SPECTRX INC
Form 10-Q/A
November 14, 2002

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

Amendment No.1 to

FORM 10-Q

[X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2002

OR

[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE TRANSITION PERIOD FROM ------ TO-------

COMMISSION FILE NUMBER: 0-22179

SPECTRX, INC.

(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

DELAWARE	**58-2029543**
(STATE OR OTHER JURISDICTION OF INCORPORATION OR ORGANIZATION)	(I.R.S. EMPLOYER IDENTIFICATION NUMBER)

6025A UNITY DRIVE
NORCROSS, GEORGIA 30071

(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES, INCLUDING ZIP CODE)

(770) 242-8723

(REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE)

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 requirements for the past 90 days.

YES [X] NO [ ]

The number of issued and outstanding shares of the Registrant's Common Stock, $0.001 par value, as of October 31, 2002, was 11,238,091.

SPECTRX, INC.

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PART 1. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

SPECTRX, INC.
CONSOLIDATED BALANCE SHEETS
(IN THOUSANDS)

		December 31, 2001	September 30,2002 (Unaudited)
	ASSETS		
CURRENT ASSETS			
	Cash and cash equivalents	$9,458	$2,290
	Accounts receivable	1,229	430
	Inventory	437	775
	Other current assets	408	1,076
	Total Current Assets	11,532	4,571
NON-CURRENT ASSETS			
	Property & equipment, net	513	463
	Intangibles	4,132	3,925
	Due from related parties	557	579
	Total Non-Current Assets	5,202	4,967
TOTAL ASSETS		$16,734	$9,538
	LIABILITIES & STOCKHOLDER'S EQUITY		
CURRENT LIABILITIES			
	Accounts payable	$1,018	$565
	Accrued liabilities	1,194	865
	Redeemable convertible preferred stock, short term portion	0	1,917
	Total Current Liabilities	2,212	3,347

COLLABORATIVE PARTNER ADVANCE		381	381
REDEEMABLE CONVERTIBLE PREFERRED STOCK, LONG TERM PORTION		4,769	3,043
STOCKHOLDERS' EQUITY (DEFICIT)			
	Preferred stock	1,125	1,170
	Common stock	11	11
	Additional paid-in-capital	47,604	47,845
	Treasury stock	(38)	(38)
	Deferred compensation	(19)	(80)
	Accumulated deficit	(39,280)	(46,110)
	Notes receivable from officers	(31)	(31)
	Total Stockholders' Equity	9,372	2,767
TOTAL LIABILITIES & EQUITY		$16,734	$9,538

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

SPECTRX, INC.
CONSOLIDATED STATEMENT OF OPERATIONS
(IN THOUSANDS, EXCEPT PER SHARE DATA)
(unaudited)

	Three Months Ended September 30		Nine months Ended September 30	
	2001	2002	2001	2002
REVENUE				
Product sales	$570	$598	$1,726	$1,924
Collaborative agreements	0	1,000	100	1,100
Total	570	1,598	1,826	3,024
COST OF SALES	410	356	1,417	1,173
GROSS MARGIN	160	1,242	409	1,851
EXPENSES				
Research & development	781	1,332	2,989	4,658
Sales & marketing	337	414	711	1,454
General & administrative	675	569	2,090	2,414
Total	1,793	2,315	5,790	8,526
Operating loss	(1,633)	(1,073)	(5,381)	(6,675)
OTHER INCOME	0	5	2	0
INTEREST INCOME	106	19	182	81
NET LOSS	(1,527)	(1,049)	(5,197)	(6,594)
Preferred Stock Dividends	(78)	(78)	(236)	(236)
Loss available to common stockholders	($1,605)	($1,127)	($5,433)	($6,830)
Net (Loss) Per Share				

Basic	($0.15)	($0.10)	($0.58)	($0.61)
Diluted	($0.15)	($0.10)	($0.58)	($0.61)
Weighted average common shares outstanding				
Basic	10,428	11,210	9,336	11,196
Diluted	10,428	11,210	9,336	11,196

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

SPECTRX, INC.
CONSOLIDATED STATEMENT OF CASH FLOWS
(IN THOUSANDS)
(unaudited)

	Nine months Ended September 30,	
	2001	2002
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(5,197)	$(6,594)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	274	410
Loss on retirement of assets	0	4
Amortization of deferred compensation	0	(61)
Changes in assets and liabilities:		
Accounts receivable	414	799
Inventory	(144)	(338)
Other current assets	(22)	(668)
Other assets	(119)	(22)
Accounts payable	(319)	(453)
Accrued liabilities	(173)	(329)
Total adjustments	(89)	(658)
Net cash used in operating activities	(5,286)	(7,252)
CASH FLOW FROM INVESTING ACTIVITIES:		
Additions to property and equipment	(61)	(157)
Net cash used in investing activities	(61)	(157)
CASH FLOW FROM FINANCING ACTIVITIES:		
Issuance of common stock (net of issuance costs)	11,290	241
Treasury stock	(33)	0

Net cash provided by financing activities	11,257	241
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	5,910	(7,168)
CASH AND CASH EQUIVALENTS, beginning of period	3,609	9,458
CASH AND CASH EQUIVALENTS, end of period	$9,519	$2,290

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

SPECTRX, INC.

NOTES TO FINANCIAL STATEMENTS (UNAUDITED)

1. BASIS OF PRESENTATION

The unaudited interim financial statements included herein have been prepared by SpectRx. These statements reflect all adjustments, all of which are of a normal, recurring nature, and which are, in the opinion of management, necessary to present fairly the financial position as of September 30, 2002, the results of operations for the three months and nine months ended September 30, 2001 and 2002, and the cash flows for the nine months ended September 30, 2001 and 2002. The results of operations for the three months and nine months ended September 30, 2001 and 2002 are not necessarily indicative of the results for a full fiscal year. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States have been condensed or omitted. Preparing financial statements requires our management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses. Actual results could differ from those estimates. Our accounting policies continue unchanged from December 31, 2001. These financial statements should be read in conjunction with the financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2001 and our subsequent quarterly reports on Form 10-Q.

2. FLUORRX

In December 1996, we sublicensed certain technology to and acquired a 64.8% interest in FluorRx, Inc., a corporation organized for the purpose of developing and commercializing technology related to fluorescence spectroscopy. Our interest in FluorRx is represented by two seats on the board of directors and 129,000 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 our ownership (on an as converted basis) to 43%. Effective with the August 1998 funding, we began accounting for our investment in FluorRx under the equity method of accounting. In connection therewith, we 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 a 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 our statement of operations or balance sheet for the quarter ended September 30, 2002 as a result of the dissolution.

3. STERLING MEDIVATIONS

On December 31, 2001, we purchased the outstanding shares of Sterling Medivations, Inc. Sterling Medivations (which is doing business as SimpleChoice(TM)) is a developer of innovative insulin delivery products for people with diabetes. The acquisition of Sterling Medivations expanded our diabetes business opportunities 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, we issued a total of 634,713 shares of our common stock in exchange for all of the outstanding Sterling common stock and preferred stock and reserved 22,151 shares for issuance upon exercise of stock options assumed in the merger with an estimated fair market value of $62,159. Sterling stockholders and option holders will also be entitled to up to an aggregate of 1,234,567 additional shares of our common stock in the future if the Sterling Medivations product line achieves specified financial goals. In connection with the acquisition of Sterling Medivations, we 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 intangibles in the accompanying consolidated balance sheets. The $4.1 million purchase price excess has been allocated between patents and non-compete agreements. The acquisition has been accounted for as a purchase in accordance with Statement of Financial Accounting Standards ("SFAS") No. 141, "Accounting for Business Combinations."

4. COMPREHENSIVE INCOME

We currently have no other comprehensive income items as defined by SFAS No. 130, "Reporting Comprehensive Income."

5. RECENT ACCOUNTING PRONOUNCEMENTS

The Financial Accounting Standards Board ("FASB") issued SFAS No. 141, "Accounting for Business Combinations," on June 30, 2001. It requires that all business combinations initiated after June 30, 2001 be accounted for using the purchase method of accounting.

The FASB issued SFAS No. 142, "Accounting for Goodwill and Other Intangible Assets," on June 30, 2001. It provides that goodwill and certain intangible assets will no longer be subject to amortization, but instead will be subject to a periodic impairment assessment by applying a fair-value based test. We adopted SFAS No. 142 on January 1, 2002, which did not have a material impact on our results of operations or financial position.

Certain amounts in the December 31, 2001 financial statements have been reclassified to conform to the current year presentation.

6. LITIGATION

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

7. STOCKHOLDERS' EQUITY

In June 2001, we announced that we had completed two private placements. On June 4, 2001, we entered into an agreement with affiliates of SAFECO Corporation, which invested about $9.5 million in SpectRx before transaction expenses. On June 13, 2001, we entered into an agreement with affiliates of Special Situations Fund, which invested about $2.5 million in SpectRx before transaction expenses. The financings consisted, in total, of sales of about 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, which represented a discount from the market price of our common stock on the dates these transactions closed. 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 proceeds to SpectRx of about $12 million before transaction expenses. The 1,895,633 shares issued in these transactions constituted 22.2% of our common stock outstanding prior to the first private placement transaction. 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 $1.7 million and are included in additional paid-in capital in the accompanying balance sheets. On August 30, 2001, the common stockholders of SpectRx, excluding the shares held by SAFECO and Special Situations Fund, approved these transactions.

In October 2001, Abbott invested an additional $1 million in SpectRx common stock, acquiring 126,199 shares at $7.92 per share, which was subject to SpectRx maintaining certain rights to sublicense technology to Abbott. The purchase was associated with a milestone under a program to commercialize our continuous glucose monitoring technology for people with diabetes. The purchase raised Abbott's common stock ownership in SpectRx to approximately 5.9%, as of September 30, 2002.

On September 19, 2001, we announced that our board of directors had approved a stock repurchase program for up to $1 million of our common stock. As of September 30, 2002, we had purchased 6,700 shares of common stock at an average price of $5.66 per share.

8. PREFERRED STOCK

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

In November 1999, the board of directors designated 525,000 shares of the preferred stock as redeemable convertible preferred stock. We issued $5.25 million of redeemable convertible preferred stock in November 1999 in conjunction with the execution of an amendment to our agreement with Abbott, of which $2,750,000 was received in November 1999 and $2,500,000 was received in January 2000.

The preferred shares, together with any accrued but unpaid dividends, are convertible into shares of common stock at a conversion rate equal to the greater of $9.39 per share or the average of the closing sales price for 30 trading days that begin on the 15th trading day prior to our receipt of a conversion notice sent by the holder of such shares. Also, the shares of preferred stock automatically convert into shares of common stock on December 31, 2004 at such conversion rate. The preferred stock also has a liquidation preference of $10 per share, plus all accrued but unpaid dividends.

In September 2001, we entered into an agreement with Abbott whereby Abbott waived its right to redeem 100,000 shares of its redeemable convertible preferred stock plus the related accrued dividends. The shares of preferred stock are mandatorily redeemable, except with respect to 100,000 shares, by us at $10 per share, plus accrued but unpaid dividends, beginning on December 31, 2002, if we receive a written notice from the holders of at least a majority of the shares of preferred stock on or before the later of September 30, 2002 or 60 days subsequent to the date that the we give notice to the holders of preferred stock of our right to redeem the shares. On September 27, 2002, Abbott sent written notice of its election to redeem the 425,000 preferred shares eligible for redemption. As a result, 162,500 of the shares of preferred stock are to be mandatorily redeemed on December 31, 2002, and the remaining 262,500 shares subject to redemption will be redeemed on or prior to January 31, 2004 if we achieve a revenue goal of $20 million during the year 2003. If we do not achieve this goal, then of such 262,500 shares of preferred stock, one-half must be redeemed prior to January 31, 2004, and the balance by December 31, 2004.

Dividends are accrued on the non-redeemable and redeemable convertible preferred stock at a rate of 6% per year and are included in the shortterm portion and longterm portion of redeemable convertible preferred stock in the accompanying balance sheets.

ITEM 2. 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 or incorporated by reference into 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;

- whether our products in development will prove safe, feasible and effective;

- whether and when we or our strategic partners will obtain approval from the Food and Drug Administration, or FDA, and corresponding foreign agencies;

- our need to achieve manufacturing scale-up in a timely manner, and our need to provide for the efficient manufacturing of sufficient quantities of our products;

- the lack of immediate alternate sources of supply for some critical components of our products;

- our patent and intellectual property position;

- the need to fully develop the marketing, distribution, customer service and technical support and other functions critical to the success of our product lines;

- the effectiveness and ultimate market acceptance of our products;

- the dependence on our strategic partners for funding, development assistance, clinical trials, distribution and marketing of some of our products; and

- other risks and uncertainties described from time to time in our reports filed with the Securities and Exchange Commission, including those contained in our Annual Report on Form 10-K for the year ended December 31, 2001 and our subsequent Quarterly Reports on Form 10-Q.

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 and funding from collaborative arrangements. 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 business strategy, we have established arrangements with leading medical device companies for the development, commercialization and introduction of some of our products. We have collaborative arrangements with Abbott Laboratories and Respironics, Inc. for our continuous glucose monitoring and BiliChek(TM) products, respectively. We also have had a collaborative agreement with Welch Allyn since 1999 to jointly develop our cervical cancer detection product, although we expect to modify our relationship with Welch Allyn by entering into a cross-licensing agreement with Welch Allyn that will allow us to independently commercialize this 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 may seek to establish strategic relationships with other leading companies for the development, commercialization, and introduction of additional products, if it is the best path to commercialization for those products.

In December 2001, we acquired 100% of the common stock of Sterling Medivations, Inc. (doing business as SimpleChoice(TM)), 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 September 30, 2002, we have an accumulated deficit of about $46.1 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 2002 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 2002, a substantial majority of our product line revenues have come from our BiliChek product line. We expect that over half of our revenue in 2003 will be derived from sales of our SimpleChoice insulin delivery products, which have not yet been introduced to the market. Our other products for glucose monitoring and cervical cancer detection are still in development.

We currently sell our products either to distributors or to a collaborative partner, which then distributes our products, which results in revenues from distributor sales, manufacturing profits and royalties. The royalties and manufacturing profits that we expect to receive from Abbott and Respironics depend on sales of the applicable products. Our collaborative partners and we may not be able to sell sufficient volumes of our products to generate substantial revenues or profits for us.

We have a licensing agreement with Respironics that grants it the right to distribute the BiliChek product line in the United States and Canada. We currently have a collaborative agreement with Abbott related to our continuous glucose monitoring product. We have a collaborative agreement with Roche related to a diabetes detection product. These collaborative arrangements grant a substantial amount of discretion to each collaborative partner. If a collaborative partner were to terminate its arrangement with us, we would either need to reach agreement with a replacement collaborative partner or undertake, at our own expense, the activities previously handled by our collaborative partner. This would require us to develop expertise we do not currently possess, would significantly increase our capital requirements and would limit the programs we could pursue. We would likely encounter significant delays in introducing our products, and the development, manufacture and sales of our products would be adversely affected by the absence of collaborative arrangements.

CRITICAL ACCOUNTING POLICIES

Our material accounting policies that 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, accruals of product warranties and inventory evaluation.

- Revenue recognition: We recognize revenue from sales of products or services upon shipment of products or services. We also recognize milestone revenue from our 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 or subsidiaries, as well as their financial condition, and revise our reserves as a result.

- Accruals of Product Warranties: We book a cost for warranty work on each of our products at the time of sale and match actual warranty work against that accrual, as the work is performed. We periodically review the level of warranty accrual and the actual warranty work incurred and adjust these as needed.

- 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.

QUARTER OVERVIEW

On September 17, 2002, we announced that Abbott Laboratories agreed to make a $1 million milestone payment under a program to commercialize our continuous glucose monitoring technology for people with diabetes. Abbott and SpectRx are developing the technology, which is designed to provide continuous glucose readings without using needles or drawing blood. The milestone payment was made on September 20 , 2002 after a previously announced dispute with Abbott regarding this milestone.

Under a 1999 agreement, Abbott has exclusive worldwide marketing rights to SpectRx's interstitial fluid continuous glucose monitoring technology. The agreement includes terms related to financing, development milestone payments, and cooperative research and development. Under the agreement, SpectRx will receive a royalty on sales of disposables and has the option to manufacture continuous monitoring devices for Abbott.

On September 27, 2002, Abbott delivered notice of its election to cause the redemption of the 425,000 shares of redeemable convertible preferred stock eligible for redemption. The agreement between Abbott and SpectRx contains a deadline of September 30, 2002 for this redemption election, after which these shares are eligible only for conversion. The conversion price, if Abbott had not elected to redeem, would have been the greater of the market price at the time of conversion and a pre-determined minimum price ($9.39 per share) contained in the agreement.

On October 4, 2002, we announced that the listing of our common stock may be moved to the Nasdaq SmallCap Market. We received a determination from Nasdaq that we did not meet either the current net tangible assets requirement or the new higher stockholders' equity requirement for continued listing on the Nasdaq National Market.

We must meet one of two maintenance standards to retain our Nasdaq National Market listing. Standard 1 currently requires at least $4.0 million of net tangible assets but changed to $10.0 million of stockholders' equity on November 1, 2002. Standard 2 requires the market value of listed securities to be $50 million.

We requested and received a hearing to present reasons why we should remain listed on the Nasdaq National Market. The hearing took place on October 31, and we are awaiting a determination.

Although there are no assurances that the appeal will be successful or that a transfer application to the Nasdaq SmallCap Market, if necessary, would be approved, we believe that we meet the applicable standards for inclusion on the Nasdaq SmallCap Market.

On October 23, 2002, we announced that we completed the multi-center, pre-pivotal clinical trial of our non-invasive cervical cancer detection device, and that we are making final preparations to begin the FDA pivotal trial required for product approval.

Analysis of results from the first 414 women in the pre-pivotal study indicates that our device detected 16% more high-grade precancers than Pap tests, the majority of which were the thin layer Pap tests. These results suggest that our device could reduce by more than half the 2.2 million unnecessary follow up colposcopic exams and 1.6 million unnecessary biopsies resulting from uncertain or false positive Pap test results. In the U.S., approximately $6 billion is spent annually on unnecessary follow-up Pap testing.

Women tested with our device were scheduled for follow-up of an ambiguous or abnormal Pap test or pre-existing disease of the cervix. This is the same type of patient population as projected for the FDA pivotal trial, which we expect to begin in early 2003, followed by an application for regulatory approval in late 2003.

Approximately 500 women participated in the clinical study, which was funded in part by the National Cancer Institute and conducted at four leading clinical centers in the U.S. Results from the study will be used to develop the final algorithm for evaluation in the upcoming FDA pivotal trials. Locations for the clinical study were the University of Miami, the Medical College of Georgia in Augusta, Georgia, Emory University/Grady Hospital in Atlanta and the Saint Francis Hospital and Medical Center in Hartford, Connecticut.

The prototype devices use our proprietary biophotonic technology to locate cancers and precancers painlessly and non-invasively by analyzing light reflected from the cervix. The device creates an image of the cervix indicating the location and severity of disease. The technology distinguishes between normal and diseased tissue by detecting biochemical and morphological changes at the cellular level. Unlike Pap or HPV tests, our test does not require a tissue sample or laboratory analysis. To date more than 1,000 women have been tested on our prototype non-invasive cervical cancer detection devices.

According to medical journal reports, cervical cancer is the third most common cancer in women worldwide. There are approximately 371,000 cases of cervical cancer diagnosed annually and approximately 190,000 deaths per year on a worldwide basis. Annually more than 60 million Pap tests are performed in the United States alone. We estimate the global market size for a non-invasive cervical cancer test at approximately $1.6 billion annually.

On October 29, 2002 we announced plans to sell our non-core BiliChek business, which will allow us to focus on our diabetes and cancer businesses. When we announced the purchase of the SimpleChoice insulin delivery business in January of this year, we stated that we would concentrate on our diabetes and cancer businesses. In light of our focus on products that serve these large and growing markets, we decided to sell our BiliChek business as a non-core asset. We have been actively pursuing this initiative over the last several months with a number of qualified prospective purchasers that have expressed significant interest in the business. Proceeds from any such sale would provide us with non-dilutive financing to grow and expand our SimpleChoice insulin delivery product line.

On October 29, 2002, we also announced that we believe we are on track to launch our first SimpleChoice product in December 2002. We expect significant revenue to be generated by our SimpleChoice products as we move into 2003. We have also been focused on our cost reduction program and other activities designed to conserve our financial resources for the launch of the SimpleChoice line of insulin delivery products and to achieve other important strategic objectives.

RESULTS OF OPERATIONS

COMPARISON OF THE THREE MONTHS ENDED SEPTEMBER 30, 2002 AND 2001.

General. Net loss available to common stockholders decreased to $1.1million during the three months ended September 30, 2002 as compared to $1.6 million for the same period in 2001. During the quarter, we received a $1.0 million milestone from Abbott for our continuous glucose monitoring program, which was offset by increased spending associated with the SimpleChoice product line and reductions in expense reimbursements from Abbott and Welch Allyn.

Revenue. Revenue increased to approximately $1.6 million for the third quarter of 2002 as compared to $570,000 for the same period in 2001, primarily due to the receipt of the milestone payment of $1.0 million. Product revenue increased to $598,000 for the quarter ended September 30, 2002 from $570,000 for the same period in 2001. Product revenue is higher for the current quarter as compared to the comparable period in 2001, primarily due to the increased revenues from our BiliCal(TM) disposable sales.

Cost of Sales. Cost of sales decreased to $356,000 for the three months ended September 30, 2002 from $410,000 during the same period in 2001. This decrease is due to a decrease in excess capacity production charges, which were lower for this period as compared to the same period in 2001, partially offset by cost of sales increases directly related to increased product revenue. We expect costs of sales to increase in the future with the ramp up and sales of products associated with our SimpleChoice product line.

Research and Development Expenses. Research and development expenses increased to $1.3 million for the three months ended September 30, 2002 compared to $781,000 for the same period in 2001. The increase in research and development expenses was primarily due to $471,000 in costs associated with activities related to

the SimpleChoice products and in reduced expense reimbursements from Abbott due to its assumption of development expense responsibility. We expect research and development expenses to remain at this level in the next quarter as we continue SimpleChoice product launch and development activities.

Sales and Marketing Expenses. Sales and marketing expenses increased to $414,000 during the three months ended September 30, 2002 from $337,000 during the same period in 2001, due to increased marketing relating to our introduction of the SimpleChoice products. Marketing expenses are expected to increase in the future as we launch and market our SimpleChoice product line.

General and Administrative Expenses. General and administrative expenses decreased to $569,000 during the three months ended September 30, 2002 compared to $675,000 incurred during the same period in 2001. The decrease is primarily due to a decrease in costs associated with contractual obligations on certain patent rights. General and administrative expenses are expected to increase in the future with increases in administrative needs related to the SimpleChoice product line.

Net Interest and Other Income. Net interest and other income decreased to about $24,000 for the three months ended September 30, 2002 as compared to $106,000 for the same period in 2001, due to lower cash balances for the period.

COMPARISON OF THE NINE MONTHS ENDED SEPTEMBER 30, 2002 AND 2001.

General. Net loss available to common stockholders increased to $6.8 million during the nine months ended September 30, 2002 as compared to $5.4 million during the same period in 2001. Increased spending associated with the SimpleChoice product line and reductions in expense reimbursements from our collaborative partners were slightly offset by a $1.0 million milestone from Abbott, decreases in excess capacity, and other expense reductions.

Revenue. Total revenue increased to $3.0 million for the nine months ended September 30, 2002 from $1.8 million for the same period in 2001, primarily due to the $1.0 million milestone received from Abbott for our continuous glucose monitoring program. Product revenue increased to $1.9 million for the nine months ended September 30, 2002 from $1.7 million for the same period in 2001. Product revenue is higher for the 2002 period than for the comparable period in 2001, due to the 4% increase in revenues from our BiliChek products, and service business revenues increase of $130,000.

Cost of Sales. Cost of sales decreased to $1.2 million for the nine months ended September 30, 2002 from $1.4 million during the same period in 2001. This decrease is due to a decrease in excess capacity production charges, which were lower for this period than in 2001, partially offset by cost of sales increases directly related to increased product revenue.

Research and Development Expenses. Research and development expenses increased to $4.7 million for the nine months ended September 30, 2002 compared to $3.0 million for the same period in 2001. The increase in research and development expenses was due to $1.3 million in expenses associated with the SimpleChoice products, and reduced expense reimbursements from Abbott, offset by reduced spending on the glucose monitoring program.

Sales and Marketing Expenses. Sales and marketing expenses increased to $1.5 million during the nine months ended September 30, 2002 from $711,000 during the same period in 2001, due to increased marketing activities relating to our introduction of the SimpleChoice products.

General and Administrative Expenses. General and administrative expenses increased to $2.4 million during the nine months ended September 30, 2002 compared to $2.1 million incurred during the same period in 2001. The increase is primarily due to an increase in costs associated with management of the SimpleChoice products.

Net Interest and Other Income. Net interest and other income decreased to about $81,000 for the nine months ended September 30, 2002 as compared to $184,000 for the same period in 2001, due to lower cash balances for the period.

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 September 30, 2002, we received approximately $48.0 million in proceeds from sales of our debt and equity securities. At September 30, 2002, we had cash of approximately $2.3 million and working capital of approximately $1.2 million.

We completed an initial public offering of our common stock on July 7, 1997, which resulted in net proceeds received by us, before expenses related to the transaction, of approximately $14.0 million.

We issued $5.25 million of redeemable convertible preferred stock in November 1999 in conjunction with the execution of amendment to our agreement with Abbott. We issued common stock in a private placement in February 2000, which resulted in gross proceeds of $5.0 million. We issued common stock and warrants in two private placements in June 2001, which resulted in net proceeds of approximately $11.2 million. We issued common stock to Abbott in October 2001 in a private placement, which resulted in gross proceeds of $1 million.

Our major cash flows in the nine months ended September 30, 2002 consisted of cash out-flow of $7.3 million from operations and $157,000 in additions to property and equipment. $1.0 million of the cash out-flow from operations resulted from a prepayment of royalties relating to our agreement with Altea Technologies, Inc.

We have historically received funds also from milestones and reimbursements from our collaborative partners. About 30% of our funds inflow has come from these sources.

We announced subsequent to the end of the third quarter that we planned to sell our BiliChek business as a non-core business to raise additional funds. 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 2002, including the approximately $1.9 million due for the redemption of redeemable convertible preferred stock on December 31, 2002.

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.

RISK FACTORS

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

RISK FACTORS RELATING TO SPECTRX

WE HAVE A SHORT OPERATING HISTORY, WHICH MAKES IT DIFFICULT FOR YOU TO EVALUATE OUR BUSINESS.

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

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

We have never been profitable, and we have had operating losses since our inception. We expect our operating losses to continue as we continue to expend substantial resources to integrate the recently acquired operations of Sterling Medivations and launch the SimpleChoice product line, to complete development of our products, obtain regulatory clearances or approvals, build our marketing, sales, manufacturing and finance organizations, and conduct further research and development. To date, we have engaged primarily in research and development efforts. The further development and commercialization of our products will require substantial development, regulatory, sales and marketing, manufacturing and other expenditures. We have only generated limited revenues from product sales. Our accumulated deficit was about $46 million at September 30, 2002.

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

We will require substantial additional capital to develop our products, including completing product testing and clinical trials, obtaining all required regulatory approvals and clearances, beginning and scaling up manufacturing, and marketing our products. Any failure of our collaborative partners to fund our capital expenditures, or our inability to obtain capital through other sources, would limit our ability to grow and operate as planned. Under our collaborative arrangements with Abbott and Respironics, these collaborative partners will either directly undertake the activities to develop specified products or will fund a substantial portion of the relevant expenditures for the relevant product. The obligations of our collaborative partners to fund our expenditures is largely discretionary and depends on a number of factors, including our ability to meet specified milestones in the development and testing of the relevant product. We may not be able to meet these milestones, or our collaborative partners may not continue to fund our expenditures.

We bear responsibility for all aspects of our SimpleChoice product line and our cervical cancer product, which will not be developed with a collaborative partner. In addition to funds that we expect to be provided by our collaborative partners, we may be required to raise additional funds through public or private financing, additional collaborative relationships or other arrangements. We believe that our existing capital resources and the funding from our collaborative partners will be sufficient to satisfy our funding requirements through 2002, but may not be sufficient to fund our operations to the point of commercial introduction of our glucose monitoring products, our cervical cancer detection product or our full line of diabetes products. Any required additional funding may not be available on terms attractive to us, or at all. To the extent we cannot obtain additional funding, our ability to continue to develop and introduce products to market will be limited. Any additional equity financing may be dilutive to stockholders, and debt financing, if available, may involve restrictive covenants that would limit how we conduct our business or finance our operations.

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

In December 2001, we acquired Sterling Medivations, a start-up medical device company that has developed a portfolio of diabetes products. We call that business and its product line SimpleChoice. SimpleChoice currently has no revenues or significant assets. The SimpleChoice product line is also significantly different from our historical product line, which focuses on non-invasive and minimally invasive products. SimpleChoice's future business will depend on our ability to develop various functions that will enable it to operate as planned, including manufacturing, marketing, and distribution capabilities. There can be no assurance that we, or SimpleChoice, will be able to successfully develop or implement these functions.

We cannot be sure that we will be able to successfully integrate the SimpleChoice business into our operations without substantial costs, delays or other problems. The difficulties of combining operations may be magnified by integrating personnel with differing business backgrounds and corporate cultures. The integration of SimpleChoice may take longer and be more disruptive to our company than originally anticipated and may result in a significant diversion of management attention and operational and financial resources. We and SimpleChoice may not be able to realize the benefits that are expected to be realized. Difficulties encountered in the integration process could have an adverse effect on our business, operations and financial condition.

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

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

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

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

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

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

product and, we believe, our glucose monitoring products will require submission of applications for premarket approval.

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

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

In order for us to market our products in Europe and some other international jurisdictions, we and our distributors and agents must obtain required regulatory registrations or approvals. We must also comply with extensive regulations regarding safety, efficacy and quality in those jurisdictions. We may not be able to obtain the required regulatory registrations or approvals, or we may be required to incur significant costs in obtaining or maintaining any regulatory registrations or approvals we receive. Delays in obtaining any registrations or approvals required to market our products, failure to receive these registrations or approvals, or future loss of previously obtained registrations or approvals would limit our ability to sell our products internationally. For example, international regulatory bodies have adopted various regulations governing product standards, packaging requirements, labeling requirements, import restrictions, tariff regulations, duties and tax requirements. These regulations vary from country to country. In order to sell our products in Europe, we must maintain ISO 9001 certification and CE mark certification, which is an international symbol of quality and compliance with applicable European medical device directives. Failure to receive or maintain ISO 9001 certification or CE mark certification or other international regulatory approvals would prevent us from selling in Europe.

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

We, as well as our collaborative partners, will be required to adhere to applicable FDA regulations regarding good manufacturing practice, which include testing, control, and documentation requirements. We are subject to

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

SINCE WE WILL RELY SIGNIFICANTLY ON OUR COLLABORATIVE PARTNERS TO OBTAIN AND MAINTAIN OUR REGULATORY APPROVALS, ANY FAILURE OF OUR COLLABORATIVE PARTNERS TO PERFORM COULD HURT OUR OPERATIONS.

Because they have primary responsibility for regulatory compliance for some of our product lines, the inability or failure of our collaborative partners to comply with the varying regulations, or the imposition of new regulations, would limit our ability to produce and sell many of our products. We will solely rely upon Abbott to obtain United States and international regulatory approvals and clearances for our glucose monitoring product. Respironics was responsible for the regulatory approvals for our BiliChek product line in the United States. If we move forward with the diabetes detection product under our collaborative agreement with Roche, Roche will be responsible for obtaining United States and international regulatory approvals and clearances. We do not have control over the timing or amount of resources our collaborative partners devote to these activities.

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

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

We have been issued, or have rights to, 40 U.S. patents (including those under license). In addition, we have filed for, or have rights to, 51 U.S. patents (including those under license) that are still pending. There are additional international patents and pending applications. One or more of the patents we hold directly or license

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

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

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

We expect that over half of our revenues in 2003 will come from sales of our new SimpleChoice diabetes product line, which has not been launched yet and some of which is still in development. Our ability to collect revenue from the BiliChek product line and our glucose monitoring product in development depends on our collaborative partners' abilities to generate sales of our products which will provide us with manufacturing revenue and royalties. The revenues that we expect to receive from each of our collaborative partners depend primarily on sales of our products, most of which are still in development. We may not be able to successfully commercialize the products we are developing. Even if we do, we, together with our collaborative partners with respect to products being jointly developed, may not be able to sell sufficient volumes of our products to generate profits for us. In addition, our profit margins on some of our products are not likely to increase over time because they are subject to predetermined royalty rates and manufacturing profit rates.

WE ARE DEVELOPING SOME PRODUCT LINES INDEPENDENTLY FROM ANY COLLABORATIVE PARTNERS, WHICH MAY REQUIRE US TO ACCESS ADDITIONAL CAPITAL

AND TO DEVELOP ADDITIONAL SKILLS TO PRODUCE, MARKET AND DISTRIBUTE THESE PRODUCTS.

We are independently finishing development, building up production capacity, launching, marketing and distributing the SimpleChoice line of products. We also currently expect to commercialize our cervical cancer detection product independently of Welch Allyn, our collaborative partner for the early phases of this product. These activities require additional resources and capital that we will need to secure. There is no assurance that we will be able to raise sufficient capital, attract and retain skilled personnel to enable us to finish development, launch and market these products. Thus, there can be no assurance that we will be able to commercialize all, or any, of these products.

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

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

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

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

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

In addition, one or more of our collaborative partners may, for competitive reasons, reduce their support of their collaborative arrangement with us or support, directly or indirectly, a company or product that competes with our products. This would limit our ability to compete with others.

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

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

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

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

Alternatively, for our products which qualify for premarket notification, the substitute components must meet our product specifications.

Since we are relying on third party manufacturing for our initial product offerings of the SimpleChoice product line, we are dependent upon those parties for product supply. Any delay in initiating production or scaling production to higher volumes could result in delays of product introduction, or create lower availability of product than our expectations. These delays could lead to lower revenue achievement and additional cash requirements for us. We announced at the end of July 2002 that we had experienced some delays in the ramp up of manufacturing that would push off the initial launch of our SimpleChoice easy product offering to at least one quarter past our original expected launch date. We also announced that initial volumes available to us would be at relatively low levels until higher volume productions become available later next year.

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

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

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

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

condition or reputation. In addition, product liability insurance is expensive and may not be available to us on acceptable terms, if at all.

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

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

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

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

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

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

Our directors, executive officers and entities affiliated with them beneficially owned an aggregate of about 28% of our outstanding common stock as of September 30, 2002. These stockholders, acting together, would be able to exert significant influence on substantially all matters requiring approval by our stockholders, including the election of directors and the approval of mergers and other business combination transactions.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISKS

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

ITEM 4. CONTROLS AND PROCEDURES

We maintain a set of disclosure controls and procedures designed to ensure that information required to be disclosed by us in reports that we file or submit under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms. Within the 90-day period prior to the filing of this report, an evaluation was carried out under the supervision and with the participation of our management, including the Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures. Based on that evaluation, the Chief Executive Officer and the Chief Financial Officer have concluded that our disclosure controls and procedures are effective.

Subsequent to the date of their evaluation, there have been no significant changes in our internal controls or in other factors that could significantly affect these controls.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

In September 2001, we announced our agreement with Abbott to postpone payment of a $1.0 million milestone due pursuant to an amendment to our agreement signed September 4, 2001. On May 17, 2002, we notified Abbott that we intended to pursue the alternative dispute resolution provisions of our agreement with Abbott regarding the non-payment of this milestone. We had provided Abbott with notice of our achievement of the milestone, but Abbott had disputed whether we have met the required conditions for the milestone payment and whether it is was due. On September 21, 2002, we received full payment of the $1.0 million milestone.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits

Exhibit Number	Exhibit Description
99.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes- Oxley Act of 2002.
99.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(b) Reports on Form 8-K

The registrant filed a Form 8-K on August 1, 2002 announcing its earnings results for the quarter ending June 30, 2002.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in Norcross, Georgia.

SPECTRX, INC.

Date: November 14, 2002

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

Thomas H. Muller, Jr.
Executive Vice President and Chief Financial Officer
(Duly Authorized Officer and Principal
Financial and Accounting Officer)

CERTIFICATIONS

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

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

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

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

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and

c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 14, 2002

/s/ MARK A. SAMUELS

Mark A. Samuels
Chief Executive Officer

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

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

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

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

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and

c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 14 , 2002

/s/ THOMAS H. MULLER, JR.

Thomas H. Muller, Jr.
Chief Financial Officer

EXHIBIT INDEX

Exhibit Number	Exhibit Description
99.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes- Oxley Act of 2002.
99.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Exhibit 99.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of SpectRx, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2002, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to such officer's knowledge:

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

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of the dates and for the periods expressed in the Report.

Date: November 14, 2002

/s/ MARK A. SAMUELS

Name: Mark A. Samuels
Title: Chief Executive Officer

Exhibit 99.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of SpectRx, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2002, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to such officer's knowledge:

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

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of the dates and for the periods expressed in the Report.

Date: November 14, 2002

/s/ THOMAS H. MULLER, JR.

Name: Thomas H. Muller, Jr.
Title: Chief Financial Officer