SPECTRX INC Form POS AM August 30, 2004 Table of Contents

As filed with the Securities and Exchange Commission on August 30, 2004

Registration No. 333-114772

### UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Post-Effective Amendment No. 1 on FORM S-1 to FORM S-2

# REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

\_\_\_\_

SpectRx, Inc.

(Exact name of registrant as specified in its charter)

Delaware

3845

58-2029543

(State or other jurisdiction of incorporation or organization) (Primary Standard Industrial Classification Code Number) (I.R.S. Employer Identification Number)

4955 Avalon Ridge Parkway Suite 300 Norcross, Georgia 30071 (770) 242-8723

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Thomas H. Muller, Jr.
Executive Vice President, Chief Financial Officer and Secretary
SpectRx, Inc.
4955 Avalon Ridge Parkway

Suite 300 Norcross, Georgia 30071 (770) 242-8723

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copy to:

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Approximate date of commencement of proposed sale to the public:

From time to time following the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act, check the following box. [X]

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. []

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. []

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. []

If delivery of the prospectus is expected to be made pursuant to Rule 434, check the following box. []

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until this registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

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The information in this prospectus is not complete and may be changed. The selling stockholders may not sell or offer these securities until the registration statement filed with the Securities and Exchange Commission is declared effective. This prospectus is not an offer to sell these securities and neither SpectRx nor the selling stockholders are soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion, Dated August 30, 2004

P	R	$\cap$	2	ΡÌ	F٥	$\mathbb{C}^r$	$\Gamma$	2

11,557,385 Shares

Common Stock

This prospectus relates to up to 11,557,385 shares of our common stock, 4,886,690 of which are issuable upon conversion of our Series A Convertible Preferred Stock, referred to in this prospectus as the preferred stock, 488,669 of which may be issued in payment of dividends on the preferred stock, 6,122,026 of which are issuable upon the exercise of warrants and 60,000 of which are presently outstanding. The shares offered by this prospectus may be sold from time to time by the selling stockholders listed in this prospectus at prevailing market prices or prices negotiated at the time of sale. This prospectus also relates to an indeterminate number of shares of our common stock that may be issued to prevent dilution resulting from stock splits, stock dividends or similar transactions in accordance with the terms of the certificate of designations governing the preferred stock and the terms of the warrants, respectively. The securities offered by this prospectus were issued to the selling stockholders in transactions exempt from registration under the Securities Exchange Act of 1933, as amended.

We will not receive any cash proceeds from the sale of shares by the selling stockholders, but if the warrants are exercised in whole or in part, we will receive payment for the exercise price. We will pay the expenses of registering these shares.

Our common stock is listed on the OTC Bulletin Board under the symbol "SPRX." The last reported sale price of our common stock on the OTC Bulletin Board on August 27, 2004 was \$1.25 per share.

Investing in our common stock involves a high degree of risk. These risks are described under the caption "Risk Factors" that begins on page 2 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of the common stock that may be offered under this prospectus, nor have any of these organizations determined if this prospectus is accurate or complete. Any representation to the contrary is a criminal offense.

# Edgar Filing: SPECTRX INC - Form POS AM The date of this prospectus is \_\_\_\_\_\_\_, 2004

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### **SUMMARY**

This summary highlights general information about SpectRx and the common stock that may be offered by the selling stockholders, but does not contain all information important to you. You should read the more detailed information and financial statements, including the related notes, appearing elsewhere in this prospectus.

### Our Company

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.

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, Inc. 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 principal executive and operations facility is located at 4955 Avalon Ridge Parkway, Suite 300, Norcross, Georgia 30071, and our telephone number is (770) 242-8723.

### Use of Proceeds

We will not receive any cash proceeds from the sale of common stock that may be offered by the selling stockholders. We may receive proceeds from the exercise of warrants entitling the selling stockholders to purchase 6,122,026 shares of our common stock. The detailed terms of the warrants are set forth under "Description of Securities-Warrants." We expect to use any proceeds we receive from the exercise of the warrants for general corporate purposes, including, but not limited to, working capital, capital expenditures and repaying or refinancing of our obligations.

### Offering

Common stock that may be offered by selling 11,557,385 shares.

OTC Bulletin Board Symbol for Common Stock SPRX.

Risk Factors

stockholders

You should read the "Risk Factors" section beginning on page 2 of this prospectus, as well as the other cautionary statements throughout the entire prospectus to ensure that you understand the risks associated with an investment in our common stock.

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### **RISK FACTORS**

Investing in our common stock involves a high degree of risk. You should carefully consider the specific factors listed below, as well as the other information included in this prospectus, before investing in our common stock.

Although we may be required to raise additional funds within the next twelve months, there is no assurance that such funds can be raised or raised on terms that we would find acceptable, or at all.

While we believe that our existing capital resources will be sufficient to fund our operations for the next twelve months, the sufficiency of these funds depends on our ability to introduce products, reach expected sales goals and manage costs according to our plan. If we experience delays, fall short of our plan, incur additional costs or require additional working capital, we will need to raise additional funds. If we are unable to satisfactorily resolve our differences with Abbott Laboratories, Inc., referred to in this prospectus as Abbott, regarding the schedule of payments for the redeemption of the redeemable preferred shares, we will need to raise additional funds. Any required additional funding may not be available on terms attractive to us or at all.

If we cannot obtain additional funds, if needed, or achieve profitability, we may not be able to continue as a going concern.

Because we must execute our plans to launch our remaining products in our SimpleChoice product line and grow our revenues to sufficiently higher levels to generate profits and cash flow from operations, there exists doubt about our ability to continue as a going concern. Management believes funds will be available from sales and royalty revenue sufficient to support planned operations through June 30, 2005. However, there can be no assurance that we will achieve planned sales volumes or if not, be able to raise additional funds. If we do not meet these targets, we will need to seek additional funding. If we do not secure additional funding, we will be unable to conduct all of our product development efforts as planned, which may cause us to alter our business plan in relation to the development of all of our products.

Our management has additional plans designed to manage our cash requirements, if required, through reductions in operating expenditures and reductions in development activities should sales targets not be met. We are managing our development of our cervical cancer detection technology with the support of contracts and grants we have secured. We also are looking for a collaborative partner to fund the development of our glucose monitoring technology. However, there can be no assurance that we will be able to successfully implement or continue these plans or that we will be able to do so without significantly harming our business, financial condition or results of operations.

We do not have a long operating history, which makes it difficult for you to evaluate our business.

Because limited historical information is available on our revenue trends and operations, it will be difficult for you to evaluate our business. Our historical financial information also includes the sale of our Bili*Chek*<sup>TM</sup> 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 \$55.4 million at June 30, 2004.

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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 will be sufficient to satisfy our funding requirements through June 30, 2005, 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 which were introduced to the market during 2003. We have shipped larger quantities of SimpleChoice products during the first six months of 2004, but those quantities are not yet at the scale we would anticipate in the future. 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.

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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, referred to in this prospectus as the FDA. We cannot be sure:

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that we or any collaborative partner will make timely filings with the FDA;

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that the FDA will act favorably or quickly on these submissions;

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that we will not be required to submit additional information or perform additional clinical studies;

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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

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that other significant difficulties and costs will not be encountered to obtain FDA clearance or approval.

The SimpleChoice products to date have been introduced subject to 510(k) premarket notification submissions. There have been 27 510(k) premarket notification submissions approved through June 30, 2004.

The premarket approval process is more rigorous and lengthier than the 510(k) clearance process for premarket notifications; it can take several years from initial filing and require the submission of extensive supporting data and clinical information. For example, Roche Diagnostics BMC, referred to in this prospectus as 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,

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

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

The medical device industry has been characterized by extensive litigation regarding patents and other intellectual property rights. In addition, the United States Patent and Trademark Office may institute interference proceedings. The defense and prosecution of intellectual property suits, Patent and Trademark Office proceedings and related legal and administrative proceedings are both costly and time consuming. Moreover, we may need to litigate to enforce our patents, to protect our trade secrets or know-how, or to determine the enforceability, scope and validity of the proprietary rights of others. Any litigation or interference proceedings involving us may require us to incur substantial legal and other fees and expenses and may require some of our employees to devote all or a substantial portion of their time to the proceedings. An adverse determination in the

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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 and we expect an additional payment in 2005, we are unable to determine such amount and there can be no assurance of additional payments. Our ability to collect additional earn out payments from the BiliChek product line depends on the efforts of Respironics, Inc., referred to in this prospectus as Respironics, 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

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are developing products that permit non-invasive and less invasive glucose monitoring. Accordingly, competition in this area is expected to increase.

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

We have little manufacturing experience, which could limit our growth.

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

Since we rely on sole source suppliers for several of our products, any failure of those suppliers to perform would hurt our operations.

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

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

Our limited marketing and sales experience makes our SimpleChoice revenue uncertain.

We are responsible for marketing our SimpleChoice product line. We have relatively limited experience in marketing or selling medical device products and only have a five person marketing and sales staff. In order to successfully continue to market and sell our products, we must either develop a marketing and sales force or expand our arrangements with third parties to market and sell our products. We may not be able to successfully develop an effective marketing and sales force, and we may not be able to enter into and maintain marketing and sales agreements with third parties on acceptable terms, if at all. If we develop our own marketing and sales capabilities, we will

compete with other companies that have experienced and well-funded marketing and sales operations. If we enter into a marketing arrangement with a third party, any revenues we would receive will be dependent on this third party, and we will likely be required to pay a sales commission or similar compensation to this party. The efforts of these third parties for the marketing and sale of our products may not be successful.

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Because we operate in an industry with significant product liability risk, and we have not specifically insured against this risk, we may be subject to substantial claims against our products.

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

The availability of third party reimbursement for our products is uncertain, which may limit consumer use and the market for our products.

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

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

Our success depends on our ability to attract and retain scientific, technical, managerial and finance personnel.

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

Adjustments to the conversion price for our series A convertible preferred stock and the exercise price for certain of our warrants will dilute the ownership interests of our existing stockholders.

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

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common stock at a per share price below the then conversion price for the series A convertible preferred stock.

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

We are significantly influenced by our directors, executive officers and their affiliated entities.

Our directors, executive officers and entities affiliated with them beneficially owned an aggregate of about 27% of our outstanding common stock as of June 30, 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.

Our forward-looking statements are subject to a variety of factors that could cause actual results to differ materially from current beliefs.

Safe harbor statement under the Private Securities Litigation Reform Act of 1995:

Statements in this prospectus 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 risks and uncertainties that could cause actual results to differ materially from historical results or anticipated results, including those identified in the foregoing "Risk Factors" and elsewhere in this prospectus. 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;
- 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;

- the effectiveness and ultimate market acceptance of our products;
- the dependence on potential strategic partners or outside investors for funding, development assistance, clinical trials, distribution and marketing of some of our products; and

other risks and uncertainties described from time to time in our reports filed with the Securities and Exchange Commission, including those contained in our annual report on Form 10-K for the year ended December 31, 2003 and our quarterly reports on Form 10-Q for the quarters ended March 31, 2004 and June 30, 2004.

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### **USE OF PROCEEDS**

All sales of the common stock covered by this prospectus will be by or for the account of the selling stockholders listed in this prospectus under "Share Ownership of Selling Stockholders." We will not receive any cash proceeds from the sales of any common stock. We may receive the proceeds from the exercise of warrants entitling the selling stockholders to purchase 6,122,026 shares of our common stock. If all warrants held by the selling stockholders are exercised, we will receive \$11,799,849 in proceeds.

We anticipate that any proceeds from the exercise of warrants by the selling stockholders will be used for general corporate purposes, including, but not limited to, working capital, capital expenditures and the repayment or refinancing of our obligations.

# 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 August 26, 2004 was 160.

The high and low last sales prices for the calendar years 2002 and 2003 and for the quarters ended March 31, 2004 and June 30, 2004 as reported by Nasdaq and the OTC Bulletin Board are as follows:

	20	2002		003	2004		
	HIGH	LOW	HIGH	LOW	HIGH	LOW	
First Quarter	\$7.18	\$4.46	\$1.76	\$1.07	\$2.30	\$1.76	
Second Quarter	\$6.60	\$3.00	\$3.45	\$1.40	\$2.14	\$1.50	
Third Quarter	\$3.91	\$1.45	\$2.59	\$0.85			
Fourth Quarter	\$2.31	\$1.09	\$2.21	\$0.90			

### **Dividend Policy**

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

Securities Authorized for Issuance Under Equity Compensation Plans

All the securities we have provided our employees, directors and consultants have been issued under our 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.

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Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	1,608,679	\$4.37	66,822
Equity compensation plans not approved by security holders	0	\$0	0
Total	1,608,679	\$4.37	66,822

SELECTED CONSOLIDATED FINANCIAL DATA

SpectRx, Inc. & Subsidiaries (In Thousands Except for Per Share Figures)

You should read the following selected consolidated financial data in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes appearing elsewhere in this prospectus.

The consolidated statements of operations data for the years ended December 31, 2001, 2002 and 2003, and the consolidated balance sheet data at December 31, 2002 and 2003, are derived from our audited consolidated financial statements appearing elsewhere in this prospectus. The consolidated statements of operations data for the years ended December 31, 1999 and December 31, 2000, and the consolidated balance sheet data at December 31, 1999, 2000 and 2001, are derived from our audited consolidated financial statements that are not included in this prospectus. The consolidated statements of operations data for the six months ended June 30, 2003 and 2004 and the consolidated balance sheet data at June 30, 2004 are derived from our unaudited consolidated financial statements included in this prospectus. The unaudited consolidated financial statements include, in the opinion of management, all adjustments that management considers necessary for the fair presentation of the financial information set forth in those statements. The historical results are not necessarily indicative of the results to be expected in any future period. The comparability of financial results was impacted by the sale of our Bili*Chek* business in March 2003 and our acquisition of Sterling Medivations in December 2001 as discussed in "Business."

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	Year Ended December 31,			Six Mont June			
	1999	2000	2001	2002	2003	2003	2004
						(unau	dited)
Consolidated Statements of Operations Data:							
Revenue	\$3,337	\$4,968	\$2,458	\$3,798	\$1,586	\$927	\$397
Cost and expenses:							
Cost of product sales	1,708	1,732	2,064	1,624	1,062	492	527
Research & development	5,170	5,804	3,842	5,827	4,108	2,219	1,917
Marketing	900	957	846	1,649	735	369	356
General & administrative	2,222	3,177	2,941	2,785	2,150	1,077	920
Loss from operations	(6,663)	(6,702)	(7,235)	(8,087)	(6,469)	(3,230)	(3,323)
Net interest & other income (expense)	125	355	269	(418)	3,858	933	(919)
Net loss	\$(6,538)	\$(6,347)	\$(6,966)	\$(8,505)	\$(2,611)	\$(2,237)	\$(4,242)
Preferred stock dividends	(14)	(315)	(315)	(315)	(299)	(153)	(141)
Deemed dividend	0	0	0	0	0	0	(4,970)
Loss attributable to common share stockholders	\$(6,552)	\$(6,662)	\$(7,281)	\$(8,820)	\$(2,910)	\$(2,390)	\$(9,353)
Net loss per common share:							
Basic & diluted	\$(.82)	\$(.79)	\$(.75)	\$(.79)	\$(.26)	\$(.21)	\$(.82)

Shares used to compute net loss per common share:

Basic & diluted	8,033	8,429	9,646	11,209	11,270	11,243	11,379
			At Decemb	er 31,			At June 30, 2004
	1999	2000	2001	:	2002	2003	
							(unaudited)
Consolidated Balance Sheet Data:							
Total assets	\$7,693	\$ 7,148	\$ 16,7	34	\$7,472	\$6,714	\$7,922
Total long term obligations, including redeemable preferred	5 615	5 060	<b>5</b> 1	50	4 705	2 645	3,724
stock	5,645	5,960	5,1	30	4,705	3,645	

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# MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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 have 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, Inc., referred to in this prospectus as Welch Allyn, and Respironics for our continuous glucose monitoring, cervical cancer detection product and BiliChek products, respectively. Over the past two years, we sold our Bili*Chek* business to our collaborative partner, Respironics, and agreed to terminate our collaborative relationships with Abbott for our continuous glucose monitoring product and Welch Allyn for our cervical cancer product. In addition, we have a collaborative agreement with Roche related to a diabetes detection product, although there is currently no development or marketing 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 addition, we are seeking venture capital funding for our non-invasive cervical cancer technology.

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 June 30, 2004, we have an accumulated deficit of about \$55.4 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 Bili*Chek* 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 products are not currently established. The royalties that we expect to receive from Respironics depend on sales of the applicable Bili*Chek* 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, inventory valuation and good will and other intangible assets.

### 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. We recognize royalty revenue on the disposable product in the Bili*Chek* line, the Bili*Cal*, when earned as and when communicated from Respironics.

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### 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.

### Goodwill and Other Intangible Assets:

Goodwill and other intangible assets with independent lives are not subject to amortization but will be subject to a periodic impairment assessment. Separate intangible assets that have an estimated use will continue to be amortized over their useful lives, but also are subject to periodic impairment testing.

### **Results of Operations**

Comparison of the Six Months Ended June 30, 2004 and 2003

### General.

Net loss attributable to common stockholders was \$9.4 million during the six months ended June 30, 2004 as compared to a net loss attributable to common stockholders of \$2.4 million for the same period in 2003. During 2004, we recognized a deemed dividend of \$5.0 million from issuance of shares of our Series A convertible preferred stock. Also during 2004, we recognized \$871,000 in interest expense for the value of the warrants issued in connection with a bridge loan. 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.

Product revenue decreased to \$397,000 for the six months ended June 30, 2004 from \$927,000 for the same period in 2003. Because the Bili*Chek* product line was sold in March 2003, there were no Bili*Chek* revenues for the six months ended June 30, 2004, versus \$684,000 for the same period of 2003. SimpleChoice sales were \$270,000 for the six months ended June 30, 2004, versus \$78,000 for the same period of 2003.

### Cost of Sales.

Cost of sales increased to \$527,000 for the six months ended June 30, 2004 from \$492,000 for the same period in 2003. This increase is due primarily to excess production overhead charges, which were lower for the 2003 period than in the 2004 period.

### Research and Development Expenses.

Research and development expenses decreased to approximately \$1.9 million for the six months ended June 30, 2004 compared to \$2.2 million for the same period in 2003. The decrease in research and development expenses was primarily due to reductions in patent maintenance of \$288,000. 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 Expenses.

Sales and marketing expenses slightly decreased to \$356,000 during the six months ended June 30, 2004 from \$369,000 for the same period in 2003, due to the reduction of our Bili*Chek* marketing function. 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 Expenses.

General and administrative expenses decreased to \$920,000 during the six months ended June 30, 2004 compared to \$1.1 million for the same period in 2003. The decrease is primarily due to a decrease in costs associated with salaries of \$135,000 and outside services and consulting fees of \$125,000, offset by an increase in rent expense of \$120,000.

### Net Interest and Other Income.

Net interest and other income decreased to an expense of \$919,000 for the six months ended June 30, 2004 as compared to income of \$69,000 for the same period in 2003. The primary cause of this decrease is the recognition of interest expense for the warrants issued related to the bridge loan during the first quarter of 2004.

During the year 2003, we recognized about \$1.1 million in gain on the sale of our Bili*Chek* product line.

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### 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.

### 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 Bili*Chek* 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 Bili*Chek* 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.

# 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. Bili*Chek* marketing decreased also (\$354,000) as a result of the sale of that product line in March 2003.

# 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), attorney fees (\$165,000), salary expense (\$166,000) and outside services (\$186,000), offset by increased consulting costs (\$9,000).

### Net Interest Expense and Other Income.

Net interest expense in 2003 was \$328,000, a \$419,000 decrease from 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 Bili*Chek* 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.

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### 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 June 30, 2004, we received approximately \$62.2 million in proceeds from sales of our debt and equity securities. At June 30, 2004, we had cash of approximately \$2.9 million and working capital of approximately \$1.4 million.

In August 2002, Abbott notified us that it intended to redeem the \$4.25 million of redeemable convertible preferred stock eligible to be redeemed. Under a settlement agreement related to the termination of our collaborative arrangement with Abbott, we agreed with Abbott to redeem the 425,000 shares of preferred stock on an extended schedule through 2006. We paid Abbott the amounts under that agreement for items due through December 31, 2003 and pursued additional negotiations for amounts due in 2004 and beyond. We have been in negotiations with Abbott since early 2003 regarding a patent issue and the payments under the settlement. On July 15, 2004 Abbott sent us a letter notifying us that we were in default on two separate payments due in 2004 and demanding payment. On July 22, 2004, we responded that we were seeking to resolve other issues and renegotiate the payment terms. (See "Business - Legal Proceedings").

We have historically 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 \$1.3 million grant, which began in February 2003, to be spent over two years, from the National Cancer Institute, referred to in this prospectus as NCI, for our cervical cancer program. In March 2003, we sold the assets related to the Bili*Chek* products, as non-core assets, for \$4.0 million of cash at closing, an additional \$1.0 million upon completion of some component replacement engineering work, which we received in November 2003, and up to \$6.25 million in 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, 2004 that it had completed a private placement to institutional and private investors of a new series of its preferred stock and of warrants to purchase shares of its common stock. Proceeds to the company were approximately \$7.3 million, prior to the payment of placement agent fees and expenses. Of the proceeds, approximately \$1.0 million represents the conversion of debt into securities issued in the financing.

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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 our common stock at a price of \$1.65 per share, and the other half, at \$2.25 per share.

Our major cash flows in the year ended December 31, 2002 consisted of cash out-flow of \$7.9 million from operations (including \$8.5 million of operating loss) and \$290,000 in additions to property and equipment. Of this cash out-flow from operations, \$1.9 million resulted from a prepayment of royalties relating to our agreement with Altea Technologies, Inc., referred to in this prospectus as Altea.

Our major cash flows in the year ended December 31, 2003 consisted of cash out-flow of \$5.8 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 investing activities includes gross proceeds of \$5.0 million from the sale of the Bili*Chek* 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.

Our major cash flows in the six months ended June 30, 2003 consisted of cash out-flow of \$3.9 million from operations. We also received \$4.0 million from the sale of our Bili*Chek* product line to Respironics. We had cash out-flow of \$96,000 for additions to property and equipment and paid down debt relating to our agreement with Abbott by \$400,000.

Our major cash flows in the six months ended June 30, 2004 consisted of cash out-flow of \$2.7 million from operations and \$5.4 million of cash flow from financing activities. The largest portion of the cash out-flow from operations was due to accrued payables paid after March 26, 2004 and the reduction of accounts payable. The cash flow from financing was primarily due to placement, legal and accounting fees related to the private placement completed on March 26, 2004.

During the next twelve months, 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 capital resources will be able to fund operations for the next twelve months. The sufficiency of these funds depends on our ability to introduce products, reach expected sales goals and manage costs according to our plan. If we experience delays, fall short of our plan, incur additional costs or require additional working capital, we will need to raise additional funds. If we are unable to satisfactorily resolve our differences with Abbott regarding the schedule of payments for the redemption of the redeemable preferred shares, we will need to raise additional funds. We also 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. Any required additional funding may not be available on terms attractive to us or at all.

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 Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 146, "Accounting for Costs Associated with Exit or Disposal Activities." Our adoption of SFAS No. 146 on January 1, 2003 did not have any material effect on our financial statements.

In December 2003, the FASB issued FASB Interpretation ("FIN") 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. We believe the impact of FIN No. 46R on our financial position and results of operations will not be material, but we will continue to evaluate the impact of FIN No. 46R.

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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 SFAS No. 150 was not material to our 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 SEC staff's interpretive guidance provided in SAB No. 101 and included in Topic 13 of the Codification of Staff Accounting Bulletins. SAB No. 104 deletes interpretative 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 No. 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 our financial position and results of operations since our revenue recognition practices previously conformed to the interpretations codified by SAB No. 104.

### Off-Balance Sheet Arrangements

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

# Tabular Disclosure of Contractual Obligations

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

Payment Due By Period
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	Total	2004	2005 to 2006	2007 to 2008	2009 & Thereafter
Long-term debt, including current maturities (1)	\$4,974	\$1,631	\$3,343	\$0	\$0
Operating Lease Obligation	\$1,242	\$95	\$451	\$468	\$228
Other long-term liabilities reflected on the Consolidated balance sheet (2)	\$381	\$0	\$0	\$0	\$381

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

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

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Quantitative and Qualitative Disclosure About 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.

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# Selected Quarterly Consolidated Financial Information

				Quarte	r Ended						
	March 31 2002	June 30 2002	September 30 2002	December 31 2002	March 31 2003	June 30 2003	September 30 2003	December 31 2003	March 31 2004	June 30 2004	
(in thousands except per share data) (unaudited)											
Total Revenue	652	774	1,598	774	801	126	209	450	125	272	
Cost of Goods Sold	424	393	356	451	312	180	216	354	286	241	
Operating Income	(2,406)	(3,196)	(1,073)	(1,412)	(1,204)	(2,026)	(1,844)	(1,395)	(1,588)	(1,735)	
Net Income (Loss)	(2,370)	(3,175)	(1,049)	(1,911)	(159)	(2,078)	(1,873)	1,499	(2,491)	(1,751)	
Preferred Stock Dividends	(79)	(79)	(78)	(79)	(79)	(74)	(73)	(73)	(73)	(68)	
Deemed Dividend on Series A Preferred Stock	0	0	0	0	0	0	0	0	(4,970)	0	
Income (Loss) Available (Attributed) to Common Stockholders	(2,449)	(3,254)	(1,127)	(1,990)	(238)	(2,152)	(1,946)	1,426	(7,534)	(1,819)	
Net Income (Loss) Per Share											
Basic	(\$0.22)	(\$0.29)	(\$0.10)	(\$0.18	(\$0.02)	(\$0.19)	(\$0.17)	\$0.13	(\$0.66)	(\$0.16)	
Diluted	(\$0.22)	(\$0.29)	(\$0.10)	(\$0.18	(\$0.02)	(\$0.19)	(\$0.17)	\$0.12	(\$0.66)	(\$0.16)	
Weighted Average Common Shares Outstanding											
Basic	11,202	11,197	11,210	11,249	11,249	11,237	11,248	11,336	11,372	11,386	
Diluted	11,202	11,197	11,210	11,249	11,249	11,237	11,248	11,600	11,372	11,386	

The Company recorded a \$508,000 charge to operations in December 2002 for the extinguishments of officers loans. (See Note 9 of the notes to consolidated financial statements included in this prospectus).

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#### **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. We are currently seeking a strategic partner for the continuous glucose monitoring development program.

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, and terminated our agreement relating to our glucose monitoring product with Abbott. We terminated our agreement relating to our cervical cancer detection product with Welch Allyn 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 FDA cleared products that are either already on the market or can be launched in the next six months. We intend to maximize the market penetration of our current products and those that are near-term product introductions to drive revenue growth.

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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 and Welch Allyn to assist in the early development efforts for certain of our technologies. Under such an arrangement with Respironics, we developed and commercialized an infant jaundice detection and monitoring product line, a business we sold to Respironics 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.

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### 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 Disetronics. Significant participants in the insulin infusion set market include Unomedical, Inc., 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 and other ancillary insulin delivery products. Since our acquisition of Sterling Medivations, we have received 27 FDA clearances for insulin delivery components and products that we are marketing or have available 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;

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.

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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 just below its surface, 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

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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

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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 was acquired in April 2004 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

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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 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 and fluid management technologies with available 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 \$3.9 million if extended to five years, of which about 42% is expected to be for direct SpectRx activities and 58% for subcontractor activities. As of June 30, 2004, we have received approximately \$735,000 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

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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.

#### Our Non-invasive Cervical Cancer Product

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

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.

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In January 2004, we reported to the 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 Cytyc, 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 NCI to support our required pivotal clinicals, some of the results of which are discussed above. As of June 30, 2004, we have received approximately \$674,000 of this grant. On June 15, 2004, we reported that we had been selected by the NCI to receive an additional grant of an estimated \$1.1 million to support development of our non-invasive cervical cancer detection technology.

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

### Infant Jaundice

Our first commercial product, the Bili*Chek* system for non-invasive detection of jaundice in infants, was introduced in 1998. The infant jaundice product was originally developed under a collaborative agreement with Respironics, which also granted Respironics an exclusive license to market and sell the product line in the United States and Canada. In March 2003, we announced that we had sold the assets related to the infant jaundice products to Respironics. Under the terms of the Asset Sale Agreement, we will receive ongoing royalties from the sale of the disposable element of the product line, trademarked the Bili*Cal*, over the base amount of unit sales to distributors sold in 2002 for a period not to exceed five years. In addition, we can receive 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

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### 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 "Business - Legal Proceedings"), these 425,000 shares will be redeemed over a period of four years. We have been in negotiations with Abbott since early 2003 regarding a patent issue and the payments and terms under the settlement. On July 15, 2004 Abbott sent us a letter notifying us that we were in default on two separate payments due in 2004 and demanding payment. On July 22, 2004 we responded that we were seeking to resolve the patent issues and renegotiate payment terms.

### 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

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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. For the six months ended June 30, 2003 and 2004, research and development costs were about \$2.2 million and \$1.9 million, respectively.

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 Bili*Chek* and Bili*Cal* 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 Bili*Chek* and Bili*Cal* products and to begin shipment of these products into international markets. We have recently passed an inspection extending our ISO 13485 certification to March 2006 and have provided documentation to the appropriate notified body. Upon review of the documentation and clearance by the notified body, we will be eligible to use the CE mark on our products.

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Sales, Marketing and Distribution

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

Our primary efforts to date have been to build the skill and information base to identify and quantify market segments to which our technologies can be economically developed and marketed, as well as to launch our two product lines that have been introduced to the market: the Bili*Chek* product system, which we sold, and our SimpleChoice line of insulin delivery products. We have developed internal marketing and a distribution program for the SimpleChoice products to an introductory stage, and we have developed packaging, advertising, display materials, and training for these products. In addition, we have signed distribution agreements or have entered into negotiations with companies we believe to be highly experienced in the diabetes supply business in the United States. Our previous experience in building a distribution system focused on entities that were experienced in neonatal markets in Europe, Asia and South America. We shipped our first insulin delivery product, the SimpleChoice reservoir, in the fourth quarter of 2002. We launched our first insulin infusion disposable product, the SimpleChoice easy, in the third quarter of 2003. We expect to launch additional products during 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 Bili*Chek* 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 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.

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Competition in cancer detection is also intense. Current screening systems, primarily the Pap smear and colposcopy, are well established and pervasive. Improvements and new technologies for cervical cancer detection, such as Thin-Prep from Cytyc Corporation and Human Papilloma Virus testing from Digene Corporation, have introduced other new competitors. In addition, there are other companies attempting to develop products using forms of biophotonic technologies in cervical cancer detection. 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 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 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.

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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.

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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 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. We currently have ISO 13485 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 June 30, 2004 we had 35 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 58 people employed or engaged by us, 21 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.

## **Properties**

We lease about 28,527 square feet in Norcross, Georgia, which comprise our administrative, research and development, marketing and production facilities and our planned manufacturing facility under a lease expiring in 2009.

### 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

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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 and \$300,000 to Abbott pursuant to the settlement, respectively, during 2003 and in the first quarter of 2004. Under the settlement, neither party admitted any liability or wrongdoing.

We have been in negotiations with Abbott since early 2003 regarding the patent issue and the payments and terms under the settlement. On July 15, 2004 Abbott sent us a letter notifying us that we were in default of two separate payments due in 2004 and demanding payment. On July 22, 2004 we responded that we were seeking to resolve the patent issues and renegotiate the payment terms. Under our settlement agreement, we are accruing interest on the payments of 1% per month.

We are also involved in certain litigation arising in the ordinary course of business. In management's opinion, the ultimate resolution of these matters will not have a material adverse effect on our results of operations or financial position.

#### **MANAGEMENT**

### **Executive Officers and Directors**

Our executive officers and directors and their ages and positions as of August 20, 2004 are as follows:

Name	Age	Position with SpectRx
Mark A. Samuels	46	Chief Executive Officer & Director
William Arthur	53	President, Chief Operating Officer
Thomas H. Muller, Jr.	62	Executive Vice President, Chief Financial Officer and Secretary
Mark L. Faupel	49	Executive Vice President, Chief Technology Officer
Richard L. Fowler	48	Senior Vice President Engineering
Walter J. Pavlicek	57	Vice President Operations
Charles G. Hadley	47	Director
Keith D. Ignotz	56	Director
Earl R. Lewis	60	Director
William E. Zachary, Jr.	61	Director
Christopher F. Monahan	65	Director

Mark A. Samuels has served as a member of our board of directors and as our 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. 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 a M.S. in Electrical Engineering from the 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 executive officer of MedFusion, Inc., a manufacturer of infusion pumps and disposables for low volume drug delivery.

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.

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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 senior 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.

Charles G. Hadley has served as a member of our board of directors since 1993. Since 1988, Mr. Hadley has been general partner of Cashon Biomedical Associates, L.P., which is the managing general partner of the Hillman Medical Ventures partnerships. These venture firms focus on investments in early stage medical technology companies. Mr. Hadley earned a B.A. from George Washington University and a J.D. and M.B.A. from Stanford University.

Keith D. Ignotz has served as a member of our board of directors since co-founding SpectRx in 1992. From November 2003 until August 17, 2004, he served as senior executive vice president, responsible for our cancer detection business, Guided Therapeutics. Until November 2003, he had served as our president and chief operating officer since 1992. Prior to that time, Mr. Ignotz was president of Humphrey Instruments SmithKline Beckman (Japan), president of Humphrey Instruments GmbH (Germany), and senior vice president of Allergan Humphrey Inc., a medical device company. Mr. Ignotz is a member of the board of directors of Vismed, Inc., an ophthalmic diagnostic products company and Pennsylvania College of Optometry. Mr. Ignotz earned a B.A. in Sociology and Political Science from the San Jose State University and a M.B.A. from Pepperdine University.

Earl R. Lewis has served as a member of our board of directors since July 1998. Mr. Lewis is president, chief executive officer, and chairman of the board of directors of FLIR Systems, Inc., a manufacturer of thermal imaging and broadcast camera systems for a wide variety of applications in the commercial and government markets. Prior to joining FLIR in 2000, Mr. Lewis was president and chief executive officer of Thermo Instrument Systems, Inc. He served in various capacities with Thermo Instrument Systems since 1986. Thermo Instrument Systems develops, manufactures and markets analytical instruments used to identify complex compounds as well as instruments used to image, inspect and measure various industrial processes and life sciences phenomena. Mr. Lewis is a member of the board of directors of Spectra Physics Laser, Inc., IGI, Inc. and Harvard Bioscience, Inc.

William E. Zachary, Jr. has served as a member of our board of directors since April 1999. Since 1971, Mr. Zachary has been a member with the law firm of Zachary & Segraves, P.A. of Decatur, Georgia, of which he is a founding member. He served on the Investigative Panel of the State Bar of Georgia Disciplinary Board from 1997 to 2000. Mr. Zachary was a founder and was chairman of the board of directors of Bank Atlanta from 1986 to 2000, at which time Bank Atlanta merged with Branch Bank & Trust Company. Mr. Zachary is a qualified arbitrator for the New York and American Stock Exchanges and the National Association of Securities Dealers, Inc.

Christopher F. Monahan has served as a member of our board of directors since October 2000. Mr. Monahan has been a private investor since 1988, following a 38-year career in the medical industry. Most recently, Mr. Monahan served as the divisional vice president and general manager in the Diagnostics Division of Abbott Laboratories, from 1992 to 1998. From 1988 to 1992 he served as president of Unipath, a division of the Unilever Co., and was responsible for its worldwide hematology business and marketing of the U.S. Clearview Rapid Assay line. From 1981 to 1988, Mr. Monahan was president and chief executive officer of Sequesta Turner Corp. Mr. Monahan earned a B.A. from the University of Notre Dame.

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#### **Board Meetings and Committees**

Our board of directors has an audit committee and a compensation committee. It does not have a nominating committee or a committee performing the functions of a nominating committee.

The audit committee selects and engages the independent public accountants to audit the company's annual financial statements and pre-approves all allowable audit services and any special assignments given to the accountants. The audit committee also determines the planned scope of the annual audit, any changes in accounting principles, the effectiveness and efficiency of the company's internal accounting staff and the independence of the company's external auditors. The audit committee currently consists of Messrs. Hadley (Chairman), Lewis, and Zachary.

The compensation committee sets the compensation for officers of the company, reviews management organization and development, reviews significant employee benefit programs and establishes and administers executive compensation programs. The compensation committee currently consists of Messrs. Lewis (Chairman), Hadley and Monahan.

#### **Director Compensation**

Non-employee directors receive payments of \$3,000 per quarter, \$1,000 per meeting attended in person or \$500 if attended by telephone, and \$500 per committee meeting attended, up to a maximum of \$20,000 per year. In 2003, in lieu of cash payments for each quarter and meeting payments for the first and second quarters, the non-employee directors were granted stock options at the market price as of the date of the regularly scheduled second quarter board meeting. All cash payments and option grants were suspended after June 30, 2003. All directors are reimbursed for expenses actually incurred in attending meetings of the board of directors and its committees. Non-employee directors may be granted options to purchase common stock under our 1995 stock plan. Each non-employee director was granted options to purchase 6,000 shares, which vested immediately, on May 22, 2003 for the first two quarters of 2003 in lieu of cash payments.

#### Compensation Committee Interlocks and Insider Participation

Charles G. Hadley, Christopher F. Monahan and Earl R. Lewis comprise the compensation committee. No member of the compensation committee has been an officer or employee of SpectRx or had a relationship that would constitute an interlocking relationship with executive officers or directors of another entity.

#### **EXECUTIVE COMPENSATION**

The following table lists specified compensation we paid during each of the fiscal years ended December 31, 2001, 2002 and 2003 to the chief executive officer, our chief operating officer and our four other most highly compensated executive officers in 2003, who are referred to as the named executive officers:

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# **Summary Compensation Table**

Name & Principal Position	Year	Annual Salary (\$)	Compensation Bonus (\$)	Long Term Compensation Securities Underlying Options/ SARs (#)	All Other Compensation (\$)
Mark A. Samuels	2003	230,562 (1)	0	(50,000)	3,188 (2)
Chairman and Chief Executive	2002	202,292 (1)	0	25,000	3,188 (2)
Officer	2001	227,532	25,000		3,148 (2)
William D. Arthur, III	2003	13,648 (3)	0	105,000	
President and Chief Operating	2002	0	0		
Officer	2001	0	0		
Keith D. Ignotz	2003	188,874 (1)	0	(45,000)	2,880 (2)
Senior Executive Vice	2002	165,486 (1)	0	15,000	2,880 (2)
President	2001	182,236	20,000		2,880 (2)
Thomas H. Muller, Jr.	2003	182,146 (1)	0	(10,000)	2,184 (2)
Executive Vice President,	2002	159,655 (1)	0	50,000	2,183 (2)
Chief Financial Officer and Secretary	2001	164,289	20,000		2,200 (2)
Mark L. Faupel	2003	143,342 (1)	0		
Executive Vice President	2002	145,805 (1)	0	15,000	
Chief Technical Officer	2001	153,806	21,000		
Walter Pavlicek	2003	129,455 (1)	0	7,000	
Vice President,	2002	133,842 (1)	0	10,000	
Operations	2001	150,355	9,268		

- (1) The named executive officers have deferred salary included in the listed compensation totals. The following amounts of salary were deferred for the year indicated: Mr. Samuels -- 2002 -- \$24,523 and 2003 -- \$120,715; Mr. Ignotz -- 2002 -- \$12,157 and 2003 -- \$85,105; Mr. Muller -- 2002 -- \$13,945 and 2003 -- \$97,423; Dr. Faupel -- 2002 -- \$10,677 and 2003 -- \$31,477 and Dr. Pavlicek -- 2002 -- \$7,105 and 2003 -- \$14,887. In 2003, \$15,215 and \$6,086 of deferred 2002 salary was paid to Messrs. Samuels and Ignotz, respectively.
- (2) Consists of insurance premiums for a term life policy, the proceeds of which are payable to each officer's named beneficiary.
- (3) Mr. Arthur joined the company on November 5, 2003.

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#### Option Grants in Last Fiscal Year

The following table lists specified information concerning stock options granted during the fiscal year ended December 31, 2003 to the named executive officers. Options are granted under our 1995 stock plan. Under the stock plan, the options were granted with an exercise price equal to the fair market value on the date of grant. The options granted in 2003 vest in variable amounts - immediate for directors and certain consultants, and 24 to 48 months for employees - and expire in 2013. In accordance with the rules of the Securities and Exchange Commission, the following table also lists the potential realizable value over the term of the options, which is the period from the grant date to the expiration date based on assumed rates of stock appreciation of 5% and 10%, compounded annually. These amounts do not represent our estimate of future stock prices. Actual realizable values, if any, of stock options will depend on the future performance of our common stock.

### Option/SAR Grants in Fiscal 2003

#### **Individual Grants**

Potential Realizable Value At Assumed Annual Rates of Stock Price Appreciation for Option Term (3)

Name	Number of Securities Underlying Options/SARs Granted (#)	% of Total Options/SARs Granted in Fiscal Year (1)	Exercise or Base Price (\$/Sh) (2)	Expiration Date	5% (\$)	10% (\$)
Mark A. Samuels	10,000	4.1%	1.5	4/13/2013	\$39,433	\$53,906
William D. Arthur, III	105,000	43.0%	1.24	11/04/2013	\$414,051	\$566,014
Keith D. Ignotz	0	0%	0		\$0	\$0
Thomas H. Muller, Jr.	20,000	8.2%	1.5	4/13/2013	\$78,867	\$107,812
Mark L. Faupel	0	0%	0		\$0	\$0
Walter Pavlicek	7,000	2.9%	1.5	4/13/2013	\$27,603	\$37,734

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<sup>(1)</sup> Based on an aggregate of 244,000 options we granted in the fiscal year ended December 31, 2003.

- (2) The exercise price per share of each option was equal to the last reported sale price of the common stock on the date of grant.
- (3) The potential realizable value is calculated based on the ten-year term of the option at its time of grant. It is calculated assuming that the fair market value of our common stock on the date of grant appreciates at the indicated annual rate compounded annually for the entire term of the option and that the option is exercised and sold on the last day of its term for the appreciated stock price.

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

There were no options exercised in 2003 by the named executive officers. The following table lists each of the named executive officers and the fiscal year end number and value of exercisable and unexercisable options:

Fiscal 2003 Year-End Option/SAR Values

	Number of Shares Underlying Unexercised Options/SARs at 12/31/03		In-The-Money	nexercised (#) Options/SARs at 03 (\$)(1)
	Exercisable	Unexercisable	Exercisable	Unexercisable
Mark A. Samuels	308,629	13,230	\$248,321	\$ 1,146
William D. Arthur, III	38,333	66,667	29,950	50,000
Keith D. Ignotz	246,296	6,563	211,967	0
Thomas H. Muller, Jr.	200,256	26,459	7,708	2,292
Mark L. Faupel	117,437	16,563	0	0
Walter Pavlicek	35,020	11,980	948	2,553

<sup>(1)</sup> Based on a value of \$2.00 per share, which was the last reported sale price of the common stock on December 31, 2003.

### Change of Control Arrangements

We have a compensatory arrangement with our executive officers that will result from a change of control of SpectRx, as described below. Under the stock option agreements with each of our executive officers named in the summary compensation table, upon a change of control, all options held by the officer will vest immediately. The board committee that administers the stock option plan may provide, by giving at least 30 days prior written notice, that all options will terminate if not exercised in connection with or before the change of control or, if provision is made for assumption of the options, permit the optionee to elect to accept the assumed options. Additionally, after a change of control, if the optionee's employment is terminated due to a reduction of responsibility, required relocation or other similar action, the executive officer will be entitled to receive, as specified in the agreement for each executive officer, three month's severance (in the case of Messrs. Faupel and Pavlicek) or twelve month's severance (in the case of Messrs. Samuels, Ignotz and Muller), which may be paid either as a lump sum or as a salary continuation, at our option. Generally, a change of control occurs upon an acquisition by any person or group in excess of 50% of our voting securities, a replacement of more than one-half of the members of our board of directors that is not approved by a majority of the members who were on the board before the transaction, the merger of SpectRx with or into another entity unless the holders of our securities before the transaction continue to hold a majority of our securities after the transaction, or the consolidation or sale of all or substantially all of our assets.

### CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

In connection with a June 1994 sale of approximately 323,500 shares of restricted stock, we loaned Mark Samuels and Keith Ignotz \$27,000 and \$21,000, respectively. These full recourse loans were secured by the related shares of our common stock held by the officers, bore interest at 6% per annum, and became payable on December 31, 2002. These notes were fully satisfied in January and February 2003, and the collateral was released.

In October 1996, we loaned Mark Samuels and Keith Ignotz \$200,000 each for a total of \$400,000. The loans were secured by shares of common stock of Laser Atlanta Optics, Inc. ("LAO") and shares of our common stock. We and LAO were related through a common group of stockholders. 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, we took possession of the collateral to fully satisfy these notes.

#### CHANGES IN REGISTRANT'S CERTIFYING ACCOUNTANT

On June 12, 2002, the audit committee of our board of directors voted to dismiss our independent public accountants, Arthur Andersen LLP, effective immediately. On June 12, 2002, the audit committee of our board of directors voted to engage the services of Ernst & Young LLP to serve as our independent public accountants for our 2002 fiscal year, effective immediately.

Arthur Andersen's reports on our consolidated financial statements for each of the fiscal years ended December 31, 2000 and 2001 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 the fiscal years ended December 31, 2000 and 2001 and in the subsequent interim period from January 1, 2002 through and including June 12, 2002, 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 our consolidated financial statements for such years; and there were no "reportable events" as that term is defined in Item 304(a)(1)(v) of Regulation S-K.

During the fiscal years ended December 31, 2000 and 2001 and in the subsequent interim period from January 1, 2002 through and including June 12, 2002, we did not consult Ernst & Young 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 our 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.

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On October 17, 2003, the audit committee of our board of directors unanimously approved the engagement of the accounting firm of Eisner LLP as its new independent public accountants effective immediately. Also on October 17, 2003, our audit committee unanimously agreed to dismiss Ernst & Young LLP.

The report of Ernst & Young LLP on our consolidated financial statements 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 our ability to continue as a going concern.

In connection with the audit of our 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 us and 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 our unaudited financial statements for the quarter ended March 31, 2003, we and Ernst & Young LLP disagreed on the amount of gain to be recognized from the sale of the Bili*Chek* line of business. The audit committee of our board of directors also discussed the subject matter of this disagreement with Ernst & Young LLP. The issue was resolved to the satisfaction of Ernst & Young LLP. We 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 our independent public accountants (June 12, 2002 to October 17, 2003).

We have 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 our 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.

#### PRINCIPAL STOCKHOLDERS

The following table lists information regarding the beneficial ownership of our common stock as of July 31, 2004 by (i) each person who is known to us to beneficially own more than 5% of the outstanding shares of our common stock, (ii) each director, (iii) each officer named in the summary compensation table below, and (iv) all directors and executive officers as a group. Unless otherwise indicated, the address of each officer and director is 4955 Avalon Ridge Parkway, Suite 300, Norcross, Georgia 30071.

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	Amount of Nature of	
Name and Address of Beneficial Owner	Beneficial Ownership (1)	Percent of Class (2)
Dr. John Imhoff (3)	1,765,820	14.1%
Cottage 441, 55 Rutledge Land		
Sea Island, GA 31561		
Easton Hunt Capital Partners, L.P. (4)	1,666,660	12.8%
SBS Tower, Suite 750		
2601 So. Bay Shore Dr.		
Miami, FL 31333		
Dolphin Offshore Partners, LP (5)	1,333,340	10.5%
129 E. 17th Street, 2nd Floor		
New York, NY 10577		
David Musket (6)	1,333,360	10.5%
125 Cambridgepark Drive		
Cambridge, MA 02140		
ProMed Management Entities (7)	1,133,360	9.1%
125 Cambridgepark Drive		
Cambridge, MA 02140		
Entities affiliated with Hillman Company (8)	1,007,233	8.8%
(Charles G. Hadley)		
824 Market Street, Suite 900		
Wilmington, DE 19801		
SDS Capital Partners (9)	1,000,000	8.1%
53 Forest Avenue		
Old Greenwich, CT 06870		
Dolores Maloof (10)	803,866	6.8%
2669 Mercedes Drive	,	
Atlanta, GA 30345		
Mark A. Samuels (11)	793,811	6.7%
Abbott Laboratories (12)	755,230	6.6%
100 Abbott Park Road	,	
Abbott Park, IL 60064		
Keith D. Ignotz (13)	696,810	5.9%
Sagamore Hill Capital Management, L.P. (14)	666,660	5.5%
10 Glenville Street	000,000	3.3 /
Greenwich, CT 06831		
Thomas H. Muller, Jr. (15)	237,931	2.1%
William Arthur III (16)	51,909	*
Walter Pavlicek (17)	42,740	*
Mark Faupel (18)	118,687	1.0%
Earl Lewis (19)	28,458	*
William Zachary (20)	39,421	*
Chris Monahan (21)	28,249	*
All directors and executive officers as a group (1		27.4%
persons) (22)	113,130,017	21.7/0
persons) (22)	42	
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- (\*) Less than 1%.
- (1) Except as otherwise indicated in the footnotes to this table and pursuant to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of common stock.
- (2) Percentage ownership is based on 11,390,079 shares of common stock outstanding as of June 30, 2004. Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission, based on factors including voting and investment power with respect to shares. Shares of common stock subject to currently exercisable options, warrants or convertible preferred stock, or any such securities exercisable within 60 days after June 30, 2004, are deemed outstanding for computing the percentage ownership of the person holding those options, but are not deemed outstanding for computing the percentage ownership of any other person.
- (3) Consists of 622,500 common shares, preferred shares convertible into 333,330 common shares and warrants to purchase 718,330 common shares held by Dr. John Imhoff; and preferred shares convertible into 33,330 common shares and warrants to purchase 58,330 common shares held by Dr. Imhoff's spouse, for which he claims no beneficial interest.
- (4) Consists of preferred shares convertible into 833,330 common shares and warrants to purchase 833,330 common shares held by Easton Hunt Capital Partners, L.P.
- (5) Consists of preferred shares convertible into 666,670 common shares and warrants to purchase 666,670 common shares held by Dolphin Offshore Partners, LP.
- (6) Consists of preferred shares convertible into 100,000 common shares and warrants to purchase 100,000 common shares held by Mr. Musket; preferred shares convertible into 422,740 common shares and warrants to purchase 422,740 common shares held by ProMed Partners, LP; preferred shares convertible into 75,940 common shares and warrants to purchase 75,940 common shares held by ProMed Partners, II, LP, and; preferred shares convertible into 68,000 common shares and warrants to purchase 68,000 common shares held by ProMed Offshore Fund, Ltd. ProMed Management shares voting and investment power of these three funds and may be deemed the beneficial owners of all of the shares, except those of Mr. Musket.
- (7) Consists of preferred shares convertible into 422,740 common shares and warrants to purchase 422,740 common shares held by ProMed Partners, LP; preferred shares convertible into 75,940 common shares and warrants to purchase 75,940 common shares held by ProMed Partners, II, LP, and; preferred shares convertible into 68,000 common shares and warrants to purchase 68,000 common shares held by ProMed Offshore Fund, Ltd. ProMed Management shares voting and investment power of these three funds and may be deemed the beneficial owner of all of the shares.
- (8) Consists of 28,458 shares held by Mr. Hadley subject to stock options that are exercisable within 60 days of July 31, 2004; 82,637 shares held by Wilmington Interstate Corporation; 9,905 shares owned by Wilmington Securities, Inc.; 494,101 shares held by Henry L. Hillman, Elsie Hilliard Hillman and C.G. Grefenstette, Trustees of the Henry L. Hillman Trust U/A dated 11/18/85; and shares in the following amounts held by C.G. Grefenstette and L.M. Wagner, Trustees of Trusts dated 12/30/76 98,033 shares for the children of Juliet Lea Hillman Simonds; 98,033 for the children of Audrey Hillman Fisher; 98,033 for the children of Henry Lea Hillman, Jr.; and 98,033 for the children of William Talbot Hillman. Wilmington Securities Corporation is an indirect, wholly owned

subsidiary of The Hillman Company. The Hillman Company is controlled by Henry L. Hillman, Elsie Hilliard Hillman and C.G. Grefenstette, trustees of the Henry L. Hillman Trust, which trustees may be deemed the beneficial owners of all the shares except those subject to options owned by Mr. Hadley.

- (9) Consists of preferred shares convertible into 166,670 common shares and warrants to purchase 166,670 common shares held by SDS Capital Group SPC, Ltd.; preferred shares convertible into 10,000 common shares and warrants to purchase 10,000 common shares held by North Sound Legacy Fund, LLC; preferred shares convertible into 110,000 common shares and warrants to purchase 110,000 common shares held by North Sound Legacy Institution Fund, LLC, and; preferred shares convertible into 213,330 common shares and warrants to purchase 213,330 common shares held by North Sound Legacy International. SDS Capital Partners shares voting and investment power of these three funds and may be deemed the beneficial owner of all of the shares.
- (10) Consists of 131,000 common shares, preferred shares convertible into 166,670 common shares, and warrants to purchase 270,670 common shares held by Mrs. Maloof; and 235,526 shares held by Mrs. Maloof's spouse, for which she claims no beneficial interest.
- (11) Consists of 271,926 common shares, preferred shares convertible into 66,670 common shares, and warrants to purchase 143,670 common shares held by Mr. Samuels; and 311,545 common shares subject to stock options that are exercisable within 60 days of July 31, 2004.

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- (12) Consists of 626,342 shares held by Abbott Laboratories and 128,888 shares that will be acquired upon conversion of its 100,000 shares of convertible preferred stock, including interest, calculated assuming a conversion price of \$9.388 at 60 days past July 31, 2004.
- (13) Consists of 238,924 common shares, preferred shares convertible into 66,670 common shares, and warrants to purchase 143,670 common shares held by Mr. Ignotz; and 247,546 shares subject to stock options that are exercisable within 60 days of July 31, 2004.
- (14) Consists of preferred shares convertible into 333,330 common shares and warrants to purchase 333,330 common shares held by Sagamore Hill Hub Fund, Ltd. According to the reporting persons' Schedule 13G dated April 12, 2004, each of Sagamore Hill Capital Management, L.P., its general partner, Sagamore Hill Capital Advisors, and its sole member, Steven H. Bloom, have sole voting and dispositive power of these shares.
- (15) Consists of 31,842 shares held by Mr. Muller and 206,089 shares subject to stock options that are exercisable within 60 days of July 31, 2004.
- (16) Consists of 38,333 shares held by Mr. Arthur subject to stock options that are exercisable within 60 days of July 31, 2004.
- (17) Consists of 3,803 shares held by Dr. Pavlicek and 38,937 shares subject to stock options that are exercisable within 60 days of July 31, 2004.
- (18) Consists of 118,687 shares held by Dr. Faupel subject to stock options that are exercisable within 60 days of July 31, 2004.
- (19) Consists of 28,458 shares held by Mr. Lewis subject to stock options that are exercisable within 60 days of July 31, 2004.
- (20) Consists of 10,963 shares held by Mr. Zachary and 28,458 shares subject to stock options that are exercisable within 60 days of July 31, 2004.
- (21) Consists of 28,249 shares held by Mr. Monahan subject to stock options that are exercisable within 60 days of July 31, 2004.
- (22) Consists of 1,545,709 common shares, preferred shares convertible into 133,332 common shares and warrants to purchase 287,332 common shares held by the directors and executive officers; and 1,190,430 shares subject to stock options that are exercisable within 60 days of July 31, 2004.

#### SHARE OWNERSHIP OF SELLING STOCKHOLDERS

We issued and sold preferred stock convertible into common stock, common stock and warrants to purchase shares of common stock in private placement transactions exempt from registration under the Securities Act of 1933. These shares of common stock we sold, as well as the shares of common stock issuable upon conversion of the preferred stock and exercise of the warrants, are covered by this prospectus.

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The following table sets forth information known to us with respect to the beneficial ownership of our common stock as of July 31, 2004 by each of the selling stockholders. Beneficial ownership is determined in accordance with the rules and regulations of the Securities and Exchange Commission and generally includes voting or investment power with respect to securities. The information in the table reflects the most recent information furnished to us by each identified selling stockholders. As of July 31, 2004, there were approximately 11,390,079 shares of our common stock issued and outstanding. Shares issuable upon conversion of the preferred stock and upon exercise of the warrants are deemed to be outstanding for purposes of the selling stockholders named in the table. The number of shares reflected in the table assumes no adjustment in the number of shares issuable upon conversion of the preferred stock or upon exercise of the warrants as a result of stock splits and stock dividends, and conversion price or exercise price adjustments pursuant to the terms of the certificate of designations governing the preferred stock and the terms of the warrants, respectively.

No offer or sale of common stock under this prospectus may be made by a selling stockholder unless that stockholder is listed in the table below or until that stockholder has notified us, provided all required information to us and a supplement to this prospectus has been filed or an amendment to the registration statement has become effective.

Unless otherwise indicated in the footnotes to the table, no selling stockholder has held any position, office or other material relationship with us or our affiliates during the past three years.

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Name	Amount of Common Stock Owned Prior to Offering (1)			Common Stock 'Pursuant to this I	Amount of Common Stock Owned After Offering (2)		
			Outstanding Common	Common Stock			
	Number	Percent	Stock	Underlying Preferred Stock	Underlying Warrants	Number	Percent
OTAPE Investments,	1 (01110 01	1 0100110	200011		,, 42141109	1 (01110-01	
LLC(3)	133,340	1.2%		66,670	66,670		
Dolphin Offshore	<b>,</b> -			,	,		
Partners, L.P.	1,333,340	10.5%		666,670	666,670		
Pamela Kaweske	80,000	*		40,000	40,000		
Baffles, S.A.	80,000	*		40,000	40,000		
Hytek International, Ltd.		*		28,000	28,000		
SEGOES Trust	104,000	*		52,000	52,000		
SF Capital Partners (3)	586,660	4.9%		293,330	293,330		
Bristol Investment Fund	,			,	,		
Ltd.	533,340	4.5%		266,670	266,670		
Bristol Investment							
Group, Inc. (4)	6,667	*			6,667		
Easton Hunt Capital	,				,		
Partners, L.P.	1,666,660	12.8%		833,330	833,330		
ProMed Partners, L.P.(3							
(5)	875,072	7.1%		422,740	452,332		
ProMed Partners II,	,			,	,		
L.P.(3) (5)	157,196	1.4%		75,940	81,256		
ProMed Offshore Fund,							
Ltd.(3) (5)	140,760	1.2%		68,000	72,760		
David Musket (3) (5)	248,222	2.1%		100,000	148,222		
SDS Capital Group SPC				,	,		
Ltd.	333,340	2.8%		166,670	166,670		
North Sound Legacy							
Fund LLC	20,000	*		10,000	10,000		
North Sound Legacy							
Institutional Fund, LLC	220,000	1.9%		110,000	110,000		
North Sound Legacy							
International, Ltd.	426,660	3.6%		213,330	213,330		
Sagamore Hill Hub							
Fund, Ltd.(6)	666,660	5.5%		333,330	333,330		
Alpha Capital AG	266,660	2.3%		133,330	133,330		
Paul Scharfer (3)	381,562	3.2%		166,670	214,892		
John E. Imhoff	1,765,820(7)	14.1%		333,330	718,330	622,500	5.2%
Susan M. Imhoff	91,660(8)	*		33,330	58,330		
Dolores Maloof (3)	803,866	6.8%		166,670	270,670	366,526	3.1%
Steven Maloof (9)	559,750	4.9%			143,000	416,750	3.5%
Keith Ignotz (10)	696,810(11)	5.9%		66,670	143,670	485,220	4.1%
Mark Samuels (12)	793,811(13)	6.7%		66,670	143,670	580,555	4.8%
Kensington Partners,	<u> </u>						
L.P.	190,560	1.6%		95,280	95,280		

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Bald Eagle Fund, Ltd.	9,440	*		4,720	4,720		
Douglas Schmidt	66,680	*		33,340	33,340		
Heidi Douglas	147,000	1.3%			17,000	130,000	1.1%
Barry Kurokawa (3)	48,222	*			48,222		
Joshua Golomb (3)	9,334	*			9,334		
Robert R. Blakely (3)	89,001	*	20,000		69,001		
Scott R. Griffith (3)	89,000	*	20,000		69,000		
Jesse B. Shelmire, III (3	3) 89,000	*	20,000		69,000		
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- \* Less than 1%.
  - (1) Represents the number of shares of outstanding common stock, common stock underlying preferred stock and common stock underlying warrants that may be offered pursuant to this prospectus and the amount of other common stock owned.
  - (2) Assumes the sale of all of the shares of common stock offered by each selling stockholder. The selling stockholders may sell all, some or none of their shares in this offering. See "Plan of Distribution."
  - (3) The selling stockholder, who is a broker-dealer or an affiliate of a broker-dealer, has advised us that such selling stockholder acquired the securities in the ordinary course of business and, at the time, had no agreements or understandings, directly or indirectly, with any person to distribute the shares.
  - (4) This selling stockholder, who is a broker-dealer and may be deemed an underwriter, has advised us that it acquired the securities in the ordinary course of business and, at the time, had no agreements or understandings, directly or indirectly, with any person to distribute the shares.
  - (5) David Musket may be deemed the beneficial owner of the securities held by ProMed Partners, L.P., ProMed Partners II, L.P. and ProMed Offshore Fund, Ltd.
  - (6) According to the selling stockholder's Schedule 13G dated April 12, 2004, each of Sagamore Hill Capital Management, L.P., its general partner, Sagamore Hill Capital Advisors, and its sole member, Steven H. Bloom have sole voting and dispositive power of these shares.
  - (7) Includes preferred shares convertible into 33,330 common shares and warrants to purchase 58,330 common shares held by Dr. Imhoff's spouse, for which he claims no beneficial interest.
  - (8) Excludes 622,500 common shares, held by Mrs. Imhoff's spouse, for which she claims no beneficial interest.
  - (9) This selling stockholder, who is a broker-dealer and may be deemed an underwriter, has advised us that he has not acquired the securities in the ordinary course of business and, at the time, had no agreements or understandings, directly or indirectly, with any person to distribute the shares.
  - (10) The selling stockholder is our former senior executive vice president and one of our directors.
  - (11) Includes 238,924 common shares and 247,546 shares subject to stock options that are exercisable within 60 days of July 31, 2004.
  - (12) The selling stockholder is the chairman of our board of directors and our chief executive officer.
  - (13) Includes 271,926 common shares and 311,545 common shares subject to stock options that are exercisable within 60 days of July 31, 2004.

We and the selling stockholders have entered into agreements which required us to file the registration statement, of which this prospectus is a part, to permit the resale of the shares of common stock issued or issuable to those stockholders. Those agreements require that we use our best efforts to keep the registration statement continuously effective from the date the registration statement becomes effective until the earliest of:

the date on which all of the shares of common stock have been disposed of in accordance with the registration statement;

the date on which all of the shares of common stock held by persons that are not our affiliates are eligible to be sold pursuant to Rule 144(k) of the Securities Act of 1933; and

the seventh anniversary of the date of the registration rights agreement.

We may require the selling stockholders to suspend the sales of the common stock covered by this prospectus if our board of directors determines in good faith that it is in our best interests not to disclose the existence of facts surrounding any proposed or pending acquisition, disposition, strategic alliance or financing, or for any other purpose in order to comply with the federal securities laws. We will be permitted to suspend the rights of the selling stockholders to make sales pursuant to the registration statement and/or postpone the preparation, filing and effectiveness of the registration statement for periods not to exceed 90 days in the aggregate in any consecutive twelve month period.

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#### PLAN OF DISTRIBUTION

Any or all of the shares offered by the selling stockholders may be offered for sale and sold by or on behalf of the selling stockholders from time to time in varying amounts, including in block transactions, on the Nasdaq Stock Market or the over-the-counter market, in privately negotiated transactions, or otherwise (other than underwritten offerings), at prices prevailing in such market or as may be negotiated at the time of the sale. The shares may be sold by the selling stockholders directly to one or more purchasers, through agents designated from time to time or to or through broker-dealers designated from time to time. In the event the shares are publicly offered through broker-dealers or agents, the selling stockholders may enter into agreements with respect thereto. Such broker-dealers or agents may receive compensation in the form of discounts, concessions or commissions from the selling stockholders and/or the purchasers of the shares. The selling stockholders and any such broker-dealers or agents that participate in the distribution of the shares may be deemed to be underwriters within the meaning of the Securities Act, and any profit on the sale of the shares by them and any discounts, commissions or concessions received by them may be deemed to be underwriting discounts and commissions under the Securities Act. Any such broker-dealers and agents may engage in transactions with, and perform services for, SpectRx. At the time a particular offer of shares is made by the selling stockholders, to the extent required, a prospectus supplement will be distributed which will set forth the aggregate number of shares being offered, and the terms of the offering, including the public offering price thereof, the name or names of any broker-dealers or agents, any discounts, commissions and other items constituting compensation from, and the resulting net proceeds to, the selling stockholders.

Any supplement and, if necessary, a post-effective amendment to the registration statement, of which this prospectus is a part, will be filed with the Securities and Exchange Commission to reflect the disclosure of additional information with respect to the distribution of the securities.

We have agreed to indemnify the selling stockholders against specified liabilities under the Securities Act of 1933 and to pay substantially all of the expenses incidental to the registration, offering and sale of the common stock to the public other than commissions, brokerage fees and stock transfer taxes applicable to the common stock sold by the selling stockholders.

To the best of our knowledge, there are currently no plans, arrangements or understandings between any selling stockholders and any broker, dealer, agent or underwriter regarding the sale of the common stock by the selling stockholders.

In order to comply with the securities laws of certain states, sales of shares offered hereby to the public in such states may be made only through broker-dealers who are registered or licensed in such states. Sales of shares offered hereby must also be made by the selling stockholders in compliance with other applicable state securities laws and regulations.

#### **DESCRIPTION OF SECURITIES**

We have 55,000,000 authorized shares of stock, consisting of 50,000,000 shares of common stock, having a par value of \$0.001 per share, and 5,000,000 shares of preferred stock, having a par value of \$0.001 per share, of which 525,000 shares have been designated as redeemable convertible preferred stock and 510,000 shares have been designated as series A convertible preferred stock.

#### Common Stock

As of July 31, 2004, there were 11,390,079 shares of common stock issued and outstanding held of record by approximately 161 holders. The holders of common stock are entitled to one vote for each share held of record on all

matters submitted to a vote of stockholders. Subject to preferences that may be applicable to any outstanding preferred stock, holders of common stock are entitled to receive ratably such dividends as may be declared by our board of directors out of funds legally available therefor and in liquidation proceedings. Holders of common stock have no preemptive or subscription rights and there are no redemption rights with respect to such shares. The outstanding shares of common stock are, and the shares of common stock offered by this prospectus will be, fully paid and nonassessable.

#### Preferred Stock

Our board of directors is authorized, without further stockholder action, to issue preferred stock in one or more series and to fix the voting rights, liquidation preferences, dividend rights, repurchase rights, conversion rights, redemption rights and terms, including sinking fund provisions, and certain other rights and preferences, of the preferred stock. Although there is no current intention to do so, our board of directors may, without stockholder approval, issue shares of a class or series of preferred stock with voting and conversion rights which could adversely affect the voting power or dividend rights of the holders of common stock and may have the effect of delaying, deferring or preventing a change in control.

#### Redeemable Convertible Preferred Stock

We currently have outstanding 525,000 shares of redeemable convertible stock, having a stated value of \$10.00 per share, held by one holder as of July 31, 2004.

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On March 7, 2003, we reached a settlement with the sole holder of our 525,000 issued and outstanding shares of redeemable convertible preferred stock regarding certain disputes in connection with a previously terminated research and development and license agreement and the election of such holder to have shares of redeemable convertible preferred stock redeemed by us. The holder had previously agreed to waive its right to have 100,000 shares of redeemable convertible preferred stock redeemed, and had elected to have the remaining 425,000 shares 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, we agreed to make quarterly payments to the holder during 2003 and 2004 and end of the year lump sum payments in 2005 and 2006 to redeem the 425,000 shares of redeemable convertible preferred stock and to pay \$0.7 million, \$1.3 million, \$1.8 million and \$1.9 million for 2003, 2004, 2005 and 2006, respectively. We paid \$400,000 and \$300,000 to the holder pursuant to the settlement during 2003 and in the first quarter of 2004, respectively. We have been in negotiations with the holder since early 2003 regarding a patent issue and the payment and terms under the settlement. On July 15, 2004, the holder sent us a letter notifying us that we were in default on two separate payments due in 2004 and demanding payment. On July 22, 2004, we responded that we were seeking to resolve the patent issues and renegotiate the payment terms.

#### Dividends.

The holders of the redeemable convertible preferred stock are entitled, when and if declared by our board of directors, to receive dividends out of assets of SpectRx legally available therefor at an annual rate of \$0.60 per share. These dividends will be cumulative and will accrue whether or not declared by our board. So long as any shares of the redeemable convertible preferred stock are outstanding, we will not declare or pay on any stock ranking junior to the redeemable convertible preferred stock any dividend or distribution on any such junior ranking stock, nor will we purchase or redeem any such junior ranking stock, or pay or make available any monies for a sinking fund for the purpose of redemption of such junior ranking stock, unless all dividends declared or accrued on any outstanding shares of redeemable convertible preferred stock have been paid or declared and a sum of money sufficient for the payment thereof set apart.

#### Conversion.

Each share of the 100,000 shares of redeemable convertible preferred stock that will be converted is convertible into the number of shares of common stock equal to the product obtained by multiplying the conversion rate by the number of shares of preferred stock being converted. The conversion price will be equal to the greater of (i) \$9.388 or (ii) the average of the closing sales price of the common stock as reported by the NASDAQ Stock Market for each day of the 30-day trading period that begins on the trading day that is 15 trading days prior to the date of our receipt of the conversion notice, as defined in the certificate of designations governing the redeemable convertible preferred stock.

Upon conversion of any shares of redeemable convertible preferred stock, we will pay all declared or accrued but unpaid dividends as to such shares to the holders thereof to and through the conversion effective date; provided, however, that we may, at our option, in lieu of making a full cash payment of all such declared or accrued but unpaid dividends, make payment thereof in that number of whole shares of common stock calculated by dividing the total of such declared or accrued but unpaid dividends due such holders by the conversion price. Each outstanding share of redeemable convertible preferred stock will automatically be converted into common stock on and as of December 31, 2004, at the then effective conversion rate.

#### Redemption.

We are required to redeem the redeemable convertible preferred stock at the election of the holders of a majority of the redeemable convertible preferred stock, which election has been made for the 425,000 shares eligible for redemption at a redemption price of \$10.00 per share, plus accrued but unpaid dividends. On or before each date scheduled for redemption, each holder of shares to be redeemed must surrender the certificate representing such shares to us and will receive payment of the redemption price therefor in cash. If fewer than all of the shares represented by a surrendered certificate are redeemed, we will issue a new certificate representing the unredeemed shares.

Voting.

Holders of the redeemable convertible preferred stock have no voting rights in respect of the redeemable convertible preferred stock, except that they have the right to vote on those matters which, under the Delaware General Corporation Law, voting by classes of stock is required. So long as any shares of the redeemable convertible preferred stock are outstanding, we may not, without the unanimous consent of the holders of the redeemable convertible preferred stock then outstanding:

- alter or change the preferences, rights, powers or privileges of the redeemable convertible preferred stock;
- allocate any earned surplus, whether now existing or hereafter arising, to capital, in accordance with Delaware law, if the effect thereof would be to reduce the legally available funds for payment of dividends or for redemption of the redeemable convertible preferred stock; or
- create or authorize any shares of any class of our capital stock having any preference or priority as to either dividends or distribution or assets upon liquidation superior to any such preference or priority of the shares of redeemable convertible preferred stock or reclassify any securities into shares of such superior stock.

### Liquidation.

In the event of our voluntary or involuntary liquidation, dissolution or winding up, before any payment or distribution of our assets is made to or set apart for the holders of any stock ranking junior to the redeemable convertible preferred stock, the holders of the redeemable convertible preferred stock will be entitled to receive in respect of their shares of redeemable convertible preferred stock payment out of our assets of \$10.00 per share, plus all accrued but unpaid dividends to the date of final distribution.

#### Series A Convertible Preferred Stock

We currently have outstanding 488,669 shares of series A convertible preferred stock, having a stated value of \$15.00 per share, held by 28 holders as of July 31, 2004.

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#### Dividends.

The holders of the series A convertible preferred stock are entitled to receive quarterly, at the end of each calendar quarter, commencing on and after March 26, 2006, out of funds legally available therefor, dividends per share at the per annum rate of \$0.75 per share, prior and in preference to any declaration or payment of any dividend on any stock ranking junior to the series A convertible preferred stock. At our election, dividends on the series A convertible preferred stock may be paid by the issuance and delivery of whole shares of common stock having an aggregate current market price at the time of issuance equal to the amount of dividends so paid. The shares of redeemable convertible preferred stock and shares of any class of our capital stock ranking equal to the series A convertible preferred stock as to dividends and the distribution of assets upon liquidation, referred to in this prospectus as *pari passu* stock, shall rank equally with the series A convertible preferred stock as to payment of dividends. If any dividend becomes due and payable to the holders of series A convertible preferred stock and there is also due and payable a dividend to the holders of the redeemable convertible preferred stock or other *pari passu* stock, and we have insufficient funds to make payment in full to all such holders of such respective dividends, then such funds as are available will be distributed among the holders, ratably in proportion to the full amounts to which they would otherwise respectively be entitled.

#### Conversion.

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

On any automatic conversion date, each share of series A convertible preferred stock then outstanding will automatically be converted into common stock at the then effective conversion rate; provided, however, the number of shares of series A convertible preferred stock to be converted on any automatic conversion date must not exceed, as measured by the aggregate number of shares of common stock issued or to be issued upon conversion thereof, the cumulative trading volume for 90 preceding consecutive trading days for the common stock on its principal trading market in the United States. An automatic conversion date, subject to certain additional limitations and requirements, will occur if our common stock trades for a period of 20 consecutive trading days on its principal trading market in the U.S. at a per share trading price of the greater of \$4.50 or three times the then conversion price.

### Voting.

Each holder of a share of the series A convertible preferred stock is entitled to the number of votes equal to the number of shares of common stock into which such share of series A convertible preferred stock would be convertible under the circumstances described above on the record date for the vote or consent of stockholders, and will otherwise have voting rights and powers equal to the voting rights and powers of the common stock; *provided*, *however*, that, so long as at least 100,000 (such number subject to adjustment) shares of series A convertible preferred stock are outstanding, with respect to the election of directors, in addition to and not in limitation of the foregoing, if requested of us in a writing delivered to us at our principal executive offices and signed by the holders of a majority of the issued and outstanding shares of series A convertible preferred stock (or their duly designated proxies), the holders of the series A convertible preferred stock will vote together as a single class to elect two members of our board of directors.

In addition, holders of the series A convertible preferred stock have the right to vote on those matters which, under the Delaware General Corporation Law, voting by classes of stock is required and, so long as at least 100,000 (such number subject to adjustment) shares of series A convertible preferred stock are outstanding, we may not, without the consent (given by vote in person or by proxy at a meeting called for the purpose, or by written consent) of the holders of a majority of the shares of series A convertible preferred stock then outstanding:

create or authorize any shares of any class or series of our capital stock having a preference or priority as to either dividends or distribution of assets upon liquidation equal or superior to any such preference or priority of the shares of series A convertible preferred stock, reclassify any existing securities into shares of such equal or superior stock or amend the terms of any existing securities in a manner inconsistent with the

foregoing restriction;

amend or repeal any provision of, or add any provision to, our certificate of incorporation or bylaws, if such action would adversely alter or change the preferences, rights, privileges, or powers of, or restrictions provided for the benefit of, the series A convertible preferred stock;

declare, pay or set aside any dividends on any stock ranking junior to the series A convertible preferred stock, or redeem or repurchase any such junior ranking stock;

increase or decrease (other than in connection with a redemption or conversion) the authorized number of shares of series A convertible preferred stock; or

alter or change the rights, preferences or privileges of the series A convertible preferred stock in a manner different from each other class of pari passu stock.

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#### Liquidation.

In the event of our voluntary or involuntary liquidation, dissolution or winding up, referred to in this prospectus as a liquidation, or a "sale or merger" (as defined in the certificate of designations governing the series A convertible preferred stock), the holders of the outstanding shares of series A convertible preferred stock will, at their election, be entitled to receive in exchange for and in redemption of each share of their series A convertible preferred stock, prior and in preference to the holders of stock ranking junior to the series A convertible preferred stock, (x) in the case of a liquidation, from any funds legally available for distribution to stockholders, and (y) in the case of a sale or merger, from the net proceeds therefrom, an amount equal to the greater of (i) the invested amount per share, plus the aggregate amount of all declared or accrued, but unpaid, dividends per share, or (ii) the amounts to which such holders would have been entitled if the shares were converted to shares of common stock immediately before the liquidation, or sale or merger as the case may be. If, upon any liquidation, our assets are insufficient to make payment in full to all holders of the series A convertible preferred stock of the liquidation preference and to make payment in full to all holders of the redeemable convertible preferred stock then our assets will be distributed among the holders of the series A convertible preferred stock and the holders of the redeemable convertible preferred stock then outstanding, ratably in proportion to the full amounts to which they would otherwise respectively be entitled.

#### Pre-emptive Rights.

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

#### Warrants

We have issued warrants to purchase our common stock from time to time in connection with certain financing arrangements. As of July 31, 2004, there were outstanding warrants to purchase an aggregate of 6,501,026 shares of common stock at a weighted average exercise price of \$2.39 per share. All of our warrants are currently exercisable. Of our warrants, warrants exercisable for 4,886,690 shares of our common stock were issued to the purchasers of our shares of series A convertible preferred stock, with the per share exercise price being \$1.65 for one half of those warrants and \$2.25 for the other half. Subject to certain exceptions, if we issue shares of common stock, or securities convertible or exercisable for common shares, for a consideration per share of less than the then conversion price for the series A convertible preferred stock, then the per share exercise price for the warrants with the \$1.65 exercise price will be adjusted to equal such lower per share consideration, and the exercise price for the warrants with the \$2.25 exercise price will be adjusted to equal 125% of such lower per share consideration. All outstanding warrant agreements provide for anti-dilution adjustments in the event of certain mergers, consolidations, reorganizations, recapitalizations, stock dividends, stock splits or other changes in our corporate structure. Holders of some of our warrants are entitled to certain rights to cause us to register the sale of such shares under the Securities Act.

#### Certain Charter and Bylaw Provisions and Delaware Anti-Takeover Statute

Certain provisions of our certificate of incorporation, as amended, and bylaws may have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from attempting to acquire, control of us. Such provisions could limit the price that certain investors might be willing to pay in the future for shares of our common stock. Certain of these provisions allow us to issue preferred stock without any vote or further action by the stockholders and eliminate the right of stockholders to act by written consent without a meeting. These provisions may make it more difficult for stockholders to take certain corporate actions, and could have the effect of delaying or preventing a change in control of us.

In addition, we are subject to Section 203 of the Delaware General Corporation Law which, subject to certain exceptions, prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that such stockholder became an interested stockholder, unless: (1) prior to such date, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder, or (2) upon consummation of the

transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding of those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer, or (iii) on or subsequent to such time the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

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#### **LEGAL MATTERS**

Jones Day, Atlanta, Georgia, has passed upon the validity of the common stock that may be offered by this prospectus.

#### **EXPERTS**

Our consolidated financial statements for the year ended December 31, 2003 have been audited by Eisner LLP, independent registered public accounting firm, as set forth in its report thereon included therein. We have included our consolidated financial statements in this prospectus in reliance upon such report given upon the authority of such firm as experts in accounting and auditing.

The consolidated financial statements for the year ended December 31, 2002 have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon appearing in this prospectus and registration statement (which contains an explanatory paragraph describing conditions that raise substantial doubt about the Company's ability to continue as a going concern) appearing elsewhere herein. We have included our consolidated financial statements in this prospectus in reliance upon such report given upon the authority of such firm as experts in accounting and auditing.

The consolidated financial statements for the year ended December 31, 2001 have been audited by Arthur Andersen LLP, which has since ceased operations. Because Arthur Andersen LLP will not be available to consent to the inclusion of its report in the registration statement, of which this prospectus is a part, you will not be able to recover against Arthur Andersen LLP under Section 11 of the Securities Act for any false or misleading statements of a material fact contained in the consolidated financial statements audited by Arthur Andersen LLP that are incorporated by reference or any omissions to state a material fact required to be stated therein. An investor's ability to seek potential recoveries from Arthur Andersen LLP related to any claims that an investor may assert as a result of the work performed by Arthur Andersen LLP may be limited significantly by the lack of Arthur Andersen LLP's consent and the absence of assets of Arthur Andersen LLP that are or may be available to satisfy any claims.

#### WHERE YOU CAN GET MORE INFORMATION

### **Available Information**

We file reports, proxy statements and other information with the Securities and Exchange Commission. You may read and copy this information at the public reference facilities maintained by the Commission at the Commission's Public Reference Room, which is located at 450 Fifth Street, N.W., Judiciary Plaza, Washington, D.C. 20549.

You may obtain information on the operation of the Public Reference Room by calling the Commission at 1-800-SEC-0330. Our filings are also available on the Commission's web site on the Internet at http://www.sec.gov.

Statements in this prospectus concerning the contents of any contract, agreement or other document are not necessarily complete. If we filed as an exhibit to any of our public filings any of the contracts, agreements or other documents referred to in this prospectus, you should read the exhibit for a more complete understanding of the document or matter involved.

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# SpectRx, Inc. Index to consolidated financial statements

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Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders

SpectRx, Inc. & Subsidiaries

We have audited the accompanying 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 the standard of the Public Company Accounting Oversight Board (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 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 U.S. generally accepted accounting principles.

/s/ Eisner LLP

New York, New York February 20, 2004 With respect to Note 14: March 26, 2004

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#### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders of SpectRx, Inc.

We have audited the accompanying consolidated balance sheet of SpectRx, Inc. 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 consolidated financial statements of SpectRx, Inc. 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 standards of the Public Company Accounting Oversight Board (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. as of December 31, 2002, and the consolidated results of its operations and its cash flows for the year then ended in conformity with U.S. generally accepted accounting principles.

As discussed above, the consolidated financial statements of SpectRx, Inc. 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 consolidated 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, 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. 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 consolidated financial statements of SpectRx, Inc. 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 consolidated financial statements have been prepared assuming that SpectRx, Inc. 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

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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 REQUIRD TO BE PRESENTED IN THE ACCOMPANYING CONSOLIDATED FINANCIAL STATEMENTS AS OF AND FOR THE YEARS ENDED DECMEBER 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

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

ASSETS			LIABILITIES AND STOCKHOLDERS'		
	2002	2003	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	291	816	Redeemable Preferred Stock;	700	1,599
of allowance for doubtful			Current Position		
accounts of \$46 and \$11					
in 2002 and 2003,					
respectively	6.40	220			4.04=
Inventories	643	238	Notes Payable	0	1,017
Other current assets	776	1,250			
Total current	2,997	2,693	Total current liabilities	1,931	4,652
assets			COLLABORATIVE PARTNER ADVANCE	201	201
			REDEEMABLE PREFERRED STOCK,	381 4,324	381 3,264
			LESS CURRENT POSITION	1,321	3,201
			COMMITMENTS & CONTINGENCIES		
			STOCKHOLDERS' EQUITY (DEFICIT):		
			Preferred stock, \$.001 par value;	1,185	1,245
			5,000 shares authorized, 100 shares		
			issued and outstanding as preferred		
			stock in 2002 and 2003,		
			respectively		
			Common stock, \$.001 par value;	11	11
			50,000 shares authorized, 11,270		
			and 11,407 shares issued and		
			11,263 outstanding in 2002 and		
			11,366 in 2003, respectively		
			Additional paid-in capital	47,913	48,335
NONCURRENT ASSETS:			Treasury stock, at cost	(38)	(95)
Property and equipment,	546	494	Deferred compensation	(88)	(69)
net	2.052	2.525	N	(47)	0
Intangibles, net	3,852	3,527	Notes receivable from officers	(49, 100)	(51.010)
Due from related parties	77	0	Accumulated deficit	(48,100)	(51,010)
T-4-1	1 175	4.001	Total -414141 - 14		
Total noncurrent	4,475	4,021	Total stockholders' equity	026	(1.502)
assets			(DEFICIT)	836	(1,583)

\$7,472 \$6,714 \$7,472 \$6,714

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

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# 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
REVENUE:			
Product sales	\$2,358	\$2,698	\$1,586
Collaborative agreements	100	1,100	0
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
	0.602	11 005	0.055
	9,693	11,885	8,055
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
NET LOSS	(6,966)	(8,505)	(2,611)
PREFERRED STOCK DIVIDENDS	(315)	(315)	(299)
LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	\$(7,281)	\$(8,820)	\$(2,910)
	Ψ(,, <b>2</b> 31)	+(0,020)	+(=,>10)
BASIC AND DILUTED NET LOSS PER COMMON SHARE	\$(0.75)	\$(0.79)	\$(0.26)
BASIC AND DILUTED WEIGHTED AVERAGE SHARES OUTSTANDING	9,646	11,209	11,270

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

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# SPECTRX, INC. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT) FOR THE YEARS ENDED DECEMBER 31, 2001, 2002 AND 2003 (In Thousands)

	Preferred Stock		on Stock .  Amount	Additional ' Paid-In Capital	•	Deferred Compensation		AccumulatedS Deficit	Stockholders' (DEFICIT) Equity
			1 11110 6/110						
BALANCE, December 31, 2000	\$0	8,508	\$9	\$30,927	\$0	\$0	\$(31)	\$(31,999)	\$(1,094)
Issuance of common stock	0	2,668	2	16,598	0	0	0	0	16,600
Conversion to preferred stock	1,125	0	0	0	0	0	0	0	1,125
Exercise of stock options	0	6	0	8	0	0	0	0	8
Employee stock purchase plan	0	12	0	71	0	0	0	0	71
Treasury stock purchase	0	(7)	0	0	(38)	0	0	0	(38)
Issuance of stock options	0	0	0	0	0	(19)	0	0	(19)
Dividends on preferred stock	0	0	0	0	0	0	0	(315)	(315)
Net loss	0	0	0	0	0	0	0	(6,966)	(6,966)
BALANCE, December 31, 2001	1,125	11,187	11	47,604	(38)	(19)	(31)	(39,280)	9,372
Amortization of deferred comp	on 0	0	0	0	0	37	0	0	37

Issuance of common stock for services	0	46	0	118	0	0	0	0	118
Non-employee stock options	0	21	0	142	0	(106)	(16)	0	20
Employee stock purchase plan	0	16	0	67	0	0	0	0	67
Sterling acquisition adjustments	0	(7)	0	(18)	0	0	0	0	(18)
Dividends on preferred stock	60	0	0	0	0	0	0	(315)	(255)
Net loss	0	0	0	0	0	0	0	(8,505)	(8,505)
BALANCE, December 31, 2002	1,185	11,263	11	47,913	(38)	(88)	(47)	(48,100)	836
Dividends	60	Н	0	0	0	0	0	0	60
Amortization of deferred comp	0	Н	0	0	0	49	0	0	49
Employee stock purchase plan	0	J4	0	27	0	0	0	0	27
Non-employee stock options	0	Н	0	54	0	(30)	0	0	24
Issuance of common stock for services	0	I14	0	149	0	0	0	0	149
Warrants	0	Н	0	192	0	0	0	0	192
Note	0	(35)	0	0	(57)	0	47	0	(10)
receivable									
Dividends on preferred stock	0	Н	0	0	0	0	0	(299)	(299)
Net loss	0	Н	0	0	0	0	0	(2,611)	(2,611)
	\$1,245	11,366	\$11	\$48,335	\$(95)	\$(69)	\$0	(\$51,010)	\$(1,583)

BALANCE, December 31, 2003

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

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# 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>	2003
			<u>(1)</u>
CASH FLOWS FROM OPERATING ACTIVITIES:			-0.0 (1.1)
Net loss	\$(6,966)	\$(8,505	<b>5</b> (2,611)
Adjustments to reconcile net loss to net cash used in operating activities excluding the effects of acquisition:		0	(4.160)
Gain on sale of Bilichek product line	0	0	(4,169)
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	356
Changes in operating assets and liabilities:	20	020	(1.0)
Accounts receivable	30	938	(16)
Inventories	44	(206)	(270)
Other current assets	(11)	(368)	(454)
Accounts payable	(85)	(453)	268
Accrued liabilities	121	(528)	432
Total adjustments	575	601	(3,225)
Net cash used in operating activities	(6,391)	(7,904)	(5,836)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Net proceeds from sale of Bilicheck product line	0	0	4,449
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)	4,247
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

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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

(1) See note 2 "Reclassification"

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

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## 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 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

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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):

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

#### **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
	\$2,495	\$2,283
Less accumulated depreciation	1,949	1,789
Property and equipment, net	\$546	\$494

#### 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
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

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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)	

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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)
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#### 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 interpretative 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.

Reclassification

Certain amounts in the 2003 cash flow statement have been reclassified to reflect the Gain on sale of Bilichek product line as investing activities rather than operating activities.

## 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

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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.

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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 Bili*Chek* 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 Repironics of \$4.2 million during 2003. 3.1 million of such gain, including \$2 million of previously deferred gain, was recognized during the fourth quarter upon the achievement of the remaining milestones under the Sale Agreement. The sale of the Bili*Chek* 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. Bili*Chek* 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.

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#### 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.

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

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:

	Opt	ions Outstandi	ng	Options Exercisable		
Range of Exercise Prices	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	1,594,089	\$ 4.53	5.54	1,274,291	\$ 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:

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	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

#### Employee Stock Purchase Plan

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)

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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	Н
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.

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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.

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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*

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.

<sup>\*</sup> Indexed to the CPI

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.

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#### **Table of Contents**

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):

 2001
 2002
 2003

 United States and Canada
 \$1,043
 \$1,602
 \$1,341

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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

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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)

	March 31 2002	June 30 2002	September I 30 2002	Quarter En December 31 2002		June 30 2003	September I 30 2003	December 31 2003
			(in thousar	_	•			
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)		(\$0.18)	(\$0.02)	(\$0.19)	· · /	\$0.13
Diluted	(\$0.22)	(\$0.29)	(\$0.10)	(\$0.18)	(\$0.02)	(\$0.19)	(\$0.17)	\$0.12
Weighted Average Comm Outstanding	on shares							
Basic	11,202	11,197	11,210	11,249	11,249	11,237	11,248	11,336
Diluted	11,202	11,197	,	11,249	11,249	11,237		11,600
The Company recorded a (See Note 9.)	\$508,000 charge	to opera	tions in Dece	ember 200	2 for the e	xtinguis	hments of of	fficer loans.

## 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 of 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.

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# SPECTRX, INC. & SUBSIDIARIES CONSOLIDATED BALANCE SHEETS (IN THOUSANDS)

December 31, June 30,2004 2003 (Unaudited)

# **ASSETS**

CURRENT ASSETS			
Cash and cash equivalents	\$389	\$2,877	
Accounts receivable	816	161	
Inventories	238	306	
Other current assets	<u>1,250</u>	<u>626</u>	
Total Current Assets	<u>2,693</u>	<u>3,970</u>	

#### **NONCURRENT ASSETS**

Property & equipment, net

494

583

Intangibles, net

3,527

3,369

**Total Noncurrent Assets** 

<u>4,021</u>

<u>3,952</u>

**TOTAL ASSETS** 

\$6,714

\$7,922

# LIABILITIES & STOCKHOLDERS' EQUITY (CAPITAL DEFICIT)

# **CURRENT LIABILITIES**

Accounts payable

\$833

	\$653
Accrued liabilities	
	1,203
	540
Redeemable preferred stock; current portion	
	1,599
	1,331
Notes payable	
	<u>1,017</u>
	0
Total Current Liabilities	
	4,652
	2,524
COLLABORATIVE PARTNER ADVANCE	
	<u>381</u>
	<u>381</u>
REDEEMABLE PREFERRED STOCK, LESS CURRENT PORTION	
	3,264
	3,343
STOCKHOLDERS' EQUITY (CAPITAL DEFICIT)	
Series A convertible preferred stock (liquidation preference \$7,330)	
	0
	4,559
Preferred stock	
	1,245
	1,275
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### Common stock

11 11 Additional paid-in-capital 48,335 51,364 Treasury stock, at cost (95) (104)Deferred compensation (69)(38)Accumulated deficit (51,010) (55,393)Total Stockholders' (Capital Deficit) Equity (1,583)1,674 TOTAL LIABILITIES & EQUITY (CAPITAL DEFICIT) \$6,714 \$7,922 The accompanying notes are an integral part of the financial statements. F-24

# SPECTRX, INC. & SUBSIDIARIES UNAUDITED CONSOLIDATED STATEMENTS OF OPERATIONS (IN THOUSANDS, EXCEPT PER SHARE DATA)

		Three Months Ended June 30,			ix Months Ended June 30,	
		2003	2004	2003	2004	
Net sales		\$126	\$272	\$927	\$397	
Cost of sales		<u>180</u>	<u>241</u>	<u>492</u>	<u>527</u>	
	Gross (loss) profit	(54)	31	435	(130)	
EXPENSES						
	Research & development	1,236	978	2,219	1,917	
	Sales & marketing	170	193	369	356	
	General & administrative	<u>566</u>	<u>595</u>	<u>1,077</u>	<u>920</u>	
	Total	<u>1,972</u>	<u>1,766</u>	<u>3,665</u>	<u>3,193</u>	
	Operating loss	(2,026)	(1,735)	(3,230)	(3,323)	
(LOSS) GAIN ON SALE OF BILICHEK TM PRODUCT LINE		(10)	0	1,062	0	
"PRODUCT I	LINE					
INTEREST EX	PENSE	<u>(42)</u>	(16)	<u>(69)</u>	(919)	
NET LOSS		(2,078)	(1,751)	(2,237)	(4,242)	
Preferred stock	dividends	(74)	(68)	(153)	(141)	
Deemed dividen	nd on series A preferred	<u>0</u>	<u>0</u>	<u>0</u>	(4,970)	
Loss attributable	e to common stockholders	(\$2,152)	(\$1,819)	(\$2,390)	(\$9,353)	
Basic & diluted	net loss per share	<u>(\$0.19)</u>	<u>(\$0.16)</u>	(\$0.21)	<u>(\$0.82)</u>	
Basic &diluted weighted average shares outstanding		11,237	11,386	11,243	11,379	

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

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# SPECTRX, INC. & SUBSIDIARIES UNAUDITED CONSOLIDATED STATEMENTS OF CASH FLOWS (IN THOUSANDS)

Six Months Ended June 30,

CACHELOWCEDOM ODED ATING ACTIVITIES.	2003	2004
CASH FLOWS FROM OPERATING ACTIVITIES: Net loss	\$(2,237)	\$(4,242)
Adjustments to reconcile net loss to net cash used in	$\Psi(2,237)$	<u>Ψ(¬,2¬2)</u>
operating activities:		
Depreciation & amortization	246	224
Amortization of deferred compensation	44	31
Gain on sale of Bili <i>Chek</i> product line	(1,062)	0
Issuance of common stock, options and warrants		
for services and debt	0	865
Changes in assets and liabilities:		
Accounts receivable	118	655
Inventory	(188)	(68)
Other current assets	(561)	624
Accounts payable	(100)	(180)
Accrued liabilities	(200)	<u>(651)</u>
Total adjustments	(1,703)	<u>1,500</u>
Net cash used in operating activities	(3,940)	(2,742)
CASH FLOW FROM INVESTING ACTIVITIES:		
Additions to property & equipment	(96)	(155)
Cash proceeds from sale of Bili <i>Chek</i> product line	<u>4,000</u>	0
Net cash provided by (used in)	<u>3,904</u>	(155)
investing activities		
CASH FLOW FROM FINANCING ACTIVITIES:  Proceeds from issuance of Series A convertible preferred stock & warrants	0	5684
Issuance of common stock	18	18
Issuance (payments) of director's notes	31	(17)
Payment on redeemable preferred stock, current portion	<u>(400)</u>	(300)
Net cash (used in) provided by financing activities	<u>(351)</u>	5,385
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(387)	<u>2,488</u>
CASH AND CASH EQUIVALENTS, beginning of period	<u>1,287</u>	<u>389</u>
CASH AND CASH EQUIVALENTS, end of period	<u>\$900</u>	\$2,877

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

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# SPECTRX, INC. & SUBSIDIARIES NOTES TO FINANCIAL STATEMENTS (UNAUDITED)

#### 1. BASIS OF PRESENTATION

The unaudited interim financial statements included herein have been prepared by SpectRx, Inc. These statements reflect all adjustments, all of which are of a normal, recurring nature, and which are, in the opinion of management, necessary to present fairly our financial position as of June 30, 2004, results of operations for the three and six months ended June 30, 2003 and 2004. The results of operations for the three and six months ended June 30, 2003 and 2004 are not necessarily indicative of the results for a full fiscal year. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States have been condensed or omitted. Preparing financial statements requires our management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses. Actual results could differ from those estimates. Our accounting policies continue unchanged from December 31, 2003. These financial statements should be read in conjunction with the financial statements and notes thereto included in our annual report on Form 10-K for the year ended December 31, 2003.

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 June 30, 2004, we have an accumulated deficit of \$55.4 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 operating losses to continue through at least 2004 as we continue to expend substantial resources 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.

In addition, a portion of our revenues and profits are expected to be derived from (a) royalties that we will receive from Respironics, Inc. resulting from sales of the Bili*Chek* infant jaundice products and (b) from the insulin delivery products developed by our subsidiary, Sterling Medivations, Inc. ("Sterling"). The royalties that we expect to receive from Respironics and profits from Sterling products depend on sales of these products. We intend to market our insulin delivery products directly to distributors and other customers. Respironics may not be able to sell sufficient volumes of the infant jaundice products to generate substantial royalties for us.

Our financial statements have been prepared and presented on a basis assuming we will continue as a going concern. Management is evaluating various operating alternatives and believes funds might be available from sales and royalty revenue sufficient to support planned operations through June 30, 2005. However, there can be no assurance that we will be able to achieve planned sales volumes or sales volumes sufficient to fund operations through 2005. These conditions raise doubt about our ability to continue as a going concern through at least June 30, 2005. These 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.

# 2. SIGNIFICANT ACCOUNTING POLICIES

Our significant accounting policies are included in the audited financial statements and notes thereto for the year ended December 31, 2003 included in our annual report on Form 10-K filed with the Securities and Exchange Commission.

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In October 2001, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." SFAS No. 144 supercedes SFAS No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of," although it retains the fundamental provisions of SFAS No. 121 related to the recognition and measurement of the impairment of long-lived assets to be "held and used." We adopted SFAS No. 144 on January 1, 2002. The March 6, 2003 sale of the Bili*Chek* assets has been accounted for in accordance with SFAS No. 144 (see Note 9).

We use the intrinsic value method for valuing our awards of stock options and restricted stock 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. FASB Statement No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure," amends the disclosure provisions of FASB Statement No. 123, "Accounting for Stock-Based Compensation," and APB Opinion No. 28, "Interim Financial Reporting," to require disclosure in the summary of significant accounting policies of the effects of an entity's policy with respect to stock-based employee compensation on reported net income and earnings per share in annual and interim financial statements. For purposes of pro forma disclosures, the estimated fair value of the options is amortized to expense over the options' vesting period. Our pro forma information follows (in thousands, except per share data):

	Three Months E	nded June 30,	Six Months En	ded June 30,
	2003	2004	2003	2004
Net loss attributable to common stockholders, as reported	(\$2,152)	(\$1,819)	(\$2,390)	(\$9,353)
Add: Stock-based employee compensation expense included in reported net loss, net of related tax effects	0	0	0	0
Deduct: Total stock-based employee compen- sation expense determined under fair value based method of all awards, net of related tax effects				
	(173)	(81)	(332)	(161)
Pro forma net loss	(\$2,325)	(\$1,900)	(\$2,722)	(\$9,514
Loss per share:				
Basic & diluted, as reported	(\$0.19)	(\$0.16)	(\$0.21)	(\$0.82)
Basic & diluted, pro forma	(\$0.21)	(\$0.17)	(\$0.24)	(\$0.84)

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

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. We believe the impact of FIN No. 46R on our financial position and results of operations will not be material, but we will continue to evaluate the impact of FIN No. 46R.

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 our financial position and results of operations.

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In December 2003, the Securities and Exchange Commission ("SEC"), published Staff Accounting Bulletin ("SAB") No. 104, "Revenue Recognition." This SAB updates portions of the SEC staff's interpretive guidance provided in SAB No. 101 and included in Topic 13 of the Codification of Staff Accounting Bulletins. SAB No. 104 deletes interpretative 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 No. 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 our financial position and results of operations since our revenue recognition practices previously conformed to the interpretations codified by SAB No. 104.

#### 3. STERLING MEDIVATIONS

On December 31, 2001, we purchased the outstanding shares of Sterling, now doing business as SimpleChoice. Sterling was a developer of innovative insulin delivery products for people with diabetes. The acquisition of Sterling expanded our diabetes business by adding a portfolio of insulin delivery products, cleared by the Food and Drug Administration, including consumables for the rapidly growing insulin pump market. As a result of the merger, we issued a total of 612,562 shares of our 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. Sterling stockholders and option holders will be entitled to receive up to an aggregate of 1,234,567 additional shares of our common stock in the future if the SimpleChoice product line achieves specified financial goals. In connection with the acquisition of Sterling, we entered into employment agreements with four employees for terms which expired in June 2003. The excess of the cost over the estimated fair value of net tangible assets acquired amounts to approximately \$4.1 million and has been included in intangible assets in the accompanying consolidated balance sheets. The \$4.1 million purchase price excess has been allocated between patents and non-compete agreements. Accumulated amortization of our intangible assets as of June 30, 2004 is approximately \$820,000. The acquisition has been accounted for as a purchase in accordance with SFAS No. 141, "Accounting for Business Combinations."

### 4. LITIGATION

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 Laboratories, Inc. 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 and \$300,000 to Abbott pursuant to the settlement during 2003 and in the first quarter of 2004, respectively. Under the settlement, neither party admitted any liability or wrongdoing.

We have been in negotiations with Abbott since early 2003 regarding the patent issue and the payments and terms under the settlement. On July 15, 2004 Abbott sent us a letter notifying us that we were in default on two separate payments due in 2004 and demanding payment. On July 22, 2004 we responded that we were seeking to resolve the patent issues and renegotiate the payment terms. Under our settlement agreement, we are accruing interest on the payments of 1% per month.

We are also involved in certain litigation arising in the ordinary course of business. In management's opinion, the ultimate resolution of these matters will not have a material adverse effect on our results of operations or financial position. See Part II, Item 1, "Legal Proceedings," for a discussion of significant litigation matters.

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#### 5. STOCKHOLDERS' EQUITY

#### Common Stock

During the year ended December 31, 2003, we issued 10,417 unregistered shares of common stock valued at \$16,000 in satisfaction of minimum royalty payments related to our 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 us 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, we recognized approximately \$19,000 in compensation expense associated with the issuance of this note. The note was paid in full on December 19, 2003.

#### 6. PREFERRED STOCK

#### Redeemable Convertible Preferred Stock

In January 1997, we 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 additional shares of the preferred stock at a rate of 6% per annum. During the years ended December 31, 2001, 2002 and 2003, we accrued dividends in the form of shares of redeemable convertible preferred stock of \$315,000, \$315,000 and \$299,000, respectively. The shares of preferred stock, together with any accrued but unpaid dividends, are convertible into shares of common stock 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 we give notice to the holder of its right to redeem the shares. The shares have a liquidation preference of \$10 per share, plus all accrued but unpaid dividends.

In November 1999, Abbott Laboratories, Inc. ("Abbott"), a former collaborative partner, 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, we 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, we 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 us redeem the shares of preferred stock. Abbott had previously elected to have 425,000 shares of 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, we agreed to make quarterly cash payments to Abbott during 2003 and 2004 and end of the year lump sum payments in 2005 and 2006 to redeem 425,000 shares of preferred stock and to pay accrued dividends as to such shares. We have paid \$700,000 to Abbott through June 30,

2004. Our remaining yearly financial obligations to Abbott under the agreement are approximately \$1.3 million, \$1.8 million and \$1.9 million during 2004, 2005 and 2006, respectively. Under the settlement, neither party admitted any liability or wrongdoing.

We have been in negotiations with Abbott since early 2003 regarding the patent issue described in Note 4 and the payments and terms under the settlement. On July 15, 2004 Abbott sent us a letter notifying us that we were in default on two separate payments due in 2004 and demanding payment. On July 22, 2004 we responded that we were seeking to resolve the patent issues and renegotiate the payment terms.

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

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Series A Convertible Preferred Stock

We currently have outstanding 488,669 shares of series A convertible preferred stock, having a stated value of \$15.00 per share, held by 28 holders as of June 30, 2004. The holders of the series A convertible preferred stock are entitled to receive quarterly, at the end of each calendar quarter, commencing on and after March 26, 2006, out of funds legally available therefor, dividends per share at the per annum rate of \$0.75 per share.

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

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

Issuing the series A convertible preferred stock triggered the recognition of the value of the beneficial conversion feature of the series A convertible preferred stock, which is deemed to be a dividend if the conversion price of the preferred is below market at the time of the transaction. We recognized a non-cash deemed dividend in the first quarter of 2004 of approximately \$5.0 million. The accounting treatment required us to recognize the difference between issuance price and market price at issuance for the convertible instrument as a deemed dividend and increase stockholders' equity in the same amount, so there was no net effect on stockholders' capital deficiency.

In connection with the series A convertible preferred stock issuance, noteholders converted \$1.0 million of notes payable into series A convertible preferred stock.

#### 7. WARRANTS

We have issued warrants to purchase our common stock from time to time in connection with certain financing arrangements. As of June 30, 2004, there were outstanding warrants to purchase an aggregate of 6,501,026 shares of common stock at a weighted average exercise price of \$2.39 per share. All of our warrants are currently exercisable. Of our warrants, warrants exercisable for 4,886,690 shares of our common stock were issued to the purchasers of our series A convertible preferred stock, with the per share exercise price being \$1.65 for one half of those warrants and \$2.25 for the other half. Subject to certain exceptions, if we issue shares of common stock, or securities convertible or exercisable for common shares, for a consideration per share of less than the then conversion price for the series A convertible preferred stock, then the per share exercise price for the warrants with the \$1.65 exercise price will be adjusted to equal such lower per share consideration, and the exercise price for the warrants with the \$2.25 exercise price will be adjusted to equal 125% of such lower per share consideration. All outstanding warrant agreements provide for anti-dilution adjustments in the event of certain mergers, consolidations, reorganizations, recapitalizations, stock dividends, stock splits or other changes in our corporate structure. Holders of some of our warrants are entitled to certain rights to cause us to register such shares under the Securities Act of 1933.

#### 8. DEBT

On July 30, 2003, for the purposes of obtaining short-term financing until permanent financing could be secured, we entered into separate promissory note agreements with a group of individuals that aggregated \$1.0 million. The notes bore interest at 12% per annum and matured on January 31, 2004. In accordance with the terms of the promissory note agreements, we issued warrants, exercisable at \$2.25 per share at any time after January 30, 2004 until July 30, 2007, to the group of individuals for each month the notes were outstanding. As of June 30, 2004, 260,000 warrants have been issued. On February 6, 2004, we entered into separate promissory note agreements with a group of individuals that aggregated \$1.0 million, which liquidated the aforementioned notes. These notes bore interest at 15% per annum and had a scheduled maturity of June 26, 2004.

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In accordance with the terms of the promissory note agreements, the Company issued warrants for 500,000 shares exercisable at \$2.00 per share at any time after February 6, 2004 until February 5, 2009, to the group of individuals. On March 26, 2004, these notes were surrendered in connection with the series A convertible preferred stock financing. During the first quarter of 2004, we recorded approximately \$871,000 as interest expense for the estimated fair value of the warrants to purchase 635,000 common shares issued during the quarter, as determined under the Black-Sholes option-pricing model.

#### 9. SALE OF BILICHEK PRODUCT LINE

On March 6, 2003, we sold our Bili*Chek* Non-invasive Bilirubin Analyzer product line and related assets to Respironics. Respironics had previously been our 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 certain 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 by Respironics. The purpose of the sale of the Bili*Chek* products was to enable us to focus on expanding our diabetes and cancer detection businesses.

In November 2003 upon completion of all remaining milestones, we received the \$1.0 million due for completion of the product development work. In February 2004, we received payments for earnout (\$509,000) and royalties (\$146,000) on sales of disposables by Respironics pursuant to the asset sale agreement. Both the earnout and the royalties were accrued as of December 31, 2003 and recognized the remaining portion of the deferred revenue at that time, \$2.0 million as gain on sale of Bili*Chek*.

#### 10. GUARANTEES

In November 2002, the FASB issued FIN 45. FIN 45 elaborates on the existing disclosure requirements for most guarantees, including loan guarantees such as standby letters of credit. It also clarifies that at the time a company issues a guarantee, the company must recognize an initial liability for the fair value, or market value, of the obligations it assumes under the guarantee and must disclose that information in its interim and annual financial statements. The provisions related to recognizing a liability at inception of the guarantee for the fair value of the guarantor's obligations do not apply to product warranties or to guarantees accounted for as derivatives. The initial recognition and initial measurement provisions apply on a prospective basis to guarantees issued or modified after December 31, 2003. The adoption of FIN 45 did not have a material impact on our results of operations or financial condition and did not result in any additional liabilities as of June 30, 2004 associated with guarantees covered by this interpretation.

#### Warranty

We provide for the estimated cost of product warranties at the time revenue is recognized. The estimated warranty obligation is affected by new unit sales and units sold less than 18 months prior to the dates of the financial statements. If actual product repair costs differ from estimates, revisions to the estimated warranty liability would be required. We evaluate our warranty obligations on a product line basis.

Information regarding the changes in our aggregate product warranty liabilities is as follows for the six month period ended June 30, 2004 (in thousands):

Balance, December 31, 2003	\$28
Accruals for warranties issued during the period	0
Settlements made (in cash or in kind) during the period	<u>0</u>

<u>\$28</u>

Balance, June 30, 2004

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#### 11. LOSS PER COMMON SHARE

Loss per common share is computed using SFAS No. 128, "Earnings per Share." SFAS No. 128 established standards for the computation, presentation and disclosure of earnings per share. Basic loss per share amounts are computed by dividing the net loss by the weighted average number of common shares outstanding during the periods. Dilutive earnings per share calculations include the potential exercise of outstanding stock options, warrants and convertible securities. The effects of stock options, warrants and convertible securities have not been included in our 2004 and 2003 loss per share computations as their effect would have been anti-dilutive. Potential common shares totaling 13,097,736, which consist of the common stock underlying all outstanding stock options, preferred stock and warrants, are considered to be anti-dilutive for the three months and six months ended June 30, 2004.

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#### **PART II**

# INFORMATION NOT REQUIRED IN PROSPECTUS

# ITEM 13. Other Expenses of Issuance and Distribution

The following table sets forth the various expenses and costs incurred or to be incurred by SpectRx, Inc. in connection with the registration, sale and distribution of the shares of common stock that may be offered hereby, other than selling commissions which will be borne by the selling stockholders. All the amounts shown are estimated except the Securities and Exchange Commission registration fee.

Securities and Exchange Commission filing fee	\$ 2,811
Legal fees and expenses	\$60,000
Accounting fees and expenses	\$15,000
Blue Sky and related expenses	\$20,000
Miscellaneous	<u>\$ 1,000</u>
Total	\$98,811

ITEM 14. Indemnification of Directors and Officers

Section 145 of the Delaware General Corporation Law permits a corporation to include in its charter documents, and in agreements between the corporation and its directors and officers, provisions expanding the scope of indemnification beyond that specifically provided by the current law. Article VII of our Certificate of Incorporation provides for the indemnification of directors to the fullest extent permissible under Delaware law. Article VII of our Bylaws provides for the indemnification of officers, directors and third parties acting on behalf of the corporation if such person acted in good faith and in a manner reasonably believed to be in and not opposed to the best interest of the corporation, and, with respect to any criminal action or proceeding, the indemnified party had no reason to believe his conduct was unlawful. We have entered into indemnification agreements with our directors and executive officers, in addition to indemnification provided for in the our Bylaws, and intend to enter into indemnification agreements with any new directors and executive officers in the future.

#### ITEM 15. Recent Sales of Unregistered Securities

On October 3, 2001, Abbott invested an additional \$1 million in our common stock, acquiring 126,199 shares at \$7.92 per share. The purchase was associated with a milestone payment under a program to commercialize our continuous glucose monitoring technology for people with diabetes. These securities were issued in reliance on the exemption from registration provided by Section 4(2) of the Securities Act of 1933 (the "Securities Act").

On December 31, 2001, we acquired Sterling Medivations, which survived the merger as our wholly owned subsidiary. The merger was effected pursuant to an Agreement and Plan of Merger, dated December 31, 2001. In connection with this transaction, we issued an initial 612,562 shares of our common stock, which was determined based upon an agreed upon price of \$7.29 per share for purposes of the merger, to former holders of Sterling Medivations' capital stock. In addition, we reserved 22,625 shares of our common stock for future issuance to holders of options to acquire shares of Sterling Medivations common stock, which were converted into options to acquire shares of our common stock in the transaction. Up to an additional 1,234,567 shares of common stock could be issued to former stockholders and reserved for option holders of Sterling Medivations, if the product line of Sterling Medivations meets specified financial goals. These securities were issued in reliance on the exemption from registration provided by Rule 506 of Regulation D under the Securities Act.

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During the year ended December 2002, we issued 46,101 shares of common stock valued at \$118,125 in satisfaction of minimum royalty payments related to our exclusive rights to certain licensed patents. In issuing these shares we relied upon the exemption from registration under section 4(2) of the Securities Act.

We issued 10,417 shares of common stock on July 8, 2003 valued at \$16,000 in satisfaction of minimum royalty payments related to our exclusive rights to certain licensed patents, 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, Inc. valued at \$80,000 for advisory services in connection with the private placement of securities. In issuing these shares we relied upon the exemption from registration under section 4(2) of the Securities Act.

We 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.

On March 26, 2004, we sold to institutional and private investors 488,669 shares of our series A convertible preferred stock, which is convertible into 4,886,690 shares of our common stock, and warrants to purchase 4,886,690 shares of our common stock, one-half of which have an exercise price of \$1.65 and the other half of which have an exercise price of \$2.25 per share, for an aggregate of \$7.3 million in gross proceeds, including the conversion of debt. The number of shares issuable upon conversion of the series A convertible preferred stock and these warrants is subject to adjustment. In addition, we issued warrants for 407,336 shares of our common stock with an exercise price of \$1.50 per share, as compensation for placement services to Bristol Investment Group, Inc., Stonegate Securities and Musket Research Associates, Inc. In conjunction with a debt financing, we also issued warrants to purchase 500,000 and 125,000 shares of our common stock at exercise prices of \$2.00 and \$2.25, respectively, to a group of lenders, including two of our officers during the quarter ended March 31, 2004 and expensed \$871,000 as interest expense relating to these warrants. All of these securities were issued in reliance on the exemption from registration under Section 4(2) of the Securities Act.

#### ITEM 16. Exhibits and Financial Statement Schedules

#### (a) Exhibits

Exhibit Number	Description of Exhibit
3.1A	Certificate of Incorporation, as amended (incorporated by reference to Exhibit 3.1 filed with the registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1997, filed August 12, 1997).
3.1B	Certificate of Designations for Redeemable Convertible Preferred Stock (incorporated by reference to Exhibit 3.1B filed with the registrant's Annual Report on Form 10-K for the year ended December 31, 2000, filed April 2, 2001).
3.1C	Certificate of Designations for Series A Convertible Preferred Stock (incorporated by reference to Exhibit 99.4 filed with the registrant's Current Report on Form 8-K, dated and filed March 29, 2004.

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Exhibit Number	Description of Exhibit
3.2	Amended Bylaws (incorporated by reference to Exhibit 3.2A filed with the registrant's Annual Report on Form 10-K for the year ended December 31, 2003, filed March 30, 2004.
4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 filed with the registrant's S-1 Registration Statement (No. 333-22429) filed February 27, 1997, as amended.
4.2A	Form of Warrant (incorporated by reference to Exhibit 99.5 filed with the registrant's Current Report on Form 8-K, dated and filed March 29, 2004).
4.2B	Form of Warrant (incorporated by reference to Exhibit 99.6 filed with the registrant's Current Report on Form 8-K, dated and filed March 29, 2004).
4.2C	Form of Common Stock Warrant (incorporated by reference to Exhibit 4.5 filed with the registrant's quarterly report on Form 10-Q for the quarter for the quarter ended June 30, 2001, filed August 14, 2001).
4.3	Registration Rights Agreement, dated March 26, 2004, by and among SpectRx and the Purchasers listed therein (incorporated by reference to Exhibit 99.3 filed with the registrant's Current Report on Form 8-K, dated and filed March 29, 2004).
***	Opinion of Jones Day regarding validity.
10.1	1997 Employee Stock Purchase Plan and form of agreement thereunder (incorporated by reference to Exhibit 10.1 filed with the registrant's S-1 Registration Statement (No. 333-22429) filed February 27, 1997, as amended).
10.2	1995 Stock Plan, as amended, and form of Stock Option Agreement thereunder (incorporated by reference to Exhibit 10.2 to the registrant's S-1 Registration Statement (No. 333-22429) filed February 27, 1997, as amended).
10.3	Assignment and Bill of Sale, dated February 29, 1996, between Laser Atlanta Optics, Inc. and SpectRx (incorporated by reference to Exhibit 10.9 filed with the registrant's S-1 Registration Statement (No. 333-22429) filed February 27, 1997, as amended).
10.4	Security Agreement, dated October 31, 1996, between Mark A. Samuels and SpectRx (incorporated by reference to Exhibit 10.10 filed with the registrant's S-1 Registration Statement (No. 333-22429) filed February 27, 1997, as

amended).

10	).5	Security Agreement, dated October 31, 1996, between Keith D. Ignotz and SpectRx (incorporated by reference to Exhibit 10.11 filed with the registrant's S-1 Registration Statement (No. 333-22429) filed February 27, 1997, as amended).
10	0.6A**	License Agreement, dated May 7, 1991, between Georgia Tech Research Corporation and Laser Atlanta Optics, Inc. (incorporated by reference to Exhibit 10.12A filed with the registrant's S-1 Registration Statement (No. 333-22429) filed February 27, 1997, as amended).
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Exhibit Number	Description of Exhibit
10.6B	Agreement for Purchase and Sale of Technology, Sale, dated January 16, 1993, between Laser Atlanta Optics, Inc. and SpectRx (incorporated by reference to Exhibit 10.12B filed with the registrant's Annual Report on Form 10-K for the year ended December 31, 2003, filed March 30, 2004).
10.6C	First Amendment to License Agreement, dated October 19, 1993, between Georgia Tech Research Corporation and SpectRx (incorporated by reference to Exhibit 10.12C filed with the registrant's S-1 Registration Statement (No. 333-22429) filed February 27, 1997, as amended).
10.7	Clinical Research Study Agreement, dated July 22, 1993, between Emory University and SpectRx (incorporated by reference to Exhibit 10.13 filed with the registrant's S-1 Registration Statement (No. 333-22429) filed February 27, 1997, as amended).
10.8A**	Development and License Agreement, dated December 2, 1994, between Boehringer Mannheim Corporation and SpectRx (incorporated by reference to Exhibit 10.14A filed with the registrant's S-1 Registration Statement (No. 333-22429) filed February 27, 1997, as amended).
10.8B**	Supply Agreement, dated January 5, 1996, between Boehringer Mannheim and SpectRx (incorporated by reference to Exhibit 10.14B filed with the registrant's S-1 Registration Statement (No. 333-22429) filed February 27, 1997, as amended).
10.9	Sole Commercial Patent License Agreement, dated May 4, 1995, between Martin Marietta Energy Systems, Inc. and SpectRx (incorporated by reference to Exhibit 10.16 filed with the registrant's S-1 Registration Statement (No. 333-22429) filed February 27, 1997, as amended).
10.10A	License and Joint Development Agreement, dated March 1, 1996, between NonInvasive-Monitoring Company, Inc., Altea Technologies, Inc. and SpectRx (incorporated by reference to Exhibit 10.19 filed with the registrant's S-1 Registration Statement (No. 333-22429) filed February 27, 1997, as amended).
10.10B**	Amendment to License and Joint Development Agreement, dated December 30, 2001, between NonInvasive-Monitoring Company, Inc., Altea Technologies, Inc. and SpectRx (incorporated by reference to Exhibit 10.17B filed with the registrant's Annual Report on Form 10-K for the year ended December 31, 2001, filed April 1, 2002).
10.11A**	Purchasing and Licensing Agreement, dated June 19, 1996, between Respironics and SpectRx (incorporated by reference to Exhibit 10.21 filed with the registrant's S-1 Registration Statement (No. 333-22429) filed

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	February 27, 1997, as amended).
10.11B	Amendment to Purchasing and Licensing Agreement, dated October 21, 1998 between Respironics and SpectRx (incorporated by reference to Exhibit 10.19B filed with the registrant's Annual Report on Form 10-K for the year ended December 31, 1998, filed March 31, 1999, as amended).
10.12	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 (incorporated by reference to Exhibit 10.22 filed with the registrant's S-1 Registration Statement (No. 333-22429) filed February 27, 1997, as amended).
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Exhibit Number	Description of Exhibit	
10.13A**	Research and Development and License Agreement, dated October 10, 1996, between Abbott Laboratories and SpectRx (incorporated by reference to Exhibit 10.23 filed with the registrant's S-1 Registration Statement (No. 333-22429) filed February 27, 1997, as amended).	
10.13B**	Letter Agreement, dated December 22, 1997, between Abbott Laboratories and SpectRx (incorporated by reference to Exhibit 10.21B filed with the registrant's Annual Report on Form 10-K for the year ended December 31, 1997, filed March 27, 1998).	
10.13C**	Third Amendment to Research and Development and License Agreement, dated November 30, 1999 between Abbott Laboratories and SpectRx (incorporated by reference to Exhibit 10.21C filed with the registrant's Annual Report on Form 10-K for the year ended December 31, 1999, filed March 30, 2000, as amended).	
10.13D**	Fourth Amendment to Research and Development and License Agreement, dated September 4, 2001 between Abbott Laboratories and SpectRx (incorporated by reference to Exhibit 10.3 filed with the registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2001, filed November 14, 2001).	
10.14	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 (incorporated by reference to Exhibit 10.24 filed with the registrant's S-1 Registration Statement (No. 333-22429) filed February 27, 1997, as amended).	
10.15A**	Development and License Agreement, dated July 13, 1999, between Roche Diagnostics Corporation and SpectRx (incorporated by reference to Exhibit 10.25A filed with the registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1999, filed August 16, 1999, as amended.	
10.15B**	Supply Agreement, dated July 13, 1999, between Roche Diagnostics Corporation and SpectRx (incorporated by reference to Exhibit 10.25B filed with the registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1999, filed August 16, 1999, as amended).	
10.16	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. (incorporated by reference to Exhibit 2.1 filed with the registrant's Current Report on Form 8-K, as amended, dated and filed January 14, 2002.	

10.17	Agreement for Termination of Development and Commercialization Agreement, dated November 19, 2002, between SpectRx and Welch Allyn, Inc. (incorporated by reference to Exhibit 99.1 filed with the registrant's Current Report on Form 8-K, dated and filed December 20, 2002).
10.18	Asset Purchase Agreement, dated March 6, 2003, between SpectRx and Respironics (incorporated by reference to Exhibit 10.1 filed with the registrant's Current Report on Form 8-K, dated and filed March 21, 2003).

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Exhibit Number	Description of Exhibit	
10.19	Securities Purchase Agreement, dated as of March 26, 2004, by and among SpectRx and the Purchasers listed on Schedule I (incorporated by reference to Exhibit 99.2 filed with the registrant's Current Report on Form 8-K, dated and filed March 29, 2004).	
10.20	Lease Agreement, dated July 16, 2004, by and between Germania Property Investors XXX, L.P. and SpectRx (incorporated by reference to exhibit 10.1 filed with the registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, as amended, dated and filed with the Commission on August 16, 2004).	
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, dated and filed June 4, 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, dated and filed October 24, 2003).	
*21	Subsidiaries of the registrant.	
*23.1	Consent of Eisner LLP.	
*23.2	Consent of Ernst & Young LLP.	
23.3	Consent of Jones Day (included in Exhibit 5).	
***	Powers of Attorney (included on signature page).	
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Previously filed.

# (b) Financial Statement Schedules

Schedules are not included in this registration statement, as they are not required or the information required to be set forth therein is included in the Consolidated Financial Statements or Notes thereto.

<sup>\*</sup> Filed herewith.

<sup>\*\*</sup> Confidential treatment granted for portions of these agreements.

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#### ITEM 17. Undertakings

- (b) The undersigned registrant hereby undertakes:
  - 1. To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
    - i. To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;
    - ii. To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and
    - iii. To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.
  - 2. That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
  - <sup>3.</sup> To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
- (c) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

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#### **SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this amendment to its registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Atlanta, in the State of Georgia, on August 30, 2004.

SPECTRX, INC.

By: /s/ THOMAS H. MULLER, JR.

Thomas H. Muller, Jr. Executive Vice President, Chief Financial Officer and Secretary

Pursuant to the requirements of the Securities Act of 1933, this amendment to the registration statement has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicted.

DATE	SIGNATURE	TITLE
	* Mark A. Samuels	Chairman, Chief Executive Officer and Director (Principal Executive Officer
	/s/ Thomas H. Muller, Jr.  Thomas H. Muller, Jr.	Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)
	* Charles G. Hadley	Director
	* Keith D. Ignotz	Director
	* Earl R. Lewis	Director

	*	Director
	William E. Zachary	
	*	Director
	Chris Monahan	
August 30, 2004	/s/ Thomas H. Muller, Jr.	
	Thomas H. Muller, Jr. Attorney-In-Fact	
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# **EXHIBIT INDEX**

Description of Exhibits
Subsidiaries of the registrant.
Consent of Eisner LLP.
Consent of Ernst & Young LLP.

<sup>\*</sup> Filed herewith.

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