

UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

**Form 10-QSB**

X QUARTERLY REPORT UNDER TO SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934

**For the quarterly period ended December 31, 2003**

— TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
**Commission File Number 000-24541**

**CORGENIX MEDICAL CORPORATION**

(Name of Small Business Issuer in its Charter)

**Nevada**

**93-1223466**

(State or other jurisdiction of  
incorporation or organization)

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

**12061 Tejon Street, Westminster, Colorado 80234**

(Address of principal executive offices, including zip code)

**(303) 457-4345**

(Issuer's telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report)

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

The number of shares of Common Stock outstanding in the public float was 2,785,185 as of December 31, 2003.

Transitional Small Business Disclosure Format. Yes  No

# CORGENIX MEDICAL CORPORATION

December 31, 2003

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**PART I**  
**Item 1. Consolidated Financial Statements**  
**CORGENIX MEDICAL CORPORATION**  
**AND SUBSIDIARIES**  
**Consolidated Balance Sheets**

	<u>December 31,</u>	<u>June 30, 2003</u>
	<u>2003</u>	
	(Unaudited)	
<b>Assets</b>		
Current Assets:		
Cash and equivalents	\$ 255,223	342,377
Accounts receivable, less allowance for doubtful accounts of \$13,000	592,304	628,717
Inventories	833,065	815,222
Prepaid expenses	42,258	42,788
Total current assets	1,722,850	1,829,104
Equipment:		
Capitalized software costs	122,855	122,855
Machinery and laboratory equipment	585,935	585,935
Furniture, fixtures, leaseholds and office equipment	509,597	503,787
	1,218,387	1,212,577
Accumulated depreciation and amortization	(852,484)	(789,564)
Net equipment	365,903	423,013
Intangible assets:		
Patents, net of accumulated amortization of \$982,226 and \$944,978	135,318	172,566
Goodwill, net of accumulated amortization of \$44,979	13,677	13,677
Net intangible assets	148,995	186,243
Due from officer	12,000	12,000
Other assets	111,890	105,356
Total assets	<u>\$2,361,638</u>	<u>2,555,716</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Current portion of notes payable	\$ 521,459	378,683
Current portion of capital lease obligations	82,435	95,881
Accounts payable	495,081	618,934
Accrued payroll and related liabilities	180,917	180,630
Accrued interest	113,147	99,660
Accrued liabilities	138,110	105,392
Total current liabilities	1,531,149	1,479,180
Notes payable, less current portion	306,981	373,167
Capital lease obligations, less current portion	26,759	61,504
Total liabilities	<u>1,864,889</u>	<u>1,913,851</u>
Redeemable common stock, 880,282 shares issued and outstanding, aggregate redemption value of \$500,000, net of unaccreted discount and issuance costs of \$108,197 and \$151,474	391,803	348,526
Stockholders' equity:		
Preferred stock, \$0.001 par value. Authorized 5,000,000 shares, none issued or outstanding	-	-
Common stock, \$0.001 par value. Authorized 40,000,000 shares; issued and outstanding 5,299,671 and 5,271,192 shares at December 31 and June 30, respectively	4,419	4,391
Additional paid-in-capital	4,937,468	4,930,576
Accumulated deficit	(4,826,475)	(4,642,297)
Accumulated other comprehensive income (loss)	(10,466)	669
Total stockholders' equity	104,946	293,339
Total liabilities and stockholders' equity	<u>\$2,361,638</u>	<u>2,555,716</u>

See accompanying notes to consolidated financial statements.

**CORGENIX MEDICAL CORPORATION  
AND SUBSIDIARIES**  
Consolidated Statements of Operations and Comprehensive Income

	Three Months Ended		Six Months Ended	
	December 31, 2003	December 31, 2002	December 31, 2003	December 31, 2002
	(Unaudited)		(Unaudited)	
Net sales	\$ 1,186,738	1,323,529	2,389,068	2,733,569
Cost of sales	446,129	464,353	917,805	876,173
Gross profit	\$ 740,609	859,176	1,471,263	1,857,396
Operating expenses:				
Selling and marketing	340,381	392,645	654,093	701,660
Research and development	182,341	215,252	370,228	425,234
General and administrative	270,487	326,631	540,047	627,051
Total expenses	793,209	934,528	1,564,368	1,753,945
Operating income (loss)	\$ (52,600)	(75,352)	(93,105)	103,451
Interest expense, net	22,920	23,283	47,795	53,341
Net income (loss)	\$ (75,520)	(98,635)	(140,900)	50,110
Accretion of discount on redeemable common stock	21,639	22,551	43,278	43,279
Net income (loss) available to common stockholders	<u>\$ (97,159)</u>	<u>(121,186)</u>	<u>(184,178)</u>	<u>6,831</u>
Net income (loss) per share, basic	\$ (0.02)	(0.03)	(0.03)	*
Net income (loss) per share, diluted	\$ (0.02)	(0.03)	(0.03)	*
Weighted average shares outstanding, Basic (note 3)	5,299,163	5,223,197	5,296,820	5,216,259
Weighted average shares outstanding, diluted (note 3)	<u>5,299,163</u>	<u>5,223,197</u>	<u>5,296,820</u>	<u>5,234,804</u>
Net income (loss)	\$ (75,520)	(98,635)	(140,900)	50,110
Other comprehensive income (loss)- foreign currency translation (loss)	<u>(10,698)</u>	<u>(4,991)</u>	<u>(11,135)</u>	<u>(28,937)</u>
Total comprehensive income (loss)	<u>\$ (86,218)</u>	<u>(103,626)</u>	<u>(152,035)</u>	<u>21,173</u>

See accompanying notes to consolidated financial statements.

\*- Less than \$0.01 per share

**CORGENIX MEDICAL CORPORATION  
AND SUBSIDIARIES**

Consolidated Statement of Stockholders' Equity  
For the six months ended December 31, 2003

	Common Stock, \$0.001 par		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive income (loss)	Total stockholders' equity
Balance at June 30, 2003	4,391	\$	4,930,576	(4,642,297)	669	293,339
Issuance of common stock and stock options for services	28		6,892			6,920
Foreign currency translation					(11,135)	(11,135)
Accretion of discount on redeemable common stock				(43,278)		(43,278)
Net loss				(140,900)		(140,900)
Balance at December 31, 2003	<u>4,419</u>	\$	<u>4,937,468</u>	<u>(4,826,475)</u>	<u>(10,466)</u>	<u>104,946</u>

**CORGENIX MEDICAL CORPORATION  
AND SUBSIDIARIES**

**Consolidated Statements of Cash Flows**

	Six Months Ended	
	December 31, 2003	December 31, 2002
	(Unaudited)	
Cash flows from operating activities:		
Net income (loss)	\$ (140,900)	50,110
Adjustments to reconcile net income to net cash used in operating activities:		
Depreciation and amortization	100,167	103,197
Equity instruments issued for services	6,920	16,930
Changes in operating assets and liabilities:		
Accounts receivable	36,413	(120,814)
Inventories	(17,843)	(12,332)
Prepaid expenses and other assets	(6,004)	(42,522)
Accounts payable	(123,853)	(108,313)
Accrued payroll and related liabilities	287	21,384
Accrued interest and other liabilities	46,205	43,019
Net cash used in operating activities	(98,608)	(49,341)
Cash flows used in investing activities:		
Purchases of equipment	(5,809)	(19,966)
Cash flows from financing activities:		
Proceeds from issuance of common stock, redeemable common stock and warrants	-	500,000
Proceeds from issuance of notes payable	165,936	19,100
Payments on notes payable	(89,347)	(188,952)
Payments on capital lease obligations	(48,190)	(45,988)
Payments for costs of issuance of common stock	-	(15,247)
Net cash provided by financing activities	28,399	268,913
Net increase (decrease) in cash and cash equivalents	(76,019)	199,606
Impact of foreign currency translation adjustment on cash	(11,135)	(28,937)
Cash and cash equivalents at beginning of period	342,377	164,378
Cash and cash equivalents at end of period	\$ 255,223	335,047
Supplemental cash flow disclosures:		
Cash paid for interest	\$ 29,234	32,939
Noncash investing and financing activity—		
Equipment acquired under capital leases	-	47,477

See accompanying notes to consolidated financial statements.

**CORGENIX MEDICAL CORPORATION AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. DESCRIPTION OF BUSINESS AND BASIS OF PRESENTATION**

Corgenix Medical Corporation (“Corgenix” or the “Company”) is engaged in the research, development, manufacture, and marketing of in vitro (outside the body) diagnostic products for use in disease detection and prevention (the "Diagnostics Products Business"). The Company currently sells 142 Diagnostic Products (the “Diagnostic Products”) on a worldwide basis to hospitals, clinical laboratories, commercial reference laboratories, and research institutions.

The Company’s corporate headquarters is located in Westminster, Colorado. Corgenix has two wholly owned operating subsidiaries:

- Corgenix, Inc., ("Corgenix, Inc."), established in 1990 and located in Westminster, Colorado. Corgenix, Inc. is responsible for sales and marketing activities for North America and Japan, and also conducts product development, product support, regulatory affairs and product manufacturing of the Diagnostic Products.
- Corgenix (UK) Ltd., ("Corgenix UK"), is located in Peterborough, England. Corgenix UK manages the Diagnostic Business’ international sales and marketing activities except for distribution in North America and Japan which is under the responsibility of Corgenix, Inc.

On August 5, 2003, the Company entered into a letter of intent to merge with Genesis Bioventures, Inc. (“Genesis” or “GBI”) a biomedical development company focused on the development of diagnostic tests. Under the terms of the letter of intent, Genesis will issue 14,000,000 Genesis shares in exchange for 100% of Corgenix’s outstanding shares. The terms of the letter of intent also provide that Corgenix’s current management team will assume the responsibility of managing the combined entity, which will be known as Genesis Bioventures, Inc. The letter of intent was amended on October 21, 2003 and as a result, the parties are seeking to complete a definitive agreement on or about February 29 of 2004 and to close the transaction in the summer of 2004.

The proposed merger is subject to the satisfaction of a number of contingencies, including satisfactory due diligence investigations by each company, negotiation and execution of mutually acceptable definitive merger documentation, approval by both company’s boards of directors and stockholders, and customary closing conditions. Based on the terms of the October 21, 2003 amended letter of intent, the merger is subject to GBI advancing to Corgenix \$500,000 out of a capital raise of at least \$2,000,000 on or about November 30, 2003 as a condition to signing a definitive merger agreement. Under further terms of the amended letter of intent, GBI and Corgenix have agreed to raise a minimum of \$6,000,000 of capital on or about March 31, 2004 to provide the combined companies with sufficient funding with which to continue to develop and further commercialize their respective technologies and product lines. The foregoing dates and amounts of these provisions may be waived at the discretion of Corgenix. Pursuant to the above, the Company recently announced that a fund raising effort, led by a full service investment bank specializing in the biotech industry, is in progress and is expected to close in February.

The accompanying consolidated financial statements have been prepared without audit and in accordance with accounting principles generally accepted in the United States of America for interim financial information and with the instructions to Form 10-QSB and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of the Company, the financial statements include all adjustments (consisting of normal recurring accruals and adjustments) required to present fairly the Company’s financial position at December 31, 2003 and June 30, 2003 and the results of operations for each of the three and six month periods ended December 31, 2003 and 2002, and the cash flows for each of the six month periods then ended. The operating results for the three and six months ended December 31, 2003 are not necessarily indicative of the results that may be expected for the year ended June 30, 2004. For further information, refer to the consolidated financial statements and footnotes thereto included in the Company’s annual report on Form 10-KSB for the fiscal year ended June 30, 2003. Management of the Company has made a number of estimates and assumptions relating to the reporting of assets and liabilities and the disclosure of contingent assets and liabilities to prepare these financial statements in conformity with accounting principles generally accepted in the United States of America. Significant

assumptions inherent in the preparation of the accompanying financial statements include, but are not limited to, revenue recognition and allowances for doubtful accounts, the provision for excess and obsolete inventories, and commitments and contingencies. Actual results could differ from those estimates.

## 2. SOFTWARE

The Company accounts for its internally developed software in compliance with Statement of Position 98-1 (“SOP 98-1”), *Accounting for the Costs of Computer Software Developed or Obtained for Internal Use*. SOP 98-1 defines the types of computer software project costs that may be capitalized. All other costs are expensed in the period incurred. In order for costs to be capitalized, the computer software project must be intended to create a new system or add identifiable functionality to an existing system. In the quarter ended December 31, 2001, the Company began development of a business-to-business web site (Corgenix On Line) for its core business reference laboratory and hospital customers and potential customers worldwide. The website is intended eventually to allow customers to place orders for the Company’s diagnostic products, pay for said orders, and track the status of such orders. It will also give full specification and details on all of the Company’s diagnostic test kits. To date, all products and enhancements thereto have utilized proven technology. The direct internal and external costs of developing the related software, other than initial design and other costs incurred during the preliminary project stage, were capitalized until the software was completed at the end of September 2002. Through September 2002, all products and enhancements thereto utilized proven technology. Such capitalized amounts, which amounted to \$122,855, began to be amortized on a straight-line basis over a three-year period commencing in October 2002. No further additions to this project are anticipated.

## 3. EARNINGS (LOSS) PER SHARE

Basic earnings (loss) per share is computed by dividing net income (loss) by the weighted average number of common shares outstanding. Diluted earnings (loss) per share is computed by dividing net income (loss) by the weighted average number of common shares outstanding increased for potentially dilutive common shares outstanding during the period. The dilutive effect of stock options and their equivalents is calculated using the treasury stock method. For the three and six months ended December 31, 2003 and 2002, options and warrants to purchase common stock totaling 1,391,219 shares in 2003, both for the three and for the six months, and 1,131,219 shares in 2002, both for the three and six months, respectively, are not included in the calculation of weighted average common shares-diluted below as their effect would be anti-dilutive.

The components of basic and diluted earnings (loss) per share are as follows:

	3 months ended December 31, 2003	3 months ended December 31, 2002	6 months ended December 31, 2003	6 months ended December 31, 2002
Net income (loss) available to common shareholders	<u>\$ (97,159)</u>	<u>(121,186)</u>	<u>(184,178)</u>	<u>6,831</u>
Common and common equivalent shares outstanding:				
Historical common shares outstanding for basic income (loss) per share at beginning of period	5,294,477	4,333,095	5,271,192	4,333,095
Weighted average common shares issued during the period	4,686	890,102	25,628	883,164
Weighted average common shares-basic	5,299,163	5,223,197	5,296,820	5,216,259
Dilutive effect of potentially dilutive securities Outstanding	-	-	-	18,545
Weighted average common shares-diluted	5,299,163	5,223,197	5,296,820	5,234,804
Net income (loss) per share-basic	<u>\$ (0.02)</u>	<u>(0.03)</u>	<u>(0.03)</u>	<u>*</u>
Net income (loss) per share-diluted	<u>\$ (0.02)</u>	<u>(0.03)</u>	<u>(0.03)</u>	<u>*</u>

\*-less than (\$0.01) per share

## 4. INCOME TAXES

A valuation allowance was provided for deferred tax assets, as the Company is unable to conclude under relevant accounting standards that it is more likely than not that deferred tax assets will be realizable.

## 5. SEGMENT INFORMATION

The Company has two segments of business: domestic and international operations. International operations primarily transact sales with customers in Europe and continents other than North America, while domestic operations transact sales primarily in North America. Sales to Chugai, emanating from the United States, have historically also been included in the domestic business segment. The following table sets forth selected financial data for these segments for the three and six month periods ended December 31, 2003 and 2002.

		<u>Three Months Ended December 31,</u>			<u>Six Months Ended December 31,</u>		
		<i>Domestic</i>	<i>International</i>	<i>Total</i>	<i>Domestic</i>	<i>International</i>	<i>Total</i>
Net sales	2003	\$ 921,292	265,446	1,186,738	1,851,487	537,581	2,389,068
	2002	\$ 1,026,374	297,155	1,323,529	2,157,892	575,677	2,733,569
Net income (loss)	2003	\$ (100,541)	47,206	(75,520)	(249,172)	108,272	(140,900)
	2002	\$ (153,061)	54,426	(98,635)	(71,201)	121,311	50,110
Depreciation and amortization	2003	\$ 50,106	513	50,619	99,141	1,026	100,167
	2002	\$ 56,332	480	56,812	102,236	961	103,197
Interest expense, net	2003	\$ (20,691)	(2,229)	(22,920)	(42,286)	(5,509)	(47,795)
	2002	\$ (22,126)	(1,157)	(23,283)	(44,158)	(9,183)	(53,341)
Segment assets	2003	\$2,028,277	333,361	2,361,638	2,028,277	333,361	2,361,638
	June 30, 2003	\$2,097,844	457,872	2,555,716	2,097,844	457,872	2,555,716

## 6. REDEEMABLE COMMON STOCK

On July 1, 2002, the Company entered into an agreement (MBL Agreement) with Medical & Biological Laboratories Co., Ltd. (MBL), a strategic partner and manufacturer of autoimmune diagnostic kits located in Nagoya, Japan, under which the Company sold 880,282 shares of its \$.001 par value common stock to MBL for gross proceeds of \$500,000. Net proceeds to the Company after issuance costs were \$484,746. Under the MBL Agreement, MBL was also granted a put option which could cause the Company to repurchase, at a future date, the common stock sold to MBL under the MBL Agreement. Thus, the common stock sold has been designated "redeemable common stock." The put option requires the stock to be repurchased at the original purchase price, payable in either a lump-sum purchase or financed over a six-month period. The put option is exercisable by MBL any time after the termination or expiration of the distribution agreement between the Company and RhiGene, MBL's U.S. subsidiary, upon any merger or consolidation of the Company with another corporation wherein in the Company's stockholders own less than 50% of the surviving corporation or upon any sale or other disposition of all or substantially all of the Company's assets. MBL has voted in favor of the GBI merger and has given no indication whatsoever that it intends to exercise its put option upon the consummation of the planned merger. The present distribution agreement with RhiGene expires on March 31, 2005, though the distribution agreement may be renewed or extended prior to that time.

Pursuant to the agreement with MBL, as long as MBL holds at least 50% of the common stock purchased under the MBL agreement, MBL must give its written consent with respect to the payment of any dividend, the repurchase of any of the Company's equity securities, the liquidation or dissolution of the Company or the amendment of any provision of the Company's Articles of Incorporation or Bylaws which would adversely affect the rights of MBL under the stock purchase transaction documents. MBL was granted standard anti-dilution rights with respect to stock issuances not registered under the Securities Act. MBL also received standard piggyback registration rights along with certain demand registration rights.

In addition, as part of the MBL Agreement and for no additional consideration, MBL was issued warrants to purchase an additional 880,282 shares of common stock at a price of \$.568 per share, which is equal to an aggregate amount of \$500,000. These warrants expire on July 3, 2007 and may be exercised in whole or in part at any time prior to their expiration. The estimated fair value of the warrant upon issuance was calculated as \$401,809 using the Black-Scholes model with the following assumptions: no expected dividend yield, 143% volatility, risk free interest rate of 4.2% and an expected life of five years. The gross proceeds of \$500,000 were allocated \$277,221 to redeemable common stock and \$222,779 to the related warrants based on the relative fair values of the respective instruments to the fair value of the aggregate transaction. Issuance costs and the discount attributed to the warrants upon issuance are being accreted on the interest method over the 33-month period prior to the presently expected first date on which the put option may be exercised, which is the present expiration date of the distribution agreement between the Company and RhiGene.

## 7. STOCK PLANS

Effective January 1, 1999, the Company adopted an Employee Stock Purchase Plan (“ESPP”) to provide eligible employees an opportunity to purchase shares of its common stock through payroll deductions, up to 10% of eligible compensation. The ESPP is registered under Section 423 of the Internal Revenue Code of 1986. Each quarter, participant account balances are used to purchase shares of stock at the lesser of 85% of the fair value of shares on the first business day (grant date) and last business day (exercise date) of each quarter. No right to purchase shares shall be granted if, immediately after the grant, the employee would own stock aggregating 5% or more of the total combined voting power or value of all classes of stock. A total of 60,000 common shares were registered with the Securities and Exchange Commission (SEC) for purchase under the ESPP. During September 2002, the Company determined that it had inadvertently issued and registered more common stock under the ESPP than had heretofore been authorized by stockholders of the Company. On December 11, 2002, the Company’s stockholders approved the Amended and Restated Employee Stock Purchase Plan (“AR-ESPP”). 200,000 shares of Corgenix common stock are reserved for issuance under the AR-ESPP. Compensation expense is recognized for the fair value of the employees purchase rights. Compensation expense recognized for the 15% discount on shares purchased under the AR-ESPP amounted to \$768 and \$513 for the three months and \$1,040 and \$1,157 for the six months ended December 31, 2003 and 2002, respectively. There were 5,194 and 12,637 shares issued under the AR-ESPP during the three months and 28,449 and 18,336 shares issued during the six months ended December 31, 2003 and 2002, respectively.

In October 1999 and July 2000 the Company reserved a total of 200,000 shares of its common stock for an Incentive Stock Option Plan (“1999 ISP”) for employees, directors and consultants. Options are granted at the discretion of the board of directors with an exercise price equal to or greater than the market value of the Company’s common stock on the grant date. On December 11, 2002, the Company’s stockholders approved the Amended and Restated 1999 Incentive Stock Plan (“AR-1999-ISP”). 800,000 shares of Corgenix common stock are reserved for issuance under the AR-1999-ISP.

Had the Company determined compensation cost based on the fair value at the date of grant for its stock options under SFAS No. 123, the Company’s net income (loss) would have been increased to the pro forma amounts indicated as follows:

<b>Three Months</b>	<b>Three Months</b>	<b>Six Months</b>	<b>Six Months</b>
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	<b>Ended December 31, 2003</b>	<b>Ended December 31, 2002</b>	<b>Ended December 31, 2003</b>	<b>Ended December 31, 2002</b>
Net income (loss) available to common stockholders as reported	\$ (97,159)	(121,186)	(184,178)	6,831
Net income (loss) available to common stockholders pro forma	(112,266)	(134,401)	(214,392)	(19,599)
Net income (loss) per share as reported	(0.02)	(0.03)	(0.03)	*
Net income (loss) per share pro forma	(0.02)	(0.03)	(0.04)	*

\*-Less than \$0.01 per share

Fair value was determined using the Black Scholes option – pricing model. There were no stock options granted during the six months ended December 31, 2003.

**Item 2.**

## **CORGENIX MEDICAL CORPORATION** **Management's Discussion and Analysis of** **Financial Condition and Results of Operations**

The following discussion should be read in conjunction with the consolidated financial statements and accompanying notes included elsewhere herein.

### **General**

Since the Company's inception, we have been primarily involved in the research, development, manufacturing and marketing/distribution of diagnostic tests for sale to hospitals, clinical laboratories, commercial reference laboratories and research institutions. We currently market 142 products covering autoimmune disorders, vascular diseases, infectious diseases and liver disease. Our products are sold in the United States, the UK and other countries through our marketing and sales organization that includes contract sales representatives, internationally through an extensive distributor network, and to several significant OEM partners. We manufacture products for inventory based upon expected sales demand, shipping products to customers, usually within 24 hours of receipt of orders. Accordingly, we do not operate with a customer order backlog. Except for the fiscal year ended June 30, 1997 and the six months ended December 31, 2003, we have experienced revenue growth since our inception, primarily from sales of products and contract revenues from strategic partners. Contract revenues consist of licensing fees and milestone payments from research and development agreements with strategic partners.

In fiscal year 1996, we began adding third-party OEM licensed products to our diagnostic product line. Currently we sell 128 products licensed from or manufactured by third party manufacturers. We expect to expand our relationships with other companies in the future to gain access to additional products.

Although we have experienced growth in revenues every year except 1997 and the six months ended December 31, 2003, there can be no assurance that, in the future, we will sustain revenue growth, current revenue levels, or achieve or maintain profitability. Our results of operations may fluctuate significantly from period-to-period as the result of several factors, including: (i) whether and when new products are successfully developed and introduced, (ii) market acceptance of current or new products, (iii) seasonal customer demand, (iv) whether and when we receive R&D milestone payments and license fees from strategic partners, (v) changes in reimbursement policies for the products that we sell, (vi) competitive pressures on average selling prices for the products that we sell, and (vii) changes in the mix of products that we sell.

### **Critical Accounting Policies**

The Company's consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). We believe that the policies identified below are critical to the understanding of our results of operations. The preparation of financial statements in conformity with GAAP requires our management to make estimates and assumptions that affect reported amounts of assets, liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenues and expenses during the reporting period. Management has made estimates and assumptions based on these policies. We do not believe that there is a great likelihood that materially different amounts would be reported if different assumptions were used. However, the application of these policies involves judgments and assumptions as to future events and, as a result, actual results could differ significantly from those estimates.

#### *Revenue Recognition*

Revenue is recognized upon shipment of products. Revenue from research and development contracts represents amounts earned pursuant to agreements to perform research and development activities for third parties and is recognized as earned as it becomes billable under the respective agreement.

#### *Equipment and Software*

Equipment and software are recorded at cost. Equipment under capital leases is recorded initially at the present value of the minimum lease payments. Depreciation and amortization is calculated primarily using the straight-line method over the estimated useful lives of the respective assets which range from 3 to 7 years. The internal and external costs of developing and enhancing software costs related to website development, other than initial design and other costs incurred during the preliminary project stage, are capitalized until the software has been completed. Such capitalized amounts are amortized commencing when the website is placed in service on a straight-line basis over a three-year period. When assets are sold, retired or otherwise disposed of, the cost and related accumulated depreciation are eliminated from the accounts and a gain or loss is recognized. Repair and maintenance costs are expensed as incurred. We evaluate the realizability of our long-lived assets, including property and equipment, whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable.

### **Results of Operations**

#### ***Three Months Ended December 31, 2003 compared to 2002***

*Net sales.* Net sales for the three months ended December 31, 2003 were \$1,186,738, a \$136,791 or 10.3% decrease from \$1,323,529 in the prior year. Domestic sales decreased 10.2% while sales to international distributors decreased 10.7% from period to period. The principal reason for the decrease was the loss of \$96,390 in sales of Hyaluronic Acid Test Kits ("HA") to Fujirebio (formerly Chugai) as a result of the loss of Fujirebio in November 2002 as the principal HA customer for distribution in Japan. Sales to Fujirebio since November 2002 have been nil. Fujirebio has not placed nor forecasted any orders for HA product since November 2002 and we are not projecting any future orders by Fujirebio of HA. The Company expects that the loss of HA sales to Fujirebio will eventually be made up via international and domestic sales of HA. The remaining fluctuation in overall sales is due to individually minor changes in other product lines.

*Cost of sales.* Gross profit, as a percentage of sales, increased slightly to 62.4% for the quarter ended December 31, 2003 from 61.6% in 2002 primarily due to increased sales of HA to customers other than Fujirebio. Said sales were made at a higher margin than that formerly sold to Fujirebio. This was partially offset by higher raw material costs associated with the new manufacturing format of the Company's main product line.

*Selling and marketing.* Selling and marketing expenses decreased 13.3% or \$52,264 to \$340,381 for the quarter ended December 31, 2003 from \$392,645 in 2002. The majority of this decrease involved decreases in labor-related and consulting costs resulting from cost controls and reductions put into place on August 1, 2003. The remainder of the change resulted from individually minor changes in other selling and marketing expenses.

*Research and development.* Research and development expenses decreased \$32,911 or 15.3% to \$182,341 for the quarter ended December 31, 2003 from \$215,252 in 2002. The majority of this decrease involved decreases in labor-related costs resulting from the August 1, 2003 company-wide cost controls and reductions mentioned above. In addition, there were reductions in purchases and development costs related to a recently ended development project.

*General and administrative.* General and administrative expenses decreased \$56,144 or 17.2% to \$270,487 for the quarter ended December 31, 2003 from \$326,631 in 2002, primarily due, as stated above, to cost controls and reductions which were recently put in place. As a result, the largest reductions came in two primary categories, outside services and printing expense. The remaining fluctuation is due to individually minor changes in other general and administrative expenses.

*Interest expense.* Interest expense decreased \$363 or 1.6% to \$22,920 for the quarter ended December 31, 2003 from \$23,283 in 2002 due primarily to a decrease in interest-bearing debt in addition to lower interest rates.

*Accretion of discount on redeemable common stock.* This item represents the accretion of the discount on redeemable common stock over the 33 month period from the date the stock was issued to the presently expected first date on which the related embedded put option may be exercised. The redeemable common stock was issued in July 2002.

#### ***Six Months Ended December 31, 2003 and 2002***

*Net sales.* Net sales for the six months ended December 31, 2003 were \$2,389,068, a \$344,501 or 12.6% decrease from \$2,733,569 in the prior year. Domestic sales decreased 14.2% while sales to international distributors decreased 6.6% from period to period. The principal reason for the decrease was the loss of \$248,000 in sales of HA to Fujirebio. Fujirebio has not placed nor forecasted any orders for HA product since November 2002 and we are not projecting any future orders by Fujirebio of HA. The Company continues to expect that the loss of HA sales to Fujirebio will eventually be made up via domestic and international sales of HA. The remaining fluctuation in overall sales is due to individually minor changes in other product lines.

*Cost of sales.* Gross profit, as a percentage of sales, decreased to 61.6% for the six months ended December 31, 2003 from 67.9% in 2002 primarily due to higher raw material costs associated with the new manufacturing format of the Company's main product line, offset somewhat by increased sales of HA, at higher margins, to customers other than Fujirebio.

*Selling and marketing.* Selling and marketing expenses decreased 6.8% or \$47,567 to \$654,093 for the six months ended December 31, 2003 from \$701,660 in 2002. The majority of this decline involved decreases in labor-related and consulting costs resulting from cost controls and reductions put into place on August 1, 2003. The remainder of this change resulted from individually minor changes in other selling and marketing expenses.

*Research and development.* Research and development expenses decreased \$55,006 or 12.9% to \$370,228 for the six months ended December 31, 2003 from \$425,234 in 2002. The majority of this decrease involved decreases in labor-related costs resulting from the August 1, 2003 company-wide cost controls and reductions mentioned above. In addition, there were reductions in purchases and development costs related to a recently ended development project.

*General and administrative.* General and administrative expenses decreased \$87,004 or 13.9% to \$540,047 for the six months ended December 31, 2003 from \$627,051 in 2002, primarily due to cost controls and reductions which were recently put in place. As a result of said cost controls, the largest reductions came in two primary categories, outside services and printing expenses. The remaining fluctuation is due to individually minor changes in other general and administrative expenses.

*Interest expense.* Interest expense decreased \$5,546 or 10.4% to \$47,795 for the six months ended December 31, 2003 from \$53,341 in 2002 due primarily to a decrease in interest-bearing debt in addition to lower interest rates.

*Accretion of discount on redeemable common stock.* This item represents the accretion of the discount on redeemable common stock over the 33 month period from the date the stock was issued to the presently expected first date on which the related embedded put option may be exercised. The redeemable common stock was issued in July 2002.

## Liquidity and Capital Resources

Cash used in operating activities was \$98,587 for the six months ended December 31, 2003 compared to cash used in operating activities of \$49,341 during the prior fiscal year's first six months. The cash used in operations resulted primarily from a substantial decrease in accounts payable plus a small increase in inventories. The decrease in accounts payable resulted primarily from a concerted attempt to bring balances due vendors more current. The Company believes that uncollectible accounts receivable will not have a significant effect on future liquidity, as a significant portion of its accounts receivable are due from enterprises with substantial financial resources.

Net cash used by investing activities, the purchase of equipment, was \$5,809 for the six months ended December 31, 2003 compared to \$19,966 for the prior fiscal year's first six months. The decrease was mainly attributable to reduced spending on manufacturing and laboratory equipment.

Net cash provided by financing activities amounted to \$28,377 for the six months ended December 31, 2003 a substantial reduction from the \$268,913 provided in the prior fiscal year. This decrease in cash provided over the comparable prior year was primarily due to there not being any proceeds from the issuance of redeemable common stock and warrants in the current period. This was partially offset by increased proceeds from the issuance of notes payable during the current period as a result of increased draws on the Company's bank line of credit.

Historically, we have financed our operations primarily through long-term debt and by sales of redeemable common, and common stock. In fiscal 2003 we raised \$500,000 before offering costs (see MBL Agreement under Redeemable Common Stock above) through a private sale of redeemable common stock and warrants.

We have also received financing for operations from sales of diagnostic products and agreements with strategic partners. Accounts receivable decreased \$36,413 or 5.8% to \$592,304 at December 31, 2003 from \$628,717 at June 30, 2003. This slight decrease correlates with the overall improvement in the financial well being of our customer base as the economy began to improve, thus facilitating more timely payments from our customers. At December 31, 2003, our accounts payable decreased \$123,853 or 20% to \$495,081 from \$618,934 at June 30, 2003 primarily as a result of a concerted effort to bring accounts payable more current.

Our future capital requirements will depend on a number of factors, including the proposed merger with GBI, our profitability or lack thereof, the rate at which we grow our business and our investment in proprietary research activities, the ability of our current and future strategic partners to fund outside research and development activities, our success in increasing sales of both existing and new products and collaborations, expenses associated with unforeseen litigation, regulatory changes, competition, technological developments, general economic conditions and potential other future merger and acquisition activity. Our principal sources of liquidity have been cash provided from operating and financing activities, cash raised from the private sale of redeemable common and common stock, and long-term debt financing. The Company and GBI are currently in the latter stages of a merger-related financing. Both companies are confident that it will be successfully completed in the near future and they are proceeding with the intent to complete the proposed merger in the summer of 2004. If, for any reason, the merger-related financing and the planned merger do not occur, we will definitely need to implement new expense reductions and seek new debt agreements and/or sell additional equity securities in fiscal year 2004 to generate additional operating capital, to develop the markets and obtain the regulatory approvals for the HA products in the United States, and to pursue all of our strategic objectives. We believe that our current availability of cash, working capital, future proceeds from the issuance of common stock, debt financing and expected cash flows from operations resulting from, if necessary, further expense reductions, will be adequate to meet our ongoing needs for at least the next twelve months. At December 31, 2003, cash on hand amounted to \$255,223 compared to \$342,377 at June 30, 2003. At December 31, 2003, the Company had available borrowings under its \$400,000 bank line of credit of approximately \$245,000 and was fully drawn on the line. The borrowings at June 30, 2003 were limited to a maximum of \$279,500 based upon the calculation of the accounts receivable borrowing base. In addition, and as part of the letter of intent with GBI, the Company expects proceeds of \$500,000 in convertible debt financing from GBI to occur in February 2004. Additionally, the Company expects the merger with GBI and the approximately \$6-

8 million equity raise to occur in the summer of 2004. This estimate of our future capital requirements is a forward-looking statement that is based on assumptions that involve varying risks and uncertainties. Actual results may differ significantly from our estimates.

### **Recently Issued Accounting Pronouncements**

In November 2002, the FASB issued Interpretation No. 45, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others* (the Interpretation), which addresses the disclosure to be made by a guarantor in its interim and annual financial statements about its obligations under guarantees. The Interpretation also requires the recognition of a liability by a guarantor at the inception of certain guarantees. The Interpretation requires the guarantor to recognize a liability for the non-contingent component of the guarantee, this is the obligation to stand ready to perform in the event that specified triggering events or conditions occur. The initial measurement of this liability is the fair value of the guarantee at inception. The recognition of the liability is required even if it is not probable that payments will be required under the guarantee or if the guarantee was issued with a premium payment or as part of a transaction with multiple elements. The Company is required to adopt the disclosure provisions of the Interpretation beginning with its fiscal 2003 consolidated financial statements, and will apply the recognition and measurement provisions for all guarantees entered into or modified after December 31, 2002. As the Company has not guaranteed any indebtedness of others, the impact of the adoption is not expected to have any impact on the Company's consolidated financial statements.

In January 2003, the Financial Accounting Standards Board issued FASB Interpretation No. 46, *"Consolidation of Variable Interest Entities"* (FIN No. 46). This interpretation clarifies existing accounting principles related to the preparation of consolidated financial statements when the equity investors in an entity do not have the characteristics of a controlling financial interest or when the equity at risk is not sufficient for the entity to finance its activities without additional subordinated financial support from other parties. FIN No. 46 requires a company to evaluate all existing arrangements to identify situations where a company has a "variable interest" (commonly evidenced by a guarantee arrangement or other commitment to provide financial support) in a "variable interest entity" (commonly a thinly capitalized entity) and further determine when such variable interests require a company to consolidate the variable interest entities' financial statement with its own. The Company is required to perform this assessment by December 31, 2003 and consolidate any variable interest entities for which it will absorb a majority of the entities' expected losses or receive a majority of the expected residual gains. The Company does not have variable interest entities that it may be required to consolidate.

In May 2003, the FASB issued SFAS No. 150, *"Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity"* (SFAS No. 150). This statement establishes standards for how an entity classifies and measures certain financial instruments with characteristics of both liabilities and equity. This statement applies specifically to a number of financial instruments that companies have historically presented within their financial statements either as equity or between the liabilities section and the equity section, rather than as liabilities. This statement is effective for financial instruments entered into or modified after May 31, 2003, and is otherwise effective at the beginning of the first interim period beginning after June 15, 2003 which was subsequently extended. Management does not expect the adoption of SFAS 150 to have a material impact on its financial condition, results of operations or cash flows.

### Item 3.

#### Controls and Procedures

Evaluation of disclosure controls and procedures. The Company, under the supervision and with the participation of the Company's management, including its Chief Executive Officer and Chief Financial Officer, recently (the "Evaluation Date") carried out an evaluation of the effectiveness of the design and operation of the Company's disclosure controls and procedures (as defined in Rules 240.13a-14(c) and 15d-14(c) under the Securities Exchange Act of 1934 (the "Exchange Act"). Based upon this evaluation, the Chief Executive Officer and Chief Financial Officer concluded that, as of the Evaluation Date, the Company's disclosure controls and procedures were effective for the purposes of recording, processing, summarizing and timely reporting information required to be disclosed by the Company in the reports that it files under the Securities Exchange Act of 1934 and that such information is accumulated and communicated to the Company's management in order to allow timely decisions regarding required disclosure.

Changes in internal controls. There have been no significant changes in the Company's internal controls or in other factors that could significantly affect the Company's disclosure controls and procedures subsequent to the Evaluation Date, nor were there any significant deficiencies or material weaknesses in the Company's internal controls.

#### Forward-Looking Statements and Risk Factors

This 10-QSB includes statements that are not purely historical and are "forward-looking statements" within the meaning of Section 21E of the Securities Act of 1934, as amended, including statements regarding our expectations, beliefs, intentions or strategies regarding the future. All statements other than historical fact contained in this 10-QSB, including, without limitation, statements regarding future product developments, acquisition strategies, strategic partnership expectations, technological developments, the availability of necessary components, research and development programs and distribution plans, are forward-looking statements. All forward-looking statements included in this 10-QSB are based on information available to us on the date hereof, and we assume no obligation to update such forward-looking statements. Although we believe that the assumptions and expectations reflected in such forward-looking statements are reasonable, we can give no assurance that such expectations will prove to have been correct or that we will take any actions that may presently be planned.

Certain factors that could cause actual results to differ materially from those expected include the following:

*Losses Incurred; Future Capital Needs; Risks Relating to the Professional Products Business; Uncertainty of Additional Funding*

We have incurred operating losses and negative cash flow from operations for most of our history. Losses incurred since our inception have aggregated \$4,826,475 and there can be no assurance that we will be able to generate positive cash flows to fund our operations in the future or to pursue our strategic objectives. Assuming no significant uses of cash in acquisition activities or other significant changes, we believe that we will have sufficient cash to satisfy our needs for at least the next twelve months. If we are not able to operate profitably and generate positive cash flows sufficient for both the diagnostic business and the consumer products business, we may need to raise additional capital to fund our operations. If we do not successfully complete the GBI-related merger financing or consummate the GBI merger itself and if we need additional financing to meet our requirements, there can be no assurance that we will be able to obtain such financing on terms satisfactory to us, if at all. Alternatively, any additional equity financing may be dilutive to existing stockholders, and debt financing, if available, may include restrictive covenants. If adequate funds are not available, we might be required to limit our research and development activities or our selling and marketing activities any of which could have a material adverse effect on the future of the business.

### *Dependence on Collaborative Relationships and Third Parties for Product Development and Commercialization*

We have historically entered into licensing and research and development agreements with collaborative partners, from which we derived a significant percentage of our revenues in past years. Pursuant to these agreements, our collaborative partners have specific responsibilities for the costs of development, promotion, regulatory approval and/or sale of our products. We will continue to rely on future collaborative partners for the development of products and technologies. There can be no assurance that we will be able to negotiate such collaborative arrangements on acceptable terms, if at all, or that current or future collaborative arrangements will be successful. To the extent that we are not able to establish such arrangements, we could experience increased capital requirements or be forced to undertake such activities at our own expense. The amount and timing of resources that any of these partners devotes to these activities will generally be based on progress by us in our product development efforts. Usually, collaborative arrangements may be terminated by the partner upon prior notice without cause and there can be no assurance that any of these partners will perform its contractual obligations or that it will not terminate its agreement. With respect to any products manufactured by third parties, there can be no assurance that any third-party manufacturer will perform acceptably or that failures by third parties will not delay clinical trials or the submission of products for regulatory approval or impair our ability to deliver products on a timely basis.

### *No Assurance of Successful or Timely Development of Additional Products*

Our business strategy includes the development of additional diagnostic products. Our success in developing new products will depend on our ability to achieve scientific and technological advances and to translate these advances into commercially competitive products on a timely basis. Development of new products requires significant research, development and testing efforts. We have limited resources to devote to the development of products and, consequently, a delay in the development of one product or the use of resources for product development efforts that prove unsuccessful may delay or jeopardize the development of other products. Any delay in the development, introduction and marketing of future products could result in such products being marketed at a time when their cost and performance characteristics would not enable them to compete effectively in their respective markets. If we are unable, for technological or other reasons, to complete the development and introduction of any new product or if any new product is not approved or cleared for marketing or does not achieve a significant level of market acceptance, our results of operations could be materially and adversely affected.

### *Competition in the Diagnostics Industry*

Competition in the human medical diagnostics industry is, and is expected to remain, significant. Our competitors range from development stage diagnostics companies to major domestic and international pharmaceutical companies. Many of these companies have financial, technical, marketing, sales, manufacturing, distribution and other resources significantly greater than ours. In addition, many of these companies have name recognition, established positions in the market and long standing relationships with customers and distributors. Moreover, the diagnostics industry has recently experienced a period of consolidation, during which many of the large domestic and international pharmaceutical companies have been acquiring mid-sized diagnostics companies, further increasing the concentration of resources. There can be no assurance that technologies will not be introduced that could be directly competitive with or superior to our technologies.

### *Governmental Regulation of Diagnostics Products*

The testing, manufacture and sale of our products is subject to regulation by numerous governmental authorities, principally the FDA and certain foreign regulatory agencies. Pursuant to the Federal Food, Drug, and Cosmetic Act, and the regulations promulgated there under, the FDA regulates the preclinical and clinical testing, manufacture, labeling, distribution and promotion of medical devices. We are not able to commence marketing or commercial sales in the United States of new products under development until we receive clearance from the FDA. The testing for, preparation of and subsequent FDA regulatory review of required filings can be a lengthy, expensive and uncertain process. Noncompliance with applicable requirements can result in, among other consequences, fines, injunctions, civil penalties, recall or seizure of products, repair, replacement or refund of the cost of products, total or partial suspension of production, failure of the government to grant premarket clearance or pre-market approval for devices, withdrawal of marketing clearances or approvals, and criminal prosecution.

There can be no assurance that we will be able to obtain necessary regulatory approvals or clearances for our products on a timely basis, if at all, and delays in receipt of or failure to receive such approvals or clearances, the loss of previously received approvals or clearances, limitations on intended use imposed as a condition of such approvals or clearances or failure to comply with existing or future regulatory requirements could have a material adverse effect on our business.

#### *Dependence on Distribution Partners for Sales of Diagnostic Products in International Markets*

We have entered into distribution agreements with collaborative partners in which we have granted distribution rights for certain of our products to these partners within specific international geographic areas. Pursuant to these agreements, our collaborative partners have certain responsibilities for market development, promotion, and sales of the products. If any of these partners fails to perform its contractual obligations or terminates its agreement, this could have a material adverse effect on our business, financial condition and results of operations.

#### *Governmental Regulation of Manufacturing and Other Activities*

As a manufacturer of medical devices for marketing in the United States, we are required to adhere to applicable regulations setting forth detailed good manufacturing practice requirements, which include testing, control and documentation requirements. We must also comply with Medical Device Report (“MDR”) requirements, which require that a manufacturer report to the United States Food and Drug Administration (“FDA”) any incident in which its product may have caused or contributed to a death or serious injury, or in which its product malfunctioned and, if the malfunction were to recur, it would be likely to cause or contribute to a death or serious injury. We are also subject to routine inspection by the FDA for compliance with FDA Quality System Regulation (“QSR”) requirements, MDR requirements and other applicable regulations. The FDA has recently implemented new QSR requirements, including the addition of design controls that will likely increase the cost of compliance. Labeling and promotional activities are subject to scrutiny by the FDA and, in certain circumstances, by the Federal Trade Commission. We may incur significant costs to comply with laws and regulations in the future, which may have a material adverse effect upon our business, financial condition and results of operations.

#### *Regulation Related to Foreign Markets*

Distribution of diagnostic products outside the United States is subject to extensive government regulation. These regulations, including the requirements for approvals or clearance to market, the time required for regulatory review and the sanctions imposed for violations, vary from country to country. We may be required to incur significant costs in obtaining or maintaining foreign regulatory approvals. In addition, the export of certain of our products that have not yet been cleared for domestic commercial distribution may be subject to FDA export restrictions. Failure to obtain necessary regulatory approval or the failure to comply with regulatory requirements could have a material adverse effect on our business, financial condition and results of operations.

#### *Uncertain Availability of Third Party Reimbursement for Diagnostic Products*

In the United States, health care providers that purchase diagnostic products, such as hospitals and physicians, generally rely on third party payers, principally private health insurance plans, federal Medicare and

state Medicaid, to reimburse all or part of the cost of the procedure. Third party payers are increasingly scrutinizing and challenging the prices charged for medical products and services and they can affect the pricing or the relative attractiveness of the product. Decreases in reimbursement amounts for tests performed using our diagnostic products, failure by physicians and other users to obtain reimbursement from third party payers, or changes in government and private third party payers' policies regarding reimbursement of tests utilizing diagnostic products, may affect our ability to sell our diagnostic products profitably. Market acceptance of our products in international markets is also dependent, in part, upon the availability of reimbursement within prevailing health care payment systems.

#### *Uncertainty of Protection of Patents, Trade Secrets and Trademarks*

Our success depends, in part, on our ability to obtain patents and license patent rights, to maintain trade secret protection and to operate without infringing on the proprietary rights of others. There can be no assurance that our issued patents will afford meaningful protection against a competitor, or that patents issued to us will not be infringed upon or designed around by others, or that others will not obtain patents that we would need to license or design around. We could incur substantial costs in defending the Company or our licensees in litigation brought by others. Our business could be adversely affected.

#### *Risks Regarding Potential Future Acquisitions*

Our growth strategy includes the desire to acquire complementary companies, products or technologies. There is no assurance that we will be able to identify appropriate companies or technologies to be acquired, to negotiate satisfactory terms for such an acquisition, or to obtain sufficient capital to make such acquisitions. Moreover, because of limited cash resources, we will be unable to acquire any significant companies or technologies for cash and our ability to effect acquisitions in exchange for our capital stock may depend upon the market prices for our Common Stock. If we do complete one or more acquisitions, a number of risks arise, such as short-term negative effects on our reported operating results, diversion of management's attention, unanticipated problems or legal liabilities, and difficulties in the integration of potentially dissimilar operations. The occurrence of some or all of these risks could have a material adverse effect on our business, financial condition and results of operations.

#### *Dependence on Suppliers*

The components of our products include chemical and packaging supplies that are generally available from several suppliers, except certain antibodies, which we purchases from single suppliers. We mitigate the risk of a loss of supply by maintaining a sufficient supply of such antibodies to ensure an uninterrupted supply for at least three months. We have also qualified second vendors for all critical raw materials and believe that we can substitute a new supplier with respect to any of these components in a timely manner. However, there can be no assurances that we will be able to substitute a new supplier in a timely manner and failure to do so could have a material adverse effect on our business, financial condition and results of operations.

#### *Limited Manufacturing Experience with Certain Products*

Although we have manufactured over twelve million diagnostic tests based on our proprietary applications of ELISA (enzyme linked immuno-absorbent assay) technology, certain of our diagnostic products in consideration for future development, incorporate technologies with which we have little manufacturing experience. Assuming successful development and receipt of required regulatory approvals, significant work may be required to scale up production for each new product prior to such product's commercialization. There can be no assurance that such work can be completed in a timely manner and that such new products can be manufactured cost-effectively, to regulatory standards or in sufficient volume.

#### *Seasonality of Products; Quarterly Fluctuations in Results of Operations*

Our revenue and operating results have historically been minimally subject to quarterly fluctuations. There can be no assurance that such seasonality in our results of operations will not have a material adverse effect on our business.

### *Dependence on Key Personnel*

Because of the specialized nature of our business, our success will be highly dependent upon our ability to attract and retain qualified scientific and executive personnel. In particular, we believe our success will depend to a significant extent on the efforts and abilities of Dr. Luis R. Lopez and Douglass T. Simpson, who would be difficult to replace. There can be no assurance that we will be successful in attracting and retaining such skilled personnel, who are generally in high demand by other companies. The loss of, inability to attract, or poor performance by key scientific and executive personnel may have a material adverse effect on our business, financial condition and results of operations.

### *Product Liability Exposure and Limited Insurance*

The testing, manufacturing and marketing of medical diagnostic devices entails an inherent risk of product liability claims. To date, we have experienced no product liability claims, but any such claims arising in the future could have a material adverse effect on our business, financial condition and results of operations. Our product liability insurance coverage is currently limited to \$2 million. Potential product liability claims may exceed the amount of our insurance coverage or may be excluded from coverage under the terms of our policy or limited by other claims under our umbrella insurance policy. Additionally, there can be no assurance that we can renew our existing insurance at a cost and level of coverage comparable to that presently in effect, if at all. In the event that we are held liable for a claim against which we are not insured or for damages exceeding the limits of our insurance coverage, such claim could have a material adverse effect on our business, financial condition and results of operations.

### *Limited Public Market; Possible Volatility in Stock Prices; Penny Stock Rules*

There has, to date, been no active public market for our Common Stock, and there can be no assurance that an active public market will develop or be sustained. Although our Common Stock has been traded on the OTC Bulletin Board® since February 1998, the trading has been sporadic with generally insignificant volume.

Moreover, the over-the-counter markets for securities of very small companies historically have experienced extreme price and volume fluctuations during certain periods. These broad market fluctuations and other factors, such as new product developments and trends in our industry and the investment markets and economic conditions generally, as well as quarterly variation in our results of operations, may adversely affect the market price of our Common Stock. In addition, our Common Stock is subject to rules adopted by the Securities and Exchange Commission regulating broker-dealer practices in connection with transactions in “penny stocks.” As a result, many brokers are unwilling to engage in transactions in our Common Stock because of the added disclosure requirements.

### *Risks Associated with Exchange Rates*

Our financial statements are presented in US dollars. At the end of each fiscal quarter and the fiscal year, we convert the financial statements of Corgenix UK, which operates in pounds sterling, into US dollars, and consolidate them with results from Corgenix, Inc. We may, from time to time, also need to exchange currency from income generated by Corgenix UK. Foreign exchange rates are volatile and can change in an unknown and unpredictable fashion. Should the foreign exchange rates change to levels different than anticipated by us, our business, financial condition and results of operations may be materially adversely affected.

# CORGENIX MEDICAL CORPORATION

## Part II

### Other Information

#### Item 1. Legal Proceedings

Corgenix is not a party to any material litigation or legal proceedings.

#### Item 2. Changes in Securities and Use of Proceeds

None

#### Item 3. Defaults Upon Senior Securities

None

#### Item 4. Submission of Matters to a Vote of Security Holders

None

#### Item 5. Other Information

None

#### Item 6. Exhibits and Reports on Form 8-K.

##### a. Index to and Description of Exhibits

<b>Exhibit Number</b>	<b>Description of Exhibit</b>
2.1	Agreement and Plan of Merger dated as of May 12, 1998 by and among Gray Wolf Technologies, Inc., Gray Wolf Acquisition Corp. and REAADS Medical Products, Inc. (filed with the Company's Registration Statement on Form 10-SB filed June 29, 1998, and incorporated herein by reference).
2.2	First Amendment to Agreement and Plan of Merger dated as of May 22, 1998 by and among Gray Wolf Technologies, Inc., Gray Wolf Acquisition Corp. and REAADS Medical Products, Inc. (filed with the Company's Registration Statement on Form 10-SB filed June 29, 1998, and incorporated herein by reference).
2.3	Second Amendment to Agreement and Plan of Merger dated as of June 17, 1998 by and among the Company and TransGlobal Financial Corporation (filed with the Company's Registration Statement on Form 10-SB filed June 29, 1998, and incorporated herein by reference).

- 3.1 Articles of Incorporation, as amended (filed with the Company's Registration Statement on Form 10-SB filed June 29, 1998, and incorporated herein by reference).
- 3.2 Bylaws (filed with the Company's Registration Statement on Form 10-SB filed June 29, 1998, and incorporated herein by reference).
- 10.4 License Agreement dated June 30, 2001 between Chugai Diagnostic Science Co., Ltd. and Corgenix Medical Corporation (filed with the Company's Form 10-KSB, and incorporated herein by reference).
- 10.5 Office Lease dated May 5, 2001 between Crossroads West LLC/Decook Metrotech LLC and Corgenix, Inc. (filed with the Company's Form-10KSB, and incorporated herein by reference).
- 10.6 Guarantee dated November 1, 1997 between William George Fleming, Douglass Simpson and Geoffrey Vernon Callen (filed with the Company's Registration Statement on Form 10-SB filed June 29, 1998, and incorporated herein by reference).
- 10.7 Employment Agreement dated April 1, 2001 between Luis R. Lopez and the Company filed with the Company's Form 10-KSB, and incorporated herein by reference.
- 10.8 Employment Agreement dated April 1, 2001 between Douglass T. Simpson and the Company filed with the Company's Form 10-KSB, and incorporated herein by reference.
- 10.9 Employment Agreement dated April 1, 2001 between Ann L. Steinbarger and the Company filed with the Company's Form 10-KSB, and incorporated herein by reference.
- 10.10 Employment Agreement dated April 1, 2001 between Taryn G. Reynolds and the Company filed with the Company's Form 10-KSB, and incorporated herein by reference.
- 10.11 Employment Agreement dated April 1, 2001 between Catherine (O'Sullivan) Fink and the Company filed with the Company's Form 10-KSB, and incorporated herein by reference.
- 10.12 Consulting Contract dated May 22, 1998 between Wm. George Fleming, Bond Bio-Tech, Ltd. and the Company (filed as Exhibit 10.16 to the Company's Registration Statement on Form 10-SB filed June 29, 1998, and incorporated herein by reference).
- 10.13 Stock Purchase Agreement dated September 1, 1993 between Chugai Pharmaceutical Co., Ltd. and REAADS Medical Products, Inc. (filed as Exhibit 10.17 to the Company's Registration Statement on Form 10-SB filed June 29, 1998, and incorporated herein by reference).
- 10.14 Note dated January 6, 1997 between REAADS Medical Products, Inc. and Eagle Bank (filed with the Company's Registration Statement on Form 10-SB filed June 29, 1998, and incorporated herein by reference).
- 10.15 Form of Indemnification Agreement between the Company and its directors and officers (filed with the Company's Registration Statement on Form 10-SB/A-1 filed September 24, 1998 and incorporated herein by reference).
- 10.16 Warrant agreement dated June 1, 2000 between the Company and Taryn G. Reynolds filed with the Company's Form 10-KSB, and incorporated herein by reference.
- 10.17 Employment Agreement dated March 1, 2001 between William H. Critchfield and the Company (filed with the Company's filing on Form 10-QSB for the fiscal quarter ended March 31, 2001).
- 10.19 Consulting Agreement dated September 29, 2002 between Eiji Matsuura, PhD and the Company filed with the Company's Form 10-QSB, and incorporated herein by reference.

- 10.20 License Agreement dated September 29, 2002 between Eiji Matsuura, PhD and the Company filed with the Company's Form 10-QSB, and incorporated herein by reference.
- 10.21 Extension to Business Development & Consulting Services Agreement dated November 27, 2002 by and between Ascendant capital Group, LLC and the Company filed with the Company's Form 10-QSB, and incorporated herein by reference.
- 10.22 Employee Stock Compensation Plan
- 10.23 Amended and Restated 1999 Incentive Stock Plan
- 10.24 Amended and Restated Employee Stock Purchase Plan
- 21.1 Amended Subsidiaries of the Registrant (filed as Exhibit 21.1 to the Company's Registration Statement on Form 10-SB filed June 29, 1998).
- 21.2 Promissory note dated October 1, 2001 between W.G. Fleming and Corgenix UK, Ltd. filed with the Company's Form 10-QSB, and incorporated herein by reference.
- 21.3 Promissory note dated October 1, 2001 between W.G. Fleming and Corgenix UK, Ltd. filed with the Company's Form 10-QSB, and incorporated herein by reference.
- 21.4 Warrant Agreement dated October 11, 2001 between Phillips V. Bradford and the Company filed with the Company's Form 10-QSB, and incorporated herein by reference.
- 21.5 Warrant Agreement dated October 11, 2001 between Charles F. Ferris and the Company filed with the Company's Form 10-QSB, and incorporated herein by reference.
- 21.6 Underlease Agreement dated October 3, 2001 between G.V. Callen, A.G. Pirmohamed and Corgenix UK, Ltd. filed with the Company's Form 10-QSB, and incorporated herein by reference.
- 21.7 Distribution Agreement and OEM Agreement dated March 14, 2002 between RhiGene, Inc. and the Company filed with the Company's Form 10-QSB, and incorporated herein by reference.
- 21.8 Distribution and OEM Agreement dated March 14, 2002 between RhiGene, Inc., and the Company filed with the Company's Form 10-QSB, and incorporated herein by reference.
- 99.1\* Certificate of Corgenix Medical Corporation's Chief Executive Officer, President and Chief Financial Officer pursuant to section 906 of the Sarbanes-Oxley Act of 2002.

\* Filed Herewith

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**(b) Reports on Form 8-K.**

None.

## CERTIFICATIONS

I, Luis R. Lopez, Chief Executive Officer, certify that:

1. I have reviewed this quarterly report on Form 10-QSB of Corgenix Medical Corporation.
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report.
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
  - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date") based on such evaluation; and
  - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal half-year that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officers and I have disclosed to the registrant's auditors and the audit committee of registrant's board of directors:
  - (a) all significant deficiencies and material weaknesses in the design or operation of internal controls which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting; and

Date: February 11, 2004

/S/Luis R. Lopez  
Chief Executive Officer

I, William H. Critchfield, Chief Financial Officer, certify that:

1. I have reviewed this quarterly report on Form 10-QSB of Corgenix Medical Corporation.
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report.
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
  - b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date") based on such evaluation; and
  - d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal half-year that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officers and I have disclosed to the registrant's auditors and the audit committee of registrant's board of directors:
  - a. all significant deficiencies and material weaknesses in the design or operation of internal controls which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting; and

Date: February 11, 2004

/S/William H. Critchfield  
Chief Financial Officer

I, Douglass T. Simpson, President, certify that:

1. I have reviewed this quarterly report on Form 10-QSB of Corgenix Medical Corporation.
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report.
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
  - b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date") based on such evaluation; and
  - d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal half-year that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officers and I have disclosed to the registrant's auditors and the audit committee of registrant's board of directors:
  - a. all significant deficiencies and material weaknesses in the design or operation of internal controls which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting; and

Date: February 11, 2004

/S/Douglass T. Simpson  
President

**Exhibit 99.1**

**CERTIFICATION  
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002  
SUBSECTIONS (a) AND (b) OF SECTION 1350, CHAPTER 63 OF TITLE 18, UNITED STATES CODE**

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of Title 18, United States Code), each of the undersigned officers of Corgenix Medical Corporation, a Nevada corporation (the "Company"), does hereby certify with respect to the Quarterly Report of the Company on Form 10-QSB for the quarter ended September 30, 2002 as filed with the Securities and Exchange Commission (the "10-QSB Report") that:

- i. the 10-QSB Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- ii. the information contained in the 10-QSB Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: February 11, 2004

/S/Luis R. Lopez  
Chief Executive Officer

/S/William H. Critchfield  
Chief Financial Officer

/S/Douglass T. Simpson  
President

**SIGNATURES**

In accordance with the requirements of the Securities Exchange Act of 1934, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CORGENIX MEDICAL CORPORATION

February 11, 2004

By: /s/ Luis R. Lopez  
Luis R. Lopez, M.D.  
Chairman and Chief Executive Officer