RETRACTABLE TECHNOLOGIES INC
Form 10-Q
August 14, 2009
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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 June 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**	**75068-0009**
(Address of principal executive offices)	(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 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 July 31, 2009.

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RETRACTABLE TECHNOLOGIES, INC.

FORM 10-Q

For the Quarterly Period Ended June 30, 2009

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements.

RETRACTABLE TECHNOLOGIES, INC.

CONDENSED BALANCE SHEETS

	June 30, 2009 (unaudited)	December 31, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	$ 20,975,485	$ 33,283,740
Accounts receivable, net	2,613,909	3,288,942
Inventories, net	10,292,680	6,641,532
Income taxes receivable	111,360	6,576
Other current assets	696,119	400,113
Total current assets	34,689,553	43,620,903
Property, plant, and equipment, net	17,143,504	14,435,667
Intangible assets, net	457,395	470,115
Other assets	9,750	18,750
Total assets	$ 52,300,202	$ 58,545,435
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 4,938,929	$ 6,144,435
Current portion of long-term debt	2,556,729	451,865
Accrued compensation	656,160	650,704
Marketing fees payable	1,419,760	1,419,760
Accrued royalties to shareholders	429,063	620,987
Other accrued liabilities	1,195,210	852,602
Income taxes payable	103,319	103,744
Total current liabilities	11,299,170	10,244,097
Long-term debt, net of current maturities	5,125,899	6,095,535
Total liabilities	16,425,069	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		54,298,518		53,952,183
Retained deficit		(20,708,651)		(14,031,646)
Total stockholders equity		35,875,133		42,205,803
Total liabilities and stockholders equity	$	52,300,202	$	58,545,435

See accompanying notes to condensed financial statements

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RETRACTABLE TECHNOLOGIES, INC.

CONDENSED STATEMENTS OF OPERATIONS

(unaudited)

	Three Months Ended June 30, 2009	Three Months Ended June 30, 2008	Six Months Ended June 30, 2009	Six Months Ended June 30, 2008
Sales, net	$ 5,752,613	$ 6,474,227	$ 11,011,078	$ 11,789,382
Cost of sales				
Cost of manufactured product	2,983,784	3,035,014	6,579,241	6,631,927
Royalty expense to shareholders	429,063	463,269	862,895	895,780
Total cost of sales	3,412,847	3,498,283	7,442,136	7,527,707
Gross profit	2,339,766	2,975,944	3,568,942	4,261,675
Operating expenses:				
Sales and marketing	1,399,932	1,301,002	2,535,599	2,468,910
Research and development	352,365	267,324	630,726	532,832
General and administrative	3,368,279	2,459,853	7,225,151	5,388,433
Total operating expenses	5,120,576	4,028,179	10,391,476	8,390,175
Loss from operations	(2,780,810)	(1,052,235)	(6,822,534)	(4,128,500)
Interest and other income	11,446	241,449	40,183	495,118
Interest expense, net		(22,269)		(63,268)
Net loss before income taxes	(2,769,364)	(833,055)	(6,782,351)	(3,696,650)
Provision (benefit) for income taxes			(105,346)	
Net loss	(2,769,364)	(833,055)	(6,677,005)	(3,696,650)
Preferred stock dividend requirements	(342,717)	(342,717)	(685,434)	(687,585)
Loss applicable to common shareholders	$ (3,112,081)	$ (1,175,772)	$ (7,362,439)	$ (4,384,235)
Loss per share basic and diluted	$ (0.13)	$ (0.05)	$ (0.31)	$ (0.18)
Weighted average common shares outstanding	23,800,064	23,800,064	23,800,064	23,789,068

See accompanying notes to condensed financial statements

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RETRACTABLE TECHNOLOGIES, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(unaudited)

	Six Months Ended June 30, 2009	Six Months Ended June 30, 2008
Cash flows from operating activities		
Net loss	$ (6,677,005)	$ (3,696,650)
Adjustments to reconcile net loss to net cash provided by (used by) operating activities:		
Depreciation and amortization	678,986	700,539
Capitalized interest	(100,884)	(96,094)
Share-based compensation	346,335	
Provisions for doubtful accounts		112,976
Accreted interest	23,030	28,539
(Increase) decrease in assets:		
Inventories	(3,651,148)	(388,900)
Accounts receivable	675,033	(1,216,136)
Income taxes receivable	(104,784)	2,345,041
Other current assets	(296,006)	(100,328)
Increase (decrease) in liabilities:		
Accounts payable	(1,205,506)	(2,100,500)
Other accrued liabilities	156,140	27,053
Income taxes payable	(425)	
Net cash used by operating activities	(10,156,234)	(4,384,460)
Cash flows from investing activities		
Purchase of property, plant, and equipment	(1,901,618)	(1,073,938)
Acquisitions of patents, trademarks, licenses and intangibles		(9,825)
Liquidation of investment in LLC		497,690
Net cash used by investing activities	(1,901,618)	(586,073)
Cash flows from financing activities		
Repayments of long-term debt and notes payable	(250,403)	(240,610)
Net cash used by financing activities	(250,403)	(240,610)
Net decrease in cash	(12,308,255)	(5,211,143)
Cash and cash equivalents at:		
Beginning of period	33,283,740	40,507,431
End of period	$ 20,975,485	$ 35,296,288
Supplemental disclosures of cash flow information:		
Interest paid	$ 77,854	$ 130,823
Income taxes paid	$ 15,883	$
Supplemental schedule of noncash financing activities:		

Debt assumed to construct warehouse		$	1,362,602	$

See accompanying notes to condensed financial statements

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RETRACTABLE TECHNOLOGIES, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

(unaudited)

1. BUSINESS OF THE COMPANY 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 0.5cc 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, 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.

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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* (FSP 157-2), the Company deferred 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, 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.

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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 one (1) significant customer, accounting for approximately $940,000, or 16.3% of net sales in the second 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 73.0% of its finished products in the first six 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

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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 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 six months ended June 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 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 123 R, the Company incurred the following share-based compensation costs:

	Three Months Ended June 30, 2009	Three Months Ended June 30, 2008	Six Months Ended June 30, 2009	Six Months Ended June 30, 2008
Cost of sales	$ 39,389	$	$ 78,471	$
Sales and marketing	48,389		96,778	

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	Three Months Ended June 30, 2009	Three Months Ended June 30, 2008	Six Months Ended June 30, 2009	Six Months Ended June 30, 2008
Research and development	6,317		12,634	
General and administrative	79,226		158,452	
	$ 173,321	$	$ 346,335	$

Recent 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. 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 Statement No. 165, *Subsequent Events*, 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. Statement 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 Statement 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.

The FASB issued Statement No. 168, *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles* (the Codification). The Codification will become the source of authoritative US GAAP recognized by the FASB to be applied by nongovernmental entities and will supersede all non-SEC accounting and reporting standards. This statement is effective for financial statements ending after September 15, 2009 and is not expected to have a material impact on the Company s financial statements.

3. INVENTORIES

Inventories consist of the following:

	June 30, 2009	December 31, 2008
Raw materials	$ 3,090,822	$ 1,885,157
Finished goods	7,407,458	4,961,975
	10,498,280	6,847,132
Inventory reserve	(205,600)	(205,600)
	$ 10,292,680	$ 6,641,532

4. INCOME TAXES

The Company s effective tax rate on the net loss before income taxes was 1.6% and 0.0% for the six months ended June 30, 2009 and June 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.

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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 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 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 and discovery is ongoing.

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, 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 October 2009. 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 Company and the officer moved to consolidate this case with the other patent case against BD that was pending in Marshall and the Court granted the motion, consolidating this case with the above-stated case filed in June 2007. The Court issued its claim construction order in this matter on January 4, 2009. Discovery has now been completed and the Company is currently set for trial on the Court s October 2009 docket.

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.

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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. The Company did not identify any material subsequent events requiring adjustment to our accompanying unaudited condensed financial statements (recognized subsequent events). Those items requiring disclosure (unrecognized subsequent events) in the financial statements have been disclosed accordingly.

The Board of Directors is currently soliciting proxies from the preferred shareholders for the amendment of the various Certificates of Designation so that the Company may purchase shares of Common Stock and junior preferred shares even while dividends are in arrears. Previously, the various Certificates of Designation provided that, if dividends were in arrears on the preferred shares, there were certain prohibitions on acquisitions for consideration by the Company of stock ranking junior to the preferred shares except on certain terms. One of the limitations included that no acquisitions for consideration could be made unless the acquisition involved the acquisition of all of the preferred shares (upon a 50% vote of each series) or unless the preferred shares were converted into or exchanged into stock of the Company ranking junior to them. The proposed amendment deletes these requirements and includes an addition that specifically provides that the Company can purchase any of its shares ranking junior to the preferred stock (including Common shares) on any terms it fixes, even where a dividend upon shares of preferred stock is in arrears, so long as: (A) the cash assets of the Company as of its latest reporting period equals or exceeds $40,000,000 or (B) if the cash assets of the Company as of its latest reporting period was less than $40,000,000, the amount of funds utilized to purchase such shares within the next quarter does not exceed 25% of the value of the cash assets as of the previous reporting period. Accordingly, if the amendment is approved, it would mean that the Company would no longer be legally bound to pay the preferred stockholders their accrued dividends before the Company bought other shares, including shares of Common Stock.

The Compensation and Benefits Committee approved a grant of a stock option to an officer for the purchase of 3,000,000 shares of Common Stock, not pursuant to any existing stock option plan, which will require shareholder approval prior to effectiveness. Proxies are currently being solicited for, among other things, approval of this option.

The Compensation and Benefits Committee also approved pursuant to the 2008 Stock Option Plan, grants of incentive stock options (ISOs) for the purchase of 1,566,931 shares of Common Stock and grants of non-qualified stock options (NQSOs) for the purchase of 319,494 shares of Common Stock. Officers and Directors received ISOs relating to the issuance of 269,956 of the 1,566,931 shares subject to ISOs that were granted and 229,494 of the 319,494 shares subject to the NQSOs that were granted.

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

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patents), 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 the event of a dramatic 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 & 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 line contamination, entered the market in 2008. Safety syringes comprised 98.2% of our sales in the first six 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, 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.

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.

At the end of the second quarter 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. We expect the reduction in workforce to decrease our annual compensation costs, as well as related expenses, such as travel and entertainment, by $2.1 million annually. An anticipated reduction of inventory should result in a minimum of $1.0 million reduction in cash outlays over the next twelve months. Our President and CEO, Thomas J. Shaw, waived future royalty payments beginning July 1, 2009, which will save an additional $1.0 million over the next three quarters. Salaries for all personnel above a certain salary level were cut by 10%. Such reduction, along with discontinuing the 401(k) matching, should save $600,000 over the next twelve months. 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 for severance pay offered to the terminated employees. All severance payments were paid in the third quarter. 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.

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.

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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 six months of 2009, approximately 73.0% 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 six months of 2009.

We had a Licensing Agreement with BTMD which expired on May 13, 2008. Royalties that were expected 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. 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 we have an effective agreement, 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. It is unclear how the upcoming flu season may be affected by additional demand for utilization for the swine flu vaccinations. There is a possibility, if the U.S. does indeed receive H1N1 (swine flu) vaccine, that our sales could increase significantly during the flu season. Our understanding is that two injections are required for H1N1 as well as an injection for the regular flu. We are prepared to ramp up production during flu season if the need arises.

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.

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 during the third quarter of 2009.

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.

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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 approximately 26%) 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 26% of our products are produced domestically.

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. It is unclear how the upcoming flu season may be affected by additional demand for utilization for the swine flu vaccinations. There is a possibility, if the U.S. does indeed receive H1N1 (swine flu) vaccine, that our sales could increase significantly during the flu season. Our understanding is that two injections are required for H1N1 as well as an injection for the regular flu. We are prepared to ramp up production during flu season if the need arises.

Licensing Agreement

We had a Licensing Agreement with BTMD which expired on May 13, 2008. Royalties that were expected 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. 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 we have an effective agreement, 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. However, working capital decreased $10 million since December 31, 2008. Litigation costs continue to be a significant expense but we expect this expense to be reduced after the Abbott Laboratories (Abbott) trial in April 2010. 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. We took such actions at the end of the second quarter. At the end of the second quarter we announced that in the interest of the long-term survival of the Company we would reorganize some of the

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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. We expect the reduction in workforce to decrease our annual compensation costs, as well as related expenses, such as travel and entertainment by $2.1 million annually. An anticipated reduction of inventory should result in a minimum of $1.0 million reduction in cash outlays over the next twelve months. Our President and CEO, Thomas J. Shaw, waived future royalty payments beginning July 1, 2009, which will save an additional $1.0 million over the next three quarters. Salaries for all personnel above a certain salary level were cut by 10%. Such reduction, along with discontinuing the 401(k) matching, should save $600,000 over the next twelve months. 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 change in the second quarter for severance pay offered to the terminated employees. All severance payments were paid in the third quarter. 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.

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.

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 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 in the third quarter.

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 June 30, 2009, or 2008.

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

Domestic sales accounted for 85.6% and 80.7% of the revenues for the three months ended June 30, 2009 and 2008, respectively. International sales accounted for the remaining revenues. Domestic revenues decreased 5.8% principally due to lower unit sales mitigated by higher average sales prices and international revenues

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decreased 33.6% due primarily to lower unit sales. Overall, unit sales decreased 17.9%. Domestic unit sales decreased 7.2% due to a one-time purchase last year. We also believe some purchasing practices have changed, resulting in lower inventory levels at some of our distributors. International unit sales decreased 38.4% primarily due to decreased funding for non-governmental organizations which provide product internationally as well as a one-time order for the same period last year. Domestic unit sales were 74.2% of total unit sales for the three months ended June 30, 2009.

Gross profit decreased primarily due to lower unit sales mitigated by somewhat higher prices. The average cost of manufactured product sold per unit increased by 19.7% due to higher capitalized unit costs in inventory in the same period last year. 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 decreased 7.4% due to lower gross sales revenues.

Operating expenses increased 27.1%. The increase in expense for Sales and marketing was attributable primarily to compensation expense related to severance costs, stock option expense, and travel and entertainment. The increase was mitigated by lower marketing and supplies. Research and development costs increased due to engineering and validation samples, severance costs, and consulting costs. General and administrative costs increased due primarily to litigation costs, and accounting fees related to tax services and Sarbanes-Oxley audit costs. Stock option expense also increased as the stock option grants in November 2008 are being amortized. Previously issued stock option grants were fully amortized. We expensed $200,000 for severance costs related to the reduction in force.

Loss from operations increased due principally to lower margins and higher expenses.

Interest expense decreased due to lower interest rates and lower volumes. Interest expense for the second quarter of 2009 was zero because capitalized interest exceeded interest expense.

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

Comparison of Six Months Ended June 30, 2009 and June 30, 2008

Domestic sales accounted for 82.4% and 83.3% of the revenues for the six months ended June 30, 2009 and 2008, respectively. International sales accounted for the remaining revenues. Domestic revenues decreased 7.6% principally due to lower unit sales mitigated by higher average selling prices and international revenues decreased 1.5% due primarily to lower unit sales mitigated by higher unit prices. Overall, unit sales decreased 10.2%. Domestic unit sales decreased 9.0% due to a one-time purchase last year as well as some distributors having financial difficulty this year. We also believe some purchasing practices have changed, resulting in lower inventory levels at some of our distributors. International unit sales decreased 13.1% primarily due to a one-time purchase last year. Domestic unit sales were 70.7% of total unit sales for the six months ended June 30, 2009.

Gross profit decreased primarily due to lower unit sales and lower profit margins. The average cost of manufactured product sold per unit increased by 10.5% due principally to higher capitalized unit costs in inventory in the same period last year. 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 decreased 3.7% due to lower gross sales.

Operating expenses increased 23.9%. The increase in expense for Sales and marketing was attributable primarily to stock option expense, severance costs, and travel and entertainment. The increase was mitigated by lower marketing costs, fees, and office supplies. Research and development costs increased due to testing, severance costs, and stock option expense. General and administrative costs increased due primarily to litigation, stock option expense, consulting, and accounting fees. Stock option expense also increased as the stock option grants in November 2008 are being amortized. Previously issued stock option grants were fully amortized. We expensed $200,000 for severance costs related to the reduction in force.

Loss from operations increased due principally to lower gross profit and higher expenses.

Interest expense decreased due to lower interest rates and balances. Interest expense for the second quarter of 2009 was zero because capitalized interest exceeded interest expense.

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The Company s effective tax rate on the net loss before income taxes was 1.6% and 0.0% for the six months ended June 30, 2009 and June 30, 2008, respectively.

The Company s balance sheet remains strong with cash making up 40.0% of total assets. Working capital was $23.4 million at June 30, 2009, a decrease of $10.0 million from December 31, 2008. The current ratio was 4.3 at December 31, 2008 and 3.1 at June 30, 2009. The quick ratio was 3.6 at December 31, 2008 and 2.2 at June 30, 2009. One reason for the decline in the current ratio as well as the quick ratio was the decline in our cash balances. However, these indicators continue to demonstrate a strong financial position. We expect the cost cutting measures described earlier will mitigate the reduction in our cash balance.

Raw materials inventory increased 64.0% due to the transition of molding activities to Little Elm. We expect to be moving the manufacturing of those 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. Finished goods inventory increased 49.3% because of expected demand for flu season and the transition of molding activities to Little Elm. We expect to reduce inventory levels over the next 12 months.

Approximately $10.2 million in cash flow was used by operating activities. The remaining uses of cash were primarily for purchases of fixed assets.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

No update

Item 4.