

SECURITIES & EXCHANGE COMMISSION EDGAR FILING

GUIDED THERAPEUTICS INC

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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.
For the fiscal year ended December 31, 2003.

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.
For the transition period from _____ to _____.

SPECTRX, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware (State or Other Jurisdiction of Incorporation)	0-22179 (Commission File Number)	58-2029543 (I.R.S. Employer Identification No.)
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6025A Unity Drive Norcross, Georgia (Address of Principal Executive Offices)	30071 (Zip Code)
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Registrants' Telephone Number, Including Area Code:	(770) 242-8723
Securities registered pursuant to Section 12(b) of the Act:	None
Securities registered pursuant to Section 12(g) of the Act:	Common Stock, \$0.001 par value
(Title of class)	

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

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

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

The aggregate market value of the voting stock held by non-affiliates of the registrant was approximately \$27 million as of June 30, 2003, based upon the average of the high and low prices of the registrant's Common Stock reported for such date by the Nasdaq SmallCap Market.

As of February 29, 2004, the registrant had outstanding **11,376,279** shares of Common Stock.

DOCUMENTS INCORPORATED BY REFERENCE.

Parts of the following documents are incorporated by reference in Part III of this Form 10-K Report: Proxy Statement for Registrant's 2004 Annual Meeting of Stockholders -- Items 10, 11, 12, 13 and 14.

PART I

ITEM 1. BUSINESS

OVERVIEW

We are a medical technology company focused on insulin delivery and glucose monitoring products for the diabetes management market and biophotonic (optics and spectroscopy) devices and technology for the non-invasive cancer diagnostics market. Historically, our technology has been 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 insulin delivery to our technology base with the purchase of Sterling Medivations, Inc., now doing business as SimpleChoice, in December of 2001. Currently, our technology, including products in development, includes innovative methods of delivering insulin to people with diabetes with our SimpleChoice product line, innovative methods of sampling interstitial fluid using laser energy to create micropores for improved glucose and alcohol monitoring and biophotonics technology for the non-invasive detection of cancers.

Diabetes Management-

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

Within our diabetes management business, our insulin delivery products, including those in development, are designed to deliver insulin more comfortably and effectively than competing products. Additionally, we are developing products that measure glucose levels more conveniently and more frequently than products currently sold by our competitors.

Cancer Diagnostics-

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

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.

Significant portions of our historical activities were undertaken in collaboration with other, larger companies. We no longer have collaborative partnerships with respect to many 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. We terminated our agreement relating to our cervical cancer detection product with Welch Allyn, Inc. in 2002.

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. 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 intend to maximize the market penetration of our current products and those that are near-term product introductions to drive revenue growth. 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 and 2005, we intend to continue to implement this strategy by:

- establishing a full product line by introducing additional products to the marketplace as part of our SimpleChoice series of innovative insulin delivery products;

- expanding our sales and marketing activities and developing additional channels of distribution for our line of insulin delivery products; and

- investing in development of additional insulin-delivery products once the current products gain market traction.

- 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. The primary focus of this activity will be on our glucose monitoring technology, which we expect to be funded by a strategic partner. We also believe that our development activities in diabetes management have significant promise for additional product offerings. For example, we believe our interstitial fluid sampling technology may be applicable for monitoring compounds other than glucose and that our insulin delivery products may be used to deliver other drugs or compounds.

- Transition Cancer Detection Activity into a Separate Entity - Guided Therapeutics. We believe the cervical cancer technology we have developed can be a significant opportunity. We also believe that the technology used in the cancer detection products we are developing can be used for the detection of other cancers and to guide the removal and sampling of cancer cells. We believe that having a separately managed entity, funded by venture capital and operated as a stand alone entity, is the best way to realize the potential of this opportunity.

- Address Large Market Opportunities. We believe that large market opportunities exist for products using our proprietary technologies. We intend to address these opportunities by selectively developing future products that we believe will meet unaddressed needs in these markets.

- Collaborate with Market Leaders. In the past, we have participated in collaborative arrangements with Abbott, Roche Diagnostics, and Welch Allyn to assist in the early development efforts for certain of our technologies. Under such an arrangement with Respiroics, we developed and commercialized an infant jaundice detection and monitoring product line, a business we sold to Respiroics in 2003. We may seek to establish strategic relationships with other leading companies for the development, commercialization and introduction of additional products, if it is the best path to commercialization for those products.

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 is the sixth leading cause of death by disease in the United States and is estimated to cost the U.S. economy over \$130 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. 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 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 16 million in the U.S., 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 90% of the people who use insulin in the U.S. use the syringe, 6% use the pen and 4% use the pump. Variances in the cost of supplies and varying degrees of insulin dependency affect the worldwide market for each of these products, which we believe is 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 and is 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 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 at about \$360 million annually worldwide. 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., Deltec, Inc., Animas Corporation and Roche Diagnostics. Significant participants in the insulin infusion set market include Unomedical, 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, Inc. 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. 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, an insulin pen 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.

We expect to market more significant levels of these products in 2004, introducing other SimpleChoice insulin infusion sets, the *quick* 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 will 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;
- compatibility with existing inserter devices; and
- a newly designed connection mechanism for quick removal.

Our first insulin pump infusion set product is 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 *quick*, which is expected to be launched in 2004, is a 90-degree insertion infusion set designed to work with the major brands of insulin pumps. The *quick* 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 2004. The *patch* is designed with microneedle technology 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.

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.

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 every day 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 \$5.0 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;
- 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, inconvenience and cost 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 Therasense, Inc. (which has announced an expected acquisition by Abbott) have filed for FDA approval or received limited FDA approval for continuous glucose monitoring devices that involve putting a sensor under the skin. Cygnus, Inc. has also obtained limited FDA approval for a wristwatch type device that can provide a continuous indication of glucose levels, however the readings must be confirmed by a finger stick blood measurement and frequent calibration is required.

Our Glucose Monitoring Product

We are developing a glucose monitoring product that should allow people with diabetes to easily and accurately measure their glucose levels. This device uses 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.

Our glucose monitoring product uses our microporation technology to collect a sample of interstitial fluid. We create micropores by directing a laser on the outer layer of the skin. We believe the creation of micropores will not damage adjacent tissue or penetrate deeply enough to reach the capillary bed or nerve layer below the outer layer of skin. The interstitial fluid sample obtained from the micropore may be measured once in a single-use application, or a stream of interstitial fluid may be repeatedly measured for a continuous monitoring application. Products using both sampling methodologies are intended to measure the glucose concentration of the interstitial fluid using disposable technology. Because our glucose monitoring products are designed to obtain a sample of interstitial fluid through the outermost layers of the skin and do not require a blood sample, their use does not significantly stimulate pain sensors and capillaries found in the deeper layers of skin. These products are expected to be free of the pain and blood involved

in conventional finger stick or alternate site techniques.

The primary focus of our development 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. 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. We also plan to seek technology and financial partners that already have experience with continuous glucose sensors.

During the course of research and development of a single-use glucose monitoring product, we discovered a technique in 1998 which 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 1998 indicates that an array of micropores may be kept viable for up to three days. A second feasibility study showed that the concentration of glucose in the interstitial fluid continued to correlate to the concentration of glucose in the blood during a three-day period.

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.

In addition to milestone payments from Abbott, we have received grants from the U.S. Centers for Disease Control and Prevention. We have now received funding of \$150,000 in 2001, \$412,000 in 2002 and \$122,000 in 2003 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 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 currently totals about \$1.5 million for the first two years, and \$3.5 million if extended to five years, of which about 47% is expected to be for direct SpectRx activities and 53% for subcontractor activities. As of December 31, 2003, we have received approximately \$380,000 for this contract. In addition, we have smaller grants to study other elements of interstitial fluid including insulin growth factor testing for the U.S. Army.

NON-INVASIVE DIAGNOSTICS PRODUCTS

CANCER DETECTION

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.

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, with 3,900 deaths predicted in 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. The average cost of a stand alone colposcope examination in the U.S. is \$185; the average cost of a colposcopy with biopsy is \$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 *BiliChek*.

To date, more than 1,000 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 old. 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. Upon completion of the pivotal trials, we plan to submit an application for regulatory approval through the premarket approval, or PMA, process. We also plan to ask for expedited review. Unexpected problems, however, may arise during the development and regulatory approval processes.

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 of age. 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.

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 Cytec, Inc., which markets the Thin Prep Pap test and Digene, Inc., which markets another method of cervical cancer screening, HPV (Human Papilloma Virus) 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. 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 the National Cancer Institute to support our required pivotal clinicals, some of the results of which are discussed above. As of December 31, 2003, we have received approximately \$634,000 for this grant.

Our Skin Cancer Detection Product

In 2002, we licensed a skin cancer detection technology for Oregon Medical Laser Center in Portland, Oregon. This technology was invented by Steve Jacques, the inventor of a key part of our *BiliChek* infant jaundice detection and monitoring product line, recently sold to Respironics. The new Jacques technology uses polarization to enable the direct viewing of subsurface structures in the skin. Imaging of these structures has the potential to allow dermatologists and other doctors to quickly determine if a suspect lesion has affected the subsurface structure in any way. We believe cancerous lesions can be separated from non-cancerous lesions using this technology.

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 *BiliChek* 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 royalties from the sale of the disposable element of the product line, trademarked the *BiliCal*, 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 earn out payments based upon certain revenue achievements of the sales of infant jaundice products by Respironics over the next four years following the sale. Our earn out and royalty payments for 2003 totaled \$655,000. 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.

Respironics retains all responsibility and a significant degree of discretion regarding the timing of 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.

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 will be redeemed over a period of four years.

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. As of December 31, 2003, 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 covers 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.

We are obligated to pay royalties to Non-Invasive Monitoring for products using its technology and to Altea for products using its technology, 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 10 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 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 2003, 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. Since inception to December 31, 2003, we incurred about \$36.3 million in research and development expenses, net of about \$12.2 million, which was reimbursed through collaborative arrangements. Research and development costs were about \$3.8 million in 2001, \$5.8 million in 2002 and \$4.1 million in 2003.

During 2003, there were three 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 infant jaundice and continuous glucose monitoring products. The second group consists of scientists and engineers focused on the development of cancer detection products. The third 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 *BiliChek* and *BiliCal* products. 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 6 individuals to accomplish the production planning, quality system management, facility development, and production scaling that will be needed to bring production to commercial levels. In 1998, we received ISO 9001/EN46001 and CE mark certification for international sales. These approvals enabled us to begin production of our *BiliChek* and *BiliCal* products and to begin shipment of these products into international markets. 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.

SALES, MARKETING AND DISTRIBUTION

We developed and managed a distribution system for our *BilChek* 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 *BiliChek* 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 2004. 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 and jointly applied with Altea for a U.S. patent and an international patent 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 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 to the *BiliChek* system to Respironics as a part of the asset sale, and have licensed Respironics for other patents for use in the infant jaundice management field. We gained access to several patent applications and one granted European patent related to insulin delivery when we acquired Sterling Medivations in December 2001.

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.) 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 Amira Medical, Inc., Johnson & Johnson, TheraSense, Inc. and Abbott. Some competitors to our continuous glucose monitoring product, including Cygnus, Inc. and Medtronic MiniMed, have developed products and have received 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 Cytoc 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. 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, which 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 which 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) submissions 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 for the modified device. 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) notification.

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 ISO 9000 series of standards for quality operations establish standards of quality to which companies must adhere to receive certification. 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 device directives. The ISO 9001 certification is one of the CE mark certification requirements. We currently have ISO 9001/EN46001 certification. If we lose the right to affix the CE mark, we would be prohibited from selling our products in member countries of the European Union. This 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, 2003 we had 36 employees and consulting or other contract arrangements with 23 additional persons to provide services to us on a full- or part-time basis. Of the 59 people employed or engaged by us, 22 are engaged in research and development activities, 8 are engaged in sales and marketing activities, 12 are engaged in clinical testing and regulatory affairs, 6 are engaged in manufacturing and development, and 11 are engaged in administration and accounting. If we are successful in our effort to finance the cancer detection business separately, approximately 8 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 our 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:

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 *BiliChek* 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 \$51.0 million at December 31, 2003.

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 prospective collaborative partners will be sufficient to satisfy our funding requirements through 2004, but may not be sufficient to fund our 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 during 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 Food and Drug Administration, or 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 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 9001 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 9001 certification or CE mark certification or other international regulatory approvals would prevent us from selling in Europe.

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, 37 U.S. patents (including those under license). In addition, we have filed for, or have rights to, 31 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 is 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 2004 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 *BiliChek* product line in 2003 and will not have continuing revenue from that source other than future earn out payments. Although, we received a payment for royalties and earn out of \$655,000 in the first quarter of 2004, there can be no assurance of additional payments. Our ability to collect additional earn out payments from the *BiliChek* product line depends on Respirationics' 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. We are also currently seeking direct funding for and expect to commercialize our cervical cancer detection product independently of any collaborative partner. 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 *BiliChek* and *BiliCaI* 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 four 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.

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 22% of our outstanding common stock as of February 29, 2004. 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. PROPERTIES

We lease about 24,000 square feet in Norcross, Georgia, which comprise our administrative, research and development, marketing and production facilities and our planned manufacturing facility. Our lease for this facility expires in March 2004, but we will continue to lease the facility on a month-to-month basis. In the event of termination, we believe we could obtain replacement space on comparable terms.

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 which 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 have 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. We paid \$400,000 to Abbott pursuant to the settlement during 2003. Under the settlement, neither party admitted any liability or wrongdoing.

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

None.

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market for Common Stock-

As of August 13, 2003, our common stock is traded on the OTC Bulletin Board Market 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, and prior to that, our common stock was traded on the Nasdaq National Market under the same symbol. The number of record holders of our common stock at March 9, 2004 was 167.

The high and low last sales prices for the calendar years 2002 and 2003 as reported by Nasdaq and OTC Bulletin Board are as follows:

	2002		2003	
	HIGH	LOW	HIGH	LOW
First Quarter	\$7.18	\$4.46	\$1.76	\$1.07
Second Quarter	\$6.60	\$3.00	\$3.45	\$1.40
Third Quarter	\$3.91	\$1.45	\$2.59	\$0.85
Fourth Quarter	\$2.31	\$1.09	\$2.21	\$0.90

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 *BillChek* Non-invasive Bilirubin Analyzer product line and related assets to Respiroics. Respiroics 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 royalties and earn out payments over the next five years based upon the achievement of certain operating results. We recognized a gain on the Sale of Assets to Respiroics 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 have also issued warrants to a group of lenders, including two of our officers, in conjunction with a debt financing, monthly from August 2003 to December 31, 2003. Those warrants for an aggregate of 27,000 shares were issued in reliance upon the exemption of registration under Section 4(2) of the Securities Act of 1933.

Securities Authorized for Issuance Under Equity Compensation Plans-

All the securities SpectRx has provided its employees, directors and consultants have been issued under its stock option plans, which are approved by our stockholders. We have issued common stock to other individuals that are not employees or directors, in lieu of cash payments, that are not part of any plan approved by our stockholders (see the information set forth above under the caption "Recent Sales of Unregistered Securities").

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders	1,594,089	\$4.53	61,522
Equity compensation plans not approved by security holders	0	\$0	\$0

TOTAL

1,594,089

\$4.53

61,522

ITEM 6. SELECTED FINANCIAL DATA

SPECTRX, INC. & SUBSIDIARIES

(IN THOUSANDS EXCEPT FOR PER SHARE FIGURES)

The table below sets forth selected consolidated financial data and should be read in conjunction with the consolidated financial statements. The comparability of financial results was impacted by the sale of our *BiliChek* business in March 2003 and our acquisition of Sterling Medivations in December 2001, as discussed in Part I, Item 1, Business.

	YEAR ENDED DECEMBER 31,				
	2003	2002	2001	2000	1999
CONSOLIDATED STATEMENTS OF OPERATIONS DATA:					
Revenue	\$1,586	\$3,798	\$2,458	\$4,968	\$3,337
Cost and Expenses:					
Cost of product sales	1,062	1,624	2,064	1,732	1,708
Research & Development	4,108	5,827	3,842	5,804	5,170
Marketing	735	1,649	846	957	900
General & Administrative	2,150	2,785	2,941	3,177	2,222
Loss from operations	(6,469)	(8,087)	(7,235)	(6,702)	(6,663)
Net interest & other income (expense)	3,858	(418)	269	355	125
Net loss	\$(2,611)	\$(8,505)	\$(6,966)	\$(6,347)	\$(6,538)
Preferred Stock Dividends	(299)	(315)	(315)	(315)	(14)
Loss attributable to common share stockholders	<u>\$(2,910)</u>	<u>\$(8,820)</u>	<u>\$(7,281)</u>	<u>\$(6,662)</u>	<u>\$(6,552)</u>
Net loss per common share					
Basic & Diluted	\$(.26)	\$(.79)	\$(.75)	\$(.79)	\$(.82)
Shares used to compute net loss per common share					
Basic & Diluted	11,270	11,209	9,646	8,429	8,033
CONSOLIDATED BALANCE SHEET DATA:					
Total Assets	\$6,714	\$7,472	\$16,734	\$7,148	\$7,693
Total Long term obligations, including redeemable preferred stock	3,645	4,705	5,150	5,960	5,645

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

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 *BiliChek* products, respectively. In 2003, we sold our *BiliChek* 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, 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, 2003, we have an accumulated deficit of about \$51.0 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 2004 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 *BiliChek* product line, which we sold in March 2003. We expect that the majority of our revenue in 2004 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 Respiroics 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 is due.

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 2003 and 2002

General. Loss attributable to common stockholders decreased to about \$2.9 million, or \$0.26 per share, in 2003 from about \$8.8 million, or \$0.79 per share, in 2002. The decreased loss was due primarily to an increase of \$4.7 million in other income, due to the sale of assets related to our infant jaundice business in 2003. We also realized a \$3.8 million reduction in expenses in 2003 related to lower cancer expenditures in research and development, as well as lower marketing expenses and general and administrative expenses. This overcame a decrease of \$1.7 million in gross profit in 2003 over 2002, primarily due to a \$1.1 million milestone achievement in 2002 as compared to none in 2003. We expect net losses to continue. We expect no 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 \$1.6 million in 2003 from about \$3.8 million in 2002. The decrease was due to a decrease in milestone payments received from collaborative partners, which decreased from \$1.1 million in 2002 and reduction in BiliChek revenue due to the sale of assets related to that business in the first quarter of 2003. Product sales decreased approximately 41% to \$1.6 million in 2003 from about \$2.7 million in 2002. There was a decrease in revenues related to the BiliChek product line because it was sold in March 2003. Cost of product sales decreased significantly to about \$1.1 million for the year ended December 31, 2003 from about \$1.6 million in 2002. 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 \$4.1 million in 2003 from about \$5.8 million in 2002 primarily due to a decrease of about \$1.3 million in development expense related to our cervical cancer detection product. We expect research and development expenses to decrease mildly 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.

Sales and Marketing. Sales and marketing expenses decreased to about \$735,000 in 2003 from about \$1.6 million in 2002. The decrease in expense was due to a significant reduction in expense related to the SimpleChoice product line (\$550,000) while products were being prepared for commercial release. BiliChek marketing decreased also (\$354,000) 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 2004.

General and Administrative Expense. General and administrative expense decreased to about \$2.1 million for 2003 from about \$2.8 million in 2002. The significant reductions were in investor relations (\$187,000), lower attorney fees (\$165,000), lower salary expense (\$166,000) and lower outside services (\$186,000), offset by increased consulting cost (\$9,000).

Net Interest Expense and Other Income. Net interest expense in 2003 was \$328,000, \$419,000 worse than the net interest income experienced in 2002 of \$91,000. Other income increased \$4.7 million from an expense of \$509,000 in 2002 to income of \$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.

Comparison of 2002 and 2001

General. Loss attributable to common stockholders increased to about \$8.8 million, or \$0.79 per share, in 2002 from about \$7.3 million, or \$0.75 per share, in 2001. The increased loss was due primarily to a \$3.1 million increase in expenses in 2002 entirely related to development, marketing and administrative expenses related to the SimpleChoice product line. This was offset by an increase of \$1.8 million in gross profit in 2002 over 2001, primarily due to a \$1.1 million milestone achievement in 2002 as compared to \$0.1 million in 2001.

Revenue and Cost of Product Sales. Total revenues increased to about \$3.8 million in 2002 from about \$2.5 million in 2001. The increase was primarily due to an increase in milestone payments received from collaborative partners, which increased to \$1.1 million in 2002 from about \$0.1 million in 2001. Product sales increased approximately 14% to \$2.7 million in 2002 from about \$2.4 million in 2001. Revenues related to the *BiliChek* product line increased approximately 8% for the year. Cost of product sales decreased significantly to about \$1.6 million for the year ended December 31, 2002 from about \$2.1 million in 2001. Cost of product sales was reduced largely as a result of reducing production overhead including excess production capacity.

Research and Development Expenses. Research and development expenses increased to about \$5.8 million in 2002 from about \$3.8 million in 2001 primarily due to an increase of about \$1.8 million in development expense related to the SimpleChoice product line.

Sales and Marketing. Sales and marketing expenses increased to about \$1.6 million in 2002 from about \$846,000 in 2001. The increase in expense was due to approximately \$1.2 million of expenditures related to establishing distributors, developing marketing materials, and building the infrastructure for the SimpleChoice brand.

General and Administrative Expense. General and administrative expense decreased to about \$2.8 million for 2002 from about \$2.9 million in 2001. Expenses related to SimpleChoice outside services and insurance caused increases of about \$400,000, \$80,000 and \$60,000 respectively, which were offset by decreases in bonus payments (\$202,000), attorney fees (\$304,000) and contractor R&D (\$32,000).

Net Interest Income and Other Expense. Net interest income and other expense decreased to a loss of about \$418,000 in 2002 from an increase of about \$269,000 in 2001. The loss resulted from lower net interest income (\$164,000) and a charge related to non-recourse loans to officers for which we received the collateral, which was at a lower value than the outstanding balance.

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. From October 27, 1992 (inception) through December 31, 2003, we received approximately \$55.9 million in proceeds from sales of our debt and equity securities. At December 31, 2003, we had cash of approximately \$389,000 and working capital of approximately a negative \$2.0 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 (see Item 3. - Legal Proceedings).

Our major cash flows in the year ended December 31, 2003 consisted of cash out-flow of \$1.4 million from operations (including \$6.5 million of operating loss) and \$202,000 in addition to property and equipment, which was offset by the issuance of notes payable of \$1.0 million. Cash flow from operations includes gross proceeds of \$5.0 million from the sale of the *BiliChek* product line. Of this cash out-flow from operations, \$1.3 million resulted from payment and prepayment of royalties relating to our agreement with Altea Technologies, Inc.

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 a \$1.4 million grant, to be spent over two years, from the National Cancer Institute for our cervical cancer program. In March 2003, we sold the assets related to the *BiliChek* 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 royalties and earn out payments based upon the future performance of the business as conducted by the buyer, Respironics. We received \$655,000 of earn out and royalty in the first quarter of 2004 for performance during 2003.

The Company announced on March 26, 2003 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 may 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 2004, including the approximately \$1.6 million 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 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 June 2002, the FASB issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities." The company's adoption of SFAS No. 146 on January 1, 2003 did not have any material effect on the financial statements of the Company.

In December 2003, the FASB issued Interpretation No. 46R, "Consolidation of Variable Interest Entities" in an effort to expand upon and strengthen existing accounting guidance that addresses when a company should include in its financial statements the assets, liabilities and activities of variable interest entities, including special-purpose entities or off-balance sheet structures. The consolidation requirements of FIN No. 46R have a variety of implementation dates. The company believes the impact of FIN No. 46R on its financial position and results of operations will not be material, but the company will continue to evaluate the impact of FIN No. 46R during the first quarter of 2004.

In May 2003, the FASB issued Statement of Financial Accounting Standards No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity." This statement affects the issuer's accounting for three types of freestanding financial statements: mandatorily redeemable shares, put and forward purchase contracts that require the issuer to buy back some of its shares in exchange for cash or other assets, and certain obligations that can be settled in shares. This statement is effective for all financial instruments entered into or modified after May 31, 2003, and otherwise effective at the beginning of the first interim period beginning after June 15, 2003. The impact of adopting FASB No. 150 was not material to the Company's financial position and results of operations.

In December 2003, the SEC published Staff Accounting Bulletin (SAB) No. 104, "Revenue Recognition." This SAB updates portions of the SEC staff's interpretive guidance provided in SAB 101 and included in Topic 13 of the Codification of Staff Accounting Bulletins. SAB 104 deletes interpretive material no longer necessary, and conforms the interpretive material retained, because of pronouncements issued by the FASB's Emerging Issues Task Force (EITF), on various revenue recognition topics, including EITF 00-21, "Revenue Arrangements with Multiple Deliverables." SAB No. 104 also incorporates into the SAB Codification certain sections of the SEC staff's "Revenue Recognition in Financial Statements - Frequently Asked Questions and Answers." SAB No. 104 does not have a material impact on the Company's financial position and results of operations since the Company's revenue recognition practices previously conformed to the interpretations codified by SAB No. 104.

Off-Balance Sheet Arrangements

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

Tabular Disclosure of Contractual Obligations

In connection with SpectRx's acquisition of Sterling Medivations, Inc. on December 31, 2001, SpectRx agreed to pay contingent consideration based on attaining certain thresholds. The following summarizes SpectRx's estimated contractual obligations:

	Payment Due By Period				
	Total	2004	2005 to 2006	2007 to 2008	2009 & Thereafter
Long-term debt, including current maturities ⁽¹⁾	\$4,863	\$1,599	\$3,264	\$0	\$0
Operating Lease Obligation	\$168	\$78	\$57	\$33	\$0
Other long-term liabilities reflected on the Consolidated Balance Sheet ⁽²⁾	\$381	\$0	\$0	\$0	\$381

(1) These amounts reflect redeemable preferred stock current balance on the balance sheet. Actual amounts due will include additional interest accrued.

(2) This amount reflects the collaborative partner advance; no set payment date.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE REGARDING MARKET RISK

We have not entered into any transactions using derivative financial instruments and believe our exposure to interest rate risk, foreign currency exchange rate risk and other relevant market risks is not material.

INDEPENDENT AUDITORS' REPORT

Board of Directors and Stockholders

SpectRx, Inc. & Subsidiaries

We have audited the accompanying consolidated balance sheet of SpectRx, Inc. & subsidiaries as of December 31, 2003, and the related consolidated statements of operations, changes in stockholders' equity and cash flows for the year then ended. 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 audit.

We conducted our audit in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. 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 audit provides 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. & subsidiaries as of December 31, 2003, and the consolidated results of their operations and their consolidated cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

/s/ Eisner LLP

New York, New York

February 20, 2004

With respect to Note 14

March 26, 2004

REPORT OF INDEPENDENT AUDITORS

SpectRx, Inc.

We have audited the accompanying consolidated balance sheet of SpectRx, Inc. and subsidiary as of December 31, 2002, and the related consolidated statements of operations, stockholders' equity, and cash flows for the year then ended. 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 audit. The financial statements of SpectRx, Inc. and subsidiary as of December 31, 2001 and for the year then ended were audited by other auditors who have ceased operations and whose report dated February 14, 2002 expressed an unqualified opinion on those statements before the disclosure and restatement adjustment described in Notes 1 and 3.

We conducted our audit in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. 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 audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of SpectRx, Inc. and subsidiary as of December 31, 2002, and the consolidated results of their operations and their cash flows for the year then ended in conformity with accounting principles generally accepted in the United States.

As discussed above, the financial statements of SpectRx, Inc. and subsidiary as of December 31, 2001 and for the year then ended were audited by other auditors who have ceased operations. As described in Notes 1 and 3, the financial statements of SpectRx, Inc. and subsidiary as of December 31, 2001 have been restated to reflect a purchase price allocation adjustment to reverse goodwill initially recorded in the December 31, 2001 acquisition of Sterling Medivations, Inc. and record a corresponding decrease in the deferred tax asset valuation allowance account equal to the deferred tax liability established for patents acquired. We audited the adjustments that were applied to restate the purchase price allocation reflected in the 2001 financial statements. Our procedures included agreeing the deferred tax liability to the purchase price allocation in accordance with the asset purchase agreement and the valuation of intangibles acquired. In addition, as discussed in Note 2, the consolidated financial statements of SpectRx, Inc. and subsidiary as of December 31, 2001 and for the year then ended have been revised to include the disclosures required by Statement of Financial Accounting Standards No. 148, Accounting for Stock-Based Compensation-Transition and Disclosure, which was adopted by SpectRx, Inc. as of December 31, 2002. Our audit procedures with respect to the disclosures in Note 2 with respect to 2001 included (a) agreeing the previously reported net loss to the previously issued financial statements, (b) agreeing the adjustments to reported net loss representing compensation expense and pro forma compensation expense related to those periods to the Company's underlying records obtained from management and (c) testing the mathematical accuracy of the reconciliation of pro forma net loss to reported net loss and related loss per share amounts. In our opinion, the purchase price allocation adjustment and revised stock compensation disclosures are appropriate and have been properly applied. However, we were not engaged to audit, review, or apply any procedures to the 2001 financial statements of SpectRx, Inc. and subsidiary other than with respect to the purchase price allocation adjustment and revised stock compensation disclosures and, accordingly, we do not express an opinion or any other form of assurance on the 2001 financial statements taken as a whole.

The accompanying financial statements have been prepared assuming that SpectRx, Inc. and subsidiary will continue as a going concern. As more fully described in Note 1, the Company has incurred recurring operating losses and is dependent on and will need to obtain additional financing or generate sufficient cash flow from sales and royalty revenue to continue its development efforts and fund its operations. These conditions 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 financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

/s/ Ernst & Young LLP

Atlanta, Georgia
March 11, 2003

NOTE: THIS IS A COPY OF THE AUDIT REPORT PREVIOUSLY ISSUED BY ARTHUR ANDERSEN LLP ("ARTHUR ANDERSEN") IN CONNECTION WITH SPECTRX, INC.'S FORM 10-K FILING FOR THE FISCAL YEAR ENDED DECEMBER 31, 2001. THE INCLUSION OF THIS PREVIOUSLY ISSUED ARTHUR ANDERSEN REPORT IS PURSUANT TO THE "TEMPORARY FINAL RULE AND FINAL RULE REQUIREMENTS FOR ARTHUR ANDERSEN LLP AUDITING CLIENTS" ISSUED BY THE U.S. SECURITIES AND EXCHANGE COMMISSION IN MARCH 2002. NOTE THAT THIS PREVIOUSLY ISSUED ARTHUR ANDERSEN REPORT INCLUDES REFERENCES TO CERTAIN FISCAL YEARS THAT ARE NOT REQUIRED TO BE PRESENTED IN THE ACCOMPANYING CONSOLIDATED FINANCIAL STATEMENTS AS OF AND FOR THE YEARS ENDED DECEMBER 31, 2001 AND 2000. THIS AUDIT REPORT HAS NOT BEEN REISSUED BY ARTHUR ANDERSEN IN CONNECTION WITH THIS FILING ON FORM 10-K.

REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

To SpectRx, Inc.:

We have audited the accompanying consolidated balance sheets of SPECTRX, INC. (a Delaware corporation) and subsidiary as of December 31, 2000 and 2001 and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2001. 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 auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. 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 referred to above present fairly, in all material respects, the financial position of SpectRx, Inc. and subsidiary as of December 31, 2000 and 2001 and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2001 in conformity with accounting principles generally accepted in the United States.

/s/ Arthur Andersen LLP

Atlanta, Georgia

February 14, 2002

SPECTRX, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
DECEMBER 31, 2002 AND 2003
(IN THOUSANDS EXCEPT PAR VALUE)

ASSETS	2002	2003	LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	2002	2003
CURRENT ASSETS:			CURRENT LIABILITIES:		
Cash equivalents	\$1,165	\$389	Accounts payable	\$ 565	\$833
Restricted Cash	122	0	Accrued liabilities	666	1,203
Accounts receivable, net of allowance for doubtful accounts of \$46 and \$11 in 2002 and 2003, respectively	291	816	Redeemable Preferred Stock; Current Position	700	1,599
Inventories	643	238	Notes Payable	0	1,017
Other current assets	776	1,250			
	<u>2,997</u>	<u>2,693</u>			
Total current assets			Total current liabilities	1,931	4,652
			COLLABORATIVE PARTNER ADVANCE	381	381
			REDEEMABLE PREFERRED STOCK, LESS CURRENT POSITION	4,324	3,264
			COMMITMENTS & CONTINGENCIES		
			STOCKHOLDERS' EQUITY (DEFICIT):		
			Preferred stock, \$.001 par value; 5,000 shares authorized, 100 shares issued and outstanding as preferred stock in 2002 and 2003, respectively	1,185	1,245
			Common stock, \$.001 par value; 50,000 shares authorized, 11,270 and 11,407 shares issued and 11,263 outstanding in 2002 and 11,366 in 2003, respectively	11	11
			Additional paid-in capital	47,913	48,335
NONCURRENT ASSETS:			Treasury stock, at cost	(38)	(95)
Property and equipment, net	546	494	Deferred compensation	(88)	(69)
Intangibles, net	3,852	3,527	Notes receivable from officers	(47)	0
Due from related parties	77	0	Accumulated deficit	(48,100)	(51,010)
	<u>4,475</u>	<u>4,021</u>			
Total noncurrent assets			Total stockholders' equity (DEFICIT)	836	(1,583)
	<u>\$7,472</u>	<u>\$6,714</u>		<u>\$7,472</u>	<u>\$6,714</u>

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, 2001, 2002 AND 2003
(In Thousands Except Per Share Data)

	2001	2002	2003
	<u> </u>	<u> </u>	<u> </u>
REVENUE:			
Product sales	\$2,358	\$2,698	\$1,586
Collaborative agreements	100	1,100	0
	<u> </u>	<u> </u>	<u> </u>
Total revenue	2,458	3,798	1,586
COSTS AND EXPENSES:			
Cost of product sales	2,064	1,624	1,062
Research and development	3,842	5,827	4,108
Sales and marketing	846	1,649	735
General and administrative	2,941	2,785	2,150
	<u> </u>	<u> </u>	<u> </u>
	9,693	11,885	8,055
	<u> </u>	<u> </u>	<u> </u>
Operating loss	(7,235)	(8,087)	(6,469)
INTEREST INCOME (EXPENSE), net	254	91	(328)
OTHER INCOME (EXPENSE), net	15	(509)	17
GAIN ON SALE OF BILICHEK PRODUCT LINE	0	0	4,169
	<u> </u>	<u> </u>	<u> </u>
NET LOSS	(6,966)	(8,505)	(2,611)
PREFERRED STOCK DIVIDENDS	(315)	(315)	(299)
	<u> </u>	<u> </u>	<u> </u>
LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	\$(7,281)	\$(8,820)	\$(2,910)
	<u> </u>	<u> </u>	<u> </u>
BASIC AND DILUTED NET LOSS PER COMMON SHARE	\$(0.75)	\$(0.79)	\$(0.26)
	<u> </u>	<u> </u>	<u> </u>
BASIC AND DILUTED WEIGHTED AVERAGE SHARES OUTSTANDING	9,646	11,209	11,270
	<u> </u>	<u> </u>	<u> </u>

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

BALANCE, December 31, 2002	1,185	11,263	11	47,913	(38)	(88)	(47)	(48,100)	836
Dividends	60	0	0	0	0	0	0	0	60
Amortization of deferred comp	0	0	0	0	0	49	0	0	49
Employee stock purchase plan	0	24	0	27	0	0	0	0	27
Non- employee stock options	0	0	0	54	0	(30)	0	0	24
Issuance of common stock for services	0	114	0	149	0	0	0	0	149
Warrants	0	0	0	192	0	0	0	0	192
Note receivable	0	(35)	0	0	(57)	0	47	0	(10)
Dividends on preferred stock	0	0	0	0	0	0	0	(299)	(299)
Net loss	0	0	0	0	0	0	0	(2,611)	(2,611)
BALANCE, December 31, 2003	\$1,245	11,366	\$11	\$48,335	\$(95)	\$(69)	\$0	(\$51,010)	\$(1,583)

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, 2001, 2002 AND 2003
(In Thousands)

	<u>2001</u>	<u>2002</u>	<u>2003</u>
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	\$(6,966)	\$(8,505)	\$(2,611)
Adjustments to reconcile net loss to net cash used in operating activities excluding the effects of acquisition:			
Depreciation and amortization	360	533	507
Loss on retirement of property and equipment	116	5	72
Amortization of deferred compensation	0	54	49
Loss on notes due from related parties	0	508	0
Issuance of common stock, options and warrants for services and debt	0	118	365
Changes in operating assets and liabilities:			
Accounts receivable	30	938	(525)
Inventories	44	(206)	405
Other current assets	(11)	(368)	(454)
Accounts payable	(85)	(453)	268
Accrued liabilities	121	(528)	537
Total adjustments	575	601	1,224
Net cash used in operating activities	(6,391)	(7,904)	(1,387)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Additions to property and equipment	(90)	(290)	(202)
Acquisition of Sterling Medivations, net of cash and cash equivalents	198	(18)	0
Net cash provided by (used in) investing activities	108	(308)	(202)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Issuance of common stock, net of issuance costs	12,199	70	27
Notes payable	0	0	1,017
Treasury stock purchase	(38)	0	0
Payment on redeemable convertible preferred stock	0	0	(400)
Due from related parties	(29)	(29)	31
Notes receivable from officers	0	0	16
Net cash provided by financing activities	12,132	41	691
NET CHANGE IN CASH AND CASH EQUIVALENTS	5,849	(8,171)	(898)
CASH AND CASH EQUIVALENTS, beginning of year	3,609	9,458	1,287
CASH AND CASH EQUIVALENTS, end of year	\$9,458	\$1,287	\$389
CASH PAID FOR:			
Interest	\$ 2	\$ 0	\$113
SUPPLEMENTAL SCHEDULE OF NONCASH INVESTING AND FINANCING ACTIVITIES:			
Payment of dividends in the form of preferred stock and redeemable convertible preferred stock	\$ 315	\$ 315	\$299
Common stock issued for royalty payments	\$ 189	\$ 118	\$18

Common stock issued to consultants	0	0	\$104
Common stock issued in acquisition of Sterling Medivations	\$ 4,229	\$ (18)	0
Stock options issued in acquisition of Sterling Medivations	\$ 62	\$ 0	0

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

SPECTRX, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2002 AND 2003

1. ORGANIZATION, BACKGROUND, AND BASIS OF PRESENTATION

SpectRx, Inc. (the "Company" or "SpectRx") together with its subsidiaries, Sterling Medivations, Inc. ("Sterling") and Guided Therapeutics, Inc., ("Guided Therapeutics") each a Delaware corporation, is a medical technology company developing and providing products for the diabetes and noninvasive diagnostic markets. The Company uses its technologies to develop insulin delivery products, minimally-invasive fluid sampling procedures, and cancer detection products. The Company's goal is to introduce products that reduce or eliminate pain, are convenient to use, and provide rapid results at the point of care, thereby improving patient well-being and reducing health care costs. 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 cancer detection are based upon its proprietary biophotonic technologies.

On December 31, 2001, the Company acquired all of the outstanding common stock of Sterling a developer of innovative insulin delivery products for people with diabetes. The Company intends to develop and market its insulin products without a collaborative partner. See Note 3.

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, to be used for its cancer detection technology.

The financial statements of SpectRx, Inc. as of December 31, 2001 and for the year ended December 31, 2001, were audited by auditors who have ceased operations. As described in Note 3, the financial statements of SpectRx, Inc. as of December 31, 2001 have been restated to reflect a purchase price allocation adjustment to reverse goodwill initially recorded in the December 31, 2001 acquisition of Sterling Medivations and record a corresponding decrease in the deferred tax asset valuation allowance account equal to the deferred tax liability established for patents acquired.

Basis of Presentation

The Company has a limited operating history upon which its prospects can be evaluated. 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 operating losses since its inception, and, as of December 31, 2003, it has an accumulated deficit of \$51.0 million. Through December 31, 2003, the Company has engaged primarily in 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 generate significant revenue or achieve profitability. 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 2004 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.

In addition, a portion of the Company's revenue and profits are expected to be derived from royalties that it will receive from Respironics resulting from sales of the infant jaundice products and from the insulin delivery products developed by its subsidiary, Sterling. The royalties that the Company expects to receive from Respironics and manufacturing profits from Sterling 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 volumes of its products to generate substantial royalties, distribution profits, and manufacturing profits for the Company.

The Company's financial statements have been prepared and presented on a basis assuming it will continue as a going concern. Management has just completed a financing transaction (See Note 14, Subsequent Events) and believes those funds along with funds from sales and royalty revenue will be sufficient to support planned operations through December 31, 2004. 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 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.

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

	2002	2003
Raw materials	\$475	\$43
Work in process	3	0
Finished goods	165	195
	<u>\$643</u>	<u>\$238</u>

Advertising Costs

All advertising costs are expensed as incurred. Approximately \$143,000, \$513,000, and \$93,000 were charged to advertising expense for the years ended December 31, 2003, 2002, and 2001, 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, (in thousands):

	2002	2003
Equipment	\$2,234	\$2,004
Furniture and fixtures	261	279
	<u>\$2,495</u>	<u>\$2,283</u>
Less accumulated depreciation	1,949	1,789
Property and equipment, net	<u>\$546</u>	<u>\$494</u>

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 lives are not subject to amortization but will be subject to a periodic impairment assessment by applying a fair-value based test. Separate intangible assets that are not deemed to have an indefinite life will continue to be amortized over their useful lives.

As of December 31, 2003, goodwill of \$57,000 relates to the excess of the purchase price of Sterling over the fair value of net assets acquired. As of December 31, 2003, the financial statements include intangible assets of \$4.2 million, net of amortization of \$663,000. These intangible assets include \$4.1 million related to patents as well as \$32,000 related to non-compete and employment agreements acquired in the Sterling acquisition which are being amortized over the estimated economic useful life of 13 years and 18 month periods, respectively.

Patent Costs

Costs incurred in filing, prosecuting, and maintaining patents are expensed as incurred. Such costs aggregated approximately \$445,000, \$411,000 and \$579,000 in 2001, 2002 and 2003, respectively.

Clinical Trials

Costs associated with internal clinical trials are expensed as incurred and contracted clinical trials are expensed as each patient is seen.

Accounts Receivable

Accounts receivable at December 31, 2003, includes \$655,000 of amounts due from Respironics for earn out (\$509,000) and royalty payments (\$146,000) under the asset sale agreement, for performance during 2003. With the exception of the Respironics receivables, there were no significant concentrations of credit risk in 2003. The Company performs periodic credit evaluations of its customers' financial condition and generally does not require collateral. For December 31, 2003, uncollectible accounts written off totaled approximately \$5,000.

Accrued Liabilities

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

	2002	2003
Accrued compensation	\$205	\$612
Accrued royalties	33	200
Other accrued expenses	428	391
	<hr/>	<hr/>
Accrued liabilities	\$666	\$1,203

Revenue Recognition

In accordance with Staff Accounting Bulletin (SAB) No. 101, and 104 regarding revenue recognition, the Company records revenue from product sales at the time the product is shipped or title passes pursuant to the terms of the agreement with the customer, the amount due from the customer is fixed or determinable, and collectibility 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 fee payments under collaborative agreements related to future performance are deferred and recognized as income when earned. Royalty revenue is recognized on sales for the period covered based upon communications from Respironics.

Research and Development

Research and development expenses consist of non-reimbursed 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 in accordance with SFAS No. 109, "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 which 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 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 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 net income, 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 and loss per share 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,		
	2001	2002	2003
Net loss, as reported	\$(6,966)	\$(8,505)	\$(2,611)
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	\$(1,103)	\$ (767)	\$(673)
Proforma net loss	\$(8,069)	\$(9,272)	\$(3,284)
Proforma net loss attributable to common stockholders	\$(8,384)	\$(9,587)	\$(3,583)
Net loss attributable to common stockholders per share:			
Basic & Diluted - as reported	\$ (0.76)	\$ (0.79)	\$(0.26)
Basic & Diluted - pro forma	\$ (0.87)	\$ (0.86)	\$(0.32)

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 the Company's collaborative partner advance is estimated based on the amount payable to settle the liability. Under this method, the fair value of the Company's collaborative partner advance was not significantly different than the stated value at December 31, 2001 and 2002.

New Accounting Pronouncements

In June 2002, the FASB issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities." The Company's adoption of SFAS No. 146 on January 1, 2003 did not have any material effect on the financial statements of the Company.

In December 2003, the FASB issued Interpretation No. 46R, "Consolidation of Variable Interest Entities" in an effort to expand upon and strengthen existing accounting guidance that addresses when a company should include in its financial statements the assets, liabilities and activities of variable interest entities, including special-purpose entities or off-balance sheet structures. The consolidation requirements of FIN No. 46R have a variety of implementation dates. The Company believes the impact of FIN No. 46R on its financial position and results of operations will not be material, but the Company will continue to evaluate the impact of FIN No. 46R during the first quarter of 2004.

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity." This statement affects the issuer's accounting for three types of freestanding financial statements: mandatorily redeemable shares, put and forward purchase contracts that require the issuer to buy back some of its shares in exchange for cash or other assets, and certain obligations that can be settled in shares. This statement is effective for all financial instruments entered into or modified after May 31, 2003, and otherwise effective at the beginning of the first interim period beginning after June 15, 2003. The impact of adopting FASB No. 150 was not material to the Company's financial position and results of operations.

In December 2003, the Securities and Exchange Commission (SEC), published Staff Accounting Bulletin (SAB) No. 104, "Revenue Recognition." This SAB updates portions of the Securities and Exchange Commission (SEC) staff's interpretive guidance provided in SAB 101 and included in Topic 13 of the Codification of Staff Accounting Bulletins. SAB 104 deletes interpretive material no longer necessary, and conforms the interpretive material retained, because of pronouncements issued by the FASB's Emerging Issues Task Force (EITF) on various revenue recognition topics, including EITF 00-21, "Revenue Arrangements with Multiple Deliverables." SAB No. 104 also incorporates into the SAB Codification certain sections of the SEC staff's "Revenue Recognition in Financial Statements - Frequently Asked Questions and Answers." SAB No. 104 does not have a material impact on the Company's financial position and results of operations since the Company's revenue recognition practices previously conformed to the interpretations codified by SAB No. 104.

3. ACQUISITION

On December 31, 2001, the Company purchased the outstanding shares of Sterling Medivations, now doing business as Simple Choice. 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 will be entitled to receive up to an aggregate of 1,234,567 additional shares of Company common stock in the future if the Sterling product line achieves specified financial goals, none of which have been achieved as of December 31, 2003. In connection with the acquisition of Sterling, the Company entered into employment agreements with four employees for terms expiring 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 financial statements of SpectRx, Inc. as of December 31, 2001 included goodwill and a related tax liability of approximately \$1.6 million for taxable temporary differences existing at December 31, 2001 related to the acquired patents and non-compete agreements. The financial statements of SpectRx, Inc. as of December 31, 2001 have been restated to reflect a purchase price allocation adjustment to reverse the goodwill initially recorded and record a corresponding decrease in the deferred tax asset valuation allowance account equal to the deferred tax liability established for patents acquired.

The restated allocation of the purchase price of \$4,291 million and transaction cost of \$385,000 arising from the acquisition is as follows (in thousands):

Net tangible assets acquired	\$ 525
Patents	4,100
Noncompete and employment agreements	32
Deferred compensation	19

During 2002, the Company recorded additional price adjustments resulting in \$57,000 of goodwill.

The following unaudited pro forma information has been prepared assuming that the acquisition occurred at the beginning of the year of acquisition (2001). The unaudited pro forma information is presented for informational purposes only and may not be indicative of the actual results of operations which would have occurred had the acquisition been consummated at the beginning of the respective periods, nor is the information necessarily indicative of the results of operation which may occur in the future operations of the combined entities (in thousands, except loss per share data).

	2001
Pro forma revenue	\$ 2,458
Pro forma net loss attributable to common stockholders	\$(8,424)
Pro forma net loss per common share (basic and diluted)	\$ (0.82)

4. INVESTMENT IN FLUORRX, INC.

In December 1996, the Company sublicensed certain technology to and acquired a 65% interest in FluorRx, Inc. ("FluorRx"), a corporation organized for the purpose of developing and commercializing technology related to fluorescence spectroscopy. The Company's interest in FluorRx is represented by two seats on the board of directors and 1.2 million shares of convertible preferred stock purchased for \$250,000. In December 1997, March 1998, August 1998, and April 1999, FluorRx sold additional convertible preferred stock for net cash proceeds of \$521,000, \$429,000, \$511,000, and \$300,000, respectively. The issuance of additional preferred stock reduced the Company's ownership (on an as converted basis) to 43%. Effective with the August 1998 funding, the Company began accounting for FluorRx under the equity method of accounting. In connection therewith, the Company began suspending the equity losses from our investment in FluorRx.

On June 18, 2002, the board of directors of FluorRx approved a series of actions that resulted in dissolution of that corporation and its business. Those actions were subsequently approved by the FluorRx stockholders, and effective August 15, 2002, FluorRx was dissolved. There is no impact on the Company's statement of operations or balance sheet for the year 2002.

5. SALE OF ASSETS

On March 6, 2003, the Company sold its *BiliChek* Non-invasive Bilirubin Analyzer product line and related assets to Respironics, Inc. 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 in royalties and earn out 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. The sale of the *BiliChek* products enables the Company to focus on expanding its diabetes and cancer detection businesses. At December 31, 2002, fixed assets of approximately \$443,000, which were fully depreciated, and inventory of \$643,000 were included in the sale. *BiliChek* revenue was approximately \$2.5 million in 2002, and \$830,000 in 2003, which represented 65% and 52%, respectively, of the Company's total revenue for these years.

6. STOCKHOLDERS' EQUITY

Common Stock

During the year ended December 31, 2001, the Company issued 25,880 shares of common stock in satisfaction of minimum royalty payments amounting to \$189,000 related to the Company's exclusive rights to certain licensed technology.

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.

In October 2001, the Company issued 126,199 shares of common stock to Abbott for gross proceeds of \$1 million. The issuance of shares of common stock was associated with a milestone under a program to commercialize the Company's continuous glucose monitoring technology for people with diabetes.

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.

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.

Preferred Stock

In January 1997, the Company 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.

In November 1999, the board of directors designated 525,000 shares of the preferred stock as redeemable convertible preferred stock. Dividends are payable annually in cash or securities (at the Company's option) at a rate of 6% per annum. During the years ended December 31, 2001, 2002 and 2003, the Company accrued dividends in the form of redeemable convertible preferred stock of \$315,000, \$315,000 and \$299,000, 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 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 (which notice could not be given prior to June 1, 2002). 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.

In September 2002, Abbott delivered notice of its election to cause the redemption of the 425,000 shares of 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, which included mutual releases, the Company has 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 to Abbott during 2003. The Company's yearly financial obligations to Abbott under the agreement are approximately \$0.7 million, \$1.3 million, \$1.8 million and \$1.9 million for 2003, 2004, 2005 and 2006, respectively. Under the settlement, neither party admitted any liability or wrongdoing.

Stock Options

In May 1995, the Company adopted the 1995 Stock Plan (the "Plan"), which was amended on January 20, 1997 and during the year ended December 31, 2000, under which a total of 1,928,572 shares of common stock were authorized, and under which a total of 1,649,521 shares remain authorized, net of exercised shares. 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, 2003, options to purchase 61,522 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, 2003, 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 three years ended December 31, 2003 is as follows:

	Number of Options	Weighted Average Exercise Price Per Share
	<u> </u>	<u> </u>
Outstanding, December 31, 2000	1,430,060	\$ 6.47
Granted	63,168	7.12
Exercised	(5,361)	1.40
Canceled	(97,500)	10.23
	<u> </u>	<u> </u>
Outstanding, December 31, 2001	1,390,367	\$6.25
	<u> </u>	<u> </u>
Granted	329,929	4.22
Exercised	(21,429)	0.70
Canceled	(157,807)	8.16
	<u> </u>	<u> </u>
Outstanding, December 31, 2002	1,541,060	\$5.70
	<u> </u>	<u> </u>
Granted	244,000	1.35
Exercised	(4,480)	1.66
Canceled	(186,491)	10.05
	<u> </u>	<u> </u>
Outstanding, December 31, 2003	1,594,089	\$4.53
	<u> </u>	<u> </u>

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, 2003:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number of Shares	Weighted Average Price	Weighted Average Contractual Life (years)	Number of Shares	Weighted Average Price
\$ 0.21-\$ 0.70	333,574	\$ 0.54	2.17	333,574	\$ 0.54
\$ 1.46-\$ 4.26	398,044	1.76	8.12	224,728	2.06
\$ 5.00-\$ 9.00	776,210	6.94	5.56	639,166	7.19
\$ 10.13-\$ 16.50	<u>86,261</u>	11.18	6.61	<u>76,823</u>	11.20
Total	<u>1,594,089</u>	\$ 4.53	5.54	<u>1,274,291</u>	\$ 4.79

In June 1996, November 1996, and December 1996, the Company granted options to purchase 269,652, 8,573, and 60,715 shares of common stock, respectively, at exercise prices of \$.70, \$2.45, and \$2.45 per share, respectively. In connection with the issuance of these options, the Company recognized \$304,000 as deferred compensation for the excess of the deemed value for accounting purposes of the common stock issuable upon exercise of such options over the aggregate exercise price of such options. This deferred compensation was amortized ratably over the vesting period of the options.

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, 2003, 6,090 of these shares remain available for exercise.

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 in each of the three years ended December 31, 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 2001, 2002 and 2003:

	2001	2002	2003
Risk-free interest rate	4.60%	3.75%	2.34%
Expected dividend yield	0%	0%	0%
Expected lives	4 years	4 years	4 years
Expected volatility	63%	78%	91%

During the year ended December 31, 2003, the Company recorded deferred compensation of \$42,000 in connection with options to purchase 39,000 shares of common stock outstanding to a non-employee. These options were issued in exchange for services. Approximately \$26,000 was expensed in 2002 relating to these options.

Company shares outstanding and reserved December 31, 2003, are as follows:

	Common Shares
Options issued and outstanding under employee incentive plans	1,594,089
Options available under employee incentive plans	149,197
Shares reserved under employee stock purchase plan	123,939
Warrant shares reserved	582,127
Preferred shares reserved	138,754

In 1997, the Company 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, 2003, there were 123,939 shares available for future issuance under this plan. During the year ended December 31, 2003, the Company sold 24,336 shares valued at \$27,000, which amount was included in stockholders equity.

7. INCOME TAXES

The Company has incurred net operating losses ("NOLs") since inception. As of December 31, 2003, the Company had net operating loss carryforwards of approximately \$49 million available to offset its future income tax liability. The NOL carryforwards begin to expire in 2007. 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):

	2002	2003
Deferred tax assets:		
Net operating loss carryforwards	\$18,030	\$18,620
Deferred tax liabilities:		
Intangible assets and other	\$1,313	\$1,004
	16,717	17,616
Valuation allowance	(16,717)	(17,616)

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:

	2001	2002	2003
Statutory federal tax rate	(34)%	(34)%	(34)%
State taxes, net of federal benefit	(4)	(4)	(4)
Nondeductible expenses	2	0	0
Valuation allowance	36	38	38
	0 %	0 %	0%

8. COMMITMENTS AND CONTINGENCIES

Operating Leases

Future minimum rental payments at December 31, 2003 under non-cancellable operating leases for office space and equipment are as follows (in thousands):

2004	78
2005	29
2006	28
2007	28
2008	5

Rental expense was \$333,000, \$288,000 and \$241,000 in 2001, 2002 and 2003, respectively.

The Company has a contingent liability of \$105,000 for additional rent to its current landlord if it does not renew its current lease in a property owned by the current landlord.

Employment Agreements

In connection with the acquisition of Sterling, the Company entered into employment agreements with four employees for terms which expired in June 2003. The agreements each provide for severance of not more than \$235,000 plus benefits for termination of employment for any reason other than cause. In the event of termination without cause, the salary and benefits are to be paid for a term not to exceed six months. Three of these employees have since left the Company. Expense incurred under these arrangements amounted to \$70,000 and \$0 during year 2002 and 2003, respectively.

Litigation and Claims

The Company has been subject to certain asserted and unasserted 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 September 2001, the Company announced its agreement with Abbott to postpone payment of a \$1.0 million milestone due pursuant to an amendment to an agreement signed September 4, 2001. On May 17, 2002, the Company notified Abbott that it intended to pursue the alternative dispute resolution provisions of its agreement with Abbott regarding the nonpayment of this milestone. The Company had provided Abbott with notice of its achievement of the milestone, but Abbott had disputed whether the Company had met the required conditions for the milestone payment and whether the payment was due. On September 21, 2002, the Company received full payment of the \$1.0 million milestone.

In January, 2003, the Company announced that it had given notice that it was initiating actions required to terminate its research, development and license agreement with Abbott to jointly develop a continuous glucose monitor. The Company further announced that it was withholding payment due in connection with the redemption of the shares of the Company's preferred stock held by Abbott as an offset to claims which have also been made by the Company under its agreement with Abbott. Under the terms of the preferred stock, 162,500 shares of SpectRx preferred stock were required to be redeemed on December 30, 2002 at \$10.00 per share. The Company also announced that it 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 the right to terminate the agreement on January 7, 2003. A settlement with Abbott Laboratories was reached on March 10, 2003 regarding the disputes in connection with the prior termination of the parties agreement and the election of Abbott to have 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 has 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 \$0.4 million in 2003 related to this settlement.

Grants

In October 2000 and September 2001, the Company received grants of \$307,000 and \$338,000, respectively, from the Center's for Disease Control and Prevention ("CDC") to adapt its glucose monitoring technology to monitor blood sugar levels of children and elderly people with diabetes. The funding will be used to conduct clinical studies, research ergonomic issues and to assist in developing a plan for regulatory approval of the technology for children and the elderly. The grant announcement represents a commitment of more than \$938,000 in funding to date from the CDC. As of December 31, 2003, there are no further amounts available under this grant.

In July 2001, the Company received a grant from the National Cancer institute for \$130,000 for the Company's cervical cancer program. In February 2003, the Company received an additional \$1.3 million grant from the National Cancer Institute to further studies into the company's cervical cancer program. As of December 31, 2003, \$634,000 remains available under this grant.

All funds received from grants are recorded as reductions in Research & Development expenses on the Company's statements of operations.

Contracts

In addition to the grants above, the Company has received contracts from the National Institute on Alcohol Abuse and Alcoholism (NIAAA) ("Institute") and the Department of the Army to develop and test devices to sense alcohol and insulin growth factor, respectively based upon the Company's interstitial fluid collection technology. The NIAAA contract runs for two years, with an Institute option to extend it to five years in total. SpectRx's share of the contract, as the prime contractor, is expected to be approximately \$900,000 of the \$1.5 million agreed for the first two years, which commenced in 2003. The Company recognized \$380,000 of revenue for the portion of the contract that was completed during 2003. The Department of the Army (DOA) contract is for one year

and the total amount of the contract is \$51,000.

9. RELATED-PARTY TRANSACTIONS

In connection with a June 1994 sale of approximately 325,500 shares of restricted stock, the Company loaned two officers of the Company \$48,000, of which \$31,000 was outstanding at December 31, 2002. These full recourse loans were secured by the related common stock of the Company held by the officers, bore interest at 6% per annum, and became payable on December 31, 2002. Outstanding balances are classified as a reduction of stockholders' equity in the accompanying balance sheets. These notes were fully satisfied in January and February 2003, and the collateral was released.

In October 1996, the Company loaned two officers a total of \$400,000. The loans were secured by shares of common stock of Laser Atlanta Optics, Inc. ("LAO") and 35,715 shares of the Company's common stock, with a fair value of \$57,000. The Company and LAO were related through a common group of shareholders. The loans, which were recourse only to the extent of the collateral, bore interest at 6.72% per annum and became due and payable on December 31, 2002. During February 2003, SpectRx took possession of the collateral. As of December 31, 2002, these loans were written down to their estimated fair value of \$57,000, which represents the value of the collateral shares at December 31, 2002. The resulting charge to operations in 2002 was approximately \$508,000. In September 2003, LAO sold its assets to another corporation, a non-related party, and SpectRx received \$17,784 from the sale of assets.

10. 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 has the option not to make required minimum royalty payments, in which case the Company loses the exclusive license to develop applicable technology. Minimum required payments to maintain exclusive rights to licensed technology are as follows at December 31, 2003 (in thousands):

2004	\$200
2005	300*
2006	300*
2007	300*

* Indexed to the CPI

During 2001, 2002 and 2003 the Company incurred royalty expense of \$1,184,000, \$1,089,000 and \$1,063,000, respectively, which has been recorded as R&D expense.

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

11. COLLABORATIVE AGREEMENTS

During 2002, the Company had collaborative research and development agreements (the "Agreements") with collaborative partners for the joint development, regulatory approval, manufacturing, marketing, distribution, and sales of products. The Agreements generally provided for nonrefundable payments upon contract signing and additional payments upon reaching certain milestones with respect to technology.

Abbott

The Abbott Agreement, as amended, required Abbott to make milestone payments based on progress achieved, to remit royalties to the Company based on net product sales, and to reimburse certain direct expenses incurred by the Company in connection with the development of glucose monitoring products. Reimbursed expenses of \$2.8 million, and \$745,000 and \$0 for the years ended December 31, 2001, 2002 and 2003, respectively, have been netted with research and development expenses in the accompanying statements of operations. The Company recorded revenues of \$0, and \$1.0 million during 2001 and 2002, respectively, related to the achievement of certain milestones.

In 1997, Abbott purchased \$3.0 million of series C preferred stock and in November 1999, subscribed to \$5.25 million of redeemable convertible preferred stock (Note 6). In 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. In 2002, Abbott delivered notice of its election to cause the redemption of the 425,000 shares of the redeemable convertible preferred stock eligible for redemption.

In January 2003, the Company's agreement with Abbott was terminated. See Notes 6 and 8.

Welch Allyn

The Welch Allyn Agreement required Welch Allyn to share equally the operating expenses and cost of capital assets, to make milestone payments based on progress achieved, and to pay the Company a technology access fee. Reimbursed expenses of \$831,000, \$0 and \$0 for the years ended December 31, 2001, 2002 and 2003, respectively, have been netted with research and development expenses in the accompanying statements of operations. In November 2002, Welch Allyn and the Company agreed to terminate this Agreement.

Roche

The Roche 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 instances.

In July 1999, the Company received \$381,000 in advance payments for inventory components with long lead times from Roche. The balance is noninterest bearing and is due upon the date in which Roche has received delivery of 250 diabetes screening devices pursuant to the Roche agreement and Federal Drug Administration regulatory clearance has been issued.

There was no development activity on this product during 2003. There have been no commercial sales of this product to end users to date.

Respironics

The Respironics Agreement required Respironics to make milestone payments based on milestones achieved and to purchase infant jaundice products manufactured by the Company at a predetermined profit margin, subject to renegotiation between the parties in certain instances. The Company recorded revenues of \$100,000, \$100,000 and \$0 in 2001, 2002 and 2003, respectively, related to the achievement of certain milestones. Additionally, Respironics purchased products amounting to \$726,000, \$900,000 and \$445,000 during 2001, 2002 and 2003, respectively, from the Company. On March 6, 2003, the Company sold its infant jaundice product line and assets to Respironics. (See Note 5.)

12. BUSINESS SEGMENT INFORMATION

The Company operates in one business segment, the research and development of medical products. The Company had no product sales prior to fiscal year 1998. During fiscal years 2001, 2002 and 2003, total product revenue of \$2,358,000, \$2,698,000 and \$1,586,000 respectively, related primarily to the Company's infant jaundice product, including, during 2003, \$146,000 of royalties due in conjunction with the asset sale agreement between the Company and Respironics. 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 Respironics. 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 are as follows (in thousands):

	<u>2001</u>	<u>2002</u>	<u>2003</u>
United States and Canada	\$1,043	\$1,602	\$1,341
Europe	958	822	189
Latin America	112	26	1
Middle East	67	37	33
Asia	144	182	4
Other	34	29	18
Total	\$2,358	\$2,698	\$1,586

SpectRx has tooling assets of \$57,000 in the People's Republic of China and \$132,000 in Mexico for the production of SimpleChoice parts and assembled devices.

13. SELECTED QUARTERLY CONSOLIDATED FINANCIAL INFORMATION (unaudited)

Quarter Ended							
March	June	September	December	March	June	September	December
31	30	30	31	31	30	30	31
2002	2002	2002	2002	2003	2003	2003	2003

(in thousands except per share data)

Total Revenue	652	774	1,598	774	801	126	209	450
Cost of Goods Sold	424	393	356	451	312	180	216	354
Operating Income	(2,406)	(3,196)	(1,073)	(1,412)	(1,204)	(2,026)	(1,844)	(1,395)
Net Income (Loss)	(2,370)	(3,175)	(1,049)	(1,911)	(159)	(2,078)	(1,873)	1,499
Preferred Stock Dividends	(79)	(79)	(78)	(79)	(79)	(74)	(73)	(73)
Income (Loss) Available (Attributed) to Common Stockholders	(2,449)	(3,254)	(1,127)	(1,990)	(238)	(2,152)	(1,946)	1,426
Net Income (Loss) Per Share								
Basic	(\$0.22)	(\$0.29)	(\$0.10)	(\$0.18)	(\$0.02)	(\$0.19)	(\$0.17)	\$0.13
Diluted	(\$0.22)	(\$0.29)	(\$0.10)	(\$0.18)	(\$0.02)	(\$0.19)	(\$0.17)	\$0.12
Weighted Average Common shares Outstanding								
Basic	11,202	11,197	11,210	11,249	11,249	11,237	11,248	11,336
Diluted	11,202	11,197	11,210	11,249	11,249	11,237	11,248	11,600

The Company recorded a \$508,000 charge to operations in December 2002 for the extinguishments of officer loans. (See Note 9.)

14. SUBSEQUENT EVENTS

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.

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. The placement also included a registration rights agreement between the Company and the purchasers, requiring registration of the underlying common shares, to be effective within 90 days of the closing, or a portion of the proceeds could be deemed an obligation.

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

15. NOTES PAYABLE

The Company issued Notes on July 30, 2003 in an aggregate amount of \$1,000,000 to five individuals, including two officers of SpectRx, for the purpose of bridge financing. The terms of the notes included a balloon payment 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 warrants for 203,000 shares with a fair value of \$193,000 and such amount was charged to interest expenses in 2003.

FINANCIAL DISCLOSURE

On June 14, 2002, we filed a Current Report on Form 8-K reporting under Item 4 "Changes in Registrant's Certifying Accountant" as follows:

"On June 12, 2002, the audit committee of the board of directors of SpectRx, Inc. voted to dismiss its independent public accountants, Arthur Andersen LLP, effective on that date. On June 12, 2002, the audit committee of the board of directors voted to engage the services of Ernst & Young LLP to serve as SpectRx's independent public accountants for its 2002 fiscal year, effective on that date.

Arthur Andersen's reports on SpectRx's consolidated financial statements for each of the past two fiscal years did not contain an adverse opinion or disclaimer of opinion, nor were they qualified or modified as to uncertainty, audit scope or accounting principles.

During SpectRx's two most recent fiscal years through the date hereof, there were no disagreements with Arthur Andersen on any matter of accounting principle or practice, financial statement disclosure, or auditing scope or procedure which, if not resolved to Arthur Andersen's satisfaction, would have caused Arthur Andersen to make reference to the subject matter in connection with Arthur Andersen's report on SpectRx's consolidated financial statements for such years; and there were no reportable events as defined in Item 304(a)(1)(v) of Regulation S-K.

SpectRx provided Arthur Andersen with a copy of the foregoing disclosures and Arthur Andersen provided a letter, dated June 14, 2002, stating its agreement with such statements.

During SpectRx's two most recent fiscal years and through the date of its filing on Form 8-K on June 14, 2002, SpectRx did not consult Ernst & Young LLP with respect to the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on SpectRx's consolidated financial statements, or any other matters or reportable events as set forth in Items 304(a)(2)(i) and (ii) of Regulation S-K."

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 *BiliChek* 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 9A. 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 the Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of December 31, 2003.

There have been no changes in our internal controls over financial reporting that occurred during the quarter ended December 31, 2003 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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 2004 Annual Meeting of Stockholders to be held on May 20, 2004, and certain information included therein is incorporated herein by reference.

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

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 29, 2004:

NAME	AGE	POSITION
Mark A. Samuels	45	Chairman, chief executive officer and director
William Arthur	52	President, chief operating officer
Keith D. Ignatz	56	Senior executive vice president and director
Thomas H. Muller, Jr.	62	Executive vice president, chief financial officer and secretary
Mark L. Faupel	48	Executive vice president, chief technology officer
Richard L. Fowler	47	Vice president engineering
Walter J. Pavlicek	57	Vice president operations

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. 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 Arthur 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.

Keith D. Ignatz has served as a member of our board of directors since co-founding SpectRx in 1992. He is currently senior executive vice president of SpectRx, responsible for the Company's cancer detection business, Guided Therapeutics. Until November 2003, he served as president and chief operating officer of SpectRx. Formerly, Mr. Ignatz was president of Humphrey Instruments SmithKline Beckman (Japan), president of Humphrey Instruments GmbH (Germany), and senior vice president of Allergan Humphrey Inc., a \$100 million per year ophthalmic diagnostic company. Mr. Ignatz is a member of the board of directors of Vismed, Inc. (Dicon), an ophthalmic diagnostic products company, and Pennsylvania College of Optometry. Mr. Ignatz earned a B.A. in Sociology from San Jose State University and an M.B.A. from Pepperdine University.

Thomas H. Muller, Jr. has served as our chief financial officer since joining us in December 1996. Prior to that time, Mr. Muller was president of Muller & Associates, an operational and financial management services company and chief financial officer of Nurse On Call, Inc. From 1984 to 1992, Mr. Muller was chief financial officer of HBO & Company, a provider of information systems and services to the health care industry. Mr. Muller is a member of the board of directors of NetBank, Inc., an Internet banking company. Mr. Muller earned a B.I.E. in Industrial Engineering from Georgia Institute of Technology and an M.B.A. from Harvard Business School.

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.

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., 6025A Unity Drive, 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 11. EXECUTIVE COMPENSATION

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

ITEM 12. 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. In addition, the information set forth in Part II, Item 5 under the caption "Securities Authorized for Issuance Under Equity Compensation Plans" is hereby incorporated by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

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

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information under the caption "Independent Auditors" in our proxy statement is hereby incorporated by reference.

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

1. CONSOLIDATED FINANCIAL STATEMENTS

- Report of Independent Auditors
- Consolidated Statements of Operations for the Years Ended December 31, 2001, 2002 and 2003
- Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2001, 2002 and 2003
- Consolidated Statements of Cash Flows for the Years Ended December 31, 2001, 2002 and 2003
- Notes to Consolidated Financial Statements

2. FINANCIAL STATEMENT SCHEDULE.

Schedules are not included in this Annual Report on Form 10-K, as they are not required or the information required to be set forth therein is included in the Consolidated Financial Statements or Notes thereto.

3. EXHIBITS

Refer to (C) below.

(B) REPORTS ON FORM 8-K

SpectRx filed the following Current Reports on Form 8-K during the quarter ended December 31, 2003.

The registrant filed a Form 8-K on October 24, 2003, announcing under Item 4, the dismissal of Ernst & Young LLP as independent public accountants and the engagement of Eisner LLP as the new independent public accountants, effective October 17, 2003.

The registrant filed a Form 8-K on November 6, 2003, announcing under Item 5, that Bill Arthur was named president and chief operating officer of SpectRx, Inc.

The registrant filed a Form 8-K on November 11, 2003, announcing under Item 12, financial results for the third quarter of 2003.

The registrant filed a Form 8-K on November 26, 2003, announcing under Item 5, the receipt of a \$1 million payment from Respirationics, Inc. as part of the sale of the *BiliChek* product line.

(C) EXHIBITS

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

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
4.2(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. Ignatz 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 Respiroics and SpectRx.
10.12B(4)*	Amendment to Purchasing and Licensing Agreement, dated October 21, 1998 between Respiroics 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	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.
16.1	Letter re Change in Certifying Accountants (incorporated by reference to Exhibit 16.1 to the Registrant's Current Report on Form 8-K, filed on June 14, 2002).
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.
23.2(13)	Consent of Ernst & Young LLP.
24.1	Power of Attorney (included on signature page).
31	Rule 13a - 14(a) / 15d - 14(a) Certifications.
32	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.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on the 30th day of March 2004.

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 and Thomas H. Muller, Jr., jointly and severally, his or her attorneys-in-fact, and each with the power of substitution, for him or her in any and all capacities, to sign any amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his or her substitute or substitutes, may do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, 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
March 30, 2004	<u>/s/ Mark A. Samuels</u> Mark A. Samuels	Chairman, Chief Executive Officer and Director (Principal Executive Officer)
March 30, 2004	<u>/s/ Thomas H. Muller, Jr.</u> Thomas H. Muller, Jr.	Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)
March 30, 2004	<u>/s/ Keith D. Igotz</u> Keith D. Igotz	Senior Executive Vice President and Director
March 30, 2004	<u>/s/ Charles G. Hadley</u> Charles G. Hadley	Director
March 30, 2004	<u>/s/ Earl R. Lewis</u> Earl R. Lewis	Director
March 30, 2004	<u>/s/ William E. Zachary</u> William E. Zachary	Director
March 30, 2004	<u>/s/ Chris Monahan</u> Chris Monahan	Director

BYLAWS
OF
SPECTRX, INC.

(as amended March 23, 2004)

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**BYLAWS
OF
SPECTRX, INC.**

(as amended March 23, 2004)

ARTICLE I

CORPORATE OFFICES

1.1 REGISTERED OFFICE

The registered office of the corporation shall be in the City of Wilmington, County of New Castle, State of Delaware. The name of the registered agent of the corporation at such location is The Corporation Trust Company.

1.2 OTHER OFFICES

The board of directors may at any time establish other offices at any place or places where the corporation is qualified to do business.

ARTICLE II

MEETINGS OF STOCKHOLDERS

2.1 PLACE OF MEETINGS

Meetings of stockholders shall be held at any place, within or outside the State of Delaware, designated by the board of directors. In the absence of any such designation, stockholders' meetings shall be held at the registered office of the corporation.

2.2 ANNUAL MEETING

The annual meeting of stockholders shall be held each year on a date and at a time designated by the board of directors. In the absence of such designation the annual meeting of shareholders shall be held on the second Monday of May of each year at 10:00 a.m. However, if such day falls on a legal holiday, then the meeting shall be held at the same time and place on the next succeeding business day. At the meeting, directors shall be elected and any other proper business may be transacted.

2.3 SPECIAL MEETING

A special meeting of the stockholders may be called at any time by the board of directors, or by the chairman of the board, or by the president, or by one or more stockholders holding shares in the aggregate entitled to cast not less than ten percent of the votes at that meeting.

If a special meeting is called by any person or persons other than the board of directors, the request shall be in writing, specifying the time of such meeting and the general nature of the business proposed to be transacted, and shall be delivered personally or sent by registered mail or by telegraphic or other facsimile transmission to the chairman of the board, the president or the secretary of the corporation. No business may be transacted at such special meeting otherwise than specified in such notice. The officer receiving the request shall cause notice to be promptly given to the stockholders entitled to vote, in accordance with the provisions of Sections 2.4 and 2.5 of this Article II, that a meeting will be held at the time requested by the person or persons calling the meeting, not less than ten (10) nor more than sixty (60) days after

the receipt of the request. Nothing contained in this paragraph of this Section 2.3 shall be construed as limiting, fixing, or affecting the time when a meeting of stockholders called by action of the board of directors may be held.

2.4 NOTICE OF STOCKHOLDERS' MEETINGS

All notices of meetings with stockholders shall be in writing and shall be sent or otherwise given in accordance with Section 2.5 of these bylaws not less than ten (10) nor more than sixty (60) days before the date of the meeting to each stockholder entitled to vote at such meeting. The notice shall specify the place, date, and hour of the meeting, and, in the case of a special meeting, the purpose or purposes for which the meeting is called.

2.5 MANNER OF GIVING NOTICE; AFFIDAVIT OF NOTICE

Written notice of any meeting of stockholders, if mailed, is given when deposited in the United States mail, postage prepaid, directed to the stockholder at his address as it appears on the records of the corporation. An affidavit of the Secretary or an Assistant Secretary or of the transfer agent of the corporation that the notice has been given shall, in the absence of fraud, be prima facie evidence of the facts stated therein.

2.6 QUORUM

The holders of a majority of the stock issued and outstanding and entitled to vote thereat, present in person or represented by proxy, shall constitute a quorum at all meetings of the stockholders for the transaction of business except as otherwise provided by statute or by the certificate of incorporation. If, however, such quorum is not present or represented at any meeting of the stockholders, then either (i) the Chairman of the meeting or (ii) the stockholders entitled to vote thereat, present in person or represented by proxy, shall have power to adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum is present or represented. At such adjourned meeting at which a quorum is present or represented, any business may be transacted that might have been transacted at the meeting as originally noticed.

2.7 ADJOURNED MEETING; NOTICE

When a meeting is adjourned to another time or place, unless these bylaws otherwise require, notice need not be given of the adjourned meeting if the time and place thereof are announced at the meeting at which the adjournment is taken. At the adjourned meeting the corporation may transact any business that might have been transacted at the original meeting. If the adjournment is for more than thirty (30) days, or if after the adjournment a new record date is fixed for the adjourned meeting, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting.

2.8 CONDUCT OF BUSINESS

The chairman of any meeting of stockholders shall determine the order of business and the procedure at the meeting, including such regulation of the manner of voting and the conduct of business.

2.9 VOTING

The stockholders entitled to vote at any meeting of stockholders shall be determined in accordance with the provisions of Section 2.12 of these bylaws, subject to the provisions of Sections 217 and 218 of the General Corporation Law of Delaware (relating to voting rights of fiduciaries, pledgors and joint owners of stock and to voting trusts and other voting agreements).

Except as provided in the last paragraph of this Section 2.9, or as may be otherwise provided in the certificate of incorporation, each stockholder shall be entitled to one vote for each share of capital stock held by such stockholder.

At a stockholders' meeting at which directors are to be elected, each stockholder shall be entitled to cumulate votes (i.e., cast for any candidate a number of votes greater than the number of votes which such stockholder normally is entitled to cast) if the candidates' names have been properly placed in nomination (in accordance with these bylaws) prior to commencement of the voting and the stockholder requesting cumulative voting or any other stockholder voting at the meeting in person or by proxy has given notice prior to commencement of the voting of the stockholder's intention to cumulate votes. If cumulative voting is properly requested, each holder of stock, or of any class or classes or of a series or series thereof, who elects to cumulate votes shall

be entitled to as many votes as equals the number of votes which (absent this provision as to cumulative voting) he would be entitled

to cast for the election of directors with respect to his shares of stock multiplied by the number of directors to be elected by him, and he may cast all of such votes for a single director or may distribute them among the number to be voted for, or for any two or more of them, as he may see fit.

2.10 WAIVER OF NOTICE

Whenever notice is required to be given under any provision of the General Corporation Law of Delaware or of the certificate of incorporation or these bylaws, a written waiver thereof, signed by the person entitled to notice, whether before or after the time stated therein, shall be deemed equivalent to notice. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting, except when the person attends a meeting for the express purpose of objecting, at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Neither the business to be transacted at, nor the purpose of, any regular or special meeting of the stockholders need be specified in any written waiver of notice unless so required by the certificate of incorporation or these bylaws.

2.11 STOCKHOLDER ACTION BY WRITTEN CONSENT WITHOUT A MEETING

Unless otherwise provided in the certificate of incorporation, any action required by this chapter to be taken at any annual or special meeting of stockholders of a corporation, or any action that may be taken at any annual or special meeting of such stockholders, may be taken without a meeting, without prior notice, and without a vote if a consent in writing, setting forth the action so taken, is signed by the holders of outstanding stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted.

Prompt notice of the taking of the corporate action without a meeting by less than unanimous written consent shall be given to those stockholders who have not consented in writing. If the action which is consented to is such as would have required the filing of a certificate under any section of the General Corporation Law of Delaware if such action had been voted on by stock holders at a meeting thereof, then the certificate filed under such section shall state, in lieu of any statement required by such section concerning any vote of stockholders, that written notice and written consent have been given as provided in Section 228 of the General Corporation Law of Delaware.

2.12 RECORD DATE FOR STOCKHOLDER NOTICE; VOTING; GIVING CONSENTS

In order that the corporation may determine the stockholders entitled to notice of or to vote at any meeting of stockholders or any adjournment thereof, or entitled to express consent to corporate action in writing without a meeting, or entitled to receive payment of any dividend or other distribution or allotment of any rights, or entitled to exercise any rights in respect of any change, conversion or exchange of stock or for the purpose of any other lawful action, the board of directors may fix, in advance, a record date, which shall not be more than sixty (60) nor less than ten (10) days before the date of such meeting, nor more than sixty (60) days prior to any other action.

If the board of directors does not so fix a record date:

- (i) The record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be at the close of business on the day next preceding the day on which notice is given, or, if notice is waived, at the close of business on the day next preceding the day on which the meeting is held.
- (ii) The record date for determining stockholders entitled to express consent to corporate action in writing without a meeting, when no prior action by the board of directors is necessary, shall be the day on which the first written consent is expressed.
- (iii) The record date for determining stockholders for any other purpose shall be at the close of business on the day on which the board of directors adopts the resolution relating thereto.

A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting; provided, however, that the board of directors may fix a new record date for the adjourned meeting.

2.13 PROXIES

Each stockholder entitled to vote at a meeting of stockholders or to express consent or dissent to corporate action in writing without a meeting may authorize another person or persons to act for him by a written proxy, signed by the stockholder and filed with the secretary of the corporation, but no such proxy shall be voted or acted upon after three (3) years from its date, unless the proxy provides for a longer period. A proxy shall be deemed signed if the stockholder's name is placed on the proxy (whether by manual signature, typewriting, telegraphic transmission or otherwise) by the stockholder or the stockholder's attorney-in-fact. The revocability of a proxy that states on its

face that it is irrevocable shall be governed by the provisions of Section 212(c) of the General Corporation Law of Delaware.

2.14 LIST OF STOCKHOLDERS ENTITLED TO VOTE

The officer who has charge of the stock ledger of a corporation shall prepare and make, at least ten (10) days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting, arranged in alphabetical order, and showing the address of each stockholder and the number of shares registered in the name of each stockholder. Such list shall be open to the

examination of any stockholder, for any purpose germane to the meeting, during ordinary business hours, for a period of at least ten (10) days prior to the meeting, either at a place within the city where the meeting is to be held, which place shall be specified in the notice of the meeting, or, if not so specified, at the place where the meeting is to be held. The list shall also be

produced and kept at the time and place of the meeting during the whole time thereof, and may be inspected by any stockholder who is present. Such list shall presumptively determine the identity of the stockholders entitled to vote at the meeting and the number of shares held by each of them.

ARTICLE III

DIRECTORS

3.1 POWERS

Subject to the provisions of the General Corporation Law of Delaware and any limitations in the certificate of incorporation or these bylaws relating to action required to be approved by the stockholders or by the outstanding shares, the business and affairs of the corporation shall be managed and all corporate powers shall be exercised by or under the direction of the board of directors.

3.2 NUMBER OF DIRECTORS

The number of directors of the corporation shall be not less than four (4) nor more than eight (8). The exact number of directors shall be six (6) until either: (a) the holders of the corporation's Series A Convertible Preferred Stock, par value \$.01 per share (the "Series A Preferred"), deliver notice to the corporation in the manner set forth in Section (d) of the Certificate of Designations, Preferences and Rights of the Series A Preferred that the holders of the Series A Preferred have elected to exercise their right to vote together as a single class to elect two (2) members of the Board of Directors, following which notice the number of directors of the corporation shall be eight (8); or (b) such number is changed, within the limited specified above, by a bylaw amending this Section 3.2, duly adopted by the board of directors or by the stockholders. The indefinite number of directors may be changed, or a definite number may be fixed without provision for an indefinite number, by a duly adopted amendment to the certificate of incorporation or by an amendment to this bylaw duly adopted by the vote or written consent of the holders of the majority of the stock issued and outstanding and entitled to vote or by resolution of the majority of the board of directors.

No reduction of the authorized number of directors shall have the effect of removing any director before that director's term of office expires."

3.3 ELECTION, QUALIFICATION AND TERM OF OFFICE OF DIRECTORS

Except as provided in Section 3.4 of these bylaws, directors shall be elected at each annual meeting of stockholders to hold office until the next annual meeting. Directors need not be stockholders unless so required by the certificate of incorporation or these bylaws, wherein other qualifications for directors may be prescribed. Each director, including a director elected to fill a vacancy, shall hold office until his successor is elected and qualified or until his earlier resignation or removal.

Elections of directors need not be by written ballot.

3.4 RESIGNATION AND VACANCIES

Any director may resign at any time upon written notice to the attention of the Secretary of the corporation. When one or more directors so resigns and the resignation is effective at a future date, a majority of the directors then in office, including those who have so resigned, shall have power to fill such vacancy or vacancies, the vote thereon to take effect when such resignation or resignations shall become effective, and each director so chosen shall hold office as provided in this section in the filling of other vacancies.

Unless otherwise provided in the certificate of incorporation or these bylaws:

(i) Vacancies and newly created directorships resulting from any increase in the authorized number of directors elected by all of the stockholders having the right to vote as a single class may be filled by a majority of the directors then in office, although less than a quorum, or by a sole remaining director.

(ii) Whenever the holders of any class or classes of stock or series thereof are entitled to elect one or more directors by the provisions of the certificate of incorporation, vacancies and newly created directorships of such class or classes or series may be filled by a majority of the directors elected by such class or classes or series thereof then in office, or by a sole

remaining director so elected.

If at any time, by reason of death or resignation or other cause, the corporation should have no directors in office, then any officer or any stockholder or an executor, administrator, trustee or guardian of a stockholder, or other fiduciary entrusted with like responsibility for the person or estate of a stockholder, may call a special meeting of stockholders in accordance with the provisions of the certificate of incorporation or these bylaws, or may apply to the Court of Chancery for a decree summarily ordering an election as

provided in Section 211 of the General Corporation Law of Delaware.

If, at the time of filling any vacancy or any newly created directorship, the directors then in office constitute less than a majority of the whole board (as constituted immediately prior to any such increase), then the Court of Chancery may, upon application of any stockholder or stockholders holding at least ten (10) percent of the total number of the shares at the time outstanding having the right to vote for such directors, summarily order an election to be held to fill any such vacancies or newly created directorships, or to replace the directors chosen by the directors then in office as aforesaid, which election shall be governed by the provisions of Section 211 of the General Corporation Law of Delaware as far as applicable.

3.5 PLACE OF MEETINGS; MEETINGS BY TELEPHONE

The board of directors of the corporation may hold meetings, both regular and special, either within or outside the State of Delaware.

Unless otherwise restricted by the certificate of incorporation or these bylaws, members of the board of directors, or any committee designated by the board of directors, may participate in a meeting of the board of directors, or any committee, by means of conference telephone or similar communications equipment by means of which all persons participating in the meeting can hear each other, and such participation in a meeting shall constitute presence in person at the meeting.

3.6 REGULAR MEETINGS

Regular meetings of the board of directors may be held without notice at such time and at such place as shall from time to time be determined by the board.

3.7 SPECIAL MEETINGS; NOTICE

Special meetings of the board of directors for any purpose or purposes may be called at any time by the chairman of the board, the president, any vice president, the secretary or any two (2) directors.

Notice of the time and place of special meetings shall be delivered personally or by telephone to each director or sent by first-class mail or telegram, charges prepaid, addressed to each director at that director's address as it is shown on the records of the corporation. If the notice is mailed, it shall be deposited in the United States mail at least four (4) days before the time of the holding of the meeting. If the notice is delivered personally or by telephone or by telegram, it shall be delivered personally or by telephone or to the telegraph company at least forty-eight (48) hours before the time of the holding of the meeting. Any oral notice given personally or by telephone may be communicated either to the director or to a person at the office of the director who the person giving the notice has reason to believe will promptly communicate

it to the director. The notice need not specify the purpose or the place of the meeting, if the meeting is to be held at the principal executive office of the corporation.

3.8 QUORUM

At all meetings of the board of directors, a majority of the authorized number of directors shall constitute a quorum for the transaction of business and the act of a majority of the directors present at any meeting at which there is a quorum shall be the act of the board of directors, except as may be otherwise specifically provided by statute or by the certificate of incorporation. If a quorum is not present at any meeting of the board of directors, then the directors present thereat may adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum is present.

A meeting at which a quorum is initially present may continue to transact business notwithstanding the withdrawal of directors, if any action taken is approved by at least a majority of the required quorum for that meeting.

3.9 WAIVER OF NOTICE

Whenever notice is required to be given under any provision of the General Corporation Law of Delaware or of the certificate of incorporation or these bylaws, a written waiver thereof, signed by the person entitled to notice, whether before or after the time stated therein, shall be deemed equivalent to notice. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting, except when the person attends a meeting for the express purpose of objecting, at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Neither the business to be transacted at, nor the purpose of, any regular or special meeting of the directors, or members of a committee of directors, need be specified in any written waiver of notice unless so required by the certificate of incorporation or these bylaws.

3.10 BOARD ACTION BY WRITTEN CONSENT WITHOUT A MEETING

Unless otherwise restricted by the certificate of incorporation or these bylaws, any action required or permitted to be taken at any meeting of the board of directors, or of any committee thereof, may be taken without a meeting if all members of the board or committee, as the case may be, consent thereto in writing and the writing or writings are filed with the minutes of proceedings of the board or committee.

3.11 FEES AND COMPENSATION OF DIRECTORS

Unless otherwise restricted by the certificate of incorporation or these bylaws, the board of directors shall have the authority to fix the

compensation of directors.

3.12 APPROVAL OF LOANS TO OFFICERS

The corporation may lend money to, or guarantee any obligation of, or otherwise assist any officer or other employee of the corporation or of its subsidiary, including any officer or employee who is a director of the corporation or its subsidiary, whenever, in the judgment of the directors, such loan, guaranty or assistance may reasonably be expected to benefit the corporation. The loan, guaranty or other assistance may be with or without interest and may be unsecured, or secured in such manner as the board of directors shall approve, including, without limitation, a pledge of shares of stock of the corporation. Nothing in this section contained shall be deemed to deny, limit or restrict the powers of guaranty or warranty of the corporation at common law or under any statute.

3.13 REMOVAL OF DIRECTORS

Unless otherwise restricted by statute, by the certificate of incorporation or by these bylaws, any director or the entire board of directors may be removed, with or without cause, by the holders of a majority of the shares then entitled to vote at an election of directors; provided, however, that, so long as shareholders of the corporation are entitled to cumulative voting, if less than the entire board is to be removed, no director may be removed without cause if the votes cast against his removal would be sufficient to elect him if then cumulatively voted at an election of the entire board of directors.

No reduction of the authorized number of directors shall have the effect of removing any director prior to the expiration of such director's term of office.

ARTICLE IV

COMMITTEES

4.1 COMMITTEES OF DIRECTORS

The board of directors may, by resolution passed by a majority of the whole board, designate one or more committees, with each committee to consist of one or more of the directors of the corporation. The board may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee. In the absence or disqualification of a member of a committee, the member or members thereof present at any meeting and not disqualified from voting, whether or not he or they constitute a quorum, may unanimously appoint another member of the board of directors to act at the meeting in the place of any such absent or disqualified member. Any such committee, to the extent provided in the resolution of the

board of directors or in the bylaws of the corporation, shall have and may exercise all the powers and authority of the board of directors in the management of the business and affairs of the corporation, and may authorize the seal of the corporation to be affixed to all papers that may require it; but no such committee shall have the power or authority to (i) amend the certificate of incorporation (except that a committee may, to the extent authorized in the resolution or resolutions providing for the issuance of shares of stock adopted by the board of directors as provided in Section 151(a) of the General Corporation Law of Delaware, fix the designations and any of the preferences or rights of such shares relating to dividends, redemption, dissolution, any distribution of assets of the corporation or the conversion into, or the exchange of such shares for, shares of any other class or classes or any other series of the same or any other class or classes of stock of the corporation or fix the number of shares of any series of stock or authorize the increase or decrease of the shares of any series), (ii) adopt an agreement of merger or consolidation under Sections 251 or 252 of the General Corporation Law of Delaware, (iii) recommend to the stockholders the sale, lease or exchange of all or substantially all of the corporation's property and assets, (iv) recommend to the stockholders a dissolution of the corporation or a revocation of a dissolution, or (v) amend the bylaws of the corporation; and, unless the board resolution establishing the committee, the bylaws or the certificate of incorporation expressly so provide, no such committee shall have the power or authority to declare a dividend, to authorize the issuance of stock, or to adopt a certificate of ownership and merger pursuant to Section 253 of the General Corporation Law of Delaware.

4.2 COMMITTEE MINUTES

Each committee shall keep regular minutes of its meetings and report the same to the board of directors when required.

4.3 MEETINGS AND ACTION OF COMMITTEES

Meetings and actions of committees shall be governed by, and held and taken in accordance with, the provisions of Article III of these bylaws, Section 3.5 (place of meetings and meetings by telephone), Section 3.6 (regular meetings), Section 3.7 (special meetings and notice), Section 3.8 (quorum), Section 3.9 (waiver of notice), and Section 3.10 (action without a meeting), with such changes in the context of those bylaws as are necessary to substitute the committee and its members for the board of directors and its members; provided, however, that the time of regular meetings of committees may be determined either by resolution of the board of directors or by resolution of the committee, that special meetings of committees may also be called by resolution of the board of directors and that notice of special meetings of committees shall also be given to all alternate members, who shall have the right to attend all meetings of the committee. The board of directors may adopt rules for the government of any committee not inconsistent with the provisions of

these bylaws.

ARTICLE V

OFFICERS

5.1 OFFICERS

The officers of the corporation shall be a president, a secretary, and a chief financial officer. The corporation may also have, at the discretion of the board of directors, a chairman of the board, one or more vice presidents, one or more assistant vice presidents, one or more assistant secretaries, one or more assistant treasurers, and any such other officers as may be appointed in accordance with the provisions of Section 5.3 of these bylaws. Any number of offices may be held by the same person.

5.2 APPOINTMENT OF OFFICERS

The officers of the corporation, except such officers as may be appointed in accordance with the provisions of Sections 5.3 or 5.5 of these bylaws, shall be appointed by the board of directors, subject to the rights, if any, of an officer under any contract of employment.

5.3 SUBORDINATE OFFICERS

The board of directors may appoint, or empower the president to appoint, such other officers and agents as the business of the corporation may require, each of whom shall hold office for such period, have such authority, and perform such duties as are provided in these bylaws or as the board of directors may from time to time determine.

5.4 REMOVAL AND RESIGNATION OF OFFICERS

Subject to the rights, if any, of an officer under any contract of employment, any officer may be removed, either with or without cause, by an affirmative vote of the majority of the board of directors at any regular or special meeting of the board or, except in the case of an officer chosen by the board of directors, by any officer upon whom such power of removal may be conferred by the board of directors.

Any officer may resign at any time by giving written notice to the corporation. Any resignation shall take effect at the date of the receipt of that notice or at any later time specified in that notice; and, unless otherwise specified in that notice, the acceptance of the resignation shall not be necessary to make it effective. Any resignation is without prejudice to the rights, if any, of the corporation under any contract to which the officer is a party.

5.5 VACANCIES IN OFFICES

Any vacancy occurring in any office of the corporation shall be filled by the board of directors.

5.6 CHAIRMAN OF THE BOARD

The chairman of the board, if such an officer be elected, shall, if present, preside at meetings of the board of directors and exercise and perform such other powers and duties as may from time to time be assigned to him by the board of directors or as may be prescribed by these bylaws. If there is no president, then the chairman of the board shall also be the chief executive officer of the corporation and shall have the powers and duties prescribed in Section 5.7 of these bylaws.

5.7 PRESIDENT

Subject to such supervisory powers, if any, as may be given by the board of directors to the chairman of the board, if there be such an officer, the president shall be the chief executive officer of the corporation and shall, subject to the control of the board of directors, have general supervision, direction, and control of the business and the officers of the corporation. He shall preside at all meetings of the stockholders and, in the absence or nonexistence of a chairman of the board, at all meetings of the board of directors. He shall have the general powers and duties of management usually

vested in the office of president of a corporation and shall have such other powers and duties as may be prescribed by the board of directors or these bylaws.

5.8 VICE PRESIDENTS

In the absence or disability of the president, the vice presidents, if any, in order of their rank as fixed by the board of directors or, if not ranked, a vice president designated by the board of directors, shall perform all the duties of the president and when so acting shall have all the powers of, and be subject to all the restrictions upon, the president. The vice presidents shall have such other powers and perform such other duties as from time to time may be prescribed for them respectively by the board of directors, these bylaws, the president or the chairman of the board.

5.9 SECRETARY

The secretary shall keep or cause to be kept, at the principal executive office of the corporation or such other place as the board of directors may direct, a book of minutes of all meetings and actions of directors, committees of directors, and stockholders. The minutes shall show the time and place of each meeting, whether regular or special (and, if special, how authorized and the notice given), the names of those present at directors' meetings or committee meetings, the number of shares present or represented at stockholders' meetings, and the proceedings thereof.

The secretary shall keep, or cause to be kept, at the principal executive office of the corporation or at the office of the corporation's transfer agent or registrar, as determined by resolution of the board of directors, a share register, or a duplicate share register, showing the names of all stockholders and their addresses, the number and classes of shares held by each, the number and date of certificates evidencing such shares, and the number and date of cancellation of every certificate surrendered for cancellation.

The secretary shall give, or cause to be given, notice of all meetings of the stockholders and of the board of directors required to be given by law or by these bylaws. He shall keep the seal of the corporation, if one be adopted, in safe custody and shall have such other powers and perform such other duties as may be prescribed by the board of directors or by these bylaws.

5.10 CHIEF FINANCIAL OFFICER

The chief financial officer shall keep and maintain, or cause to be kept and maintained, adequate and correct books and records of accounts of the properties and business transactions of the corporation, including accounts of its assets, liabilities, receipts, disbursements, gains, losses, capital retained earnings, and shares. The books of account shall at all reasonable times be open to inspection by any director.

The chief financial officer shall deposit all moneys and other valuables in the name and to the credit of the corporation with such depositories as may be designated by the board of directors. He shall disburse the funds of the corporation as may be ordered by the board of directors, shall render to the president and directors, whenever they request it, an account of all his transactions as chief financial officer and of the financial condition of the corporation, and shall have other powers and perform such other duties as may be prescribed by the board of directors or these bylaws.

The chief financial officer shall be the treasurer of the corporation.

5.11 ASSISTANT SECRETARY

The assistant secretary, or, if there is more than one, the assistant secretaries in the order determined by the stockholders or board of directors (or if there be no such determination, then in the order of their election) shall, in the absence of the secretary or in the event of his or her inability or refusal to act, perform the duties and exercise the powers of the secretary and shall perform such other duties and have such other powers as may be prescribed by the board of directors or these bylaws.

5.12 ASSISTANT TREASURER

The assistant treasurer, or, if there is more than one, the assistant treasurers, in the order determined by the stockholders or board of directors (or if there be no such determination, then in the order of their election), shall, in the absence of the chief financial officer or in the event of his or her inability or refusal to act, perform the duties and exercise the powers of the chief financial officer and shall perform such other duties and have such other powers as may be prescribed by the board of directors or these bylaws.

5.13 REPRESENTATION OF SHARES OF OTHER CORPORATIONS

The chairman of the board, the president, any vice president, the chief financial officer, the secretary or assistant secretary of this corporation, or any other person authorized by the board of directors or the president or a vice president, is authorized to vote, represent, and exercise on behalf of this corporation all rights incident to any and all shares of any other corporation or corporations standing in the name of this corporation. The authority granted herein may be exercised either by such person directly or by any other person authorized to do so by proxy or power of attorney duly executed by such person having the authority.

5.14 AUTHORITY AND DUTIES OF OFFICERS

In addition to the foregoing authority and duties, all officers of the corporation shall respectively have such authority and perform such duties in the management of the business of the corporation as may be designated from time to time by the board of directors or the stockholders.

ARTICLE VI

INDEMNITY

6.1 THIRD PARTY ACTIONS

The corporation shall indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending, or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of

the corporation) by reason of the fact that he is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement (if such settlement is approved in advance by the corporation, which approval shall not be unreasonably withheld) actually and reasonably incurred by him in connection with such

action, suit or proceeding if he acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful. The termination of any action, suit or proceeding by judgment, order, settlement, conviction, or upon a plea of nolo contendere or its equivalent, shall not, of itself, create a presumption that the person did not act in good faith and in a manner which he reasonably believed to be in or not opposed to the best interest of the

corporation, and, with respect to any criminal action or proceeding, had reasonable cause to believe that his conduct was unlawful.

6.2 ACTIONS BY OR IN THE RIGHT OF THE CORPORATION

The corporation shall indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that he is or was a director, officer, employee or agent of corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against expenses (including attorneys' fees) and amounts paid in settlement (if such settlement is approved in advance by the corporation, which approval shall not be unreasonably withheld) actually and reasonably incurred by him in connection with the defense or settlement of such action or suit if he acted in good faith and in manner he reasonably believed to be in or not opposed to the best interests of the corporation, except that no

indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Delaware Court of Chancery or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Delaware Court of Chancery or such other court shall deem proper. Notwithstanding any other provision of this Article VI, no person shall be indemnified hereunder for any expenses or amounts paid in settlement with respect to any action to recover short-swing profits under Section 16(b) of the Securities Exchange Act of 1934, as amended.

6.3 SUCCESSFUL DEFENSE

To the extent that a director, officer, employee or agent of the corporation has been successful on the merits or otherwise in defense of any action, suit or proceeding referred to in Sections 6.1 and 6.2, or in defense of any claim, issue or matter therein, he shall be indemnified against expenses (including attorneys' fees) actually and reasonably incurred by him in connection therewith.

6.4 DETERMINATION OF CONDUCT

Any indemnification under Sections 6.1 and 6.2 (unless ordered by a court) shall be made by the corporation only as authorized in the specific case upon a determination that the indemnification of the director, officer, employee or agent is proper in the circumstances because he has met the applicable standard of conduct set forth in Sections 6.1 and 6.2. Such determination shall be made (1) by the Board of Directors or the Executive Committee by a majority vote of a quorum consisting of directors who were not parties to such action, suit or proceeding or (2) if such quorum is not obtainable or, even if obtainable, a quorum of disinterested directors so directs, by independent legal counsel in a written opinion, or (3) by the stockholders. Notwithstanding the foregoing, a director, officer, employee or agent of the Corporation shall be entitled to contest any determination that the director, officer, employee or agent has not met the applicable standard of conduct set forth in Sections 6.1 and 6.2 by petitioning a court of competent jurisdiction.

6.5 PAYMENT OF EXPENSES IN ADVANCE

Expenses incurred in defending a civil or criminal action, suit or proceeding, by an individual who may be entitled to indemnification pursuant to Section 6.1 or 6.2, shall be paid by the corporation in advance of the final disposition of such action, suit or proceeding upon receipt of an undertaking by or on behalf of the director, officer, employee or agent to repay such amount if it shall ultimately be determined that he is not entitled to be indemnified by the corporation as authorized in this Article VI.

6.6 INDEMNITY NOT EXCLUSIVE

The indemnification and advancement of expenses provided by or granted pursuant to the other sections of this Article VI shall not be deemed exclusive of any other rights to which those seeking indemnification or advancement of expenses may be entitled under any by-law, agreement, vote of stockholders or disinterested directors or otherwise, both as to action in his official capacity and as to action in another capacity while holding such office.

6.7 INSURANCE INDEMNIFICATION

The corporation shall have the power to purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of

another corporation, partnership, joint venture, trust or other enterprise, against any liability asserted against him and incurred by him in any such capacity or arising out of his status as such, whether or not the corporation would have the power to indemnify him against such liability under the provisions of this Article VI.

6.8 THE CORPORATION

For purposes of this Article VI, references to "the corporation" shall include, in addition to the resulting corporation, any constituent corporation (including any constituent of a constituent) absorbed in a consolidation or merger which, if its separate existence had continued, would have had power and authority to indemnify its directors, officers, and employees or agents, so that any person who is or was a director, officer, employee or agent of such constituent corporation, or is or was serving at the request of such constituent corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise,

shall stand in the same position under and subject to the provisions of this Article VI (including, without limitation the provisions of Section 6.4) with respect to the resulting or surviving corporation as he would have with respect to such constituent corporation if its separate existence had continued.

6.9 EMPLOYEE BENEFIT PLANS

For purposes of this Article VI, references to "other enterprises" shall include employee benefit plans; references to "fines" shall include any excise taxes assessed on a person with respect to an employee benefit plan; and references to "serving at the request of the corporation" shall include any service as a director, officer, employee or agent of the corporation which imposes duties on, or involves services by, such director, officer, employee, or agent with respect to an employee benefit plan, its participants, or beneficiaries; and a person who acted in good faith and in a manner he reasonably believed to be in the interest of the participants and beneficiaries of an employee benefit plan shall be deemed to have acted in a manner "not opposed to the best interests of the corporation" as referred to in this Article VI.

6.10 CONTINUATION OF INDEMNIFICATION AND ADVANCEMENT OF EXPENSES

The indemnification and advancement of expenses provided by, or granted pursuant to, this Article VI shall, unless otherwise provided when authorized or ratified, continue as to a person who has ceased to be a director, officer, employee or agent and shall inure to the benefit of the heirs, executors and administrators of such a person.

ARTICLE VII

RECORDS AND REPORTS

7.1 MAINTENANCE AND INSPECTION OF RECORDS

The corporation shall, either at its principal executive officer or at such place or places as designated by the board of directors, keep a record of its stockholders listing their names and addresses and the number and class of shares held by each stockholder, a copy of these bylaws as amended to date, accounting books, and other records.

Any stockholder of record, in person or by attorney or other agent, shall, upon written demand under oath stating the purpose thereof, have the right during the usual hours for business to inspect for any proper purpose the corporation's stock ledger, a list of its stockholders, and its other books and records and to make copies or extracts therefrom. A proper purpose shall mean a purpose reasonably related to such person's interest as a stockholder. In every instance where an attorney or other agent is the person who seeks the right to inspection, the demand under oath shall be accompanied by a power of attorney or such other writing that authorizes the attorney or other agent so to act on behalf of the stockholder. The demand under oath shall be directed to the corporation at its registered office in Delaware or at its principal place of business.

The officer who has charge of the stock ledger of the corporation shall prepare and make, at least ten (10) days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting, arranged in alphabetical order, showing the address of each stockholder and the number of shares registered in the name of each stockholder. Such list shall be open to the examination of any stockholder, for any purpose germane to the meeting, during ordinary business hours, for a period of at least ten (10) days prior to the meeting, either at a place within the city where the meeting

is to be held, which place shall be specified in the notice of the meeting, or, if not so specified, at the place where the meeting is to be held. The list shall also be produced and kept at the time and place of the meeting during the whole time thereof, and may be inspected by any stockholder who is present.

7.2 INSPECTION BY DIRECTORS

Any director shall have the right to examine the corporation's stock ledger, a list of its stockholders, and its other books and records for a purpose reasonably related to his position as a director. The Court of Chancery is hereby vested with the exclusive jurisdiction to determine whether a director is entitled to the inspection sought. The Court may summarily order the corporation to permit the director to inspect any and all books and records, the stock ledger, and the stock list and to make copies or extracts therefrom. The

Court may, in its discretion, prescribe any limitations or conditions with reference to the inspection, or award such other and further relief as the Court may deem just and proper.

7.3 ANNUAL STATEMENT TO STOCKHOLDERS

The board of directors shall present at each annual meeting, and at any special meeting of the stockholders when called for by vote of the stockholders, a full and clear statement of the business and condition of the corporation.

ARTICLE VIII

GENERAL MATTERS

8.1 CHECKS

From time to time, the board of directors shall determine by resolution which person or persons may sign or endorse all checks, drafts, other orders for payment of money, notes or other evidences of indebtedness that are issued in the name of or payable to the corporation, and only the persons so authorized shall sign or endorse those instruments.

8.2 EXECUTION OF CORPORATE CONTRACTS AND INSTRUMENTS

The board of directors, except as otherwise provided in these bylaws, may authorize any officer or officers, or agent or agents, to enter into any contract or execute any instrument in the name of and on behalf of the corporation; such authority may be general or confined to specific instances. Unless so authorized or ratified by the board of directors or within the agency power of an officer, no officer, agent or employee shall have any power or authority to bind the corporation by any contract or engagement or to pledge its credit or to render it liable for any purpose or for any amount.

8.3 STOCK CERTIFICATES; PARTLY PAID SHARES

The shares of the corporation shall be represented by certificates, provided that the board of directors of the corporation may provide by resolution or resolutions that some or all of any or all classes or series of its stock shall be uncertificated shares. Any such resolution shall not apply to shares represented by a certificate until such certificate is surrendered to the corporation. Notwithstanding the adoption of such a resolution by the board of directors, every holder of stock represented by certificates and upon request every holder of uncertificated shares shall be entitled to have a certificate signed by, or in the name of the corporation by the chairman or vice-chairman of the board of directors, or the president or vice-president, and by the chief financial officer or an assistant treasurer, or the secretary or an assistant secretary of such corporation representing the number of shares registered in certificate form. Any or all of the signatures on the certificate may be a facsimile. In case any officer, transfer agent or registrar who has signed or whose facsimile signature has been placed upon a certificate has ceased to be such officer, transfer agent or registrar before such certificate is issued, it may be issued by the corporation with the same effect as if he were such officer, transfer agent or registrar at the date of issue.

The corporation may issue the whole or any part of its shares as partly paid and subject to call for the remainder of the consideration to be paid therefor. Upon the face or back of each stock certificate issued to represent any such partly paid shares, upon the books and records of the corporation in the case of uncertificated partly paid shares, the total amount of the consideration to be paid therefor and the amount paid thereon shall be stated. Upon the declaration of any dividend on fully paid shares, the corporation shall declare a dividend upon partly paid shares of the same class, but only upon the basis of the percentage of the consideration actually paid thereon.

8.4 SPECIAL DESIGNATION ON CERTIFICATES

If the corporation is authorized to issue more than one class of stock or more than one series of any class, then the powers, the designations, the preferences, and the relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights shall be set forth in full or summarized on the face or back of the certificate that the corporation shall issue to represent such class or series of stock; provided, however, that, except as otherwise provided in Section 202 of the General Corporation Law of Delaware, in lieu of the foregoing requirements there may be set forth on the face or back of the certificate that the corporation shall issue to represent such class or series of stock a statement that the corporation will furnish without charge to each stockholder who so requests the powers, the designations, the preferences, and the relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights.

8.5 LOST CERTIFICATES

Except as provided in this Section 8.5, no new certificates for shares shall be issued to replace a previously issued certificate unless the latter is surrendered to the corporation and cancelled at the same time. The corporation may issue a new certificate of stock or uncertificated shares in the place of any certificate theretofore issued by it, alleged to have been lost, stolen or destroyed, and the corporation may require the owner of the lost, stolen or destroyed certificate, or his legal representative, to give the corporation a

bond sufficient to indemnify it against any claim that may be made against it on account of the alleged loss, theft or destruction of any such certificate or the issuance of such new certificate or uncertificated shares.

8.6 CONSTRUCTION; DEFINITIONS

Unless the context requires otherwise, the general provisions, rules of construction, and definitions in the Delaware General Corporation Law shall govern the construction of these bylaws. Without limiting the generality of this provision, the singular number includes the plural, the plural number includes the singular, and the term "person" includes both a corporation and a natural person.

8.7 DIVIDENDS

The directors of the corporation, subject to any restrictions contained in (i) the General Corporation Law of Delaware or (ii) the certificate of incorporation, may declare and pay dividends upon the shares of its capital stock. Dividends may be paid in cash, in property, or in shares of the corporation's capital stock.

The directors of the corporation may set apart out of any of the funds of the corporation available for dividends a reserve or reserves for any proper purpose and may abolish any such reserve. Such purposes shall include but not be limited to equalizing dividends, repairing or maintaining any property of the corporation, and meeting contingencies.

8.8 FISCAL YEAR

The fiscal year of the corporation shall be fixed by resolution of the board of directors and may be changed by the board of directors.

8.9 SEAL

The corporation may adopt a corporate seal, which shall be adopted and which may be altered by the board of directors, and may use the same by causing it or a facsimile thereof to be impressed or affixed or in any other manner reproduced.

8.10 TRANSFER OF STOCK

Upon surrender to the corporation or the transfer agent of the corporation of a certificate for shares duly endorsed or accompanied by proper evidence of succession, assignation or authority to transfer, it shall be the duty of the corporation to issue a new certificate to the person entitled thereto, cancel the old certificate, and record the transaction in its books.

8.11 STOCK TRANSFER AGREEMENTS

The corporation shall have power to enter into and perform any agreement with any number of stockholders of any one or more classes of stock of the corporation to restrict the transfer of shares of stock of the corporation of any one or more classes owned by such stockholders in any manner not prohibited by the General Corporation Law of Delaware.

8.12 REGISTERED STOCKHOLDERS

The corporation shall be entitled to recognize the exclusive right of a person registered on its books as the owner of shares to receive dividends and to vote as such owner, shall be entitled to hold liable for calls and assessments the person registered on its books as the owner of shares, and shall not be bound to recognize any equitable or other claim to or interest in such share or shares on the part of another person, whether or not it shall have express or other notice thereof, except as otherwise provided by the laws of Delaware.

ARTICLE IX

AMENDMENTS

The bylaws of the corporation may be adopted, amended or repealed by the stockholders entitled to vote; provided, however, that the corporation may, in its certificate of incorporation, confer the power to adopt, amend or repeal bylaws upon the directors. The fact that such power has been so conferred upon the directors shall not divest the stockholders of the power, nor limit their power to adopt, amend or repeal bylaws.

CONSENT OF INDEPENDENT AUDITORS

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 February 20, 2004 (with respect to Note 14, March 26, 2004) relating to our audit of the consolidated financial statements of SpectRx, Inc. included in the 2003 annual report on Form 10-K.

/s/ Eisner LLP

New York, New York

March 30, 2004

CONSENT OF INDEPENDENT AUDITORS

We consent to the incorporation by reference in the Registration Statements (Form S-8 Nos. 333-63758 and 333-81326) of SpectRx, Inc. of our report dated March 11, 2003, with respect to the consolidated financial statements of SpectRx, Inc. for the year ended December 31, 2002 included in the Annual Report (Form 10-K) for the year ended December 31, 2003.

/s/ Ernst & Young LLP

Atlanta, Georgia

March 30, 2004

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

I, Mark A. Samuels, Chief Executive Officer of SpectRx, Inc., certify that:

1. I have reviewed this annual report on Form 10-K 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 registrant'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 registrant 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 registrant, 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 registrant'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 registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant'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 registrant'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 registrant's internal control over financial reporting.

Date: March 30, 2004

/s/ Mark A. Samuels

Mark A. Samuels
Chief Executive Officer

I, Thomas H. Muller, Jr., Chief Financial Officer of SpectRx, Inc., certify that:

1. I have reviewed this annual report on Form 10-K 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 registrant'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 registrant 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 registrant, 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 registrant'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 registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant'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 registrant'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 registrant's internal control over financial reporting.

Date: March 30, 2004

/s/ Thomas H. Muller, Jr.

Thomas H. Muller, Jr.
Chief Financial Officer

SECTION 1350 CERTIFICATION

In connection with the Annual Report of SpectRx, Inc. (the "Company") on Form 10-K for the year ended December 31, 2003, 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: March 30, 2004

/s/ MARK A. SAMUELS

Name: Mark A. Samuels

Title: Chief Executive Officer

SECTION 1350 CERTIFICATION

In connection with the Annual Report of SpectRx, Inc. (the "Company") on Form 10-K for the year ended December 31, 2003, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Thomas H. Muller, Jr., Chief Financial Officer of the Company certifies, 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: March 30, 2004

/s/ THOMAS H. MULLER, JR.

Name: Thomas H. Muller, Jr.

Title: Chief Financial Officer