SPECTRX INC
Form 10KSB
May 05, 2005

U.S. SEC

Washington, D.C. 20549

FORM 10-KSB

(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, 2004.**

[ ] 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:

0-22179

SPECTRX, INC.

(Name of small business issuer in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)

58-2029543
(I.R.S. Employer Identification No.)

4955 Avalon Ridge Parkway, Suite 300
Norcross, Georgia
(Address of principal executive offices)

30071

(Zip Code)

Issuer's telephone number: **(770) 242-8723**

Securities registered under Section 12(b) of the Exchange Act: **None**

Securities registered under Section 12(g) of the Exchange Act: **Common Stock, $0.001 par value**

(Title of class)

Check whether the issuer: (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 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 [ ]

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B contained in this form, and no disclosure will be contained, to the best of issuer's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB. [ ]

State issuer'

The aggregate market value of the voting stock held by non-affiliates of the registrant was approximately **$13.4 million** as of **June 30, 2004**, based upon the closing sales price of the registrant's Common Stock reported for such date by the OTC Bulletin Board.

As of **May 2, 2005**, the registrant had outstanding **11,557,437** shares of Common Stock.

DOCUMENTS INCORPORATED BY REFERENCE.

Parts of the following documents are incorporated by reference in Part III of this Form 10-KSB: Proxy Statement for Issuer's 2005 Annual Meeting of Stockholders - Items 9, 10, 11, 12, and 13.

PART I

ITEM 1. DESCRIPTION OF BUSINESS

OVERVIEW

We are a medical technology company, incorporated in 1992, focused on developing innovative medical devices that have the potential to improve health care. Currently, we are conducting research, development and marketing of products for the diabetes management market and developing a product for the non-invasive cancer diagnostics market. Prior to 2001, our technology was primarily based upon biophotonic technology, which we define as the use of light and other forms of energy to access the human body to diagnose and monitor disease. We added sterile disposable products and technology for insulin delivery to our technology base with the purchase of Sterling Medivations, Inc., now doing business as SimpleChoice, in December of 2001. Our technology, including products in research and development, includes: a) innovative methods of delivering insulin to people with diabetes with our SimpleChoice product line, b) innovative methods of sampling interstitial fluid using laser energy to create micropores for improved glucose and alcohol monitoring and c) biophotonics technology for the non-invasive detection of cancers.

Diabetes Management-

Our diabetes management activities include our SimpleChoice® brand of insulin pump disposables and a non-invasive interstitial fluid-based continuous and discrete glucose monitoring research and development program, for which we are currently seeking a strategic partner.

Our insulin delivery products, including those in development, are designed with a goal of delivering insulin more comfortably and effectively than competing products. In glucose monitoring, we are conducting activities intended to produce a product that can measure glucose levels more conveniently and more frequently than products currently sold by our competitors.

Non-Invasive Cancer Diagnostics-

We have created a wholly owned subsidiary, Guided Therapeutics, Inc., to facilitate the separation, for both financing and operational purposes, of our biophotonics activities, which currently consist of a non-invasive cervical cancer detection platform.

In our non-invasive cancer diagnostic business, we are developing products that we believe will provide less invasive and painless alternatives to products that are currently available for cancer detection. We believe the products in these areas can improve patient well-being and reduce healthcare costs since they reduce or eliminate pain, are convenient to use and provide rapid results at the point of care. The focus of these activities is a non-invasive device for the detection of cervical cancers and precancers which is currently undergoing tests as part of an FDA pivotal trial.

Strategic Partnerships-

Significant portions of our historical activities were undertaken in collaboration with other, larger companies. We no longer have collaborative partnerships with respect to any of our historical products. In 2003, we sold our infant jaundice detection product to our former collaborative partner, Respironics, Inc. and terminated our agreement relating to our glucose monitoring product with Abbott Laboratories, Inc.

We are currently developing our insulin infusion product line, the glucose monitoring product and cervical cancer detection product independently of any strategic partnership, upon which we have historically relied for a significant amount of the funding for product development. We will need to obtain additional funding to continue developing our

products. We have announced that we plan to seek a collaborative partner to help develop and commercialize our glucose monitoring product. We have also announced that we intend to finance our cancer detection product activities independently and separately through direct financing of our subsidiary, Guided Therapeutics. In addition, we may need or choose to seek and rely on collaborative partners in the future to distribute and market the products we are developing.

OUR BUSINESS STRATEGY

We exist to provide innovative medical products that improve the quality of life. Our mission is to build a profitable business that develops and commercializes medical products that improve people's lives and increases stockholder value. To achieve this mission, we are pursuing the following business strategies:

- Focus on Generating Near Term Revenue with Insulin Infusion Products. A key element of our strategy is to achieve profitability and revenue growth with the United States Food and Drug Administration (FDA) cleared products that are either already on the market or can be launched in the next twelve months. We introduced our first product, an insulin pump reservoir intended to be marketed with our SimpleChoice infusion sets, in the fourth quarter of 2002 and introduced our first insulin infusion set product, the SimpleChoice *easy*™, in the second half of 2003. In 2004, we were unable to complete the planned launch of additional products. These additional products are now planned for 2005 and 2006.

- Complete FDA Pivotal Trial and Obtain Financing for Cervical Cancer Diagnostic Product. Our cancer diagnostic activities have been financed to date through a combination of government grants, strategic partners and direct investment. In order to adequately finance the completion of the FDA pivotal trials, complete product development and prepare for marketing of the cervical cancer detection product, additional capital will be needed. We are seeking this capital from a variety of sources, including strategic partners, venture financing and other sources. It is likely that completion of a significant financing will result in the sale of a significant interest in the cervical cancer business.

- Develop Additional Products. To ensure a new product pipeline, we intend to leverage our proprietary technologies to develop additional products from our other product development activities. We also believe that our development activities in diabetes management have significant promise for additional product offerings. For example, we believe that our interstitial fluid sampling technology may be applicable for monitoring compounds other than glucose. Our insulin delivery products may be used to deliver other drugs or compounds and our cervical cancer detection technology may be used to detect other cancers.

INDUSTRY OVERVIEWS

DIABETES MANAGEMENT

Background

Diabetes is a major health care problem and, according to recent estimates by the World Health Organization, the number of people with diabetes will grow to 300 million people worldwide over the next 25 years. If undiagnosed or untreated, diabetes can lead to severe medical complications over time, including blindness, loss of kidney function, nerve degeneration, and cardiovascular disease. Diabetes was the sixth leading cause of death by disease in the United States in 2000 and was estimated in 2002 to cost the U.S. economy over $132 billion annually, including indirect costs such as lost productivity.

Diabetes occurs when the body does not produce sufficient levels of, or cannot effectively use, insulin, a hormone that regulates the body's use of glucose, a simple sugar and key carbohydrate. Glucose levels in the blood must be within a specific concentration range to ensure proper health. Insulin deficiency results in an abnormally high blood glucose concentration, which causes detectable changes in some proteins throughout the body, impairs the ability of cells to intake glucose and has other adverse effects. There are two types of diabetes. Type I diabetes is generally characterized as juvenile-onset and results in insulin dependency. In Type I diabetes, which affects from 5% to 10% of all people with diagnosed diabetes, the cells that make insulin have been damaged or destroyed. Type I diabetes is treated with daily insulin injections or with an insulin pump. Type II diabetes is the more prevalent form of diabetes accounting for 90% to 95% of all diagnosed cases, and is generally characterized as adult-onset; it does not

necessarily result in insulin dependency. In Type II diabetes, the insulin producing cells are unable to produce enough insulin to compensate for the patient's poor sensitivity to the hormone in glucose-using tissues such as skeletal muscle, a condition called insulin resistance. Type II diabetes is initially managed with proper diet, exercise and oral medication, although it can eventually require insulin use.

Insulin Delivery Market

Of the estimated over 100 million people with diabetes worldwide, including 18.2 million in the U.S. as of 2002, approximately 5-10% have Type I diabetes. Of the remaining people with diabetes, about 35% use insulin periodically to manage their condition. It is estimated that between 2.5 to 3.0 million individuals with Type II diabetes in the U.S. use insulin on a regular basis.

Currently, the most common means of insulin delivery are syringe, insulin pen and insulin pump. Approximately 86.5% of the people who use insulin in the U.S. use the syringe, 6% use the pen and 7.5% use the pump. Variances in the cost of supplies and varying degrees of insulin dependency affected the 2003 worldwide market for each of these products, which we believe was about $500 million for syringes, growing at 5% per year, $250 million for insulin pens and pre-filled syringes, growing at 30% per year, and $660 million for pumps, which includes $300 million for devices and $360 million for disposable components, growing at 15-20% per year.

Infusion sets attach to the insulin pump and transport the insulin through tubing to a catheter that is inserted under the skin, where the insulin is absorbed into the tissue. Infusion sets are generally used for about three days and discarded. A new infusion set is inserted under the skin at a different location and attached to the pump to continue treatment for about another three days. In addition to insulin infusion sets, disposable products include insulin reservoirs, batteries and tapes.

We estimate the insulin pump infusion disposables market was about $360 million annually worldwide in 2003. Consumers generally purchase infusion sets and other supplies from the pump manufacturer, distributors or durable medical equipment sellers. The average insulin pump user consumes about $1,300 annually in disposable supplies. Significant players in the insulin pump business include Medtronic MiniMed, Inc., Smiths Medical, Inc. (formerly Deltec), Animas Corporation and Roche Disetronics. Significant participants in the insulin infusion set market include Unomedical A/S, which manufactures or sells sets to all of the pump manufacturers, and Medtronic MiniMed, which both manufactures for itself and uses Unomedical as a contract manufacturer while selling infusion sets directly to its customers.

Our Insulin Delivery Products

We commenced our entry into the insulin delivery business through our acquisition of Sterling Medivations on December 31, 2001. Sterling Medivations, a start-up medical device company, had designed a line of FDA-cleared insulin delivery products. We issued approximately 610,000 shares of our common stock to former stockholders of Sterling Medivations in the acquisition. We also assumed the existing stock option plan of Sterling Medivations, and if all assumed stock options were exercised, we would be required to issue approximately 22,000 additional shares of our common stock to former holders of options to purchase Sterling Medivations common stock. The number of shares issued or reserved in connection with the merger is subject to further adjustment. Up to an aggregate of approximately 1.2 million additional shares of our common stock could be issued to former stockholders, or reserved for issuance to former option holders, of Sterling Medivations, if the products developed by Sterling Medivations meet specified financial goals. Based on sales to date, it is unlikely these financial goals will be met. The closing sales price for a share of our common stock on December 31, 2001 was $6.90, which, based on the shares of our common stock issued or reserved for issuance in connection with the merger, initially valued the transaction at approximately $4.3 million. If any of the additional shares are issued in the future, we will make an adjustment to the purchase price based upon the value of the issued shares. We have structured the activities in this market category under the registered trademark SimpleChoice.

In the fourth quarter of 2002, we shipped a small quantity of SimpleChoice diabetes management products, including a reservoir for holding insulin in an insulin pump that is intended to be marketed with our insulin infusion sets. We launched our first insulin infusion set, which includes the tubing and catheter that connect to an insulin pump, the SimpleChoice *easy*, in the third quarter of 2003. The SimpleChoice products under development include a variety of additional pump infusion sets and other ancillary insulin delivery products. Since our acquisition of Sterling Medivations, we have received 10 FDA clearances for these products, bringing the number to 27 FDA clearances for components and products that we expect to market. In 2004, we focused our efforts on the development of the SimpleChoice *patch* (a multiple needle, shallow insertion 90-degree infusion set) and the SimpleChoice *twist* (a 90-degree rotating infusion set formerly referred to as the *quick*). We were unable to launch these products in 2004 due to development and manufacturing problems.

We expect to market more significant levels of these products in 2005, introducing other SimpleChoice insulin infusion sets, the *twist* and the *patch,* followed by additional product launches in coming years. Our SimpleChoice insulin pump infusion sets are designed to compete with infusion sets already on the market, as well as create new market segments for users of the *patch*. Our products contain innovations and additional features, which we believe consumers are likely to prefer over their existing insulin infusion sets. The features and benefits of our products will include:

- compatibility with the major insulin pump brands and products;

- 360 degree rotating hub for increased comfort through better flexibility and movement; and

- compatibility with existing inserter devices.

Our first insulin pump infusion set product was the SimpleChoice *easy*. This product is a 30-degree insertion infusion set designed to work with the major brands of insulin pumps on the market today. SimpleChoice *twist,* which is expected to be launched in the second quarter of 2005, is a 90-degree insertion infusion set designed to work with the major brands of insulin pumps. The *twist* will also feature a 360-degree rotating hub, which will allow the wearer more freedom of movement and greater flexibility.

Another product in the SimpleChoice product line is our insulin infusion patch, which we also expect to launch in 2005. The *patch* is designed with microneedle technology intended to reduce pain and improve comfort over existing infusion sets. The microneedles in the *patch* penetrate the skin about 2.5 mm, as compared to up to 9 mm for conventional infusion sets. We attempted to launch the patch in 2004, however we were unable to do so because of manufacturing, user acceptability and cost of goods issues.

In addition to insulin sets and reservoirs, the SimpleChoice product line includes insertion devices and other disposables. Initially, we are selling our products through distributors and durable medical equipment sellers. We also ultimately plan to make our products more widely available than infusion sets available from other manufacturers by expanding our distribution channels, which will provide our customers with easier access to our products, although there can be no assurance that we can do so.

The Glucose Monitoring Market

People with diabetes have difficulty achieving optimal glucose control. For proper glucose control, each insulin injection or other form of medication should be adjusted to reflect the person's current blood glucose concentration, carbohydrate consumption, exercise pattern, stress or other health factors. Accordingly, personal glucose monitoring products have become critical in managing diabetes by allowing people with diabetes to measure their glucose levels in order to adjust their diet, exercise and use of oral medication or insulin.

In June 1993, the National Institutes of Health announced the results of the Diabetes Control and Complications Trial. This long-term study of about 1,400 people with Type I diabetes confirmed the importance of glucose control as a determinant of long-term risk of degenerative complications. The results from the trial demonstrated that the risk of degenerative complications is significantly reduced if blood glucose concentrations in people with Type I diabetes can be brought closer to the concentrations measured in individuals without diabetes. For example, the trial demonstrated that the risk of complications of diabetic retinopathy, the leading cause of blindness in the United States, could be reduced up to 76% through proper glucose control. The trial panel recommended that people with Type I diabetes measure their blood glucose four times per day in order to maintain proper control over their glucose levels. Although the study involved people with Type I diabetes only, similar Japanese and United Kingdom studies on people with Type II diabetes support the conclusion of the Diabetes Control and Complications Trial that maintaining low average glucose levels reduces the risks of complications associated with diabetes.

Because glucose monitoring is an important part of everyday life for people diagnosed with diabetes, the worldwide personal glucose monitoring market is substantial. We believe that the worldwide market for glucose monitoring products at manufacturers' price levels is about $6.0 billion annually and is growing at about 12%-18% per year. We believe that the market for personal glucose monitoring products is driven by four main factors:

- an aging and more obese population;
- the realization that tight glucose control dramatically reduces the risk of complications associated with diabetes;
- the availability of third-party reimbursement in developed nations; and
- the promotion and increased availability of glucose monitoring products.

It is estimated that people with diabetes currently monitor their glucose on average less than twice a day, instead of four times a day as recommended by the Diabetes Control and Complications Trial. We believe that the pain and inconvenience associated with conventional finger stick blood glucose monitoring systems, as described below, are the primary reasons that most people with diabetes fail to comply with this recommendation. We believe that greater awareness of the benefit of frequent self-monitoring and the availability of less painful, more convenient monitoring products could significantly increase the global market.

Most commercially available conventional glucose monitoring systems are painful and inconvenient. These systems require that a blood sample be obtained from a patient, applied to a disposable test strip and then measured for glucose concentrations using a battery-powered, handheld monitor. Under most of these systems, the blood sample is usually obtained from a patient's fingertip because of the high concentration of capillaries at this site and because the blood produced at the fingertip can most easily be applied directly to test strips used in these devices. These systems typically require the patient to complete the following steps: insert the disposable test strip into the meter, lance the body part, apply the drop of blood to the test strip and wait for the meter to display the results. Because nerve endings are concentrated in the fingertips, the sampling process used in most systems can be painful. The level of patient discomfort is compounded by the fact that the fingertips offer a limited surface area from which to obtain a blood sample. Thus, the patient can be required to repeatedly sample from the same site, eventually resulting in callouses. In addition, applying the drop of blood to the test strip is difficult for those people with diabetes who have lost dexterity in their extremities due to nerve degeneration.

Glucose monitoring products have evolved rapidly over time. The largest portion of this market is in conventional finger stick products. In the past, various factors have allowed new entrants to establish market share in the glucose monitoring product market, including technological advances, broader product distribution and increased patient awareness of product innovations. These factors have also expanded the overall size of the market for glucose monitoring products. There are blood glucose monitoring products now on the market that are designed to draw blood from the arm or leg, called alternate site products. Also in development are a number of continuous glucose monitoring products, which may reduce the need for finger sticks to draw blood. Many of these continuous monitoring products under development require a probe or sensor to be inserted under the skin and require frequent calibration with a conventional single use blood-based finger stick product. Recently, both Medtronic MiniMed and Abbott

Diabetes Products a division of Abbott laboratories, Inc. (formerly Therasense, Inc.) have filed for FDA approval or received limited FDA approval for continuous glucose monitoring devices that involve putting a sensor under the skin.

Our Glucose Monitoring Activities

We are developing technology for use in a glucose monitoring product that should allow people with diabetes to easily, less painfully and accurately measure their glucose levels. Our focus is on refining our proprietary interstitial fluid sampling technology. Interstitial fluid is an extracellular fluid that is prevalent throughout the body just beneath the skin. Interstitial fluid is the means by which proteins and chemicals, including glucose, pass between capillaries and cells. Studies based on our research, as well as independent research, have shown that interstitial fluid glucose levels correlate closely with blood glucose levels. We believe that using interstitial fluid to measure glucose levels is more efficient than using blood because it is free of interferences such as red blood cells, which must often be separated from the plasma before it can be measured to obtain an accurate result.

Because our glucose monitoring technology is designed to obtain a sample of interstitial fluid through the outermost layers of the skin and does not require a blood sample, its use does not significantly stimulate pain sensors and capillaries found in the deeper layers of skin. This technology is expected to be free of the pain and blood involved in conventional finger stick or alternate site techniques. The primary focus of our activity is currently on the continuous monitoring product. We had previously been developing our single-use glucose monitoring product under a 1996 collaborative agreement with Abbott, which was terminated in January 2003. Abbott provided investments, milestone payments and reimbursement for research and development in support of the development program. On February 17, 2005, we announced that we had filed suit in Cobb County, Georgia against Abbott Laboratories related to confidential information we provided in relation to the glucose program.

We plan to proceed with the development of our continuous glucose monitoring technology as quickly as possible as a key element of our diabetes business unit. In order to proceed, we need to identify a low glucose volume assay technology and obtain funding from a strategic partner or other source.

During the course of our research and development, we identified a technique that allows for continuous monitoring of glucose. By applying a constant state of low-level vacuum to an array of micropores, a stream of interstitial fluid is produced. This stream of interstitial fluid may be passed over a sensor, which measures the glucose concentration, periodically providing the patient with readings. Feasibility data we generated in 2004 indicates that an array of micropores may be kept viable for up to four days.

The product concept of the continuous glucose monitoring product consists of a disposable patch wirelessly connected to a small remote display unit. The patch would be placed over an array of approximately four micropores created on the surface of the skin. This array could be placed in a number of locations, but the current concept would have it placed on the torso. The patch would be designed to eliminate spent interstitial fluid. The remote display unit would receive data from the patch via a wireless connection and display the results. The system would automatically collect a new glucose reading periodically, which would be recorded and presented on the remote display unit. The stored information could be downloaded for analysis. The remote display could also indicate if the current reading is higher or lower than any previous reading, showing a trend. The system would also be capable of giving an alarm for high or low glucose levels.

We have received grants related to glucose monitoring from the U.S. Centers for Disease Control and Prevention. We received funding of $412,000 in 2002, $122,000 in 2003 and $0 in 2004 to adapt our glucose monitoring technology to monitor blood sugar levels of children and elderly people with diabetes. The primary studies under this grant have taken place at the Barbara Davis Center in Denver, Colorado.

Our research and development on the continuous glucose monitoring technology is focused on the integration of our microporation, fluid management and a suitable glucose assay technology into a product. We expect product

development to be followed by clinical trials and a regulatory submission.

We have announced that we intend to seek another collaborative partner to support our activities to commercialize our glucose monitoring product. We will need to reach an agreement with such collaborative partner to provide needed funding for additional product development, regulatory approval, production ramp-up and commercialization activities, or raise additional funds. There can be no assurance that we will be able to reach agreement with a collaborative partner or to find additional funding sources.

In addition to our activities aimed at using our laser-based micropore technology for glucose, we are also involved in externally funded research and development activities aimed at using interstitial fluid for continuous alcohol testing. Our research contract for alcohol testing with the National Institutes of Health totaled about $1.5 million for the first two years, and was recently extended to three years. In addition, we have smaller grants to study other elements of interstitial fluid, including insulin-like growth factor-1 (IGF-1) testing for the U.S. Army. These smaller projects generate approximately $80,000 -$100,000 in revenues per year and address areas of markers for battlefield readiness (Department of Defense - DOD), Dengue Fever (University of Massachusetts) and skin health.

NON-INVASIVE DIAGNOSTICS PRODUCTS

CERVICAL CANCER DETECTION - GUIDED THERAPEUTICS

Background

According to the American Cancer Society, cancer is a group of many related diseases. All forms of cancer involve the out-of-control growth and spread of abnormal cells. Normal body cells grow, divide, and die in an orderly fashion. Cancer cells, however, continue to grow and divide, and can spread to other parts of the body. In America, half of all men and one-third of all women will develop cancer during their lifetimes. According to the American Cancer Society, the sooner a cancer is found, and the sooner treatment begins, the better a patient's chances are of a cure. We began investigating the applications of our technologies to cancer detection before 1997, when we initiated a market analysis for these uses. We concluded that our biophotonic technologies had applications to detect a variety of cancers that could be exposed to light. We selected cervical cancer and skin cancer from a list of the ten most attractive applications as categories of cancer to pursue initially, and currently are focused only on the development of our non-invasive cervical cancer detection product.

Cervical Cancer

Cervical cancer is a cancer that begins in the lining of the cervix, the lower part of the uterus. Cervical cancer forms over time and may spread to other parts of the body if left untreated. There is generally a gradual change from a normal cervix to a cervix with precancerous cells to cervical cancer. For some women, precancerous changes may go away without any treatment. While the majority of precancerous changes do not advance to cancer, if these precancers are treated, true cancers can be prevented. The Pap smear, where a sample of cervical tissue is placed on a slide and observed in a laboratory, is currently the most common form of cervical cancer screening.

Cervical Cancer Market

The American Cancer Society estimates that about 10,570 cases of invasive cervical cancer will be diagnosed annually in the United States, and predicted 3,900 deaths predicted for 2004. According to published data, cervical cancer results in about 200,000 deaths annually worldwide, with 370,000 new cases reported each year.

We believe the major market opportunities related to cervical cancer are in screening and diagnosis. Since the introduction of better screening and diagnostic methods, the number of cervical cancer deaths in the U.S. has declined dramatically, due mainly to the increased use of the Pap smear screening test. However, the Pap smear screening test

has a wide variation in sensitivity, which is the ability to detect the disease, and specificity, which is the ability to exclude false positives. A study by Duke University for the U.S. Agency for HealthCare Policy and Research published in 1999 showed Pap test performance ranging from a sensitivity of 22% and specificity of 78% to sensitivity of 95% and specificity of 10%. About 55 million Pap tests are given annually in the U.S. The average price of a Pap test in the U.S. is $26. New technologies improving the sensitivity and specificity of Pap smear screening have recently been introduced and are finding acceptance in the marketplace.

After screening for cervical cancer by use of a Pap smear, if necessary, a visual examination of the cervix using a colposcope is usually followed by a biopsy, sampling at one to two locations. This method looks for visual changes attributable to cancer. There are about two million colposcope examinations annually in the U.S. and Europe. In 2003, the average cost of a stand-alone colposcope examination in the U.S. was $185; the average cost of a colposcopy with biopsy was $277, plus approximately $190.

Our Non-invasive Cervical Cancer Product

We are developing a non-invasive cervical cancer detection product. The product is based on our proprietary biophotonic technology. The intended design is expected to identify cancers and precancers painlessly, non-invasively and at the point-of-care by shining light onto the cervix, then analyzing the light reflected or emanating from the cervix. The information presented by the light will be used to produce a map or image of diseased tissue. This test, unlike the Pap smear test or biopsy, preserves the perspective and positional information of disease on the cervix, allowing for more accurate diagnosis. This feature of our system also allows doctors to make intelligent choices in selecting biopsy sites and could be expanded for use in assisting the detection of cancerous margins for cancer removal. Our product, in addition to detecting the structural changes attributed to cancer, is also expected to detect the biochemical changes that precede the development of visual lesions. In this way, the cancer may be detected earlier in its development, which should increase the chances of effective treatment. The product is expected to incorporate a single-use, disposable calibration and alignment component similar to those we developed and manufactured for our former infant jaundice product, the Bili*Chek*™, which was sold in 2003.

To date, more than 1,250 women have been tested with various prototype devices in multiple clinical settings. During 2000, we conducted human clinical feasibility studies of laboratory prototypes at two U.S. research centers, detecting 31% more cervical precancerous lesions than conventional Pap tests. The results were presented at the World Health Organization/European Research Organization on Genital Infection and Neoplasia Joint Experts Conference in Paris in April 2000. The study population consisted of 133 women scheduled for colposcopy and biopsy, if indicated. A total of 318 tissue-specific comparisons were made between our device and colposcopy/biopsy results. Of the 318 patients included in this study, 20 had high-grade precancers, 36 had low-grade precancers, 146 had benign lesions and 116 had normal tissues. Compared to the Pap test, our product detected 31% more precancers and 25% more high-grade precancers without increasing the false positive rate.

In 2001, a study published in the Journal of Lower Genital Tract Disease reported that prototypes of our non-invasive cervical cancer detection device detected 25% more incidences of disease than Pap tests. The study of 111 women, conducted at two U.S. sites, also showed that the performance of the prototypes was not affected by age, history of childbirth or previous cervical surgical history and generated results across an age range of 18 to 73 years. The data from the examinations of the patients in the study using our prototypes and Pap tests were compared to colposcopy and biopsy results. The results showed that our devices were able to distinguish low-grade and high-grade precancers, as well as their locations on the cervix. Of the 111 patients included in the study, 19 had high-grade precancer, 30 had low-grade precancer, 34 had other diseases or scar tissue and 28 were considered normal.

In 2002, we collected additional data on 600 patients using three prototype devices. This data was used to develop our algorithm in preparation for FDA pivotal trials. The FDA pivotal trials are expected to start using our existing prototype devices and conclude using a production prototype.

In December 2003, the Journal of Lower Genital Tract Disease reported that 81% of women tested with our non-invasive cervical cancer detection prototypes wanted the test to be used as a replacement for the invasive Pap test. Additionally, 87% of women who took our test would recommend it to a friend who is to undergo an exam for cervical disease. More than 96% of women surveyed favored the SpectRx test as a method for locating the presence of disease and reducing the number of biopsies. Additionally, the study reported that 85% of participants wanted their doctor to have the test and 91% wanted their insurance company to pay for it.

The study was conducted at the Medical College of Georgia Gynecologic Cancer Prevention Center by principal investigator Daron G. Ferris, MD. A group of 176 women who completed the non-invasive test and a colposcopic examination completed a 24-item questionnaire, which included a series of questions regarding their willingness to use or recommend the test. We provided the device for the trial, but did not provide any financial assistance for the independent study.

In January 2004, we reported to the National Cancer Institute (NCI) results of a pre-pivotal clinical trial sponsored by the agency. The study cohort consisted of 506 women ranging in age from 16-years to 75-years. Results of the NCI-sponsored study indicated that our technology could reduce by 55% the number of unnecessary follow-up procedures as a result of false positive Pap test results. The potential savings to the U.S. healthcare system could be as high as $181 million annually if the technology is widely adopted.

In May 2004, we announced that the FDA had completed its review of our pivotal trial protocol using a prototype device and we began enrollment of patients for the pivotal trial in June. Upon completion of the pivotal trials, we plan to submit an application for regulatory approval through the premarket approval, or PMA, process of a production prototype, although we must obtain additional funding. We also plan to ask for expedited review. Unexpected problems, however, may arise during the development and regulatory approval processes.

The market for cervical cancer screening is currently dominated by lab-based cytological screening of samples obtained from patients. The market for primary screening is dominated by Cytyc, Inc., which markets the Thin Prep Pap test and Digene, Inc., which markets another method of cervical cancer screening, human papilloma virus (HPV) detection. Digene is attempting to gain permission to use its device for primary screening. The Digene HPV test is already approved for use as a follow-up to ambiguous PAP results and as an adjunct to the PAP test for screening women aged 30 and over. We have conducted several marketing research programs related to the cervical cancer market and the impact of the growth of the lab-based cytological screening products. We are reviewing the impact of the changing competitive landscape related to our product development pace and our initial and potential positioning. We will have to demonstrate clinical and commercial effectiveness to be able to change current medical practice behavior and capture market share. Accordingly, we cannot be sure that these events will occur.

We spent most of our development effort from 1998 to 2001 under a collaborative agreement with Welch Allyn specifically focused on the development of a cervical cancer detection product. In November 2002, we reached an agreement terminating the collaborative development arrangement with Welch Allyn, effective as of December 10, 2001, and agreeing to certain cross-licensing provisions of technology developed under the collaborative agreement. As part of the termination agreement, we agreed to provide certain royalties to Welch Allyn if a product is commercialized, subject to offsets for patent expenses and other limitations.

In February 2003, we announced we had received a two-year, $1.3 million grant from NCI to support our required pivotal clinical trials, some of the results of which are discussed above. In June 2004, we announced that we were selected to receive another grant of $1.1 million from NCI to develop one commercial version of the device. As of December 31, 2004, we have received approximately $74,000 for this grant.

We have also announced that we are seeking additional funding for our cervical cancer program from outside sources, and intend to separate these activities into an independent entity, in order to move the commercialization program

forward for these cancer products.

INFANT JAUNDICE

Our first commercial product, the Bili*Chek* system for non-invasive detection of jaundice in infants, was introduced in 1998. The infant jaundice product was originally developed under a collaborative agreement with Respironics, which also granted Respironics an exclusive license to market and sell the product line in the United States and Canada. In March 2003, we announced that we had sold the assets related to the infant jaundice products to Respironics. Under the terms of the Asset Sale Agreement, we will receive ongoing payments from the sale of the disposable element of the product line, trademarked the Bili*Cal*, over the base amount of unit sales to distributors sold in 2002 for a period not to exceed five years. In addition, we can receive earnout payments based upon certain revenue achievements of the sales of infant jaundice products by Respironics over the four years following the sale. We also provided some engineering work to Respironics and received a $1.0 million payment in the fourth quarter of 2003 related to the transaction. Our earnout accrual for 2003 totaled $655,000 and for 2004 totaled $1,030,000.

Respironics retains all responsibility and discretion regarding all activities related to sales of this product and the amount and quality of financial, personnel and other resources that it devotes to these activities.

On October 14, 2004, Respironics notified us that an allegation of patent infringement related to the Bili*Chek* product had been made and that it believed that this matter was subject to the indemnification provision of our asset sale agreement (see Note 5) which could require the Company to pay a portion of the costs related to certain infringement of intellectual property brought within two years of the closing date. On April 20, 2005 Respironics and SpectRx entered into a settlement agreement resolving the matter. In connection with the settlement and in exchange for Respironics agreeing to pay the earnout payments early due for 2004, Respironics will withhold approximately $275,000 of earnout payments due for 2006.

COLLABORATIVE ARRANGEMENTS

Our business strategy for the development and commercialization of our products has depended, to a significant degree, on our ability to enter into and maintain collaborative arrangements with leading medical device companies. We have had collaborative arrangements with Abbott, Respironics, Welch Allyn and Roche. We have terminated our collaborative relationships with Abbott and Welch Allyn, and we have sold the assets related to our infant jaundice business to our collaborative partner, Respironics. Roche, our collaborative partner with respect to our diabetes detection product, is currently inactive with respect to our collaboration. There have been no commercial sales of the diabetes detection product to end users to date. We are, however, seeking a new collaborative arrangement for our glucose monitoring product, which was formerly being developed with Abbott. If we enter into a new collaborative agreement, we will be, to varying degrees, dependent upon any collaborative partner for funding or providing the development, clinical testing, regulatory approval, manufacturing, and commercialization of our products.

We have continuing obligations related to our collaborative agreement with Abbott. We issued 525,000 shares of redeemable convertible preferred stock to Abbott for $5.25 million in December 1999 and January 2000. Of that preferred stock, 100,000 shares are not subject to redemption rights, and 425,000 shares have been designated for redemption. Pursuant to a settlement agreement, dated March 7, 2003, between Abbott and us (see Item 3. - Legal Proceedings), these 425,000 shares were to be redeemed over a period of four years.

On February 17, 2005, we initiated litigation against Abbott Laboratories relating to a previously disclosed dispute over intellectual property issues, as attempts to resolve these issues through negotiations failed. We are represented in this matter under a contingency fee arrangement.

LICENSING ARRANGEMENTS

Georgia Tech Research Corporation

We have a license agreement with Georgia Tech Research Corporation. Under this agreement, entered into in May 1991, as amended, Georgia Tech Research Corporation has granted us an exclusive, worldwide license, including the right to grant sublicenses, to make, use and sell products that incorporate its know-how related to a method of using non-invasive instrumentation to quantitatively measure molecular changes in living human lenses for the purposes of diagnosing diabetes and precataractous conditions. Under the license, we must pay a royalty to Georgia Tech Research on net sales of any products manufactured and sold by us. The term of this agreement is until the expiration date of the last expiring patent covering any of the technology licensed or, if no patent issues, for 15 years from the date of execution of the agreement. The current expiration date for this agreement is July of 2011. As of December 31, 2004, we did not owe any amounts under this agreement.

Altea Technologies, Inc.

In March 1996, we entered into a license and joint development agreement among us, Altea and Non-Invasive Monitoring Company, Inc. Under this agreement, specified rights in respect of jointly developed technology are allocated between us and Altea. Both Altea and Non-Invasive Monitoring are jointly controlled by Jonathan Eppstein, formerly our vice president, and his sister. This agreement also covered one granted patent and know-how related to our glucose monitoring products, the joint application by us and Altea for a U.S. patent and an international patent related to the glucose monitoring products. It also outlined continued joint development efforts between us and Altea for the first year subject to both parties' approval. The agreement further provides for the joint ownership by us and Altea of some patents and technology relating to the transdermal/intradermal movement of substances using various methods. Under this agreement, we receive worldwide, exclusive rights to any technology for monitoring applications covered by the Non-Invasive Monitoring patents and related joint technology, and Altea receives exclusive, worldwide rights to any technology for delivery applications covered by the joint technology. There are currently ten granted U.S. patents, eight U.S. patent applications and a variety of foreign patents and patent applications covered by the agreement.

We are obligated to pay royalties to Non-Invasive Monitoring for products using technology it owns under the agreement and to Altea for products using technology it owns under the agreement, in each case based on net sales of products and net revenues from sublicensees. Royalties on products using technology of both companies will be allocated as mutually agreed. Minimum annual royalties are payable by us to Altea (see Note 8 of the notes to consolidated financial statements). If actual accrued royalties are less than the minimum royalty amount, we must pay Altea the difference. To date, we have only paid minimum royalty payments to Altea.

We and Altea and Non-Invasive Monitoring have twice arbitrated specified claims under these agreements. In December 2001, we and Altea reached a settlement related to our most recent arbitration, which amended the agreement with Altea and provided several changes to the obligations of both parties. Under the settlement, we both agreed to a process to agree on what is joint technology covered by the agreement, to end the inclusion of future intellectual property into joint technology, to eliminate any test for commercialization other than ordinary due diligence and to modify the scope of royalty payments. As part of the settlement, we agreed to pay minimum royalties due from 2002 through 2004 in advance during 2002 and 2003, in exchange for a reduction in minimum royalties in future years. In November 2002 and in July 2003, we modified our agreement with Altea to postpone some of the advance payments of minimum royalties until 2003 and 2004.

The term of the agreement is for the life of the patents covered by the agreement. The agreement may be terminated by any party in the event of a default by any other party that is not cured within 90 days of notice to the defaulting party. We may terminate the agreement upon not less than three months prior notice to Altea and Non-Invasive Monitoring if given before we have commercialized the technology and upon not less than six months prior notice to each party if given after commercialization has begun. Except in the case of termination of the agreement by us for breach, upon termination, all jointly owned technology developed prior to the execution of the amended agreement

becomes the exclusive property of Altea, except the Non-Invasive Monitoring patents. If the agreement is terminated by us for breach, all rights to the monitoring technology in the countries in which we have retained our exclusive rights become our exclusive property, each party retains non-exclusive rights to the monitoring technology in other countries, and Altea retains all rights to the delivery technology.

RESEARCH, DEVELOPMENT AND ENGINEERING

To date, we have been engaged primarily in the research, development and testing of our glucose monitoring, diabetes detection, infant jaundice and cancer detection products, including research for and development of our core biophotonic technologies. During 2004, we spent a significant amount of resources on research and development in the area of insulin delivery as a consequence of our 2001 acquisition of Sterling Medivations. From inception to December 31, 2004, we incurred about $39.9 million in research and development expenses, net of about $12.2 million, which was reimbursed through collaborative arrangements. Research and development costs were about $4.1 million in 2003 and $3.6 million in 2004.

During 2004, there were two distinct groups conducting research, development and engineering. One group consisted of engineers and support personnel who design optics, electronics, mechanical components and software for the cancer detection products market, alcohol detection products under the contract with the National Institute on Alcohol Abuse and Alcoholism (NIAAA) and continuous glucose monitoring products. The second group consists of engineers developing insulin delivery products.

We believe that the interstitial fluid sampling technology we have under development for use in connection with our glucose monitoring products may also be used to develop alternatives for some blood tests where the analyte being tested is also present in comparable volumes in interstitial fluid.

To date, only prototypes of our glucose monitoring and cancer detection products have been tested. Because our research and clinical development programs are at an early stage, substantial additional research and development and clinical trials will be necessary before commercial prototypes of our glucose monitoring and cancer detection products are produced. Our SimpleChoice line of insulin delivery products is at various stages of development. While significant progress has been made in development and engineering, considerable additional effort and expense will be required for commercialization to occur and for products still in the development pipeline to become ready for commercial introduction.

MANUFACTURING

We plan to manufacture some of our products and to outsource the production of other, high volume products and associated disposables. To date, our manufacturing activities have consisted of building prototype devices, developing production infrastructure and building production versions of our Bili*Chek* and Bili*Cal* products. In 1998, we received ISO 9001/EN46001 and CE mark certification for international sales. These approvals enabled us to begin production of our Bili*Chek* and Bili*Cal* products and to begin shipment of these products into international markets. We sold the assets related to the infant jaundice products in March of 2003. We have little historical experience manufacturing products in the volumes that would be necessary for us to achieve significant commercial sales.

To help us reach our goal of selling a high volume of insulin infusion disposable products, we have entered into supply agreements with experienced contract manufacturers. Currently, we employ four individuals to accomplish the production planning, quality system management, facility development, and production scaling that will be needed to bring production to commercial levels. We are currently in the process of expanding our international certification to ISO13485 and have recently passed an inspection aimed at allowing us to CE mark our sterile medical disposable products.

We achieved certification under ISO 13485:1996 Canadian Medical Devices Conformity Assessment System (CMDCAS) in 2004, a requirement for the CE mark, as well as Canadian distribution. The CE mark was awarded in September 2004 for SimpleChoice infusion sets and infusion pump reservoirs, which are now being distributed on a limited basis in Europe. We must upgrade to ISO 13485:2003 by June 2006 to maintain this status.

SALES, MARKETING AND DISTRIBUTION

We developed and managed a distribution system for our Bili*Chek* product line prior to its sale. We have also developed the initial distribution system for our insulin delivery products. In addition, we expect to further develop, manage and service distribution channels for our insulin delivery products. Historically, we have elected to focus much of the sales and distribution of our products through our collaborative partners, although we do not currently have any collaborative agreements in effect with respect to these functions. We are seeking a collaborative partner for our glucose monitoring technology, which may include a sales and distribution agreement, although such an arrangement is not assured.

Our primary efforts to date have been to build the skill and information base to identify and quantify market segments to which our technologies can be economically developed and marketed, as well as to launch our two product lines that have been introduced to the market: the Bili*Chek* product system, which we sold, and our SimpleChoice line of insulin delivery products. We have developed internal marketing and a distribution program for the SimpleChoice products to an introductory stage, and we have developed packaging, advertising, display materials, and training for these products. In addition, we have signed distribution agreements or have entered into negotiations with companies we believe to be highly experienced in the diabetes supply business in the United States. Our previous experience in building a distribution system focused on entities that were experienced in neonatal markets in Europe, Asia and South America. We shipped our first insulin delivery product, the SimpleChoice *reservoir*, in the fourth quarter of 2002. We launched our first insulin infusion disposable product, the SimpleChoice *easy*, in the third quarter of 2003. We expect to launch additional products during 2005. We have also added or engaged marketing personnel to develop and execute the programs necessary to launch the SimpleChoice product line and to manage sales of these products. We are still early in this product line's market introduction, and the efficacy of the marketing programs or the distributors has not yet been fully tested with our products.

PATENTS

We have pursued a course of developing and acquiring patents and patent rights and licensing technology. Our success depends in large part on our ability to establish and maintain the proprietary nature of our technology through the patent process and to license from others patents and patent applications necessary to develop our products. We have licensed from Non-Invasive Monitoring one granted patent and know-how related to its glucose monitoring product. We have been jointly granted 10 patents with Altea, and have jointly applied with Altea for eight additional U.S. patents and several international patents related to this device. We have license agreements with Georgia Tech Research Corporation that give us the right to use two patents related to our diabetes detection product, and we previously licensed this proprietary technology to Roche, although there is currently no development activity on this product. We have assigned our patents and patent licenses related solely to the Bili*Chek* system to Respironics as a part of the asset sale of that product, and have licensed from Respironics other patents that have dual uses for use in the infant jaundice management field. We now have eight pending patent applications in the U.S. and 11 granted U.S. patents related to insulin delivery. In addition, we have several granted and pending international patents and patent applications related to insulin delivery.

One or more of the patents held directly by us or licensed by us from third parties, including the disposable components to be used in connection with our glucose monitoring product and the infant jaundice product, as well as processes used in the manufacture of our products, may be successfully challenged, invalidated or circumvented. Additionally, we may not otherwise be able to rely on these patents. In addition, we cannot be sure that competitors, many of whom have substantial resources and have made substantial investments in competing technologies, will not

seek to apply for and obtain patents that prevent, limit or interfere with our ability to make, use and sell our products either in the United States or in foreign markets. If any of our patents are successfully challenged, invalidated or circumvented or our rights or ability to manufacture our products were to be proscribed or limited, our ability to continue to manufacture and market our products could be adversely affected, which would likely have a material adverse effect upon our business, financial condition and results of operations.

COMPETITION

The medical device industry in general, and the markets for insulin delivery, glucose monitoring, diabetes detection tests and cervical cancer detection in particular, are intensely competitive. If successful in our product development, we will compete with other providers of insulin delivery systems, personal glucose monitors, diabetes detection tests, and cancer detection products.

A number of competitors, including Johnson & Johnson, Inc. (which owns Lifescan, Inc.), Roche, Bayer AG (which owns Miles Laboratories, Inc.) and Abbott (which owns MediSense, Inc. and recently purchased TheraSense, Inc.) are currently marketing traditional single-use glucose monitors. These monitors are widely accepted in the health care industry and have a long history of effective use. Furthermore, a number of companies have developed products for alternate site glucose monitoring, including Johnson & Johnson, Roche and Abbott. Some competitors to our continuous glucose monitoring product, including Abbott and Medtronic MiniMed, have developed products and have received, or expect to receive, some form of FDA clearance. Accordingly, competition in this area is expected to increase.

Competition in cancer detection is also intense. Current screening systems, primarily the Pap smear and colposcopy, are well established and pervasive. Improvements and new technologies for cervical cancer detection, such as Thin-Prep from Cytyc Corporation and Human Papilloma Virus testing from Digene Corporation, have introduced other new competitors. In addition, there are other companies attempting to develop products using forms of biophotonic technologies in cervical cancer detection such as MediSpectra. We will be required to develop devices that are more accurate, easier to use or less costly to administer to create devices that have a competitive advantage.

The competition in the insulin delivery business includes existing manufacturers of insulin meters that utilize insulin delivery infusion sets that will compete with our products. The U.S. market for insulin pumps is dominated by MiniMed, a subsidiary of Medtronic, Inc. In addition, there are companies that produce and market insulin delivery pens, syringes and other devices, which will compete with our products.

GOVERNMENT REGULATION

All of our products are or will be regulated as medical devices. Medical device products are subject to rigorous FDA and other governmental agency regulations in the United States and may be subject to regulations of relevant foreign agencies. Noncompliance with applicable requirements can result in import detentions, fines, civil penalties, injunctions, suspensions or losses of regulatory approvals or clearances, recall or seizure of products, operating restrictions, denial of export applications, governmental prohibitions on entering into supply contracts, and criminal prosecution. Failure to obtain regulatory approvals or the restriction, suspension or revocation of regulatory approvals or clearances, as well as any other failure to comply with regulatory requirements, would have a material adverse effect on our business, financial condition and results of operations.

The FDA regulates the clinical testing, manufacture, labeling, packaging, marketing, distribution and record keeping for these products to ensure that medical products distributed in the United States are safe and effective for their intended uses. The Clinical Chemistry Branch of the FDA's Division of Clinical Laboratory Devices has traditionally been the reviewing branch for blood-based personal glucose monitoring products. The Clinical Chemistry and Clinical Toxicology Devices Panel is an external advisory panel that provides advice to the Clinical Chemistry Branch regarding devices that it reviews. This panel meets from time to time and provides comments on testing guidelines.

There may be new FDA policies or changes in FDA policy that are materially adverse to us.

In the United States, medical devices are classified into one of three classes on the basis of the controls deemed necessary by the FDA to reasonably assure the devices' safety and effectiveness. Under FDA regulations, Class I devices are subject to general controls, such as labeling requirements, notification to the FDA before beginning marketing activities and adherence to specified good manufacturing practices. Class II devices are subject to general and special controls, such as performance standards, surveillance after beginning market activities, patient registries, and FDA guidelines. Generally, Class III devices are those which must receive premarket approval from the FDA to ensure their safety and effectiveness. Examples of Class III devices include life-sustaining, life-supporting and implantable devices, as well as new devices that have not been found substantially equivalent to legally marketed Class I or II devices.

A medical device manufacturer may seek clearance to market a medical device by filing a 510(k) premarket notification with the FDA if the manufacturer establishes that a newly developed device is substantially equivalent to either a device that was legally marketed before May 28, 1976, the date upon which the Medical Device Amendments of 1976 were enacted, or to a device that is currently legally marketed and has received 510(k) premarket clearance from the FDA. The 510(k) premarket notification must be supported by appropriate information, which may include data from clinical trials to establish the claim of substantial equivalence. Commercial distribution of a device for which a 510(k) premarket notification is required can begin only after the FDA issues an order finding the device to be substantially equivalent to a legally marketed device. The FDA has recently been requiring a more rigorous demonstration of substantial equivalence than in the past. It generally takes from four to 12 months from the date of submission to obtain clearance of a 510(k) submission, but it may take substantially longer. The FDA may determine that a proposed device is not substantially equivalent to a legally marketed device, or may require additional information.

An adverse determination or a request for additional information could delay the market introduction of new products that fall into this category, which could have a material adverse effect on our business, financial condition and results of operations. For any of our products that are or will be cleared through the 510(k) process, modifications or enhancements that could significantly affect the safety or effectiveness of the device or that constitute a major change to the intended use of the device will require new 510(k) premarket notification or approval of an application for premarket approval. Any modified device for which a new 510(k) premarket notification is required cannot be distributed until 510(k) clearance is obtained. We may not be able to obtain 510(k) clearance in a timely manner, if at all, for any devices or modifications to devices for which we may submit a 510(k).

An application for premarket approval must be submitted if a proposed device is not substantially equivalent to a legally marketed Class I or Class II device or for specified Class III devices. The application must contain valid scientific evidence to support the safety and effectiveness of the device, which includes the results of clinical trials, all relevant bench tests, and laboratory and animal studies. The application must also contain a complete description of the device and its components, as well as a detailed description of the methods, facilities and controls used for its manufacture, including, where appropriate, the method of sterilization and its assurance. In addition, the application must include proposed labeling, advertising literature and any required training methods. If human clinical trials of a device are required in connection with an application and the device presents a significant risk, the sponsor of the trial is required to file an application for an investigational device exemption before beginning human clinical trials. Usually, the manufacturer or distributor of the device is the sponsor of the trial. The application must be supported by data, typically including the results of animal and laboratory testing, and a description of how the device will be manufactured. If the application is reviewed and approved by the FDA and one or more appropriate institutional review boards, human clinical trials may begin at a specified number of investigational sites with a specified number of patients. If the device presents a non-significant risk to the patient, a sponsor may begin clinical trials after obtaining approval for the study by one or more appropriate institutional review boards, but FDA approval for the commencement of the study is not required. Sponsors of clinical trials are permitted to sell those devices distributed in the course of the study if the compensation received does not exceed the costs of manufacture, research, development

and handling. A supplement for an investigational device exemption must be submitted to and approved by the FDA before a sponsor or an investigator may make a significant change to the investigational plan that may affect the plan's scientific soundness or the rights, safety or welfare of human subjects.

Upon receipt of a premarket approval application, the FDA makes a threshold determination as to whether the application is sufficiently complete to permit a substantive review. If the FDA makes this determination, it will accept the application for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the application. An FDA review of a premarket approval application generally takes one to two years from the date the application is accepted for filing. However, this review period is often significantly extended by requests for more information or clarification of information already provided in the submission. During the review period, the submission may be sent to an FDA-selected scientific advisory panel composed of physicians and scientists with expertise in the particular field. The FDA scientific advisory panel issues a recommendation to the FDA that may include conditions for approval. The FDA is not bound by the recommendations of the advisory panel. Toward the end of the premarket approval application review process, the FDA will conduct an inspection of the manufacturer's facilities to ensure that the facilities are in compliance with applicable good manufacturing practice. If the FDA evaluations of both the premarket approval application and the manufacturing facilities are favorable, the FDA will issue a letter. This letter usually contains a number of conditions, which must be met in order to secure final approval of the application. When those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue an approval letter authorizing commercial marketing of the device for specified indications and intended uses.

The premarket approval application review process can be expensive, uncertain and lengthy. A number of devices for which a premarket approval has been sought have never been approved for marketing. The FDA may also determine that additional clinical trials are necessary, in which case the premarket approval may be significantly delayed while trials are conducted and data is submitted in an amendment to the premarket approval application. Modifications to the design, labeling or manufacturing process of a device that has received premarket approval may require the FDA to approve supplements or new applications. Supplements to a premarket approval application often require the submission of additional information of the same type required for an initial premarket approval, to support the proposed change from the product covered by the original application. The FDA generally does not call for an advisory panel review for premarket approval supplements. If any premarket approvals are required for our products, we may not be able to meet the FDA's requirements or we may not receive any necessary approvals. Failure to comply with regulatory requirements would have a material adverse effect on our business, financial condition and results of operations.

Regulatory approvals and clearances, if granted, may include significant labeling limitations and limitations on the indicated uses for which the product may be marketed. In addition, to obtain regulatory approvals and clearances, the FDA and some foreign regulatory authorities impose numerous other requirements with which medical device manufacturers must comply. FDA enforcement policy strictly prohibits the marketing of approved medical devices for unapproved uses. Any products we manufacture or distribute under FDA clearances or approvals are subject to pervasive and continuing regulation by the FDA. The FDA also requires us to provide it with information on death and serious injuries alleged to have been associated with the use of our products, as well as any malfunctions that would likely cause or contribute to death or serious injury.

The FDA requires us to register as a medical device manufacturer and list our products. We are also subject to biannual inspections by the FDA and state agencies acting under contract with the FDA to confirm compliance with good manufacturing practice. The good manufacturing practice regulations require that we manufacture our products and maintain documents in a prescribed manner with respect to manufacturing, testing, quality assurance and quality control activities. The FDA also has promulgated final regulatory changes to these regulations that require, among other things, design controls and maintenance of service records. These changes will increase the cost of complying with good manufacturing practice requirements.

We are also subject to a variety of other controls that affect our business. Labeling and promotional activities are subject to scrutiny by the FDA and, in some instances, by the Federal Trade Commission. The FDA actively enforces regulations prohibiting marketing of products for unapproved users. We are also subject, as are our products, to a variety of state and local laws and regulations in those states and localities where our products are or will be marketed. Any applicable state or local regulations may hinder our ability to market our products in those regions. Manufacturers are also subject to numerous federal, state and local laws relating to matters such as safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances. We may be required to incur significant costs to comply with these laws and regulations now or in the future. These laws or regulations may have a material adverse effect on our ability to do business.

International sales of our products are subject to the regulatory requirements of each country in which we market our products. The regulatory review process varies from country to country. The European Union has promulgated rules that require medical products to affix the CE mark, an international symbol of adherence to quality assurance standards and compliance with applicable European medical directives. The appropriate ISO certification is one of the CE mark requirements. We currently have ISO 13485:1996 (CMDCAS) certification and the CE mark, and we must upgrade to ISO 13485:2003 by June 2006 to maintain this status, which allows us to sell our SimpleChoice medical devices in the countries of the European Union. Losing the right to affix the CE mark could have a material adverse effect on our business, financial condition and results of operations.

We will be responsible for obtaining and maintaining regulatory approvals for our products. The inability or failure to comply with the varying regulations or the imposition of new regulations would materially adversely affect our business, financial condition and results of operations.

EMPLOYEES AND CONSULTANTS

As of December 31, 2004 we had 30 regular employees and consulting or other contract arrangements with 13 additional persons to provide services to us on a full- or part-time basis. Of the 43 people employed or engaged by us, 21 are engaged in research and development activities, 4 are engaged in sales and marketing activities, 3 are engaged in clinical testing and regulatory affairs, 5 are engaged in manufacturing and development, and 10 are engaged in administration and accounting. If we are successful in our effort to finance the cancer detection business separately, approximately 6 of these employees are expected to transfer to the new subsidiary. No employees are covered by collective bargaining agreements, and we believe we maintain good relations with our employees.

Our ability to operate successfully and manage our potential future growth depends in significant part upon the continued service of key scientific, technical, managerial and finance personnel, and our ability to attract and retain additional highly qualified personnel in these fields. None of these key employees has an employment contract with us, nor are any of these employees covered by key person or similar insurance, except our chief executive officer. In addition, if we, possibly together with future collaborative partners, are able to successfully develop and commercialize our products, we will need to hire additional scientific, technical, marketing, managerial and finance personnel. We face intense competition for qualified personnel in these areas, many of whom are often subject to competing employment offers. The loss of key personnel or our inability to hire and retain additional qualified personnel in the future could have a material adverse effect on our business, financial condition and results of operations.

RISK FACTORS

The following risk factors should be considered carefully in addition to the other information presented in this report. This report contains forward-looking statements that involve risks and uncertainties. Our actual results may differ significantly from the results discussed in the forward-looking statements. Factors that might cause such differences include, but are not limited to, the following:

ALTHOUGH IT IS LIKELY THAT WE WILL BE REQUIRED TO RAISE ADDITIONAL FUNDS WITHIN THE NEXT NINE MONTHS, THERE IS NO ASSURANCE THAT SUCH FUNDS CAN BE RAISED ON TERMS THAT WE WOULD FIND ACCEPTABLE, OR AT ALL.

Management believes that the funds from expected SimpleChoice working capital financing (accounts receivable and inventory), sales, research and development reimbursement, contracts and royalty income will not be sufficient to support planned operations beyond November 30, 2005. Management has implemented operating actions to reduce cash requirements and is evaluating various options to raise additional funds, including pursuing loans using certain assets as collateral. In addition, if we experience delays, are unable to finance our SimpleChoice working capital, are unable to meet our sales projections or if we are unable to satisfactorily resolve our differences with Abbott regarding the schedule of payments for the redemption of the redeemable preferred shares, we will need to raise an even greater amount of additional funds. Any required additional funding may not be available on terms attractive to us or at all.

IF WE CANNOT OBTAIN ADDITIONAL FUNDS OR ACHIEVE PROFITABILITY, WE MAY NOT BE ABLE TO CONTINUE AS A GOING CONCERN.

Because we must execute our plans to launch our remaining products in our SimpleChoice product line and grow our revenues to sufficiently higher levels to generate profits and cash flow from operations, there exists doubt about our ability to continue as a going concern. Management believes funds from expected SimpleChoice working capital financing (accounts receivable and inventory), sales, research and development reimbursement, contracts and royalty income will not be sufficient to support planned operations through November 30, 2005. Therefore it will be necessary to raise additional funds. If we have delays or are unable to meet our financial plan, we will have to raise additional funds before November 30, 2005. There can be no assurance that we will be able to raise these additional funds. If we do not secure additional funding when needed, we will be unable to conduct all of our product development efforts as planned, which may cause us to alter our business plan in relation to the development of all of our products. Even if we obtain additional funding, we will need to achieve profitability thereafter.

Our management has implemented reductions in operating expenditures and reductions in development activities. We are managing the development of our cervical cancer detection technology with the support of contracts and grants we have secured. We are managing the development of our glucose monitoring and ISF technology through a contract with the NIAAA while we also look for a collaborative partner to fund the development of our glucose monitoring technology. However, there can be no assurance that we will be able to successfully implement or continue these plans or that we will be able to do so without significantly harming our business, financial condition or results of operations.

WE DO NOT HAVE A LONG OPERATING HISTORY, WHICH MAKES IT DIFFICULT FOR YOU TO EVALUATE OUR BUSINESS.

Because limited historical information is available on our revenue trends and operations, it will be difficult for you to evaluate our business. Our historical financial information also includes the sale of our Bili*Chek* product line in March of 2003. Our prospects must be considered in light of the substantial risks, expenses, uncertainties and difficulties encountered by entrants into the medical device industry, which is characterized by increasing intense competition and a high failure rate.

WE HAVE A HISTORY OF LOSSES, AND WE EXPECT LOSSES TO CONTINUE.

We have never been profitable, and we have had operating losses since our inception. We expect our operating losses to continue as we continue to expend substantial resources to launch the SimpleChoice product line, to complete development of our products, obtain regulatory clearances or approvals, build our marketing, sales, manufacturing and finance organizations, and conduct further research and development. To date, we have engaged primarily in research and development efforts. The further development and commercialization of our products will require substantial

development, regulatory, sales and marketing, manufacturing and other expenditures. We have only generated limited revenues from product sales. Our accumulated deficit was about $60.8 million at December 31, 2004.

IF WE CANNOT OBTAIN ADDITIONAL FUNDS WHEN NEEDED, WE WILL NOT BE ABLE TO IMPLEMENT OUR BUSINESS PLAN.

We will require substantial additional capital to develop our products, including completing product testing and clinical trials, obtaining all required regulatory approvals and clearances, beginning and scaling up manufacturing, and marketing our products. We have historically funded a significant portion of our activities through collaborative partners. We are seeking a collaborative partner for our glucose monitoring technology and are seeking separate funding for our cervical cancer program. Any failure to find a collaborative partner to fund our operations and capital expenditures, or our inability to obtain capital through other sources, would limit our ability to grow and operate as planned. Even if we do enter into an agreement with a collaborative partner, the obligations of a collaborative partner to fund our expenditures will be largely discretionary and will depend on a number of factors, including our ability to meet specified milestones in the development and testing of the relevant product. We may not be able to meet these milestones, or our collaborative partner may not continue to fund our expenditures.

We bear responsibility for all aspects of our SimpleChoice product line and our cervical cancer product, which are not being developed with a collaborative partner. In addition to any funds that may be provided by collaborative partners, we will be required to raise additional funds through public or private financing, additional collaborative relationships or other arrangements. We believe that our existing capital resources, and the funding from various sources will be sufficient to satisfy our funding requirements through November 2005, but may not be sufficient to fund our planned operations to the point of commercial introduction of our glucose monitoring products, our cervical cancer detection product or our full line of diabetes products. Any failure to agree on a collaborative arrangement or to achieve adequate funding in a timely fashion would delay our development programs and could lead to abandonment of one or more of our development initiatives. Any required additional funding may not be available on terms attractive to us, or at all. To the extent we cannot obtain additional funding, our ability to continue to develop and introduce products to market will be limited. Any additional equity financing may be dilutive to stockholders, and debt and certain types of equity financing, if available, may involve restrictive covenants or other provisions that would limit how we conduct our business or finance our operations.

WE ARE NO LONGER LISTED ON A NASDAQ MARKET, WHICH MAY AFFECT OUR ABILITY TO OBTAIN ADDITIONAL FUNDS WHEN NEEDED AND THE LIQUIDITY AND VALUE OF OUR COMMON STOCK.

The Nasdaq National Market and SmallCap Market have minimum listing requirements. In December 2002, we applied for and moved to the Nasdaq SmallCap Market because we could not continue to meet the National Market listing requirements. A key requirement is the level of stockholders' equity. At June 30, 2003, our stockholders' equity was below the minimum Nasdaq requirements and, as a result, our stock was delisted from the SmallCap Market. Our stock is now listed on the OTC Bulletin Board, which does not have similar listing requirements. As a result, our ability to raise additional capital may be impacted and the liquidity and value of our common stock may be impaired.

OUR SIMPLECHOICE PRODUCT LINE HAS A DIFFERENT FOCUS THAN OUR NON-INVASIVE PRODUCTS, AND WE WILL BE REQUIRED TO DEVELOP NEW CAPABILITIES TO SUCCESSFULLY MANAGE THESE OPERATIONS.

Prior to our acquisition of the SimpleChoice product line, it did not have revenues or significant assets. The SimpleChoice product line is also significantly different from our historical product line, which focuses on non-invasive and minimally invasive products. We shipped small quantities of our first SimpleChoice products to be introduced to the market beginning in 2003. SimpleChoice's future business will depend on our ability to develop more fully various functions that will enable it to operate as planned, including manufacturing, marketing, and

distribution capabilities. There can be no assurance that we, or our subsidiary doing business as SimpleChoice, will be able to successfully develop or implement these functions.

OUR ABILITY TO SELL OUR PRODUCTS IS CONTROLLED BY GOVERNMENT REGULATIONS, AND WE MAY NOT BE ABLE TO OBTAIN ANY NECESSARY CLEARANCES OR APPROVALS.

The design, manufacturing, labeling, distribution and marketing of medical device products are subject to extensive and rigorous government regulation, which can be expensive and uncertain and can cause lengthy delays before we can begin selling our products.

IN THE UNITED STATES, THE FOOD AND DRUG ADMINISTRATION'S ACTIONS COULD DELAY OR PREVENT OUR ABILITY TO SELL OUR PRODUCTS, WHICH WOULD ADVERSELY AFFECT OUR GROWTH AND STRATEGY PLANS.

In order for us to market our products in the United States, we must obtain clearance or approval from the FDA. We cannot be sure:

- that we, or any collaborative partner, will make timely filings with the FDA;
- that the FDA will act favorably or quickly on these submissions;
- that we will not be required to submit additional information or perform additional clinical studies;
- that we would not be required to submit an application for premarket approval, rather than a 510(k) premarket notification submission as described below; or
- that other significant difficulties and costs will not be encountered to obtain FDA clearance or approval.

The SimpleChoice products to date have been introduced subject to 510(k) premarket notification submissions. There have been 27 510(k) premarket notification submissions related to SimpleChoice approved by the FDA through December 31, 2004.

The premarket approval process is more rigorous and lengthier than the 510(k) clearance process for premarket notifications; it can take several years from initial filing and require the submission of extensive supporting data and clinical information. For example, Roche, as part of our collaborative agreement, had previously filed a premarket notification for our diabetes detection product, which was withdrawn when the FDA indicated that this product should be submitted for premarket approval, including submission of clinical study data. We do not have any premarket notifications or premarket approval applications pending, but our cervical cancer detection product and, we believe our glucose monitoring products will require submission of applications for premarket approval.

The FDA may impose strict labeling or other requirements as a condition of its clearance or approval, any of which could limit our ability to market our products. Further, if we wish to modify a product after FDA clearance of a premarket notification or approval of a premarket approval application, including changes in indications or other modifications that could affect safety and efficacy, additional clearances or approvals will be required from the FDA. Any request by the FDA for additional data, or any requirement by the FDA that we conduct additional clinical studies or submit to the more rigorous and lengthier premarket approval process, could result in a significant delay in bringing our products to market and substantial additional research and other expenditures. Similarly, any labeling or other conditions or restrictions imposed by the FDA on the marketing of our products could hinder our ability to effectively market our products. Any of the above actions by the FDA could delay or prevent altogether our ability to market and distribute our products. Further, there may be new FDA policies or changes in FDA policies that could be adverse to us.

IN FOREIGN COUNTRIES, INCLUDING EUROPEAN COUNTRIES, WE ARE ALSO SUBJECT TO GOVERNMENT REGULATION, WHICH COULD DELAY OR PREVENT OUR ABILITY TO SELL OUR PRODUCTS IN THOSE JURISDICTIONS.

In order for us to market our products in Europe and some other international jurisdictions, we and our distributors and agents must obtain required regulatory registrations or approvals. We must also comply with extensive regulations regarding safety, efficacy and quality in those jurisdictions. We may not be able to obtain the required regulatory registrations or approvals, or we may be required to incur significant costs in obtaining or maintaining any regulatory registrations or approvals we receive. Delays in obtaining any registrations or approvals required to market our products, failure to receive these registrations or approvals, or future loss of previously obtained registrations or approvals would limit our ability to sell our products internationally. For example, international regulatory bodies have adopted various regulations governing product standards, packaging requirements, labeling requirements, import restrictions, tariff regulations, duties and tax requirements. These regulations vary from country to country. In order to sell our products in Europe, we must maintain ISO 13485:1996 certification and CE mark certification, which is an international symbol of quality and compliance with applicable European medical device directives. Failure to receive or maintain ISO 13485:1996 certification or CE mark certification or other international regulatory approvals would prevent us from selling in some countries in the European Union. We must upgrade to ISO 1345:2003 by June 2006 to retain the CE mark.

EVEN IF WE OBTAIN CLEARANCE OR APPROVAL TO SELL OUR PRODUCTS, WE ARE SUBJECT TO ONGOING REQUIREMENTS AND INSPECTIONS THAT COULD LEAD TO THE RESTRICTION, SUSPENSION OR REVOCATION OF OUR CLEARANCE.

We, as well as our potential collaborative partners, will be required to adhere to applicable FDA regulations regarding good manufacturing practice, which include testing, control, and documentation requirements. We are subject to similar regulations in foreign countries. Ongoing compliance with good manufacturing practice and other applicable regulatory requirements will be strictly enforced in the United States through periodic inspections by state and federal agencies, including the FDA, and in international jurisdictions by comparable agencies. Failure to comply with these regulatory requirements could result in, among other things, warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure to obtain premarket clearance or premarket approval for devices, withdrawal of approvals previously obtained, and criminal prosecution. The restriction, suspension or revocation of regulatory approvals or any other failure to comply with regulatory requirements would limit our ability to operate and could increase our costs.

OUR SUCCESS LARGELY DEPENDS ON OUR ABILITY TO OBTAIN AND PROTECT THE PROPRIETARY INFORMATION ON WHICH WE BASE OUR PRODUCTS.

Our success depends in large part upon our ability to establish and maintain the proprietary nature of our technology through the patent process, as well as our ability to license from others patents and patent applications necessary to develop our products. If any of our patents are successfully challenged, invalidated or circumvented, or our right or ability to manufacture our products were to be limited, our ability to continue to manufacture and market our products could be adversely affected. In addition to patents, we rely on trade secrets and proprietary know-how, which we seek to protect, in part, through confidentiality and proprietary information agreements. The other parties to these agreements may breach these provisions, and we may not have adequate remedies for any breach. Additionally, our trade secrets could otherwise become known to or be independently developed by competitors.

We have been issued, or have rights to, 39 U.S. patents (including those under license). In addition, we have filed for, or have rights to, 25 U.S. patents (including those under license) that are still pending. There are additional international patents and pending applications. One or more of the patents we hold directly or license from third parties, including those for the disposable components to be used with our glucose monitoring, infant jaundice and insulin delivery products, may be successfully challenged, invalidated or circumvented, or we may otherwise be unable to rely on these patents. These risks are also present for the process we use or will use for manufacturing our products. In addition, our competitors, many of whom have substantial resources and have made substantial investments in competing technologies, may apply for and obtain patents that prevent, limit or interfere with our ability to make, use and sell our products, either in the United States or in international markets.

The medical device industry has been characterized by extensive litigation regarding patents and other intellectual property rights. In addition, the United States Patent and Trademark Office may institute interference proceedings. The defense and prosecution of intellectual property suits, Patent and Trademark Office proceedings and related legal and administrative proceedings are both costly and time consuming. Moreover, we may need to litigate to enforce our patents, to protect our trade secrets or know-how, or to determine the enforceability, scope and validity of the proprietary rights of others. Any litigation or interference proceedings involving us may require us to incur substantial legal and other fees and expenses and may require some of our employees to devote all or a substantial portion of their time to the proceedings. An adverse determination in the proceedings could subject us to significant liabilities to third parties, require us to seek licenses from third parties or prevent us from selling our products in some or all markets. We may not be able to reach a satisfactory settlement of any dispute by licensing necessary patents or other intellectual property. Even if we reached a settlement, the settlement process may be expensive and time consuming, and the terms of the settlement may require us to pay substantial royalties. An adverse determination in a judicial or administrative proceeding or the failure to obtain a necessary license could prevent us from manufacturing and selling our products.

WE MAY NOT BE ABLE TO GENERATE SUFFICIENT SALES REVENUES TO SUSTAIN OUR GROWTH AND STRATEGY PLANS.

We expect that the majority of our revenues in 2005 will come from sales of our new SimpleChoice diabetes product line, which has just been launched and some of which is still in development. We sold our Bili*Chek* product line in 2003 and will not have continuing revenue from that source other than future earnout payments. Although we received a payment for earnout of about $1.0 million for 2004, there can be no assurance of additional payments. Our ability to collect additional earnout payments from the Bili*Chek* product line depends on Respironics' efforts in conducting that business. Our glucose monitoring product in development depends on finding a new partner and the collaborative partner's ability to generate sales of our products, which will provide us with revenue. We may not be able to successfully commercialize the products we are developing. Even if we do, we, together with any collaborative partners with respect to products being jointly developed, may not be able to sell sufficient volumes of our products to generate profits for us.

WE ARE DEVELOPING OUR CURRENT PRODUCT LINES INDEPENDENTLY FROM ANY COLLABORATIVE PARTNERS, WHICH WILL REQUIRE US TO ACCESS ADDITIONAL CAPITAL AND TO DEVELOP ADDITIONAL SKILLS TO PRODUCE, MARKET AND DISTRIBUTE THESE PRODUCTS.

We are independently finishing development, building up production capacity, launching, marketing and distributing our SimpleChoice line of products. These activities require additional resources and capital that we will need to secure. There is no assurance that we will be able to raise sufficient capital or attract and retain skilled personnel to enable us to finish development, launch and market these products. Thus, there can be no assurance that we will be able to commercialize all, or any, of these products.

BECAUSE OUR PRODUCTS, WHICH USE DIFFERENT TECHNOLOGY OR APPLY TECHNOLOGY IN MORE INNOVATIVE WAYS THAN OTHER MEDICAL DEVICES, ARE OR WILL BE NEW TO THE MARKET, WE MAY NOT BE SUCCESSFUL IN LAUNCHING OUR PRODUCTS AND OUR OPERATIONS AND GROWTH WOULD BE ADVERSELY AFFECTED.

Our products are based on new methods of glucose monitoring and cervical cancer detection and new methods of delivery for our diabetes products. If our products do not achieve significant market acceptance, our sales will be limited and our financial condition may suffer. Physicians and individuals may not recommend or use our products unless they determine that these products are an attractive alternative to current tests that have a long history of safe and effective use. To date, our products have been used by only a limited number of people, and few independent studies regarding our products have been published. The lack of independent studies limits the ability of doctors or consumers to compare our products to conventional products.

IF WE ARE UNABLE TO COMPETE EFFECTIVELY IN THE HIGHLY COMPETITIVE MEDICAL DEVICE INDUSTRY, OUR FUTURE GROWTH AND OPERATING RESULTS WILL SUFFER.

The medical device industry in general, and the markets in which we expect to offer products in particular, are intensely competitive. Many of our competitors have substantially greater financial, research, technical, manufacturing, marketing and distribution resources than we do and have greater name recognition and lengthier operating histories in the health care industry. We may not be able to effectively compete against these and other competitors. A number of competitors offer insulin infusion disposable products and a number of competitors are currently marketing traditional glucose monitors. These disposable products and monitors are widely accepted in the health care industry and have a long history of accurate and effective use. Further, if our products are not available at competitive prices, health care administrators who are subject to increasing pressures to reduce costs may not elect to purchase them. Also, a number of companies have announced that they are developing products that permit non-invasive and less invasive glucose monitoring. Accordingly, competition in this area is expected to increase.

Furthermore, our competitors may succeed in developing, either before or after the development and commercialization of our products, devices and technologies that permit more efficient, less expensive non-invasive and less invasive glucose monitoring, insulin delivery, or cancer detection. It is also possible that one or more pharmaceutical or other health care companies will develop therapeutic drugs, treatments or other products that will substantially reduce the prevalence of diabetes or otherwise render our products obsolete.

WE HAVE LITTLE MANUFACTURING EXPERIENCE, WHICH COULD LIMIT OUR GROWTH.

We do not have manufacturing experience that would enable us to make products in the volumes that would be necessary for us to achieve significant commercial sales, and we rely upon our suppliers. In addition, we may not be able to establish and maintain reliable, efficient, full scale manufacturing at commercially reasonable costs, in a timely fashion. Difficulties we encounter in manufacturing scale-up, or our failure to implement and maintain our manufacturing facilities in accordance with good manufacturing practice regulations, international quality standards or other regulatory requirements, could result in a delay or termination of production. To date, our manufacturing activities have included our former Bili*Chek* and Bili*Cal* products, as well as the diabetes detection product on a limited scale. We are having our initial product offerings in the SimpleChoice insulin delivery area manufactured by a third party. We may decide to manufacture these products ourselves in the future or may decide to manufacture products that are currently under development in this market segment. Companies often encounter difficulties in scaling up production, including problems involving production yield, quality control and assurance, and shortages of qualified personnel.

SINCE WE RELY ON SOLE SOURCE SUPPLIERS FOR SEVERAL OF OUR PRODUCTS, ANY FAILURE OF THOSE SUPPLIERS TO PERFORM WOULD HURT OUR OPERATIONS.

Several of the components used in our products are available from only one supplier, and substitutes for these components are infeasible or would require substantial modifications to our products. Any significant problem experienced by one of our sole source suppliers may result in a delay or interruption in the supply of components to us until that supplier cures the problem or an alternative source of the component is located and qualified. Any delay or interruption would likely lead to a delay or interruption in our manufacturing operations. For our products which require premarket approval, the inclusion of substitute components could require us to qualify the new supplier with the appropriate government regulatory authorities. Alternatively, for our products which qualify for premarket notification, the substitute components must meet our product specifications.

Since we are relying on third party manufacturing for our initial product offerings in the SimpleChoice product line, we are dependent upon those parties for product supply. Any delay in initiating production or scaling production to higher volumes could result in delays of product introduction, or create lower availability of product than our expectations. These delays could lead to lower revenue achievement and additional cash requirements for us.

OUR LIMITED MARKETING AND SALES EXPERIENCE MAKES OUR SIMPLECHOICE REVENUE UNCERTAIN.

We are responsible for marketing our SimpleChoice product line. We have relatively limited experience in marketing or selling medical device products and only have a five person marketing and sales staff. In order to successfully continue to market and sell our products, we must either develop a marketing and sales force or expand our arrangements with third parties to market and sell our products. We may not be able to successfully develop an effective marketing and sales force, and we may not be able to enter into and maintain marketing and sales agreements with third parties on acceptable terms, if at all. If we develop our own marketing and sales capabilities, we will compete with other companies that have experienced and well-funded marketing and sales operations. If we enter into a marketing arrangement with a third party, any revenues we would receive will be dependent on this third party, and we will likely be required to pay a sales commission or similar compensation to this party. The efforts of these third parties for the marketing and sale of our products may not be successful.

BECAUSE WE OPERATE IN AN INDUSTRY WITH SIGNIFICANT PRODUCT LIABILITY RISK, AND WE HAVE NOT SPECIFICALLY INSURED AGAINST THIS RISK, WE MAY BE SUBJECT TO SUBSTANTIAL CLAIMS AGAINST OUR PRODUCTS.

The development, manufacture and sale of medical products entail significant risks of product liability claims. We currently have no product liability insurance coverage beyond that provided by our general liability insurance. Accordingly, we may not be adequately protected from any liabilities, including any adverse judgments or settlements, we might incur in connection with the development, clinical testing, manufacture and sale of our products. A successful product liability claim or series of claims brought against us that results in an adverse judgment against or settlement by us in excess of any insurance coverage could seriously harm our financial condition or reputation. In addition, product liability insurance is expensive and may not be available to us on acceptable terms, if at all.

THE AVAILABILITY OF THIRD-PARTY REIMBURSEMENT FOR OUR PRODUCTS IS UNCERTAIN, WHICH MAY LIMIT CONSUMER USE AND THE MARKET FOR OUR PRODUCTS.

In the United States and elsewhere, sales of medical products are dependent, in part, on the ability of consumers of these products to obtain reimbursement for all or a portion of their cost from third-party payors, such as government and private insurance plans. Any inability of patients, hospitals, physicians and other users of our products to obtain sufficient reimbursement from third-party payors for our products, or adverse changes in relevant governmental policies or the policies of private third-party payors regarding reimbursement for these products, could limit our ability to sell our products on a competitive basis. We are unable to predict what changes will be made in the reimbursement methods used by third-party health care payors. Moreover, third-party payors are increasingly challenging the prices charged for medical products and services, and some health care providers are gradually adopting a managed care system in which the providers contract to provide comprehensive health care services for a fixed cost per person. Patients, hospitals and physicians may not be able to justify the use of our products by the attendant cost savings and clinical benefits that we believe will be derived from the use of our products, and therefore may not be able to obtain third-party reimbursement.

Reimbursement and health care payment systems in international markets vary significantly by country and include both government sponsored health care and private insurance. We may not be able to obtain approvals for reimbursement from these international third-party payors in a timely manner, if at all. Any failure to receive international reimbursement approvals could have an adverse effect on market acceptance of our products in the international markets in which approvals are sought.

OUR SUCCESS DEPENDS ON OUR ABILITY TO ATTRACT AND RETAIN SCIENTIFIC, TECHNICAL, MANAGERIAL AND FINANCE PERSONNEL.

Our ability to operate successfully and manage our future growth depends in significant part upon the continued service of key scientific, technical, managerial and finance personnel, as well as our ability to attract and retain additional highly qualified personnel in these fields. We may not be able to attract and retain key employees when necessary, which would limit our operations and growth. None of our key employees have an employment contract with us, nor are any of these employees, except our chief executive officer, covered by key person or similar insurance. In addition, if we are able to successfully develop and commercialize our products, we will need to hire additional scientific, technical, marketing, managerial and finance personnel. We face intense competition for qualified personnel in these areas, many of whom are often subject to competing employment offers.

ADJUSTMENTS TO THE CONVERSION PRICE FOR OUR SERIES A CONVERTIBLE PREFERRED STOCK AND THE EXERCISE PRICE FOR CERTAIN OF OUR WARRANTS WILL DILUTE THE OWNERSHIP INTERESTS OF OUR EXISTING STOCKHOLDERS.

On March 26, 2004, we entered into agreements with investors to raise capital in a private placement of our series A convertible preferred stock and warrants. As a result of this private placement transaction, there are 488,669 shares of our series A convertible preferred stock outstanding convertible into 4,886,690 shares of our common stock at a conversion price of $1.50 per share, plus warrants exercisable for 2,443,345 shares of our common stock at an exercise price of $1.65 per share and warrants exercisable for 2,443,345 shares of our common stock at an exercise price of $2.25 per share. The conversion price for the series A convertible preferred stock and the exercise price for the warrants may be lowered under certain price adjustment provisions in the certificate of designations relating to the series A convertible preferred stock and the warrants if we issue common stock at a per share price below the then conversion price for the series A convertible preferred stock.

Subject to certain exceptions, if we issue shares of our common stock, or securities convertible into or exercisable for shares of our common stock, at a price per share less than the then effective conversion price for the series A convertible preferred stock, the conversion price for the series A convertible preferred stock will be adjusted to equal such lower per share consideration, the exercise price for the warrants with the $1.65 exercise price will be adjusted to equal such lower per share consideration, and the exercise price for the warrants with the $2.25 exercise price will be adjusted to equal 125% of such lower per share consideration. A reduction in the conversion price for the series A convertible preferred stock and the exercise price for the warrants may result in the issuance of a significant number of additional shares of our common stock upon conversion of the series A convertible preferred stock and the exercise of the warrants, respectively. The downward adjustment of the conversion price for the series A convertible preferred stock and the exercise price for these warrants would result in dilution in the value of the shares of our outstanding common stock and the voting power represented thereby.

WE ARE SIGNIFICANTLY INFLUENCED BY OUR DIRECTORS, EXECUTIVE OFFICERS AND THEIR AFFILIATED ENTITIES.

Our directors, executive officers and entities affiliated with them beneficially owned an aggregate of about 20% of our outstanding common stock as of February 29, 2005. These stockholders, acting together, would be able to exert significant influence on substantially all matters requiring approval by our stockholders, including the election of directors and the approval of mergers and other business combination transactions.

ITEM 2. DESCRIPTION OF PROPERTY

On August 1, 2004, we moved our offices from 6025A Unity Drive, Norcross, GA 30071 to 4955 Avalon Ridge Parkway, Suite 300, Norcross, Georgia 30071. Our current lease is for 28,427 square feet, which comprise our administrative, research and development, marketing and production facilities and our planned manufacturing facility and expires in July 2009. We do not invest in real estate or mortgage directly or indirectly.

ITEM 3. LEGAL PROCEEDINGS

In January 2003, we announced that we had given notice that we were initiating actions required to terminate our research, development and license agreement with Abbott to jointly develop a continuous glucose monitor. We further announced that we were withholding payment due in connection with the redemption of the shares of our preferred stock held by Abbott as an offset to claims that have also been made by us under our agreement with Abbott. Under the terms of the preferred stock, 162,500 shares of our preferred stock were required to be redeemed on December 30, 2002 at $10 per share. We also announced that we had asked the U.S. patent office to resolve an inventorship dispute involving issued Abbott patents related to Abbott's glucose monitoring technology. Abbott exercised its right to terminate the agreement on January 7, 2003. We filed a Form 8-K on March 10, 2003, announcing that we had reached a settlement with Abbott Laboratories regarding the disputes in connection with the prior termination of the parties' Research & Development and License Agreement and the election of Abbott to have shares of our preferred stock redeemed, with 162,500 shares to be redeemed on December 30, 2002 at $10 per share, plus accrued dividends, and the remaining shares to be redeemed no later than January 31, 2004. Under the settlement, which included mutual releases, we agreed to make quarterly payments to Abbott during 2003 and 2004 and end of the year lump sum payments in 2005 and 2006 to redeem 425,000 preferred shares and to pay approximately $1.4 million, $1.8 million and $1.9 million for 2004, 2005 and 2006, respectively. We paid $400,000 and $300,000 to Abbott pursuant to the settlement, respectively, during 2003 and 2004. Under the settlement, neither party admitted any liability or wrongdoing.

We were in negotiations with Abbott from early 2003 through February of 2005 regarding the patent issue described in Note 4 to the Financial Statements and the payments of "outstanding accrued dividends" and "redemption" under the settlement. On July 15, 2004 Abbott sent us a letter notifying us that we were in default on two separate payments due in 2004 and demanding payment. On July 22, 2004 we responded that we were seeking to resolve the patent issues and renegotiate the payment terms. On October 25, 2004, Abbott sent us a letter notifying us that we were in default on an additional payment due in 2004 and demanding payment. We again responded that we expect to continue to seek to resolve the patent issues and renegotiate the payment terms.

On February 17, 2005, we initiated litigation against Abbott Laboratories relating to our dispute over intellectual property issues. We are represented in this matter under a contingency fee arrangement. In connection with the dispute and litigation, the Company has not made the four payments totaling $1.4 million due in 2004. On April 6, 2005, Abbott notified us that it considered the Company in default on a total of $1.4 million.

On October 14, 2004, Respironics notified us that an allegation of patent infringement related to the Bili*Chek* product had been made and that it believed that this matter was subject to the indemnification provision of our asset sale agreement (see Note 5) which could require the Company to pay a portion of the costs related to certain infringement of intellectual property brought within two years of the closing date. On April 20, 2005 Respironics and SpectRx entered into a settlement agreement resolving the matter. In connection with the settlement and in exchange for Respironics agreeing to pay the earnout payments early due for 2004, Respironics will withhold approximately $ 275,000 of earnout payments due for 2006.

On February 22, 2005, we received a letter of patent infringement from ICU Medical related to our SimpleChoice product line. We received the letter shortly after meeting with the CEO of ICU Medical, Inc. to discuss partnering opportunities related to SimpleChoice. Management believes that the infringement claim is without merit and has provided information to ICU Medical, Inc. that supports our position.

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

None.

PART II

ITEM 5. MARKET FOR COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND SMALL BUSINESS ISSUER PURCHASES OF EQUITY SECURITIES

Market for Common Stock-

As of August 13, 2003, our common stock is traded on the OTC Bulletin Board under the ticker symbol SPRX. From December 12, 2002 to August 13, 2003, our common stock was traded on the Nasdaq SmallCap Market under the same symbol. The number of record holders of our common stock at March 22, 2005 was 165.

The high and low last sales prices for the calendar years 2003 and 2004 as reported by Nasdaq and OTC Bulletin Board are as follows:

	2003		**2004**	
	HIGH	LOW	**HIGH**	**LOW**
First Quarter	$1.76	$1.07	**$2.30**	**$1.76**
Second Quarter	$3.45	$1.40	**$2.14**	**$1.50**
Third Quarter	$2.59	$0.85	**$1.80**	**$0.41**
Fourth Quarter	$2.21	$0.90	**$0.83**	**$0.34**

We have not paid any dividends since our inception and do not intend to pay any dividends in the foreseeable future.

On March 6, 2003, we sold our Bili*Chek* Non-invasive Bilirubin Analyzer product line and related assets to Respironics. Respironics had previously been the exclusive U.S. licensee and distributor of the product line. The base cash purchase price was $4 million with an additional $1 million to be paid based upon completion of product development work, which was paid in November 2003, and up to an additional $6.25 million to be paid in earnout payments over the next five years based upon the achievement of certain operating results. We recognized a gain on the Sale of Assets to Respironics of $4.2 million during 2003.

Recent Sales of Unregistered Securities-

The Company issued 10,417 shares of common stock on July 8, 2003 valued at $16,000 in satisfaction of minimum royalty payments related to the company's exclusive rights to certain licensed patents and issued 43,647 shares of common stock on November 7, 2003 to RJ Falkner valued at $52,000 in payment for certain investor relation services and 60,000 shares of common stock on August 25, 2003 and October 25, 2003 to Stonegate Securities valued at $80,000 for advisory services in connection with the private placement of securities. These shares were privately placed as unregistered sales of equity securities. In issuing these shares we relied upon the exemption from registration under section 4(2) of the Securities Act of 1933.

We issued warrants to a group of lenders, including two of our officers, in conjunction with a debt financing, monthly from July 30, 2003 to March 26, 2004. Those warrants, which are exercisable for an aggregate of 270,000 shares at $2.25 per share and 500,000 shares at $2.00 per share, were issued in reliance upon the exemption of registration under Section 4(2) of the Securities Act of 1933.

ITEM 6. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL OR PLAN OF OPERATION

Statements in this report which express "belief", "anticipation" or "expectation" as well as other statements which are not historical facts are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from historical results or anticipated results, including those set forth under "Risk Factors" in this "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this report. Examples of these uncertainties and risks include, but are not limited to:

- access to sufficient debt or equity capital to meet our operating and financial needs;
- the effectiveness and ultimate market acceptance of our products;
- whether our products in development will prove safe, feasible and effective;
- whether and when we or any potential strategic partners will obtain approval from the FDA and corresponding foreign agencies;
- our need to achieve manufacturing scale-up in a timely manner, and our need to provide for the efficient manufacturing of sufficient quantities of our products;
- the lack of immediate alternate sources of supply for some critical components of our products;
- our patent and intellectual property position;
- the need to fully develop the marketing, distribution, customer service and technical support and other functions critical to the success of our product lines; and
- the dependence on potential strategic partners or outside investors for funding, development assistance, clinical trials, distribution and marketing of some of our products.

The following discussion should be read in conjunction with our financial statements and notes thereto included elsewhere in this report.

OVERVIEW

We were incorporated on October 27, 1992, and since that date, we raised capital through the sale of preferred stock, issuance of debt securities, public and private sales of common stock, funding from collaborative arrangements and sales of assets. Following our initial funding in early 1993, we immediately began research and development activities with the objective of commercializing less invasive diagnostic, screening and monitoring products. As part of our initial business strategy, we established arrangements with leading medical device companies for the development, commercialization and introduction of some of our products. We developed collaborative arrangements with Abbott, Welch Allyn and Respironics for our continuous glucose monitoring, cervical cancer detection product and Bili*Chek* products, respectively. In 2003, we sold our Bili*Chek* business to our collaborative partner, Respironics, and agreed to terminate our collaborative relationships with Abbott for our continuous glucose monitoring product. In 2002, we and Welch Allyn, terminated our collaborative relationship for our cervical cancer product. In addition, we have a collaborative agreement with Roche related to a diabetes detection product, although there is currently little development activity with regard to this product, and we expect no revenue from this product in the foreseeable future. We are pursuing a collaborative partner for our glucose monitoring product, and we may seek to establish strategic relationships with other leading companies for the development, commercialization, and introduction of additional products, such as our cervical cancer detection product, if we believe that is the best path to commercialization for those products.

In December 2001, we acquired 100% of the common stock of Sterling Medivations, Inc. (doing business as SimpleChoice), a company formed for the purpose of developing and marketing insulin-delivery products.

We have a limited operating history upon which our prospects can be evaluated. Our prospects must be considered in light of the substantial risks, expenses and difficulties encountered by entrants into the medical device industry. This industry is characterized by an increasing number of participants, intense competition and a high failure rate. We have experienced operating losses since our inception, and, as of December 31, 2004, we have an accumulated deficit of

about $60.8 million. To date, we have engaged primarily in research and development efforts. We first generated revenues from product sales in 1998, but do not have significant experience in manufacturing, marketing or selling our products. Our development efforts may not result in commercially viable products, and we may not be successful in introducing our products. Moreover, required regulatory clearances or approvals may not be obtained in a timely manner, or at all. Our products may not ever gain market acceptance, and we may not ever generate significant revenues or achieve profitability. The development and commercialization of our products will require substantial development, regulatory, sales and marketing, manufacturing and other expenditures. We expect our operating losses to continue through at least May 2006 as we continue to expend substantial resources to introduce our SimpleChoice product line, further the development of our products, obtain regulatory clearances or approvals, build our marketing, sales, manufacturing and finance organizations and conduct further research and development.

Our product revenues to date have been limited. For 2003, a majority of our product line revenues came from our Bili*Chek* product line, which we sold in March 2003. For 2004, a majority of our revenues came from our SimpleChoice insulin delivery product and research contract revenue. We expect that the majority of our revenue in 2005 will be derived from sales of our SimpleChoice insulin delivery products. Our other products for glucose monitoring and cervical cancer detection are still in development.

We currently sell our insulin delivery products to distributors, which then distribute our products, resulting in revenues from distributor sales. The channels for sales of our glucose monitoring and cervical cancer detection are not currently established. The royalties that we expect to receive from Respironics depend on sales of the applicable products. We, or our collaborative partner, if we secure one, may not be able to sell sufficient volumes of our products to generate substantial revenues or profits for us.

CRITICAL ACCOUNTING POLICIES

Our material accounting policies, which we believe are the most critical to an investor's understanding of our financial results and condition, are discussed below. Because we are still early in our enterprise development, the number of these policies requiring explanation are limited. As we begin to generate increased revenue from different sources, we expect that the number of applicable policies and complexity of the judgments required will increase.

Currently, our policies that could require critical management judgment are in the areas of revenue recognition, reserves for accounts receivable and inventory valuation.

Revenue Recognition: We recognize revenue from sales of products or services upon shipment of products or delivery of services. We also recognize milestone revenue from collaborative partners when a milestone has been accomplished or when we, and our partner, agree that a milestone has been reached.

Reserve for Accounts Receivable: We estimate losses from the inability of our customers to make required payments and periodically review the payment history of each of our customers, as well as their financial condition, and revise our reserves as a result.

Inventory Valuation: Inventories are valued at the lower of cost or market value and have been reduced by an allowance for excess and obsolete inventories.

RESULTS OF OPERATIONS

Comparison of 2004 and 2003

General. Loss attributable to common stockholders increased to about $14.4 million or $1.26 per share in 2004 from about $2.9 million, or $0.26 per share, in 2004. A significant portion of the 2004 loss was a result of financing activity

and impairment of intangible assets. During 2004, we recognized a deemed dividend of $4.6 million from issuance of shares of our series A convertible preferred stock. We also recognized $871,000 in interest expense for the value of the warrants issued in conjunction with a bridge loan in 2004. We recognized an expense of $3.2 million in 2004 for the impairment of intangible assets related to our SimpleChoice business. In comparison, during 2003, we had recognized a gain of $4.2 million on gain of sale of assets related to our infant jaundice business. Offsetting those charges, we also realized a $831,000 reduction in certain operating expenses in 2004, compared to 2003, primarily the result of lower cancer expenditures in research and development, as well as lower marketing expenses and general and administrative expenses. We expect net losses to continue. We have no agreements that provide for additional milestone revenue for the foreseeable future, so we are dependent upon the growth of product revenue to provide funding for both the SimpleChoice product line as well as our development programs. It is possible that our product revenue will not meet our expectations. If this were to happen, future net losses could increase as a result of spending increases necessary to complete research, development and clinical trials of our products, begin sales and marketing efforts and establish manufacturing capabilities. This would delay some of our product development activities. In addition, we expect net losses to continue as we begin sales and marketing efforts and establish marketing capabilities for our SimpleChoice product line.

Revenue and Cost of Product Sales. Total revenues decreased to about $1.1 million from about $1.6 million in 2003. The decrease was due to the reduction in Bili*Chek* revenue due to the sale of assets related to that business in the first quarter of 2003 and to a change in the way we accounted for earnout payments related to the Bili*Chek* disposable. Cost of product sales remained approximately the same at $1.1 million from about $1.1 million for the year ended December 31, 2003. Cost of product sales was reduced also as a result of the asset sale.

Research and Development Expenses. Research and development expenses decreased to about $3.6 million from about $4.1 million in 2003 primarily due to a decrease of about $335,000 in development expense related to our SimpleChoice products. We expect research and development expenses to decrease in the future based upon lower expected expenditures on our glucose monitoring and cervical cancer programs, and continued expenditures as we develop our SimpleChoice insulin delivery products and also due to reimbursements from the NCI grants.

Sales and Marketing. Sales and marketing expenses remained approximately the same at $679,000 as compared to $735,000 in 2003. The slight decrease in expense was due to the elimination of Bili*Chek* marketing expense as a result of the sale of that product line in March 2003. We expect sales and marketing expenses to increase in the future as we expand our marketing and sales activities for our SimpleChoice product line in support of the product launches expected to occur in 2005.

General and Administrative Expense. General and administrative expense decreased to about $1.9 million from about $2.2 million for 2003. The significant reductions were in investor relations ($145,000), lower salary expense ($79,000), lower consulting fees ($205,000) and lower miscellaneous expenses ($101,000), offset by increased rent ($171,000).

Net Interest Expense and Other Income. Net interest expense in 2004 was $920,000 as compared to $328,000 in 2003. The increase is primarily due to the recognition of interest expenses of $871,000 relating to the warrants issued in conjunction with the bridge loan financing during the first quarter of 2004. Other income decreased to $815,000 in 2004 from $4.2 million in 2003. The major portion of the income was due to the gain on sale of assets related to the infant jaundice business, net of the cost of assets sold in 2003.

LIQUIDITY AND CAPITAL RESOURCES

We have financed our operations since inception primarily through private sales of debt and private and public sales of our equity securities. At December 31, 2004, we had cash of approximately $247,000 and negative working capital of approximately $2.4 million.

In August 2002, Abbott notified us that it intended to redeem the $4.25 million of redeemable convertible preferred stock eligible to be redeemed. Under a settlement agreement related to the termination of our collaborative arrangement with Abbott, we agreed with Abbott to redeem the 425,000 shares of preferred stock on an extended schedule through 2006, but are not currently doing so (see Item 3. - Legal Proceedings).

Our major cash flows in the year ended December 31, 2004 consisted of cash out-flows of $5.4 million from operations (including $9.4 million of operating loss, of which $3.2 million was an impairment charge) and an addition of $205,000 to property and equipment and $5.8 million cash in flow from the issuance of shares of our series A convertible preferred stock during March 2004.

We have historically also received funds from milestones and reimbursements from our collaborative partners. About 30% of our funds inflow has come from these sources prior to 2003. We are currently seeking a collaborative partner for our glucose monitoring technology. Until we reach an agreement with a new partner, we expect no such milestones or reimbursements. We have been successful in securing grants to support some of our programs, including grants totaling over $2.5 million, to be spent over two years, from the NCI for our cervical cancer program. In March 2003, we sold the assets related to the Bili*Chek* products, as non-core assets, for $4.0 million of cash at closing, an additional $1.0 million upon completion of some component replacement engineering work, which we received in November 2003, and up to $6.25 million in earnout payments based upon the future performance of the business as conducted by the buyer, Respironics. We received $655,000 of earnout in the first quarter of 2004 for performance during 2003 and we have received approximately $1.0 million of earnout in 2005 for performance during 2004.

The Company announced on March 26, 2004 that it had completed a private placement to institutional and private investors of a new series of its preferred stock and of warrants to purchase shares of its common stock. Proceeds to the company were approximately $7.3 million, prior to the payment of placement agent fees and expenses.

Of the proceeds, approximately $1.0 million represents the conversion of debt into securities issued in the financing.

Subject to customary adjustments, the preferred stock is convertible into, and the warrants are exercisable for, 4,886,690 and 4,886,690 shares of common stock, respectively. The warrants are currently exercisable. One-half of the warrants permit the holders to purchase shares of SpectRx common stock at a price of $1.65 per share, and the other half, at $2.25 per share.

We will be required to raise additional funds through public or private financing, additional collaborative relationships or other arrangements in addition to those sources. We believe our existing and available capital resources will be sufficient to satisfy our funding requirements through November 2005, excluding any amounts due on redeemable convertible preferred stock during the year, although we need to secure a collaborative partner to move forward with our continuous glucose program and will need funding in addition to that provided by grants to complete our pivotal trials for our cervical cancer product in a timely fashion. We are evaluating various options to further reduce our cash requirements to operate at a reduced rate, as well as options to raise additional funds, including loans using certain assets as collateral.

We currently invest our excess cash balances primarily in short-term, investment-grade, interest-bearing obligations or direct or guaranteed obligations of the U.S. government until such funds are utilized in operations. Substantial capital will be required to develop our products, including completing product testing and clinical trials, obtaining all required United States and foreign regulatory approvals and clearances, and commencing and scaling up manufacturing and marketing our products. Any failure of our collaborative partners to fund our development expenditures, or our inability to obtain capital through other sources, would have a material adverse effect on our business, financial condition and results of operations.

New Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board (FASB) issued a revised Statement of Financial Accounting Standards (SFAS) No. 123, "Shares Based Payment." The revised SFAS No. 123 requires that the fair value of stock options be recorded in the results of operations beginning no later than July 1, 2005. Upon adoption of the revised standard, prior awards are charged to expense under the prior rules, and awards after adoption are charged to expense under the revised rules. We have not determined the effect of the new standard on our earnings; however, expense under the new standard could be somewhat higher. The effect of adopting the new rules on reported diluted earnings per share is dependent on the number of options granted in the future; the terms of those awards and their fair values, and therefore, the effect on diluted earnings per share could change. We expect to adopt the revised rules on July 1, 2005, but have not determined whether we will adopt them prospectively, or retrospectively to January 1, 2005. See footnote 6 under stock options to the consolidated financial statements for assumptions used by management in calculating the fair value of employee stock options.

In November 2004, the FASB issued SFAS No. 151, "Inventory Costs." This statement clarifies the accounting for the abnormal amount of idle facilities expense, freight, handling costs and wasted material. This statement requires that those items be recognized as current-period expense. In addition, the statement requires that allocation of fixed overhead to the cost of conversion be based on the normal capacity of the production facilities. This statement is effective for inventory costs incurred after December 31, 2005. Adoption of this statement will not have a material effect on our financial statements.

Off-Balance Sheet Arrangements

We have no material off-balance sheet arrangements; no special purpose entities; nor activities that include non-exchange-traded contracts accounted for at fair value.

Impairment of Long-Lived Assets

Effective January 1, 2002 we adopted SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." These new rules on asset impairment supersede SFAS No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of." The adoption of SFAS No. 144 did not have a material effect on our financial statements for the year ended December 31, 2003.

We evaluate our long-lived assets for impairment annually or when events or changes in circumstances indicate that the carrying amount of such assets may not be fully recoverable. We evaluate the recoverability of long-lived assets not held for sale by measuring the carrying amount of the assets against the estimated undiscounted future cash flows associated with them. As of December 31, 2004, the Company has experienced delays in expanding the line of products which are covered by the patents, underlying the intangibles. While our projection for the sales of these products over the life of these patents is significant, the range of outcomes regarding the product introductions is highly subjective, such that the full recoverability of the carrying value of the intangible assets is questionable. Although management believes that the SimpleChoice products continue to have substantial potential for the foreseeable future, the range of estimates of the undiscounted cash flows required us to treat these assets as impaired for accounting purposes and we recorded an impairment charge of $3,211,000 for the period ended December 31, 2004.

ITEM 7. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
SpectRx, Inc.

We have audited the accompanying consolidated balance sheet of SpectRx, Inc. and subsidiaries (the "Company") as of December 31, 2004, and the related consolidated statements of operations, changes in capital and cash flows for each of the years ended December 31, 2004 and 2003. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements enumerated above present fairly, in all material respects, the consolidated financial position of SpectRx, Inc. and subsidiaries as of December 31, 2004, and the consolidated results of their operations and their consolidated cash flows for each of the years ended December 31, 2004 and 2003, in conformity with U.S. generally accepted accounting principles.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses and has a negative working capital position and a capital deficit. The Company is also in default on payments due under its settlement with Abbott Laboratories, Inc. regarding its redeemable preferred stock agreement. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Eisner LLP

New York, New York
March 19, 2005

SPECTRX, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEET
DECEMBER 31, 2004
(IN THOUSANDS EXCEPT PAR VALUE)

ASSETS	2004
CURRENT ASSETS:	
Cash and equivalents	$247
Accounts receivable, net of allowance for doubtful accounts of $11	1,336
Inventories	363
Other current assets	203
Total current assets	2,149
NONCURRENT ASSETS:	
Property and equipment, net	573
Other assets	83
Total noncurrent assets	656
TOTAL ASSETS	**$2,805**
LIABILITIES AND CAPITAL DEFICIT	
CURRENT LIABILITIES:	
Accounts payable	$566
Accrued liabilities	491
Redeemable convertible preferred stock and accrued dividends in default	1,436
Redeemable convertible preferred stock, current portion	1,711
Advance payable	381
Total current liabilities	4,585
LONG TERM LIABILITIES	
	1,634
Redeemable convertible preferred stock and accrued dividends	
Dividends payable - series A	281
TOTAL LIABILITIES	6,500
COMMITMENTS & CONTINGENCIES	
CAPITAL DEFICIT:	
Series A preferred stock, $.001 par value; 5,000 shares authorized,	
489 shares issued and outstanding convertible	
(Liquidation preference $7,330)	4,559
Common stock, $.001 par value; 50,000 shares authorized,	
11,604 shares issued and 11,557 outstanding	12
Additional paid-in capital	52,688
Treasury stock, at cost	(104)
Deferred compensation	(42)

Accumulated deficit	(60,808)
TOTAL CAPITAL DEFICIT	(3,695)
TOTAL LIABILITIES AND CAPITAL DEFICIT	**$2,805**

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

SPECTRX, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE YEARS ENDED DECEMBER 31, 2003 AND 2004

(In Thousands Except Per Share Data)

	2003	2004
REVENUE:		
NET REVENUE	$1,586	**$1,073**
COSTS AND EXPENSES:		
Cost of product sales	1,062	**1,109**
Research and development	4,108	**3,618**
Sales and marketing	735	**679**
General and administrative	2,150	**1,865**
Impairment of intangible assets	0	**3,211**
	8,055	**10,482**
Operating loss	(6,469)	**(9,409)**
INTEREST INCOME (EXPENSE), net	(328)	**(920)**
OTHER INCOME (EXPENSE), net	17	**0**
GAIN ON SALE OF BILI*CHEK* PRODUCT LINE	4,169	**1,090**
NET LOSS	(2,611)	**(9,239)**
PREFERRED STOCK DIVIDENDS	(299)	**(559)**
DEEMED DIVIDEND ON SERIES A PREFERRED	0	**(4,559)**
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	$(2,910)	**$(14,357)**
BASIC AND DILUTED NET LOSS PER SHARE ATTRIBUTABLE TO COMMON STOCKHOLDERS	$(0.26)	**$(1.26)**
BASIC AND DILUTED WEIGHTED AVERAGE SHARES OUTSTANDING	11,270	**11,393**

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

SPECTRX, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CHANGES IN CAPITAL
FOR THE YEARS ENDED DECEMBER 31, 2003 AND 2004

(In Thousands)

	Preferred Stock		Common Stock		Additional Paid-In Capital	Treasury Stock	Deferred Compensation	Notes Receivable From Officers	Accumulated Deficit	TOTAL
	Shares	**Amount**	Shares	Amount						
BALANCE, December 31, 2002	**100**	**$1,185**	**11,263**	**$11**	**$47,913**	**$(38)**	**$(88)**	**$(47)**	**$(48,100)**	**$836**
Dividends	0	60	0	0	0	0	0	0	0	60
Amortization of deferred compensation	0	0	0	0	0	0	49	0	0	49
Employee stock purchase plan	0	0	24	0	27	0	0	0	0	27
Options issued for services	0	0	0	0	54	0	(30)	0	0	24
Issuance of common stock for services	0	0	114	0	149	0	0	0	0	149
Warrants	0	0	0	0	192	0	0	0	0	192
Note receivable	0	0	(35)	0	0	(57)	0	47	0	(10)
Dividends on preferred stock	0	0	0	0	0	0	0	0	(299)	(299)
Net loss	0	0	0	0	0	0	0	0	(2,611)	(2,611)
BALANCE, December 31, 2003	**100**	**1,245**	**11,366**	**11**	**48,335**	**(95)**	**(69)**	**0**	**(51,010)**	**(1,583)**
Dividends	0	60	0	0	0	0	0	0	0	60
Amortization of deferred	0	0	0	0	0	0	37	0	0	37

compensation										
Employee stock purchase plan	0	0	36	0	23	0	0	0	0	23
Options issued for services	0	0	0	0	4	0	(10)	0	0	(6)
Exercise of stock options	0	0	16	0	27	0	0	0	0	27
Issuance of warrants	0	0	0	0	870	0	0	0	0	870
Shares received for exercise of stock options	0	0	0	0	0	(9)	0	0	0	(9)
Dividends on preferred stock	0	0	0	0	0	0	0	0	(559)	(559)
Issuance of series A preferred stock and warrants	489	4,559	0	0	2,125	0	0	0	0	6,684
Conversion of preferred stock into common stock	(100)	(1,305)	139	1	1,304	0	0	0	0	H
Net loss	0	0	0	0	0	0	0	0	(9,239)	(9,239)
BALANCE, December 31, 2004	**489**	**$4,559**	**11,557**	**$12**	**$52,688**	**$(104)**	**$(42)**	**$0**	**$(60,808)**	**$(3,695)**

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

SPECTRX, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED DECEMBER 31, 2003 AND 2004

(In Thousands)

	2003	2004
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(2,611)	$(9,239)
Adjustments to reconcile net loss to net cash used in operating activities		
Gain on sale of Bili*Chek* product line	(4,169)	(815)
Depreciation and amortization	507	442
Loss on retirement of property and equipment	72	0
Amortization of deferred compensation	49	37
Impairment of intangible assets	0	3,211
Issuance of options and warrants	356	795
Changes in operating assets and liabilities:		
Accounts receivable	(16)	230
Inventories	(270)	(125)
Other current assets	(454)	1,047
Other assets	0	(83)
Accounts payable	268	(267)
Accrued liabilities	432	(647)
Total adjustments	(3,225)	3,825
Net cash used in operating activities	(5,836)	(5,414)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Net proceeds from sale of Bilicheck product line	4,449	0
Additions to property and equipment	(202)	(205)
Net cash provided by (used in) investing activities	4,247	(205)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Issuance of common stock, net of issuance costs	27	28
Proceeds from (repayment of) notes payable	1,017	(17)
Issuance of series A preferred stock and warrants	0	5,766
Dividends paid on redeemable convertible preferred stock	(400)	(300)
Repayment from related parties	31	0
Repayment of notes receivable from officers	16	0
Net cash provided by financing activities	691	5,477

NET DECREASE IN CASH AND CASH EQUIVALENTS	(898)	(142)
CASH AND EQUIVALENTS, beginning of year	1,287	389
CASH AND EQUIVALENTS, end of year	$389	$247
CASH PAID FOR:		
Interest	$113	$33
SUPPLEMENTAL SCHEDULE OF NONCASH INVESTING AND FINANCING ACTIVITIES:		
Dividends in the form of preferred stock and redeemable convertible preferred stock	$299	$278
Series A preferred stock dividends payable	0	281
Common stock issued for royalty payments	$18	$0
Common stock issued to consultants	$104	$0

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

SPECTRX, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2003 AND 2004

1. ORGANIZATION, BACKGROUND, AND BASIS OF PRESENTATION

SpectRx, Inc. together with its wholly-owned subsidiaries, Sterling Medivations, Inc. ("Sterling")

and Guided Therapeutics, Inc., ("Guided Therapeutics") (collectively the "Company"), each a Delaware corporation, is a medical technology company developing and providing products for the diabetes and non-invasive diagnostic markets. The Company uses its technologies to develop insulin delivery products, minimally-invasive fluid sampling procedures, and cervical cancer detection products. The Company's products are based upon a variety of proprietary technologies. The technologies employed in its insulin delivery products, including those under development, are designed to deliver insulin more comfortably and effectively to people who have diabetes. The Company's products in development for glucose monitoring and cervical cancer detection are based upon its proprietary biophotonic technologies.

On March 6, 2003, SpectRx sold the assets related to its infant jaundice detection products to Respironics, Inc. (Respironics), its former collaborative partner in these products (see Note 5).

On November 6, 2003, the Company established a subsidiary, Guided Therapeutics, Inc., to be used to develop its cancer detection technology.

Basis of Presentation

The Company's prospects must be considered in light of the substantial risks, expenses and difficulties encountered by entrants into the medical device industry. This industry is characterized by an increasing number of participants, intense competition and a high failure rate. The Company has experienced net losses since its inception, and, as of December 31, 2004, it had an accumulated deficit of approximately $61 million. Through December 31, 2004, the Company has devoted substantial resources to research and development efforts. The Company first generated revenue from product sales in 1998, but does not have significant experience in manufacturing, marketing or selling its products. The Company's development efforts may not result in commercially viable products, and it may not be successful in introducing its products. Moreover, required regulatory clearances or approvals may not be obtained in a timely manner, or at all. The Company's products may not ever gain market acceptance, and the Company may not ever achieve levels of revenue to sustain further development costs and support ongoing operations and achieve profitability. A portion of the Company's cash flow is expected to be derived from earnout payments that it will receive from Respironics resulting from sales of the infant jaundice products. The payments depend on sales of these products. The Company intends to market its insulin delivery products directly to distributors and other customers. The Company and Respironics may not be able to sell sufficient product volumes to generate substantial payments. The development and commercialization of the Company's products will require substantial development, regulatory, sales and marketing, manufacturing and other expenditures. The Company expects operating losses to continue through at least 2005 as it continues to expend substantial resources to complete development of its products, obtain regulatory clearances or approvals, build its marketing, sales, manufacturing and finance organizations and conduct further research and development.

Going Concern

The Company's financial statements have been prepared and presented on a basis assuming it will continue as a going concern. At December 31, 2004, the Company's current liabilities exceeded current assets by approximately $ 2.4 million and it has a capital deficit due principally to its recurring losses from operations. The Company is in default on payments due under its settlement with Abbott regarding its redeemable preferred stock agreement. These factors raise substantial doubt about the Company's ability to continue as a going concern. Additional debt or equity financing will be required for the Company to continue as a going concern. The consolidated financial statements do not include any adjustments that might be required from the outcome of this uncertainty. If additional funds do not become available,

the Company has plans to curtail operations by reducing discretionary spending and staffing to levels to those supportable by available funding. Under certain circumstances, the Company may have to curtail its SimpleChoice operations and only pursue activities for which it has external financial support, such as the NIAAA contract and the National Cancer Institute funding. Management is working to obtain additional funds and believes those funds along with funds from sales and earnout revenues may be sufficient to support planned operations through December 31, 2005. However, there can be no assurance that the Company will be able to raise additional funds on acceptable terms, or at all, or achieve planned sales volumes.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant areas where estimates are used include impairment of long-lived assets and the allowance for doubtful accounts.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of SpectRx and its wholly owned subsidiaries, Sterling Medivations and Guided Therapeutics. All significant intercompany balances and transactions have been eliminated.

Cash Equivalents

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be a cash equivalent.

Inventories

Inventories are stated at the lower of cost or market using the first-in, first-out method. Inventories are summarized as follows at December 31, 2004 (in thousands):

Raw materials	$114
Finished goods	249
	$363

Advertising Costs

All advertising costs are expensed as incurred. Approximately $143,000 and $67,000 were charged to advertising expense for the years ended December 31, 2003 and 2004, respectively.

Property and Equipment

Property and equipment are recorded at cost. Depreciation is computed using the straight-line method over estimated useful lives of three to seven years. Expenditures for repairs and maintenance are expensed as incurred. Property and

equipment are summarized as follows at December 31, 2004 (in thousands):

Equipment	$2,209
Furniture and fixtures	279
	2,488
Less accumulated depreciation	(1,915)
Property and equipment, net	$573

Goodwill and Other Intangible Assets

The Company adopted Statement of Financial Accounting Standards (SFAS) No. 142, "*Goodwill and Other Intangible Assets*," on January 1, 2002. Under the new rules, goodwill and intangible assets with indefinite useful lives are not subject to amortization but will be subject to a periodic impairment assessment (at a minimum annually) by applying a fair-value-based test. Separate intangible assets that do not have an indefinite useful life will continue to be amortized over their useful lives (see Note 4).

Patent Costs (Principally Legal Fees)

Costs incurred in filing, prosecuting, and maintaining patents are expensed as incurred. Such costs aggregated approximately $579,000 and $297,000 in 2003 and 2004, respectively.

Clinical Trials

Costs associated with internal and contracted clinical trials are expensed as incurred as research and development expenses.

Accounts Receivable

Accounts receivable at December 31, 2004, included $1 million of amounts due from Respironics for the earnout ($750,000) and royalty payments ($280,000) under the asset sale agreement, for performance during 2004. With the exception of the Respironics receivables, there were no significant concentrations of credit risk in 2004. The Company performs periodic credit evaluations of its customers' financial condition and generally does not require collateral. The Company reviews all outstanding accounts receivable for collectability on a quarterly basis. An allowance for doubtful accounts is recorded for any amounts deemed uncollectible.

Accrued Liabilities

Accrued liabilities are summarized as follows at December 31, 2004 (in thousands):

Accrued compensation	$179
Other accrued expenses	312
Accrued liabilities	$491

Revenue Recognition

The Company records revenue from product sales at the time the product is shipped and title passes pursuant to the

terms of the agreement with the customer, the amount due from the customer is fixed or determinable, and collectability of the related receivable is reasonably assured. Revenue is recorded at gross, which includes all shipping and handling costs, and recognized only when the Company has no significant future performance obligation. Revenue from collaborative agreements is recorded when milestones have been met. Periodic license fees received under collaborative agreements related to future performance are deferred and recognized as income when earned. Although some of the Company's products have expiration dates, the company has not issued any credits or allowances for expired products. The Company did allow a onetime credit of $25,000 related to test marketing of a new product by a single distributor.

Research and Development

Research and development expenses consist of expenditures for research conducted by the Company and payments made under contracts with consultants or other outside parties. All research and development costs are expensed as incurred.

Income Taxes

The Company uses the liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Management provides valuation allowances against the deferred tax assets for amounts that are not considered more likely than not to be realized.

Stock Based Compensation

In December 2002, the Financial Accounting Standards Board (FASB) issued SFAS No. 148, "*Accounting for Stock-Based Compensation-Transition and Disclosure*." SFAS No. 148 amends SFAS No. 123, "*Accounting for Stock-Based Compensation*," to provide alternative methods of transition for a voluntary change to the fair value method of accounting for stock-based compensation. In addition, SFAS No. 148 amends the disclosure requirements of SFAS No. 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method on reported results.

The Company uses the intrinsic value method for valuing its employee/director awards of stock options and recording the related compensation expense, if any, in accordance with Accounting Principles Board (APB) Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations. No stock-based employee or director compensation cost for stock options is reflected in the net loss, as all options granted have exercise prices equal to the market value of the underlying common stock on the date of grant. The Company records compensation expense related to options granted to non-employees based on the fair value of the award.

The following table illustrates the effect on net loss attributable to common stockholders and net loss per share attributable to common stockholders, if the Company had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee compensation (in thousands):

	Years Ended December 31,	
	2003	**2004**
Net loss attributable to common stockholders, as reported	$(2,611)	$(14,357)
Add: Total stock based compensation expense included in the reported net loss		

	0
	0
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(673)
	(330)
Proforma net loss attributable to common stockholders	$(3,583)
	$(14,687)
Net loss attributable to common stockholders per share:	
Basic & Diluted - as reported	$(0.26)
	$(1.26)
Basic & Diluted - pro forma	$(0.32)
	$(1.29)

Fair Value of Financial Instruments

The book values of cash, accounts receivable, accounts payable, and other financial instruments approximate their fair values principally because of the short-term maturities of these instruments. The fair value of advance payable is estimated based on the amount payable to settle the liability. Under this method, the fair value of the Company's collaborative partner advance payable was not significantly different than the carrying value at December 31, 2004.

New Accounting Pronouncements

In December 2004, the FASB issued a revised SFAS No. 123(R), "*Shares Based Payment*." The revised SFAS No. 123 requires that the fair value of stock options be recorded in the results of operations commencing with the first annual period beginning after June 15, 2005. Upon adoption of the revised standard, prior awards are charged to

expense under the prior rules, and awards after adoption are charged to expense under the revised rules. The Company has not determined the effect of the new standard on its earnings; however, employee stock options expense under the new standard could be somewhat higher. The effect of adopting the new rules on reported diluted earnings (loss) per share attributable to common stockholders will be dependent on the number of options granted in the future, the terms of those awards and their fair values, and therefore, the effect on diluted earnings (loss) per share attributable to common stockholders could change. The Company will adopt the revised rules on January 1, 2006. (See Note 6 for assumptions used by management in calculating the fair value of employee stock options.)

In November 2004, the FASB issued SFAS No. 151, "*Inventory Costs*." This statement clarifies the accounting for the abnormal amount of idle facilities expense, freight, handling costs, and wasted material. This statement requires that those items be recognized as current-period expense. In addition, the statement requires that allocation of fixed overhead to the cost of conversion be based on the normal capacity of the production facilities. This statement is effective for inventory costs incurred after December 31, 2005. Adoption of this statement will not have a material effect on our financial statements.

3. ACQUISITION

On December 31, 2001, the Company purchased the outstanding shares of Sterling, now doing business as SimpleChoice. Sterling is a developer of innovative insulin delivery products for people with diabetes. The acquisition of Sterling expands the Company's diabetes business by adding a portfolio of FDA-cleared insulin delivery products, including consumables for the rapidly growing insulin pump market. As a result of the merger, the Company issued a total of 612,562 shares of the Company's common stock in exchange for all of the outstanding Sterling common stock and preferred stock and reserved 22,151 shares of our common stock for issuance upon exercise of stock options assumed in the merger with an estimated fair market value of $62,159. Following the merger, Sterling stockholders and option holders are entitled to receive up to an aggregate of 1,234,567 additional shares of our common stock in the future if the Sterling product line achieves specified financial goals, none of which have been achieved as of December 31, 2004. In connection with the acquisition of Sterling, the Company entered into employment agreements with four employees for terms that expired in June 2003. The excess of the cost over the estimated fair value of net tangible assets acquired amounts to approximately $4.1 million and has been included in intangible assets in the accompanying consolidated balance sheets. The $4.1 million purchase price excess has been allocated between patents and non-compete agreements. In addition, goodwill and a related deferred tax liability of approximately $1.6 million have been recorded to reflect taxable temporary differences existing at December 31, 2001. The acquisition has been accounted for as a purchase in accordance with SFAS No. 141, "*Accounting for Business Combinations*."

The final allocation of the purchase price of $4,291 and transaction costs of $385 arising from the acquisition is as follows (in thousands):

Net tangible assets acquired	$ 525
Patents	4,100
Non-compete and employment agreements	32
Deferred compensation	19

The remaining intangible assets related to the acquisition were determined to be impaired as of December 31, 2004 (see Note 4).

4. IMPAIRMENT LOSS

(In thousands)	Goodwill	Patents	Total
Balance at January 1, 2004	$57	$3,469	$3,526

Amortization recorded	0	(315)	(315)
Impairment loss	(57)	(3,154)	(3,211)
Balance at December 31, 2004	**$0**	**$0**	**$0**

The Company evaluates the recoverability of its long-lived assets not held for sale by measuring the carrying cost against the undiscounted future cash flows associated with them. The Company tested its intangible assets for impairment as of December 31, 2004. The Company has experienced delays in expanding the line of products which are covered by the patents underlying the intangibles. While the projected sales of these products over the life of these patents is significant, the range of outcomes regarding the cash flow assumptions attributable to the product introductions is highly subjective. Accordingly, the Company wrote off all the goodwill and remaining unamortized patent cost based on estimated fair value.

5. SALE OF ASSETS

On March 6, 2003, the Company sold its Bili*Chek* Non-invasive Bilirubin Analyzer product line and related assets to Respironics, Inc., pursuant to an asset sale agreement. Respironics had previously been the exclusive U.S. licensee and distributor of the product line. The base cash purchase price was $4 million with an additional $1 million to be paid based upon completion of product development work, and up to an additional $6.25 million to be paid based upon the incremental sales of certain disposable Bili*Chek* products over the next five years and upon the achievement of certain sales thresholds on an annual and cumulative basis over the next four years. The Company recognized a gain on the sale of assets to Respironics of $4.2 million during 2003. The sale of the Bili*Chek* products enables the Company to focus on expanding its diabetes and cancer detection businesses. Bili*Chek* revenue was approximately $2.5 million in 2003, and $0 in 2004, which represented 65% and 0%, respectively, of the Company's total revenue for these years.

6. STOCKHOLDERS' EQUITY

Common Stock

In June 2001, the Company completed two private placements. On June 4, 2001, the Company entered into an agreement with an investor, which invested about $9.5 million in SpectRx common stock before transaction expenses. On June 13, 2001, the Company entered into an agreement with another investor, which invested about $2.5 million in SpectRx common stock before transaction expenses. The financings consisted, in total, of sales of approximately 1.9 million shares of common stock and warrants to purchase 379,127 shares of common stock. Under the terms of the agreements, each share of common stock was sold at a price of $6.319 per share. The first transaction, funded on June 4, 2001, involved the private placement of 1.5 million shares of common stock. The second transaction, funded on June 13, 2001, involved the private placement of 395,633 shares of common stock. The combination of these two transactions resulted in net proceeds to SpectRx of approximately $11.2 million after transaction expenses. In addition, the purchasers of common stock also received warrants to purchase an aggregate of 379,127 shares of common stock for $9.8874 per share. These warrants expire on the fifth anniversary of their issuance date. The warrants are valued at approximately $1.7 million and are included in additional paid-in capital in the accompanying consolidated balance sheets.

In September 2001, the Company's board of directors approved a stock repurchase program whereby the Company can purchase up to $1.0 million of its common stock. As of December 31, 2001, the Company has purchased 6,700 shares of common stock at an average price of $5.66 per share. No shares were repurchased in 2003 and 2004. On March 31, 2005 the SpectRx board of directors terminated the stock repurchase program.

During November 2002, a former employee issued a note to the Company for the exercise of options for 21,000 shares of common stock in the amount of $16,000,which was non-interest bearing. The shares were held in escrow for collateral on the note. The note was payable upon sale of all the shares or December 31, 2003, whichever occurred earlier. During 2002, the Company recognized approximately $19,000 in compensation expense associated with the issuance of this note. The note was paid in full on December 19, 2003.

During the year ended December 2003, the Company issued 10,417 unregistered shares of common stock valued at $16,000 in satisfaction of minimum royalty payments related to the Company's exclusive rights to certain licensed patents and issued 103,647 shares of common stock valued at $132,000 for services. There were no shares issued for services during 2004.

Preferred Stock

The Company has authorized 5,000,000 shares of preferred stock with a $.001 par value. The board of directors has the authority to issue these shares and to fix dividends, voting and conversion rights, redemption provisions, liquidation preferences, and other rights and restrictions.

The board of directors has designated 525,000 shares of the preferred stock as redeemable convertible preferred stock. Dividends are payable in cash and accrue at the rate of $.60 per share per annum. Upon conversion, the Company, at its option, may pay accrued dividends in shares of common stock. During the years ended December 31, 2003 and 2004, the Company accrued dividends of $299,000 and $278,000, respectively. The preferred shares, together with any accrued but unpaid dividends, are convertible into common shares at the greater of $9.39 per share or the average of the closing sales price for 15 days prior and 15 days subsequent to the conversion and shares still outstanding automatically convert on December 31, 2004 at the then conversion rate. The shares were mandatorily redeemable at $10 per share, plus accrued but unpaid dividends, at the later of September 30, 2002 or 60 days subsequent to the date upon which the Company gives notice to Abbott of Abbott's right to redeem the shares. The shares have a liquidation preference of $10 per share, plus all accrued but unpaid dividends.

In November 1999, Abbott subscribed to 525,000 shares of Redeemable Convertible Preferred Stock for consideration of $5,250,000 of which $2,750,000 was received in November 1999 and $2,500,000 was received in January 2000.

In September 2001, the Company entered into an agreement with Abbott whereby Abbott waived its right to redeem 100,000 shares of its Redeemable Convertible Preferred Stock plus the related accrued but unpaid dividends. On December 31, 2004, these were automatically converted into 139,007 shares of our common stock at $9.39 per share.

In September 2002, Abbott delivered notice of its election to cause the redemption of the 425,000 shares of the remaining redeemable convertible preferred stock eligible for redemption. On March 7, 2003, the Company reached a settlement with Abbott regarding their disputes in connection with the prior termination of the parties' Research & Development and License Agreement and the election of Abbott to have shares of the Company's preferred stock held by Abbott redeemed by the Company. Abbott had previously elected to have 425,000 shares of the Company's preferred stock redeemed, with 162,500 shares to be redeemed on December 30, 2002 at $10.00 per share, plus accrued dividends, and the remaining shares to be redeemed no later than January 31, 2004. Under the settlement, the Company had agreed to make quarterly payments to Abbott during 2003 and 2004 and end of the year lump sum payments in 2005 and 2006 to redeem 425,000 preferred shares and to pay accrued dividends as to such shares. The Company paid $400,000 and $300,000 to Abbott during 2003 and 2004, respectively. The Company's yearly financial obligations to Abbott under the agreement are approximately $1.4 million, $1.8 million and $1.9 million for 2004, 2005 and 2006, respectively. Under the settlement, neither party admitted any liability or wrongdoing.

Dividends are accrued on the non-redeemable preferred stock at a rate of 6% per year and are included in the short-term portion and long-term portion of redeemable preferred stock in the accompanying consolidated balance sheets.

The Company was in negotiations with Abbott from early 2003 through February of 2005 regarding the patent issue (see Note 6) and the payments of "outstanding accrued dividends" and "redemption" under the settlement. Abbott notified the Company that it was in default on four separate payments due in 2004 and demanded payment.

On February 17, 2005, the Company initiated litigation against Abbott Laboratories relating to our dispute over intellectual property issues. The Company is represented in this matter under a contingency fee arrangement.

In connection with this matter, the Company has not paid $1.4 million of the amounts due in 2004.

Series A Convertible Preferred Stock

The Company had outstanding 488,669 shares of series A convertible preferred stock, having a stated value of $15.00 per share, held by 28 holders as of December 31, 2004. The holders of the series A convertible preferred stock are entitled to receive quarterly, at the end of each calendar quarter, commencing on and after March 26, 2006, out of funds legally available therefor, dividends per share at the per annum rate of $0.75 per share.

Each share of series A convertible preferred stock is convertible into the number of shares of common stock equal to the quotient obtained by dividing the sum of (i) $15.00 (as adjusted for changes in the series A convertible preferred stock by stock split, stock dividend, or the like occurring after March 26, 2004), referred to as the invested amount, plus (ii) all declared or accrued but unpaid dividends on such shares of series A convertible preferred stock, by the conversion price per share. The current per share conversion price is $1.50. The conversion price is subject to adjustment under certain circumstances to protect the holders of series A convertible preferred stock from dilution relative to certain issuances of common shares, or securities convertible into or exercisable for common shares. Subject to certain exceptions, if the Company issues common shares, or such other securities, at a price per share less than the then effective conversion price, the conversion price will be adjusted to equal such lower per share consideration.

The holders of the series A convertible preferred stock have the right of first refusal to purchase their pro-rata shares of any new securities, as defined in the certificate of designations governing the series A convertible preferred stock, that the Company may, from time to time, propose to sell and issue.

Issuing the series A convertible preferred stock triggered recognition of the value attributable to the beneficial conversion feature of the series A convertible preferred stock, which is deemed to be a dividend if the effective conversion price of the preferred stock is below market at the time of the transaction. The Company recognized a deemed dividend in the first quarter of 2004 of approximately $4.6 million recognizing the difference between issuance price and market price at issuance for the convertible instrument as a deemed dividend and increased stockholders' equity in the same amount, so that there was no net effect on the capital deficit.

In connection with the series A convertible preferred stock issuance, noteholders, at the request of the Company, exchanged $1.0 million of notes payable into series A convertible preferred stock**.**

Stock Options

The Company's 1995 Stock Plan (the "Plan"), as amended, provides a total of 1,928,572 shares of common stock, of which a total of 1,638,221 shares remain available. The Plan allows the issuance of incentive stock options, nonqualified stock options, and stock purchase rights. The exercise price of options is determined by the Company's board of directors, but incentive stock options must be granted at an exercise price equal to the fair market value of the Company's common stock as of the grant date. Options generally become exercisable over four years and expire ten years from the date of grant. At December 31, 2004, options to purchase 43,632 shares of common stock were available for future grant under the Plan.

In January 2002, the Company assumed the Sterling Medivations 2000 Stock Option Plan, with authorized shares of 93,765. No options have been exercised under this plan. At December 31, 2004, 6,090 options were outstanding under this plan, and 87,675 shares were still available for future grant, subject to the provisions of the Agreement and Plan of Merger between SpectRx and Sterling Medivations.

Stock option activity for each of the two years ended December 31 is as follows:

	Number of Options (including shares under the Sterling Plan)	Weighted Average Exercise Price Per Share
Outstanding, December 31, 2002	**1,541,060**	**$5.70**
Granted	244,000	1.35
Exercised	(4,480)	1.66
Cancelled	(186,491)	

	10.05
Outstanding, December 31, 2003	
	1,594,089
	4.53
Granted	
	177,000
	1.00
Exercised	
	(11,300)
	1.64
Canceled	
	(159,110)
	6.95
Outstanding, December 31, 2004	
	1,600,679
	$3.94

The following table sets forth the range of exercise prices, number of shares, weighted average exercise price, and remaining contractual lives by groups of similar price as of December 31, 2004:

	Options Outstanding		Options Exercisable	
Range of Exercise Prices	Number of Shares			

	Weighted Average Exercise Price	Weighted Average Contractual Life (years)
	Number of Shares	
	Weighted Average Price	
$ 0.21-$ 0.70		
		429,574
	$ 0.50	
	3.08	
		337,574
	$ 0.54	
$ 1.46-$ 4.26		
		445,044
	1.77	
	7.44	
		297,589
	1.90	
$ 5.00-$ 9.00		
		650,300
	6.85	
	6.22	
		579,356
	6.98	

$ 10.13-$ 16.50			
			75,761
		11.17	
		5.42	
			75,761
		11.17	
Total			
			1,600,679
		$ 3.94	
		5.68	
			1,290,280
		$ 4.37	

In December 2001, as a result of the acquisition of Sterling, the Company granted options to purchase 22,024 shares of common stock at an exercise price of $7.29 per share in exchange for all the outstanding options, vested and unvested, of Sterling. As of December 31, 2004, 6,090 of these shares have not been exercised.

The Company has elected to account for its stock-based compensation plan under APB Opinion No. 25, "*Accounting for Stock Issued to Employees,*" however, the Company has computed for pro forma disclosure purposes the value of all options granted for the years ended December 31 2003 and 2004, using the Black-Scholes option pricing model as prescribed by SFAS No. 123, "*Accounting for Stock-Based Compensation*," and using the following weighted average assumptions used for grants in 2003 and 2004:

	2003	2004
Risk-free interest rate	2.34%	3.33%
Expected dividend yield	0%	0%
Expected lives	4 years	4 years
Expected volatility	91%	101%

During the year ended December 31, 2004, the Company recorded as deferred compensation, $10,000 in connection with non qualified options to purchase 31,000 shares of common stock issued to a consultant. These options were issued in exchange for services to be provided. Approximately $357 was expensed in 2004 relating to these options.

Company shares reserved as of December 31, 2004 are as follows:

	Common Shares
Options issued and outstanding under employee incentive plans	1,600,679
Options under employee incentive plans	43,632
Shares under employee stock purchase plan	111,194
Warrant shares	6,501,153
Preferred shares	4,886,690
TOTAL	**13,143,348**

Employee Stock Purchase Plan

The Company has adopted an employee stock purchase plan under which the Company may issue up to 214,286 shares of common stock. Eligible employees may use up to 10% of their compensation to purchase, through payroll deductions, the Company's common stock at the end of each plan period for 85% of the lower of the beginning or ending stock price in the plan period. At December 31, 2004, there were 111,194 shares available for future issuance under this plan. During the year ended December 31, 2004, the Company sold 35,229 shares valued at $23,000, based upon 85% of market value as described under the provisions of the plan, which amount was included in stockholders equity.

7. INCOME TAXES

The Company has incurred net operating losses ("NOLs") since inception. As of December 31, 2004, the Company had net operating loss (NOL) carryforwards of approximately $55.6 million available to offset its future income tax liability. The NOL carryforwards begin to expire in 2008. The Company has recorded a valuation allowance for all NOL carryforwards. Utilization of existing NOL carryforwards may be limited in future years based on significant ownership changes.

Components of deferred taxes are as follows at December 31, (in thousands):

	2003	2004
Deferred tax assets:		

Net operating loss carry forwards	$18,620	$21,135
Deferred tax liabilities:		
Intangible assets and other	1,004	2,269
	17,616	18,866
Valuation allowance	(17,616)	(18,866)
	$ 0	$ 0

The following is a summary of the items, which caused recorded income taxes to differ from taxes computed using the statutory federal income tax rate for the years ended December 31:

	2003	2004
Statutory federal tax rate	(34)%	(34)%
State taxes, net of federal benefit	(4)	(4)
Nondeductible expenses	H	0
Valuation allowance	38	38
	0%	0%

8. COMMITMENTS AND CONTINGENCIES

Operating Leases

Future minimum rental payments at December 31, 2004 under non-cancellable operating leases for office space and equipment are as follows ($ in thousands):

2005	$215
2006	274
2007	281
2008	266
2009	269

Rental expense was $241,000 and $339,000 in 2003 and 2004, respectively.

Litigation and Claims

The Company has been subject to certain asserted and threatened claims, against certain intellectual property rights owned and licensed by the Company. A successful claim against intellectual property rights owned or licensed by the Company could subject the Company to significant liabilities to third parties, require the Company to seek licenses from third parties, or prevent the Company from selling its products in certain markets or at all. In the opinion of management based upon advice from counsel, there are no known claims against the Company's owned or licensed intellectual property rights that will have a material adverse impact on the Company's financial position or results of operations.

Legal Proceedings

In January 2003, the Company announced that it was initiating actions required to terminate our research, development and license agreement with Abbott to jointly develop a continuous glucose monitor. The Company was withholding payment due in connection with the redemption of the shares of its preferred stock held by Abbott in

connection with its claims under the agreement with Abbott. Under the terms of the preferred stock, 162,500 shares of the Company's preferred stock was required to be redeemed on December 30, 2002 at $10 per share. The Company had asked the U.S. patent office to resolve an inventorship dispute involving issued Abbott patents related to Abbott's glucose monitoring technology. Abbott exercised its right to terminate the agreement on January 7, 2003. The Company had reached a settlement with Abbott Laboratories regarding the disputes in connection with the prior termination of the parties' Research & Development and License Agreement and the election of Abbott to have shares of our preferred stock redeemed, with the 162,500 shares to be redeemed on December 30, 2002 at $10 per share, plus accrued dividends, and the remaining shares to be redeemed no later than January 31, 2004. Under the settlement, which included mutual releases, the Company agreed to make quarterly payments to Abbott during 2003 and 2004 and end of the year lump sum payments in 2005 and 2006 to redeem 425,000 preferred shares and to pay approximately $0.7 million, $1.3 million, $1.8 million and $1.9 million for 2003, 2004, 2005 and 2006, respectively. The Company paid $400,000 and $300,000 to Abbott pursuant to the settlement, respectively, during 2003 and in the first quarter of 2004. Under the settlement, neither party admitted any liability or wrongdoing.

On July 15, 2004, Abbott sent the Company a letter notifying that it was in default on two separate payments due in 2004 and demanded payment. On July 22, 2004 the Company responded that it was seeking to resolve the patent issues and renegotiate the payment terms. On October 25, 2004, Abbott sent a letter notifying that the Company was in default on an additional payment due in 2004 and demanded payment. The Company again responded that it expected to continue to seek to resolve the patent issues and renegotiate the payment terms.

On February 17, 2005, the Company initiated litigation against Abbott Laboratories relating to the dispute over intellectual property issues. The Company is represented in this matter under a contingency fee

arrangement. In connection with the dispute and litigation, the Company has not paid $1.4 million of the amount due in 2004. This amount has been shown as a current liability.

On October 14, 2004, Respironics notified the Company that an allegation of patent infringement related to the Bili*Chek* product had been made and that it believed that this matter was subject to the indemnification provision of our asset sale agreement (see Note 5) which could require the Company to pay a portion of the costs related to certain infringement of intellectual property brought within two years of the closing date. On April 20, 2005 Respironics and SpectRx entered into a settlement agreement resolving the matter. In connection with the settlement and in exchange for Respironics agreeing to pay the earnout payments early due for 2004, Respironics will withhold approximately $275,000 of earnout payments due for 2006. No additional claims are expected under the indemnification clause because more than two years have passed since the closing date of the Bili*Chek* asset sale.

Roche

The Company has an agreement with Roche for the development, manufacturing, marketing and sale of a product that detects diabetes by laser fluorescence. The agreement requires Roche to make milestone payments based on progress achieved and to purchase diabetes screening products manufactured by the Company at a predetermined profit margin, subject to renegotiation between the parties in certain circumstances.

The agreement also requires the Company to develop and manufacture diabetes screening products.

In July 1999, the Company received $381,000 in advance payments for inventory components with long lead times associated with the diabetes screening instrument from Roche. Neither the Company or Roche are currently conducting any activities related to this product, and there was no development activity on this product during 2003 or 2004. There have been no commercial sales of this product to end users.

Grants

In July 2001, the Company received an SBIR grant from the National Cancer Institute (NCI) for $130,000 to partially support clinical trials for the Company's cervical cancer program. In February 2003, the Company received an additional $1.3 million SBIR Phase II grant from the NCI to partially support FDA pivotal clinical trials for the Company's cervical cancer program. As of December 31, 2004, $474,000 remains available under this February 2003 grant. In August 2004, the Company received an additional $1.1 million SBIR "fast track," combined Phase I and Phase II, grant from NCI to support product development in preparation for commercialization. As of December 31, 2004, $1.0 million remains available under this August 2004 grant.

The Company files for reimbursement of the expenses incurred for activities conducted under the grant on a routine basis. .All funds received from grants are recorded as reductions in Research & Development expenses on the Company's statements of operations.

Contracts

The Company has received contracts from the National Institute on Alcohol Abuse and Alcoholism (NIAAA) and the Department of the Army to develop and test devices to sense alcohol and insulin growth factor (IGF-1), respectively, based upon the Company's interstitial fluid collection technology. The NIAAA contract runs for two years, and can be extended for an additional three years at their option. The Company has been notified that it has received an extension for 2005 and expects to be notified in March of 2006 if the NIAAA plans to extend the contract further. The Company recognized $377,000 and $331,000 of revenue upon completion of certain activities specified under the contract during 2003 and 2004, respectively.

9. LICENSE AND TECHNOLOGY AGREEMENTS

As part of the Company's efforts to conduct research and development activities and to commercialize potential products, the Company, from time to time, enters into agreements with certain organizations and individuals that further those efforts but also obligate the Company to make future minimum payments or to remit royalties ranging from 1% to 3% of revenue from the sale of commercial products developed from the research.

The Company generally is required to make minimum royalty payments for the exclusive license to develop certain technology. In accordance with the renegotiation of the license for the glucose monitoring technology in 2001, the minimum required payment was reduced to $300,000 per year, starting in 2005,to maintain this license. The Company has not had any significant sales of products coverd by this license, however additional amounts will be due upon the Company achieving significant sales..

During 2003 and 2004, the Company incurred royalty expense of $1,063,000 and $1,080,000, respectively, which has been recorded as research and development expense.

Additionally, the Company is obligated to obtain and maintain certain patents, as defined by the agreements.

10. BUSINESS CONCENTRATION INFORMATION

The Company operates in one business segment, medical products. During fiscal years 2003 and 2004, total product revenue was $1,586,000 and $1,073,000, respectively, related primarily to the Company's infant jaundice product in 2003 and to a combination of SimpleChoice and contract revenue in 2004. The Company had exclusively licensed the right to distribute the infant jaundice product within the United States and Canada to Respironics prior to its sale in March 2003 to them. The Company distributed the product outside the United States and Canada through a diverse group of foreign distributors. All sales are payable in United States dollars. Product revenue attributable to countries based on the location of the customer is as follows (in thousands):

	2003	2004

United States and Canada	$1,341	$1,073
Europe	189	0
Latin America	1	0
Middle East	33	0
Asia	4	0
Other	18	0
Total	$1,586	$1,073

As of December 31, 2004, SpectRx had tooling assets of U.S. $57,000 in the People's Republic of China and U.S. $132,000 in Mexico for the production of SimpleChoice parts and assembled devices at our contract manufacturers facilities.

Sales Concentration

As of December 31, 2003, Respiroinics represented 61% and the National Cancer Institute represented 10% of the accounts receivable. NIAAA and Respironics represented 25% and 16% of the 2003 revenue, respectively.

As of December 31, 2004, Respironics represented 77% of the accounts receivable. NIAAA and two SimpleChoice distributors accounted for 31%, 15% and 10% of revenue for 2004, respectively. Two other SimpleChoice distributors accounted for 13% of total revenue combined.

11. NOTES PAYABLE

The Company issued $1,000,000 of notes on July 30, 2003 to five individuals, including two officers of SpectRx, for bridge financing. The terms of the notes included a balloon payment in six months from the date of issuance, monthly interest payments at a rate of 12% per annum and monthly issuances of warrants so long as the notes remained outstanding.

The Company issued as additional consideration for the notes to purchase warrants, 203,000 and 635,000 shares of common stock with a fair value of $193,000 and $871,000, as determined using the Black-Scholes option pricing model, and such amounts were charged to interest expense in 2003 and 2004, respectively.

At the request of the Company on March 26, 2003, the note holders converted their shares into series A convertible preferred stock concurrent with the series A convertible preferred financing (see Note 6).

ITEM 8. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

On October 24, 2003, we filed a Current Report on Form 8-K reporting under Item 4 "Changes in Registrants Certifying Accountant" as follows:

> On October 17, 2003, the Audit Committee of the Board of Directors of SpectRx, Inc. (the "Company") unanimously approved the engagement of the accounting firm of Eisner LLP as its new independent public accountants effective immediately. Also on October 17, 2003, the Company's Audit Committee unanimously agreed to dismiss Ernst & Young LLP.
>
> The report of Ernst & Young LLP on the consolidated financial statements of the Company, for the year ended December 31, 2002 did not contain an adverse opinion or a disclaimer of opinion and was not qualified or modified as to audit scope or accounting principles. Ernst & Young LLP's opinion included an explanatory paragraph pertaining to an uncertainty regarding the ability of the Company to continue as a going concern.
>
> In connection with the audit of the Company's financial statements for the year ended December 31, 2002 and in the subsequent interim period from January 1, 2003 through and including October 17, 2003, there was one disagreement between the Company and its auditors, Ernst & Young LLP, on a matter of accounting principle or practices, consolidated financial statement disclosure, or auditing scope and procedures, which, if not resolved to the satisfaction of Ernst & Young LLP would have caused Ernst & Young LLP to make reference to the matter in its report. During the review of the Company's unaudited financial statements for the quarter ended March 31, 2003, the Company and Ernst & Young LLP disagreed on the amount of gain to be recognized from the sale of the Bili*Chek* line of business. The audit committee of the board of directors also discussed the subject matter of this disagreement and other items with Ernst & Young LLP. The issue was resolved to the satisfaction of Ernst & Young LLP. The Company has authorized Ernst & Young LLP to respond fully to inquiries of the successor accountant concerning the subject matter of this disagreement.
>
> There were no "reportable events" as that term is described in Item 304(a)(1)(v) of Regulation S-K during the period of Ernst & Young LLP's retention as the Company's independent public accountants (June 12, 2002 to October 17, 2003).
>
> The Company has not consulted with Eisner LLP during the last two fiscal years ended December 31, 2002 and 2001 or during the subsequent interim periods from January 1, 2003 through and including October 17, 2003, on either the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on the Company's consolidated financial statements, or any other matter that was the subject of a disagreement or a reportable event as set forth in Item 304(a)(2)(i)and(ii) of Regulation S-K.
>
> The Company requested Ernst & Young LLP to furnish a letter addressed to the Securities and Exchange Commission stating whether Ernst & Young LLP agrees with the statements made above by the Company.

ITEM 8A. CONTROLS AND PROCEDURES

We maintain a set of disclosure controls and procedures designed to ensure that information required to be disclosed by us in reports that we file or submit under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms. We carried out an evaluation under the supervision and with the participation of our management, including the Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures. Based on that evaluation, the Chief Executive Officer and Chief Financial Officer has concluded that our disclosure controls and procedures were effective as of December 31, 2004.

There have been no changes in our internal controls over financial reporting that occurred during the quarter ended December 31, 2004 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 8B. OTHER INFORMATION

Not applicable.

PART III

Certain information required by Part III is omitted from this Report on Form 10-K in that the registrant will file a definitive proxy statement within 120 days after the end of the fiscal year covered by this Report pursuant to Regulation 14A relating to the registrant's 2005 Annual Meeting of Stockholders to be held on June 2, 2005, and certain information included therein is incorporated herein by reference.

ITEM 9. DIRECTORS, EXECUTIVE OFFICERS PROMOTERS AND CONTROL PERSONS; COMPLIANCE WITH SECTION 16(a) OF THE EXCHANGE ACT

The information under the captions "Election of Directors" and "Section 16(a) Beneficial Ownership Reporting Compliance" in our proxy statement is hereby incorporated by reference. Our executive officers are elected by and serve at the discretion of our board of directors. The following table lists information about our executive officers as of February 28, 2005:

NAME	AGE	POSITION
Mark A. Samuels	47	Chairman, chief executive officer, chief financial officer and director
William D. Arthur, III	53	President, chief operating officer and secretary
Mark L. Faupel	49	Executive vice president and chief technology officer
Richard L. Fowler	48	Vice president engineering
Walter J. Pavlicek	58	Vice president operations
Siraj Noorani	31	Chief accounting officer and controller

Except as set forth below, all of the executive officers have been associated with us in their present or other capacities for more than the past five years. Officers are elected annually by the board of directors and serve at the discretion of the board. There are no family relationships among any of our executive officers and directors.

Mark A. Samuels has served as a member of our board of directors and chief executive officer since co-founding SpectRx in 1992. In addition, he has served as chief financial officer since November 2004. Prior to that time, Mr. Samuels was a founder of Laser Atlanta Optics, Inc., an optical sensor company, where he held the position of president and chief executive officer until 1992, and was a director until October 1996. While at Laser Atlanta Optics, Mr. Samuels focused on the development of commercial and medical applications of electro-optics. Mr. Samuels earned a B.S. in Physics and an M.S. (Electrical Engineering) from Georgia Institute of Technology.

William D. Arthur, III has served as president and chief operating officer since November 6, 2003. He was vice president, sales for MiniMed, the leading manufacturer of insulin infusion pumps in the United States, from 1993 to 2001. From 1984 to 1993, he was founder, president and chief financial officer of MedFusion, Inc., a manufacturer of infusion pumps for low volume drug delivery.

Mark L. Faupel, Ph.D. has served as our vice president of research and development since August 1998. Dr. Faupel joined us on February 2, 1998 in the capacity of vice president, new product development. Prior to that time, Dr. Faupel was an independent consultant to us and other firms in cancer research. From 1987-1997, Dr. Faupel held various positions with Biofield Corporation, a medical device company in the area of breast cancer detection, a firm, which he co-founded and served as vice president, director of science and vice president, research and development.

Richard L. Fowler has served as our vice president of engineering since August 2002. He also served as vice president of technology assessment from August 2000 until August 2002, and our vice president of engineering when he joined us in February 1996. Prior to that time, Mr. Fowler worked for Laser Atlanta Optics, Inc., where he held the positions

of president and chief executive officer from August 1994 to February 1996. As vice president of engineering for Laser Atlanta Optics from 1992 to 1994, Mr. Fowler managed the development of three laser sensor products. Mr. Fowler earned a B.S. in Electrical Engineering from University of Texas.

Walter J. Pavlicek, Ph.D. has served as our vice president of operations since August 2002 and our vice president of engineering when he joined us in July 2000. From 1995 to 2000, Dr. Pavlicek was director of new products for Bayer Diagnostics and from 1991 to 1995, he was an executive, information management for Boehringer Mannheim (since acquired by Roche). From 1980 to 1991, Dr. Pavlicek was member of technical staff-supervisor at Bell Laboratories. Dr. Pavlicek earned a Ph.D. and M.S. from Saint Louis University and a B.S. from the University of San Francisco. All his degrees are in Mathematics.

Siraj Noorani has served as chief accounting officer and controller since November 2004. Prior thereto, he also served as accounting manager and in other financial positions since August 1999. Mr. Noorani is a Certified Public Accountant in Georgia and is also a Chartered Accountant from India. He has a Bachelor of Commerce from Osmania University in India.

We have adopted a code of ethics that applies to all of our directors, officers and employees. To obtain a copy without charge, contact our Corporate Secretary, SpectRx, Inc., 4955 Avalon Ridge Parkway, Suite 300, Norcross, Georgia 30071. If we amend our code of ethics, other than a technical, administrative or non-substantive amendment, or we grant any waiver, including any implicit waiver, from a provision of the code that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, we will disclose the nature of the amendment or waiver on our website, www.spectrx.com under the "Investor Relations" tab under the tab "About Us." Also, we may elect to disclose the amendment or waiver in a report on Form 8-K filed with the Securities and Exchange Commission.

ITEM 10. EXECUTIVE COMPENSATION

The information under the captions "Election of Directors - Director Compensation" and "Executive Compensation" in our proxy statement is hereby incorporated by reference.

ITEM 11. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information under the caption "Share Ownership of Directors, Officers and Certain Beneficial Owners" in our proxy statement is hereby incorporated by reference.

Securities authorized for issuance under equity compensation plans:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securitiesremaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	1,600,679	$3.94	43,632
Equity compensation plans not approved by security holders	0	0	0
TOTAL	1,600,679	$3.94	43,632

ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information, if any, under the caption "Certain Transactions" in our proxy statement is hereby incorporated by reference.

ITEM 13. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

The exhibits listed on the accompanying Index to Exhibits are filed as part hereof, or incorporated by reference into, this Report. All documents referenced below were filed pursuant to the Securities and Exchange Act of 1934 by SpectRx, Inc., file number 0-22179, unless otherwise indicated.

EXHIBIT INDEX

EXHIBIT

EXHIBIT NO.	DESCRIPTION
3.1A(2)	Certificate of Incorporation, as amended.
3.1B(7)	Certificate of Designations for Redeemable Convertible Preferred Stock.
3.1C(12)	Certificate of Designations for Series A Preferred Stock.
3.2A(13)	Amended Bylaws.
4.1(1)	Specimen Common Stock Certificate.
4.2A(12)	Form of Warrant 1
4.2B(12)	Form of Warrant 2
4.2C(8)	Form of Common Stock Warrant.
4.3(12)	Registration Rights Agreement, dated March 26, 2004.
10.1(1)	1997 Employee Stock Purchase Plan and form of agreement thereunder.
10.2(1)	1995 Stock Plan, as amended, and form of Stock Option Agreement thereunder.
10.4(1)	Assignment and Bill of Sale, dated February 29, 1996, between Laser Atlanta Optics, Inc. and SpectRx.
10.5(1)	Security Agreement, dated October 31, 1996, between Mark A. Samuels and SpectRx.
10.6(1)	Security Agreement, dated October 31, 1996, between Keith D. Ignotz and SpectRx.
10.7A(1)*	License Agreement, dated May 7, 1991, between Georgia Tech Research Corporation and Laser Atlanta Optics, Inc.
10.7B(1)	Agreement for Purchase and Sale of Technology, Sale, dated January 16, 1993, between Laser Atlanta Optics, Inc. and SpectRx.
10.7C(1)	First Amendment to License Agreement, dated October 19, 1993, between Georgia Tech Research Corporation and SpectRx.
10.8(1)	Clinical Research Study Agreement, dated July 22, 1993, between Emory University and SpectRx.
10.9A(1)*	Development and License Agreement, dated December 2, 1994, between Boehringer Mannheim Corporation and SpectRx.
10.9B(1)*	Supply Agreement, dated January 5, 1996, between Boehringer Mannheim and SpectRx.
10.10(1)	Sole Commercial Patent License Agreement, dated May 4, 1995, between Martin Marietta Energy Systems, Inc. and SpectRx.
10.11A(1)	License and Joint Development Agreement, dated March 1, 1996, between NonInvasive-Monitoring Company, Inc., Altea Technologies, Inc. and SpectRx.
10.11B(11)*	Amendment to License and Joint Development Agreement, dated December 30, 2001, between NonInvasive-Monitoring Company, Inc., Altea Technologies, Inc. and SpectRx.
10.12A(1)*	Purchasing and Licensing Agreement, dated June 19, 1996, between Respironics and SpectRx.
10.12B(4)*	Amendment to Purchasing and Licensing Agreement, dated October 21, 1998 between Respironics and SpectRx.
10.13(1)	Research Services Agreement, dated September 3, 1996, between Sisters of Providence in Oregon doing business as the Oregon Medical Laser Center, Providence St. Vincent

	Medical Center and SpectRx.
10.14A(1)*	Research and Development and License Agreement, dated October 10, 1996, between Abbott Laboratories and SpectRx.
10.14B(3)*	Letter Agreement, dated December 22, 1997, between Abbott Laboratories and SpectRx.
10.14C(6)*	Third Amendment to Research and Development and License Agreement, dated November 30, 1999 between Abbott Laboratories and SpectRx.
10.14D(9)*	Fourth Amendment to Research and Development and License Agreement, dated November 30, 1999 between Abbott Laboratories and SpectRx.
10.15A(1)	Lease, dated September 21, 1993, between National Life Insurance Company d/b/a Plaza 85 Business Park and SpectRx, together with amendments 1, 2, 3 and 4 thereto and Tenant Estoppel Certificate, dated September 20, 1994.
10.16A(5)*	Development and License Agreement, dated July 13, 1999, between Roche Diagnostics Corporation and SpectRx.
10.16B(5)*	Supply Agreement, dated July 13, 1999, between Roche Diagnostics Corporation and SpectRx.
10.17(10)	Agreement and Plan of Merger, dated December 31, 2001 by and between SpectRx, Inc. Sterling Medivations, Inc., SM Merger Sub, Inc. and certain shareholders of Sterling Medivations, Inc.
10.18(10)	Agreement and Plan of Merger, dated December 31, 2001, by and among SpectRx, SM Merger Sub, Inc., Sterling Medivations, Inc. and certain stockholders (incorporated by reference to Exhibit 21 the Registrant's Current Report on Form 8-K filed January 14, 2002).
10.19	Agreement for Termination of Development and Commercialization Agreement, dated November 19, 2002, between SpectRx and Welch Allyn, Inc. (incorporated by reference to the Registrant's Current Report on Form 8-K filed December 20, 2002).
10.20(11)	Asset Sale Agreement, dated March 6, 2003, between SpectRx and Respironics.
10.21(12)	Securities Purchase Agreement dated March 26, 2004 among SpectRx, Inc. and the purchasers listed on Schedule I.
16.2	Letter re Change in Certifying Accountants (incorporated by reference to Exhibit 99.1 to the Registrant's Current Report on Form 8-K, filed October 24, 2003).
23.1(13)	Consent of Eisner LLP.
24.1	Power of Attorney (included on signature page).
31(13)	Rule 13a - 14(a) / 15d - 14(a) Certifications.
32(13)	Section 1350 Certifications.

* Confidential treatment granted for portions of these agreements.

1. Incorporated by reference to the exhibit filed with the Registrant's Registration Statement on Form S-1 (No. 333-22429) filed February 27, 1997, and amended on April 24, 1997, June 11, 1997, and June 30, 1997, which Registration Statement became effective June 30, 1997.

2. Incorporated by reference to the exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1997, filed August 12, 1997.

3. Incorporated by reference to the exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1997, filed March 27, 1998.

4. Incorporated by reference to the exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1998, filed March 30, 1999, as amended.

5. Incorporated by reference to the exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1999, filed August 16, 1999,as amended.

6. Incorporated by reference to the exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1999, filed March 30, 2000, as amended.

7. Incorporated by reference to the exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 2001, filed April 2, 2002.

8. Incorporated by reference to the exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2002, filed May 14, 2002.

9. Incorporated by reference to the exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002, filed November 14, 2002.

10. Incorporated by reference to the exhibit filed with the Registrant's Current Report on Form 8-K, as amended, filed January 14, 2002.

11. Incorporated by reference to the exhibit filed with the Registrant's Current Report on Form 8-K, filed March 21, 2003.

12. Incorporated by reference to the exhibit filed with the Registrant's Current Report on Form 8-K, filed March 29, 2004.

13. Filed herewith.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information under the caption "Independent Registered Public Accounting Firm" in our proxy statement is hereby incorporated by reference.

SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on the 4th day of May, 2005.

SPECTRX, INC.
/s/ MARK A. SAMUELS
By: Mark A. Samuels
Chairman and Chief Executive Officer

KNOW ALL MEN AND WOMEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Mark A. Samuels his attorney-in-fact, and each with the power of substitution, for him in any and all capacities, to sign any amendments to this Annual Report on Form 10-KSB, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his substitute or substitutes, may do or cause to be done by virtue thereof.

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

DATE	SIGNATURE	TITLE
May 4, 2005	/s/ Mark A. Samuels Mark A. Samuels	Chairman, Chief Executive Officer, Chief Financial Officer & Director (Principal Executive Officer)
May 4, 2005	/s/ William D. Arthur, III William D. Arthur, III	President, Chief Operating Officer and Secretary
May 4, 2005	/s/ Keith D. Ignotz Keith D. Ignotz	Director
May 4, 2005	/s/ Charles G. Hadley Charles G. Hadley	Director
May 4, 2005	/s/ Earl R. Lewis Earl R. Lewis	Director
May 4, 2005	/s/ William E. Zachary William E. Zachary	Director
May 4, 2005	/s/ Christopher F. Monahan Christopher F. Monahan	Director

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the registration statements on Form S-8 (Registration Nos. 333-63758 and 333-81326) of our report dated March 19, 2005 on our audit of the consolidated financial statements of SpectRx, Inc. included in the 2004 annual report on Form 10-KSB.

/s/ Eisner LLP

New York, New York
May 2, 2005

Exhibit 31

Rule 13a-14(a)/15(d)-14(a) Certifications

I, Mark A. Samuels, certify that:

1. I have reviewed this annual report on Form 10-KSB of SpectRx, Inc.;

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

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

4. The small business issuer's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the small business issuer and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the small business issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Evaluated the effectiveness of the small business issuer's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(c) Disclosed in this report any change in the small business issuer's internal control over financial reporting that occurred during the small business issuer's most recent fiscal quarter (the small business issuer's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the small business issuer's internal control over financial reporting; and

5. The small business issuer's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the small business issuer's auditors and the audit committee of the small business issuer's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the small business issuer's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the small business issuer's internal control over financial reporting.

Date: May 4, 2005 /s/ *Mark A. Samuels*

Mark A. Samuels
Chief Executive Officer and Chief Financial Officer

EXHIBIT 32

SECTION 1350 CERTIFICATION

In connection with the Annual Report of SpectRx, Inc. (the "Company") on Form 10-KSB for the year ended December 31, 2004, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Mark A. Samuels, Chief Executive Officer of the Company certify, pursuant to 18 U.S.C. Sec 1350, as adopted pursuant to Sec 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 4, 2005

/s/ Mark A. Samuels

Name: Mark A. Samuels
Title: Chief Executive Officer and Chief Financial Officer