RETRACTABLE TECHNOLOGIES INC
Form 10-Q
November 16, 2009

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2009

or

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

For the transition period from to

Commission file number: 000-30885

Retractable Technologies, Inc.

(Exact name of registrant as specified in its charter)

Texas	**75-2599762**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
511 Lobo Lane **Little Elm, Texas** (Address of principal executive offices)	**75068-0009** (Zip Code)

(972) 294-1010

(Registrant s telephone number, including area code)

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer o	Accelerated filer o
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x

APPLICABLE ONLY TO ISSUERS INVOLVED IN BANKRUPTCY

PROCEEDINGS DURING THE PRECEDING FIVE YEARS:

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13, or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. Yes o No o

APPLICABLE ONLY TO CORPORATE ISSUERS

Indicate the number of shares outstanding of each of the issuer s classes of common stock, as of the latest practicable date: 23,820,064 shares of Common Stock, no par value, issued and outstanding on November 2, 2009.

RETRACTABLE TECHNOLOGIES, INC.

FORM 10-Q

For the Quarterly Period Ended September 30, 2009

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements.

RETRACTABLE TECHNOLOGIES, INC.

CONDENSED BALANCE SHEETS

	September 30, 2009 (unaudited)	December 31, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	$ 17,502,934	$ 33,283,740
Accounts receivable, net	6,111,552	3,288,942
Inventories, net	8,442,180	6,641,532
Income taxes receivable	23,422	6,576
Other current assets	136,072	400,113
Total current assets	32,216,160	43,620,903
Property, plant, and equipment, net	17,052,253	14,435,667
Intangible assets, net	447,285	470,115
Other assets	9,000	18,750
Total assets	$ 49,724,698	$ 58,545,435
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 4,729,785	$ 6,144,435
Current portion of long-term debt	2,548,606	451,865
Accrued compensation	655,532	650,704
Marketing fees payable	1,419,760	1,419,760
Accrued royalties to shareholders	100,000	620,987
Other accrued liabilities	1,124,766	852,602
Income taxes payable		103,744
Total current liabilities	10,578,449	10,244,097
Long-term debt, net of current maturities	5,020,867	6,095,535
Total liabilities	15,599,316	16,339,632
Stockholders equity:		
Preferred stock $1 par value:		
Series I, Class B	144,000	144,000
Series II, Class B	219,700	219,700
Series III, Class B	130,245	130,245
Series IV, Class B	552,500	552,500
Series V, Class B	1,238,821	1,238,821
Common stock, no par value		
Additional paid-in capital	55,983,084	53,952,183

Retained deficit			(24,142,968)	(14,031,646)
Total stockholders equity			34,125,382	42,205,803
Total liabilities and stockholders equity		$	49,724,698	$ 58,545,435

See accompanying notes to condensed financial statements

RETRACTABLE TECHNOLOGIES, INC.

CONDENSED STATEMENTS OF OPERATIONS

(unaudited)

	Three Months Ended September 30, 2009	Three Months Ended September 30, 2008	Nine Months Ended September 30, 2009	Nine Months Ended September 30, 2008
Sales, net	$ 10,752,445	$ 8,997,038	$ 21,763,523	$ 20,786,420
Cost of sales				
Cost of manufactured product	7,034,384	6,219,614	13,613,625	12,851,542
Royalty expense to shareholders	782,335	651,502	1,645,230	1,547,281
Total cost of sales	7,816,719	6,871,116	15,258,855	14,398,823
Gross profit	2,935,726	2,125,922	6,504,668	6,387,597
Operating expenses:				
Sales and marketing	1,024,191	1,139,052	3,559,790	3,607,962
Research and development	195,753	271,174	826,479	804,006
General and administrative	5,264,302	2,896,205	12,489,453	8,284,638
Total operating expenses	6,484,246	4,306,431	16,875,722	12,696,606
Loss from operations	(3,548,520)	(2,180,509)	(10,371,054)	(6,309,009)
Interest and other income	14,176	158,664	54,359	653,782
Interest expense, net		(13,893)		(77,161)
Net loss before income taxes	(3,534,344)	(2,035,738)	(10,316,695)	(5,732,388)
Benefit for income taxes	(100,027)		(205,373)	
Net loss	(3,434,317)	(2,035,738)	(10,111,322)	(5,732,388)
Preferred stock dividend requirements	(342,717)	(342,717)	(1,028,151)	(1,030,302)
Loss applicable to common stockholders	$ (3,777,034)	$ (2,378,455)	$ (11,139,473)	$ (6,762,690)
Loss per share basic and diluted	$ (0.16)	$ (0.10)	$ (0.47)	$ (0.28)
Weighted average common shares outstanding	23,803,397	23,800,064	23,801,175	23,792,733

See accompanying notes to condensed financial statements

RETRACTABLE TECHNOLOGIES, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(unaudited)

	Nine Months Ended September 30, 2009	Nine Months Ended September 30, 2008
Cash flows from operating activities		
Net loss	$ (10,111,322)	$ (5,732,388)
Adjustments to reconcile net loss to net cash provided by (used by) operating activities:		
Depreciation and amortization	1,079,954	1,048,773
Capitalized interest	(150,910)	(153,226)
Stock option compensation	1,329,566	
Provisions for doubtful accounts	182,000	143,496
Accreted interest	33,459	41,807
(Increase) decrease in assets		
Inventories	(1,800,648)	1,079,318
Accounts receivable	(3,004,610)	(1,919,584)
Income taxes receivable	(16,846)	2,345,041
Other current assets	264,041	(302,136)
Increase (decrease) in liabilities		
Accounts payable	(1,414,650)	(925,913)
Other accrued liabilities	438,340	621,415
Income taxes payable	(103,744)	
Net cash used by operating activities	(13,275,370)	(3,753,397)
Cash flows from investing activities		
Purchase of property, plant, and equipment	(2,150,449)	(2,161,789)
Acquisitions of patents, trademarks, licenses and intangibles		(89,152)
Investment in LLC		497,690
Net cash used by investing activities	(2,150,449)	(1,753,251)
Cash flows from financing activities		
Repayments of long-term debt and notes payable	(373,987)	(366,571)
Proceeds from long-term debt		1,328,859
Proceeds from the exercise of stock options	19,000	
Net cash provided by (used by) financing activities	(354,987)	962,288
Net decrease in cash	(15,780,806)	(4,544,360)
Cash and cash equivalents at:		
Beginning of period	33,283,740	40,507,431
End of period	$ 17,502,934	$ 35,963,071
Supplemental disclosures of cash flow information:		
Interest paid	$ 117,451	$ 188,581
Income taxes paid	$ 15,883	$
Supplemental disclosure of non-cash investing and financing activities:		
Forgiveness of royalties by a shareholder	$ 682,335	$
Debt assumed to construct warehouse	$ 1,362,602	$

See accompanying notes to condensed financial statements

RETRACTABLE TECHNOLOGIES, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

(unaudited)

1. BUSINESS OF THE COMPANY AND BASIS OF PRESENTATION

Business of the Company

Retractable Technologies, Inc. (the Company) was incorporated in Texas on May 9, 1994, and designs, develops, manufactures and markets 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 with Notice of Substantial Equivalence to the FDA are the VanishPoint® 0.5cc insulin syringe; 1cc tuberculin, insulin, and allergy antigen syringes; the 3cc, 5cc, and 10cc syringes; the small diameter tube adapter; the blood collection tube holder; the allergy tray; the IV safety catheter; and the Patient Safe syringe.

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 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 incorporated into its Form 10-K filed on March 31, 2009 for the year ended December 31, 2008. Certain prior year amounts have been reclassified to conform with the current period s presentation.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Accounting estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles (GAAP) 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, money market accounts, 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

Inventories are valued at the lower of cost or market, with cost being determined using a standard cost method, which approximates average cost. A reserve is established 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. 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
Buildings	39 years
Building improvements	15 years
Automobiles	7 years

Long-lived assets

The Company assesses the recoverability of long-lived assets using an assessment of the estimated undiscounted 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.

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 Company estimates the fair market value of financial instruments through the use of public market prices, quotes from financial institutions and other available information. Judgment is required in interpreting data to develop estimates of market value and, accordingly, amounts are not necessarily indicative of the amounts that could be realized in a current market exchange. Short-term financial instruments, including cash and cash equivalents, accounts receivable, accounts payable and other liabilities, consist primarily of instruments without extended maturities, the fair value of which, based on Management s estimates, equals their recorded values.

Concentration risks

The Company s financial instruments exposed to concentrations of credit risk consist primarily of cash, cash equivalents, and accounts receivable. Cash balances, some of which exceed 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 had a high concentration of sales with two significant customers, accounting for approximately $2.9 million, or 27% of net sales in the third quarter of 2009.

The Company manufactures syringes in Little Elm, Texas as well as utilizing manufacturers in China. The Company purchases most of its product components from single suppliers, including needle adhesives and packaging materials. There are multiple sources of these materials. The Company obtained roughly 67.4% of its finished products in the first nine months of 2009 through Double Dove, a Chinese manufacturer. In the event that the Company becomes unable to purchase such product from Double Dove, the Company would need to find an alternate supplier for its 0.5cc insulin syringe, its 5cc and 10cc syringes and its autodisable syringe and increase domestic production for 1cc and 3cc syringes to avoid a disruption in supply.

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, less contractual pricing allowances. Contractual pricing allowances consist of: (i) rebates granted to distributors who provide tracking reports which show, among other things, the facility that purchased the products, and (ii) a provision for estimated contractual pricing allowances for products that the Company has not received tracking reports. Rebates are recorded when issued and are applied against the customer s receivable balance. The provision for contractual pricing allowances is reviewed at the end of each quarter and adjusted for changes in levels of products for which there is no tracking report. Additionally, if it becomes clear that tracking reports will not be provided by individual distributors, the provision is further adjusted. The estimated contractual allowance is netted against individual distributor s accounts receivable balances for financial reporting purposes. The resulting net balance is reflected in accounts receivable or accounts payable, as appropriate. The terms and conditions of contractual pricing allowances are governed by contracts between the Company and its distributors. Revenue for shipments directly to end-users is recognized when title and risk of ownership pass from the Company. Any product shipped or distributed for evaluation purposes is expensed.

The Company s domestic return policy is set forth in its standard Distribution Agreement. This policy provides that a customer may return incorrect shipments within 10 days following arrival at the distributor s facility. In all such cases the distributor must obtain an authorization code from the Company and affix the code to the returned product. The Company will not accept returned goods without a returned goods authorization number. The Company may refund the customer s money or replace the product.

The Company s return policy also provides that a customer may return product that is overstocked. Overstocking returns are limited to two times in each 12-month period up to one percent of distributor s total purchase of products for the prior 12-month period. All product overstocks and returns are subject to inspection and acceptance by manufacturer.

The Company s international distribution agreements do not provide for any returns.

The Company records an allowance for estimated returns as a reduction to Accounts receivable and Gross sales. Historically, returns have been less than 0.5% of total sales.

Marketing fees

Under a sales and marketing agreement with Abbott Laboratories (Abbott), the Company paid marketing fees until the Company terminated the contract for breach. The contracted services were to 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 were accrued at the time of the sale of product to Abbott. These fees were paid after Abbott provided the Company a tracking report of product sales to end-users. These costs were included in Sales and marketing expense in the Condensed Statements of Operations. No marketing fees have been accrued since October 15, 2003, the date the National Marketing and Distribution Agreement with Abbott was terminated. The Company filed suit against Abbott in August 2005 for breach of contract. The District Court has issued a scheduling order calling for trial in May 2010. See **Note 5. COMMITMENTS AND CONTINGENCIES** for further discussion.

Income taxes

The Company provides for deferred income taxes through the use of an asset and liability approach for financial accounting and reporting 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 differences reverse in future periods. Deferred tax assets are periodically reviewed for realizability. The Company had sufficient taxable income from prior carryback years to realize all of its taxable losses through December 31, 2006. Taxable losses for 2007 and thereafter are subject to loss carryforwards. The Company has established a valuation allowance for its net deferred tax asset as future taxable income cannot be reasonably assured. Penalties and interest on uncertain tax positions are classified as income taxes in the Condensed Statements of Operations.

Earnings per share

The Company computes basic earnings per share by dividing net earnings for the period (adjusted for any cumulative dividends for the period) by the weighted average number of common shares outstanding during the period. The Company s potentially dilutive Common Stock equivalents, consisting of options, convertible debt and convertible Preferred Stock, are all antidilutive for the three and nine months ended September 30, 2009 and 2008. Accordingly basic loss per share is equal to diluted earnings per share.

Shipping and handling costs

The Company classifies shipping and handling costs as part of Cost of sales in the Condensed Statements of Operations.

Research and development costs

Research and development costs are expensed as incurred.

Share-based compensation

The Company s share-based payments are accounted for using the fair value method. The Company records share-based compensation expense on a straight-line basis over the requisite service period. The Company incurred the following share-based compensation costs:

Three Months Ended September 30, 2009	Three Months Ended September 30, 2008	Nine Months Ended September 30, 2009	Nine Months Ended September 30, 2008

Cost of sales	$	123,030	$	$	201,501 $
Sales and marketing		74,414			171,192
Research and development		16,903			29,537
General and administrative		768,884			927,336
	$	983,231	$	$	1,329,566 $

Recent Pronouncements

In June 2009, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standard (SFAS) No. 168, *The FASB Accounting Standards CodificationTM and the Hierarchy of Generally Accepted Accounting Principles a replacement of FASB Statement No. 162* (SFAS 168) (FASB ASC 105-10). SFAS 168 replaces all previously issued accounting standards and establishes the *FASB Accounting Standards CodificationTM* (FASB ASC or the Codification) as the source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in the preparation of financial statements in conformity

with U.S. GAAP. SFAS 168 is effective for all interim and annual periods ending after September 15, 2009. The FASB ASC is not intended to change existing U.S. GAAP. The adoption of this pronouncement only resulted in changes to the Company s financial statement disclosure references. As such, the adoption of this pronouncement had no effect on the Company s condensed financial position, results of operations, or cash flows.

In order to facilitate the transition to the FASB ASC, the Company has elected to show all references to FASB ASC within this report on Form 10-Q along with a parenthetical reference to the previous accounting standard.

In April 2008, the FASB issued FASB Staff Position (FSP) FAS 142-3, *Determination of the Useful Life of Intangible Assets,* included in the Codification under FASB ASC 350. This FSP amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under FASB Statement No. 142, *Goodwill and Other Intangible Assets* (SFAS 142). The intent of this FSP is to improve the consistency between the useful life of a recognized intangible asset under SFAS 142 and the period of expected cash flows used to measure the fair value of the asset under SFAS 141R, and other GAAP. FSP FAS 142-3 was effective for the Company beginning January 1, 2009. The adoption of FSP FAS 142-3 did not have a material impact on the Company s financial position, results of operations, or cash flows.

In May 2009, the FASB issued SFAS No. 165, *Subsequent Events*, included in the Codification under FASB ASC 855, which establishes general standards of accounting for and disclosure of events occurring after the balance sheet date, but before the financial statements are issued or available to be issued. SFAS No. 165 also requires entities to disclose the date through which it has evaluated subsequent events and the basis for that date. The Company adopted SFAS No. 165 for its second quarter ended June 30, 2009. Its adoption did not have a material impact on the Company s financial position, results of operations, or cash flows. Refer to **Note 6 SUBSEQUENT EVENTS** for more information regarding the Company s evaluation of subsequent events.

3. INVENTORIES

Inventories consist of the following:

	September 30, 2009	**December 31, 2008**
Raw materials	$ 2,735,386	$ 1,885,157
Finished goods	5,912,394	4,961,975
	8,647,780	6,847,132
Inventory reserve	(205,600)	(205,600)
	$ 8,442,180	$ 6,641,532

4. INCOME TAXES

The Company s effective tax rate on the net loss before income taxes was 2.0% and 0.0% for the nine months ended September 30, 2009 and September 30, 2008, respectively. During the quarter ended March 31, 2009, the Company recorded a state tax receivable of approximately $100,000 attributable to amended returns which were received in the third quarter. Additionally, during the three months ended September 30, 2009 the Company reduced its accrual for uncertain tax positions as the potential tax payment is not likely to be incurred.

5. COMMITMENTS AND CONTINGENCIES

On August 12, 2005, the Company filed a lawsuit against Abbott in the U.S. District Court in the Eastern District of Texas, Texarkana Division. The Company is alleging fraud and breach of contract in connection with the National Marketing and Distribution Agreement dated as of May 4, 2000, which was terminated on October 15, 2003. It is seeking damages which it estimates to be in millions of dollars of lost profits, out of pocket expenses, and other damages. In addition, it is seeking punitive damages, pre- and post-judgment interest, and attorneys fees. Following Abbott s unsuccessful attempt to get the case dismissed and ordered to arbitration, Abbott filed an answer and counterclaim on July 15, 2008, alleging several breaches of contract, breach of implied warranty of merchantability, and breach of express warranty, seeking in excess of $6,000,000 in compensatory damages as well as seeking attorneys fees. The Company denies the validity of

Abbott s counterclaims. Some discovery has already taken place (related to the hearings addressing the prior motion to compel arbitration) and additional discovery is underway. The District Court has issued a revised scheduling order calling for trial in May 2010.

In April 2008, the Company sued Occupational and Medical Innovations Limited (OMI) in the U.S. District Court for the Eastern District of Texas, Tyler Division, alleging that OMI has infringed two U.S. patents that were not at issue in the Australian litigation (6,572,584 and 7,351,224). The Company also alleged theft of confidential information, intentional interference with contracts and engaging in false advertising that wrongfully disparaged and mischaracterized our syringe products. The Company further alleged that OMI made false allegations regarding the source of origin of its safety syringe products being offered in the U.S. The Company is seeking injunctive relief, unspecified damages (including treble damages) and reimbursement of attorneys fees in the suit. OMI has counterclaimed, seeking declaratory judgments of non-infringement and invalidity of the Company s asserted patents. OMI is not seeking monetary damages. Trial is set for December 2009.

In June 2007, the Company sued Becton Dickinson and Company (BD) in the U.S. District Court for the Eastern District of Texas, Marshall Division, alleging infringement of three patents (5,578,011; 5,632,733; and 6,090,077) and violations by BD of the federal and state antitrust laws, and of the Lanham Act. The Company subsequently dropped the 5,578,011 patent allegations from the lawsuit. The Company and an officer, a co-plaintiff, were seeking injunctive relief, unspecified monetary damages and reimbursement of attorneys fees in the suit. BD counterclaimed for non-infringement and invalidity of the asserted patents. In January 2008, the Court severed the patent claims from the other claims pending resolution of the patent dispute. In April 2008, the Company and the officer sued BD in the U.S. District Court for the Eastern District of Texas, Marshall Division, alleging infringement of another recently issued patent (7,351,224), and seeking injunctive relief, unspecified monetary damages (including treble damages) and reimbursement of attorneys fees. BD counterclaimed for non-infringement and invalidity of the asserted patent. The Court consolidated this case with the above-stated case filed in June 2007. The case was tried to a jury from October 30 to November 9, 2009. On November 9, the jury returned a verdict finding that BD has infringed all three asserted patents, that the three asserted patents are not invalid, and that BD owes the Company and officer five million dollars ($5,000,000). Judgment has not yet been entered on the verdict, and post-trial briefing is presently underway. The Company and officer are also requesting that, based upon the jury verdict of patent infringement, the Court enjoin BD from selling the accused Integra® syringes. Because the jury also found that the infringement was not willful, there is no probability that the Company and officer will recover enhanced damages. Any judgment entered upon the jury verdict will be subject to appeal by all parties to the litigation.

In September 2007, BD and MDC Investment Holdings, Inc. (MDC) sued the Company in the United States District Court for the Eastern District of Texas, Texarkana Division, initially alleging that the Company is infringing two U.S. patents of MDC (6,179,812 and 7,090,656) that are licensed to BD. BD and MDC seek injunctive relief and unspecified damages. The Company counterclaimed for declarations of non-infringement, invalidity, and unenforceability of the asserted patents. The plaintiffs subsequently dropped allegations with regard to patent no. 7,090,656 and the Company subsequently dropped its counterclaims for unenforceability of the asserted patents. The Court conducted a claims construction hearing on September 25, 2008 and issued its claims construction order on November 14, 2008. No trial date has been set. The parties have agreed to request a stay of this litigation until after the case against BD has been tried.

In September 2008, the Company and an officer sued Safety Medical International (SMI) in the United States District Court for the Eastern District of Texas, Tyler Division, alleging infringement of U.S. patent nos. 6,572,584 and 7,351,224, and seeking injunctive relief, unspecified monetary damages and reimbursement of attorneys fees. SMI has counterclaimed, seeking declaratory judgments of non-infringement and invalidity of the asserted patents. SMI is not seeking monetary damages. SMI has filed a notice of bankruptcy in this case and it has been stayed pending the outcome of those proceedings.

6. SUBSEQUENT EVENTS

The Company has evaluated events occurring after the date of its accompanying unaudited Condensed Balance Sheets through the date of the filing of this Quarterly Report on Form 10-Q (November 16, 2009) in accordance with SFAS No. 165 and has determined that such events are properly recorded and disclosed.

The consolidated patent infringement case brought by the Company and officer against BD was tried to a jury in United States District Court for the Eastern District of Texas, Marshall Division, from October 30 to November 9, 2009. On November 9, the jury returned a verdict finding that BD has infringed all three asserted patents, that the three asserted patents are not invalid, and that BD owes the Company and officer five million dollars ($5,000,000). Judgment has not yet been entered on the verdict, and post-trial briefing is presently underway. The Company and officer are also requesting that, based upon the jury verdict of patent infringement, the Court enjoin BD from selling the accused Integra® syringes. Because the jury also found that the infringement was not willful, there is no probability that the Company and officer will recover enhanced damages. Any judgment entered upon the jury verdict will be subject to appeal by all parties to the litigation.

Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations.

FORWARD-LOOKING STATEMENT WARNING

Certain statements included by reference in this filing containing the words could, may, believes, anticipates, intends, expects, and simila 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 our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements. Such factors include, among others, our ability to maintain liquidity, our maintenance of patent protection, the impact of current litigation (as it affects our costs as well as market access), our ability to maintain favorable supplier arrangements and relationships, our ability to receive royalties from Baiyin Tonsun Medical Device Co., Ltd. (BTMD), our ability to quickly increase capacity in response to an increase in demand (such as by increased orders due to swine flu vaccinations), our ability to access the market, our ability to maintain or lower production costs, our ability to continue to finance research and development as well as operations and expansion of production, the increased interest of larger market players, specifically Becton Dickinson and Company (BD), in providing devices to the safety market, and other factors referenced in **Item 1A. Risk Factors** in **Part II**. Given these uncertainties, undue reliance should not be placed on forward-looking statements.

OVERVIEW

We have been manufacturing and marketing our products into the marketplace since 1997. We currently provide other safety medical products in addition to safety syringe products. One such product is the Patient Safe syringe which reduces the risk of syringe and/or medication contamination and the potential for healthcare associated illnesses, such as catheter-related bloodstream infections. Safety syringes comprised 98.6% of our sales in the first nine months of 2009.

Our products have been and continue to be distributed nationally through numerous distributors. However, we have been blocked from access to the market by exclusive marketing practices engaged in by BD, which dominates the market. We believe that its monopolistic business practices continue despite its paying $100 million in 2004 to settle a prior lawsuit with us for anticompetitive practices, business disparagement, and tortious interference and despite the fact that a jury recently returned a verdict finding that all three patents asserted by us against BD are valid and infringed by BD. Although we have made limited progress in some areas, such as the alternate care and international markets, our volumes are not as high as they should be given the nature and quality of our products, the federal and state legislation requiring the use of safe needle devices, and various Senate Subcommittee hearings on Group Purchasing Organizations.

We continue to pursue various strategies to have better access to the hospital market, as well as other markets, including attempting to gain access to the market through our sales efforts, our innovative technology, introduction of new products, and, when necessary, litigation. We are also marketing more products internationally.

Historically, unit sales have increased in the latter part of the year due, in part, to the demand for syringes during the flu season. We expect the H1N1 virus (Swine Flu) to have a longer worldwide immunization duration than the seasonal flu. We have been awarded a contract by the Department of Health and Human Services (DHHS) to supply a portion of the safety engineered syringes to be used in the U.S. efforts to vaccinate the U.S. population against the Swine Flu (the H1N1 Program). The impact on us is likely to be material. Sales to the DHHS comprised 5.4% and 2.7% of our revenues for the three months and nine months ended September 30, 2009, respectively. We expect our revenues and the percentage of revenues attributable to the H1N1 Program to increase significantly in the fourth quarter of 2009 and the first quarter of 2010, provided the H1N1 Program continues as scheduled and we can continue to meet the demands of the H1N1 Program as well as

supplying our traditional customers.

In the event we continue to have only limited market access, the cash provided by the litigation settlements and generated from operations becomes insufficient, and royalties from BTMD are not forthcoming, we would take additional cost cutting measures to reduce cash requirements. Such measures could result in the reduction of units being produced, the reduction of workforce, reduction of salaries of officers and other nonhourly employees, and the deferral of royalty payments. We took such actions at the end of the second quarter of 2009.

At the end of the second quarter of 2009 we announced that in the interest of the long-term survival of the Company we would reorganize some of the Company s functions and implement staff reductions, all in order to minimize our cash expenditures and conserve our resources. Our workforce was reduced by 16% on July 1, 2009. However, due to the expected increase in production from sales to DHHS, we have recently increased the workforce at the Little Elm facility. Our prior estimate that annual compensation costs and related expenses would be reduced by $2.1 million annually due to the layoffs will only be slightly affected by the recent rehiring. An anticipated reduction of inventory was estimated to result in a minimum of $1.0 million reduction in cash outlays over the subsequent twelve months. However, due to the potential orders from the DHHS, that particular initiative is on hold. Our President and CEO, Thomas J. Shaw, waived future royalty payments beginning July 1, 2009, for an aggregate savings of $1.0 million which we expect to be fully utilized by the end of the year. Salaries for all personnel above a certain salary level were cut by 10%. Such reduction, along with discontinuing the 401(k) matching, was estimated to save $600,000. We expect to save an additional $1.6 million by the following actions: moving most, if not all, of the molding of piece parts back to Little Elm; reducing professional fees; and various other cost cutting measures. These measures will remain in place as long as Management deems them necessary.

We recorded a $200,000 charge in the second quarter of 2009 for severance pay offered to the terminated employees. All severance payments were paid in the third quarter of 2009. We will incur a noncash expense of $2.8 million related to the issuance of stock options, most of which will be amortized over twelve months beginning in the third quarter of 2009.

We are focusing on methods of upgrading our manufacturing capability and efficiency in order to reduce costs. We believe our current capitalization provides the resources necessary to implement some of these changes and improve our manufacturing capacity and efficiency, thereby reducing our unit costs.

Product purchases from Double Dove, a Chinese manufacturer, have enabled us to increase manufacturing capacity with little capital outlay and have provided a competitive manufactured cost. Double Dove manufactured, in the first nine months of 2009, approximately 67.4% of the units we produced. The cost of production per unit has generally declined as volumes increased. Double Dove increased the prices in the fourth quarter of 2008 to us by $0.005 per unit. Product cost reductions could be adversely affected by increased material and transportation costs. We believe we could make up any long-term disruption in these supplies by utilizing more of the capacity at the Little Elm facility, except for the 0.5cc insulin syringe, the 5cc and 10cc syringes and the autodisable syringe which altogether comprised about 5.2% of our revenues for the first nine months of 2009.

We previously entered into a License Agreement with BTMD as of May 13, 2005. That license expired on May 13, 2008 (prior to the manufacture and delivery of any products). Nevertheless, BTMD continued to work toward completing the facility and gaining the necessary approvals in order to manufacture and sell products. The facility has been completed and BTMD has met Chinese government requirements. BTMD received a Registration Certificate for Medical Device on August 24, 2009. Production efforts are currently underway and are being tested. We entered into a new agreement (effective as of July 1, 2009) with BTMD along similar terms as the prior agreement. This agreement expires on July 1, 2010 which may automatically extend under certain conditions. Such terms include granting to BTMD a limited exclusive license to manufacture and a limited exclusive right to sell syringes in the People s Republic of China (PRC) having retractable needles that incorporate our technology. This License Agreement is subject to the Technology License Agreement dated June 23, 1995 between Mr. Thomas J. Shaw, our founder and CEO, as licensor, and the Company, as licensee (as amended). Accordingly, Mr. Shaw will receive 5% of the licensing proceeds we receive. BTMD has agreed to manufacture and sell these products in the PRC and to pay us a quarterly royalty of two and one-half cents per unit on 3 cc and 5 cc syringes and a royalty of three and one-half cents per unit on 0.5cc, 1 cc, and 10 cc syringes. The obligation to pay the royalties continues even if any and all of our patent rights in the PRC are found to be invalid or unenforceable for any reason. We still

continue to expect royalty payments although we are unable to predict the date we will begin to receive such royalties.

With increased volumes, our manufacturing unit costs have generally tended to decline. Factors that could affect our unit costs, in addition to Double Dove s increase in unit costs of $0.005, include changing production volumes, costs of petroleum products, and transportation costs. Increases in such costs may not be recoverable through price increases of our products.

We completed the expansion of an existing warehouse in the first quarter of 2009. This expansion increased our warehouse area, provided for additional office space, and added a second Controlled Environment. This will enable us to do more molding in-house.

LIQUIDITY

At the present time, Management does not intend to raise equity capital. Due to the funds received from prior litigation settlements, we have sufficient cash reserves and intend to rely on operations, cash reserves, and debt financing as the primary ongoing sources of cash.

Historical Sources of Liquidity

We have historically funded operations primarily from the proceeds from private placements, loans, and litigation settlements.

Internal Sources of Liquidity

Margins and Market Access

To achieve break-even quarters, we need minimal access to hospital markets which has been difficult to obtain due to the monopolistic marketplace which was the subject of our initial lawsuit and now also included in our second antitrust lawsuit against BD. We will continue to attempt to gain access to the market through our sales efforts, innovative technology, the introduction of new products and, when necessary, litigation.

We are focusing on methods of upgrading our manufacturing capability and efficiency in order to reduce costs. We believe our current capitalization provides the resources necessary to implement some of these changes and improve our manufacturing capacity and efficiency, thereby reducing our unit costs.

Beginning in early 2004, we began to receive shipment of product from Double Dove which enabled us to lower our unit costs. Fluctuations in the cost and availability of raw materials and inventory and our ability to maintain favorable supplier arrangements and relationships could result in the need to manufacture all (as opposed to approximately 31.8%) of our products in the U.S. This could temporarily increase unit costs as we ramp up domestic production.

The mix of domestic and international sales affects the average sales price of our products. Generally, the higher the ratio of domestic sales to international sales, the higher the average sales price will be. Typically international sales are shipped directly from China to the customer. Purchases of product manufactured in China, if available, usually decrease the average cost of manufacture for all units as domestic costs, such as indirect labor and overhead, remain relatively constant. Double Dove increased their prices to us by $0.005 per unit in the fourth quarter of 2008. The number of units produced by the Company versus manufactured in China can have a significant effect on the carrying costs of inventory as well as Cost of sales. We will continue to evaluate the appropriate mix of products manufactured domestically and those manufactured in China to achieve economic benefits as well as to maintain our domestic manufacturing capability. Currently, approximately 31.8% of our products are produced domestically. We and Double Dove have increased production to meet the flu season demand.

Fluctuations in the cost of oil (since our products are petroleum based), transportation costs, and the volume of units purchased from Double Dove may have an impact on the unit costs of our products. Increases in such costs may not be recoverable through price increases of our products. Reductions in oil prices may not quickly affect petroleum product prices.

Seasonality

Historically, unit sales have increased in the latter part of the year due, in part, to the demand for syringes during the flu season. We expect the Swine Flu to have a longer worldwide immunization duration than the seasonal flu. We have been awarded a contract by the DHHS to supply a portion of the safety engineered syringes to be used in the U.S. efforts to vaccinate the U.S. population against the Swine Flu. The impact on us is likely to be material. Sales to the DHHS comprised 5.4% and 2.7% of our revenues for the three months and nine months ended September 30, 2009, respectively. We expect our revenues and the percentage of revenues attributable to the H1N1 Program to increase significantly in the fourth quarter of 2009 and the first quarter of 2010, provided the H1N1 Program continues as scheduled and we can continue to meet the demands of the H1N1 Program as well as supplying our traditional customers.

Licensing Agreement

We previously entered into a License Agreement with BTMD as of May 13, 2005. That license expired on May 13, 2008 (prior to the manufacture and delivery of any products). Nevertheless, BTMD continued to work toward completing the facility and gaining the necessary approvals in order to manufacture and sell products. The facility has been completed and BTMD has met Chinese government requirements. BTMD received a Registration Certificate for Medical Device on August 24, 2009. Production efforts are currently underway and are being tested. We entered into a new agreement (effective as of July 1, 2009) with BTMD along similar terms as the prior agreement. This agreement expires on July 1, 2010 which may automatically extend under certain conditions. Such terms include granting to BTMD a limited exclusive license to manufacture and a limited exclusive right to sell syringes in the PRC having retractable needles that incorporate our technology. This License Agreement is subject to the Technology License Agreement dated June 23, 1995 between Mr. Thomas J. Shaw, our founder and CEO, as licensor, and the Company, as licensee (as amended). Accordingly, Mr. Shaw will receive 5% of the licensing proceeds we receive. BTMD has agreed to manufacture and sell these products in the PRC and to pay us a quarterly royalty of two and one-half cents per unit on 3 cc and 5 cc syringes and a royalty of three and one-half cents per unit on 0.5cc, 1 cc, and 10 cc syringes. The obligation to pay the royalties continues even if any and all of our patent rights in the PRC are found to be invalid or unenforceable for any reason. We still continue to expect royalty payments although we are unable to predict the date we will begin to receive such royalties.

Cash Requirements

Due to funds received from prior litigation settlements, we have sufficient cash reserves and intend to rely on operations, cash reserves, and debt financing as the primary ongoing sources of cash. However, working capital has decreased $11.7 million since December 31, 2008. Litigation costs continue to be a significant expense but we expect this expense to decline after the Abbott Laboratories (Abbott) trial in May 2010. We anticipate that decreases in certain operating expenses and a projected increase in sales will help mitigate cash decreases.

In the event we continue to have only limited market access, the cash provided by the litigation settlements and generated from operations becomes insufficient, and royalties from BTMD are not forthcoming, we would take additional cost cutting measures to reduce cash requirements. Such measures could result in the reduction of units being produced, the reduction of workforce, the reduction of salaries of officers and other nonhourly employees, and the deferral of royalty payments. We took such actions at the end of the second quarter of 2009.

At the end of the second quarter of 2009 we announced that in the interest of the long-term survival of the Company we would reorganize some of the Company s functions and implement staff reductions, all in order to minimize our cash expenditures and conserve our resources. Our workforce was reduced by 16% on July 1, 2009. However, due to the expected increase in production from sales to DHHS, we have recently increased the workforce at the Little Elm facility. Our prior estimate that annual compensation costs and related expenses would be reduced by

$2.1 million annually due to the layoffs will only be slightly affected by the recent rehiring. An anticipated reduction of inventory was estimated to result in a minimum of $1.0 million reduction in cash outlays over the subsequent twelve months. However, due to the potential orders from the DHHS, that particular initiative is on hold. Our President and CEO, Thomas J. Shaw, waived future royalty payments beginning July 1, 2009, for an aggregate savings of $1.0 million which we expect to be fully utilized by the end of the year. Salaries for all personnel above a certain salary level were cut by 10%. Such reduction, along with discontinuing the 401(k) matching, was estimated to save $600,000. We expect to save an additional $1.6 million by the following actions: moving most, if not all, of the molding of piece parts back to Little Elm; reducing professional fees; and various other cost cutting measures. These measures will remain in place as long as Management deems them necessary. We expect these cost cutting measures to mitigate the reduction in our cash balance.

We recorded a $200,000 charge in the second quarter of 2009 for severance pay offered to the terminated employees. All severance payments were paid in the third quarter of 2009. We will incur a noncash expense of $2.8 million related to the issuance of stock options, most of which will be amortized over twelve months beginning in the third quarter of 2009.

External Sources of Liquidity

We have obtained several loans since our inception, which have, together with the proceeds from the sales of equities and litigation efforts, enabled us to pursue development and production of our products. Given the current economic conditions, our ability to obtain additional funds through loans may be limited.

The shareholders previously authorized an additional 5,000,000 shares of a Class C Preferred Stock that could, if necessary, be designated and used to raise funds through the sale of equity. Due to the current market price of our Common Stock, it is unlikely we would choose to raise funds by the sale of equity.

In 2008, we received a construction line of credit for up to $4,210,000 to fund an expansion of our warehouse. We expect to replace this loan with a permanent financing arrangement before its maturity in the first quarter of 2010.

CAPITAL RESOURCES

Trends in Capital Resources

Interest expense will increase due to the recent loan of approximately $4.2 million, but will be somewhat mitigated by lower borrowing rates if current conditions in the credit markets continue. Interest income will continue to be negatively affected by lower interest rates and our prior movement of cash to U.S. Treasury bills and other U.S. government backed securities. Although we believe that we have granted credit to credit-worthy firms, current economic conditions may affect the timing and/or collectability of some accounts.

Material Commitments for Expenditures

We completed expansion of our warehouse (including additional warehouse space, additional office space, and a new Controlled Environment) in the first quarter of 2009. We funded most of this expansion with a construction line of credit from Lewisville State Bank, a division of 1st International Bank, for approximately $4.2 million, secured by a second lien deed on the land and existing buildings. This will be replaced by permanent financing before its maturity in the first quarter of 2010.

Due to the increased activity from flu season, our working capital requirements will be somewhat increased at least through the end of March 2010. Such increase will be funded by anticipated increased revenues and cash on hand.

MATERIAL CHANGES IN FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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, 2009, or 2008.

Comparison of Three Months Ended September 30, 2009, and September 30, 2008

Domestic sales accounted for 84.8% and 86.2% of the revenues for the three months ended September 30, 2009 and 2008, respectively. International sales accounted for the remaining revenues. Domestic revenues increased 17.6% principally due to higher volumes. Approximately 42.6% of the increase in domestic revenues is attributable to sales to the DHHS. International revenues increased 31.7% due primarily to higher volumes and higher prices. Overall, unit sales increased 19.5%. Domestic unit sales increased 20.1% due to flu season. International unit sales increased 17.9% primarily due to flu season, additional distributors, and new customers for existing distributors. Domestic unit sales were 75.5% of total unit sales for the three months ended September 30, 2009.

Gross profit increased primarily due to higher revenues and lower unit cost of production. The average cost of manufactured product sold per unit decreased by 5.4% due to higher volumes of product sold. Profit margins

can fluctuate depending upon, among other things, the cost of product manufactured and the capitalized cost of product recorded in inventory, as well as product sales mix. Royalty expense increased 20.1% due to higher gross sales, but payment of $682,335 has been waived by the shareholder and recorded as additional paid-in capital.

Operating expenses increased 50.6%. General and administrative costs increased due primarily to litigation costs and stock option expense. Compensation costs declined. The decrease in expense for Sales and marketing was attributable primarily to lower compensation costs and marketing expenses. The decrease was mitigated by additional stock option expense. Research and development costs decreased due to lower compensation costs and samples.

Loss from operations increased due principally to increased litigation cost and stock option expense mitigated by a higher gross profit.

Interest expense decreased due to capitalized interest offsetting interest expense. Interest expense for the third quarter of 2009 was zero because of the effect of capitalized interest.

The Company s effective tax rate on the net loss before income taxes was 2.8% and 0% for the three months ended September 30, 2009 and September 30, 2008, respectively.

Comparison of Nine Months Ended September 30, 2009 and September 30, 2008

Domestic sales accounted for 83.6% and 84.5% of the revenues for the nine months ended September 30, 2009 and 2008, respectively. International sales accounted for the remaining revenues. Domestic revenues increased 3.5% principally due to sales to the DHHS and international revenues increased 11.3% due primarily to higher average sales prices. Overall, unit sales increased 2.3%. Domestic unit sales increased 3.8% due to flu season. International unit sales decreased 1.5%. Domestic unit sales were 73.1% of total unit sales for the nine months ended September 30, 2009.

Gross profit increased primarily due to increased volumes and higher average sales price. The average cost of manufactured product sold per unit increased slightly. Profit margins can fluctuate depending upon, among other things, the cost of product manufactured and the capitalized cost of product recorded in inventory, as well as product sales mix. Royalty expense increased 6.3% due to higher gross sales, but payment of $682,335 has been waived by the shareholder and recorded as additional paid-in capital.

Operating expenses increased 32.9%. General and administrative costs increased due primarily to litigation costs and stock option expense. The decrease in expense for Sales and marketing was attributable primarily to lower compensation costs. The decrease was mitigated by higher stock option costs. Research and development costs increased due to higher consulting, stock option expense, and testing costs, mitigated by lower compensation costs.

Loss from operations increased due principally to litigation costs and stock option expense mitigated by a higher gross profit.

Interest expense decreased due to capitalized interest. Interest expense for the third quarter of 2009 was zero because of the offsetting credit of capitalized interest.

The Company s effective tax rate on the net loss before income taxes was 2.0% and 0.0% for the nine months ended September 30, 2009 and September 30, 2008, respectively.

Discussion of Balance Sheet and Statement of Cash Flow Items

The Company s balance sheet remains strong with cash making up 35.2% of total assets. Working capital was $21.6 million at September 30, 2009, a decrease of $11.7 million from December 31, 2008. The current ratio was 4.3 at December 31, 2008 and 3.0 at September 30, 2009. The quick ratio was 3.6 at December 31, 2008 and 2.2 at September 30, 2009. One reason for the decline in the current ratio as well as the quick ratio was the decline

in cash. However, these indicators continue to demonstrate a strong financial position. We expect the cost cutting measures described earlier, as well as our sales to the DHHS, to mitigate the reduction in our cash balance.

Raw materials inventory increased 45.1% since December 31, 2008 due to preparation for the DHHS order. We expect to be moving the manufacturing of piece parts to Little Elm as a cost saving measure. In the meantime, we increased inventory to ensure a smooth transition of the move of molding from California to the Little Elm facility as well as to address potential orders from DHHS. Finished goods inventory increased 19.2% since December 31, 2008 because of flu season.

Other liabilities increased due to prepayments for orders from international customers.

Approximately $13.3 million in cash flow in 2009 was used by operating activities. The remaining uses of cash were primarily for property, plant, and equipment.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Fluctuations in the cost of oil (since our products are petroleum based) and transportation costs may have an impact on the unit costs of our products. Increases in such costs may not be recoverable through price increases of our products. Reductions in oil prices may not quickly affect petroleum product prices. We do not currently anticipate a material impact resulting from fluctuations in oil prices.

Item 4. Controls and Procedures.

Disclosure Controls and Procedures

Pursuant to Rule 13a-15(b) of the Securities Exchange Act of 1934, Management, with the participation of our President, Chairman, and Chief Executive Officer, Thomas J. Shaw (the CEO), and our Vice President and Chief Financial Officer, Douglas W. Cowan (the CFO), acting in their capacities as our principal executive and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures, as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934. The term disclosure controls and procedures means controls and other procedures that are designed to ensure that information required to be disclosed by us in our periodic reports is: i) recorded, processed, summarized, and reported, within the time periods specified in the Securities and Exchange Commission s rules and forms; and ii) accumulated and communicated to our Management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Based upon this evaluation, the CEO and CFO concluded that, as of September 30, 2009, our disclosure controls and procedures were effective.

Changes in Internal Control Over Financial Reporting

There have been no changes during the third quarter of 2009 or subsequent to September 30, 2009 in our internal control over financial reporting or in any other factor that has materially affected or is reasonably likely to materially affect our internal control over financial reporting.

PART II OTHER INFORMATION

Item 1. Legal Proceedings.

On August 12, 2005, we filed a lawsuit against Abbott in the U.S. District Court in the Eastern District of Texas, Texarkana Division. We are alleging fraud and breach of contract in connection with the National Marketing and Distribution Agreement dated as of May 4, 2000, which was terminated on October 15, 2003. We are seeking damages which we estimate to be in millions of dollars of lost profits, out of pocket expenses, and other damages. In addition, we are seeking punitive damages, pre- and post-judgment interest, and attorneys fees. Following Abbott s unsuccessful attempt to get the case dismissed and ordered to arbitration, Abbott filed an answer and counterclaim on July 15, 2008, alleging several breaches of contract, breach of implied warranty of merchantability, and breach of express warranty, seeking in excess of $6,000,000 in compensatory damages as well as seeking attorneys fees. We deny the validity of Abbott s counterclaims. Some discovery has already taken place (related to the hearings addressing the prior motion to compel arbitration) and additional discovery is underway. The District Court has issued a revised scheduling order calling for trial in May 2010.

In April 2008, we sued Occupational and Medical Innovations Limited (OMI) in the U.S. District Court for the Eastern District of Texas, Tyler Division, alleging that OMI has infringed two U.S. patents that were not at issue in the Australian litigation (6,572,584 and 7,351,224). We also alleged theft of confidential information, intentional interference with contracts and engaging in false advertising that wrongfully disparaged and mischaracterized our syringe products. We further alleged that OMI made false allegations regarding the source of origin of its safety syringe products being offered in the U.S. We are seeking injunctive relief, unspecified damages (including treble damages) and reimbursement of attorneys fees in the suit. OMI has counterclaimed, seeking declaratory judgments of non-infringement and invalidity of our asserted patents. OMI is not seeking monetary damages. Trial is set for December 2009.

In June 2007, we sued Becton Dickinson and Company (BD) in the U.S. District Court for the Eastern District of Texas, Marshall Division, alleging infringement of three patents (5,578,011; 5,632,733; and 6,090,077) and violations by BD of the federal and state antitrust laws, and of the Lanham Act. We subsequently dropped the 5,578,011 patent allegations from the lawsuit. We and Thomas J. Shaw, a co-plaintiff, were seeking injunctive relief, unspecified monetary damages and reimbursement of attorneys fees in the suit. BD counterclaimed for non-infringement and invalidity of the asserted patents. In January 2008, the Court severed the patent claims from the other claims pending resolution of the patent dispute. In April 2008, we and Thomas J. Shaw sued BD in the U.S. District Court for the Eastern District of Texas, Marshall Division, alleging infringement of another recently issued patent (7,351,224), and seeking injunctive relief, unspecified monetary damages (including treble damages) and reimbursement of attorneys fees. BD counterclaimed for non-infringement and invalidity of the asserted patent. The court consolidated this case with the above-stated case filed in June 2007. This case was tried to a jury from October 30 to November 9, 2009. On November 9, the jury returned a verdict finding that BD has infringed all three asserted patents, that the three asserted patents are not invalid, and that BD owes us and Thomas J. Shaw five million dollars ($5,000,000). Judgment has not yet been entered on the verdict, and post-trial briefing is presently underway. We and Thomas J. Shaw are also requesting that, based upon the jury verdict of patent infringement, the Court enjoin BD from selling the accused Integra® syringes. Because the jury also found that the infringement was not willful, there is no probability that we and Thomas J. Shaw will recover enhanced damages. Any judgment entered upon the jury verdict will be subject to appeal by all parties to the litigation.

In September 2007, BD and MDC Investment Holdings, Inc. (MDC) sued us in the United States District Court for the Eastern District of Texas, Texarkana Division, initially alleging that we are infringing two U.S. patents of MDC (6,179,812 and 7,090,656) that are licensed to BD. BD and MDC seek injunctive relief and unspecified damages. We counterclaimed for declarations of non-infringement, invalidity, and unenforceability of the asserted patents. The plaintiffs subsequently dropped allegations with regard to patent no. 7,090,656 and we subsequently dropped our counterclaims for unenforceability of the asserted patents. The Court conducted a claims construction hearing on September 25, 2008 and issued its claims construction order on November 14, 2008. No trial date has been set. The parties have agreed to request a stay of this litigation until after the case against BD has been tried.

In September 2008, we and Thomas J. Shaw sued Safety Medical International (SMI) in the United States District Court for the Eastern District of Texas, Tyler Division, alleging infringement of U.S. patent nos. 6,572,584 and 7,351,224, and seeking injunctive relief, unspecified monetary damages and reimbursement of attorneys fees. SMI has counterclaimed, seeking declaratory judgments of non-infringement and invalidity of the asserted patents. SMI is not seeking monetary damages. SMI has filed a notice of bankruptcy in this case and it has been stayed pending the outcome of those proceedings.

Item 1A. Risk Factors.

There were no material changes in the Risk Factors applicable to the Company as set forth in our Form 10-K annual report for 2008 which was filed on March 31, 2009, and which is available on EDGAR.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Unregistered Sales of Equity Securities and Use of Proceeds

None.

Working Capital Restrictions and Limitations on the Payment of Dividends

We maintain cash for use as collateral for letters of credit we provide from time to time to enable, among other things, the purchase of product from China. As of September 30, 2009, we had no funds held as restricted cash for such purposes. The Board of Directors has authorized Management to borrow and incur indebtedness in the form of letters of credit in an aggregate amount, at any one time, of $5,000,000.

The certificates of designation for each of the outstanding series of Class B Convertible Preferred Stock each currently provide that, if a dividend upon any shares of Preferred Stock is in arrears, no dividends may be paid or declared or any other distribution made upon any stock ranking junior to such stock and generally no such junior stock may be redeemed.

Item 3. Defaults Upon Senior Securities.

Series I Class B Convertible Preferred Stock

As of the nine months ended September 30, 2009, the amount of dividends in arrears was $54,000 and the total arrearage was $162,000.

Series II Class B Convertible Preferred Stock

As of the nine months ended September 30, 2009, the amount of dividends in arrears was $165,000 and the total arrearage was $496,000.

Series III Class B Convertible Preferred Stock

As of the nine months ended September 30, 2009, the amount of dividends in arrears was $99,000 and the total arrearage was $3,213,000.

Series IV Class B Convertible Preferred Stock

As of the nine months ended September 30, 2009, the amount of dividends in arrears was $414,000 and the total arrearage was $7,445,000.

Series V Class B Convertible Preferred Stock

As of the nine months ended September 30, 2009, the amount of dividends in arrears was $297,000 and the total arrearage was $3,594,000.

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

The 2009 Annual Meeting of Stockholders (the Annual Meeting) was held on September 25, 2009, at 10:00 a.m., Central time. The purposes of the meeting were to: 1) elect two Class 1 Directors; and 2) approve a stock option grant to Thomas J. Shaw for the purchase of 3,000,000 shares of Common Stock.

Of the 23,800,064 shares of Common Stock entitled to vote, 20,869,270 were represented in person or by proxy at the Annual Meeting, which is more than the 11,900,032 required to constitute a quorum.

1) The election of two Class 1 Directors was put to a vote and the results were as follows:

Nominees	For	Withheld
Marco Laterza	20,364,655	504,615
Amy Mack	20,344,316	524,954

Accordingly, Mr. Laterza and Ms. Mack were elected as Class 1 Directors to serve until our 2011 Annual Meeting. As of the adjournment of the Annual Meeting, the Board of Directors consisted of the following members:

Thomas J. Shaw	Class 2 Director
Douglas W. Cowan	Class 2 Director
Marco Laterza	Class 1 Director
Amy Mack	Class 1 Director
Marwan Saker	Class 2 Director
Steven R. Wisner	Class 2 Director
Clarence Zierhut	Class 2 Director

2) The approval of a stock option grant for the purchase of 3,000,000 shares of Common Stock to Thomas J. Shaw was put to a vote and the results were as follows:

For	**Against**	**Abstain**	**Broker Non-Votes**
15,436,068	536,085	319,859	4,577,258

Accordingly, the stock option grant was approved.

A Special Meeting of Preferred Shareholders (the Special Meeting) was held on September 25, 2009, at 11:00 a.m., Central time. The purposes of the meeting were to: 1) approve an amendment to the Certificate of Designation, Preferences, Rights and Limitations of Class B Convertible Preferred Stock (the Series I Certificate of Designation); 2) approve an amendment to the Certificate of Designation, Preferences, Rights and Limitations of the Series II Class B Convertible Preferred Stock (the Series II Certificate of Designation); 3) approve an amendment to the Certificate of Designation, Preferences, Rights and Limitations of the Series III Class B Convertible Preferred Stock (the Series III Certificate of Designation); 4) approve an amendment to the Certificate of Designation, Preferences, Rights and Limitations of the Series IV Class B Convertible Preferred Stock (the Series IV Certificate of Designation); and 5) approve an amendment to the Certificate of Designation, Preferences, Rights and Limitations of the Series V Class B Convertible Preferred Stock (the Series V Certificate of Designation). The Company is considering purchasing its Common Stock from time to time pursuant to a stock repurchase program, when and if the Board of Directors determines it is appropriate. The amendment which we proposed is necessary in order to effectuate a stock purchase plan while dividends are in arrears. It authorizes the purchase of stock under certain conditions even when payment of past due preferred stock dividends are in arrears.

An insufficient number of the Preferred Shares of Series I Class B, Series II Class B, Series III Class B, and Series IV Class B were represented in person or by proxy at the Special Meeting to constitute quorum. The meeting was adjourned as to the aforementioned series until January 22, 2010 at 10:00 a.m. Central time because there was no quorum as to such series. A notice of such rescheduled meeting will be sent out in the fourth quarter of 2009.

Of the 1,238,821 shares of Series V Class B Preferred Stock entitled to vote, 998,821 were represented in person or by proxy at the Annual Meeting, which is more than the 619,411 required to constitute a quorum.

The approval of an amendment to the Series V Certificate of Designation was put to a vote and the results were as follows:

For	Against	Abstain	Broker Non-Votes
977,321	21,500	0	0

Accordingly, the Series V Class B Designation amendment was approved and such amendment was filed with the Secretary of State. The amended Certificate of Designation is attached hereto as an exhibit.

Item 5. Other Information.

A rescheduled Special Meeting of the Preferred Shareholders of Series I Class B, Series II Class B, Series III Class B, and Series IV Class B Convertible Preferred Stock will be held January 22, 2010 at 10:00 a.m. Central time. A notice of such rescheduled meeting will be sent out in the fourth quarter of 2009.

Item 6. Exhibits.

Exhibit No.	Description of Document
3(i)	Third Amended and Restated Articles of Incorporation of RTI filed on November 1, 2004* as amended by that Statement of Change of Registered Office/Agent** as further amended by the Certificate of Amendment filed October 16, 2009***
3(ii)	Third Amended and Restated Bylaws of RTI** **
4(v)	Amended Certificate of Designation, Preferences, Rights and Limitations of the Series V Class B Convertible Preferred Stock***
31.1	Certification of Principal Executive Officer ***
31.2	Certification of Principal Financial Officer ***
32	Certification Pursuant to 18 U.S.C. Section 1350 ***
*	Incorporated herein by reference to RTI s Form 10-Q filed on November 14, 2005
**	Incorporated herein by reference to RTI s Form 10-K filed on March 31, 2008
***	Attached hereto
** **	Incorporated herein by reference to RTI s Form 10-Q filed on November 14, 2008

SIGNATURES

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

DATE: November 16, 2009

RETRACTABLE TECHNOLOGIES, INC.
(Registrant)

BY: s/ Douglas W. Cowan
DOUGLAS W. COWAN
VICE PRESIDENT AND
CHIEF FINANCIAL OFFICER