

RETRACTABLE TECHNOLOGIES INC  
Form 10QSB  
November 14, 2003  
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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

**FORM 10-QSB**

(Mark One)

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

For the quarterly period ended September 30, 2003

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 000-30885

Retractable Technologies, Inc.

(Exact name of small business issuer as specified in its charter)

Texas

(State or other jurisdiction of  
incorporation or organization)

75-2599762

(IRS Employer  
Identification No.)

511 Lobo Lane

Little Elm, Texas 75068-0009

(Address of principal executive offices)

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(972) 294-1010

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(Issuer's telephone number)

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(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

**APPLICABLE ONLY TO ISSUERS INVOLVED IN BANKRUPTCY**

**PROCEEDINGS DURING THE PRECEDING FIVE YEARS**

Check whether the registrant filed all documents and reports required to be filed by Section 12, 13, or 15(d) of the Exchange Act after the distribution of securities under a plan confirmed by a court. Yes  No

**APPLICABLE ONLY TO CORPORATE ISSUERS**

State the number of shares outstanding of each of the issuer's classes of common equity, as of the latest practicable date: 21,559,464 shares of Common Stock, no par value, issued and outstanding on November 10, 2003.

Transitional Small Business Disclosure Format (Check one): Yes  No

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	<b>September 30, 2003</b>	<b>December 31, 2002</b>
	<u>          </u>	<u>          </u>
	<b>(unaudited)</b>	
<b>ASSETS</b>		
Cash and cash equivalents	\$ 8,335,319	\$ 1,342,117
Accounts receivable, net	1,208,541	2,666,866
Inventories, net	4,837,932	2,779,554
Other current assets	276,065	276,524
	<u>          </u>	<u>          </u>
Total current assets	14,657,857	7,065,061
Property, plant, and equipment, net	9,813,027	10,515,480
Intangible assets, net	405,405	405,641
Other assets	63,238	72,671
	<u>          </u>	<u>          </u>
Total assets	<u>\$ 24,939,527</u>	<u>\$ 18,058,853</u>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Liabilities:		
Accounts payable	\$ 2,499,720	\$ 4,229,396
Current portion of long-term debt	238,252	840,899
Accrued compensation	333,028	328,717
Marketing fees payable	1,828,733	1,874,571
Accrued royalties	642,010	602,777
Other accrued liabilities	159,629	145,116
	<u>          </u>	<u>          </u>
Total current liabilities	5,701,372	8,021,476
	<u>          </u>	<u>          </u>
Long-term debt, net of current maturities	2,696,573	2,600,298
	<u>          </u>	<u>          </u>
Stockholders' equity:		
Preferred Stock \$1 par value		
Series A		1,056,000
Series I, Class B	249,400	259,400
Series II, Class B	418,500	431,000
Series III, Class B	145,245	150,745
Series IV, Class B	1,066,000	1,066,000
Series V, Class B	2,314,571	2,416,221
Common Stock, no par value		

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Additional paid-in capital	50,674,669	49,411,177
Accumulated deficit	(38,326,803)	(47,353,464)
	<hr/>	<hr/>
Total stockholders' equity	16,541,582	7,437,079
	<hr/>	<hr/>
Total liabilities and stockholders' equity	\$ 24,939,527	\$ 18,058,853
	<hr/>	<hr/>

See accompanying notes to condensed financial statements.

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## RETRACTABLE TECHNOLOGIES, INC.

## CONDENSED STATEMENTS OF OPERATIONS

(unaudited)

	Three Months ended September 30, 2003	Three Months ended September 30, 2002	Nine Months ended September 30, 2003	Nine Months ended September 30, 2002
Sales, net	\$ 4,143,807	\$ 4,399,356	\$ 13,059,115	\$ 13,383,353
Cost of sales	3,487,691	3,778,294	9,838,884	10,308,412
Product recall and recovery				481,637
Gross profit	656,116	621,062	3,220,231	2,593,304
Operating expenses:				
Sales and marketing	827,461	831,793	2,980,850	2,764,887
Research and development	125,309	81,988	385,539	246,560
General and administrative	1,582,392	1,215,195	4,502,785	3,214,424
Debt conversion expense				2,319,073
Total operating expenses	2,535,162	2,128,976	7,869,174	8,544,944
Loss from operations	(1,879,046)	(1,507,914)	(4,648,943)	(5,951,640)
Interest income	16,208	2,165	31,160	6,942
Interest expense	(68,073)	(93,162)	(235,067)	(394,918)
Litigation settlement, net			13,879,511	
Net income (loss)	(1,930,911)	(1,598,911)	9,026,661	(6,339,616)
Preferred Stock dividend requirements	(627,233)	(617,747)	(1,954,002)	(1,594,910)
Net income (loss) applicable to common shareholders	\$ (2,558,144)	\$ (2,216,658)	\$ 7,072,659	\$ (7,934,526)
Net income (loss) per share basic	\$ (0.12)	\$ (0.11)	\$ 0.34	\$ (0.39)
Net income (loss) per share diluted	\$ (0.12)	\$ (0.11)	\$ 0.30	\$ (0.39)
Weighted average common shares outstanding	21,504,353	20,311,017	20,781,379	20,294,572

See accompanying notes to condensed financial statements.

**Table of Contents****RETRACTABLE TECHNOLOGIES, INC.****CONDENSED STATEMENTS OF CASH FLOWS****(unaudited)**

	<b>Nine Months ended September 30, 2003</b>	<b>Nine Months ended September 30, 2002</b>
<b>Cash flows from operating activities</b>		
Net income (loss)	\$ 9,026,661	\$ (6,339,616)
Adjustments to reconcile net income (loss) to net cash provided (used) by operating activities:		
Depreciation and amortization	981,317	1,000,147
Capitalized interest	(20,769)	(19,191)
Stock option compensation	286,931	48,927
Provision for doubtful accounts	62,807	8,016
Accreted interest	75,839	
Waiver of vacation pay		(100,936)
Debt conversion expense		2,319,073
Changes in assets and liabilities		
(Increase) decrease in inventories	(2,058,377)	321,396
(Increase) decrease in accounts receivable	1,395,518	(869,064)
(Increase) decrease in other current assets	3,013	(1,389)
Increase (decrease) in accounts payable	(1,729,677)	1,906,032
Increase (decrease) in marketing fees payable	(45,838)	(819,817)
Increase (decrease) in other accrued liabilities	58,060	603,478
Net cash provided (used) by operating activities	<u>8,035,485</u>	<u>(1,942,944)</u>
<b>Cash flows from investing activities</b>		
Purchase of property, plant, and equipment	(210,005)	(68,409)
Acquisition of patents, trademarks, licenses, and intangibles	(24,713)	(2,372)
Net cash used by investing activities	<u>(234,718)</u>	<u>(70,781)</u>
<b>Cash flows from financing activities</b>		
Repayments of long-term debt and notes payable	(348,477)	(419,112)
Proceeds from the sale of Preferred Stock		2,225,600
Payment of Preferred Stock dividends	(459,088)	
Offering expense for Series V stock		(86,517)
Net cash provided (used) by financing activities	<u>(807,565)</u>	<u>1,719,971</u>
Net increase (decrease) in cash	6,993,202	(293,754)
Cash and cash equivalents at:		
Beginning of period	<u>1,342,117</u>	<u>1,220,244</u>
End of period	<u>\$ 8,335,319</u>	<u>\$ 926,490</u>
<b>Supplemental schedule of cash flow information:</b>		
Interest paid	\$ 224,107	\$ 389,026
<b>Supplemental schedule of noncash investing and financing activities:</b>		

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Conversion of long-term debt into Common Stock	\$	249,998	\$
Debt assumed to acquire assets	\$	16,294	\$
Forgiveness of royalties by an officer	\$		\$ 1,500,000
Conversion of accounts payable into Preferred Stock	\$		\$ 1,550,000
Conversion of long-term debt into Preferred Stock	\$		\$ 3,679,284
Series V stock subscriptions issued	\$		\$ 2,100,000
Loan origination fee paid in stock options	\$		\$ 299,346

See accompanying notes to condensed financial statements.



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**RETRACTABLE TECHNOLOGIES, INC.**

**NOTES TO CONDENSED FINANCIAL STATEMENTS**

**(unaudited)**

**1. BUSINESS OF THE COMPANY, BASIS OF PRESENTATION, AND RECENT DEVELOPMENTS**

**Business of the Company**

Retractable Technologies, Inc. (the Company) was incorporated in Texas on May 9, 1994, to design, develop, manufacture, and market safety syringes and other safety medical products for the healthcare profession. The Company began to develop its manufacturing operations in 1995. The Company's manufacturing and administrative facilities are located in Little Elm, Texas. The Company's primary products are the VanishPoint® syringe in 1cc, 3cc, 5cc, and 10cc sizes and blood collection tube holders. The Company has conducted clinical evaluations and worked with national distributors to encourage healthcare facilities to transition from the use of standard syringes to the VanishPoint® syringe. Preliminary shipments, which commenced in February 1997, included syringes for hospital product evaluations as well as for sale in clinics and other healthcare settings.

**Basis of presentation**

The accompanying condensed financial statements are unaudited and, in the opinion of management, reflect all adjustments that are necessary for a fair presentation of the financial position and results of operations for the periods presented. All of such adjustments are of a normal and recurring nature. The results of operations for the periods presented are not necessarily indicative of the results to be expected for the entire year. The condensed financial statements should be read in conjunction with the financial statement disclosures contained in the Company's audited financial statements for the year ended December 31, 2002.

**Recent developments**

The National Marketing and Distribution Agreement (the Agreement) the Company had with Abbott Laboratories (Abbott) has been terminated as of October 14, 2003. The Company notified Abbott in August 2003 that Abbott had breached its contract with the Company and the Company intended to terminate the Agreement. According to the terms and conditions of the Agreement, Abbott had sixty (60) days from the date of the notice to remedy a breach of material terms or conditions. Since the breach was not remedied within the sixty (60) day period, the Agreement was terminated.

**2. LIQUIDITY**

The Company has been successful in raising funds through private equity financing totaling approximately \$52.6 million, including approximately \$5.2 million in conversion of debt and accounts payable, over the last seven and one-half years. However, the Company has incurred substantial losses and negative cash flows from operations in every fiscal period since inception. For the years ended December 31,

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2002, 2001, and 2000, the Company incurred losses from operations of approximately \$6.4 million, \$6.7 million, and \$10.4 million, respectively. For the nine months ended September 30, 2003, the Company incurred a loss from operations of approximately \$4.6 million. For the years ended December 31, 2002, 2001, and 2000, the Company had negative cash flows from operating activities of approximately \$1.5 million, \$3.7 million, and \$8.6 million, respectively. For the nine months ended September 30, 2003, the Company had cash flows from operating activities of \$8.0 million. As of September 30, 2003, and December 31, 2002 and 2001, the Company had accumulated deficits of approximately \$38.3 million, \$47.4 million, and \$40.5 million, respectively.

On July 15, 2003, Katie Petroleum converted the remaining balance of \$250,003 of its note secured by land and building into 35,714 shares of Common Stock of the Company.

The Company has agreed to a loan proposal from 1<sup>st</sup> International Bank for \$2,500,000. The proceeds from the loan will be used to pay off the remaining \$475,000 of the revolving credit agreement and fund a new warehouse and related infrastructure. Payments on the new note will be interest only during construction. Upon completion, payments will be based on a twenty-year amortization with a five-year maturity. The exact terms will be based on the amount of funds kept on deposit with the bank. Accordingly, interest will vary from the Wall Street Journal Prime Rate ( WSJPR ) to the WSJPR plus 1 percent, with floors that may range from 4.25 percent to 6.50 percent. Compensating balances at 1 International affecting the interest rate will range from \$0 to \$500,000.

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During the second quarter of 2003, the Company called for redemption of the remaining 1,021,000 shares of Series A Convertible Preferred Stock (the Series A Stock ) as provided in the certificate of designation. The certificate of designation also provided that the shareholders had the option to convert each share of Series A Stock into one share of the Company s Common Stock. All of the Series A Stock was converted into Common Stock of the Company. The Company also paid all accumulated dividends on the Series A Stock, which amounted to approximately \$460,000. On an annual basis, this transaction reduced the Company s preferred dividend requirement by \$122,520.

Abbott accounted for 38.6 percent and 45.2 percent of net sales for the nine months ended September 30, 2003 and 2002, respectively. One other distributor accounted for 11.2 percent and 11.1 percent of net sales for the same periods, respectively. Management expects to reach a break-even operating point when the Company has more access to the market. Management believes that the settlement agreements with TYCO International (U.S.), Inc., TYCO Healthcare Group, L.P., Novation, L.L.C., VHA, Inc., Premier, Inc., and Premier Purchasing Partners, L.P. (the Settlement Agreements ) will provide sufficient funds for its current needs and facilitate the sale of the Company s products.

### **3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

#### **Accounting estimates**

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

#### **Cash and cash equivalents**

For purposes of reporting cash flows, cash and cash equivalents include unrestricted cash and investments with original maturities of three months or less.

#### **Accounts receivable**

The Company records trade receivables when revenue is recognized. No product has been consigned to customers. The Company s allowance for doubtful accounts is primarily determined by review of specific trade receivables. Those accounts that are doubtful of collection are included in the allowance. An additional allowance has been established based on a percentage of receivables outstanding. These provisions are reviewed to determine the adequacy of the allowance for doubtful accounts. Trade receivables are charged off when there is certainty as to their being uncollectible. Trade receivables are considered delinquent when payment has not been made within contract terms.

#### **Inventories**

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Inventories are valued at the lower of cost or market, with cost being determined using a standard cost method, which approximates average cost. Provision is made for any excess or obsolete inventories.

### Property, plant, and equipment

Property, plant, and equipment are stated at cost. Expenditures for maintenance and repairs are charged to operations as incurred. Cost includes major expenditures for improvements and replacements which extend useful lives or increase capacity and interest cost associated with significant capital additions. For the nine months ended September 30, 2003 and 2002, the Company capitalized interest of \$20,769 and \$19,191, respectively. Gains or losses from property disposals are included in income.

Depreciation and amortization are calculated using the straight-line method over the following useful lives:

Production equipment	3 to 13 years
Office furniture and equipment	3 to 10 years
Building	39 years
Building improvements	15 years
Automobiles	7 years

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### **Long-lived assets**

When events or changes in circumstances indicate that the carrying amount of long-lived assets may not be recoverable, the Company will review the net realizable value of the long-lived assets through an assessment of the estimated future cash flows related to such assets. In the event that assets are found to be carried at amounts which are in excess of estimated gross future cash flows, the assets will be adjusted for impairment to a level commensurate with a discounted cash flow analysis of the underlying assets.

### **Reclassifications**

Certain prior period amounts have been reclassified to conform with the current period's presentation.

### **Intangible assets**

Intangible assets are stated at cost and consist primarily of patents, a license agreement granting exclusive rights to use patented technology, and trademarks which are amortized using the straight-line method over 17 years.

### **Financial instruments**

The fair market value of financial instruments is determined by reference to various market data and other valuation techniques as appropriate. The Company believes that the fair value of financial instruments approximates its recorded value.

### **Concentrations of credit risk**

The Company's financial instruments exposed to concentrations of credit risk consist primarily of cash, cash equivalents, and accounts receivable. Cash balances, which may exceed the federally insured limits, are maintained in financial institutions; however, management believes the institutions are of high credit quality. The majority of accounts receivable are due from companies which are well-established entities. As a consequence, management considers any exposure from concentrations of credit risks to be limited. The Company has a high concentration of sales with two significant customers, but the contract with one major customer was terminated and the Company has no remaining credit exposure from that customer.

### **Revenue recognition**

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Revenue is recognized for sales to distributors when title and risk of ownership passes to the distributor, generally upon shipment. Revenue is recorded on the basis of sales price to distributors. Revenues on sales to distributors are recorded net of contractual pricing allowances. Revenue for shipments directly to end-users is recognized when title and risk of ownership passes from the Company. Any product shipped or distributed for evaluation purposes is expensed.

### **Marketing fees**

The Company paid a distributor marketing fees for services provided by the distributor. These services include participation in promotional activities, development of educational and promotional materials, representation at trade shows, clinical demonstrations, inservicing and training, and tracking reports detailing the placement of the Company's products to end-users. Marketing fees are accrued at the time of the sale of product to the distributor. These fees are paid after the distributor provides the Company a tracking report of product sales to end-users. These costs are included in sales and marketing expense in the Condensed Statements of Operations.

### **Income taxes**

The Company provides for deferred income taxes in accordance with Statement of Financial Accounting Standard No. 109, *Accounting for Income Taxes* ( SFAS 109 ). SFAS 109 requires an asset and liability approach for financial accounting and reporting for income taxes based on the tax effects of differences between the financial statement and tax bases of assets and liabilities, based on enacted rates expected to be in effect when such basis differences reverse in future periods. Deferred tax assets are periodically reviewed for realizability. Valuation allowances are recorded when realizability of deferred tax assets is not likely.

**Table of Contents****Earnings per share**

The Company has adopted Statement of Financial Accounting Standards No. 128, *Earnings Per Share*, which establishes standards for computing and presenting earnings per share. Basic earnings per share are computed by dividing net earnings for the period (adjusted for any cumulative preferred dividends for the period) by the weighted average number of common shares outstanding during the period. The Company's potentially dilutive Common Stock equivalents, options and convertible debt, are dilutive for the nine months ended September 30, 2003, and antidilutive for the three months ended September 30, 2003, and the prior year periods as the Company was in a loss position. The Company's Common Stock equivalents consisting of convertible preferred stock are antidilutive for all periods presented. The following table indicates the computation of earnings per share for the nine months ended September 30, 2003.

	<b>Nine Months Ended September 30, 2003</b>
Net income	\$ 9,026,661
Preferred dividend requirements	(1,954,002)
Net income applicable to common shareholders	7,072,659
Effect of dilutive securities:	
convertible debt interest and loan fees	(441,334)
Net income applicable to common shareholders after assumed conversions	\$ 6,631,325
Average common shares outstanding	20,781,379
Dilutive stock equivalents from stock options	288,548
Shares issuable upon conversion of convertible debt	750,000
Average common and common equivalent shares outstanding - assuming dilution	21,819,927
Net income per share basic	\$ 0.34
Net income per share diluted	\$ 0.30

**Research and development costs**

Research and development costs are expensed as incurred.

**Stock-based compensation**

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The Company has three stock-based director, officer, and employee compensation plans. Prior to 2002, the Company accounted for those plans under the recognition and measurement provisions (intrinsic value method) of APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and related Interpretations. Effective January 1, 2002, the Company adopted the fair value recognition provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*, prospectively to all director, officer, and employee awards granted, modified, or settled after December 31, 2001. Awards under the Company's plans vest over periods up to three years. Therefore, the cost related to stock-based compensation included in the determination of net income after December 31, 2001, is less than what would have been recognized if the fair value method had been applied to all awards since the original effective date of SFAS No. 123. SFAS No. 123 indicates that the fair value method is the preferable method of accounting. The following table indicates



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the effect on net income and earnings per share if the fair value method had been applied to all outstanding and unvested awards in each period.

	Three Months Ended September 30		Nine Months Ended September 30	
	2003	2002	2003	2002
Net income (loss), as reported	\$ (1,930,911)	\$ (1,598,911)	\$ 9,026,661	\$ (6,339,616)
Add: Stock-based employee compensation expense included in reported net income, net of related tax effects	171,393	48,927	286,931	48,927
Deduct: Total stock-based employee compensation expense determined by fair value based method for all awards, net of related tax effects	(199,352)	(87,182)	(387,545)	(164,827)
Pro forma net income	\$ (1,958,871)	\$ (1,637,166)	\$ 8,926,047	\$ (6,455,516)
Earnings (loss) per share basic-as reported	\$ (0.12)	\$ (0.11)	\$ 0.34	\$ (0.39)
Earnings (loss) per share diluted-as reported	\$ (0.12)	\$ (0.11)	\$ 0.30	\$ (0.39)
Earnings (loss) per share basic-pro forma	\$ (0.12)	\$ (0.11)	\$ 0.34	\$ (0.40)
Earnings (loss) per share diluted-pro forma	\$ (0.12)	\$ (0.11)	\$ 0.30	\$ (0.40)

**Recent pronouncements**

On May 31, 2003, the FASB issued Statement No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity* ( SFAS 150 ). SFAS 150 establishes standards for how an issuer classifies and measures in its statement of financial position certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument within its scope as a liability (or an asset in some circumstances) because that financial instrument embodies an obligation of the issuer. SFAS 150 is effective at the beginning of the first interim period beginning after June 15, 2003. The Company does not have any financial instruments that fall under the guidance of SFAS 150 and, therefore, the adoption did not have any effect on its financial position or results of operations.

On July 31, 2003 the Emerging Issues Task Force ( EITF ) discussed Issue No. 03-7, *Accounting for the Settlement of the Equity-Settled Portion of a Convertible Debt Instrument That Permits or Requires the Conversion Spread to Be Settled in Stock (Instrument C of Issue 90-19)*. The Task Force revised the consensus in EITF Issue No. 90-19, *Convertible Bonds with Issuer Option to Settle for Cash Upon Conversion*. EITF Issue No. 03-7 is effective for reporting periods beginning after August 13, 2003. The Company does not have any debt instruments that fall under the guidance of EITF Issue No. 03-7 and, therefore, adoption will not have any effect on its financial position or results of operations.

**Item 2. Management's Discussion and Analysis or Plan of Operation.**

FORWARD-LOOKING STATEMENT WARNING

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Certain statements included by reference in this Form 10-QSB containing the words believes, anticipates, intends, expects, and similar such words constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act. Any forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause actual results, performance, or achievements of the Company to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements. Such factors include, among others, the impact of dramatic increases in demand, our ability to quickly increase our capacity in the event of a dramatic increase in demand, our ability to access the market, our ability to successfully resolve our litigation with B-D, among others, our ability to continue to finance research and development as well as operations and expansion of production, and the recently increased interest of larger market players, specifically B-D, in providing safety needle devices. Given these uncertainties, undue reliance should not be placed on forward-looking statements.

The following discussion contains trend information and other forward-looking statements that involve a number of risks and uncertainties. Our actual future results could differ materially from our historical results of operations and those discussed in the forward-looking statements. Variances have been rounded for ease of reading. All period references are to the periods ended September 30, 2003, or September 30, 2002.

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*Comparison of Three Months Ended*

*September 30, 2003, and September 30, 2002*

Net sales were \$4,143,807 and \$4,399,356 for the three months ended September 30, 2003 and 2002, respectively. The decrease of \$255,549 was due to a decrease in sales of 1cc, 5cc, and 10cc syringes and blood collection tube holders mitigated by an increase in sales of 3cc syringes. Sales to Abbott as a percentage of units sold decreased from 28.9 percent to 8.4 percent of total units sold. Unit sales to other distributors increased from 71.1 percent to 91.6 percent of units sold. Sales revenues from Abbott decreased about 71.3 percent whereas sales revenues to other distributors increased 28.7 percent. Two other distributors accounted for more than 10 percent of units sold.

Cost of sales decreased from \$3,778,294 in 2002 to \$3,487,691 in 2003, a decrease of \$290,603 or 7.7 percent. The decrease is due to reduced costs of manufacturing due to lower volumes and more efficient production.

Gross profit increased from \$621,062 in 2002 to \$656,116 in 2003, an increase of \$35,054. Gross profit as a percentage of net sales was 14.1 percent and 15.8 percent for the three months ended September 30, 2002 and 2003, respectively.

Sales and marketing expense decreased from \$831,793 in 2002 to \$827,461 in 2003, a decrease of \$4,332. The decrease is principally due to reduced fees to distributors of \$221,000 offset by increased payroll of \$58,000, stock option expense of \$42,000, travel and entertainment of \$32,000, freight of \$27,000, and samples, promotional materials, meetings, and trade shows of \$68,000.

Research and development costs increased from \$81,988 in 2002 to \$125,309 in 2003, an increase of \$43,321. The increase is principally due to increased payroll costs of \$14,000 and samples of \$30,000.

General and administrative costs increased from \$1,215,195 in 2002 to \$1,582,392 in 2003, an increase of \$367,197. Increases in wages were \$155,000, legal expenses increased \$98,000 due principally to the NMT litigation offset by a reduction in legal fees related to Sortimat, travel and entertainment increased \$18,000, and stock option expense for 2003 increased \$37,000.

Net interest expense declined from \$90,997 to \$51,685 due principally to the exchange of the Katie Petroleum note for Series V Class B Convertible Preferred Stock (the Series V Stock) of the Company and higher invested cash balances.

Preferred Stock dividend requirements were \$627,233 for 2003 compared to \$617,747 in 2002, an increase of \$9,486. The increase is due to an increase in the outstanding Preferred Stock as a result of sales of Series V Stock offset by the reduction in dividend requirements related to the redemption of the Series A stock.

Basic and diluted loss per share was \$(0.11) in 2002 and \$(0.12) in 2003.

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### *Comparison of Nine Months Ended*

*September 30, 2003, and September 30, 2002*

Net sales were \$13,059,115 and \$13,383,353 for the nine months ended September 30, 2003 and 2002, respectively. The decrease of \$324,238 was due to a decrease in sales of 3cc, 5cc, and 10cc syringes and blood collection tube holders offset by an increase in sales of 1cc syringes. Sales to Abbott as a percentage of units sold decreased from 41.5 percent to 33.5 percent of total units sold. Unit sales to other distributors increased from 58.5 percent to 66.5 percent of units sold. Sales revenues from Abbott decreased about 17.8 percent whereas sales revenues to other distributors increased 10.6 percent. One other distributor accounted for more than 10 percent of units sold.

Cost of sales decreased from \$10,308,412 in 2002 to \$9,838,884 in 2003, a decrease of \$469,528 or 4.6 percent. The decrease is due to reduced costs of manufacturing due to lower volumes and more efficient production. The nine months ended September 30, 2003, also included bonus expenses of \$258,000.

During the three months ended June 30, 2002, the Company recorded an expense of \$481,637 related to a recall and recovery of certain lots of its blood collection tube holders. The Company found that, upon testing, some blood collection tube holders would retract prior to the blood draw being completed. The Company has since redesigned certain aspects of the blood collection tube holder which we believe cured the premature retraction.

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Gross profit increased from \$2,593,304 in 2002 to \$3,220,231 in 2003, an increase of \$626,927. Gross profit as a percentage of net sales was 19.4 percent and 24.7 percent for the nine months ended September 30, 2002 and 2003, respectively.

Sales and marketing expense increased from \$2,764,887 in 2002 to \$2,980,850 in 2003, an increase of \$215,963 or 7.8 percent. The increase is principally due to an increase of travel and entertainment expense of \$110,000, trade shows and meetings expense of \$46,000, freight expense of \$32,000, payroll expense of \$30,000, other expenses of \$23,000, bonuses of \$95,000, stock option expense of \$42,000, and a decrease in fees to distributors of \$174,000.

Research and development costs increased from \$246,560 in 2002 to \$385,539 in 2003, an increase of \$138,979. The increase is principally due to an increase in payroll of \$42,000, bonuses of \$25,000, experimental parts, and samples of \$54,000 and consulting of \$24,000.

General and administrative costs increased from \$3,214,424 in 2002 to \$4,502,785 in 2003, an increase of \$1,288,361. Increases in wages were \$275,000, bonuses increased \$241,000, legal expenses increased \$378,000 due principally to the NMT litigation offset by decreases in other legal expenses, travel and entertainment increased \$59,000, and stock option expense for 2003 was \$153,000.

Debt conversion expense incurred in 2002 consisted of \$1,821,246 for Series V Stock issued in excess of the original conversion term of the real estate note and working capital loan, \$440,000 for stock options issued in connection with the conversion, and \$57,827 of unamortized debt expenses.

Net interest expense decreased from \$387,976 to \$203,907 due principally to the exchange of the Katie Petroleum note into Series V stock of the Company and higher invested cash balances.

Preferred Stock dividend requirements were \$1,954,002 for 2003 compared to \$1,594,910 in 2002, an increase of \$359,092. The increase is due to an increase in the outstanding Preferred Stock as a result of sales of Series V Stock, offset by the reduction in individual requirements related to the redemption of the Series A Stock. During the second quarter of 2003, the Company called for redemption of the remaining 1,021,000 shares of Series A Stock as provided in the certificate of designation. The certificate of designation also provided that the shareholders had the option to convert each share of Series A Stock into one share of the Company's Common Stock. All of the Series A Stock was converted into Common Stock of the Company. The Company also paid all accumulated dividends on the Series A Stock, which amounted to approximately \$460,000. On an annual basis, this transaction reduced the Company's preferred dividend requirement by \$122,520.

Basic and diluted loss per share was \$(0.39) in 2002 and basic earnings per share was \$0.34 in 2003 due principally to the Settlement Agreements reached in litigation offset by the loss from operations. Diluted earnings per share were \$0.30 in 2003 assuming the conversion of debt securities and exercise of dilutive stock options. Conversion of debt securities and exercise of stock options were antidilutive in 2002, and conversion of preferred stock was antidilutive in 2002 and 2003.

Cash flow increased from a negative \$293,754 for the nine months ended September 30, 2002, to a positive \$6,993,202 for the nine months ended September 30, 2003, a net increase of \$7,286,956. Positive changes in cash flows from operations of \$10.0 million were due to an increase in net income related to the Settlement Agreements reached in litigation offset by losses from operations and increased cash flows from operations due to a decrease in accounts receivable and decreased cash flows from operations due to an increase in inventories and a decrease in payables. Negative changes in cash flows from investing activities of \$164,000 were due to an increase in purchases of property plant and

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equipment and intangibles. Negative changes in cash flows from financing activities of \$2.5 million were due to payments of dividends in 2003 and a decrease in proceeds from the sale of Preferred Stock.

Cash used in investing activities increased \$163,937 due to increased capital expenditures and acquisition of patents, trademarks, and intangibles.

### **SIGNIFICANT ACCOUNTING POLICIES**

The Company considers the following to be its most significant accounting policies. Careful consideration and Company review are given to these and all accounting policies on a routine basis to ensure that they are accurately and consistently applied.

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### **Revenue Recognition**

Revenue is recognized for sales to distributors when title and risk of ownership passes to the distributor, generally upon shipment. Revenue is recorded on the basis of sales price to distributors. Revenues on sales to distributors are recorded net of contractual pricing allowances. Revenue for shipments directly to end-users is recognized when title and risk of ownership passes from the Company. Any product shipped or distributed for evaluation purposes is expensed.

### **Accounts Receivable**

The Company records trade receivables when revenue is recognized. No product has been consigned to customers. The Company's allowance for doubtful accounts is primarily determined by review of specific trade receivables. Those accounts that are doubtful of collection are included in the allowance. An additional allowance has been established based on a percentage of receivables outstanding. These provisions are reviewed to determine the adequacy of the allowance for doubtful accounts. Trade receivables are charged off when there is certainty as to their being uncollectible. Trade receivables are considered delinquent when payment has not been made within contract terms.

### **Marketing Fees**

The Company paid a distributor marketing fees for services provided by the distributor. These services include participation in promotional activities, development of educational and promotional materials, representation at trade shows, clinical demonstrations, inservicing and training, and tracking reports detailing the placement of the Company's products to end-users. Marketing fees are accrued at the time of the sale of product to the distributor. These fees are paid after the distributor provides the Company a tracking report of product sales to end-users. These costs are included in sales and marketing expense in the Condensed Statements of Operations.

### **Stock-Based Compensation**

Prior to 2002, the Company accounted for stock-based compensation under the recognition and measurement provisions (intrinsic value method) of APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and related Interpretations. Effective January 1, 2002, the Company adopted the fair value recognition provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*, prospectively to all director, officer, and employee awards granted, modified, or settled after December 31, 2001. The prospective method is one of the alternative transition methods provided in FAS 148. Awards under the Company's plans vest over periods up to three years. Therefore, the cost related to stock-based compensation included in the determination of net income after December 31, 2001, is less than would have been recognized if the fair value method had been applied to all awards since the original effective date of SFAS No. 123. SFAS No. 123 indicates that the fair value method is the preferable method of accounting.

### **Long-lived assets**

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When events or changes in circumstances indicate that the carrying amount of long-lived assets may not be recoverable, the Company will review the net realizable value of the long-lived assets through an assessment of the estimated future cash flows related to such assets. In the event that assets are found to be carried at amounts which are in excess of estimated gross future cash flows, the assets will be adjusted for impairment to a level commensurate with a discounted cash flow analysis of the underlying assets.

### Recent Pronouncements

On May 31, 2003, the FASB issued Statement No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity* ( SFAS 150 ). SFAS 150 establishes standards for how an issuer classifies and measures in its statement of financial position certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument within its scope as a liability (or an asset in some circumstances) because that financial instrument embodies an obligation of the issuer. SFAS 150 is effective at the beginning of the first interim period beginning after June 15, 2003. The Company does not have any financial instruments that fall under the guidance of SFAS 150 and, therefore, the adoption did not have any effect on its financial position or results of operations.

On July 31, 2003 the Emerging Issues Task Force ( EITF ) discussed Issue No. 03-7, *Accounting for the Settlement of the Equity-Settled Portion of a Convertible Debt Instrument That Permits or Requires the Conversion Spread to Be Settled in Stock (Instrument C of Issue 90-19)*. The Task Force revised the consensus in EITF Issue



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No. 90-19, *Convertible Bonds with Issuer Option to Settle for Cash Upon Conversion*. EITF Issue No. 03-7 is effective for reporting periods beginning after August 13, 2003. The Company does not have any debt instruments that fall under the guidance of EITF Issue No. 03-7 and, therefore, adoption will not have any effect on its financial position or results of operations.

## **LIQUIDITY AND FUTURE CAPITAL REQUIREMENTS**

### Internal Sources of Liquidity

Management believes that the Settlement Agreements will provide sufficient funds to facilitate the sale of the Company's products.

Unit sales increased 3.4 percent from 2002 to 2003 for the nine months ended September 30. Abbott purchases comprised 41.5 percent and 33.5 percent of our unit sales in these periods, respectively. Unit sales to Abbott decreased 16.4 percent for this period. For the three month periods ended September 30, 2002 and 2003 sales to Abbott as a percentage of units sold decreased from 28.9 percent to 8.4 percent of total units sold, respectively. Unit sales to other distributors increased from 71.1 percent to 91.6 percent of units sold. Sales revenues from Abbott decreased about 71.3 percent whereas sales revenues to other distributors increased 28.7 percent. We anticipate no further sales to Abbott. The Company expects to supply the acute care market through its existing distributors as well as new distributors. The Agreement the Company had with Abbott has been terminated as of October 14, 2003. The Company notified Abbott in August that Abbott had breached its contract with the Company and the Company intended to terminate the Agreement. According to the terms and conditions of the Agreement, Abbott had sixty (60) days from the date of the notice to remedy a breach of material term or condition. Since the breach was not remedied within the sixty (60) day period, the Agreement was terminated. The Company intends to utilize its current network of distributors, as well as adding new ones, to continue to supply the hospital market.

Unit sales to customers other than Abbott were 58.5 percent and 66.5 percent of sales for the nine months ended 2002 and 2003, respectively. Unit sales to others increased 17.6 percent from 2002 to 2003. Sales to others consist primarily of sales into the alternate care market.

We believe we can achieve our break-even quarter utilizing our existing equipment. To achieve our break-even quarter we would need minimal access to hospital markets which has been difficult to obtain due to the monopolistic marketplace which is the subject of our lawsuit discussed in greater detail in our Form 10-KSB for 2002 and Form 10-QSBs for the first two quarters of 2003.

### External Sources of Liquidity

We have obtained several loans over the past seven and one-half years. We have further obtained approximately \$52.6 million in equity from six separate private placement offerings. Historically, the loans and proceeds from the sales of equities have enabled us to pursue development and production of our products.

The Company has agreed to a loan proposal from 1<sup>st</sup> International Bank for \$2,500,000. The proceeds from the loan will be used to pay off the remaining \$475,000 of the revolving credit agreement and fund a new warehouse and related infrastructure. Payments on the new note will be

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interest only during construction. Upon completion, payments will be based on a twenty-year amortization with a five-year maturity. The exact terms will be based on the amount of funds kept on deposit with the bank. Accordingly, interest will vary from the WSJPR to the WSJPR plus one percent, with floors that may range from 4.25 percent to 6.50 percent. Compensating balances at 1<sup>st</sup> International affecting the interest rate will range from \$0 to \$500,000.

Furthermore, we have 676,634 shares of Series V Class B stock and the shareholders have authorized an additional 5,000,000 shares of a Class C stock that could, if necessary, be used to raise equity funds.

In the event our claims against Becton Dickinson and Company are successfully resolved, it will likely have a further beneficial and material impact on our liquidity position and the demand for our products.

**Table of Contents****Contractual Obligations and Commercial Commitments**

The following chart summarizes all of our material obligations and commitments to make future payments under contracts such as debt and lease agreements as of September 30, 2003:

<b>Contractual Obligations</b>	<b>Payments Due by Period</b>				
	<b>Total</b>	<b>2003</b>	<b>2004-2006</b>	<b>2007-2008</b>	<b>After 2008</b>
Long-Term Debt	\$ 3,484,458	\$ 4,054	\$ 874,085	\$ 1,148,088	\$ 1,458,231
Capital Lease Obligations	86,373	25,862	60,511	0	0
<b>Total Contractual Cash Obligations</b>	<b>\$ 3,570,831</b>	<b>\$ 29,916</b>	<b>\$ 934,596</b>	<b>\$ 1,148,088</b>	<b>\$ 1,458,231</b>

**Material Commitments for Expenditures**

The Board of Directors has authorized the expenditure of \$2 million for the immediate construction of a warehouse. The Company has agreed to a loan proposal from 1<sup>st</sup> International Bank for \$2,500,000 which shall be the source for construction funds. Additional capital expenditures may include additional assembly lines, manufacturing space, warehousing, and related infrastructure. The expansion could include those products that have been developed but not yet marketed, as well as expanding manufacturing capacity for existing products. The amount of capital required would be dependent on our analysis of the extent of the potential market penetration if we are able to compete in a free market environment.

We had \$234,718 in capital expenditures for the nine months ended September 30, 2003.

**Item 3. Controls and Procedures.**

As of September 30, 2003, the Company carried out an evaluation, with the participation of the Company's principal executive officer, Thomas J. Shaw, and principal financial officer, Douglas W. Cowan, of the effectiveness of the Company's disclosure controls and procedures (as defined in Rule 13a-15(e) or Rule 15d-15(e) under the Securities Exchange Act of 1934). Based on the evaluation of these controls and procedures required by paragraph (b) of Rule 13a-15 or Rule 15d-15 under the Exchange Act, the principal executive officer and principal financial officer determined that these procedures are effective in ensuring that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the United States Securities and Exchange Commission's rules and forms.

There were no changes in the Company's internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 or Rule 15d-15 under the Exchange Act that occurred during the third quarter of 2003 that has materially affected or is reasonably likely to materially affect, the Company's internal control over financial reporting.

**PART II**

**OTHER INFORMATION**

**Item 3. Defaults Upon Senior Securities.**

Series I Class B Convertible Preferred Stock

For the three months ended September 30, 2003, \$31,175 in dividends is in arrears. The total arrearage is \$2,530,669.

Series II Class B Convertible Preferred Stock

For the three months ended September 30, 2003, \$104,625 in dividends is in arrears. The total arrearage is \$4,382,161.

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Series III Class B Convertible Preferred Stock

For the three months ended September 30, 2003, \$36,572 in dividends is in arrears. The total arrearage is \$2,403,350.

Series IV Class B Convertible Preferred Stock

For the three months ended September 30, 2003, \$266,500 in dividends is in arrears. The total arrearage is \$3,665,998.

Series V Class B Convertible Preferred Stock

For the three months ended September 30, 2003, \$188,361 in dividends is in arrears. The total arrearage is \$929,048.

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

The 2003 Annual Meeting of Stockholders (the Annual Meeting ) of the Company was held on September 19, 2003, at 10:00 a.m., CST. The purposes of the meeting were to: (1) elect three Series II Directors by the holders of the outstanding Series II Class B Convertible Preferred Stock (the Series II Stock ); (2) elect one Class 1 Director by the holders of the outstanding Common Stock; and (3) ratify the re-appointment of CF & Co., L.L.P., formerly Cheshier & Fuller, L.L.P., as independent accountants for the Company for the year ended December 31, 2003.

Of the 418,500 shares of Series II Stock of the Company entitled to vote, less than the 209,250 required to constitute a quorum were represented in person or by proxy. Accordingly, no business of the Series II shareholders could be transacted except for the rescheduling of the Series II shareholder meeting.

The Series II shareholders present in person voted in favor of November 21, 2003, as the rescheduled date for the Series II business of the Annual Meeting. The business of the Series II shareholders was, accordingly, adjourned until 10:00 a.m., CST on November 21, 2003. No other business was transacted by the Series II shareholders.

Of the 21,399,600 shares of Common Stock of the Company entitled to vote, 19,695,569 shares were represented in person or by proxy at the Annual Meeting, which is more than the 10,699,800 required to constitute a quorum. Accordingly, the following matters were submitted to a vote of the common stockholders.

1. The election of one Class 1 Director was put to a vote by the holders of Common Stock present in person or by proxy at the Annual Meeting and the result was as follows:

<u>NOMINEE</u>	<u>FOR</u>	<u>WITHHELD</u>
Russell B. Kuhlman	19,476,155	219,414

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Accordingly, by majority vote of those common shares represented at the meeting, Russell B. Kuhlman was elected as a Class 1 Director to serve until the Company's 2005 Annual Meeting.

2. The proposal to ratify the re-appointment of CF & Co., L.L.P., formerly Cheshier & Fuller, L.L.P., as the Company's independent accountants for the year ended December 31, 2003, was put to a vote by the holders of Common Stock present in person or by proxy at the Annual Meeting and the result was as follows:

<u>FOR</u>	<u>AGAINST</u>	<u>ASBTENTIONS</u>
19,582,999	83,125	29,445

Accordingly, by majority vote the Common Stockholders ratified the re-appointment of CF & Co., L.L.P. as the Company's independent accountants for the year ended December 31, 2003.

No other matters were voted on at the Annual Meeting.

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As of the adjournment of the September 19, 2003, Annual Meeting of Stockholders, the Board of Directors consists of the following members:

Thomas J. Shaw	Class 2 Director
Steven R. Wisner	Class 2 Director
Russell B. Kuhlman	Class 1 Director
Douglas W. Cowan	Class 2 Director
Clarence Zierhut	Class 2 Director
Marwan Saker	Class 2 Director
Kenneth W. Biermacher	Series II Director*
Timothy G. Greene	Series II Director*
John J. McDonald, Jr.	Series II Director*

\* The Series II Directors terms expired at the September 19, 2003, Annual Meeting. However, their successors have yet to be elected by the Series II Stockholders. These Directors terms will continue until their successors are elected. The election of their successors will be held on November 21, 2003, a meeting date set by the Series II Stockholders at the Annual Meeting. Such Series II Directors will serve terms that expire at the earlier of the next annual meeting or until such time as dividends are no longer in arrears. Series II Stockholders will have the right to elect one-third of the Board of Directors only until such time as their dividends are no longer in arrears.

**Item 5. Other Information.**

The Agreement the Company had with Abbott has been terminated as of October 14, 2003. The Company notified Abbott in August that Abbott had breached its contract with the Company and the Company intended to terminate the Agreement. According to the terms and conditions of the Agreement, Abbott had sixty (60) days from the date of the notice to remedy a breach of material term or condition. Since the breach was not remedied within the sixty (60) day period, the Agreement was terminated. The Company intends to utilize its current network of distributors, as well as adding new ones, to continue to supply the hospital market.

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

(a) EXHIBITS

<u>Exhibit No.</u>	<u>Description of Document</u>
31.1	Certification of Principal Executive Officer
31.2	Certification of Principal Financial Officer
32	Certification Pursuant to 18 U.S.C. Section 1350

(b) REPORTS ON FORM 8-K

On July 8, 2003, we filed a Form 8-K with an Item 5 disclosure regarding a press release issued on July 7, 2003, announcing the conversion of Series A Stock and the payment of related dividends.

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On August 21, 2003, we filed a Form 8-K with an Item 5 disclosure regarding a press release issued on August 19, 2003, of earnings information for the quarter ended June 30, 2003. The Form 8-K included a Balance Sheet for the periods ended June 30, 2003, and December 31, 2002, and Statements of Operations for the three and six months periods ended June 30, 2003.

On September 2, 2003, we filed a Form 8-K with an Item 5 disclosure regarding a press release issued on August 29, 2003, announcing the Company's intent to terminate the Agreement with Abbott.



