

RETRACTABLE TECHNOLOGIES INC

Form 10-Q

November 16, 2015

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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, 2015**

**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)

**75068-5295**

(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: 27,891,874 shares of Common Stock, no par value, outstanding on November 2, 2015.

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RETRACTABLE TECHNOLOGIES, INC.

FORM 10-Q

For the Quarterly Period Ended September 30, 2015

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|                                             | <b>September 30, 2015</b><br><b>(unaudited)</b> | <b>December 31, 2014</b> |
|---------------------------------------------|-------------------------------------------------|--------------------------|
| <b>ASSETS</b>                               |                                                 |                          |
| Current assets:                             |                                                 |                          |
| Cash and cash equivalents                   | \$ 19,703,945                                   | \$ 22,128,977            |
| Restricted cash                             |                                                 | 600,897                  |
| Accounts receivable, net                    | 5,027,043                                       | 5,642,091                |
| Inventories, net                            | 6,111,034                                       | 4,663,548                |
| Other current assets                        | 774,817                                         | 1,194,055                |
| Total current assets                        | 31,616,839                                      | 34,229,568               |
| Property, plant, and equipment, net         | 11,478,045                                      | 10,852,853               |
| Intangible and other assets, net            | 263,760                                         | 270,693                  |
| Total assets                                | \$ 43,358,644                                   | \$ 45,353,114            |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b> |                                                 |                          |
| Current liabilities:                        |                                                 |                          |
| Accounts payable                            | \$ 5,105,807                                    | \$ 5,142,796             |
| Litigation proceeds subject to stipulation  |                                                 | 7,724,826                |
| Current portion of long-term debt           | 246,110                                         | 149,744                  |
| Accrued compensation                        | 630,050                                         | 504,188                  |
| Dividends payable                           | 56,363                                          |                          |
| Accrued royalties to shareholders           | 770,197                                         | 787,434                  |
| Other accrued liabilities                   | 994,821                                         | 782,322                  |
| Income taxes payable                        | 5,405                                           | 8,290                    |
| Total current liabilities                   | 7,808,753                                       | 15,099,600               |
| Long-term debt, net of current maturities   | 3,481,555                                       | 3,425,028                |
| Total liabilities                           | 11,290,308                                      | 18,524,628               |
| Commitments and contingencies               | see Note 6                                      |                          |
| Stockholders' equity:                       |                                                 |                          |
| Preferred stock \$1 par value:              |                                                 |                          |
| Series I, Class B                           | 98,500                                          | 98,500                   |
| Series II, Class B                          | 176,200                                         | 176,200                  |
| Series III, Class B                         | 129,245                                         | 130,245                  |
| Series IV, Class B                          | 542,500                                         | 542,500                  |
| Series V, Class B                           | 40,000                                          | 40,000                   |
| Common stock, no par value                  |                                                 |                          |
| Additional paid-in capital                  | 58,178,551                                      | 59,273,769               |

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|                                            |               |               |
|--------------------------------------------|---------------|---------------|
| Retained deficit                           | (27,096,660)  | (32,336,119)  |
| Common stock in treasury at cost           |               | (1,096,609)   |
| Total stockholders' equity                 | 32,068,336    | 26,828,486    |
| Total liabilities and stockholders' equity | \$ 43,358,644 | \$ 45,353,114 |

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, 2015</b> | <b>Three Months<br/>Ended<br/>September 30, 2014</b> | <b>Nine Months<br/>Ended<br/>September 30, 2015</b> | <b>Nine Months<br/>Ended<br/>September 30, 2014</b> |
|-------------------------------------------------|------------------------------------------------------|------------------------------------------------------|-----------------------------------------------------|-----------------------------------------------------|
| Sales, net                                      | \$ 9,482,866                                         | \$ 10,886,680                                        | \$ 22,376,912                                       | \$ 23,803,420                                       |
| Cost of sales:                                  |                                                      |                                                      |                                                     |                                                     |
| Cost of manufactured product                    | 5,489,151                                            | 6,191,232                                            | 12,307,440                                          | 14,109,159                                          |
| Royalty expense to shareholders                 | 770,197                                              | 843,730                                              | 1,846,438                                           | 1,941,267                                           |
| Total cost of sales                             | 6,259,348                                            | 7,034,962                                            | 14,153,878                                          | 16,050,426                                          |
| Gross profit                                    | 3,223,518                                            | 3,851,718                                            | 8,223,034                                           | 7,752,994                                           |
| Operating expenses:                             |                                                      |                                                      |                                                     |                                                     |
| Sales and marketing                             | 954,955                                              | 919,842                                              | 2,826,224                                           | 3,079,361                                           |
| Research and development                        | 125,780                                              | 129,189                                              | 409,764                                             | 506,150                                             |
| General and administrative                      | 2,342,165                                            | 2,381,799                                            | 7,321,847                                           | 7,076,688                                           |
| Total operating expenses                        | 3,422,900                                            | 3,430,830                                            | 10,557,835                                          | 10,662,199                                          |
| Income (loss) from operations                   | (199,382)                                            | 420,888                                              | (2,334,801)                                         | (2,909,205)                                         |
| Litigation proceeds                             |                                                      |                                                      | 7,724,826                                           |                                                     |
| Interest and other income                       | 4,916                                                | 7,598                                                | 20,836                                              | 26,430                                              |
| Interest expense, net                           | (58,316)                                             | (55,185)                                             | (165,269)                                           | (168,388)                                           |
| Income (loss) before income taxes               | (252,782)                                            | 373,301                                              | 5,245,592                                           | (3,051,163)                                         |
| Provision for income taxes                      | 2,044                                                | 1,876                                                | 6,133                                               | 5,627                                               |
| Net income (loss)                               | (254,826)                                            | 371,425                                              | 5,239,459                                           | (3,056,790)                                         |
| Preferred stock dividend requirements           | (227,499)                                            | (228,999)                                            | (682,802)                                           | (686,997)                                           |
| Income (loss) applicable to common shareholders | \$ (482,325)                                         | \$ 142,426                                           | \$ 4,556,657                                        | \$ (3,743,787)                                      |
| Basic earnings (loss) per share                 | \$ (0.02)                                            | \$ 0.01                                              | \$ 0.16                                             | \$ (0.14)                                           |
| Diluted earnings (loss) per share               | \$ (0.02)                                            | \$ 0.00                                              | \$ 0.15                                             | \$ (0.14)                                           |
| Weighted average common shares outstanding:     |                                                      |                                                      |                                                     |                                                     |
| Basic                                           | 27,873,447                                           | 27,394,061                                           | 27,759,333                                          | 27,326,966                                          |
| Diluted                                         | 27,873,447                                           | 29,173,359                                           | 29,436,008                                          | 27,326,966                                          |

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,<br/>2015</b> | <b>Nine Months<br/>Ended<br/>September 30,<br/>2014</b> |
|--------------------------------------------------------------------------------------|---------------------------------------------------------|---------------------------------------------------------|
| <b>Cash flows from operating activities</b>                                          |                                                         |                                                         |
| Net income (loss)                                                                    | \$ 5,239,459                                            | \$ (3,056,790)                                          |
| Adjustments to reconcile net income (loss) to net cash used by operating activities: |                                                         |                                                         |
| Provision for doubtful accounts                                                      | 141,000                                                 |                                                         |
| Depreciation and amortization                                                        | 645,038                                                 | 835,163                                                 |
| (Increase) decrease in assets:                                                       |                                                         |                                                         |
| Inventories                                                                          | (1,447,486)                                             | 868,864                                                 |
| Accounts receivable                                                                  | 474,048                                                 | (2,672,064)                                             |
| Other current assets                                                                 | 419,238                                                 | 460,769                                                 |
| Increase (decrease) in liabilities:                                                  |                                                         |                                                         |
| Accounts payable                                                                     | (36,989)                                                | 912,974                                                 |
| Litigation proceeds subject to stipulation                                           | (7,724,826)                                             |                                                         |
| Other accrued liabilities                                                            | 321,124                                                 | (1,099,026)                                             |
| Income taxes payable                                                                 | (2,885)                                                 | (85,233)                                                |
| Net cash used by operating activities                                                | (1,972,279)                                             | (3,835,343)                                             |
| <b>Cash flows from investing activities</b>                                          |                                                         |                                                         |
| Purchase of property, plant, and equipment                                           | (1,263,296)                                             | (970,170)                                               |
| Changes in restricted cash                                                           | 600,897                                                 | (600,594)                                               |
| Net cash used by investing activities                                                | (662,399)                                               | (1,570,764)                                             |
| <b>Cash flows from financing activities</b>                                          |                                                         |                                                         |
| Repayments of long-term debt and notes payable                                       | (123,602)                                               | (200,236)                                               |
| Proceeds from the exercise of stock options                                          | 283,933                                                 | 223,680                                                 |
| Proceeds from long-term debt                                                         | 276,495                                                 |                                                         |
| Payment of Preferred Stock dividends                                                 | (227,180)                                               | (172,839)                                               |
| Net cash provided (used) by financing activities                                     | 209,646                                                 | (149,395)                                               |
| Net decrease in cash and cash equivalents                                            | (2,425,032)                                             | (5,555,502)                                             |
| Cash and cash equivalents at:                                                        |                                                         |                                                         |
| Beginning of period                                                                  | 22,128,977                                              | 27,629,359                                              |
| End of period                                                                        | \$ 19,703,945                                           | \$ 22,073,857                                           |
| Supplemental schedule of cash flow information:                                      |                                                         |                                                         |
| Interest paid                                                                        | \$ 165,269                                              | \$ 168,388                                              |
| Income taxes paid                                                                    | \$ 9,017                                                | \$ 94,029                                               |
| Supplemental schedule of noncash investing and financing activities:                 |                                                         |                                                         |
| Preferred dividends declared, not paid                                               | \$ 56,363                                               | \$                                                      |



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 commercially available products are the VanishPoint® 0.5mL insulin syringe; 1mL tuberculin, insulin, and allergy antigen syringes; 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® syringes; the Patient Safe® Luer Cap; and the VanishPoint® Blood Collection Set. The Company also sells VanishPoint® autodisable syringes in the international market in addition to other products.

**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, 2015 for the year ended December 31, 2014.

**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, the proceeds subject to a stipulation, money market accounts, and investments with original maturities of three months or less.

### **Restricted cash**

Amounts pledged as collateral for an underlying letter of credit for equipment is classified as restricted cash. Changes in restricted cash have been presented as investing activities in the Condensed Statements of Cash Flows.

### **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. This provision is 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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The Company requires certain customers to make a prepayment prior to beginning production or shipment of their order. Customers 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.

**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 fair value determined using a discounted cash flow analysis of the underlying assets.

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

### **Intangible assets**

Intangible assets are stated at cost and consist primarily of intellectual property which is amortized using the straight-line method over 17 years.

### **Financial instruments**

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

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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 for the first three and nine months of 2015 and 2014:

|                                                               | <b>Three Months<br/>ended<br/>September 30, 2015</b> | <b>Three Months<br/>Ended<br/>September 30, 2014</b> | <b>Nine Months<br/>ended<br/>September 30, 2015</b> | <b>Nine Months<br/>ended<br/>September 30, 2014</b> |
|---------------------------------------------------------------|------------------------------------------------------|------------------------------------------------------|-----------------------------------------------------|-----------------------------------------------------|
| Number of significant customers                               | 2                                                    | 3                                                    | 2                                                   | 2                                                   |
| Aggregate dollar amount of net sales to significant customers | \$5.1 million                                        | \$6.0 million                                        | \$10.3 million                                      | \$9.0 million                                       |
| Percentage of net sales to significant customers              | 53.5%                                                | 55.0%                                                | 46.0%                                               | 37.6%                                               |

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 78.2% and 70.8% of its VanishPoint® finished products in the first nine months of 2015 and 2014, respectively, from its primary Chinese manufacturer. Purchases from this Chinese manufacturer aggregated 82.4% and 78.3% of VanishPoint® finished products in the three month periods ended September 30, 2015 and 2014, respectively. In the event that the Company becomes unable to purchase products from its primary Chinese manufacturer, the Company would need to find an alternate manufacturer for its 0.5mL insulin syringe, its 2mL, 5mL, and 10mL syringes and its autodisable syringe and increase domestic production for 1mL and 3mL syringes.

**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 for which 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 included in Accounts payable in the Balance

Sheets and deducted from revenues in the Statements of Operations. Accounts payable included estimated contractual allowances for \$3,923,870 and \$4,160,099 as of September 30, 2015 and December 31, 2014, respectively. 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. Major customers said they have ceased the practices resulting in 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 expense for the reserve is recorded in Operating expense, General and administrative. The reserve for such non-contractual deductions is included in the allowance for doubtful accounts. There has been no change to the reserve for contractual rebates in the periods currently presented.

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 generally 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 generally do not provide for any returns.

**Litigation proceeds**

Proceeds from litigation are recognized when realizable. Generally, realization is not reasonably assured and expected until proceeds are collected.

On September 30, 2013, the Company received payment of \$7,724,826 (the Judgment Amount) from Becton, Dickinson and Company (BD) pursuant to a stipulation in the patent infringement case *Retractable Technologies, Inc. and Thomas Shaw v. Becton Dickinson and Company*, Civil Action No. 2:07-cv-250, in the U.S. District Court for the Eastern District of Texas, Marshall Division. The Judgment Amount was included as income in the second quarter of 2015 due to the conclusion of the case and related appeals. Prior to the second quarter of 2015, the Judgment Amount had been shown as a liability on the balance sheet.

**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.



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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 has established a valuation allowance for its net deferred tax asset as future taxable income cannot be reasonably assured. Penalties and interest related to income tax are classified as General and administrative expense and Interest expense, respectively, in the Condensed Statements of Operations.

Table of Contents**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. The calculation of diluted EPS excluded 1,853,154 shares of Common Stock underlying issued and outstanding stock options for the nine months ended September 30, 2014 as the effect was antidilutive. The calculation of diluted EPS excluded 1,648,401 shares of Common Stock underlying issued and outstanding stock options for the three months ended September 30, 2015 as the effect was antidilutive. The potential dilution, if any, is shown on the following schedule:

|                                                                             | Three Months<br>Ended<br>September 30, 2015 | Three Months<br>Ended<br>September 30, 2014 | Nine Months<br>Ended<br>September 30, 2015 | Nine Months<br>Ended<br>September 30, 2014 |
|-----------------------------------------------------------------------------|---------------------------------------------|---------------------------------------------|--------------------------------------------|--------------------------------------------|
| Net income (loss)                                                           | \$ (254,826)                                | \$ 371,425                                  | \$ 5,239,459                               | \$ (3,056,790)                             |
| Preferred dividend requirements                                             | (227,499)                                   | (228,999)                                   | (682,802)                                  | (686,997)                                  |
| Earnings (loss) applicable to common shareholders after assumed conversions | \$ (482,325)                                | \$ 142,426                                  | \$ 4,556,657                               | \$ (3,743,787)                             |
| Average common shares outstanding                                           | 27,873,447                                  | 27,394,061                                  | 27,759,333                                 | 27,326,966                                 |
| Average common and common equivalent shares outstanding assuming dilution   | 27,873,447                                  | 29,173,359                                  | 29,436,008                                 | 27,326,966                                 |
| Basic earnings (loss) per share                                             | \$ (0.02)                                   | \$ 0.01                                     | \$ 0.16                                    | \$ (0.14)                                  |
| Diluted earnings (loss) per share                                           | \$ (0.02)                                   | \$ 0.00                                     | \$ 0.15                                    | \$ (0.14)                                  |

**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.

#### **Recent Pronouncements**

In July 2015, the Financial Accounting Standards Board ( FASB ) issued Accounting Standards Update ( ASU ) No. 2015-11, Inventory (Topic 330) Simplifying the Measurement of Inventory, which is part of the FASB's Simplification Initiative. Inventory, including inventory measured at average cost, would be valued at the lower of cost or net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. ASU 2015-11 is effective for the Company's annual periods and interim periods within those annual periods beginning January 1, 2017. Amendments in this ASU should be applied prospectively with earlier application permitted at the beginning of an interim or annual reporting period. The Company is currently assessing the potential impact of this ASU on its financial statements.

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In May 2014, FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers*, which provides guidance for revenue recognition. This ASU's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects consideration to which the company expects to be entitled in exchange for those goods or services. This ASU also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments, and assets recognized from costs incurred to obtain or fulfill a contract. ASU No. 2014-09 allows for either full retrospective or modified retrospective adoption. In July 2015, the FASB voted to delay the effective date of this ASU by one year. The ASU will now be effective commencing with the Company's quarter ending March 31, 2018. Early adoption of this ASU is allowed no sooner than the original effective date. The Company is currently assessing the potential impact of this ASU on its financial statements.

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements Going Concern (Subtopic 205-40) Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. Currently there is no guidance in GAAP about management's responsibility to evaluate whether there is substantial doubt about the entity's ability to continue as a going concern. This ASU requires management to assess the entity's ability to continue as a going concern. This guidance is effective for the Company's annual reporting period ending December 31, 2016 and for subsequent interim periods. Early adoption is permitted. The Company expects to adopt this guidance when effective, and upon adoption, will evaluate going concern based on this guidance.

In June 2014, the FASB issued ASU 2014-12, *Compensation - Stock Compensation (Topic 718): Accounting for Shared Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved After the Requisite Service Period* (a consensus of the FASB Emerging Issues Task Force). ASU 2014-12 is effective for the Company's annual periods and interim periods within those annual periods beginning January 1, 2016. The Company is assessing the impact, if any, to its financial statements.

In January 2015, the FASB issued ASU 2015-01, *Income Statement - Extraordinary and Unusual Items (Subtopic 225-20): Simplifying Income Statement Presentation by Eliminating the Concept of Extraordinary Items*. The amendments in ASU 2015-01 eliminate from U.S. GAAP the concept of extraordinary items. Subtopic 225-20, *Income Statement - Extraordinary and Unusual Items*, required that an entity separately classify, present, and disclose extraordinary events and transactions. Presently, an event or transaction is presumed to be an ordinary and usual activity of the reporting entity unless evidence clearly supports its classification as an extraordinary item. ASU 2015-01 is effective for the Company's annual periods and interim periods within those annual periods beginning January 1, 2016. Early adoption is permitted. The Company is not currently reporting any extraordinary or unusual items in its financial statements.

In April 2015, the FASB issued ASU 2015-03, *Interest - Imputation of Interest*. To simplify presentation of debt issuance costs, the amendments in this ASU would require that debt issuance costs be presented in the balance sheet as a direct deduction from the carrying amount of debt liability, consistent with debt discounts or premiums. The recognition and measurement guidance for debt issuance costs would not be affected by the amendments in this ASU. This ASU is the final version of Proposed Accounting Standards Update 2014-250 *Interest - Imputation of Interest (Subtopic 835-30)*, which has been deleted. The amendments in this ASU are effective for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. The Company is currently evaluating the effects of ASU 2015-03 on its financial statements.

**3. INVENTORIES**

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Inventories consist of the following:

|                   | <b>September 30, 2015</b> | <b>December 31, 2014</b> |
|-------------------|---------------------------|--------------------------|
| Raw materials     | \$ 1,749,335              | \$ 1,510,225             |
| Finished goods    | 5,043,093                 | 3,834,717                |
|                   | 6,792,428                 | 5,344,942                |
| Inventory reserve | (681,394)                 | (681,394)                |
|                   | \$ 6,111,034              | \$ 4,663,548             |

Table of Contents**4. INCOME TAXES**

The Company's effective tax rate on the net earnings (loss) before income taxes was 0.1% and (0.2)% for the nine months ended September 30, 2015 and September 30, 2014, respectively. For the three months ended September 30, 2015 and September 30, 2014, the Company's effective tax rate on the net earnings (loss) before income taxes was (0.8)% and 0.5%, respectively.

**5. OTHER ACCRUED LIABILITIES**

Other accrued liabilities consist of the following:

|                            | <b>September 30, 2015</b> | <b>December 31, 2014</b> |
|----------------------------|---------------------------|--------------------------|
| Prepayments from customers | \$ 366,085                | \$ 435,821               |
| Accrued property taxes     | 299,076                   | 7,554                    |
| Accrued professional fees  | 188,127                   | 201,866                  |
| Other accrued expenses     | 141,533                   | 137,081                  |
|                            | <b>\$ 994,821</b>         | <b>\$ 782,322</b>        |

**6. COMMITMENTS AND CONTINGENCIES**

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 trial commenced on September 9, 2013 in the U.S. District Court for the Eastern District of Texas, Tyler Division, and the jury found that BD illegally engaged in anticompetitive conduct with the intent to acquire or maintain monopoly power in the safety syringe market and engaged in false advertising under the Lanham Act. The jury awarded the Company \$113,508,014 in damages, which was trebled pursuant to statute. The Court granted injunctive relief to take effect January 15, 2015. In doing so, the Court found that BD's business practices limited innovation, including false advertisements that suppressed sales of the VanishPoint®. The specific injunctive relief includes: (1) enjoining BD's use of "World's Sharpest Needle" or any similar assertion of superior sharpness; (2) requiring notification to all customers who purchased BD syringe products from July 2, 2004 to date that BD wrongfully claimed that its syringe needles were sharper and that its statement that it had "data on file" was false and misleading; (3) requiring notification to employees, customers, distributors, GPOs, and government agencies that the deadspace of the VanishPoint® has been within ISO standards since 2004 and that BD overstated the deadspace of the VanishPoint® to represent that it was higher than some of BD's syringes when it was actually less, and that BD's statement that it had "data on file" was false and misleading, and, in addition, posting this notice on its website for a period of three years; (4) enjoining BD from advertising that its syringe products save medication as compared to VanishPoint® products for a period of three years; (5) requiring notification to all employees, customers, distributors, GPOs, and government agencies that BD's website, cost calculator, printed materials, and oral representations alleging BD's syringes save medication as compared to the VanishPoint® were based on false and inaccurate measurement of the VanishPoint®, and, in addition, posting this notice on its website for a period of three years; and (6) requiring the implementation of a comprehensive training program for BD employees and distributors that specifically instructs them not to use old marketing materials and not to make false representations regarding VanishPoint® syringes. Final judgment was entered on January 15, 2015, awarding the Company \$340,524,042 in damages and \$11,722,823 in attorneys' fees, as well as granting injunctive relief consistent with the orders as indicated above. The parties stipulated that the amount of litigation costs recoverable by the Company is \$295,000. On January 14, 2015, the District Court stayed the portion of the injunctive

relief that requires BD to notify end-user customers but also ordered BD to comply with internal correction activities as well as mandatory disclosures as set out above to its employees, customers, distributors and Group Purchasing Organizations. BD filed an appeal of that ruling with the 5<sup>th</sup> Circuit Court of Appeals and that appeal was denied on February 3, 2015. On February 12, 2015, BD filed a motion to amend the judgment directed most specifically to the issue of award of prejudgment interest. On April 23, 2015, the Court entered an Amended Final Judgment that removed prejudgment interest but kept all other monetary and injunctive relief the same as was granted in the original Final Judgment. BD filed its brief in the appeal on July 20, 2015. The Company filed its responsive brief on September 18, 2015 and BD filed its brief in reply on October 19, 2015 to complete the briefing. Based on current information, oral argument is expected during the first quarter of 2016. In many cases, the 5<sup>th</sup> Circuit Court of Appeals issues its decision several months after oral argument, but there is no set time limit.

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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. On June 30, 2015, the Court ordered that further proceedings in this matter be stayed and that this case remain administratively closed until resolution of all appeals in the case detailed in the first paragraph of this Note 6.

**7. BUSINESS SEGMENTS**

|                                                   | Three Months<br>Ended<br>September 30, 2015 | Three Months<br>Ended<br>September 30, 2014 | Nine Months<br>Ended<br>September 30, 2015 | Nine Months<br>Ended<br>September 30, 2014 |
|---------------------------------------------------|---------------------------------------------|---------------------------------------------|--------------------------------------------|--------------------------------------------|
| U.S. sales                                        | \$ 6,152,873                                | \$ 8,264,437                                | \$ 17,423,389                              | \$ 18,372,109                              |
| North and South America sales<br>(excluding U.S.) | 3,065,507                                   | 2,479,666                                   | 4,345,044                                  | 4,477,311                                  |
| Other international sales                         | 264,486                                     | 142,577                                     | 608,479                                    | 954,000                                    |
| Total sales                                       | \$ 9,482,866                                | \$ 10,886,680                               | \$ 22,376,912                              | \$ 23,803,420                              |

|                   | September 30, 2015 | December 31, 2014 |
|-------------------|--------------------|-------------------|
| Long-lived assets |                    |                   |
| U.S.              | \$ 11,286,141      | \$ 10,642,859     |
| International     | \$ 191,904         | \$ 209,994        |

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. DIVIDENDS**

On March 24, 2015, the Board of Directors declared dividends on the Series I Class B Preferred Stock in the amount of \$37,891 which were paid on April 30, 2015. The Company also declared and paid dividends to Series II Class B Preferred Stockholders in the amount of \$132,926 on the same dates. As of June 25, 2015, the Board of Directors declared dividends on the Series I Class B Preferred Stock in the amount of \$12,313 which were paid on July 20, 2015. The Company also declared and paid dividends to the Series II Class B Preferred Stockholders in the amount of \$44,050 on the same dates. As of September 25, 2015, the Board of Directors declared dividends on the Series I Class B Preferred Stock in the amount of \$12,313 which were paid on October 22, 2015. The Company also declared and paid dividends to the Series II Class B Preferred Stockholders in the amount of \$44,050 on the same dates.

**9. TREASURY SHARES**

The Board of Directors of the Company cancelled all treasury shares effective August 11, 2015.





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**10. SUBSEQUENT EVENTS**

The Company caused a restatement of the Form 10-Q for the period ended June 30, 2015 to be filed with the U.S. Securities and Exchange Commission on November 13, 2015 due to a misstatement in inventories and Costs of goods sold.

**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 third party manufacturing and 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 continuing interest of larger market players, specifically Becton, Dickinson and Company ( *BD* ), in providing devices to the safety market, and other factors referenced in Item 1A. Risk Factors in Part II. Given these uncertainties, undue reliance should not be placed on forward-looking statements.

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

*Overview*

We have been manufacturing and marketing our products since 1997. Safety syringes comprised 98.1% of our sales in the first nine months of 2015. 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.

On June 17, 2014, we received notice of substantial equivalence from the Food and Drug Administration for the EasyPoint needle. The EasyPoint is a retractable needle that can be used with Luer lock syringes, Luer slip syringes, and prefill syringes to give injections. The EasyPoint needle can also be used to aspirate fluids and obtain blood collection. We have received two molding machines and the molds required to manufacture the piece parts for EasyPoint. The assembly equipment for EasyPoint was delivered to our plant on July 17, 2015. We are in the process of installing, testing, and

validating the equipment.

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, physician services, health clinics, and retail pharmacies.

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.

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We have reported in the past that our progress is limited principally due to the marketing practices engaged in by BD, the dominant maker and seller of disposable syringes. In our litigation against BD alleging anticompetitive conduct and false advertising, a final judgment for \$352 million plus post-judgment interest and costs as well as some injunctive relief has been granted by the District Court. We have not received any of the amounts indicated by the District Court in its final judgment. BD is currently under court order to make certain disclosures regarding its exclusionary conduct to a specified class of distributors and customers. BD has appealed to the United States Court of Appeals for the Fifth Circuit.

On September 30, 2013, we received payment of \$7,724,826 (the Judgment Amount) from BD pursuant to a stipulation in the patent infringement case *Retractable Technologies, Inc. and Thomas Shaw v. Becton Dickinson and Company*, Civil Action No. 2:07-cv-250, in the U.S. District Court for the Eastern District of Texas, Marshall Division. The Judgment Amount was included as income in the second quarter of 2015 due to the conclusion of the case and related appeals. Prior to the second quarter of 2015, the Judgment Amount had been shown as a liability on the balance sheet.

In 2014, we took steps to decrease our non-litigation legal costs. In accordance with these steps, our non-litigation legal costs were reduced by approximately \$130 thousand in 2015. We continue to evaluate these costs. Additionally, since the beginning of 2014, we have reduced our workforce. Steven R. Wisner, a former executive officer, resigned on May 29, 2015 and was granted a one-time payment in connection therewith. The combined effect of both the lower non-litigation costs and the reduced workforce, offset by the payment to Mr. Wisner, was approximately \$275 thousand for the nine months ended September 30, 2015. In the future, if such cost cutting measures prove insufficient, we may reduce other operating expenses, further reduce the workforce, further reduce the salaries of officers as well as other employees, and/or defer royalty payments.

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. At the present time, the excise tax is applicable to domestic sales of our products, except those which are sold to exempt organizations. The majority of our sales are domestic and not in the retail market. The tax is imposed on sales, not profits. We have not passed this tax along to our customers. We expect the impact of this tax to be approximately \$600 thousand in 2015, net of expected refunds attributable to rebate credits. We received a refund of \$287 thousand in the third quarter of 2015. We filed for refunds for \$400 thousand in the third quarter of 2015 attributable to 2014 rebates.

Product purchases from our primary Chinese manufacturer have enabled us to increase manufacturing capacity with little capital outlay and have provided a competitive manufacturing cost. In the first nine months of 2015, our primary Chinese manufacturer produced approximately 78.2% of our VanishPoint® units. In the event that we become unable to purchase products from our primary Chinese manufacturer, we would need to find an alternate manufacturer for the 0.5mL insulin syringe, the 0.5mL autodisable syringe, and the 2mL, 5mL, and 10mL syringes and we would increase domestic production for the 1mL and 3mL syringes.

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 license agreement generally provides for quarterly payments of a 5% royalty fee on gross sales.

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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.

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, 2015 or 2014.

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**RESULTS OF OPERATIONS**

*Comparison of Three Months Ended September 30, 2015 and September 30, 2014*

Sales

Domestic sales accounted for 64.9% and 75.9% of the revenues for the three months ended September 30, 2015 and 2014, respectively. Domestic revenues decreased 25.6% principally due to lower volume of unit sales. Domestic unit sales decreased 22.4%. Domestic unit sales were 52.2% of total unit sales for the three months ended September 30, 2015. International revenue and unit sales increased 27.0% and 25.0%, respectively, due to fluctuation in units sold and a slight uptick in average sales price. Our international orders may be subject to significant fluctuation over time. Overall unit sales decreased 5.2%.

Gross Profit and Cost of Sales

Gross profit decreased 16.3% primarily due to decreased sales volume and average price.

The Cost of manufactured product decreased by 11.3% due to fewer units sold and lower cost of manufacture. 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 8.7% due to lower gross revenues.

Operating Expenses

Operating expenses decreased 0.2% or \$8 thousand. The decrease was due to lower travel and entertainment costs and medical device excise tax, offset by increased Sales and marketing costs and office expenses.

Loss from Operations

Our operating loss was \$199 thousand compared to a gain from operations of \$421 thousand for the same period last year due primarily to lower gross profit.

Income Taxes

Our effective tax rate on the net earnings (loss) before income taxes was (0.8)% and 0.5% for the three months ended September 30, 2015 and September 30, 2014, respectively.

*Comparison of Nine Months Ended September 30, 2015 and September 30, 2014*

Sales

Domestic sales accounted for 77.9% and 77.2% of the revenues for the nine months ended September 30, 2015 and 2014, respectively. Domestic revenues decreased 3.2% principally due to lower unit sales mitigated by slightly higher average sales prices. Domestic unit sales decreased 8.1%. Domestic unit sales were 66.4% of total unit sales for the nine months ended September 30, 2015. International revenue and unit sales decreased 8.8% and 1.3%, respectively, due to lower average sales prices and lower volumes. Our international orders may be subject to significant fluctuation over time. Overall unit sales decreased 5.9%.

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Gross Profit and Cost of Sales

Gross profit increased 6.1% primarily due to lower costs of manufacturing.

The Cost of manufactured product decreased by 12.8% due to lower manufacturing cost and fewer units sold. 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 4.9% due to lower gross sales.

Operating Expenses

Operating expenses decreased 1.0% or \$104 thousand. The decrease was due to lower compensation costs, legal fees, and medical device excise tax. These reductions were mitigated by higher severance costs, donations of product, and additional bad debt accrual.

Litigation Proceeds

A non-recurring recognition of \$7,724,826 received from BD in the second quarter of 2015 pursuant to a patent infringement case had a significant impact on income for the nine months ended September 30, 2015.

Loss from Operations

Our operating loss was \$2.3 million compared to an operating loss for the same period last year of \$2.9 million due primarily to lower manufacturing costs.

Income Taxes

Our effective tax rate on the net earnings (loss) before income taxes was 0.1% and (0.2)% for the nine months ended September 30, 2015 and September 30, 2014, respectively.



Our balance sheet remains strong with cash making up 45.4% of total assets. Working capital was \$23.8 million at September 30, 2015, an increase of \$4.7 million from December 31, 2014. The recognition of \$7,724,826 received from BD pursuant to a patent infringement case had a significant impact on the balance sheet at September 30, 2015, reducing current liabilities and increasing stockholders' equity.

Approximately \$2.0 million in cash flow in the nine months ended September 30, 2015 was used by operating activities.

## LIQUIDITY

At the present time, Management does not intend to raise equity capital. Due to the funds received from prior litigation, we have sufficient cash reserves and intend to rely on operations, cash reserves, and debt financing, when available, as the primary ongoing sources of cash. Our ability to obtain additional funds through loans is uncertain. Our financial statements do not reflect a 2015 judgment in our favor for \$352 million plus post-judgment interest.

### Historical Sources of Liquidity

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

### Internal Sources of Liquidity

### *Margins and Market Access*

To routinely achieve positive or break even quarters, we need increased access to hospital markets which has been difficult to obtain. 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 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 manufacturing arrangements and relationships could result in the need to manufacture all (as opposed to 21.7%) 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, large international sales of VanishPoint® syringes are shipped directly from China to the customer. Purchases of product manufactured in China usually decrease the average cost of manufacture for all units. 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 our Chinese manufacturers 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 during the flu season.

*Cash Requirements*

Due to funds received from prior litigation, we have sufficient cash reserves and intend to rely on operations, cash reserves, and debt financing, when available, as the primary ongoing sources of cash. We have taken steps to decrease our non-litigation legal costs and we continue to evaluate these costs. Additionally, since the beginning of 2014, we have reduced our workforce. In the future, if such cost cutting measures prove insufficient, we may reduce the number of units being produced, further reduce the workforce, further reduce the salaries of officers and other employees, and/or defer royalty payments.

External Sources of Liquidity

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

On September 30, 2013, we received payment of \$7,724,826 (the Judgment Amount ) from BD pursuant to a stipulation in the patent infringement case *Retractable Technologies, Inc. and Thomas Shaw v. Becton Dickinson and Company*, Civil Action No. 2:07-cv-250, in the U.S. District Court for the Eastern District of Texas, Marshall Division. The Judgment Amount was included as income in the second quarter of 2015 due to the conclusion of the case and related appeals. Prior to the second quarter of 2015, the Judgment Amount had been shown as a liability on the balance sheet.

In our litigation against BD alleging anticompetitive conduct and false advertising, a final judgment for \$352 million plus post-judgment interest and costs as well as some injunctive relief has been granted by the District Court. We have not received any of the amounts indicated by the District Court in its final judgment. BD is currently under court order to make certain disclosures regarding its exclusionary conduct to a specified class of distributors and customers. BD has appealed to the United States Court of Appeals for the Fifth Circuit.

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**CAPITAL RESOURCES**

We purchased two molding machines for \$276 thousand. We have also purchased assembly equipment for our EasyPoint™ product for \$1.0 million.

**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 our disclosures and controls had a material weakness. This weakness was discovered during the preparation of the financial statements for the period ended September 30, 2015. It was found that inventories were understated at June 30, 2015 and the change is reflected in our amended Form 10-Q/A for the period ended June 30, 2015 filed with the U.S. Securities and Exchange Commission on November 13, 2015. Our level of supervision and the length of our review of the financial statements will be increased, as discussed below.

Changes in Internal Control Over Financial Reporting

There were no changes during the third quarter of 2015 in our internal control over financial reporting that have materially affected or are reasonably likely to materially affect our internal control over financial reporting. However, beginning November 10, 2015, additional senior members of the accounting team, including the CFO, will analyze critical accounting procedures and related calculations for completeness and accuracy. Furthermore, the information necessary to perform such analysis will be developed in a more timely basis. We believe these steps will strengthen our internal control over financial reporting.

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We are committed to a strong internal control environment and will continue to review the effectiveness of our internal controls over financial reporting and other disclosure controls as procedures. As we continue to evaluate and work to improve our internal control over financial reporting, Management may determine to take additional measures.

### **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.**

There were no material changes in the Risk Factors applicable to the Company as set forth in our Form 10-K annual report for 2014 which was filed on March 31, 2015, and which is available on EDGAR.

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

Working Capital Restrictions and Limitations on the Payment of Dividends

As of September 25, 2015, 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 \$56,363. This dividend was paid on October 22, 2015.

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.

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

Series I Class B Convertible Preferred Stock

For the nine months ended September 30, 2015, the amount of dividends in arrears was \$12,313 and the total arrearage was \$12,313 as of September 30, 2015.

Series II Class B Convertible Preferred Stock

For the nine months ended September 30, 2015, the amount of dividends in arrears was \$44,050 and the total arrearage was \$44,050 as of September 30, 2015.

Series III Class B Convertible Preferred Stock

For the nine months ended September 30, 2015, the amount of dividends in arrears was \$97,239 and the total arrearage was \$3,854,447 as of September 30, 2015.

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### Series IV Class B Convertible Preferred Stock

For the nine months ended September 30, 2015, the amount of dividends in arrears was \$406,875 and the total arrearage was \$8,373,073 as of September 30, 2015.

### Series V Class B Convertible Preferred Stock

For the nine months ended September 30, 2015, the amount of dividends in arrears was \$9,600 and the total arrearage was \$964,586 as of September 30, 2015.

### **Item 6. Exhibits.**

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

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| <u>Exhibit No.</u> | <u>Description of Document</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|--------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 101                | The following materials from Retractable Technologies, Inc.'s Form 10-Q for the quarter ended September 30, 2015, formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Balance Sheets as of September 30, 2015 and December 31, 2014, (ii) Condensed Statements of Operations for the nine months and three months ended September 30, 2015 and 2014, (iii) Condensed Statements of Cash Flows for the nine months ended September 30, 2015 and 2014, and (iv) Notes to Condensed Financial Statements |



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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 16, 2015

RETRACTABLE TECHNOLOGIES, INC.  
(Registrant)

BY:

/s/ Douglas W. Cowan  
DOUGLAS W. COWAN  
VICE PRESIDENT, CHIEF FINANCIAL OFFICER,  
AND CHIEF ACCOUNTING OFFICER