RETRACTABLE TECHNOLOGIES INC
Form 10-Q
November 14, 2008

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, 2008

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 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: 23,800,064 shares of Common Stock, no par value, issued and outstanding on November 3, 2008.

RETRACTABLE TECHNOLOGIES, INC.

FORM 10-Q

For the Quarterly Period Ended September 30, 2008

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements.

RETRACTABLE TECHNOLOGIES, INC.

CONDENSED BALANCE SHEETS

	September 30, 2008 (unaudited)	December 31, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 35,963,071	$ 40,507,431
Accounts receivable, net	3,443,724	1,667,636
Inventories, net	5,957,811	7,037,129
Income taxes receivable		2,345,041
Other current assets	660,943	358,807
Total current assets	46,025,549	51,916,044
Property, plant, and equipment, net	12,784,588	11,483,423
Intangible assets, net	481,785	424,560
Other assets	5,212	505,899
Total assets	$ 59,297,134	$ 64,329,926
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 4,609,452	$ 5,535,365
Current portion of long-term debt	500,310	387,906
Accrued compensation	723,044	539,330
Marketing fees payable	1,419,760	1,419,760
Accrued royalties to shareholders	651,502	619,304
Other accrued liabilities	668,842	263,339
Current deferred tax liability	17,464	20,626
Total current liabilities	8,590,374	8,785,630
Long-term debt, net of current maturities	4,638,949	3,747,259
Long-term deferred tax liability	23,508	36,200
Total liabilities	13,252,831	12,569,089
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	553,500
Series V, Class B	1,238,821	1,282,471
Common stock, no par value		
Additional paid-in capital	53,879,491	53,818,987
Accumulated deficit	(10,120,454)	(4,388,066)
Total stockholders equity	46,044,303	51,760,837

Total liabilities and stockholders equity	$ 59,297,134	$ 64,329,926

See accompanying notes to condensed financial statements

RETRACTABLE TECHNOLOGIES, INC.

CONDENSED STATEMENTS OF OPERATIONS

(unaudited)

	Three Months Ended September 30, 2008	Three Months Ended September 30, 2007	Nine Months Ended September 30, 2008	Nine Months Ended September 30, 2007
Sales, net	$ 8,997,038	$ 8,040,127	$ 20,786,420	$ 19,088,932
Cost of sales				
Cost of manufactured product	6,219,614	5,228,549	12,851,542	12,031,550
Royalty expense to shareholders	651,502	624,967	1,547,281	1,468,292
Total cost of sales	6,871,116	5,853,516	14,398,823	13,499,842
Gross profit	2,125,922	2,186,611	6,387,597	5,589,090
Operating expenses:				
Sales and marketing	1,139,052	1,334,680	3,607,962	4,025,682
Research and development	271,174	375,264	804,006	796,979
General and administrative	2,896,205	2,906,156	8,284,638	7,894,510
Total operating expenses	4,306,431	4,616,100	12,696,606	12,717,171
Loss from operations	(2,180,509)	(2,429,489)	(6,309,009)	(7,128,081)
Interest and other income	158,664	521,226	653,782	1,511,121
Interest expense, net	(13,893)	(86,235)	(77,161)	(257,427)
Net loss before income taxes	(2,035,738)	(1,994,498)	(5,732,388)	(5,874,387)
Benefit for income taxes		(1,406,360)		(1,406,360)
Net loss	(2,035,738)	(588,138)	(5,732,388)	(4,468,027)
Preferred stock dividend requirements	(342,717)	(348,147)	(1,030,302)	(1,052,398)
Loss applicable to common stockholders	$ (2,378,455)	$ (936,285)	$ (6,762,690)	$ (5,520,425)
Loss per share basic and diluted	$ (0.10)	$ (0.04)	$ (0.28)	$ (0.23)
Weighted average common shares outstanding	23,800,064	23,745,206	23,792,733	23,717,845

See accompanying notes to condensed financial statements

RETRACTABLE TECHNOLOGIES, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(unaudited)

	Nine Months Ended September 30, 2008	Nine Months Ended September 30, 2007
Cash flows from operating activities		
Net loss	$ (5,732,388)	$ (4,468,027)
Adjustments to reconcile net loss to net cash provided by (used by) operating activities:		
Depreciation and amortization	1,048,773	1,077,370
Capitalized interest	(153,226)	(132,930)
Stock option compensation		6,478
Provisions for doubtful accounts	143,496	2,242
Accreted interest	41,807	92,103
(Increase) decrease in assets		
Inventories	1,079,318	(784,702)
Accounts receivable	(1,919,584)	(1,284,247)
Income taxes receivable	2,345,041	(1,494,412)
Other current assets	(302,136)	(494,227)
Increase (decrease) in liabilities		
Accounts payable	(925,913)	274,521
Other accrued liabilities	621,415	769,501
Net cash used by operating activities	(3,753,397)	(6,436,330)
Cash flows from investing activities		
Purchase of property, plant, and equipment	(2,161,789)	(321,961)
Acquisitions of patents, trademarks, licenses and intangibles	(89,152)	(131,400)
Investment in LLC	497,690	
Net cash used by investing activities	(1,753,251)	(453,361)
Cash flows from financing activities		
Repayments of long-term debt and notes payable	(366,571)	(278,694)
Proceeds from long-term debt	1,328,859	
Payment of dividends on Series I and II Class B Convertible Preferred Stock		(1,053,544)
Net cash provided by (used by) financing activities	962,288	(1,332,238)
Net decrease in cash	(4,544,360)	(8,221,929)
Cash and cash equivalents at:		
Beginning of period	40,507,431	46,814,689
End of period	$ 35,963,071	$ 38,592,760
Supplemental disclosures of cash flow information:		
Interest paid	$ 188,581	$ 298,250

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® 0.5 cc insulin syringe; 1cc tuberculin, insulin, and allergy antigen syringes; the 3cc, 5cc, and 10cc syringes; the autodisable syringe; 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, 2008 for the year ended December 31, 2007.

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

Effective January 1, 2008, the Company adopted Statement of Financial Accounting Standard (SFAS) No. 157, *Fair Value Measurements* (SFAS 157). SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with accounting principles generally accepted in the U.S., and expands disclosure requirements about fair value measurements. In accordance with Financial Accounting Standards Board (FASB) Staff Position FAS 157-2, *Effective Date of FASB Statement No. 157*, the Company will defer the adoption of SFAS 157 for its nonfinancial assets and nonfinancial liabilities, except those items recognized or disclosed at fair value on an annual or more frequent recurring basis, until January 1, 2009. The adoption of SFAS 157 did not have a material impact on the Company s fair value measurements.

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, estimates 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.

Considering the current economic climate, the situation could change. As a result, the Company increased its Provision for doubtful accounts by approximately $144,000 this year.

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 71.1% of its finished products in the first nine months of 2008 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 0.5 cc 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 0.48% 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. Abbott filed an answer and counterclaim July 15, 2008. See Note 5 **COMMITMENTS AND CONTINGENCIES-**Litigation for further discussion.

Income taxes

The Company provides for deferred income taxes in accordance with SFAS 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 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 has adopted SFAS No. 128, *Earnings Per Share*, which establishes standards for computing and presenting earnings per share. Basic earnings per share is computed 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, 2008 and 2007. 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

On September 26, 2008, the Company s shareholders approved the 2008 Stock Option Plan and also approved an Offer to Exchange Stock Options (the Exchange Offer) whereby employees, including executive officers, and Directors may exchange certain outstanding underwater options for options issued under the 2008 Stock Option Plan. See Note 6 **SUBSEQUENT EVENTS** for further discussion.

The Company has issued options under three stock-based Director, independent contractor and employee compensation plans as well as several individual option agreements. Two of the plans have terminated; however, the options continue until their expected maturity dates.

The Company s share-based payments are accounted for in accordance with the provisions of SFAS No. 123 (Revised 2004) (SFAS 123 R), *Share-Based Payment*, using the fair value method. The Company records share-based compensation expense on a straight-line basis over the requisite service period. In accordance with the disclosure requirements of SFAS No. 123 R, the Company incurred the following share-based compensation costs:

	Three Months Ended September 30, 2008	Three Months Ended September 30, 2007	Nine Months Ended September 30, 2008	Nine Months Ended September 30, 2007
Cost of sales	$	$	$	$ 6,648
Sales and marketing				3,086
Research and development				(7,863)
General and administrative				4,607
	$	$	$	$ 6,478

Accounting Pronouncements

In April 2008, the Financial Accounting Standards Board (FASB) issued FASB Staff Position (FSP) FAS 142-3, *Determination of the Useful Life of Intangible Assets* . 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. This FSP is effective for financial statements issued for fiscal years and interim periods beginning after December 15, 2008. Early adoption of the standard is prohibited. FAS 142-3 is effective on January 1, 2009. We are currently evaluating the impact of FAS 142-3, and have not yet determined the impact, if any, that the adoption of FSP FAS 142-3 will have on the Company s financial statements.

3. INVENTORIES

Inventories consist of the following:

	September 30, 2008	December 31, 2007
Raw materials	$ 1,551,250	$ 1,743,990
Finished goods	4,612,161	5,498,739
	6,163,411	7,242,729
Inventory reserve	(205,600)	(205,600)
	$ 5,957,811	$ 7,037,129

4. OTHER ASSETS

In 2006, the Company invested $500,000 in a limited liability company. The Company exercised its option to have that investment returned. The investment was returned in April 2008.

5. COMMITMENTS AND CONTINGENCIES

Litigation

On August 12, 2005, the Company filed a lawsuit against Abbott in the United States District Court in the Eastern District of Texas, Texarkana Division. It 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 attorney s 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 scheduling order calling for trial in January 2010.

In August 2006, the Company was sued by Occupational and Medical Innovations Limited (OMI) in Federal Court of Australia, alleging that two letters written to OMI by outside counsel contained unjustified threats of patent infringement, but seeking no damages. OMI later amended its complaint to seek a declaratory judgment that OMI does not infringe Australian Patent No. 701878, again seeking no damages. Following a one-day trial in June 2007, the Court held that one of the two letters written by outside counsel contained a threat of patent infringement, and awarded costs to OMI in an amount that has not yet been determined. Following a one-day trial in June 2008, the Court issued a declaratory judgment in August 2008 stating that OMI s syringe does not infringe the Australian patent no. 701878 but also awarding costs to the Company. The amount of costs to be awarded will be determined at a later date.

In June 2007, the Company sued Becton Dickinson and Company (BD) in the United States 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, are 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, which is set for trial in March 2009. In April 2008, the Company and that same officer sued BD in the United States 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 Company and officer moved to consolidate this case with the other patent case against BD that was pending in Marshall and the Court granted the Company s motion, consolidating this case with the above-stated case filed in June 2007.

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 but has not ruled. No trial date has been set.

In March 2008, MedSafe Technologies LLC (MedSafe) initially sued the Company and BD in the United States District Court for the District of South Carolina, Greenville Division, alleging infringement of a MedSafe patent (6,074,370) and seeking injunctive relief and unspecified monetary damages. The Company counterclaimed for declarations of non-infringement, invalidity, and unenforceability of the asserted patent. BD subsequently settled with MedSafe. The case is set for trial in October 2009.

In April 2008, the Company sued OMI in the United States District Court for the Eastern District of Texas, Tyler Division, alleging that OMI has infringed two U.S. patents that are not at issue in the Australian litigation (6,572,584 and 7,351,224). The Company also alleges theft of confidential information, intentional interference with contracts and engaging in false advertising that wrongfully disparages and mischaracterizes the Company s syringe products. The Company further alleges that OMI made false allegations regarding the source of origin of its safety syringe products being offered in the U.S. The Company seeks injunctive relief, unspecified damages (including treble damages) and reimbursement of attorneys fees in the suit. OMI has counterclaimed against the Company, seeking declaratory judgments of non-infringement and invalidity of the

asserted patents. OMI is not seeking monetary damages. Trial is set for December 2009 and discovery is commencing.

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 was served on October 20, 2008, and no answer has yet been filed.

Other Matters

The Company has begun expansion of its warehouse (including additional warehouse space, additional office space, and a new Clean Room). This expansion is being funded by a construction line of credit from a bank for approximately $4.2 million, secured by a second lien deed to the land and existing buildings.

The Company had a licensing agreement with Baiyin Tonsun Medical Device Co., Ltd. (BTMD) which expired on May 13, 2008. As a result of the expiration of the contract, the Company recognized $100,000 of prepaid royalty income as other income in the second quarter of 2008. The Company is in the process of negotiating a new agreement. Royalties that were expected in 2007 were not received due to the time needed to build the factory, assembly equipment, and the related infrastructure as well as the need of BTMD to meet the requisite Chinese government requirements. The facility has been completed and BTMD is in the process of meeting Chinese governmental requirements. Although successful completion of an agreement cannot be assured, the Company still continues to expect royalty payments although it is unable to predict the date it will begin to receive such royalties. The Company should begin earning royalties once Chinese government requirements are met and BTMD is able to produce and sell products.

6. SUBSEQUENT EVENTS

On September 26, 2008, the Company s shareholders approved the 2008 Stock Option Plan and also approved an Exchange Offer whereby employees, including executive officers, and Directors may exchange certain outstanding underwater options for options issued under the 2008 Stock Option Plan.

The Company filed an Offer to Exchange Stock Options on October 17, 2008, allowing existing employees, including executive officers, and Directors to exchange underwater stock options for new options to be granted under the 2008 Stock Option Plan. The Exchange Offer will terminate on November 18, 2008, unless extended. Any new options granted pursuant to the Exchange Offer will allow the purchase of one half the number of shares underlying the underwater options and such new options will have exercise prices equal to the higher of: (1) the last sales price of the Common Stock as reported on the NYSE Alternext US, LLC (NYSE Alternext) on the date of grant rounded to the next highest dime or (2) $1.30. Shares underlying outstanding options, if all eligible options are exchanged, would be reduced by approximately 970,000 shares.

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 and the viability of our patents), our ability to maintain favorable supplier arrangements and relationships, our ability to successfully complete a new license agreement with Baiyin Tonsun Medical Device Co., Ltd. (BTMD) and our receipt of payments thereunder, the impact of dramatic increases in demand, our ability to quickly increase capacity, 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 & 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, the Patient Safe Syringe, which reduces the risk of infection resulting from IV contamination, entered the market in 2008. Safety syringes comprised 98.6% of our sales in the first nine months of 2008.

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, who 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. 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 product internationally. Beginning in 2004, we were given an award (from PATH) to supply syringes to various African countries. Awards increased significantly from 2004 to 2007. However, currently funding is uncertain for this program. Despite the loss of these orders, thus far we have managed to maintain international sales volumes. Additionally, an Australian distributor was awarded a one-year contract in March 2007 to supply our VanishPoint® automated retraction syringes to all of Queensland Health s 202 acute care facilities. Queensland Health is a department within the government of Queensland, Australia. The contract was renewed for an additional two years. VanishPoint® products are distributed in Australia by Brisbane-based Scientific Educational Supplies Pty Ltd. The number of international distributors continues to increase.

In the event we continue to have only limited market access and the cash provided by the litigation settlements and generated from operations becomes insufficient, we would take 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 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 cost.

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 2008, approximately 71.1% of the units we produced. These purchases have improved profit margins in spite of limited revenues. The cost of production per unit has generally declined as volumes increased. Double Dove increased the prices in the fourth quarter 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 0.5 cc insulin syringe, the 5cc and 10cc syringes, and the autodisable syringe which altogether comprised about 1.1% of our third quarter 2008 revenues.

We had a Licensing Agreement with BTMD which expired on May 13, 2008. As a result of the expiration of the contract, we recognized $100,000 of prepaid royalty income in the second quarter of 2008 as other income. We are in the process of negotiating a new agreement. Royalties that were expected in 2007 were not received due to the time needed to build the factory, assembly equipment, and the related infrastructure as well as the need of BTMD to meet the requisite Chinese government requirements. The facility has been completed and BTMD is in

the process of meeting Chinese government requirements. Although successful completion of an agreement cannot be assured, we still continue to expect royalty payments although we are unable to predict the date we will begin to receive such royalties. We should begin earning royalties once Chinese government requirements are met and BTMD is able to produce and sell products.

Historically, unit sales have increased in the latter part of the year due, in part, to the demand for syringes during the flu season.

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 recent 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 have begun the expansion of an existing warehouse. This expansion will increase our warehouse area, provide for additional office space, and add a second Clean Room. The expansion is expected to be completed in the first quarter of 2009.

LIQUIDITY AND FUTURE CAPITAL REQUIREMENTS

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. We were capitalized with approximately $52,600,000 raised from six separate private placement offerings. We raised $47,375,600 in cash from the private sales of an aggregate of 11,710,221 shares of Convertible Preferred Stock. In addition, we obtained a cancellation of $3,679,284 in debt and $1,550,000 in Accounts payable in exchange for Series V Class B Convertible Preferred Stock.

We obtained $3,910,000 in 2000 from bank loans of which $3,435,000 has been repaid and $475,000 was refinanced with a new note with Lewisville State Bank, a division of 1st International Bank. Additionally, we received a Small Business Administration loan of $1,000,000 in 1996 to pay for portions of automated assembly equipment, multi-cavity molds, and other equipment. This loan has been repaid. Furthermore, we borrowed $5,000,000 in 2000 under our Credit Agreement with Abbott Laboratories (Abbott). In October 2002 we repaid the Abbott note with proceeds from a new note from Katie Petroleum, Inc. for $3,000,000 and a portion of the proceeds from a private placement. In 2008, we received a construction line of credit for up to $4,210,000 to fund an expansion of our warehouse.

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 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 cost.

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 28.9%) 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. 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 has increased their prices to us by $0.005 per unit. 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 28.9% of our products are produced domestically.

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

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.

Licensing Agreement

We had a Licensing Agreement with BTMD which expired on May 13, 2008. As a result of the expiration of the contract, we recognized $100,000 of prepaid royalty income in the second quarter of 2008 as other income. We are in the process of negotiating a new agreement. Royalties that were expected in 2007 were not received due to the time needed to build the factory, assembly equipment, and the related infrastructure as well as the need of BTMD to meet the requisite Chinese government requirements. The facility has been completed and BTMD is in the process of meeting Chinese government requirements. Although successful completion of an agreement cannot be assured, we still continue to expect royalty payments, although we are unable to predict the date we will begin to receive such royalties. We should begin earning royalties once Chinese government requirements are met and BTMD is able to produce and sell products.

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. In the event we continue to have only limited market access and cash generated from operations becomes insufficient to support operations, we would take 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.

External Sources of Liquidity

We have obtained several loans from 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. Currently we believe we could obtain additional funds through loans if needed. Furthermore, 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.

CAPITAL RESOURCES

Material Commitments for Expenditures

We have begun expansion of our warehouse (including additional warehouse space, additional office space, and a new Clean Room). We are funding 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. Draws under the construction line of credit will be converted to permanent financing upon completion of the building. Completion is expected in the first quarter of 2009.

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 may 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 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, 2008, or 2007.

Comparison of Three Months Ended

September 30, 2008, and September 30, 2007

Domestic sales accounted for 86.2% and 89.7% of the revenues for the three months ended September 30, 2008 and 2007, respectively. International sales accounted for the remaining revenues. Domestic revenues increased 8.8% principally due to higher volumes and higher average selling prices arising as a result of sales mix and international revenues increased 36.4% due primarily to higher volumes mitigated somewhat by lower selling prices arising as a result of sales mix. Overall, unit sales increased 12.8%. Domestic unit sales increased 4.8% and international unit sales increased 46.2%. Domestic unit sales were 75.2% of total unit sales for the three months ended September 30, 2008.

Gross profit decreased primarily due to higher cost of goods sold. Costs of manufactured product increased by 19.0% due to higher volumes and higher unit cost of manufactured product. The average cost of manufactured product sold per unit increased by 5.5% principally due to lower capitalized unit costs in inventory, thereby increasing costs of goods sold, and higher period costs. 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 4.2% due to higher gross sales.

Operating expenses decreased 6.7%. The decrease in expense for Sales and marketing was attributable primarily to travel and entertainment, marketing expenses, and office expenses. The decrease in Research and development costs was due principally to lower validation and engineering expense and lower consulting costs. General and administrative costs decreased due to lower litigation costs and travel costs, mitigated by higher taxes other than income taxes, and higher legal expenses other than litigation expenses. Bad debt expense increased.

Loss from operations decreased due principally to lower operating expenses.

Interest expense and interest income declined due to lower interest rates and lower debt and cash equivalents balances. In addition to generally declining interest rates, we shifted the bulk of our funds into U.S. Treasury bills and other U.S. government backed securities in April 2008.

Our effective tax rate on the net loss before income taxes was 0% for the three months ended September 30, 2008 and 70.5% (a benefit due to a settlement in our favor of a state tax audit) for the three months ended September 30, 2007.

The Net loss for 2008 was $1.4 million higher than the Net loss for 2007 due principally to the benefit for income taxes in 2007 of $1.4 million.

Comparison of Nine Months Ended

September 30, 2008, and September 30, 2007

Domestic sales accounted for 84.5% and 83.6% of the revenues for the nine months ended September 30, 2008 and 2007, respectively. International sales accounted for the remaining revenues. Domestic revenues increased 11.1% principally due to higher volumes and higher average selling prices arising as a result of sales mix and international revenues decreased 1.7% due primarily to lower average selling prices arising as a result of sales mix. Overall, unit sales increased 5.0%. Domestic unit sales increased 7.0% and international unit sales increased 0.2%. Domestic unit sales were 72.0% of total unit sales for the nine months ended September 30, 2008.

Gross profit increased primarily due to higher revenues and slightly improved profit margins. Costs of manufactured product increased due to higher volumes and increased unit costs. The average cost of manufactured product sold per unit increased by 1.7%. 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 5.4% due to higher gross sales.

Operating expenses decreased 0.2%. The decrease in expense for Sales and marketing was attributable primarily to lower marketing expenses, travel and entertainment, employee compensation, and office expenses. Consulting expenses increased. The increase in Research and development costs was due principally to higher compensation costs, mitigated by lower validation and consulting costs. General and administrative costs increased due to higher taxes other than income taxes, bad debt accrual, compensation costs, fees paid to distributors and office expenses. Decreases in General and administrative costs were attributable to lower travel and entertainment, consulting, and temporary services costs. Other income increased.

Loss from operations decreased due principally to higher gross profits.

Interest expense and interest income declined due to lower interest rates and lower debt and cash equivalents balances. In addition to generally declining interest rates, we shifted the bulk of our funds into U.S. Treasury bills and

other U.S. government backed securities in April 2008.

The Company s effective tax rate on the net loss before income taxes was 0% for the nine months ended September 30, 2008 and 23.9% (a benefit due to a settlement in our favor of a state tax audit) for the nine months ended September 30, 2007.

The Net loss for 2008 was $1.3 million higher than the Net loss for 2007 due principally to the benefit for income taxes in 2007 of $1.4 million.

Our balance sheet remains strong with cash making up 60.7% of total assets. Working capital was $37.4 million at September 30, 2008, a decrease of $5.7 million from December 31, 2007. The current ratio was 5.4 at September 30, 2008 and 5.9 at December 31, 2007. The quick ratio was 4.6 at September 30, 2008 and 4.8 at December 31, 2007. These indicators continue to demonstrate a strong financial position.

Approximately $3.8 million in cash flow was used by operating activities. The remaining uses of cash were for capital costs incurred for the acquisition of plant, property and equipment and intangible assets, and the repayment of long-term debt. We utilized $1,300,000 of a $4,210,000 construction line of credit.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

No update

Item 4. **Controls and Procedures.**

Our Management, including the Chief Executive Officer (the CEO) and Chief Financial Officer (the CFO), does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all errors and all instances of fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system s objectives will be met.

Pursuant to paragraph (b) of Rule 13a-15 or Rule 15d-15 of the Securities Exchange Act of 1934 and on November 14, 2008, Management, with the participation of our President, Chairman, and CEO, Thomas J. Shaw, and our Vice President and CFO, Douglas W. Cowan, acting in their capacities as our principal executive and financial officers, evaluated the effectiveness of our disclosure controls and procedures, as defined in Rule 13a-15(e) or Rule 15d-15(e). The CEO and CFO concluded that, as of September 30, 2008 (the end of the period covered by the report), based on the evaluation of these controls and procedures required by paragraph (b) of Rule 13a-15 or Rule 15d-15, there were no significant deficiencies in these controls and procedures. The CEO and CFO concluded that our disclosure controls and procedures are effective to ensure that information required to be disclosed in our periodic reports is recorded, processed, summarized, and reported within the time periods specified in the U.S. Securities and Exchange Commission (SEC) rules and forms.

There have been no changes during the third quarter of 2008 or subsequent to September 30, 2008 identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 or 15d-15 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 United States 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 attorney s 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 scheduling order calling for trial in January 2010.

In August 2006, we were sued by Occupational and Medical Innovations Limited (OMI) in Federal Court of Australia, alleging that two letters written to OMI by outside counsel contained unjustified threats of patent infringement, but seeking no damages. OMI later amended its complaint to seek a declaratory judgment that OMI does not infringe Australian Patent No. 701878, again seeking no damages. Following a one-day trial in June 2007, the Court held that one of the two letters written by outside counsel contained a threat of patent infringement, and awarded costs to OMI in an amount that has not yet been determined. Following a one-day trial in June 2008, the Court issued a declaratory judgment in August 2008 stating that OMI s syringe does not infringe our Australian patent no. 701878 but also awarding costs to us. The amount of costs to be awarded will be determined at a later date.

In June 2007, we sued BD in the United States 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, are 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, which is set for trial in March 2009. In April 2008, we and Thomas J. Shaw sued BD in the United States 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. We moved to consolidate this case with the other patent case against BD that was pending in Marshall and the Court granted our motion, consolidating this case with our above-stated case filed in June 2007.

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 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. 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 but has not ruled. No trial date has been set.

In March 2008, MedSafe Technologies LLC (MedSafe) initially sued us and BD in the United States District Court for the District of South Carolina, Greenville Division, alleging infringement of a MedSafe patent (6,074,370) and seeking injunctive relief and unspecified monetary damages. We counterclaimed for declarations of non-infringement, invalidity, and unenforceability of the asserted patent. BD subsequently settled with MedSafe. The case is set for trial in October 2009.

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

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 was served on October 20, 2008, and no answer has yet been filed.

We previously reported in our Form 10-Q for the second quarter of 2008 updates with regard to all of the above legal proceedings with the exception of the new suit against SMI.

Item 1A. Risk Factors.

The following is an updated list of risk factors as set forth in our Form 10-K filed on March 31, 2008. You should carefully consider the following material risks facing us. If any of these risks occur, our business, results of operations, or financial condition and the value of our Common Stock could be materially affected.

We Compete in a Monopolistic Marketplace

We operate in an environment that is dominated by the major syringe manufacturer in the U.S., BD. We believe that its monopolistic business practices continue despite its paying us $100 million to settle a prior lawsuit for anticompetitive practices, business disparagement, and tortious interference. 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, and the federal and state legislation requiring use of safe needle devices.

Our Cash Position Is Decreasing and Legal Expenses Are Increasing

Due to our operating losses and currently increasing legal fees, our cash position declined $4.5 million as of September 30, 2008. Our litigation efforts will continue to require a significant amount of cash until the issues are resolved. Our lawsuit against BD is currently scheduled for trial in March 2009. After conclusion of the trial, legal expenses are expected to decrease significantly despite multiple ongoing cases.

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

We Have Generally Been Unable to Gain Sufficient Market Access to Achieve Profitable Operations

We have incurred net operating losses including through all fiscal quarters of 2007 and through the third quarter of 2008. We may experience operating losses in the future. If we are unable to gain sufficient market access and market share, we may be unable to continue to finance research and development as well as support operations and expansion of production.

We Are Dependent On Our Aging Patent Protection

Our main competitive strength is our technology. We are dependent on our patent rights, and if our patent rights are invalidated or circumvented, our business would be adversely affected. Patent protection is considered, in the aggregate, to be of material importance in our marketing of products in the U.S. and in most major foreign markets. Patents covering products that we have introduced normally provide market exclusivity, which is important for the successful marketing and sale of our products.

As our technology ages (and the associated patent life expires), our competitive position in the marketplace will weaken. The initial patents protecting our revolutionary spring action syringe will expire beginning in May 2015. Patent life may be extended, not through the original patents, but through related improvements. Eventually, however, our patent protection may decrease and we will be vulnerable to other competitors utilizing our technology.

Our Patents Are Subject to Litigation

We are currently involved in multiple patent disputes. Patent litigation and challenges involving our patents are costly and unpredictable and may deprive us of market exclusivity for a patented product or, in some cases, third party patents may prevent us from marketing and selling a product in a particular geographic area.

We Are Vulnerable to New Technologies

Because we have a narrow focus on particular product lines and technology (currently predominantly retractable needle products), we are vulnerable to the development of superior competing products and to changes in technology which could eliminate or reduce the need for our products. If a superior technology is created, the demand for our products could greatly diminish.

Our Competitors Have Greater Resources

The three leading manufacturers of hypodermic syringes and blood collection products are BD with a worldwide market share in the safety syringe market of approximately 50%, Sherwood with approximately 26%, and Terumo with a market share of approximately 10%. All three companies offer both standard syringes and at least one safety syringe alternative. BD also offers a retractable syringe. These competitors have greater financial resources, larger and more established sales and marketing and distribution organizations, and greater market influence, including long-term contracts with Group Purchasing Organizations. These competitors may be able to use these resources to improve their products through research and acquisitions or develop new products, which may

compete more effectively with our products. If our competitors choose to use their resources to create products superior to ours, we may be unable to sell our products and our ability to continue operations would be weakened.

The Majority of Our International Sales Are Filled Using One Supplier

Most international sales are filled by production from Double Dove. In the event that we become unable to purchase such product from Double Dove, we would need to find an alternate supplier for the 0.5 cc insulin syringe and the 5cc and 10cc syringes and increase domestic production for the 1cc and 3cc syringes to avoid a disruption in supply. As of September 30, 2008, approximately 71.1% of our production was provided by Double Dove.

Fluctuations in Supplies of Inventory Could Temporarily Increase Costs

Fluctuations in the cost and availability of raw materials and inventory and the ability to maintain favorable supplier arrangements and relationships could result in the need to manufacture all (as opposed to 28.9%) of the products in the U.S. This could temporarily increase unit costs as we ramp up domestic production.

We Are Controlled by One Shareholder

Thomas J. Shaw, our President and Chairman of the Board, and Ms. Suzanne August own 35.3% and 11.8%, respectively, of the outstanding Common Stock as of November 3, 2008. The shares held by Ms. August are controlled by Mr. Shaw pursuant to a Voting Agreement, which terminates upon sale of all the shares for value or if terminated by both parties in writing. Mr. Shaw will, therefore, have the ability to direct our operations and financial affairs and to substantially influence the election of members of our Board of Directors. His interests may not always coincide with our interests or the interests of other stockholders. This concentration of ownership, for example, may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us or discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us, which in turn could materially adversely affect the market price of our Common Stock. Of the 23,800,064 shares of Common Stock outstanding as of November 3, 2008, executive officers and Directors own or control 11,236,000 (47.2%) of the shares of outstanding Common Stock.

We Have Limited Access to the Capital Markets

The volume of trading in our Common Stock on the NYSE Alternext is low. Accordingly, it is unclear if there is any significant market for our shares. This may reduce our ability to raise cash through public or private offerings

in the future.

Our Stock Price Sometimes Decreases Below NYSE Alternext Listing Standards

Our share price fluctuates and has fallen below $2.00 which is required for listing on the NYSE Alternext under its alternative listing standards. The NYSE Alternext may initiate delisting procedures, in its discretion. Delisting of our shares would greatly affect the liquidity of our shares and would reduce our ability to raise funds from the sale of equity in the future. However, we believe such delisting application to be unlikely. Furthermore, in the event that we receive a deficiency letter from the NYSE Alternext, we will have the right to appeal such determination. In addition, entities that are given such notices were previously (under the American Stock Exchange standards) given up to 18 months to execute a plan to bring themselves into compliance with the listing standards.

Oil Prices and Transportation Costs May Increase Our Costs

As our products are made from petroleum products, fluctuations in the costs of oil and transportation may have an impact on our costs. Increases in costs may not be recoverable through price increases of our products.

Current Economic Conditions May Decrease Collectability of Accounts

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. The Provision for doubtful accounts increased by $143,496 for the nine months ended September 30, 2008 which brings the balance to $418,830.

We Face Inherent Product Liability Risks

As a manufacturer and provider of safety needle products, we face an inherent business risk of exposure to product liability claims in the event of product failure or claim of harm caused by product operation. Product failure could result in injury to the patient and could expose healthcare workers to the risk of blood borne pathogens. If any of our products prove to be defective, we may be required to recall those products. We do not have recall insurance.

If a product liability claim is made and damages are in excess of our product liability coverage, our competitive position could be weakened by the amount of money we could be required to pay to compensate those injured by our products. We have products liability coverage with St. Paul Insurance Company covering up to $1,000,000 per occurrence, with coverage up to $2,000,000 in the aggregate. Each claim is subject to a $25,000 deductible. Additionally, we have additional product liability protection under an Umbrella Liability Policy. This policy provides an additional $10,000,000 per occurrence and aggregate limits in the event claims exceed the primary commercial general liability policy limit. We have not had any product liability claims.

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

Unregistered Sales of Equity Securities and Use of Proceeds

Not applicable

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 goods and services. As of September 30, 2008, we had $48,000 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

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, 2008, the amount of dividends in arrears was $54,000 and the total arrearage was $90,000.

Series II Class B Convertible Preferred Stock

As of the nine months ended September 30, 2008, the amount of dividends in arrears was $165,000 and the total arrearage was $276,000.

Series III Class B Convertible Preferred Stock

As of the nine months ended September 30, 2008, the amount of dividends in arrears was $98,000 and the total arrearage was $3,083,000.

Series IV Class B Convertible Preferred Stock

As of the nine months ended September 30, 2008, the amount of dividends in arrears was $414,000 and the total arrearage was $6,892,000.

Series V Class B Convertible Preferred Stock

As of the nine months ended September 30, 2008, the amount of dividends in arrears was $299,000 and the total arrearage was $3,198,000.

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

The 2008 Annual Meeting of Stockholders (the Annual Meeting) was held on September 26, 2008, at 10:00 a.m., CST. The purposes of the meeting were to: 1) elect five Class 2 Directors; 2) approve the 2008 Stock Option Plan; 3) approve the Option Exchange Plan; and 4) approve the Third Amended and Restated Bylaws.

Of the 23,800,064 shares of Common Stock entitled to vote, at least 21,533,483 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 five Class 2 Directors was put to a vote and the results were as follows:

Nominees	For	Withheld
Thomas J. Shaw	20,832,963	700,520
Douglas W. Cowan	20,974,579	558,904
Marwan Saker	19,976,280	1,557,203
Steven R. Wisner	21,025,491	507,992
Clarence Zierhut	20,763,206	770,277

Accordingly, Messrs Shaw, Cowan, Saker, Wisner, and Zierhut were elected as Class 2 Directors to serve until our 2010 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 the 2008 Stock Option Plan was put to a vote and the results were as follows:

For	**Against**	**Abstain**	**Broker Non-votes**
16,031,282	1,645,169	84,812	3,772,220

3) The approval of the Option Exchange Plan was put to a vote and the results were as follows:

For	**Against**	**Abstain**	**Broker Non-votes**
15,569,793	2,179,019	12,450	3,772,221

4) The approval of the Third Amended and Restated Bylaws was put to a vote and the results were as follows:

For	**Against**	**Abstain**	**Broker Non-votes**
17,170,998	472,395	117,870	3,772,220

Item 5. **Other Information.**

We filed an Exchange Offer on October 17, 2008, allowing existing employees, including executive officers, and Directors to exchange underwater stock options for new options to be granted under the 2008 Stock Option Plan. The Exchange Offer will terminate on November 18, 2008, unless extended. Any new options granted will allow the purchase of one half the number of shares underlying the underwater options and such new options will have exercise prices equal to the higher of: (1) the last sales price of our Common Stock as reported on the NYSE Alternext on the date of grant rounded to the next highest dime or (2) $1.30.

We have amended our Audit Committee Charter primarily to better track the language of various applicable rules and regulations. The amendments also change the nature of the reports due to the Audit Committee from the independent accountants to require only those required for companies listed on the NYSE Alternext. The amendments also delete the requirement that members of the committee be elected annually. A copy of this charter is attached hereto as Exhibit no. 99.1 to this Form 10-Q.

We have amended our Nominating Committee Charter primarily to incorporate the shareholder nominating rules set out in our bylaws for ease of reference by shareholders and to clarify that the committee makes recommendations to the Board regarding committee members and chairpersons only upon request of the Board. A copy of this charter is attached hereto as Exhibit no. 99.2 to this Form 10-Q.

We have amended our Compensation and Benefits Committee charter primarily, among other things, to reduce the independence requirements for committee members and to clarify that the committee serves as the grantor and administrator of our compensation plans in the absence of action by the full Board of Directors. Previously, the independence requirements included satisfying inapplicable and unnecessarily restrictive standards such as those for the Audit Committee members (no related party transactions at all) as well as lesser requirements such as those for the definition of non-employee director under Rule 16b-3 and outside director for purposes of Section 162(m) of the Internal Revenue Code. The charter has been amended to require that the Directors fulfill the independence requirements for independent Directors as determined by the NYSE Alternext. A copy of this amended charter is incorporated herein by reference as Exhibit No. 99.3.

The Employment Agreement between us and Mr. Thomas J. Shaw has been modified to avoid adverse tax consequences to Mr. Shaw created by the passage of the American Jobs Creation Act of 2004. The agreement also reflects past salary increases to Thomas J. Shaw. A copy of this Employment Agreement is attached hereto as Exhibit no. 10 to this Form 10-Q.

Item 6. **Exhibits.**

Exhibit No.	Description of Document
3(ii)	Third Amended and Restated Bylaws*
10	Employment Agreement between RTI and Thomas J. Shaw dated as of January 1, 2008*
31.1	Certification of Principal Executive Officer*
31.2	Certification of Principal Financial Officer*
32	Certification Pursuant to 18 U.S.C. Section 1350*
99.1	Audit Committee Charter*
99.2	Nominating Committee Charter*
99.3	Compensation and Benefits Committee Charter**

* Attached hereto

** Incorporated herein by reference to Appendix A of our definitive Schedule 14A, filed with the SEC on August 19, 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 14, 2008

RETRACTABLE TECHNOLOGIES, INC.
(Registrant)

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