott Laboratories and Corvette Acquisition Corp., a Delaware corporation and a wholly-owned subsidiary of Abbott, providing for the merger of Corvette Acquisition Corp., with and into TheraSense, with TheraSense continuing as the surviving corporation. Pursuant to the merger agreement, at the effective time of the merger, each share of our common stock issued and outstanding immediately before the effective time (other than shares held by us, Abbott, Corvette Acquisition Corp. or their respective subsidiaries) will be automatically cancelled and extinguished and converted into the right to receive $27.00 per share in cash, without interest. Pursuant to the merger agreement, prior to the effective time, each option to purchase our common stock or portion thereof that

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is outstanding and unexercised immediately prior to the effective time, whether or not vested, shall immediately terminate, and the holder of any such option shall be entitled to receive the excess (if any) of (A) $27.00 over (B) the exercise price per share subject to such option. We publicly announced the signing of the merger agreement on January 13, 2004. From January 13, 2004 through March 1, 2004, the closing prices for our common stock as reported by Nasdaq was between $26.57 and $26.88. If the merger contemplated by the merger agreement is not consummated, our stock price would decrease and would be highly volatile as it was prior to our announcement of the merger agreement.

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

Sales of a significant number of shares of our common stock in the public market or the market perception that these sales may occur, could negatively affect the market price for our common stock. As of March 1, 2004, we had 42,566,797 shares of common stock outstanding. Most of these shares are available for sale. Also, many of our employees and consultants may exercise their stock options in order to sell the stock underlying their options in the market under a registration statement we have filed with the SEC.

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

Our executive officers and directors and entities affiliated with them beneficially own, in the aggregate, approximately 11.2% of our outstanding shares of common stock as of March 1, 2004. This significant concentration of share ownership may adversely affect the trading price for our common stock because investors often perceive disadvantages in owning stock in companies with concentrated ownership. These stockholders, acting together, would have the ability to exert substantial influence over all matters requiring approval by our stockholders, including the election and removal of directors and any proposed merger, consolidation or sale of all or substantially all of our assets. In addition, they could exert substantial influence over the management of our business and affairs. This concentration of ownership could have the effect of delaying, deferring or preventing a change in control, or impeding a merger or consolidation, takeover or other business combination that could be favorable to our investors. As a condition to its entering into the merger agreement with Abbott Laboratories and Corvette Acquisition Corp., Abbott required that certain of our stockholders enter into a stockholder agreement under which they have agreed to vote all of the their TheraSense securities they beneficially own in favor of approval and adoption of the merger agreement and related matters, and against any competing transaction or proposal or any proposal or transaction that could reasonably be expected to prevent or impede the completion of the merger. The stockholders who have signed the stockholder agreement beneficially own approximately 14.7% of our outstanding shares of common stock and include certain of our executive officers and directors and entities affiliates with them.

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

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

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

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

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In addition, we are governed by the provisions of Section 203 of Delaware General Corporate Law. These provisions may prohibit stockholders owning 15% or more of our outstanding voting stock from merging or combining with us. Section 203 of Delaware General Corporate Law, our Stockholder Rights Plan and other provisions in our amended and restated certificate of incorporation and bylaws and under Delaware law could reduce the price that investors might be willing to pay for shares of our common stock in the future and result in the market price being lower than it would be without these provisions. In connection with the merger agreement by and among TheraSense, Abbott Laboratories and Corvette Acquisition Corp., we amended the Stockholder Rights Plan to exempt Abbott, Corvette Acquisition Corp. or any affiliate or associate thereof, and the execution and delivery of the merger agreement and consummation of the transactions contemplated thereby, from certain provisions of the Stockholder Rights Plan, including provisions that would have triggered a distribution of the Rights upon signing of the merger agreement.

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

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

Item 7A. ***Quantitative and Qualitative Disclosures about Market Risk***

Because we translate foreign currencies into United States dollars for reporting purposes, exchange rates can have an impact on our financial results, although this impact is generally immaterial. We believe that our exposure to currency exchange risk is low because our Canadian and United Kingdom subsidiaries satisfy their financial obligations almost exclusively in their local currencies. As of December 31, 2003, we did not engage in foreign currency hedging activities.

The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our invested cash without significantly increasing risk of loss. As of December 31, 2003, our cash, cash equivalents and available-for-sale securities consisted primarily of money market funds maintained at three major U.S. financial institutions. The recorded carrying amounts of cash and cash equivalents approximate fair value due to their short-term maturities. We do not believe that an increase in market rates would have any significant negative impact on the realized value of our investments, but an increase in market rates could negatively impact the interest expense associated with a portion of our long-term debt. Substantially all of our long-term debt obligations have a fixed rate of interest.

Item 8. ***Financial Statements and Supplementary Data***

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

Item 9. ***Changes in and Disagreements with Accountants on Accounting and Financial Disclosure***

Not applicable.

Item 9A. ***Controls and Procedures***

(a) Evaluation of disclosure controls and procedures. Our chief executive officer and our chief financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in the Securities Exchange Act of 1934 Rules 13a-15(e) or 15d-15(e)) as of the end of the period covered by this report, have concluded that as of the end of the period covered by this report, our disclosure controls and procedures were adequate and designed to ensure that material information relating to us and our consolidated subsidiaries would be made known to them by others within those entities.

(b) Changes in internal controls over financial reporting. There were no changes in our internal controls over financial reporting identified in connection with the evaluation required by paragraph (d) of Exchange Act Rule 13a-15 or 15d-15 that occurred during the quarter ended December 31, 2003 or to our knowledge, in other factors that have materially affected or are reasonably likely to materially affect our internal controls over financial reporting.

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PART III

Item 10. ***Directors and Executive Officers of the Registrant***

Our directors and executive officers and their ages as of March 1, 2004, are as follows:

Name	Age	Position
W. Mark Lortz [1]	52	Chairman of the Board, Chief Executive Officer and President
Charles T. Liamos [2]	44	Chief Operating Officer and Chief Financial Officer
Arthur A. Autorino	57	Vice President of Operations
Robert D. Brownell [2]	42	Vice President, General Counsel and Secretary
Eve A. Conner, Ph.D.	58	Vice President
Timothy T. Goodnow, Ph.D.	42	Vice President of Research and Development
Shawna P. Gvazdauskas	48	Vice President of Sales
James C. Hey	44	Vice President of Marketing
Lawrence W. Huffman	59	Vice President of International Business Development
Holly D. Kulp	46	Vice President of Professional Relations and Customer Services
Nelson O. Lam	40	Vice President of Quality Assurance and Regulatory Affairs
Carl Silverman	56	Vice President of Intellectual Property
Mark C. Tatro	41	Vice President of Finance
Jerry Tu	47	Vice President of International Sales
Nan T. Watanabe, Ph.D.	48	Vice President of Human Resources
Bradford A. Bowlus	48	Director
Rod F. Dammeyer [3]	63	Director
Ross A. Jaffe, M.D. [3] [5]	45	Director
Jonathan T. Lord, M.D.	49	Director
Robert R. Momsen [4] [5]	57	Director
Richard P. Thompson [3]	52	Director

[1] Director and executive officer of TheraSense s wholly-owned subsidiaries, TheraSense Canada, TheraSense UK Limited and TheraSense Sales Corp.

[2] Executive officer of TheraSense s wholly-owned subsidiaries, TheraSense Canada, TheraSense UK Limited and TheraSense Sales Corp.

[3] Member of Audit Committee. Mr. Dammeyer is the Chairman.

[4] Member of Nominating and Corporate Governance Committee. Mr. Momsen is the Chairman.

[5] Member of Compensation Committee. Dr. Jaffe is the Chairman.

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

Charles T. Liamos has served as our Chief Operating Officer and Chief Financial Officer since November 2001, and as our Vice President and Chief Financial Officer from July 1999 to November 2001, and as our Director of Purchasing and Finance from April 1998 to July 1999. Mr. Liamos has served on our Board of Directors since April 2002. From May 1995 to April 1998, Mr. Liamos was Director, Worldwide Sourcing at LifeScan, Inc., a division of Johnson & Johnson, a diversified health care company. He holds a B.S. in Business Administration from the University of Vermont and is a graduate of the General Electric Financial Management Program.

Arthur A. Autorino has served as our Vice President of Operations since June 2002. From October 2000 to September 2001, Mr. Autorino was Vice President, China Operations & Chief Representative Shanghai Office at Murray, Inc., a manufacturer and marketer of outdoor power equipment and recreational vehicles. From 1997 to 2000, Mr. Autorino was Vice President of the Jackson/McKenzie division of Murray, Inc. Mr. Autorino has also served in various executive positions at General Electric and Smith & Wesson. Mr. Autorino holds a Master s in Industrial Administration from Union College and a B.S. in Aerospace Engineering from the University of Virginia.

Robert D. Brownell has served as our Vice President and General Counsel since March 2001 and Secretary since June 2001. From June 2001 to December 2001, Mr. Brownell served as our Vice President of Human Resources. From February 1996 to

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April 2000, Mr. Brownell was a member of Wilson Sonsini Goodrich & Rosati, P.C., a leading technology law firm. Prior to becoming a member, Mr. Brownell was an associate at Wilson Sonsini Goodrich & Rosati, P.C. Mr. Brownell holds a J.D. from the University of California, Los Angeles and a B.A. in Jurisprudence and Social Policy from the University of California, Berkeley.

Eve. A. Conner, Ph.D. has served as our Vice President focusing on FreeStyle Navigator clinical affairs and other projects since August 2003 and as Vice President of Quality Assurance and Regulatory Affairs from January 1999 to August 2003. From June 1996 to December 1998 she served as Vice President, Clinical/Regulatory Affairs and Quality Assurance for Somnus Medical Technologies, Inc., a manufacturer of electrosurgical devices. From October 1991 to June 1996, Dr. Conner was Vice President, Regulatory/Clinical Affairs and Quality Assurance for Baxter Healthcare s Novacor Division, a manufacturer of implantable heart assist devices. Dr. Conner holds a Ph.D. in Pharmacology from the University of Minnesota and a B.A. in Biology from Keuka College.

Timothy T. Goodnow, Ph.D. has served as our Vice President of Research and Development since November 2000. From June 1999 to October 2000, Dr. Goodnow held the position of Vice President of Research and Development for Verax Biomedical Incorporated, a blood safety start-up company. From July 1998 to June 1999, Dr. Goodnow served in the capacity of Vice President of Research and Development for ZymeQuest, Inc., a start-up company specializing in the development of enzymic blood conversion processing systems for use in blood transfusion medicine. From January 1983 to July 1998, he served in various positions of increasing responsibility, including Vice President of Research and Development for Baxter Healthcare/Dade Behring, a global corporation providing products and support services to clinical laboratories. Dr. Goodnow holds a B.S. and Ph.D. in Chemistry from the University of Miami.

Shawna Gvazdauskas has served as our Vice President of Sales since May 2002. From August 2001 to May 2002 she served as National Sales Director for Ortho Neutrogena, a Division of Neutrogena Corporation, a Johnson & Johnson company that manufactures and sells over-the-counter and prescription skin and hair care products. From June 1998 to August 2001, Ms. Gvazdauskas was Director of Professional Sales at Neutrogena Corporation. Ms. Gvazdauskas has also held sales and sales management positions at Neutrogena Corporation, Colgate Oral Pharmaceuticals, MediSense, Inc., Syntex Laboratories and Pharmacia Opthalmics Ms. Gvazdauskas holds a B.S. in Biology, Magna Cum Laude from Worcester State College.

James C. Hey has served as our Vice President of Marketing since January 2004. From April 1999 to March 2003, Mr. Hey held various senior executive marketing and general management positions with Lexmark International, Inc., a manufacturer of inkjet and laser printers, most recently as Vice President and General Manager of Worldwide Inkjet Supplies and Vice President of Worldwide Marketing. From 1997 to January 1999, Mr. Hey was Vice President of Marketing for Mead Johnson Nutritionals Europe, Middle East & Africa Division of Bristol-Myers Squibb Company. Mr. Hey holds an M.B.A. Degree from Harvard University Graduate School of Business Administration and a B.S. Degree in Chemical Engineering from Clarkson University.

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

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

Nelson O. Lam has served as our Vice President of Quality Assurance and Regulatory Affairs since August 2003, as Director of Quality Assurance from October 2000 to August 2003, and as the Quality Assurance Manager from March 1999 to October 2000. From November 1998 to February 1999, he was the Sr. Quality Systems Engineer at Cardima, Inc., a micro-catheter device company. Mr. Lam holds a Bachelors of Science in Electrical Engineering from New Jersey Institute of Technology.

Carl Silverman has served as our Vice President of Intellectual Property since March 2004. From February 1987 to February 2004, Mr. Silverman held various positions at Intel Corporation, a semiconductor chip maker, most recently as Group General Counsel. Mr. Silverman holds a J.D. from Brooklyn Law School and a B.S. in Physics from the City University of New York.

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Mark C. Tatro has served as our Vice President of Finance since December 2001 and as our Corporate Controller from June 2000 to December 2001. From September 1996 to June 2000, Mr. Tatro was Vice President of Finance for Gatan Inc., a scientific equipment manufacturing company. Mr. Tatro holds a B.S. in Accounting from Florida State University.

Jerry Tu has served as our Vice President of International Sales since December 2003. From June 1997 to November 2003, Mr. Tu served as Country Manager, Abbott Labs Services Corp. Taiwan Branch of Abbott Diagnostics, a division of Abbott Laboratories. Mr. Tu holds a M.B.A. from Central Missouri State University and a B.A. in International Trade from Fong Chia University in Taiwan.

Nan T. Watanabe has served as our Vice President of Human Resources since January 2002. Prior to that, in June 1999 she founded and is the principal of Z Dimensions, a human resources consulting services firm. Through Z Dimensions, Dr. Watanabe provided organizational development consulting services to us from May 2001 through December 2001. From September 1996 to August 1999, Dr. Watanabe was the Director of Organizational Development at International Network Services, an enterprise networking services and solutions company. Dr. Watanabe holds a B. Mus. Ed. in Music Education from Lawrence University and a M.S. in Music Education and a Ph.D. in Instructional Technology from the University of Illinois.

Bradford A. Bowlus has served on our Board of Directors since June 2003. Mr. Bowlus has been President and Chief Executive Officer of PacifiCare Health Systems Health Plan division since 1999. Mr. Bowlus was President and Chief Executive Officer of PacifiCare of California from 1997 to 1999. From 1994 to 1997, Mr. Bowlus served in various capacities for PacifiCare, including President and Chief Executive Officer of PacifiCare of Washington, Inc., President and Chief Executive Officer of PacifiCare Dental and Vice President of PacifiCare of California. Mr. Bowlus received his bachelor s degree in Business from California State University, Northridge and his M.B.A. from Pepperdine University.

Rod F. Dammeyer has served on our Board of Directors since April 2002. Mr. Dammeyer is president of CAC, llc, a private company offering capital investment and management advisory services. From 1995 until his retirement in June 2000, Mr. Dammeyer was a managing partner of Equity Group Investments, Inc., a corporate investment company. He was formerly the Vice Chairman of Anixter Inc., a global distributor of wire, cable, communications connectivity products, and C Class inventory components. Mr. Dammeyer is a member of the boards of directors of GATX Corporation, Stericycle, Inc. and Ventana Medical Systems, Inc., in addition to several private companies. He is also a trustee of Van Kampen Closed-End Funds, and a member of the board of directors of the University of Chicago Hospitals and Health Systems and The Scripps Research Institute. Mr. Dammeyer holds a B.S. degree in Accounting from Kent State University.

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

Jonathan T. Lord, M.D. has served on our Board of Directors since May 2003. Dr. Lord joined Humana Inc., a health benefits company, in April 2000, and currently serves as Humana s Senior Vice President and Chief Clinical Strategy and Innovation Officer. From October 1999 to April 2000, Dr. Lord served as President of Health Dialog, a health information provider. From April 1997 to October 1999, he served as Chief Operating Officer of the American Hospital Association, a national organization that represents hospitals, health care networks and their patients. Dr. Lord holds a M.D. from the University of Miami and a B.S. in Chemistry from the University of Miami.

Robert R. Momsen has served on our Board of Directors since October 1998 Since August 1982, Mr. Momsen has been a general partner at Interwest Partners. While Mr. Momsen is not a general partner of Interwest VII and VIII, he continues as a general partner of Interwest IV, V and VI. He currently serves as a director of Corixa Corporation in addition to two private companies. Mr. Momsen graduated with a B.S. in engineering from Stanford University and a M.B.A. from Stanford University.

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

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

Committees of the Board of Directors

The Board has an audit committee, a compensation committee, and a nominating and corporate governance committee. Each committee is composed entirely of directors who are independent as that term is defined in the Nasdaq listing standards and Section 301 of the Sarbanes Oxley Act of 2002.

The audit committee consists of Messrs. Dammeyer (Chairman) and Thompson and Dr. Jaffe. Mr. Dammeyer is our audit committee financial expert as that term is defined in Item 401(h) of Regulation S-K promulgated under the Securities Act of 1933, as amended. The audit committee reviews and monitors our consolidated financial statements and assists the Board in fulfilling its responsibility for oversight of our accounting, internal control over financial reporting, auditing and financial reporting practices. In addition, the audit committee makes recommendations to the Board regarding the selection of independent accountants, consults with, and reviews the audit services provided by our independent accountants and preapproves the non-audit services provided by our independent accountants. The audit committee operates pursuant to a written charter that has been approved and adopted by the Board.

The compensation committee consists of Dr. Jaffe (Chairman) and Mr. Momsen. The compensation committee reviews and approves the compensation and benefits of our executive officers, reviews the compensation policy for directors and reviews the general compensation guidelines and goals for our employees. The compensation committee also administers our stock plans and employee benefit plans. The compensation committee operates pursuant to a written charter that has been approved and adopted by the Board.

The nominating and corporate governance committee consists of Mr. Momsen (Chairman). The nominating and corporate governance committee identifies and recommends individuals for membership on the Board and service on committees of the Board. In addition, the nominating and corporate governance committee oversees an annual evaluation of the progress and effectiveness of the Board and its committees. The nominating and corporate governance committee operates pursuant to a written charter that has been approved and adopted by the Board.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934 requires our directors, certain executive officers and persons who own more than 10% of a registered class of our equity securities, to file certain reports regarding ownership of, and transactions in, our securities with the Securities and Exchange Commission. Such executive officers, directors and 10% stockholders are also required by Securities and Exchange Commission rules to furnish us with copies of all Section 16(a) forms that they file. Based solely on our review of the copies of such forms received by us, or written representations from certain reporting persons, we believe that for the fiscal year ended December 31, 2003, all reporting persons complied with Section 16(a) filing requirements.

Code of Business Conduct and Ethics

In accordance with Section 406 of the Sarbanes-Oxley Act of 2002, we have adopted a Code of Business Conduct and Ethics. The Code of Business Conduct and Ethics was adopted by our Board of Directors in February 2003 and is applicable to all of our employees. The Code of Business Conduct and Ethics summarizes standards of conduct that are intended to guide the conduct of each company employee. Covered categories of conduct include conflicts of interest relating to employment, business activities and related-party relationships, corporate opportunities, records management, quality of public disclosures, protection and proper use of our assets, fair dealing, industrial espionage, gifts and payments, compliance with laws and reporting of violations of and accountability for adherence to the Code of Business Conduct and Ethics. The Code of Business Conduct and Ethics is filed as an exhibit to this report.

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Item 11. ***Executive Compensation***

Compensation Of Executive Officers

Summary Compensation Table

The following table provides certain summary information concerning the compensation received for services rendered to us during the fiscal years ended December 31, 2001, 2002 and 2003 by each of our Chief Executive Officer and our four other most highly compensated executive officers, collectively known as the Named Executive Officers, as of December 31, 2003.

		Annual Compensation		Long Term Compensation	
Name and Principal Position	Year	Salary	Bonus	Securities Underlying Options [4]	All Other Compensation
W. Mark Lortz					
Chief Executive Officer and President	2001	$ 265,465	$ 159,250(1)	350,000	$ 10,590(5)
	2002	$ 353,173	$ 43,750(2)	150,000	$ 16,000(5)
	2003	$ 368,172	$ 251,738(3)	27,750	$ 16,000(5)
Charles T. Liamos					
Chief Operating Officer and Chief	2001	$ 189,616	$ 75,000(1)	127,400	
Financial Officer	2002	$ 254,615	$ 20,000(2)	40,000	
	2003	$ 278,459	$ 162,616(3)	13,000	
Robert D. Brownell [6]	2001	$ 157,692	$ 50,000(1)	255,800	
Vice President, General Counsel and	2002	$ 223,538	$ 21,000(2)	10,000	
Secretary	2003	$ 251,412	$ 112,911(3)	15,000	
Timothy T. Goodnow, Ph.D.					
Vice President of Research and Development	2001	$ 201,924	$ 59,777(1)	43,800	$ 45,023(7)
	2002	$ 233,654	$ 15,000(2)	8,000	$ 59,982(7)
	2003	$ 245,883	$ 83,957(3)	14,000	$ 61,988(7)
Lawrence W. Huffman					
Vice President of International Business	2001	$ 194,924	$ 65,000(1)	50,000	
Development	2002	$ 225,149	$ 17,000(2)	10,000	
	2003	$ 241,007	$ 82,957(3)	10,500	

(1) Represents a bonus earned in 2001 but paid in 2002.

(2) Represents a bonus earned in 2002 but paid in 2003.

(3) Represents a bonus earned in 2003 but paid in 2004.

(4)

On January 5, 2004, our compensation committee granted the following options to purchase shares of our common stock to the Named Executive Officers: W. Mark Lortz, President, Chief Executive Officer and Chairman of the Board, was granted an option to purchase 100,269 shares; Charles T. Liamos, Chief Operating Officer and Chief Financial Officer, was granted an option to purchase 41,621 shares; Robert D. Brownell, Vice President, General Counsel and Secretary, was granted an option to purchase 40,307 shares; Timothy T. Goodnow, Ph.D., Vice President of Research and Development, was granted an option to purchase 28,390 shares; and Lawrence W. Huffman, Vice President of International Business Development, was granted an option to purchase 23,658 shares. Each option has an exercise price of $ 20.20 per share and vests at a rate 1/48 th per month over a four-year period, commencing January 1, 2004.

(5) Consists of life insurance premium payments by the Company on behalf of Mr. Lortz.

(6) Mr. Brownell s employment commenced in March 2001.

(7) Consists of housing assistance payments made to Mr. Goodnow.

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Option Grants in Last Fiscal Year

The following table provides summary information regarding stock options granted to the Named Executive Officers during the fiscal year ended December 31, 2003. The 5% and 10% assumed annual rates of compounded stock price appreciation are mandated by the rules of the SEC and do not reflect management s projections of future performance of our stock price. Actual gains, if any, on stock option exercises will be dependent on the future performance of the common stock.

	Individual Grants				Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation For Option Term [4]	
Name	Number of Securities Underlying Options Granted[1]	Percent of Total Options Granted to Employees in Fiscal Year [2]	Exercise Price Per Share [3]	Expiration Date	5%	10%
W. Mark Lortz	27,750	1.9%	$ 7.09	February 25, 2013	$ 123,765.00	$ 313,575.00
Charles T. Liamos	13,000	0.9%	$ 7.09	February 25, 2013	$ 57,980.00	$ 146,900.00
Robert D. Brownell	15,000	1.0%	$ 7.09	February 25, 2013	$ 66,900.00	$ 169,500.00
Timothy T. Goodnow, Ph.D.	14,000	1.0%	$ 7.09	February 25, 2013	$ 62,440.00	$ 158,200.00
Lawrence W. Huffman	10,500	0.7%	$ 7.09	February 25, 2013	$ 46,830.00	$ 118,500.00

(1) Options were granted under our 2001 Stock Plan. The shares vest over 48 months from the date of grant.

(2) Based on an aggregate of 1,440,027 options granted by us during the fiscal year ended December 31, 2003 to our employees, directors of and consultants, including the Named Executive Officers.

(3) The exercise price per share of each option was equal to the closing sales price of our common stock as reported on the Nasdaq National Market on the trading day immediately prior to the date of grant by the Board.

(4) The potential realizable value is calculated based on the term of the option at its time of grant (ten years). It is calculated assuming that the fair market value of the common stock on the date of grant appreciates at the indicated annual rate compounded annually for the entire term of the option and that the option is exercised and sold on the last day of its term for the appreciated stock price.

Aggregated Option Exercises in Last Fiscal Year and Fiscal Year-End Option Values

The following table provides summary information concerning stock option exercises by the Named Executive Officers and the shares of common stock represented by outstanding stock options held by each of the Named Executive Officers as of December 31, 2003. The value of unexercised in-the-money options is calculated based on the difference between the exercise price of the option and $20.18, the fair market value of the common stock at December 31, 2003.

The option information presented in the table below assumes we will continue to operate as a stand-alone company and that the merger with Abbott Laboratories will not be completed. In the event the merger with Abbott Laboratories is consummated, then pursuant to the terms of the January 12, 2004 merger agreement by and among Abbott, Corvette Acquisition Corp. and us and our stock option agreements, all of our directors, executive officers, employees and consultants will have their unvested stock options effectively accelerated and their vested and unvested options cashed out in connection with the merger, meaning that they will receive cash payments for each share underlying their options equal to the excess of $27.00 per share over the exercise price per share of their options. Since the exercise price for all of the options set forth below is less than $27.00 per share, all of these options would be in-the-money.

Name	Shares Acquired On Exercise	Value Realized [1]	Number of Securities Underlying Unexercised Options at Fiscal Year-End		Value of Unexercised In-the-Money Options at Fiscal Year-End	
			Exercisable	Unexercisable	Exercisable	Unexercisable
W. Mark Lortz			765,212	287,538	$ 9,952,540.03[2]	$ 2,050,207.47[2]
Charles T. Liamos			185,024	105,876	$ 1,969,187.87[3]	$ 634,604.13[3]
Robert D. Brownell	50,000	$ 413,741.00	47,236	104,397	$ 403,175.15[4]	$ 1,212,347.28[4]
Timothy T. Goodnow, Ph.D.	18,000	$ 189,113.00	152,258	75,542	$ 2,062,801.72[5]	$ 901,602.28[5]
Lawrence W. Huffman			131,406	73,049	$ 1,692,014.54[6]	$ 814,950.46[6]

(1) Based upon the market price of the purchased shares on the exercise date less the option exercise price paid for such shares.

(2) Excludes (i) 75,000 exercisable stock options with an exercise price of $20.49 per share, (ii) 75,000 unexercisable stock options with an exercise price of $20.49 per share, (iii) 50,000 exercisable stock options with an exercise price of $23.80 per share and (iv) 50,000 unexercisable stock options with an exercise price of $23.80 per share.

(3) Excludes (i) 10,000 exercisable stock options with an exercise price of $20.49 per share, (ii) 10,000 unexercisable stock options with an exercise price of $20.49 per share, (iii) 45,833 exercisable stock options with an exercise price of $23.80 per share and (iv) 44,167 unexercisable stock options with an exercise price of $23.80 per share.

(4) Excludes (i) 5,000 exercisable stock options with an exercise price of $20.49 per share, (ii) 5,000 unexercisable stock options with an exercise price of $20.49 per share, (iii) 12,500 exercisable stock options with an exercise price of $23.80 per share and (iv) 12,500 unexercisable stock options with an exercise price of $23.80 per share.

(5) Excludes (i) 4,000 exercisable stock options with an exercise price of $20.49 per share, (ii) 4,000 unexercisable stock options with an exercise price of $20.49 per share, (iii) 7,500 exercisable stock options with an exercise price of $23.80 per share and (iv) 7,500 unexercisable stock options with an exercise price of $23.80 per share.

(6) Excludes (i) 5,000 exercisable stock options with an exercise price of $20.49 per share, (ii) 5,000 unexercisable stock options with an exercise price of $20.49 per share, (iii) 10,000 exercisable stock options with an exercise price of $23.80 per share and (iv) 10,000 unexercisable stock options with an exercise price of $23.80 per share.

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Change of Control and Severance Agreements

We have change of control severance agreements with each of our executive officers.

W. Mark Lortz, our Chairman, President and Chief Executive Officer, is entitled to the following severance benefits under his change of control and severance agreement:

- 75% of Mr. Lortz s unvested stock options will vest and become exercisable upon the Change of Control Effective Date, provided his employment is not terminated for Cause or his employment is not voluntary terminated subsequent to the Change of Control and prior to the Change of Control Effective Date;

- in the event of an Involuntary Termination between the Change of Control and the date 12 months after the Change of Control Effective Date, all of Mr. Lortz s unvested stock options will immediately vest and become exercisable;

- in the event of an Involuntary Termination between the Change of Control and the date 12 months after the Change of Control Effective Date, a lump sum severance payment of 200% of Mr. Lortz s then-current base salary and a lump sum payment equal to the cost of 24 months health care coverage after payment of any applicable taxes;

- in the event of a termination without Cause at any time other than the period between the Change of Control and the date 12 months after the Change of Control Effective Date, a lump sum severance payment of 150% of Mr. Lortz s then-current annual base salary and a lump sum payment equal to the cost of 18 months health care coverage after payment of any applicable taxes; and

- in the event that any compensation to Mr. Lortz is deemed to be an excess parachute payment and is therefore subject to the excise tax imposed by Section 4999 of the Internal Revenue Code of 1986, which we refer to as the Code, a lump sum gross-up payment in an amount such that Mr. Lortz s after-tax compensation is equal to what it would have been had no such excise tax been imposed.

Under both Mr. Lortz s change of control severance agreement and those of our other executive officers, the following terms have the following meanings:

Change of Control means the occurrence of any of the following events: (i) the signing of an agreement by us and another entity relating to a merger or consolidation of us with the other entity, other than a merger or consolidation which would result in our voting securities outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) more than fifty percent (50%) of the total voting power represented by our voting securities or such surviving entity outstanding immediately after such merger or consolidation; (ii) the approval by our stockholders of a plan of complete liquidation of us or the signing of an agreement by us and another entity relating to the sale or disposition by us of all or substantially all of our assets to the other entity; (iii) any person (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended) becoming the beneficial owner (as defined in Rule 13d-3 under said Act), directly or indirectly, of our securities representing 50% or more of the total voting power represented by our then outstanding voting securities; or (iv) a change in the composition of our Board, as a result of which fewer than a majority of the directors are Incumbent Directors. Incumbent Directors shall mean directors who either (A) are our directors of as of the date the executive signed the change of control agreement, or (B) are elected, or nominated for election, to the Board with the affirmative votes of at least a majority of those directors whose election or nomination was not in connection with any transactions described in subsections (i), (ii), or (iii) or in connection with an actual or threatened proxy contest relating to the election of directors of the company.

Change of Control Effective Date means the effective date of the Change of Control described in items (iii) and (iv) of the above paragraph and the effective date of the Change of Control approved by stockholders described in items (i) and (ii) of the above paragraph.

Involuntary Termination means (i) without the employee s written consent, a significant reduction of the employee s duties, position or responsibilities relative to the employee s duties, position or responsibilities in effect immediately prior to such reduction, or the removal of the employee from such position, duties and responsibilities; provided,

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however, that a reduction in duties, position or responsibilities solely by virtue of our being acquired and made part of a larger entity (as, for example, when our Chief Financial Officer remains as such following a change of control but is not made the Chief Financial Officer of the acquiring corporation) shall not constitute an involuntary termination , (ii) without the employee s written consent, a substantial reduction, without good business reasons, of the facilities and perquisites (including office space and location) available to the employee immediately prior to such reduction, (iii) without the employee s express written consent, a reduction by us of the employee s base salary as in effect immediately prior to such reduction, (iv) without the employee s express written consent, a material reduction by us in the kind or level of employee benefits (including cash and stock bonus plans) to which the employee is entitled immediately prior to such reduction with the result that the employee s overall benefits package is significantly reduced, (v) without the employee s express written consent, the relocation of the employee to a facility or a location that increases the employee s one-way commute from the employee s residence at the time of the change of control by more than 30 miles, (vi) any purported termination of the employee by us that is not effected for cause, or (vii) our failure to obtain the assumption of the employee s change of control severance agreement by any successors.

Cause means (i) any act of personal dishonesty taken by the employee in connection with his responsibilities as an employee that is intended to result in substantial personal enrichment of the employee, (ii) the employee s conviction of a felony that our board of directors reasonably believes has had or will have a material detrimental effect on our reputation or business, (iii) a willful act by the employee that constitutes misconduct and is injurious to us, or (iv) continued willful violations by the employee of the employee s obligations to us after there has been delivered to the employee a written demand for performance from us that describes the basis for our belief that the employee has not substantially performed his duties.

Charles T. Liamos, our Chief Operating Officer and Chief Financial Officer, is entitled to the following severance benefits under his change of control and severance agreement:

- 75% of Mr. Liamos unvested stock options will vest and become exercisable upon the Change of Control Effective Date, provided his employment is not terminated for Cause or his employment is not voluntarily terminated subsequent to the Change of Control and prior to the Change of Control Effective Date;

- in the event of an Involuntary Termination between the Change of Control and the date 12 months after the Change of Control Effective Date, all of Mr. Liamos unvested stock options will immediately vest and become exercisable;

- in the event of an Involuntary Termination between the Change of Control and the date 12 months after the Change of Control Effective Date, a lump sum severance payment of 150% of Mr. Liamos then-current base salary and a lump sum payment equal to the cost of 18 months health care coverage after payment of any applicable taxes;

- in the event of a termination without Cause at any time other than the period between the Change of Control and the date 12 months after the Change of Control Effective Date, a lump sum severance payment of 100% of Mr. Liamos then-current annual base salary and a lump sum payment equal to the cost of 12 months health care coverage after payment of any applicable taxes; and

- in the event that any compensation to Mr. Liamos is deemed to be an excess parachute payment and is therefore subject to the excise tax imposed by Section 4999 of the Code, a lump sum gross-up payment in an amount such that Mr. Liamos after-tax compensation is equal to what it would have been had no such excise tax been imposed.

All of the Company s vice presidents are entitled to the following severance benefits under their respective change of control severance agreements:

75% of such employee s unvested stock options will vest and become exercisable upon the Change of Control Effective Date, provided his or her employment is not terminated for Cause or his/her employment is not voluntarily terminated subsequent to the Change of Control and prior to the Change of Control Effective Date;

in the event of an Involuntary Termination between the Change of Control and the date 12 months after the Change of Control Effective Date, all of such employee s unvested stock options will immediately vest and become exercisable;

in the event of an Involuntary Termination between the Change of Control and the date 12 months after the Change of Control Effective Date, a lump sum severance payment of 100% of such employee s then-current base salary and a lump sum payment equal to the cost of 12 months health care coverage after payment of any applicable taxes; and

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in the event that any compensation to such employee is deemed to be an excess parachute payment and is therefore subject to the excise tax imposed by Section 4999 of the Code, the Company must either pay such compensation in full or reduce it to an amount at which none of it would be subject to such excise tax, whichever results in greater after-tax compensation to the employee.

On January 12, 2004, we entered into an agreement and plan of merger with Abbott Laboratories and Corvette Acquisition Corp., a Delaware corporation and a wholly-owned subsidiary of Abbott, providing for the merger of Corvette Acquisition Corp., with and into TheraSense, with TheraSense continuing as the surviving corporation. Pursuant to the merger agreement, Abbott will assume our obligations under all of these these change of control severance agreements if the merger is completed. If the merger is consummated, certain provisions of these change of control severance agreements will be triggered. As described above, each of the change of control severance agreements, including those of Mr. Lortz and Mr. Liamos, provides for varying degrees of accelerated vesting of unvested options upon the effective date of the merger. However, because the merger agreement provides that all vested and unvested stock options will be accelerated and cashed out on the effective date of the merger, these provisions of the change of control severance agreements will be of no effect if the merger is completed.

Compensation of Directors

Non-employee directors are reimbursed for their expenses incurred in connection with attending Board and committee meetings. Beginning in 2003, each non-employee director received $30,000 per year payable quarterly and each non-employee director who is a committee chairman receives an additional $5,000 per year payable quarterly.

The Board has discretion to grant options to non-employee directors from time to time under our 2001 Stock Plan, but the Board has never exercised that right. Each non-employee director who joins the Board receives a non-discretionary, automatic grant of options to purchase 30,000 shares of our common stock upon joining the Board. In addition, each of our non-employee directors receives yearly non-discretionary automatic grants of options to purchase 5,000 shares of our common stock, pursuant to our 2001 Stock Plan.

Compensation Committee Report On Executive Compensation

The compensation committee of the Board currently consists of Dr. Jaffe (Chairman) and Mr. Momsen, both of whom are independent as that term is defined in the Nasdaq listing standards and Section 301 of the Sarbanes Oxley Act of 2002. The compensation committee reviews and recommends to the Board the compensation and benefits of all of our executive officers and Board members and establishes and reviews general policies relating to compensation and benefits of our employees. The following is the report of the compensation committee describing compensation policies and reasons therefore applicable to our executive officers with respect to the compensation paid to such executive officers for the fiscal year ended December 31, 2003. The information contained in this report shall not be deemed to be soliciting material or to be filed with the Securities and Exchange Commission, nor shall such information be incorporated by reference into any future filing under the Securities Act of 1933, as amended, or the 1934 Securities Exchange Act, as amended, except to the extent that we specifically incorporate such information by reference in such filing.

Compensation Philosophy and Review

Our executive compensation program is designed to align the interests of executives with the interests of stockholders and to reward executives for achieving corporate and individual objectives. The executive compensation program is also designed to attract and retain the services of qualified executives in the highly competitive medical device industry. Executive compensation currently consists of a base salary, long-term

equity incentives, annual incentive plans and other compensation and benefit programs generally available to other employees.

The compensation committee has considered the potential impact of Section 162(m) of the Internal Revenue Code on the compensation paid to our executive officers. Section 162(m) disallows a tax deduction for any publicly-held corporation for individual compensation exceeding $1.0 million in any taxable year for any of the executive officers, unless compensation is performance-based. In general, it is the compensation committee s policy to qualify, to the maximum extent possible, its executives compensation for deductibility under applicable tax laws.

Base Salaries

Base salary levels for the Chief Executive Officer and other executive officers are intended to compensate executives competitively within the medical device industry. Base salaries are determined on an individual basis by evaluating each executive s scope of responsibility, past performance, prior experience and data on prevailing compensation levels in relevant markets for executive talent. The compensation committee reviews base salaries for executives annually.

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Long-Term Equity Incentives

We provide long-term equity incentives to our executive officers and to all other employees through the grant of stock options under our stock option plans. The purpose of granting stock options is to create a direct link between compensation and our long-term performance. Stock options are generally granted at an exercise price equal to 100% of the fair market on the date of grant and have a ten-year term provided that the optionee is still employed by us. For the initial stock option grant to an executive officer, the stock option generally vests 25% after the first year of employment with us and monthly thereafter for the following 36 months. For subsequent stock option grants to an executive officer, the stock option generally vests in installments over 48 months from the date of grant. Because the receipt of value by an executive officer under a stock option is dependent upon an increase in the price of our Common Stock, this portion of the executives compensation is directly aligned with an increase in stockholder value. The primary stock options granted to executive officers are generally in conjunction with the executive officer s acceptance of employment with us. When determining the number of stock options to be awarded to an executive officer, the compensation committee considers the executive s current contribution to our performance, the executive officer s anticipated contribution in meeting our long-term strategic performance goals, and comparisons to formal and informal surveys of executive stock option grants made by other medical device and technology companies. The compensation committee also reviews stock option levels upon the promotion of employees to the executive officer level.

Annual Incentive Plans

We provide for annual cash bonuses and annual grants of long term equity incentives. These annual incentives are available to executive officers and all other employees, and are intended to provide a direct link between employee compensation and the achievement of corporate and individual objectives. An additional objective of the annual incentives is to make significant distinctions between our top performers and others. Each individual s target bonus for cash and stock is based on a percentage of base salary and initial stock option grant, respectively. At the beginning of each year we set certain corporate goals including financial performance goals. In addition, each employee has individual goals to support the achievement of the corporate goals. At the end of the year, our performance against the corporate goals is assessed and this determines the total available cash and stock option pools, if any. Individual bonuses from these two pools are determined based on the achievement of individual goals and any additional contributions toward achieving the corporate goals. Assuming we meet our objectives: top performers can receive amounts in excess of their target bonus; average performers may receive less than their target bonus; and some employees may not receive a bonus. At the end of 2003 the compensation committee assessed our performance against our goals for the year and recommended to the full Board the distribution of 65% of the targeted cash and stock option pools. The Board authorized this distribution and in January 2004 the Chief Executive Officer was granted a 100,269 share stock option and a $251,738 cash bonus. The other Named Executive Officers received cash bonuses in the total amount of $442,441 and stock options exercisable for a total of 133,976 shares. These options vest monthly over 48 months from January 1, 2004. In the event the merger with Abbott Laboratories is consummated pursuant to the terms of the January 12, 2004 merger agreement by and among Abbott, Corvette Acquisition Corp. and us, all of these stock options shall terminate immediately prior to the closing of the merger, and the Named Executive Officers shall be entitled to receive the excess of (A) $27.00 over (B) $20.20, the exercise price per share for all of these options.

Other Compensation

Our executive officers are also eligible to participate in compensation and benefit programs generally available to other employees, including our Employee Stock Purchase Plan. Mr. Lortz has a life insurance policy, the beneficiary of which is of his

choosing. We pay Mr. Lortz s life insurance premium on his behalf. In addition, from time to time, executive officers have received sign-on bonuses or other bonuses based on extraordinary effort.

Compensation for Chief Executive Officer

W. Mark Lortz is President, Chief Executive Officer and Chairman of the Board. The compensation committee reviews Mr. Lortz s compensation annually using the same criteria and policies as are employed for other executive officers. Mr. Lortz received an increase in base salary from $353,173 for 2002 to $368,172 for 2003. The compensation committee based this increase on a variety of factors including his contributions in leading us to our achievements in 2002. In January 2004 Mr. Lortz received an increase in base salary to $395,000 for 2004 in recognition of our continued strong performance under his leadership. As described above, Mr. Lortz received a cash bonus of $251,738 and a stock option for 100,269 shares, in recognition of his contributions in leading us to our achievements in the 2003 fiscal year, including significant increase in revenues, four quarters of positive cash flow from operations, greater predictability of financial results, filing the premarket approval application for the FreeStyle Navigator continuous glucose monitoring system and launching the FreeStyle Flash blood glucose monitoring system.

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SUBMITTED BY THE COMPENSATION COMMITTEE OF THE BOARD OF DIRECTORS:

Ross A. Jaffe, M.D.

Robert R. Momsen

Compensation Committee Interlocks and Insider Participation

No member of the Board or the compensation committee serves as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of the Board or compensation committee.

Stock Performance Graph

The following graph shows a comparison of cumulative total stockholder returns for our common stock, the Nasdaq Stock Market Index for U.S. Companies, and the Standard and Poor s Mid Cap 400 Health Care Index. The graph assumes the investment of $100 on October 12, 2001, the date of our initial public offering. The data regarding us assumes an investment at the initial public offering price of $19.00 per share of our common stock. The performance shown is not necessarily indicative of future performance. The information contained in the following graph shall not be deemed to be soliciting material or to be filed with the Securities and Exchange Commission, nor shall such information be incorporated by reference into any future filing under the Securities Act of 1933, as amended, or the 1934 Securities Exchange Act, as amended, except to the extent that we specifically incorporate such information by reference in such filing.

COMPARISON OF 26 MONTH CUMULATIVE TOTAL RETURN*

AMONG THERASENSE, INC., THE NASDAQ STOCK MARKET (U.S.) INDEX

AND THE S & P MIDCAP HEALTHCARE INDEX

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Item 12. ***Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters***

Security Ownership By Certain Beneficial Owners and Management

The following table sets forth information regarding the beneficial ownership of our common stock as of March 1, 2004 by:

- each person who is known to us to own beneficially more than 5% of our common stock;
- each of our directors and executive officers; and
- all directors and executive officers as a group.

Percentage of beneficial ownership is based on 42,566,797 shares of common stock outstanding as of March 1, 2004.

Except as otherwise noted, the address of each person listed in the table is c/o TheraSense, Inc., 1360 South Loop Road, Alameda, California 94502, and, unless otherwise indicated in the footnotes below, the persons named in the table have sole voting and investment power with respect to all shares of common stock shown as beneficially owned by them, subject to community property laws where applicable.

	Shares Beneficially Owned			
Name and Address of Beneficial Owner	No. of Shares [1]	No. of Options [1]	Percent	Additional Shares Underlying Unvested Options [2]
Five Percent Stockholders				
Abbott Laboratories [3]	6,256,163	1,689,967	17.95%	
InterWest Partners [4]	4,957,381		11.65%	
Delphi Ventures [5]	3,302,941		7.76%	
Wellington Management Company, LLP [6]	3,241,100		7.61%	
Directors and Named Executive Officers				
W. Mark Lortz [3][7]	509,339	847,809	3.13%	305,210
Charles T. Liamos [3]	81,700	210,189	*	122,332
Arthur A. Autorino [8]	1,587	96,218	*	159,185
Robert D. Brownell [3]	26,768	74,296	*	117,644
Eve A. Conner, Ph.D. [3]	5,853	67,682	*	57,278
Timothy T. Goodnow, Ph.D. [3]	6,745	178,091	*	76,099
Shawna Gvazdauskas		99,770	*	160,745
James Hey	2,000		*	150,000
Lawrence W. Huffman [3][9]	443	151,900	*	76,258
Holly D. Kulp	3,247	65,459	*	54,401

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Nelson O. Lam		38,501		130,979
Carl Silverman				150,000
Mark C. Tatro	3,511	128,514	*	91,089
Jerry Tu			*	150,000
Nan T. Watanabe	5,218	126,353	*	140,677
Bradford A. Bowlus				30,000
Ross A. Jaffe, M.D. [3][10]	404,379	35,000	1.03%	5,000
Jonathan T. Lord, M.D.		35,000	*	30,000
Robert R. Momsen [3][11]	3,466,550	35,000	8.22%	5,000
Richard P. Thompson [3]	31,200	35,000	*	5,000
Rod F. Dammeyer [3][12]	205,150	20,000	*	15,000
All directors, director nominees and all executive officers as a group (21 people)	4,755,690	2,209,782	15.56%	2,031,897

* Less than one percent.

(1) This table is based on information supplied by our directors, all executive officers and principal stockholders and on any Schedules 13D or 13G filed with the Securities and Exchange Commission. Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of common stock subject to options or warrants held by that person that are currently exercisable or will become exercisable within 60 days after March 1, 2004 are deemed outstanding, while such shares are not deemed outstanding for purposes of computing percentage ownership of any other person.

(2) The column labeled Additional Shares Underlying Unvested Options represents shares of common stock subject to options or warrants that are not currently exercisable and that would not become exercisable within 60 days after March 1, 2004 except in connection with the merger between Abbott Laboratories and us pursuant to the terms of the January 12, 2004 merger agreement by and among Abbott, Corvette Acquisition Corp. and us. Under the terms of the merger agreement and our stock option agreements, our directors, executive officers, employees and consultants will have their unvested stock options effectively accelerated and their vested and unvested options cashed out in connection with the merger, meaning that they will receive cash payments for each share underlying their options equal to the excess of $27.00 per share over the exercise price per share of their options. Accordingly, the column labeled additional shares underlying unvested options is intended to represent shares underlying options that are not represented elsewhere in the above table and for which our directors, executive officers or principal stockholders will receive consideration pursuant to the merger agreement.

(3) Each of these company securities indicated as beneficially owned Abbott Laboratories or Corvette Acquisition Corp. is also indicated as being beneficially owned in the table above by InterWest Partners or one or more of our directors or executive officers. On January 12, 2004, we entered into an Agreement and Plan of Merger with Abbott Laboratories and Corvette Acquisition Corp., a Delaware corporation and a wholly-owned subsidiary of Abbott, providing for the merger of Corvette Acquisition Corp., with and into TheraSense, with TheraSense continuing as the surviving corporation. As a condition to its entering into the merger agreement, Abbott required that such stockholders enter into a stockholder agreement under which they have agreed to vote all of our securities they beneficially own in favor of approval and adoption of the merger agreement and related matters, and against any competing transaction or proposal or any proposal or transaction that could reasonably be expected to prevent or impede the completion of the merger. The following company securities held by the parties to the stockholder agreement are subject to the restrictions set forth in the stockholder agreement: (i) an aggregate 6,256,163 shares of our common stock; and (ii) an aggregate of 1,689,967 options to purchase shares of our common stock. Abbott Laboratories or Corvette Acquisition Corp. may be deemed to have beneficial ownership of these company securities. Neither Abbott Laboratories nor Corvette Acquisition Corp. admits that it is the beneficial owner of any of the company securities referred to herein for purposes of Section 13(d) of the Securities Exchange Act of 1934, as amended, or for any other purpose, and such beneficial ownership is expressly disclaimed. Abbott s address is 100 Abbott Park Road, Abbott Park, IL 60064-6049.

(4) The InterWest Partners shares include 100,306 shares held by InterWest Partners V, L.P., 3,237,103 shares held by InterWest Partners VI, L.P., 1,449,082 shares purchased by InterWest Partners VII, L.P., 101,494 shares held by InterWest Investors VI, L.P., and 69,396 shares purchased by InterWest Investors VII, L.P. InterWest Partners VII, L.P. and InterWest Investors VII, L.P. are managed by InterWest Management Partners VII, LLC. InterWest Management Partners VII, LLC has sole voting and investment control over shares owned by InterWest Partners VII and InterWest Investors VII. The Managing Directors of InterWest Management Partners VII, LLC are Harvey B. Cash, Alan W. Crites, Philip T. Gianos, W. Scott Hedrick, W. Stephen Holmes, Gilbert H. Kliman, Thomas L. Rosch and Arnold L.

Oronsky. Stephen C. Bowsher is a Venture Member. Managing Directors and Venture Members share voting and investment control. InterWest Management Partners VI, LLC has sole voting and investment control over the shares held by InterWest Partners VI, L.P. and InterWest Investors VI, L.P Managing Directors are Harvey B. Cash, Philip T.Gianos, W. Scott Hedrick, W. Stephen Holmes, Robert R. Momsen (one of the Company s directors) and Arnold L. Oronsky.

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The sole Venture Member is Gilbert H. Kliman. Managing Directors and Venture Members share voting and investment control. The address of InterWest Partners is 2710 Sand Hill Road, Second Floor, Menlo Park, CA 94025.

(5) The Delphi Ventures shares include 2,389,336 shares purchased by Delphi Ventures III, L.P., 853,002 shares purchased by Delphi Ventures IV, L.P., 43,017 shares purchased by Delphi BioInvestments III, L.P. and 17,586 shares purchased by Delphi BioInvestments IV, L.P. The managing members of Delphi Management Partners III, L.L.C., which is the general partner of Delphi Ventures III, L.P. and Delphi BioInvestments III, L.P., disclaim beneficial ownership except to the extent of their pecuniary interest therein. The managing members of Delphi Management Partners III, L.P., all of whom share voting and disparities power over these shares, are James J. Bochnowski, David L. Douglass and Donald J. Lothrop. The managing members of Delphi Management Partners IV, L.L.C., which is the general partner of Delphi Ventures IV, L.P. and Delphi BioInvestments IV, L.P., disclaim beneficial ownership except to the extent of their pecuniary interest therein. The managing members of Delphi Management Partners IV, L.P., all of whom share voting and dispositive power over these shares, are James J. Bochnowski, David L. Douglass and Donald J. Lothrop. The address of Delphi Ventures is 3000 Sand Hill Road, Building, Suite 135, Menlo Park, California 94025.

(6) Wellington Management Company, LLP s address is 7 State Street, Boston, MA 02109.

(7) Includes 502,490 shares held by the W. Mark Lortz And Patrice Rae Lortz, Co-Trustees or Successor Trustee, of the W. Mark Lortz and Patrice Rae Lortz Revocable Living Trust, under Agreement Dated February 10, 1999, as community property.

(8) Consists of shares held by Arthur Autorino c/f Jennifer Autorino UTMA/TN. Mr. Autorino disclaims beneficial ownership of these shares except to the extent of his pecuniary interest therein.

(9) Includes 442 shares held by Patricia Lagakos Huffman, Lawrence Huffman s wife.

(10) Includes 400,000 shares held by Brentwood Associates VIII, L.P. Dr. Jaffe is a managing member of Brentwood VIII Ventures, LLC, the general partner of Brentwood Associates VIII, L.P. Dr. Jaffe disclaims beneficial ownership of these shares except to the extent of his pecuniary interest therein.

(11) Includes shares purchased by InterWest Partners, as follows: 100,306 shares held by InterWest Partners V, L.P., 3,237,103 shares held by InterWest Partners VI, L.P., and 101,494 shares held by InterWest Investors VI, L.P. Mr. Momsent is a general partner of InterWest Partners V, L.P., InterWest Partners VI, L.P. and InterWest Investors VI, L.P., and a limited partner of InterWest Investors VI, L.P. Mr. Momsen disclaims beneficial ownership of these shares except to the extent of his pecuniary interest therein.

(12) Includes 102,575 shares purchased by the DRD Family Partnership, L.P. Mr. Dammeyer is the general partner of the DRD Family Partnership, L.P. Mr. Dammeyer disclaims beneficial ownership of these shares except to the extent of his pecuniary interest therein.

Securities Authorized For Issuance Under Equity Compensation Plans

The following table sets forth certain information about our equity compensation plans as of December 31, 2003 that have been approved by our stockholders. We do not have any equity compensation plans that have not been approved by our stockholders.

Equity Compensation Plan Information

Plan category	Number of securities to be issued upon exercise of outstanding options (a)	Weighted-average exercise price of outstanding options (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
1997 Stock Plan	3,461,219	$ 5.45	
2001 Stock Plan	4,170,512	$ 15.96	5,415,605
Total	7,631,731	$ 11.19	5,415,605

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Item 13. ***Certain Relationships and Related Transactions***

Loans to Directors and Executive Officers

In December 1997 and March 1999, we loaned an aggregate of $135,145 to W. Mark Lortz, our President, Chief Executive Officer and Chairman of the Board, in connection with his purchase of an aggregate of 592,490 shares of our restricted common stock. The loans were made pursuant to two full-recourse promissory notes in the amounts of $62,650 and $72,495. The notes do not bear interest and are secured by the shares of common stock purchased. Mr. Lortz has paid off both notes.

In July 1998, March 1999 and September 1999, we loaned an aggregate of $93,938 to Charles T. Liamos, our Chief Operating Officer and Chief Financial Officer, in connection with the purchase of an aggregate of 180,375 shares of our restricted common stock. The loans were made pursuant to three full-recourse promissory notes in the amounts of $17,500, $15,188 and $61,250. The notes do not bear interest and are secured by the shares of common stock purchased. Mr. Liamos has paid off all three notes.

Agreement with Flextronics

In November 1999, we entered into an agreement with Flextronics International related to the manufacturing of our FreeStyle meters. Flextronics is exclusively responsible for building the FreeStyle meters and assembling the FreeStyle system kits. Our contract with Flextronics expires in November 2005, and is renewable annually thereafter. This agreement may be terminated by either party upon one year s prior written notice. In 2003, the Company purchased approximately $40.7 million under this agreement. In addition, approximately $2.7 million is included in accounts payable as of December 31, 2003, and approximately $1.8 million is included in accrued liabilities as of December 31, 2003, relating to this agreement. In March 2004, we paid $1.0 million to Flextronics as full and final payment for all accrued liabilities owed to Flextronics. As of December 31, 2003, Flextronics owed the Company $14,000 for raw materials purchased. Michael McNamara, a member of the Board until June 2003, is President of Americas Operations of Flextronics.

Agreement with Creative Press International

Creative Press International is one of our commercial printing vendors. It provides commercial printing services directly to us and to Flextronics for our benefit. We paid approximately $27,400 to Creative Press International in 2003. We did not transact any business with Creative Press prior to 2003. In 2003, Flextronics purchased approximately $101,000 in products and services from Creative Press International. Rod F. Dammeyer, a member of our Board of Directors and Chairman of the Audit Committee, is a principal stockholder of Creative Press International.

Indemnification Agreements of Officers and Directors

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

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Item 14. ***Principal Accountant Fees and Services***

Principal Accountant Fees and Services

The following is a summary of the fees billed to us by PricewaterhouseCoopers LLP, our independent accountants, for professional services rendered for the fiscal years ended December 31, 2003 and December 31, 2002:

Fee Category	2003 Fees	2002 Fees
Audit Fees	$ 195,400	$ 174,200
Audit-Related Fees	47,735	
Tax Fees	44,296	100,526
All Other Fees	11,908	
Total Fees	$ 299,339	$ 274,762

Audit Fees consists of fees billed for professional services rendered for the audit of our financial statements, review of the interim financial statements included in quarterly reports, review of SEC filings, and consultation on accounting matters.

Audit-Related Fees consists of fees billed for assurance and related services that are reasonably related to the performance of the audit or review of our financial statements and are not reported under Audit Fees. These services consist of consultations related to our proposed merger with Abbott Laboratories.

Tax Fees consists of fees billed for professional services for tax compliance, tax advice and tax planning.

All Other Fees consists of all other non-audit services. These services include consultations regarding the Sarbanes-Oxley Act and licensing fees paid to our independent auditors for software we licensed to facilitate our compliance with certain provisions of the Sarbanes-Oxley Act.

Policy on Audit Committee Pre-Approval of Audit Services and Permissible Non-Audit Services of Independent Auditors

Pursuant to our audit committee charter, the audit committee pre-approves all audit and permissible non-audit services performed by the independent auditors. These services may include audit services, audit-related services, tax services and other services. For audit services, the independent auditor provides the audit committee with an audit plan including proposed fees in advance of the annual audit. The audit committee approves the plan and fees for the audit.

For non-audit services, our senior management will submit from time to time to the audit committee for approval non-audit services that it recommends the audit committee engage the independent auditor. The audit committee must approve permissible non-audit services. Our senior

management and the independent auditor will each confirm to the audit committee that each non-audit service is permissible under all applicable legal requirements. In addition, a budget for the non-audit services will be provided to the audit committee along with the request.

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PART IV

Item 15. ***Exhibits, Financial Statement Schedules and Reports on Form 8-K***

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

(1) **Consolidated Financial Statements**

(2) **Financial Statement Schedules**

The following financial statement schedule of TheraSense for the years ended December 31, 2001, 2002 and 2003 is filed as part of this Annual Report and should be read in conjunction with the financial statements of TheraSense:

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

(3) **Exhibits**

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

*10.5	Technology Purchase Agreement between TheraSense and E. Heller & Co. dated as of October 10, 2000
*10.6	Cooperative Development Agreement between TheraSense, Inc. and Facet Technologies LLC (f/k/a Gainor Medical North America LLC), dated as of December 1, 1998
*10.6(a)	First Amendment to Cooperative Development Agreement between TheraSense, Inc. and Facet Technologies LLC (f/k/a Gainor Medical North America LLC), effective June 1, 2001
*10.6(b)	Master Purchase Agreement between TheraSense, Inc. and Facet Technologies LLC effective June 1, 2001
*10.7	Standard Industrial/Commercial Single-Tenant Lease between TheraSense, Inc. and PlyProperties, a Partnership, dated as of February 26, 1999, and addendum thereto
***10.7(a)	Second Amendment to Standard Industrial/Commercial Single-Tenant Lease between TheraSense, Inc. and PlyProperties, a Partnership dated May 7, 2002
*10.8	Master Purchase Agreement between TheraSense and Flextronics International USA, Inc., dated as of November 3, 1999
*10.9	Assignment of Patent Rights and Technology by and among Board of Regents of the University of Texas System, an agency of the State of Texas, Dr. Adam Heller, E. Heller & Company and TheraSense Inc. dated August 1, 1991

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Exhibit Number	Description of Document
*10.10	First Amendment, dated March 19, 1998, to the Agreement entitled Assignment of Patent Rights and Technology by and among Board of Regents of the University of Texas System, an agency of the State of Texas, Dr. Adam Heller, E. Heller & Company and TheraSense Inc. dated August 1, 1991
*10.11	License Agreement between TheraSense, Inc. and Asulab SA., dated February 23, 2000
*10.12	Warehouse Distribution Contract between TheraSense, Inc. and Livingston Healthcare Service, Inc., dated March 15, 2000
****10.12(a)	October 23, 2002 amendment to Warehouse Distribution Contract between TheraSense, Inc. and UPS Supply Chain Management f/d/b/a Livingston Healthcare Service, Inc., dated March 15, 2000
*10.13	International Distributor Agreement between TheraSense, Inc. and Nipro Corporation, dated April 1, 2001
*10.14	International Distributor Agreement between TheraSense, Inc. and Disetronic Handels AG, dated September 13, 2000
**10.14(a)	Amendment No. 1 to International Distributor Agreement between TheraSense, Inc. and Disetronic Handels AG, dated February 8, 2002
*#10.14(b)	Amendment No. 2 to International Distributor Agreement between TheraSense, Inc. and Disetronic Handels AG, dated January 1, 2003
*10.15	Management Services Agreement between TheraSense, Inc. and ICT Group, Inc., dated January 31, 2000
*10.16	License Agreement between TheraSense, Inc. and Unilever PLC dated February 10, 2000
*10.17	Amended and Restated Investors Rights Agreement by and among holders of TheraSense Preferred Stock and TheraSense, Inc., dated January 23, 2001, as amended
*10.18	First Amendment to the Agreement Entitled Sponsored Research Agreement No. UTA 98-0296 entered into as of October 10, 2000, by and between TheraSense, Inc. and the Board of Regents of the University of Texas System on behalf of the University of Texas at Austin
*##10.19	Form of Amended and Restated Change of Control Agreement between TheraSense, Inc. and W. Mark Lortz.
*##10.20	Form of Amended and Restated Change of Control Agreement between TheraSense, Inc. and Charles T. Liamos
*##10.21	Form of Amended and Restated Change of Control Agreement between TheraSense, Inc. and each Vice President of TheraSense, Inc.
*****10.22	Rights Agreement dated as of March 7, 2003 between TheraSense, Inc. and Computershare Investor Services, as Rights Agent, which includes the Form of Certificate of Designation of Series A Participating Cumulative Preferred Stock as Exhibit A, the Summary of Terms of the Rights Agreement as Exhibit B and the Form of Right Certificate s Exhibit C.
*###10.22(a)	Amendment to the Rights Agreement dated as of March 7, 2003, between TheraSense, Inc. and ComputerShare Investor Services, as Rights Agent.
*###10.23	Agreement and Plan of Merger dated as of January 12, 2004, among Abbott Laboratories, Corvette Acquisition Corp. and TheraSense, Inc.
*###10.24	Stockholder Agreement dated as of January 12, 2004, among Abbott Laboratories, Corvette Acquisition Corp. and the individuals and other parties listed on Schedule A thereto.
14	Code of Business Conduct and Ethics.
21.1	List of subsidiaries of TheraSense, Inc.
23.1	Consent of independent auditors
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.