SPECTRX INC
Form 424B3
November 15, 2004

Filed Pursuant to Rule 424(b)(3)
Registration No. 333-114772

SPECTRX, INC.

PROSPECTUS SUPPLEMENT NO. 2 DATED NOVEMBER 15, 2004

TO PROSPECTUS DATED SEPTEMBER 3, 2004

Sticker Supplement to Prospectus

This prospectus supplement supplements the prospectus dated September 3, 2004, as supplemented by Supplement No. 1 dated September 8, 2004, relating to up to 11,557,385 shares of our common stock. On November 15, 2004, we filed a quarterly report on Form 10-Q (the "10-Q") for the quarterly period ended September 30, 2004. The text of the 10-Q, including the exhibits thereto, is attached hereto and incorporated herein by reference.

FORM 10-Q

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

(Mark One)

[X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended **September 30, 2004**
OR

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

For the transition period from to

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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. EmployerIdentification Number)

4955 AVALON RIDGE PKWY., SUITE 300
NORCROSS, GEORGIA 30071
(Address of principal executive offices)

(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 filing requirements for the past 90 days.

YES [X] NO [ ]

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

YES [ ] **NO [X]**

The number of issued and outstanding shares of the registrant's common stock, $0.001 par value, as of **October 31, 2004**, was **11,390,079**.

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Part I. Financial Information

Item 1. Financial Statements

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

	December 31, 2003	September 30, 2004 (Unaudited)
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$389	$1,343
Accounts receivable	816	212
Inventories	238	233
Other current assets	1,250	508
Total Current Assets	2,693	2,296
NONCURRENT ASSETS		
Property & equipment, net	494	574
Intangibles, net	3,527	3,291
Other assets	0	83
Total Noncurrent Assets	4,021	3,948

TOTAL ASSETS	
	$6,714
	$6,244
LIABILITIES & STOCKHOLDERS' DEFICIT	
CURRENT LIABILITIES	
Accounts payable	
	$833
	$538
Accrued liabilities	
	1,203
	684
Redeemable preferred stock; current portion	
	1,599
	1,345
Notes payable	
	1,017
	0
Total Current Liabilities	
	4,652
	2,567
COLLABORATIVE PARTNER ADVANCE	
	381
	381

REDEEMABLE PREFERRED STOCK, LESS CURRENT PORTION	
	3,264
	3,382
STOCKHOLDERS' DEFICIT	
Series A convertible preferred stock (liquidation preference $7,330)	
	0
	4,559
Preferred stock	
	1,245
	1,290
Common stock	
	11
	11
Additional paid-in-capital	
	48,335
	51,363
Treasury stock, at cost	
	(95)
	(104)
Deferred compensation	
	(69)
	(35)
Accumulated deficit	
	(51,010)
	(57,170)

Total Stockholders' Deficit		
	(1,583)	
	(86)	
TOTAL LIABILITIES & STOCKHOLDERS' DEFICIT		
	$6,714	
	$6,244	

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2004	2003	2004
Net sales	$209	$276	$1,136	$673
Cost of sales	216	348	708	875
Gross (loss) profit	(7)	(72)	428	(202)
EXPENSES				
Research & development	1,091	922	3,310	2,839
Sales & marketing	191	189	560	545
General & administrative	555	515	1,632	1,435
Total	1,837	1,626	5,502	4,819
Operating loss	(1,844)	(1,698)	(5,074)	(5,021)
GAIN ON SALE OF BILI*CHEK* ™ **PRODUCT LINE**	0	0	1,062	0
INTEREST EXPENSE	(29)	(11)	(98)	(930)
NET LOSS	(1,873)	(1,709)	(4,110)	(5,951)
Preferred stock dividends	(73)	(68)	(226)	(209)
Deemed dividend on series A preferred	0	0	0	(4,970)
Loss attributable to common stockholders	($1,946)	($1,777)	($4,336)	($11,130)
Basic & diluted net loss per share	($0.17)	($0.16)	($0.39)	($0.98)
Basic &diluted weighted average shares outstanding	11,248	11,390	11,258	11,383

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

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

	Nine Months Ended September 30, 2003	2004
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(4,110)	$(5,951)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation & amortization	365	311
Amortization of deferred compensation	87	34
Gain on sale of Bili*Chek* product line	(1,062)	0
Issuance of common stock, options and warrants for services and debt	0	865
Changes in assets and liabilities:		
Accounts receivable	201	604
Inventory	(212)	5
Other current assets	(400)	742
Other assets	0	(83)
Accounts payable	(43)	(295)
Accrued liabilities	(98)	(508)
Total adjustments	(1,162)	1,675
Net cash used in operating activities	(5,272)	(4,276)
CASH FLOW FROM INVESTING ACTIVITIES:		
Additions to property & equipment	(163)	(155)
Cash proceeds from sale of Bili*Chek* product line	4,000	0
Net cash provided by (used in) investing activities	3,837	(155)
CASH FLOW FROM FINANCING ACTIVITIES:		
Proceeds from issuance of Series A convertible preferred stock & warrants	0	5,684
Issuance of common stock	18	18
Proceeds from issuance of notes payable	1,000	0
Issuance (payments) of director's notes	31	(17)
Payment on redeemable preferred stock, current portion	(400)	(300)
Net cash provided by financing activities	649	5,385
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(387)	954
CASH AND CASH EQUIVALENTS, beginning of period	1,287	389
CASH AND CASH EQUIVALENTS, end of period	$900	$1,343

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

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

1. BASIS OF PRESENTATION

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

We have a limited operating history upon which our prospects can be evaluated. Our prospects must be considered in light of the substantial risks, expenses and difficulties encountered by entrants into the medical device industry. This industry is characterized by an increasing number of participants, intense competition and a high failure rate. We have experienced operating losses since our inception, and, as of September 30, 2004, we have an accumulated deficit of $57.2 million. To date, we have engaged primarily in research and development efforts. We first generated revenues from product sales in 1998, but do not have significant experience in manufacturing, marketing or selling our products. Our development efforts may not result in commercially viable products, and we may not be successful in introducing our products. Moreover, required regulatory clearances or approvals may not be obtained in a timely manner, or at all. Our products may not ever gain market acceptance, and we may not ever generate significant revenues or achieve profitability. The development and commercialization of our products will require substantial development, regulatory, sales and marketing, manufacturing and other expenditures. We expect operating losses to continue through at least mid-2005 as we continue to expend substantial resources to complete development of our products, obtain regulatory clearances or approvals, build our marketing, sales, manufacturing and finance organizations and conduct further research and development.

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

Our financial statements have been prepared and presented on a basis assuming we will continue as a going concern. Management believes that the funds from sales and royalty income will not be sufficient to support planned operations through September 30, 2005. Management has implemented operating actions to reduce cash requirements and is evaluating various options to raise additional funds. However, there can be no assurance that we will be able to achieve planned sales volumes or sales volumes sufficient to fund operations through 2005. These conditions raise doubt about our ability to continue as a going concern through September 30, 2005 and possibly thereafter. These financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

2. SIGNIFICANT ACCOUNTING POLICIES

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

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

We use the intrinsic value method for valuing our awards of stock options and restricted stock and recording the related compensation expense, if any, in accordance with Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations. FASB Statement No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure," amends the disclosure provisions of FASB Statement No. 123, "Accounting for Stock-Based Compensation," and APB Opinion No. 28, "Interim Financial Reporting," to require disclosure in the summary of significant accounting policies of the effects of an entity's policy with respect to stock-based employee compensation on reported net income and earnings per share in annual and interim financial statements. For purposes of pro forma disclosures, the estimated fair value of the options is amortized to expense over the options' vesting period. Our pro forma information follows (in thousands, except per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2004	2003	2004
Net loss attributable to common stockholders, as reported	($1,946)	($1,777)	($4,336)	($11,130)
Add: Stock-based employee compensation expense included in reported net loss, net of related tax effects	0	0	0	0
Deduct: Total stock-based employee compensation expense determined under fair value based method of all awards, net of related tax effects	(161)	(82)	(493)	(243)
Pro forma net loss	($2,107)	($1,859)	($4,829)	($11,373)
Loss per share:				
Basic & diluted, as reported	($0.17)	($0.16)	($0.39)	($0.98)
Basic & diluted, pro forma	($0.19)	($0.16)	($0.43)	($1.00)

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

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

material, because we have no variable interest entities.

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

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

3. STERLING MEDIVATIONS

On December 31, 2001, we purchased the outstanding shares of Sterling, now doing business as SimpleChoice. Sterling was a developer of innovative insulin delivery products for people with diabetes. The acquisition of Sterling expanded our diabetes business by adding a portfolio of insulin delivery products, cleared by the Food and Drug Administration, including consumables for the rapidly growing insulin pump market. As a result of the merger, we issued a total of 612,562 shares of our common stock in exchange for all of the outstanding Sterling common stock and preferred stock and reserved 22,151 shares of our common stock for issuance upon exercise of stock options assumed in the merger with an estimated fair market value of $62,159. Sterling stockholders and option holders will be entitled to receive up to an aggregate of 1,234,567 additional shares of our common stock in the future if the SimpleChoice product line achieves specified financial goals. As of September 30, 2004, such goals were not met; as a result, no additional shares have been issued. In connection with the acquisition of Sterling, we entered into employment agreements with four employees for terms which expired in June 2003. The excess of the cost over the estimated fair value of net tangible assets acquired amounts to approximately $4.1 million and has been included in intangible assets in the accompanying consolidated balance sheets. The $4.1 million purchase price excess has been allocated between patents and non-compete agreements. Accumulated amortization of our intangible assets as of September 30, 2004 is approximately $899,000. The acquisition has been accounted for as a purchase in accordance with SFAS No. 141, "Accounting for Business Combinations."

4. LITIGATION

In January 2003, we announced that we had given notice that we were initiating actions required to terminate our research, development and license agreement with Abbott Laboratories, Inc. ("Abbott") to jointly develop a continuous glucose monitor. We further announced that we were withholding payment due in connection with the redemption of the shares of our preferred stock held by Abbott as an offset to claims which have also been made by us under our agreement with Abbott. Under the terms of the preferred stock, 162,500 shares of our preferred stock were required to be redeemed on December 30, 2002 at $10 per share. We also announced that we had asked the U.S. patent office to resolve an inventorship dispute involving issued Abbott patents related to Abbott's glucose monitoring technology. Abbott exercised its right to terminate the agreement on January 7, 2003. We filed a Form 8-K on March 10, 2003, announcing that we had reached a settlement with Abbott Laboratories regarding the disputes in connection with the prior termination of the parties' Research & Development and License Agreement and the election of Abbott

to have shares of our preferred stock redeemed, with 162,500 shares to be redeemed on December 30, 2002 at $10 per share, plus accrued dividends, and the remaining shares to be redeemed no later than January 31, 2004. Under the settlement, which included mutual releases, we have agreed to make quarterly payments to Abbott during 2003 and 2004 and end of the year lump sum payments in 2005 and 2006 to redeem 425,000 preferred shares and to pay approximately $0.7 million, $1.3 million, $1.8 million and $1.9 million for 2003, 2004, 2005 and 2006, respectively. We paid $400,000 and $300,000 to Abbott pursuant to the settlement during 2003 and in the first quarter of 2004, respectively. Under the settlement, neither party admitted any liability or wrongdoing.

We have been in negotiations with Abbott since early 2003 regarding the patent issue and the payments and terms under the settlement. On July 15, 2004 Abbott sent us a letter notifying us that we were in default on two separate payments due in 2004 and demanding payment. On July 22, 2004 we responded that we were seeking to resolve the patent issues and renegotiate the payment terms. Under our settlement agreement, we are accruing interest on the payments of 1% per month. On October 25, 2004, Abbott sent us a letter notifying us that we were in default on an additional payment due in 2004 and demanding payment. We have again responded that we expect to continue to seek to resolve the patent issues and renegotiate the payment terms.

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

5. STOCKHOLDERS' EQUITY

Common Stock

During the year ended December 31, 2003, we issued 10,417 unregistered shares of common stock valued at $16,000 in satisfaction of minimum royalty payments related to our exclusive rights to certain licensed patents and issued 103,647 shares of common stock valued at $132,000 for services.

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

6. PREFERRED STOCK

Redeemable Convertible Preferred Stock

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

In November 1999, the board of directors designated 525,000 shares of the preferred stock as redeemable convertible preferred stock. Dividends are payable annually in cash or additional shares of the preferred stock at a rate of 6% per annum. During the years ended December 31, 2001, 2002 and 2003, we accrued dividends in the form of shares of redeemable convertible preferred stock of $315,000, $315,000 and $299,000, respectively. The shares of preferred stock, together with any accrued but unpaid dividends, are convertible into shares of common stock at the greater of $9.39 per share or the average of the closing sales price for 15 days prior and 15 days subsequent to the conversion and automatically convert on December 31, 2004 at the then conversion rate. The shares were mandatorily redeemable at $10 per share, plus accrued but unpaid dividends, at the later of September 30, 2002 or 60 days subsequent to the date upon which we give notice to the holder of its right to redeem the shares. The shares have a liquidation preference

of $10 per share, plus all accrued but unpaid dividends.

In November 1999, Abbott, a former collaborative partner, subscribed to 525,000 shares of redeemable convertible preferred stock for consideration of $5,250,000, of which $2,750,000 was received in November 1999 and $2,500,000 was received in January 2000.

In September 2001, we entered into an agreement with Abbott whereby Abbott waived its right to redeem 100,000 shares of its redeemable convertible preferred stock plus the related accrued but unpaid dividends.

In September 2002, Abbott delivered notice of its election to cause the redemption of the 425,000 shares of redeemable convertible preferred stock eligible for redemption. On March 7, 2003, we reached a settlement with Abbott regarding the disputes in connection with the prior termination of the parties' Research & Development and License Agreement and the election of Abbott to have us redeem the shares of preferred stock. Abbott had previously elected to have 425,000 shares of preferred stock redeemed, with 162,500 shares to be redeemed on December 30, 2002 at $10.00 per share, plus accrued dividends, and the remaining shares to be redeemed no later than January 31, 2004. Under the settlement, which included mutual releases, we agreed to make quarterly cash payments to Abbott during 2003 and 2004 and end of the year lump sum payments in 2005 and 2006 to redeem 425,000 shares of preferred stock and to pay accrued dividends as to such shares. We have paid $700,000 to Abbott through September 30, 2004. Our remaining yearly financial obligations to Abbott under the agreement are approximately $1.3 million, $1.8 million and $1.9 million during 2004, 2005 and 2006, respectively. Under the settlement, neither party admitted any liability or wrongdoing.

We have been in negotiations with Abbott since early 2003 regarding the patent issue described in Note 4 and the payments and terms under the settlement. On July 15, 2004 Abbott sent us a letter notifying us that we were in default on two separate payments due in 2004 and demanding payment. On July 22, 2004 we responded that we were seeking to resolve the patent issues and renegotiate the payment terms. On October 25, 2004, Abbott sent us a letter notifying us that we were in default on an additional payment due in 2004 and demanding payment. We have again responded that we expect to continue to seek to resolve the patent issues and renegotiate the payment terms.

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

Series A Convertible Preferred Stock

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

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

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

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

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

7. WARRANTS

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

8. DEBT

On July 30, 2003, for the purposes of obtaining short-term financing until permanent financing could be secured, we entered into separate promissory note agreements with a group of individuals that aggregated $1.0 million. The notes bore interest at 12% per annum and matured on January 31, 2004. In accordance with the terms of the promissory note agreements, we issued warrants, exercisable at $2.25 per share at any time after January 30, 2004 until July 30, 2007, to the group of individuals for each month the notes were outstanding. As of September 30, 2004, 260,000 warrants have been issued. On February 6, 2004, we entered into separate promissory note agreements with a group of individuals that aggregated $1.0 million, which liquidated the aforementioned notes. These notes bore interest at 15% per annum and had a scheduled maturity of June 26, 2004. In accordance with the terms of the promissory note agreements, the Company issued warrants for 500,000 shares exercisable at $2.00 per share at any time after February 6, 2004 until February 5, 2009, to the group of individuals. On March 26, 2004, these notes were surrendered in connection with the series A convertible preferred stock financing. During the first quarter of 2004, we recorded approximately $871,000 as interest expense for the estimated fair value of the warrants to purchase 635,000 common shares issued during the quarter, as determined under the Black-Sholes option-pricing model.

9. SALE OF BILI*CHEK* PRODUCT LINE

On March 6, 2003, we sold our Bili*Chek* Non-invasive Bilirubin Analyzer product line and related assets to Respironics. Respironics had previously been our exclusive U.S. licensee and distributor of the product line. The base cash purchase price was $4 million with an additional $1 million to be paid based upon completion of certain product

development work, and up to an additional $6.25 million to be paid in royalties and earn out payments over the next five years based upon the achievement of certain operating results by Respironics. The purpose of the sale of the Bili*Chek* products was to enable us to focus on expanding our diabetes and cancer detection businesses.

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

On October 14, 2004, Respironics notified us that an allegation of patent infringement related to the Bili*Chek* product had been made and that it believed that this action was subject to the indemnification provision of our asset sale agreement. The allegation relates to a patent filed more than one year after the Bili*Chek* was launched. Management believes that the infringement claim is without merit and is working with Respironics to resolve the question of infringement.

10. GUARANTEES

In November 2002, the FASB issued Interpretation No. 45. Interpretation No. 45 elaborates on the existing disclosure requirements for most guarantees, including loan guarantees such as standby letters of credit. It also clarifies that at the time a company issues a guarantee, the company must recognize an initial liability for the fair value, or market value, of the obligations it assumes under the guarantee and must disclose that information in its interim and annual financial statements. The provisions related to recognizing a liability at inception of the guarantee for the fair value of the guarantor's obligations do not apply to product warranties or to guarantees accounted for as derivatives. The initial recognition and initial measurement provisions apply on a prospective basis to guarantees issued or modified after December 31, 2003. The adoption of Interpretation No. 45 did not have a material impact on our results of operations or financial condition and did not result in any additional liabilities as of September 30, 2004 associated with guarantees covered by this interpretation.

Warranty

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

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

Balance, December 31, 2003	$28
Accruals for warranties issued during the period	0
Settlements made (in cash or in kind) during the period	0
Balance, September 30, 2004	$28

11. LOSS PER COMMON SHARE

Loss per common share is computed using SFAS No. 128, "Earnings per Share." SFAS No. 128 established standards for the computation, presentation and disclosure of earnings per share. Basic loss per share amounts are computed by dividing the net loss by the weighted average number of common shares outstanding during the periods. Dilutive earnings per share calculations include the potential exercise of outstanding stock options, warrants and convertible securities. The effects of stock options, warrants and convertible securities have not been included in our 2004 and

2003 loss per share computations as their effect would have been anti-dilutive. Potential common shares totaling 13,101,736, which consist of the common stock underlying all outstanding stock options, preferred stock and warrants, are considered to be anti-dilutive for the three months and nine months ended September 30, 2004.

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 ("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 our annual report on Form 10-K for the year ended December 31, 2003.

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

OVERVIEW

We were incorporated on October 27, 1992, and since that date we have raised capital through the sale of preferred stock, issuance of debt securities, public and private sales of common stock and warrants, 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 Laboratories, Inc. ("Abbott"), Welch Allyn, Inc. ("Welch Allyn") and Respironics, Inc. ("Respironics") for our continuous glucose monitoring, cervical cancer detection product and Bili*Chek* products, respectively. Over the past two years, we have sold our Bili*Chek* business to our collaborative partner, Respironics, and have agreed to terminate our collaborative relationships with Abbott for our continuous glucose monitoring product and with Welch Allyn for our cervical cancer detection product. In addition, we have a collaborative agreement with Roche Diagnostics BMC related to a diabetes detection product, although there is currently no development or marketing activity with regard to this product, and we expect no revenue from this product in the foreseeable future. We are pursuing a collaborative partner for our glucose monitoring product, and we may seek to establish strategic relationships with other leading companies for the development, commercialization, and introduction of additional products, if it is the best path to commercialization for those products. In addition, we are seeking venture capital funding for our non-invasive cervical cancer technology.

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

We have a limited operating history upon which our prospects can be evaluated. Our prospects must be considered in light of the substantial risks, expenses and difficulties encountered by entrants into the medical device industry. This industry is characterized by an increasing number of participants, intense competition and a high failure rate. We have experienced operating losses since our inception, and, as of September 30, 2004, we have an accumulated deficit of about $57.2 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 mid-2005 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 SimpleChoice products to distributors, which then distribute our products, resulting in revenues from distributor sales. The channels for sales of our future glucose monitoring and cervical cancer detection products are not currently established. The royalties and earn out that we expect to receive from Respironics depend on sales of the applicable Bili*Chek* products. We, or any collaborative partner we secure, 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 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 is limited. As we begin to generate increased revenue from different sources, we expect that the number of applicable policies and complexity of the judgments required will increase.

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

Revenue Recognition: We recognize revenue from sales of products or services upon shipment of products or delivery of services. We also have recognized milestone revenue from our collaborative partners when a milestone was accomplished or when we, and our partner, agreed that a milestone was due. We recognize royalty revenue on the disposable product in the Bili*Chek* line, the Bili*Cal,* when earned as and when communicated from Respironics.

Reserves 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.

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

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

QUARTER OVERVIEW

On August 11, 2004 we announced the commencement of the pivotal clinical trial necessary for FDA approval for our non-invasive cervical cancer detection device. The University of Texas Medical Center in Dallas is conducting the clinical study at Parkland Hospital in Dallas. The clinical trial is being primarily supported by a grant from the National Cancer Institute ("NCI"). An additional NCI grant will support product engineering and commercialization work.

On September 9, 2004, we announced the launch of our new SimpleChoice® *easy* and *easy* Pr*o* insulin pump infusion sets with shorter catheters. The less invasive catheters, which are about 25 percent shorter than standard catheters, are designed for a more comfortable insertion and wearing experience for people with diabetes who use insulin pumps. The new infusion sets are for use with insulin pumps made by Medtronic®, Deltec®, Animas® and Disetronic®.

On September 15, 2004, we announced that we received CE Mark approval for our SimpleChoice® line of insulin pump supplies. The CE Mark award allows the sale of SimpleChoice® insulin pump infusion sets and reservoirs in the European Union.

RESULTS OF OPERATIONS

COMPARISON OF THE THREE MONTHS ENDED SEPTEMBER 30, 2004 AND 2003.

General. Net loss attributable to common stockholders was $1.8 million during the three months ended September 30, 2004 as compared to a net loss attributable to common stockholders of $1.9 million for the same period in 2003. The reduction in loss is primarily due to reduced research and development expenses.

Net loss was $1.7 million during the three months ended September 30, 2004, as compared to a net loss of $1.9 million for the same period in 2003. Product revenue increased to $276,000 from $209,000. Gross profit decreased from a loss of $7,000 in the third quarter of 2003 to a loss of $72,000 in the third quarter of 2004. Operating expense was $211,000 less in the third quarter of 2004 than the same period in 2003. Operating loss in the third quarter of 2004 as a result was $1.7 million as compared to $1.8 million in the third quarter of 2003.

Revenue. Product revenue increased to $276,000 for the quarter ended September 30, 2004 from $209,000 for the same period in 2003. Product revenue is higher for the 2004 quarter than for the comparable period in 2003 due to the increase in SimpleChoice product revenue.

Cost of Sales. Cost of sales increased to $348,000 for the three months ended September 30, 2004 from $216,000 for the same period in 2003. The increase is primarily due to higher sales, but also due to lower current margins. The primary reason for the gross loss during the quarter is the fixed production overhead, which is not completely absorbed by current low volumes. 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 decreased to $922,000 for the three months ended September 30, 2004 compared to $1.1 million for the same period in 2003. The reduction in expenses is primarily due to lower cancer research and development expense during 2004, due to funding from grants and contracts, and the elimination of Bili*Chek*. We expect research and development expenses to remain at a high level this year as we continue development in our diabetes management business.

Sales and Marketing Expenses. Sales and marketing expenses remained approximately the same at $189,000 during the three months ended September 30, 2004 from $191,000 for the same period in 2003. Marketing expenses are expected to increase in the future as we continue to market and sell our SimpleChoice product line.

General and Administrative Expenses. General and administrative expenses decreased to $515,000 during the three months ended September 30, 2004 compared to $555,000 for the same period in 2003. The reductions are primarily due to expense reduction in our investor relations spending. General and administrative expenses are expected to increase in the future with increases in SimpleChoice administrative needs.

Net Interest and Other Expense. Net interest and other income improved to an expense of $11,000 for the three months ended September 30, 2004 as compared to an expense of $29,000 for the same period in 2003. The reduction in the interest expense is due to the conversion of notes payable, which were outstanding in 2003, into preferred stock in March of 2004.

COMPARISON OF THE NINE MONTHS ENDED SEPTEMBER 30, 2004 AND 2003.

General. Net loss attributable to common stockholders was $11.1 million during the nine months ended September 30, 2004 as compared to a net loss attributable to common stockholders of $4.3 million for the same period in 2003. During 2004, we recognized a deemed dividend of $5.0 million from issuance of shares of our series A convertible preferred stock. Also during 2004, we recognized $871,000 interest expense for the value of the warrants issued in connection with a bridge loan.

Revenue. Product revenue decreased to $673,000 for the nine months ended September 30, 2004 from $1.1 million for the same period in 2003. Because the Bili*Chek* product line was sold in March 2003, there were no Bili*Chek* revenues for the nine months ended September 30, 2004, versus $684,000 for the same period in 2003. SimpleChoice sales were $442,000 for the nine months ended September 30 2004, versus $126,000 for the same period in 2003.

Cost of Sales. Cost of sales increased to $875,000 for the nine months ended September 30, 2004 from $708,000 for the same period in 2003. The increase is due to increased costs for higher volumes of SimpleChoice products, offset by a decrease of Bili*Chek* costs due to the sale of that product line in 2003.

Research and Development Expenses. Research and development expenses decreased to approximately $2.8 million for the nine months ended September 30, 2004 compared to $3.3 million for the same period in 2003. The decrease in research and development expenses was primarily due to the elimination of the Bili*Chek* research and development program in 2004.

Sales and Marketing Expenses. Sales and marketing expenses slightly decreased to $545,000 during the nine months ended September 30, 2004 from $560,000 for the same period in 2003, due to the reduction of our Bili*Chek* marketing function.

General and Administrative Expenses. General and administrative expenses decreased to $1.4 million during the nine months ended September 30, 2004 compared to $1.6 million for the same period in 2003. The decrease is primarily due to a decrease in costs associated with salaries of $62,000 and outside services and consulting fees of $188,000, offset by an increase in rent expense of $152,000.

Net Interest and Other Income. Net interest and other income decreased to an expense of $930,000 for the nine months ended September 30, 2004 as compared to an expense of $98,000 for the same period in 2003. The primary causes of this decrease are the recognition of interest expense for the warrants issued related to the bridge loan during the first quarter of 2004.

For the nine months ending September 30, 2003, we recognized about $1.1 million in gain on the sale of our Bili*Chek* product line.

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, 2004, we received approximately $62.3 million in proceeds from sales of our debt and equity securities. At September 30, 2004, we had cash of approximately $1.3 million and a working capital deficit of approximately $271,000.

In August 2002, Abbott notified us that it intended to redeem the $4.25 million of redeemable convertible preferred stock eligible to be redeemed. Under a settlement agreement related to the termination of our collaborative arrangement with Abbott, we agreed with Abbott to redeem the 425,000 shares of preferred stock on an extended schedule through 2006. We paid Abbott the amounts under that agreement for items due through December 31, 2003 and pursued additional negotiations for amounts due in 2004 and beyond. We have been in negotiations with Abbott since early 2003 regarding a patent issue and the payments and terms under the settlement. On July 15, 2004 Abbott sent us a letter notifying us that we were in default on two separate payments due in 2004 and demanding payment. On July 22, 2004 we responded that we were seeking to resolve other issues and renegotiate the payment terms. Under our settlement agreement, we are accruing interest on the payments of 1% per month. On October 25, 2004, Abbott sent us a letter notifying us that we were in default on an additional payment due in 2004 and demanding payment. We have again responded that we expect to continue to seek to resolve the patent issues and renegotiate the payment terms. (see Part II, Item 1. - Legal Proceedings)

Our major cash flows in the nine months ended September 30, 2004 consisted of cash out-flow of $4.3 million from operations and $5.4 million of cash flow from financing activities. The largest portion of the cash outflow from operations was due to accrued payables paid after March 26, 2004 and the reduction of accounts payable. The cash flow from financing was primarily due to the private placement completed on March 26, 2004

We have historically also received funds from milestones and reimbursements from our collaborative partners. About 30% of our funds inflow has come from these sources prior to 2003. We are currently seeking a collaborative partner for our glucose monitoring technology. Until we reach an agreement with a new partner, we expect no such milestones or reimbursements. We have been successful in securing grants to support some of our programs, including a $1.3 million grant, which began in February 2003, 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.

We announced on March 26, 2004 that we had completed a private placement to institutional and private investors of a new series of our preferred stock and of warrants to purchase shares of our 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 represented 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 our common stock at a price of $1.65 per share, and the other half, at $2.25 per share.

During the next twelve months we will be required to raise additional funds through public or private financing, additional collaborative relationships or other arrangements in addition to those sources. Management believes that the funds from sales and royalty income will not be sufficient to support planned operations through September 30, 2005. Management has implemented operating actions to reduce cash requirements and is evaluating various options to raise additional funds. However, there can be no assurance that we will be able to achieve planned sales volumes or sales volumes sufficient to fund operations through 2005. These conditions raise doubt about our ability to continue as a going concern through September 30, 2005 and possibly thereafter.. The level of funds needed depends on our ability to introduce products, reach expected sales goals and manage costs according to our plan. If we experience delays, fall short of our plan, incur additional costs or require additional working capital, we will need to raise additional funds. If we are unable to satisfactorily resolve our differences with Abbott regarding the schedule of payments for the redemption of the redeemable preferred shares, we will need to raise additional funds. We also need to secure a collaborative partner to move forward with our continuous glucose monitoring program and will need funding in addition to that provided by grants to complete our pivotal trials for our cervical cancer product in a timely fashion. Any required additional funding may not be available on terms attractive to us or at all.

We currently invest our excess cash balances primarily in short-term, investment-grade, interest-bearing obligations or direct or guaranteed obligations of the U.S. government until such funds are utilized in operations. Substantial capital will be required to develop our products, including completing product testing and clinical trials, obtaining all required United States and foreign regulatory approvals and clearances, and commencing and scaling up manufacturing and marketing our products. Any failure of our potential 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

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

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

Management believes that the funds from sales and royalty income will not be sufficient to support planned operations through September 30, 2005. Management has implemented operating actions to reduce cash requirements and is evaluating various options to raise additional funds. In addition, if we experience delays or if we are unable to satisfactorily resolve our differences with Abbott regarding the schedule of payments for the redemption of the redeemable preferred shares, we will need to raise greater additional funds. Any required additional funding may not be available on terms attractive to us or at all.

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

Because we must execute our plans to launch our remaining products in our SimpleChoice product line and grow our revenues to sufficiently higher levels to generate profits and cash flow from operations, there exists doubt about our ability to continue as a going concern. Management believes funds from sales and royalty revenue will not be sufficient to support planned operations through September 30, 2005. There can be no assurance that we will be able

to raise additional funds. If we do not meet these targets, we will need to seek additional funding. If we do not secure additional funding, we will be unable to conduct all of our product development efforts as planned, which may cause us to alter our business plan in relation to the development of all of our products. Even if we obtain additional funding, we will need to achieve profitability thereafter.

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

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

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

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

We have never been profitable, and we have had operating losses since our inception. We expect our operating losses to continue as we continue to expend substantial resources to launch the SimpleChoice product line, to complete development of our products, obtain regulatory clearances or approvals, build our marketing, sales, manufacturing and finance organizations, and conduct further research and development. To date, we have engaged primarily in research and development efforts. The further development and commercialization of our products will require substantial development, regulatory, sales and marketing, manufacturing and other expenditures. We have only generated limited revenues from product sales. Our accumulated deficit was about $57.2 million at September 30, 2004.

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

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

We bear responsibility for all aspects of our SimpleChoice product line and our cervical cancer product, which are not being developed with a collaborative partner. In addition to any funds that may be provided by collaborative partners, we will be required to raise additional funds through public or private financing, additional collaborative relationships or other arrangements. We believe that our existing capital resources, and the funding from prospective collaborative partners will be sufficient to satisfy our funding requirements through 2004, but may not be sufficient to fund our operations to the point of commercial introduction of our glucose monitoring products, our cervical cancer detection

product or our full line of diabetes products. Any failure to agree on a collaborative arrangement or to achieve adequate funding in a timely fashion would delay our development programs and could lead to abandonment of one or more of our development initiatives. Any required additional funding may not be available on terms attractive to us, or at all. To the extent we cannot obtain additional funding, our ability to continue to develop and introduce products to market will be limited. Any additional equity financing may be dilutive to stockholders, and debt and certain types of equity financing, if available, may involve restrictive covenants or other provisions that would limit how we conduct our business or finance our operations.

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

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

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

Prior to our acquisition of the SimpleChoice product line, it did not have revenues or significant assets. The SimpleChoice product line is also significantly different from our historical product line, which focuses on non-invasive and minimally invasive products. We shipped small quantities of our first SimpleChoice products to be introduced to the market during 2003. SimpleChoice's future business will depend on our ability to develop more fully various functions that will enable it to operate as planned, including manufacturing, marketing, and distribution capabilities. There can be no assurance that we, or our subsidiary doing business as SimpleChoice, will be able to successfully develop or implement these functions.

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

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

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

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

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

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

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

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

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

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

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

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

We, as well as our potential collaborative partners, will be required to adhere to applicable FDA regulations regarding good manufacturing practice, which include testing, control, and documentation requirements. We are subject to similar regulations in foreign countries. Ongoing compliance with good manufacturing practice and other applicable

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

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

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

We have been issued, or have rights to, 38 U.S. patents (including those under license). In addition, we have filed for, or have rights to, 30 U.S. patents (including those under license) that are still pending. There are additional international patents and pending applications. One or more of the patents we hold directly or license from third parties, including those for the disposable components to be used with our glucose monitoring, infant jaundice and insulin delivery products, may be successfully challenged, invalidated or circumvented, or we may otherwise be unable to rely on these patents. These risks are also present for the process we use or will use for manufacturing our products. In addition, our competitors, many of whom have substantial resources and have made substantial investments in competing technologies, may apply for and obtain patents that prevent, limit or interfere with our ability to make, use and sell our products, either in the United States or in international markets.

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

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

We expect that the majority of our revenues in 2004 will come from sales of our new SimpleChoice diabetes product line, which has just been launched and some of which is still in development. We sold our Bili*Chek* product line in 2003 and will not have continuing revenue from that source other than future earn out payments. Although we

received a payment for royalties and earn out of $655,000 in the first quarter of 2004, there can be no assurance of additional payments. Our ability to collect additional earn out payments from the Bili*Chek* product line depends on Respironics' efforts in conducting that business. Our glucose monitoring product in development depends on finding a new partner and the collaborative partner's ability to generate sales of our products, which will provide us with revenue. We may not be able to successfully commercialize the products we are developing. Even if we do, we, together with any collaborative partners with respect to products being jointly developed, may not be able to sell sufficient volumes of our products to generate profits for us.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

On March 26, 2004, we entered into agreements with investors to raise capital in a private placement of our series A convertible preferred stock and warrants. As a result of this private placement transaction, there are 488,669 shares of our series A convertible preferred stock outstanding convertible into 4,886,690 shares of our common stock at a conversion price of $1.50 per share, plus warrants exercisable for 2,443,345 shares of our common stock at an

exercise price of $1.65 per share and warrants exercisable for 2,443,345 shares of our common stock at an exercise price of $2.25 per share. The conversion price for the series A convertible preferred stock and the exercise price for the warrants may be lowered under certain price adjustment provisions in the certificate of designations relating to the series A convertible preferred stock and the warrants if we issue common stock at a per share price below the then conversion price for the series A convertible preferred stock.

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

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

Our directors, executive officers and entities affiliated with them beneficially owned an aggregate of about 27% of our outstanding common stock as of September 30, 2004. These stockholders, acting together, would be able to exert significant influence on substantially all matters requiring approval by our stockholders, including the election of directors and the approval of mergers and other business combination transactions.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

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. We carried out an evaluation under the supervision and with the participation of our management, including the Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures. Based on that evaluation, the Chief Executive Officer and the Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of September 30, 2004.

There have been no changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2004 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

In January 2003, we announced that we had given notice that we were initiating actions required to terminate our research, development and license agreement with Abbott to jointly develop a continuous glucose monitor. We further announced that we were withholding payment due in connection with the redemption of the shares of our preferred stock held by Abbott as an offset to claims which have also been made by us under our agreement with Abbott. Under the terms of the preferred stock, 162,500 shares of our preferred stock were required to be redeemed on December 30, 2002 at $10 per share. We also announced that we had asked the U.S. patent office to resolve an inventorship dispute involving issued Abbott patents related to Abbott's glucose monitoring technology. Abbott exercised its right to terminate the agreement on January 7, 2003. We filed a Form 8-K on March 10, 2003, announcing that we had reached a settlement with Abbott Laboratories regarding the disputes in connection with the prior termination of the parties' Research & Development and License Agreement and the election of Abbott to have shares of our preferred stock redeemed, with 162,500 shares to be redeemed on December 30, 2002 at $10 per share, plus accrued dividends, and the remaining shares to be redeemed no later than January 31, 2004. Under the settlement, which included mutual releases, we have agreed to make quarterly payments to Abbott during 2003 and 2004 and end of the year lump sum payments in 2005 and 2006 to redeem 425,000 preferred shares and to pay approximately $0.7 million, $1.3 million, $1.8 million and $1.9 million for 2003, 2004, 2005 and 2006, respectively. We paid $400,000 and $300,000 to Abbott pursuant to the settlement, respectively, during 2003 and in the first quarter of 2004. Under the settlement, neither party admitted any liability or wrongdoing.

We have been in negotiations with Abbott since early 2003 regarding the patent issue and the payments and terms under the settlement. On July 15, 2004 Abbott sent us a letter notifying us that we were in default on two separate payments due in 2004 and demanding payment. On July 22, 2004 we responded that we were seeking to resolve the patent issues and renegotiate the payment terms. On October 25, 2004, Abbott sent us a letter notifying us that we were in default on an additional payment due in 2004 and demanding payment. We have again responded that we expect to continue to seek to resolve the patent issues and renegotiate the payment terms.

On October 14, 2004, Respironics notified us that an allegation of patent infringement related to the Bili*Chek* product had been made and that it believed that this action was subject to the indemnification provision of our asset sale agreement. The allegation relates to a patent filed more than one year after the BiliChek was launched. Management believes that the infringement claim is without merit and is working with Respironics to resolve the question of infringement.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

As a result of the disputes and settlement with Abbott described in "Item 1. - Legal Proceedings," we did not redeem the shares of redeemable convertible preferred stock subject to redemption or pay the accrued dividends of $250,000 at December 30, 2002. Under the settlement with Abbott, we have agreed to make certain payments to Abbott in connection with the redemption of these shares. As described in Part II, Item 1 "Legal Proceedings", Abbott has sent us a notice of default on three of those payments, the terms of which we are attempting to renegotiate.

ITEM 6. EXHIBITS

Exhibit Number	Exhibit Description
10.1	Form of Option Agreement under 1995 Stock Option Plan
31.1	Rule 13a-14(a)/15d-14(a) Certification
31.2	Rule 13a-14(a)/15d-14(a) Certification

32.1	Section 1350 Certification
32.2	Section 1350 Certification

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.

Date: November 15, 2004

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)

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