SPECTRX INC Form 10-K/A July 08, 2004

## UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## **FORM 10-K/A**

(Mark One)
[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.
For the fiscal year ended December 31, 2003.
or
[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR $15(d)$ OF THE SECURITIES EXCHANGE ACT OF 1934.
For the transition period from to
SPECTRX, INC.
(Exact Name of Registrant as Specified in Its Charter)
Delaware
(State or Other Jurisdiction of Incorporation)
0-22179
(Commission File Number)
58-2029543

(I.R.S. Employer Identification No.)

6025A Unity Drive Norcross, Georgia

(Address of Principal Executive Offices)

2	Λ	Λ	7	1
J	v	v	1	1

(Zip Code)

Registrants' Telephone Number, Including Area Code: Securities registered pursuant to Section 12(b) of the Act: Securities registered pursuant to Section 12(g) of the Act: (Title of class) (770) 242-8723 None Common Stock, \$0.001 par value

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

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

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

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

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

Items 7, 8 & 15 of the registrant's form 10-K for the year ended December 31, 2003 are hereby amended and restated in their entirety.

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

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

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

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

#### **OVERVIEW**

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

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

We have a limited operating history upon which our prospects can be evaluated. Our prospects must be considered in light of the substantial risks, expenses and difficulties encountered by entrants into the medical device industry. This industry is characterized by an increasing number of participants, intense competition and a high failure rate. We have experienced operating losses since our inception, and, as of December 31, 2003, we have an accumulated deficit of about \$51.0 million. To date, we have engaged primarily in research and development efforts. We first generated revenues from product sales in 1998, but do not have significant experience in manufacturing, marketing or selling our products. Our development efforts may not result in commercially viable products, and we may not be successful in introducing our products. Moreover, required regulatory clearances or approvals may not be obtained in a timely manner, or at all. Our products may not ever gain market acceptance, and we may not ever generate significant revenues or achieve profitability. The development and commercialization of our products will require substantial development, regulatory, sales and marketing, manufacturing and other expenditures. We expect our operating losses to continue through at least 2004 as we continue to expend substantial resources to introduce our SimpleChoice product line, further the development of our products, obtain regulatory clearances or approvals, build our marketing, sales, manufacturing and finance organizations and conduct further research and development.

Our product revenues to date have been limited. For 2003, a majority of our product line revenues came from our 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 are not currently established. The royalties that we expect to receive from Respironics depend on sales of the applicable products. We, or our collaborative partner, if we secure one, may not be able to sell sufficient volumes of our products to generate substantial revenues or profits for us.

#### CRITICAL ACCOUNTING POLICIES

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

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

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

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

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

#### RESULTS OF OPERATIONS

Comparison of 2003 and 2002

General. Loss attributable to common stockholders decreased to about \$2.9 million, or \$0.26 per share, in 2003 from about \$8.8 million, or \$0.79 per share, in 2002. The decreased loss was due primarily to an increase of \$4.7 million in other income, due to the sale of assets related to our infant jaundice business in 2003. We also realized a \$3.8 million reduction in expenses in 2003 related to lower cancer expenditures in research and development, as well as lower marketing expenses and general and administrative expenses. This overcame a decrease of \$1.7 million in gross profit in 2003 over 2002, primarily due to a \$1.1 million milestone achievement in 2002 as compared to none in 2003. We expect net losses to continue. We expect no additional milestone revenue for the foreseeable future, so we are dependent upon the growth of product revenue to provide funding for both the SimpleChoice product line as well as our development programs. It is possible that our product revenue will not meet our expectations. If this were to happen, future net losses could increase as a result of spending increases necessary to complete research, development and clinical trials of our products, begin sales and marketing efforts and establish manufacturing capabilities. This would delay some of our product development activities. In addition, we expect net losses to continue as we begin sales and marketing efforts and establish marketing efforts product line.

Revenue and Cost of Product Sales. Total revenues decreased to about \$1.6 million in 2003 from about \$3.8 million in 2002. The decrease was due to a decrease in milestone payments received from collaborative partners, which decreased from \$1.1 million in 2002 and reduction in 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. We expect research and development expenses to decrease mildly in the future based upon lower expected expenditures on our glucose monitoring and cervical cancer programs, and continued expenditures as we develop our SimpleChoice insulin delivery products.

Sales and Marketing. Sales and marketing expenses decreased to about \$735,000 in 2003 from about \$1.6 million in 2002. The decrease in expense was due to a significant reduction in expense related to the SimpleChoice product line (\$550,000) while products were being prepared for commercial release. Bili*Chek* marketing decreased also (\$354,000) as a result of the sale of that product line in March 2003. We expect sales and marketing expenses to increase in the future as we expand our marketing and sales activities for our SimpleChoice product line in support of the product launches expected to occur in 2004.

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

Net Interest Expense and Other Income. Net interest expense in 2003 was \$328,000, \$419,000 worse than the net interest income experienced in 2002 of \$91,000. Other income increased \$4.7 million from an expense of \$509,000 in 2002 to income of \$4.2 million in 2003. The major portion of the income was due to the gain on sale of assets related to the infant jaundice business, net of the cost of assets sold.

#### Comparison of 2002 and 2001

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

million milestone achievement in 2002 as compared to \$0.1 million in 2001.

Revenue and Cost of Product Sales. Total revenues increased to about \$3.8 million in 2002 from about \$2.5 million in 2001. The increase was primarily due to an increase in milestone payments received from collaborative partners, which increased to \$1.1 million in 2002 from about \$0.1 million in 2001. Product sales increased approximately 14% to \$2.7 million in 2002 from about \$2.4 million in 2001. Revenues related to the 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.

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

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

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

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

#### LIQUIDITY AND CAPITAL RESOURCES

We have financed our operations since inception primarily through private sales of debt and private and public sales of our equity securities. From October 27, 1992 (inception) through December 31, 2003, we received approximately \$55.9 million in proceeds from sales of our debt and equity securities. At December 31, 2003, we had cash of approximately \$389,000 and working capital of approximately a negative \$2.0 million.

In August 2002, Abbott notified us that it intended to redeem the \$4.25 million of redeemable convertible preferred stock eligible to be redeemed. Under a settlement agreement related to the termination of our collaborative arrangement with Abbott, we agreed with Abbott to redeem the 425,000 shares of preferred stock on an extended schedule through 2006 (see Item 3. - Legal Proceedings).

Our major cash flows in the year ended December 31, 2003 consisted of cash out-flow of \$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 the cash out-flow from operations, \$1.3 million resulted from payment and prepayment of royalties relating to our agreement with Altea Technologies, Inc.

We have historically also received funds from milestones and reimbursements from our collaborative partners. About 30% of our funds inflow has come from these sources prior to 2003. We are currently seeking a collaborative partner for our glucose monitoring technology. Until we reach an agreement with a new partner, we expect no such milestones or reimbursements. We have been successful in securing grants to support some of our programs, including a \$1.4 million grant, to be spent over two years, from the National Cancer Institute for our cervical cancer program. In

March 2003, we sold the assets related to the 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, 2003 that it had completed a private placement to institutional and private investors of a new series of its preferred stock and of warrants to purchase shares of its common stock. Proceeds to the company were approximately \$7.3 million, prior to the payment of placement agent fees and expenses. Of the proceeds, approximately \$1.0 million represents the conversion of debt into securities issued in the financing.

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

We may be required to raise additional funds through public or private financing, additional collaborative relationships or other arrangements in addition to those sources. We believe our existing and available capital resources will be sufficient to satisfy our funding requirements through 2004, including the approximately \$1.6 million due on redeemable convertible preferred stock during the year, although we need to secure a collaborative partner to move forward with our continuous glucose program and will need funding in addition to that provided by grants to complete our pivotal trials for our cervical cancer product in a timely fashion.

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

#### **New Accounting Pronouncements**

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

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

In May 2003, the FASB issued Statement of Financial Accounting Standards No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity." This statement affects the issuer's accounting for three types of freestanding financial statements: mandatorily redeemable shares, put and forward purchase contracts that require the issuer to buy back some of its shares in exchange for cash or other assets, and certain obligations that can be settled in shares. This statement is effective for all financial instruments entered into or

modified after May 31, 2003, and otherwise effective at the beginning of the first interim period beginning after June 15, 2003. The impact of adopting FASB No. 150 was not material to the Company's financial position and results of operations.

In December 2003, the SEC published Staff Accounting Bulletin (SAB) No. 104, "Revenue Recognition." This SAB updates portions of the SEC staff's interpretive guidance provided in SAB 101 and included in Topic 13 of the Codification of Staff Accounting Bulletins. SAB 104 deletes 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.

#### **Off-Balance Sheet Arrangements**

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

#### Tabular Disclosure of Contractual Obligations

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

		F	2000 P. Thomaston		
	Total	2004	2005 to 2006	2007 to 2008	2009 & Thereafter
Long-term debt, including current maturities (1)	\$4,863	\$1,599	\$3,264	4 \$0	\$0
Operating Lease Obligation	\$168	\$78	\$57	7 \$33	\$0
Other long-term liabilities reflected on the Consolidated Balance Sheet (2)	\$381	\$0	\$0	0 \$0	\$381
(1)					

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

(2)

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

#### ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders

SpectRx, Inc. & Subsidiaries

We have audited the accompanying consolidated balance sheet of SpectRx, Inc. & subsidiaries as of December 31, 2003, and the related consolidated statements of operations, changes in stockholders' equity and cash flows for the year then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with 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

#### REPORT OF INDEPENDENT AUDITORS

SpectRx, Inc.

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

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

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

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

The accompanying financial statements have been prepared assuming that SpectRx, Inc. and subsidiary will continue as a going concern. As more fully described in Note 1, the Company has incurred recurring operating losses and is dependent on and will need to obtain additional financing or generate sufficient cash flow from sales and royalty revenue to continue its development efforts and fund its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in

Note 1. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

/s/ Ernst & Young LLP

Atlanta, Georgia March 11, 2003

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

#### REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

#### To SpectRx, Inc.:

We have audited the accompanying consolidated balance sheets of SPECTRX, INC. (a Delaware corporation) and subsidiary as of December 31, 2000 and 2001 and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2001. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of SpectRx, Inc. and subsidiary as of December 31, 2000 and 2001 and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2001 in conformity with accounting principles generally accepted in the United States.

/s/ Arthur Andersen LLP

Atlanta, Georgia

February 14, 2002

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

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

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

## SPECTRX, INC. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF OPERATIONS FOR THE YEARS ENDED DECEMBER 31, 2001, 2002 AND 2003 (In Thousands Except Per Share Data)

	2001	2002	2003
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:	2,430	3,190	1,500
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
	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)
LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	Ψ(7,201)	Φ(0,020)	$\Psi(2,710)$
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 consolidat	ed statement	S.	

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

Preferred Common Stock Additional Treasury Deferred Notes AccumulatedStockholders' Paid-In Stock Stock Compensation Receivable Deficit (DEFICIT) Capital From Equity Officers Shares Amount BALANCE, \$0 \$30,927 \$0 \$(31,999) \$(1,094) 8,508 \$9 \$0 \$(31) December 31, 2000 Issuance of 0 2,668 2 16,598 0 0 0 0 16,600 common stock Conversion 1,125 0 0 0 0 0 0 0 1,125 to preferred stock 0 0 0 Exercise of 6 0 8 0 0 8 stock options 12 71 **Employee** 0 0 0 0 0 0 71 stock purchase plan Treasury 0 (7)0 0 (38)0 0 0 (38)stock purchase 0 0 0 0 0 0 Issuance of (19)0 (19)stock options Dividends 0 0 0 0 0 0 0 (315)(315)on preferred stock 0 Net 0 0 0 0 0 0 (6,966)(6,966)loss BALANCE, 1,125 11,187 11 47,604 (38)(19)(31)(39,280)9,372 December 31, 2001 Amortization 0 0 0 0 0 37 0 0 37 of deferred comp 0 46 0 118 0 0 0 0 118 Issuance of common

Edgar Filing: SPECTRX INC - Form 10-K/A

stock for services									
Non-employee stock	0	21	0	142	0	(106)	(16)	0	20
options 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 receivable	0	(35)	0	0	(57)	0	47	0	(10)
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)
BALANCE, December 31, 2003	\$1,245	11,366	\$11	\$48,335	\$(95)	\$(69)	\$0	(\$51,010)	\$(1,583)

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

## SPECTRX, INC. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF CASH FLOWS FOR THE YEARS ENDED DECEMBER 31, 2001, 2002 AND 2003 (In Thousands)

	<u>2001</u>	<u>2002</u>	<u>2003</u>
			<u>(1)</u>
CASH FLOWS FROM OPERATING ACTIVITIES:			
	\$(6,966)	\$(8,505	\$(2,611)
	Ψ(0,500)	Φ(0,502	
Adjustments to reconcile net loss to net cash used in operating activities excluding the effects of acquisition:  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:			
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
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.

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

#### 1. ORGANIZATION, BACKGROUND, AND BASIS OF PRESENTATION

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

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

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

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

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

#### **Basis of Presentation**

The Company has a limited operating history upon which its prospects can be evaluated. The Company's prospects must be considered in light of the substantial risks, expenses and difficulties encountered by entrants into the medical device industry. This industry is characterized by an increasing number of participants, intense competition and a high failure rate. The Company has experienced operating losses since its inception, and, as of December 31, 2003, it has an accumulated deficit of \$51.0 million. Through December 31, 2003, the Company has engaged primarily in research and development efforts. The Company first generated revenue from product sales in 1998, but does not have significant experience in manufacturing, marketing or selling its products. The Company's development efforts may not result in commercially viable products, and it may not be successful in introducing its products. Moreover, required regulatory clearances or approvals may not be obtained in a timely manner, or at all. The Company's products may not ever gain market acceptance, and the Company may not ever generate significant revenue or achieve profitability. The development and commercialization of the Company's products will require substantial development, regulatory, sales and marketing, manufacturing and other expenditures. The Company expects operating losses to continue through at least 2004 as it continues to expend substantial resources to complete development of its products, obtain regulatory clearances or approvals, build its marketing, sales, manufacturing and finance organizations and conduct further research and development.

In addition, a portion of the Company's revenue and profits are expected to be derived from royalties that it will receive from Respironics resulting from sales of the infant jaundice products and from the insulin delivery products developed by its subsidiary, Sterling. The royalties that the Company expects to receive from Respironics and manufacturing profits from Sterling depend on sales of these products. The Company intends to market its insulin delivery products directly to distributors and other customers. The Company and Respironics may not be able to sell sufficient volumes of its products to generate substantial royalties, distribution profits, and manufacturing profits for the Company.

The Company's financial statements have been prepared and presented on a basis assuming it will continue as a going concern. Management has just completed a financing transaction (See Note 14, Subsequent Events) and believes those funds along with funds from sales and royalty revenue will be sufficient to support planned operations through December 31, 2004. However, there can be no assurance that the Company will be able to raise additional funds on acceptable terms, or at all, or achieve planned sales volumes.

#### 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

#### Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

#### Principles of Consolidation

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

#### Cash Equivalents

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

#### **Inventories**

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

	2002	2003
Raw materials	\$475	\$43
Work in process	3	0
Finished goods	165	195
	\$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
	40.105	** ***
	\$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 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 2		2003	
Net loss, as reported	\$(6,966)	\$(8,505)	\$(2,611)	
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	\$(1,103)	\$ (767)	\$(673)	
Proforma net loss	\$(8,069)	\$(9,272)	\$(3,284)	
Proforma net loss attributable to common stockholders	\$(8,384)	\$(9,587)	\$(3,583)	
N				
Net loss attributable to common stockholders per share:				
Basic & Diluted - as reported	\$ (0.76)	\$ (0.79)	\$(0.26)	
Basic & Diluted - pro forma	\$ (0.87)	\$ (0.86)	\$(0.32)	

#### Fair Value of Financial Instruments

The book values of cash, accounts receivable, accounts payable, and other financial instruments approximate their fair values principally because of the short-term maturities of these instruments. The fair value of the Company's collaborative partner advance is estimated based on the amount payable to settle the liability. Under this method, the fair value of the Company's collaborative partner advance was not significantly different than the stated value at December 31, 2001 and 2002.

#### **New Accounting Pronouncements**

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

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

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

In December 2003, the Securities and Exchange Commission (SEC), published Staff Accounting Bulletin (SAB) No. 104, "Revenue Recognition." This SAB updates portions of the Securities and Exchange Commission (SEC) staff's interpretive guidance provided in SAB 101 and included in Topic 13 of the Codification of Staff Accounting Bulletins. SAB 104 deletes 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 up to an aggregate of 1,234,567 additional shares of Company common stock in the future if the Sterling product line achieves specified financial goals, none of which have been achieved as of December 31, 2003. In connection with the acquisition of Sterling, the Company entered

into employment agreements with four employees for terms expiring June 2003. The excess of the cost over the estimated fair value of net tangible assets acquired amounts to approximately \$4.1 million and has been included in intangible assets in the accompanying consolidated balance sheets. The \$4.1 million purchase price excess has been allocated between patents and non-compete agreements. In addition, goodwill and a related deferred tax liability of approximately \$1.6 million have been recorded to reflect taxable temporary differences existing at December 31, 2001. The acquisition has been accounted for as a purchase in accordance with SFAS No. 141, "Accounting for Business Combinations."

The financial statements of SpectRx, Inc. as of December 31, 2001 included goodwill and a related tax liability of approximately \$1.6 million for taxable temporary differences existing at December 31, 2001 related to the acquired patents and non-compete agreements. The financial statements of SpectRx, Inc. as of December 31, 2001 have been restated to reflect a purchase price allocation adjustment to reverse the goodwill initially recorded and record a corresponding decrease in the deferred tax asset valuation allowance account equal to the deferred tax liability established for patents acquired.

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

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

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

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

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

#### 4. INVESTMENT IN FLUORRX, INC.

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

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

#### 5. SALE OF ASSETS

On March 6, 2003, the Company sold its 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.

#### Preferred Stock

In January 1997, the Company authorized 5,000,000 shares of preferred stock with a \$.001 par value. The board of directors has the authority to issue these shares and to fix dividends, voting and conversion rights, redemption provisions, liquidation preferences, and other rights and restrictions.

In November 1999, the board of directors designated 525,000 shares of the preferred stock as redeemable convertible preferred stock. Dividends are payable annually in cash or securities (at the Company's option) at a rate of 6% per annum. During the years ended December 31, 2001, 2002 and 2003, the Company accrued dividends in the form of redeemable convertible preferred stock of \$315,000, \$315,000 and \$299,000, respectively. The preferred shares, together with any accrued but unpaid dividends, are convertible into common shares at the greater of \$9.39 per share or the average of the closing sales price for 15 days prior and 15 days subsequent to the conversion and automatically convert on December 31, 2004 at the then conversion rate. The shares were mandatorily redeemable at \$10 per share, plus accrued but unpaid dividends, at the later of September 30, 2002 or 60 days subsequent to the date upon which the Company gives notice to Abbott of Abbott's right to redeem the shares (which notice could not be given prior to June 1, 2002). The shares have a liquidation preference of \$10 per share, plus all accrued but unpaid dividends.

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

In September 2001, the Company entered into an agreement with Abbott whereby Abbott waived its right to redeem 100,000 shares of its Redeemable Convertible Preferred Stock plus the related accrued but unpaid dividends.

In September 2002, Abbott delivered notice of its election to cause the redemption of the 425,000 shares of redeemable convertible preferred stock eligible for redemption. On March 7, 2003, the Company reached a settlement with Abbott regarding their disputes in connection with the prior termination of the parties' Research & Development and License Agreement and the election of Abbott to have shares of the Company's preferred stock held by Abbott redeemed by the Company. Abbott had previously elected to have 425,000 shares of the Company's preferred stock redeemed, with 162,500 shares to be redeemed on December 30, 2002 at \$10.00 per share, plus accrued dividends, and the remaining shares to be redeemed no later than January 31, 2004. Under the settlement, which included mutual releases, the Company has agreed to make quarterly payments to Abbott during 2003 and 2004 and end of the year lump sum payments in 2005 and 2006 to redeem 425,000 preferred shares and to pay accrued dividends as to such shares. The Company paid \$400,000 to Abbott during 2003. The Company's yearly financial obligations to Abbott

under the agreement are approximately \$0.7 million, \$1.3 million, \$1.8 million and \$1.9 million for 2003, 2004, 2005 and 2006, respectively. Under the settlement, neither party admitted any liability or wrongdoing.

#### **Stock Options**

In May 1995, the Company adopted the 1995 Stock Plan (the "Plan"), which was amended on January 20, 1997 and during the year ended December 31, 2000, under which a total of 1,928,572 shares of common stock were authorized, and under which a total of 1,649,521 shares remain authorized, net of exercised shares. The Plan allows the issuance of incentive stock options, nonqualified stock options, and stock purchase rights. The exercise price of options is determined by the Company's board of directors, but incentive stock options must be granted at an exercise price equal to the fair market value of the Company's common stock as of the grant date. Options generally become exercisable over four years and expire ten years from the date of grant. At December 31, 2003, options to purchase 61,522 shares of common stock were available for future grant under the Plan.

In January 2002, the Company assumed the Sterling Medivations 2000 Stock Option Plan, with authorized shares of 93,765. No options have been exercised under this plan. At December 31, 2003, 6,090 options were outstanding under this plan, and 87,675 shares were still available for future grant, subject to the provisions of the Agreement and Plan of Merger between SpectRx and Sterling Medivations.

Stock option activity for each of the three years ended December 31, 2003 is as follows:

Number of
Options

Weighted
Average
Exercise
Price Per
Share

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		4.404.000
		1,594,089 \$4.53
The following table sets forth the range remaining contractual lives by groups of	of similar price as of December 31, 2	2003:
	Options Outstanding	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

\$ 5.00-\$ 9.00	
	776,210
	6.94
	5.56
	639,166
	7.19
\$ 10.13-\$ 16.50	
	<u>86,261</u>
	11.18
	6.61
	<u>76,823</u>
	11.20
Total	<u>1,594,089</u>

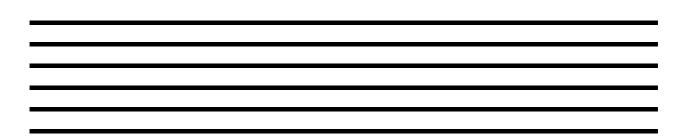
\$ 4.53

5.54

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:

	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):

Edgar Filing: SPECTRX INC - Form 10-K/A

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

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

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

In January, 2003, the Company announced that it had given notice that it was initiating actions required to terminate its research, development and license agreement with Abbott to jointly develop a continuous glucose monitor. The Company further announced that it was withholding payment due in connection with the redemption of the shares of the Company's preferred stock held by Abbott as an offset to claims which have also been made by the Company under its agreement with Abbott. Under the terms of the preferred stock, 162,500 shares of SpectRx preferred stock were required to be redeemed on December 30, 2002 at \$10.00 per share. The Company also announced that it had asked the U.S. patent office to resolve an inventorship dispute involving issued Abbott patents related to Abbott's glucose monitoring technology. Abbott exercised the right to terminate the agreement on January 7, 2003. A settlement with Abbott Laboratories was reached on March 10, 2003 regarding the disputes in connection with the prior termination of the parties agreement and the election of Abbott to have shares of the Company's preferred stock redeemed, with 162,500 shares to be redeemed on December 30, 2002 at \$10.00 per share, plus accrued dividends, and the remaining shares to be redeemed no later than January 31, 2004. Under the settlement, the Company has agreed to make quarterly payments to Abbott during 2003 and 2004 and end of the year lump sum payments in 2005 and 2006 to redeem 425,000 preferred shares and to pay approximately \$0.7 million, \$1.3 million, \$1.8 million, and \$1.9 million for 2003, 2004, 2005, and 2006, respectively. The Company paid \$0.4 million in 2003 related to this settlement.

#### Grants

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

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

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

#### Contracts

In addition to the grants above, the Company has received contracts from the National Institute on Alcohol Abuse and Alcoholism (NIAAA) ("Institute") and the Department of the Army to develop and test devices to sense alcohol and insulin growth factor, respectively based upon the Company's interstitial fluid collection technology. The NIAAA contract runs for two years, with an Institute option to extend it to five years in total. SpectRx's share of the contract, as the prime contractor, is expected to be approximately \$900,000 of the \$1.5 million agreed for the first two years, which commenced in 2003. The Company recognized \$380,000 of revenue for the portion of the contract that was completed during 2003. The Department of the Army (DOA) contract is for one year and the total amount of the contract is \$51,000.

### 9. RELATED-PARTY TRANSACTIONS

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

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

### 10. LICENSE AND TECHNOLOGY AGREEMENTS

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

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

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

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

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

### 11. COLLABORATIVE AGREEMENTS

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

#### Abbott

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

In 1997, Abbott purchased \$3.0 million of series C preferred stock and in November 1999, subscribed to \$5.25 million of redeemable convertible preferred stock (Note 6). In 2001, the Company entered into an agreement with Abbott whereby Abbott waived its right to redeem 100,000 shares of its redeemable convertible preferred stock plus the related accrued but unpaid dividends. In 2002, Abbott delivered notice of its election to cause the redemption of the 425,000 shares of the redeemable convertible preferred stock eligible for redemption.

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

## Welch Allyn

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

## Roche

The Roche Agreement requires Roche to make milestone payments based on progress achieved and to purchase diabetes screening products manufactured by the Company at a predetermined profit margin, subject to renegotiation between the parties in certain instances.

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

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

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

### Respironics

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

# 12. BUSINESS SEGMENT INFORMATION

The Company operates in one business segment, the research and development of medical products. The Company had no product sales prior to fiscal year 1998. During fiscal years 2001, 2002 and 2003, total product revenue of \$2,358,000, \$2,698,000 and \$1,586,000 respectively, related primarily to the Company's infant jaundice product, including, during 2003, \$146,000 of royalties due in conjunction with the asset sale agreement between the Company and Respironics. The Company had exclusively licensed the right to distribute the infant jaundice product within the United States and Canada to Respironics prior to its sale in March 2003 to Respironics. The Company distributed the product outside the United States and Canada through a diverse group of foreign distributors. All sales are payable in United States dollars. Product revenue attributable to countries based on the location of the customer are as follows (in thousands):

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

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

## 13. SELECTED QUARTERLY CONSOLIDATED FINANCIAL INFORMATION (unaudited)

Quarter Ended

December 31

Edgar Filing: SPECTRX INC - Form 10-K/A

	March 31 2002	June 30 2002	September I 30 2002	December 31 2002	March 31 2003	June 30 2003	September 30 2003	2003
•			(in thousar	nds except	per share	data)		
Total Revenue	652	774		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	11,210	11,249	11,249	11,237	11,248	11,600
The Company recorded a	\$508,000 charge	to opera	tions in Dece	ember 200	2 for the e	xtinguis	hments of of	ficer loans.

# 14. SUBSEQUENT EVENTS

(See Note 9.)

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

Subject to customary adjustments, the preferred stock is convertible into, and the warrants are exercisable for, 4,886,690 and 4,886,690 shares of common stock, respectively. The warrants are currently exercisable. One-half of the warrants permit the holders to purchase shares of SpectRx common stock at a price of \$1.65 per share, and the other half, at \$2.25 per share. The placement also included a registration rights agreement between the Company and the purchasers, requiring registration of the underlying common shares, to be effective within 90 days of the closing, or a portion of the proceeds could be deemed an obligation.

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

### 15. NOTES PAYABLE

The Company issued Notes on July 30, 2003 in an aggregate amount of \$1,000,000 to five individuals, including two officers of SpectRx, for the purpose of bridge financing. The terms of the notes included a balloon payment six

months from the date of issuance, monthly interest payments at a rate of 12% per annum and monthly issuances of warrants so long as the notes remained outstanding.

The Company issued warrants for 203,000 shares with a fair value of \$193,000 and such amount was charged to interest expenses in 2003.

PART IV

## ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K

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

### 1. CONSOLIDATED FINANCIAL STATEMENTS

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

### 2. FINANCIAL STATEMENT SCHEDULE.

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

#### 3. EXHIBITS

Refer to (C) below.

### (B) REPORTS ON FORM 8-K

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

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

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

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

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

#### (C) EXHIBITS

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

# **EXHIBIT INDEX**

# **EXHIBIT**

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

	Amendment to License and Joint Development Agreement, dated December 30, 2001, between NonInvasive-Monitoring Company, Inc., Altea Technologies, Inc. and SpectRx.
10.12A(1)*	Purchasing and Licensing Agreement, dated June 19, 1996, between Respironics and SpectRx.
10.12B(4)*	Amendment to Purchasing and Licensing Agreement, dated October 21, 1998 between Respironics and SpectRx.
10.13(1)	Research Services Agreement, dated September 3, 1996, between Sisters of Providence in Oregon doing business as the Oregon Medical Laser Center, Providence St. Vincent Medical Center and SpectRx.
10.14A(1)*	Research and Development and License Agreement, dated October 10, 1996, between Abbott Laboratories and SpectRx.
10.14B(3)*	Letter Agreement, dated December 22, 1997, between Abbott Laboratories and SpectRx.
10.14C(6)*	Third Amendment to Research and Development and License Agreement, dated November 30, 1999 between Abbott Laboratories and SpectRx.
10.14D(9)*	Fourth Amendment to Research and Development and License Agreement, dated November 30, 1999 between Abbott Laboratories and SpectRx.
10.15A(1)	Lease, dated September 21, 1993, between National Life Insurance Company d/b/a Plaza 85 Business Park and SpectRx, together with amendments 1, 2, 3 and 4 thereto and Tenant Estoppel Certificate, dated September 20, 1994.
10.16A(5)*	Development and License Agreement, dated July 13, 1999, between Roche Diagnostics Corporation and SpectRx.
10.16B(5)*	Supply Agreement, dated July 13, 1999, between Roche Diagnostics Corporation and SpectRx.
10.17(10)	Agreement and Plan of Merger, dated December 31, 2001 by and between SpectRx, Inc. Sterling Medivations, Inc., SM Merger Sub, Inc. and certain shareholders of Sterling Medivations, Inc.
10.18	Agreement and Plan of Merger, dated December 31, 2001, by and among SpectRx, SM Merger Sub, Inc., Sterling Medivations, Inc. and certain stockholders (incorporated by reference to Exhibit 21 the Registrant's Current Report on Form 8-K filed January 14, 2002).
10.19	Agreement for Termination of Development and Commercialization Agreement, dated November 19, 2002, between SpectRx and Welch Allyn, Inc. (incorporated by reference to the Registrant's Current Report on Form 8-K filed December 20, 2002).
10.20(11)	Asset Sale Agreement, dated March 6, 2003, between SpectRx and Respironics.
10.21(12)	Securities Purchase Agreement dated March 26, 2004 among SpectRx, Inc. and the purchasers listed on Schedule I.
16.1	Letter re Change in Certifying Accountants (incorporated by reference to Exhibit 16.1 to the Registrant's Current Report on Form 8-K, filed on June 14, 2002).
16.2	Letter re Change in Certifying Accountants (incorporated by reference to Exhibit 99.1 to the Registrant's Current Report on Form 8-K, filed October 24, 2003).

23.1(13)	Consent of Eisner LLP.
23.2(13)	Consent of Ernst & Young LLP.
24.1 **	Power of Attorney (included on signature page).
31(13)	Rule 13a - 14(a) / 15d - 14(a) Certifications.
32(13)	Section 1350 Certifications

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

- 1. Incorporated by reference to the exhibit filed with the Registrant's Registration Statement on Form S-1 (No. 333-22429) filed February 27, 1997, and amended on April 24, 1997, June 11, 1997, and June 30, 1997, which Registration Statement became effective June 30, 1997.
- 2. Incorporated by reference to the exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1997, filed August 12, 1997.
- 3. Incorporated by reference to the exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1997, filed March 27, 1998.
- 4. Incorporated by reference to the exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1998, filed March 30, 1999, as amended.
- 5. Incorporated by reference to the exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1999, filed August 16, 1999, as amended.
- 6. Incorporated by reference to the exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1999, filed March 30, 2000, as amended.
- 7. Incorporated by reference to the exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 2001, filed April 2, 2002.
- 8. Incorporated by reference to the exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2002, filed May 14, 2002.
- 9. Incorporated by reference to the exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002, filed November 14, 2002.
- 10. Incorporated by reference to the exhibit filed with the Registrant's Current Report on Form 8-K, as amended, filed January 14, 2002.
- 11. Incorporated by reference to the exhibit filed with the Registrant's Current Report on Form 8-K, filed March 21, 2003.
- 12. Incorporated by reference to the exhibit filed with the Registrant's Current Report on Form 8-K, filed March 29, 2004.
- 13. Filed herewith.

<sup>\*\*</sup> Previously filed.

#### **SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this amended report to be signed on its behalf by the undersigned, thereunto duly authorized on the 8th day of July 2004.

SPECTRX, INC.

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

By: Thomas H. Muller, Jr.

Executive Vice President & Chief Financial

Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this amended report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

DATE SIGNATURE TITLE

<u>k</u> Chairman, Chief Executive Officer and Director (Principal

Mark A. Samuels Executive Officer)

July 8, 2004 /s/ Thomas H. Muller, Jr. Executive Vice President and Chief Financial Officer (Principal

Financial and Accounting Officer)

Thomas H. Muller, Jr.

Senior Executive Vice President and Director

Keith D. Ignotz

<u>\*</u> Director

Charles G. Hadley

\* Director

Earl R. Lewis

<u>\*</u> Director

William E. Zachary

\* Director

Chris Monahan

July 8, 2004 /s/ Thomas H. Muller, Jr.

Thomas H. Muller, Jr. Attorney-in-fact

