

RETRACTABLE TECHNOLOGIES INC

Form 10-Q

November 14, 2012

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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 September 30, 2012**

**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: 001-16465**

## Retractable Technologies, Inc.

(Exact name of registrant as specified in its charter)

**Texas**

(State or other jurisdiction of  
incorporation or organization)

**75-2599762**

(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 ☒ No ☐

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 ☒ No ☐

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 ☐

Accelerated filer ☐

Non-accelerated filer ☐

Smaller reporting company ☒

(Do not check if a smaller reporting company)

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

APPLICABLE ONLY TO ISSUERS INVOLVED IN BANKRUPTCY

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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 ☐ No ☐

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: 27,273,164 shares of Common Stock, no par value, outstanding on November 5, 2012.

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**RETRACTABLE TECHNOLOGIES, INC.**

**FORM 10-Q**

**For the Quarterly Period Ended September 30, 2012**

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|   | <b>September 30, 2012</b><br><b>(unaudited)</b> | <b>December 31, 2011</b> |
|---|---|--------------------------|
| <b>ASSETS</b>                               |   |                          |
| Current assets:                             |   |                          |
| Cash and cash equivalents                   | \$ 25,008,688                                   | \$ 25,673,263            |
| Accounts receivable, net                    | 5,220,775                                       | 3,576,411                |
| Inventories, net                            | 4,946,034                                       | 6,237,419                |
| Income taxes receivable                     | 79,334  | 39,485                   |
| Other current assets                        | 672,941   | 218,529                  |
| Total current assets                        | 35,927,772                                      | 35,745,107               |
| Property, plant, and equipment, net         | 11,980,357                                      | 12,653,856               |
| Intangible and other assets, net            | 332,275   | 362,976                  |
| Total assets                                | \$ 48,240,404                                   | \$ 48,761,939            |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b> |   |                          |
| Current liabilities:                        |   |                          |
| Accounts payable                            | \$ 2,738,389                                    | \$ 3,500,301             |
| Current portion of long-term debt           | 310,556   | 620,472                  |
| Accrued compensation                        | 589,220   | 628,794                  |
| Dividends payable                           | 57,613  |                          |
| Accrued royalties to shareholders           | 772,142   | 122,239                  |
| Other accrued liabilities                   | 1,465,334                                       | 1,065,943                |
| Income taxes payable                        | 28,297  | 29,471                   |
| Total current liabilities                   | 5,961,551                                       | 5,967,220                |
| Long-term debt, net of current maturities   | 3,913,663                                       | 4,143,267                |
| Total liabilities                           | 9,875,214                                       | 10,110,487               |
| Commitments and contingencies               | see Note 6                                      |                          |
| Stockholders' equity:                       |   |                          |
| Preferred stock \$1 par value:              |   |                          |
| Series I, Class B                           | 103,500   | 103,500                  |
| Series II, Class B                          | 178,700   | 178,700                  |
| Series III, Class B                         | 130,245   | 130,245                  |
| Series IV, Class B                          | 542,500   | 542,500                  |
| Series V, Class B                           | 46,607  | 46,607                   |
| Common stock, no par value                  |   |                          |
| Additional paid-in capital                  | 58,674,220                                      | 57,284,670               |

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|  |               |               |
|--|---------------|---------------|
| Retained deficit   | (21,226,790)  | (19,634,770)  |
| Common Shares in treasury - at cost                      | (83,792)      |               |
| Total stockholders' equity                               | 38,365,190    | 38,651,452    |
| Total liabilities and stockholders' equity               | \$ 48,240,404 | \$ 48,761,939 |
| See accompanying notes to condensed financial statements |               |               |

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

|   | <b>Three Months<br/>Ended<br/>September 30, 2012</b> | <b>Three Months<br/>Ended<br/>September 30, 2011</b> | <b>Nine Months<br/>Ended<br/>September 30, 2012</b> | <b>Nine Months<br/>Ended<br/>September 30, 2011</b> |
|---|--|--|---|---|
| Sales, net  | \$ 9,444,157   | \$ 8,270,608   | \$ 25,602,046                                       | \$ 25,994,211                                       |
| Cost of sales                                     |  |  |   |   |
| Cost of manufactured product                      | 5,318,351  | 4,208,993  | 14,114,956  | 14,175,830  |
| Royalty expense to shareholders                   | 772,142  | 672,084  | 1,962,780   | 2,002,720   |
| Total cost of sales                               | 6,090,493  | 4,881,077  | 16,077,736  | 16,178,550  |
| Gross profit                                      | 3,353,664  | 3,389,531  | 9,524,310   | 9,815,661   |
| Operating expenses:                               |  |  |   |   |
| Sales and marketing                               | 1,034,419  | 937,868  | 2,939,142   | 2,487,136   |
| Research and development                          | 244,015  | 169,279  | 601,008   | 539,161   |
| General and administrative                        | 2,286,614  | 2,308,759  | 7,372,663   | 7,903,586   |
| Total operating expenses                          | 3,565,048  | 3,415,906  | 10,912,813  | 10,929,883  |
| Loss from operations                              | (211,384)  | (26,375)   | (1,388,503)   | (1,114,222)   |
| Interest and other income                         | 11,286   | 15,322   | 34,199  | 48,920  |
| Interest expense, net                             | (68,994)   | (62,455)   | (211,344)   | (184,911)   |
| Litigation settlements, net                       |  | 1,900,000  |   | 5,700,000   |
| Income (loss) before income taxes                 | (269,092)  | 1,826,492  | (1,565,648)   | 4,449,787   |
| Provision (benefit) for income taxes              | 3,869  | (1,952)  | 26,372  | 50,514  |
| Net income (loss)                                 | (272,961)  | 1,828,444  | (1,592,020)   | 4,399,273   |
| Preferred stock dividend requirements             | (229,527)  | (342,217)  | (688,581)   | (1,026,651)   |
| Earnings (loss) applicable to common shareholders | \$ (502,488)   | \$ 1,486,227   | \$ (2,280,601)                                      | \$ 3,372,622  |
| Basic earnings (loss) per share                   | \$ (0.02)  | \$ 0.06  | \$ (0.09)   | \$ 0.14   |
| Diluted earnings (loss) per share                 | \$ (0.02)  | \$ 0.06  | \$ (0.09)   | \$ 0.13   |
| Weighted average common shares outstanding:       |  |  |   |   |
| Basic   | 26,972,818   | 24,027,053   | 25,870,073  | 24,005,761  |
| Diluted   | 26,972,818   | 25,950,804   | 25,870,073  | 26,364,753  |

See accompanying notes to condensed financial statements

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

|  | <b>Nine Months<br/>Ended<br/>September 30, 2012</b> | <b>Nine Months<br/>Ended<br/>September 30, 2011</b> |
|--|---|---|
| <b>Cash flows from operating activities</b>  |   |   |
| Net income (loss)  | \$ (1,592,020)                                      | \$ 4,399,273  |
| Adjustments to reconcile net income (loss) to net cash provided by (used by) operating activities: |   |   |
| Depreciation and amortization  | 986,761   | 987,161   |
| Provision for doubtful accounts  | 30,854  | 429,815   |
| Provision for inventory valuation  | 90,000  | 52,835  |
| Reserve for non-contractual deductions   |   | 471,072   |
| Accreted interest  | 3,773   | 14,518  |
| (Increase) decrease in assets:   |   |   |
| Inventories  | 1,201,385   | 981,766   |
| Accounts receivable  | (1,675,218)   | 868,033   |
| Income taxes receivable  | (39,849)  | (4,431)   |
| Other current assets   | (454,412)   | 560,141   |
| Increase (decrease) in liabilities:  |   |   |
| Accounts payable   | (761,912)   | (918,429)   |
| Accrued liabilities, other   | 1,009,720   | (2,740,123)   |
| Income taxes payable   | (1,174)   | (106,254)   |
| Net cash provided by (used by) operating activities  | (1,202,092)   | 4,995,377   |
| <b>Cash flows from investing activities</b>  |   |   |
| Purchase of property, plant, and equipment   | (282,560)   | (653,873)   |
| Net cash used by investing activities  | (282,560)   | (653,873)   |
| <b>Cash flows from financing activities</b>  |   |   |
| Repayments of long-term debt and notes payable   | (543,293)   | (444,552)   |
| Proceeds from the exercise of stock options  | 1,620,000   | 44,001  |
| Repurchase of Common Stock   | (83,792)  |   |
| Payment of Preferred Stock dividends   | (172,838)   | (291,700)   |
| Net cash used by financing activities  | 820,077   | (692,251)   |
| Net increase (decrease) in cash and cash equivalents   | (664,575)   | 3,649,253   |
| Cash and cash equivalents at:  |   |   |
| Beginning of period  | 25,673,263  | 23,266,039  |
| End of period  | \$ 25,008,688                                       | \$ 26,915,292                                       |
| Supplemental disclosures of cash flow information:   |   |   |
| Interest paid  | \$ 207,571  | \$ 210,307  |
| Income taxes paid  | \$ 71,328   | \$ 134,057  |
| Supplemental disclosure of noncash investing and financing activities:                             |   |   |
| Preferred dividends declared   | \$ 57,613   | \$ 72,925   |
| Debt assumed for the purchase of molding machines  | \$  | \$ 327,725  |



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® 0.5mL insulin syringe; 1mL tuberculin, insulin, and allergy antigen syringes; the 0.5mL, 2mL, 3mL, 5mL, and 10mL syringes; the small diameter tube adapter; the blood collection tube holder; the allergy tray; the IV safety catheter; the Patient Safe® syringe; the Patient Safe® Luer Cap; and the VanishPoint® Blood Collection Set.

**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 30, 2012 for the year ended December 31, 2011.

**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. 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.

The Company requires certain distributors to make a prepayment prior to beginning production or shipment of their order. Distributors may apply such prepayments to their outstanding invoices or pay the invoice and continue to carry forward the deposit for future orders. Such amounts are included in Other accrued liabilities on the Condensed Balance Sheets and are shown in Note 5, Other Accrued Liabilities.

The Company records an allowance for estimated returns as a reduction to Accounts receivable and Gross sales. Historically, returns have been immaterial.

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**Inventories**

Inventories are valued at the lower of cost or market, with cost being determined using actual average cost. The Company compares the average cost to the market price and records the lower value. Management considers such factors as the amount of inventory on hand and in the distribution channel, estimated time to sell such inventory, the shelf life of inventory, and current market conditions when determining excess or obsolete inventories. A reserve is established for any excess or obsolete inventories or they may be written off.

**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.

The Company's property, plant, and equipment primarily consists of buildings, land, assembly equipment for syringes, molding machines, molds, office equipment, furniture, and fixtures.

**Intangible assets**

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

### **Financial instruments**

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

Table of Contents**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 following table reflects our significant customers in 2012 and 2011:

|   | <b>Nine Months ended<br/>September 30, 2012</b> | <b>Nine Months ended<br/>September 30, 2011</b> | <b>Three Months ended<br/>September 30, 2012</b> | <b>Three Months ended<br/>September 30, 2011</b> |
|---|---|---|--|--|
| Number of significant customers                               | 3   | 4   | 2  | 3  |
| Aggregate dollar amount of net sales to significant customers | \$10.6 million                                  | \$13.0 million                                  | \$3.4 million                                    | \$4.1 million                                    |
| Percentage of net sales to significant customers              | 41.3%   | 50.1%   | 35.6%  | 49.6%  |

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 69.6% and 68.6% of its finished products in the first nine months of 2012 and 2011, respectively, from Double Dove, a Chinese manufacturer. Purchases from Double Dove aggregated 71.9% and 62.8% of finished products in the three month periods ended September 30, 2012 and 2011, respectively. 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 0.5mL insulin syringe, its 2mL, 5mL, and 10mL syringes and its autodialable syringe and increase domestic production for 1mL and 3mL syringes to avoid a disruption in supply.

**Revenue recognition**

Revenue is recognized for sales when title and risk of ownership passes to the customer, generally upon shipment. Under certain contracts, 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. Distributors receive a rebate for the difference between the Wholesale Acquisition Cost and the appropriate contract price as reflected on a tracking report provided by the distributor to the Company. If product is sold by a distributor to an entity that has no contract, there is a standard rebate (lower than a contracted rebate) given to the distributor. One of the purposes of the rebate is to encourage distributors to submit tracking reports to the Company. 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 the 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.

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Certain distributors have taken rebates to which they are not entitled, such as utilizing a rebate for products not purchased directly from the Company. The Company has been in discussions with the principal customers that claimed non-contractual rebates. Major customers said they have ceased the practices resulting in

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claiming non-contractual rebates. Rebates can only be claimed on purchases made directly from the Company. The Company has established a reserve for the collectability of these non-contractual rebate amounts. The majority of expense for the reserve is recorded as a reduction of revenues and the remaining expense is recorded in Operating expense, General and administrative. The reserve for such non-contractual deductions is a reduction of accounts receivable.

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 domestic 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 1% 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 the Company.

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

**Litigation settlements**

Proceeds from litigation settlements are recognized when realizable. Generally, realization is not reasonably assured and expected until proceeds are collected. In 2010 and 2011, the Company received quarterly option payments, totaling \$8 million, from Hospira, Inc. (Hospira) for a one-year option to negotiate a licensing agreement for certain uses of the Patient Safe® syringe. This option expired unexercised in July 2011. The Company recognizes proceeds from litigation settlements net of any associated royalty expense.

**Income taxes**

The Company evaluates tax positions taken or expected to be taken in a tax return for recognition in the financial statements based on whether it is more-likely-than-not that a tax position will be sustained based upon the technical merits of the position. Measurement of the tax position is based upon the largest amount of benefit that is greater than 50% likely of being realized upon ultimate settlement.

The Company provides for deferred income taxes through utilizing an asset and liability approach for financial accounting and reporting based on the tax effects of differences between the financial statement and tax bases of assets and liabilities, based on enacted rates expected to be in effect when such differences reverse in future periods. Deferred tax assets are periodically reviewed for realizability. The Company utilized some of its net operating loss carry forwards in 2011 and paid Alternative Minimum Tax on its taxable income. The Company has established a valuation allowance for its net deferred tax asset as future taxable income cannot be reasonably assured. Penalties and interest on uncertain tax positions are classified as income taxes in the Condensed Statements of Operations.



**Earnings per share**

The Company computes basic earnings per share ( EPS ) 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. Diluted EPS includes the determinants of basic EPS and, in addition, reflects the dilutive effect, if any, of the common stock deliverable pursuant to stock options or common stock issuable upon the conversion of convertible preferred stock and convertible debt. The potential dilution, if any, is shown on the following schedule:

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|   | Three Months<br>Ended<br>September 30, 2012 | Three Months<br>Ended<br>September 30, 2011 | Nine Months<br>Ended<br>September 30, 2012 | Nine Months<br>Ended<br>September 30, 2011 |
|---|---|---|--|--|
| Net income (loss)   | \$ (272,961)                                | \$ 1,828,444                                | \$ (1,592,020)                             | \$ 4,399,273                               |
| Preferred dividend requirements   | (229,527)                                   | (342,217)                                   | (688,581)                                  | (1,026,651)                                |
| Effect of dilutive securities:  |   |   |  |  |
| Convertible debt interest and loan fees                                     |   | 2,259                                       |  | (6,955)                                    |
| Earnings (loss) available to common shareholders                            | \$ (502,488)                                | \$ 1,488,486                                | \$ (2,280,601)                             | \$ 3,365,667                               |
| Average common shares outstanding   | 26,972,818                                  | 24,027,053                                  | 25,870,073                                 | 24,005,761                                 |
| Dilutive stock equivalents from stock options                               |   | 1,815,360                                   |  | 2,250,601                                  |
| Shares issuable upon conversion of convertible debt                         |   | 108,391                                     |  | 108,391                                    |
| Average common and common equivalent shares outstanding - assuming dilution | 26,972,818                                  | 25,950,804                                  | 25,870,073                                 | 26,364,753                                 |
| Basic earnings (loss) per share   | \$ (0.02)                                   | \$ 0.06                                     | \$ (0.09)                                  | \$ 0.14                                    |
| Diluted earnings (loss) per share   | \$ (0.02)                                   | \$ 0.06                                     | \$ (0.09)                                  | \$ 0.13                                    |

## Shipping and handling costs

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

## Research and development costs

Research and development costs are expensed as incurred.

## Share-based compensation

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

## 3. INVENTORIES

Inventories consist of the following:

September 30, 2012

December 31, 2011

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|                   |    |           |    |           |
|-------------------|----|-----------|----|-----------|
| Raw materials     | \$ | 1,441,584 | \$ | 1,282,357 |
| Finished goods    |    | 3,714,203 |    | 5,213,497 |
|                   |    | 5,155,787 |    | 6,495,854 |
| Inventory reserve |    | (209,753) |    | (258,435) |
|                   | \$ | 4,946,034 | \$ | 6,237,419 |

Table of Contents**4. INCOME TAXES**

The Company's effective tax rate on the net income (loss) before income taxes was (1.7)% and 1.1% for the nine months ended September 30, 2012 and September 30, 2011, respectively. For the three months ended September 30, 2012 and September 30, 2011, the Company's effective tax rate on the net income (loss) before income taxes was (1.4)% and (0.1)%, respectively.

**5. OTHER ACCRUED LIABILITIES**

Other accrued liabilities consist of the following:

|                            | <b>September 30, 2012</b> | <b>December 31, 2011</b> |
|----------------------------|---------------------------|--------------------------|
| Prepayments from customers | \$ 917,039                | \$ 869,334               |
| Accrued property taxes     | 349,787                   |                          |
| Accrued professional fees  | 120,339                   | 134,790                  |
| Other accrued expenses     | 78,169                    | 61,819                   |
|                            | <b>\$ 1,465,334</b>       | <b>\$ 1,065,943</b>      |

Prepayments from customers are attributable primarily to purchases by South American customers.

**6. COMMITMENTS AND CONTINGENCIES**

In June 2010, Becton, Dickinson and Company ( "BD" ) filed an appeal in the U.S. Court of Appeals (the "Court" ) for the Federal Circuit appealing a final judgment entered on May 19, 2010 for the Company and against BD's counterclaims in patent litigation. Such final judgment ordered that the Company recover \$5,000,000 plus prejudgment interest, and ordered a permanent injunction for BD's 1mL and 3mL Integra syringes until the expiration of certain patents. The permanent injunction was stayed for the longer of the exhaustion of the appeal of the district court's case or twelve months from May 19, 2010. In July 2011, a three-judge panel of the Court reversed the district court's judgment that BD's 3mL Integra infringed the Company's 224 patent and 077 patent. The Court affirmed the district court's judgment that the 1mL Integra infringes the Company's 244 and 733 patents. The Court also affirmed the district court's judgment that the 077 patent is not invalid for anticipation or obviousness. Out of eight principal issues that were contested in the appeal, the Company and an officer prevailed on six and BD prevailed on two. The Company had petitioned for a rehearing by all the judges of the Federal Circuit as to whether the three-judge panel properly construed the Company's patent claim language in finding that the 3mL Integra did not infringe. The Company's petition for rehearing by all of the judges of the Federal Circuit was denied with two dissents being issued. The Company filed a petition for certiorari asking the Supreme Court to review the matter. That petition should be accepted or rejected by December 2012.

In May 2010, the Company and an officer's suit against BD in the U.S. District Court for the Eastern District of Texas, Marshall Division alleging violations of antitrust acts, false advertising, product disparagement, tortious interference, and unfair competition was reopened. The Company and an officer filed a Second Amended Complaint on July 23, 2010 setting forth additional detail regarding the allegations of BD's

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illegal conduct. BD filed a motion to dismiss and the Court denied that motion in part and granted it in part, granting the Company the right to re-plead certain allegations by May 13, 2011. The Company and an officer filed a Third Amended Complaint in May 2011, setting forth additional detail regarding the alleged illegal conduct by BD. Trial was initially set for February 2012. However, in January 2012 the parties agreed to a continuance to allow the petition for certiorari to be considered. As a result of retirement, a new judge will be assigned. It is currently believed that trial will proceed in the spring of 2013.

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

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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. The case has been stayed pending resolution of the Company's first filed case against BD described above.

## 7. BUSINESS SEGMENTS

|   | Three Months<br>Ended<br>September 30, 2012 | Three Months<br>Ended<br>September 30, 2011 | Nine Months<br>Ended<br>September 30, 2012 | Nine Months<br>Ended<br>September 30, 2011 |
|---|---|---|--|--|
| U.S. sales  | \$ 7,157,486                                | \$ 7,956,439                                | \$ 19,943,687                              | \$ 21,120,938                              |
| North and South America sales<br>(excluding U.S.) | 124,988                                     | 218,969                                     | 544,960                                    | 4,422,056                                  |
| Other international sales                         | 2,161,683                                   | 95,200                                      | 5,113,399                                  | 451,217                                    |
| Total sales                                       | \$ 9,444,157                                | \$ 8,270,608                                | \$ 25,602,046                              | \$ 25,994,211                              |

|                   | September 30, 2012 | December 31, 2011 |
|-------------------|--------------------|-------------------|
| Long-lived assets |                    |                   |
| U.S.              | \$ 11,754,977      | \$ 12,412,502     |
| International     | \$ 225,380         | \$ 241,354        |

The Company does not operate in separate reportable segments. The Company has minimal long-lived assets in foreign countries. Shipments to international customers generally require a prepayment either by wire transfer or an irrevocable confirmed letter of credit. The Company does extend credit to international customers on some occasions depending upon certain criteria, including, but not limited to, the credit worthiness of the customer, the stability of the country, banking restrictions, and the size of the order. All transactions are in U.S. currency.

## 8. STOCK REPURCHASE PROGRAM

On July 10, 2012, the Company authorized a Common Stock repurchase plan structured to comply with Rules 10b5-1 and 10b-18 under the Securities Exchange Act of 1934. Under the plan, the Company purchased 38,315 shares in the three months ended September 30, 2012. Notwithstanding the terms of the plan, the exact number of shares which may be purchased in the future pursuant to the plan is difficult to predict given the current market in the Company's Common Stock. The plan will expire on August 1, 2014 at the latest.

Pursuant to the Certificates of Designation, Preferences, Rights And Limitations of the Series I Class B and Series II Class B Convertible Preferred Stock, the Company would be prohibited from purchasing its Common Stock while dividends are in arrears. Therefore, in order to continue the Common Stock repurchase plan, the Company plans to continue to pay dividends on the Series I Class B and Series II Class B Preferred Stock if such payments can be made in accordance with state law and other contractual obligations. The Company paid such dividends on July 31, 2012 to the Series I Class B and Series II Class B Convertible Preferred Stockholders in the amounts of \$38,813 and \$134,025, respectively. On September 28, 2012, the Company declared dividends to holders of the Series I Class B and Series II Class B Convertible Preferred Stock in the amounts of \$12,938 and \$44,675, respectively. The dividends were paid on October 22, 2012 to shareholders of record as of the close of business on October 10, 2012.

**9. STOCK OPTION EXERCISE**

On July 10, 2012, the chief executive officer of the Company exercised a portion of his stock option. The Company issued 2,000,000 shares of Common Stock to him at an exercise price of \$0.81 (aggregate consideration of \$1,620,000).

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**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 similar 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, our ability to maintain favorable supplier arrangements and relationships, our ability to quickly increase capacity in response to an increase in demand, our ability to access the market, our ability to maintain or lower production costs, our ability to continue to finance research and development as well as operations and expansion of production, the increased interest of larger market players, specifically Becton Dickinson and Company ("BD"), in providing devices to the safety market, the applicability of a new medical device excise tax to our products, 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.

**MATERIAL CHANGES IN FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*Overview*

We have been manufacturing and marketing our products into the marketplace since 1997. Safety syringes comprised 99.1% of our sales in the first nine months of 2012. We also manufacture and market the blood collection tube holder, IV safety catheter, and VanishPoint® Blood Collection Set. We currently provide other safety medical products in addition to safety products utilizing retractable technology. One such product is the Patient Safe® syringe, which is uniquely designed to reduce the risk of bloodstream infections resulting from catheter hub contamination.

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

Our products have been and continue to be distributed nationally and internationally through numerous distributors. Although we have made limited progress in some areas, such as the alternate care market, 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 the use of safe needle devices. The alternate care market is composed of alternate care facilities that provide long-term nursing and out-patient surgery, emergency care, and physician services. The fact that our progress is limited is principally due to exclusive marketing practices engaged in by BD, the dominant maker and seller of disposable syringes and other needle products, which practices have blocked us from access to the market. A suit against BD is currently pending alleging violations of state and federal antitrust acts and false advertising. BD has ceased marketing the infringing 1mL Integra syringe.

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.



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 additional cost cutting measures to reduce cash requirements. Such measures could result in the reduction of units being produced, the reduction of workforce, the reduction of salaries of officers and other nonhourly employees, and the deferral of royalty payments. We took such actions at the end of the second quarter of 2009. Salary reductions put in place in the second quarter of 2009 remain in place for executive officers, but all other employees affected by the salary reduction had their salaries increased by the amount of the reduction, effective August 6, 2012.

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Section 4191 of the Internal Revenue Code, enacted by the Health Care and Education Reconciliation Act of 2010 in conjunction with the Patient Protection and Affordable Care Act provides for an excise tax of 2.3% on medical devices beginning in 2013. At the present time the excise tax is applicable to domestic sales of our products, except those which are sold at retail. The majority of our sales are domestic and not in the retail market. The tax is imposed on sales, not profits. We estimate the impact of this tax to be in excess of \$500 thousand in 2013. There is no assurance this tax can be passed along to our customers.

We have brought additional molding operations to Little Elm as a cost saving measure. The addition of four molding machines in 2011 was part of that endeavor. We continue to focus on methods of upgrading our manufacturing capability and efficiency in order to reduce costs.

In 2010 and 2011, the Company received quarterly option payments, totaling \$8 million, from Hospira, Inc. ( Hospira ) for a one-year option to negotiate a licensing agreement for certain uses of the Patient Safe® syringe. This option expired unexercised in July 2011.

On September 12, 2011, we commenced an offer to purchase outstanding Class B Convertible Preferred Stock (the Preferred Stock ) for cash and Common Stock (the 2011 Exchange Offer ) and also engaged in private purchases with three Preferred Stockholders. As of December 31, 2011, Preferred Stockholders had tendered a total of 1,277,464 shares of Preferred Stock. A total of \$1,357,275 and 1,277,464 shares of Common Stock were issued as consideration to these Preferred Stockholders. These Preferred Stockholders agreed to waive all unpaid dividends in arrears associated with their tendered Preferred Stock, which resulted in a waiver of a total of \$3,637,025 in unpaid dividends in arrears.

On July 10, 2012, we authorized a Common Stock repurchase plan structured to comply with Rules 10b5-1 and 10b-18 under the Securities Exchange Act of 1934. Under the plan, we purchased 38,315 shares in the three months ended September 30, 2012. Notwithstanding the terms of the plan, the exact number of shares which may be purchased in the future pursuant to the plan is difficult to predict given the current market in our Common Stock.

Pursuant to the Certificates of Designation, Preferences, Rights And Limitations of the Series I Class B and Series II Class B Convertible Preferred Stock, we would be prohibited from purchasing our Common Stock while dividends are in arrears. Therefore, in order to continue the Common Stock repurchase plan, we plan to continue to pay dividends on the Series I Class B and Series II Class B Preferred Stock if such payments can be made in accordance with state law and other contractual obligations. We paid such dividends on July 31, 2012 to the Series I Class B and Series II Class B Convertible Preferred Stockholders in the amounts of \$38,813 and \$134,025, respectively. On September 28, 2012, we declared dividends to holders of the Series I Class B and Series II Class B Convertible Preferred Stock in the amounts of \$12,938 and \$44,675, respectively. The dividends were paid on October 22, 2012 to shareholders of record as of the close of business on October 10, 2012.

Product purchases from Double Dove, a Chinese manufacturer, have enabled us to increase manufacturing capacity with little capital outlay and have provided a competitive manufacturing cost. In the nine months ended September 30, 2012, Double Dove manufactured approximately 69.6% of the units we produced. We believe we could make up any long-term disruption in these purchases by utilizing more of the capacity at the Little Elm facility, except for the 0.5mL insulin syringe, the 2mL, 5mL and 10mL syringes, and the autodisable syringe which altogether comprised about 8.2% of our revenues for the nine months ended September 30, 2012.

In 1995, we entered into a license agreement with Thomas J. Shaw for the exclusive right to manufacture, market, and distribute products utilizing automated retraction technology. This technology is the subject of various patents and patent applications owned by Mr. Shaw. The

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license agreement generally provides for quarterly payments of a 5% royalty fee on gross sales. This license agreement was amended as of September 7, 2012 to clarify and set forth the calculation and amount of the royalty, including in the event that we have sublicensed our products.

With increased volumes, our manufacturing unit costs have generally tended to decline. Factors that could affect our unit costs include increases in costs by third party manufacturers, changing production volumes, costs of petroleum products, and transportation costs. Increases in such costs may not be recoverable through price increases of our products.

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The following discussion may contain 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 any forward-looking statements. Dollar amounts have been rounded for ease of reading. All period references are to the periods ended September 30, 2012 or 2011.

**RESULTS OF OPERATIONS**

*Comparison of Three Months Ended September 30, 2012 and September 30, 2011*

Domestic sales accounted for 75.8% and 96.2% of the revenues for the three months ended September 30, 2012 and 2011, respectively. Domestic revenues decreased 10.0% principally due to lower average selling prices mitigated by higher sales volumes. Domestic unit sales increased 5.9%. Domestic unit sales were 64.8% of total unit sales for the three months ended September 30, 2012. International revenues increased from \$314 thousand in 2011 to \$2.3 million in 2012, primarily due to increased sales volume. Overall unit sales increased 54.7%.

Gross profit decreased 1.1% primarily due to lower average sales prices mitigated by lower average unit cost of manufacture. The cost of manufactured product increased by 26.4% due to higher volume mitigated by lower unit cost. Gross profit as a percentage of net sales was 35.5% in the three months ended September 30, 2012 as compared to 41.0% in 2011 due to lower average selling prices. Profit margins can fluctuate depending upon, among other things, the cost of manufactured product and the capitalized cost of product recorded in inventory, as well as product sales mix. Royalty expense increased 14.9% due to higher gross sales.

Operating expenses increased 4.4%. The decrease in General and administrative expense was due primarily to lower legal costs. The increase of \$97 thousand in Sales and marketing expense was due to the addition of sales personnel and sales bonuses. The increase was mitigated by lower fees and consulting costs. Research and development costs increased \$75 thousand due principally to increased labor costs and testing costs.

Our operating loss was \$211 thousand compared to an operating loss for the same period last year of \$26 thousand due primarily to slightly lower gross profit and marginally higher operating expenses.

In the three months ended September 30, 2011, Litigation settlements, net reflects cash proceeds of \$2.0 million from Hospira less royalty expense of \$100 thousand.

Our effective tax rate on the net income (loss) before income taxes was (1.4)% and (0.1)% for the three months ended September 30, 2012 and September 30, 2011, respectively.

*Comparison of Nine Months Ended September 30, 2012 and September 30, 2011*

Domestic sales accounted for 77.9% and 81.3% of the revenues for the nine months ended September 30, 2012 and 2011, respectively. Domestic revenues decreased 5.6% principally due to lower sales volumes and lower average sales prices. Domestic unit sales decreased 4.2%. Domestic unit sales were 65.4% of total unit sales for the nine months ended September 30, 2012. International revenues increased from \$4.9 million in 2011 to \$5.7 million in 2012 primarily due to increased sales volumes. Overall unit sales increased 4.0%.

Gross profit decreased 3.0% primarily due to lower average sales prices. The average cost of manufactured product sold per unit decreased by 4.3%. Gross profit as a percentage of net sales was 37.2% in the nine months ended September 30, 2012 as compared to 37.8% in 2011 due to lower average sales price mitigated by higher sales volumes. Profit margins can fluctuate depending upon, among other things, the cost of manufactured product and the capitalized cost of product recorded in inventory, as well as product sales mix. Royalty expense decreased 2.0% due to lower gross sales.

Operating expenses decreased 0.2%. General and administrative expense decreased \$531 thousand due principally to a lower accrual for bad debt expense, lower legal costs, larger donations, and higher consulting fees. The increase of \$452 thousand in Sales and marketing expense was due to the addition of sales personnel and sales bonuses. Travel and entertainment costs also increased. Research and development costs increased 11.5% due principally to increased labor costs and testing costs.

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Our operating loss was \$1.4 million compared to an operating loss for the same period last year of \$1.1 million due primarily to lower average sales prices.

For the nine months ended September 30, 2011, Litigation settlements, net reflects cash proceeds of \$6.0 million from Hospira less royalty expense of \$300,000.

Our effective tax rate on the net income (loss) before income taxes was (1.7)% and 1.1% for the nine months ended September 30, 2012 and September 30, 2011, respectively.

*Discussion of Balance Sheet and Statement of Cash Flow Items*

Our balance sheet remains strong with cash making up 51.8% of total assets. Working capital was \$30.0 million at September 30, 2012, an increase of \$188 thousand from December 31, 2011.

Finished goods inventory decreased 28.8% since December 31, 2011 because of increasing unit sales.

Approximately \$1.2 million in cash flow in the nine months ended September 30, 2012 was used by operating activities. Our cash balance decreased primarily due to our net loss (exclusive of noncash charges) and an increase in certain working capital items.

We purchased 38,315 shares of our Common Stock pursuant to our Common Stock repurchase plan as of September 30, 2012. The average share price since the plan's start date on August 1, 2012 was \$1.16.

Our preferred stock dividend requirements were reduced \$337 thousand and \$112 thousand for the nine months and three months ended September 30, 2012, respectively, as a result of the 2011 Exchange Offer in the fourth quarter of 2011.

**LIQUIDITY**

Historical Sources of Liquidity

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

Internal Sources of Liquidity

*Margins and Market Access*

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

We continue to focus on methods of upgrading our manufacturing capability and efficiency in order to reduce 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 29.6%) 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

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available, usually decrease the average cost of manufacture for all units. Domestic costs, such as indirect labor and overhead, remain relatively constant. The number of units produced by us 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.

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. 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.

*Licensing Agreement*

In 2010 and 2011, the Company received quarterly option payments, totaling \$8 million, from Hospira, Inc. ( Hospira ) for a one-year option to negotiate a licensing agreement for certain uses of the Patient Safe® syringe. This option expired unexercised in July 2011.

*Cash Requirements*

Due to funds received from prior litigation settlements and operating at minimal cash usage, 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 additional cost cutting measures to reduce cash requirements. Such measures could result in the reduction of units being produced, the reduction of workforce, the reduction of salaries of officers and other nonhourly employees, and the deferral of royalty payments.

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. Given the current economic conditions, our ability to obtain additional funds through loans is uncertain. 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. Due to the current market price of our Common Stock, it is unlikely we would choose to raise funds by the sale of equity.



In 2010 and 2011, the Company received quarterly option payments, totaling \$8 million, from Hospira, Inc. ( Hospira ) for a one-year option to negotiate a licensing agreement for certain uses of the Patient Safe® syringe. This option expired unexercised in July 2011.

On July 10, 2012, Thomas J. Shaw, our chief executive officer, exercised a portion of his stock option. The Company issued 2,000,000 shares of Common Stock to him at an exercise price of \$0.81 (aggregate consideration of \$1,620,000).

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**CAPITAL RESOURCES**

Repurchase of Preferred Shares

On September 12, 2011, we commenced the 2011 Exchange Offer and also engaged in private purchases with three Preferred Stockholders. As of December 31, 2011, Preferred Stockholders had tendered a total of 1,277,464 shares of Preferred Stock. A total of \$1,357,275 and 1,277,464 shares of Common Stock were issued as consideration to these Preferred Stockholders. These Preferred Stockholders agreed to waive all unpaid dividends in arrears associated with their tendered Preferred Stock, which resulted in a waiver of a total of \$3,636,793 in unpaid dividends in arrears.

Repurchase of Common Stock

On July 10, 2012, we authorized a Common Stock repurchase plan structured to comply with Rules 10b5-1 and 10b-18 under the Securities Exchange Act of 1934. Under the plan, we purchased 38,315 shares in the three months ended September 30, 2012. Notwithstanding the terms of the plan, the exact number of shares which may be purchased in the future pursuant to the plan is difficult to predict given the current market in our Common Stock.

Pursuant to the Certificates of Designation, Preferences, Rights And Limitations of the Series I Class B and Series II Class B Convertible Preferred Stock, we would be prohibited from purchasing our Common Stock while dividends are in arrears. Therefore, in order to continue the Common Stock repurchase plan, we plan to continue to pay dividends on the Series I Class B and Series II Class B Preferred Stock if such payments can be made in accordance with state law and other contractual obligations.

Material Commitments for Expenditures

In 2011, we purchased molding machines to expand our in-house molding capability and further reduce costs. Financing was completed in the second quarter of 2011 for three molding machines in the amount of \$327,725. The purchase and financing for a fourth molding machine for \$207,261 was completed in the fourth quarter of 2011.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

No update.

**Item 4. Controls and Procedures.**

Disclosure Controls and Procedures

Pursuant to Rule 13a-15(b) of the Securities Exchange Act of 1934, Management, with the participation of our President, Chairman, and Chief Executive Officer, Thomas J. Shaw (the "CEO"), and our Vice President and Chief Financial Officer, Douglas W. Cowan (the "CFO"), acting in their capacities as our principal executive and principal financial officers, evaluated the effectiveness of our disclosure controls and procedures, as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934. The term disclosure controls and procedures means controls and other procedures that are designed to ensure that information required to be disclosed by us in our periodic reports is: i) recorded, processed, summarized, and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms; and ii) accumulated and communicated to our Management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Based upon this evaluation, the CEO and CFO concluded that, as of September 30, 2012, our disclosure controls and procedures were effective.

Changes in Internal Control Over Financial Reporting

There have been no changes during the third quarter of 2012 or subsequent to September 30, 2012 in our internal control over financial reporting that has materially affected or is reasonably likely to materially affect our internal control over financial reporting.

Table of Contents**PART II OTHER INFORMATION****Item 1. Legal Proceedings.**

Please refer to Note 6 to the financial statements for a complete description of all legal proceedings.

**Item 1A. Risk Factors.**

Section 4191 of the Internal Revenue Code, enacted by the Health Care and Education Reconciliation Act of 2010 in conjunction with the Patient Protection and Affordable Care Act provides for an excise tax of 2.3% on medical devices beginning in 2013. At the present time the excise tax is applicable to domestic sales of our products, except those which are sold at retail. The majority of our sales are domestic and not in the retail market. The tax is imposed on sales, not profits. We estimate the impact of this tax to be in excess of \$500 thousand in 2013. There is no assurance this tax can be passed along to our customers.

There were no other material changes in the Risk Factors applicable to the Company as set forth in our Form 10-K annual report for 2011 which was filed on March 30, 2012, and which is available on EDGAR.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.**Purchases of Equity Securities by the Issuer and Affiliated Purchasers

## Issuer Purchases of Equity Securities

| Period                                 | Total<br>Number of<br>Shares (or<br>Units)<br>Purchased | Average<br>Price Paid<br>Per Share<br>(or Unit) | Total Number of<br>Shares (or Units)<br>Purchased as Part<br>of Publicly<br>Announced Plans<br>or Programs | Maximum Number<br>(or Approximate<br>Dollar Value) of<br>Shares (or Units) that<br>May Yet Be<br>Purchased Under the<br>Plans or Programs |
|--|---|---|--|---|
| July 10, 2012                          | 2,000,000(1)  | \$0.81  |  | N/A   |
| August 1, 2012 through August 31, 2012 | 18,490(2)   | \$1.15  | 18,490   | \$2,978,715(2)  |

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|  |           |        |        |                |
|--|-----------|--------|--------|----------------|
| September 1, 2012 through September 30, 2012 | 19,825(2) | \$1.17 | 19,825 | \$2,955,525(2) |
| TOTAL  | 2,038,315 |        |        |                |

(1) These shares were purchased by an affiliated purchaser in a private transaction (stock option exercise), not through a publicly announced plan or program.

(2) These shares were purchased pursuant to our Common Stock repurchase plan structured to comply with Rules 10b5-1 and 10b-18 under the Securities Exchange Act of 1934, announced on Form 8-K on July 12, 2012. On July 10, 2012, the Board of Directors authorized the repurchase of up to \$3 million of Common Stock subject to Rule 10b-18 limitations as well as certain market value constraints specified in the plan. Notwithstanding the terms of the plan, the exact dollar amount and number of shares which may be purchased pursuant to the plan is difficult to predict given the current market in the Company's Common Stock. The plan will expire on August 1, 2014 at the latest.

### Working Capital Restrictions and Limitations on the Payment of Dividends

On September 28, 2012, the Board of Directors declared a dividend to the Series I Class B and Series II Class B Convertible Preferred Shareholders in the aggregate amount of \$57,613. This dividend was paid on October 22, 2012.

The certificates of designation for each of the outstanding series of Class B Convertible Preferred Stock each currently provide that, if a dividend upon any shares of Preferred Stock is in arrears, no dividends may be paid or declared upon any stock ranking junior to such stock and generally no junior preferred stock may be redeemed. However, under certain conditions, and for certain Series of Class B Convertible Preferred Stock, we may purchase junior stock when dividends are in arrears.

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

Series I Class B Convertible Preferred Stock

For the nine month period ended September 30, 2012, the amount of dividends in arrears was \$13,000 and the total arrearage at the end of the period was \$13,000.

Series II Class B Convertible Preferred Stock

For the nine month period ended September 30, 2012, the amount of dividends in arrears was \$45,000 and the total arrearage at the end of the period was \$45,000.

Series III Class B Convertible Preferred Stock

For the nine month period ended September 30, 2012, the amount of dividends in arrears was \$99,000 and the total arrearage at the end of the period was \$3,464,000.

Series IV Class B Convertible Preferred Stock

For the nine month period ended September 30, 2012, the amount of dividends in arrears was \$408,000 and the total arrearage at the end of the period was \$6,746,000.

Series V Class B Convertible Preferred Stock

For the nine month period ended September 30, 2012, the amount of dividends in arrears was \$12,000 and the total arrearage at the end of the period was \$926,000.

**Item 6. Exhibits.**

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| <u>Exhibit No.</u> | <u>Description of Document</u>  |
|--------------------|---|
| 10                 | Second Amendment to Technology License Agreement between Thomas J. Shaw and Retractable Technologies, Inc. dated as of the 7th day of September, 2012 *   |
| 31.1               | Certification of Principal Executive Officer *  |
| 31.2               | Certification of Principal Financial Officer *  |
| 32                 | Certification Pursuant to 18 U.S.C. Section 1350 *  |
| 101                | The following materials from Retractable Technologies, Inc. s Form 10-Q for the quarter ended September 30, 2012, formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Balance Sheets as of September 30, 2012 and December 31, 2011, (ii) Condensed Statements of Operations for the nine months and three months ended September 30, 2012 and 2011, (iii) Condensed Statements of Cash Flows for the nine months ended September 30, 2012 and 2011, and (iv) Notes to Condensed Financial Statements** |
| *                  | Filed herewith  |
| **                 | Furnished herewith  |

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**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, 2012

RETRACTABLE TECHNOLOGIES, INC.  
(Registrant)

BY: /s/ Douglas W. Cowan  
DOUGLAS W. COWAN

VICE PRESIDENT,

CHIEF FINANCIAL OFFICER, AND CHIEF  
ACCOUNTING OFFICER