

RETRACTABLE TECHNOLOGIES INC

Form 10-Q

November 14, 2018

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2018

or

☐ **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)

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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 ☒

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

PROCEEDINGS DURING THE PRECEDING FIVE YEARS:

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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: 32,666,454 shares of Common Stock, no par value, outstanding on November 1, 2018.

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RETRACTABLE TECHNOLOGIES, INC.

FORM 10-Q

For the Quarterly Period Ended September 30, 2018

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	September 30, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 13,640,696	\$ 14,877,899
Accounts receivable, net	4,475,695	5,105,556
Inventories, net	7,385,413	6,206,161
Other current assets	404,530	418,154
Total current assets	25,906,334	26,607,770
Property, plant, and equipment, net	10,976,350	11,353,202
Income taxes receivable	188,456	188,456
Other assets	3,477	6,052
Total assets	\$ 37,074,617	\$ 38,155,480
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 4,908,336	\$ 4,957,750
Current portion of long-term debt	424,421	410,949
Accrued compensation	670,498	547,021
Dividends payable	55,113	55,113
Accrued royalties to shareholder	1,102,583	793,489
Insurance proceeds	312,424	466,293
Other accrued liabilities	1,046,480	657,923
Income taxes payable	10,234	11,407
Total current liabilities	8,530,089	7,899,945
Long-term debt, net of current maturities	2,726,146	3,081,409
Total liabilities	11,256,235	10,981,354
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	171,200	171,200
Series III, Class B	129,245	129,245
Series IV, Class B	342,500	342,500
Series V, Class B	40,000	40,000
Common stock, no par value		
Additional paid-in capital	61,926,869	62,092,206
Accumulated deficit	(36,889,932)	(35,699,525)
Total stockholders' equity	25,818,382	27,174,126
Total liabilities and stockholders' equity	\$ 37,074,617	\$ 38,155,480

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See accompanying notes to condensed unaudited financial statements

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

	Three Months Ended September 30, 2018	Three Months Ended September 30, 2017	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017
Sales, net	\$ 9,863,272	\$ 10,412,036	\$ 25,011,066	\$ 24,981,833
Cost of sales				
Cost of manufactured product	6,203,842	6,304,397	15,112,538	15,116,805
Royalty expense to shareholder	863,295	847,301	2,174,778	2,070,699
Total cost of sales	7,067,137	7,151,698	17,287,316	17,187,504
Gross profit	2,796,135	3,260,338	7,723,750	7,794,329
Operating expenses:				
Sales and marketing	1,033,295	1,220,451	3,251,231	3,472,004
Research and development	146,487	159,921	432,179	465,765
General and administrative	1,676,579	1,912,824	5,196,224	6,346,731
Total operating expenses	2,856,361	3,293,196	8,879,634	10,284,500
Loss from operations	(60,226)	(32,858)	(1,155,884)	(2,490,171)
Interest and other income	39,290	19,477	102,133	44,155
Interest expense	(42,481)	(52,962)	(136,446)	(159,053)
Loss before income taxes	(63,417)	(66,343)	(1,190,197)	(2,605,069)
Provision for income taxes		283	210	848
Net loss	(63,417)	(66,626)	(1,190,407)	(2,605,917)
Preferred stock dividend requirements	(176,249)	(176,249)	(528,747)	(528,747)
Loss applicable to common shareholders	\$ (239,666)	\$ (242,875)	\$ (1,719,154)	\$ (3,134,664)
Basic loss per share	\$ (0.01)	\$ (0.01)	\$ (0.05)	\$ (0.10)
Diluted loss per share	\$ (0.01)	\$ (0.01)	\$ (0.05)	\$ (0.10)
Weighted average common shares outstanding:				
Basic	32,666,454	32,166,454	32,666,454	31,722,010
Diluted	32,666,454	32,166,454	32,666,454	31,722,010

See accompanying notes to condensed unaudited financial statements

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

	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017
Cash flows from operating activities		
Net loss	\$ (1,190,407)	\$ (2,605,917)
Adjustments to reconcile loss to net cash used by operating activities:		
Provision for doubtful accounts		(81,152)
Share-based compensation		652,862
Depreciation and amortization	669,584	603,580
(Increase) decrease in operating assets:		
Accounts receivable	629,861	(1,897,332)
Inventories	(1,179,252)	(336,023)
Other current assets	13,624	(313,108)
Increase (decrease) in operating liabilities:		
Accounts payable	(49,414)	574,258
Other accrued liabilities	821,128	507,768
Insurance proceeds	(153,869)	876,250
Income taxes payable	(1,173)	
Net cash used by operating activities	(439,918)	(2,018,814)
Cash flows from investing activities		
Purchase of property, plant, and equipment	(290,153)	(172,305)
Net cash used by investing activities	(290,153)	(172,305)
Cash flows from financing activities		
Repayments of long-term debt	(341,795)	(326,227)
Proceeds from the sale of common stock		2,350,100
Payment of Preferred Stock dividends	(165,337)	(165,339)
Net cash provided (used) by financing activities	(507,132)	1,858,534
Net decrease in cash and cash equivalents	(1,237,203)	(332,585)
Cash and cash equivalents at:		
Beginning of period	14,877,899	16,199,043
End of period	\$ 13,640,696	\$ 15,866,458
Supplemental schedule of cash flow information:		
Interest paid	\$ 136,445	\$ 159,053
Income taxes paid	\$ 1,050	\$ 2,000
Supplemental schedule of noncash investing and financing activities:		
Preferred dividends declared, not paid	\$ 55,113	\$ 55,113

See accompanying notes to condensed unaudited financial statements

Table of Contents**RETRACTABLE TECHNOLOGIES, INC.****CONDENSED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY****(unaudited)**

The following shows the changes in stockholders' equity for the three month period ended September 30, 2018:

	Common Stock	Series I Class B Preferred Stock	Series II Class B Preferred Stock	Series III Class B Preferred Stock	Series IV Class B Preferred Stock	Series V Class B Preferred Stock	Additional Paid-In Capital	Accumulated Deficit	Total
Balance at June 30, 2018	\$	\$ 98,500	\$ 171,200	\$ 129,245	\$ 342,500	\$ 40,000	\$ 61,981,981	\$ (36,826,515)	\$ 25,936,911
Dividends							(55,112)		(55,112)
Net Loss								(63,417)	(63,417)
Balance at September 30, 2018	\$	\$ 98,500	\$ 171,200	\$ 129,245	\$ 342,500	\$ 40,000	\$ 61,926,869	\$ (36,889,932)	\$ 25,818,382

The following shows the changes in stockholders' equity for the three month period ended September 30, 2017:

	Common Stock	Series I Class B Preferred Stock	Series II Class B Preferred Stock	Series III Class B Preferred Stock	Series IV Class B Preferred Stock	Series V Class B Preferred Stock	Additional Paid-In Capital	Accumulated Deficit	Total
Balance at June 30, 2017	\$	\$ 98,500	\$ 171,200	\$ 129,245	\$ 342,500	\$ 40,000	\$ 61,430,417	\$ (34,502,778)	\$ 27,709,084
Issuance of New Common Stock							570,100		570,100
Dividends							(55,112)		(55,112)
Share-based Compensation							182,551		182,551
Net Loss								(66,626)	(66,626)
Balance at September 30, 2017	\$	\$ 98,500	\$ 171,200	\$ 129,245	\$ 342,500	\$ 40,000	\$ 62,127,956	\$ (34,569,404)	\$ 28,339,997

The following shows the changes in stockholders' equity for the nine month period ended September 30, 2018:

	Common Stock	Series I Class B Preferred Stock	Series II Class B Preferred Stock	Series III Class B Preferred Stock	Series IV Class B Preferred Stock	Series V Class B Preferred Stock	Additional Paid-In Capital	Accumulated Deficit	Total
Balance at December 31, 2017	\$	\$ 98,500	\$ 171,200	\$ 129,245	\$ 342,500	\$ 40,000	\$ 62,092,206	\$ (35,699,525)	\$ 27,174,126
Dividends							(165,337)		(165,337)
Net Loss								(1,190,407)	(1,190,407)
Balance at September 30, 2018	\$	\$ 98,500	\$ 171,200	\$ 129,245	\$ 342,500	\$ 40,000	\$ 61,926,869	\$ (36,889,932)	\$ 25,818,382

See accompanying notes to condensed unaudited financial statements

Table of Contents**RETRACTABLE TECHNOLOGIES, INC.****CONDENSED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY****(unaudited)**

The following shows the changes in stockholders' equity for the nine month period ended September 30, 2017:

	Common Stock	Series I Class B Preferred Stock	Series II Class B Preferred Stock	Series III Class B Preferred Stock	Series IV Class B Preferred Stock	Series V Class B Preferred Stock	Additional Paid-In Capital	Accumulated Deficit	Total
Balance at December 31, 2016	\$	\$ 98,500	\$ 171,200	\$ 129,245	\$ 342,500	\$ 40,000	\$ 59,290,333	\$ (31,963,487)	\$ 28,108,291
Issuance of New Common Stock							2,350,100		2,350,100
Dividends							(165,339)		(165,339)
Share-based Compensation							652,862		652,862
Net Loss								(2,605,917)	(2,605,917)
Balance at September 30, 2017	\$	\$ 98,500	\$ 171,200	\$ 129,245	\$ 342,500	\$ 40,000	\$ 62,127,956	\$ (34,569,404)	\$ 28,339,997

See accompanying notes to condensed unaudited 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 products are the VanishPoint® 0.5mL insulin syringe; 1mL tuberculin, insulin, and allergy antigen syringes; 0.5mL, 1mL, 2mL, 3mL, 5mL, and 10mL syringes; the blood collection tube holder; the small diameter tube adapter; the allergy tray; the IV safety catheter; the Patient Safe® syringes; the Patient Safe® Luer Cap; the VanishPoint® Blood Collection Set; and the EasyPoint® needle. The Company also sells VanishPoint® autodisable syringes in the international market in addition to the Company's 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 unaudited 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 April 2, 2018 for the year ended December 31, 2017.

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 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. 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. The Allowance for bad debt was \$102 thousand as of December 31, 2017 and also as of September 30, 2018.

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.

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Inventories

Inventories are valued at the lower of cost or net realizable value, with cost being determined using actual average cost. The Company compares the average cost to the net realizable value and records the lower value. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. 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 operations.

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

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 or appraised value of the underlying assets.

Financial instruments

The Company estimates the fair 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 fair 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.

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.

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As a consequence, Management considers any exposure from concentrations of credit risks to be limited. The following table reflects our significant customers for the three and nine months ended September 30, 2018 and 2017:

	Three Months ended September 30, 2018	Three Months ended September 30, 2017	Nine Months ended September 30, 2018	Nine Months ended September 30, 2017
Number of significant customers	3	3	2	2
Aggregate dollar amount of net sales to significant customers	\$5.4 million	\$5.1 million	\$10.0 million	\$9.4 million
Percentage of net sales to significant customers	55.2%	49.1%	39.9%	37.5%

The Company manufactures some of its products in Little Elm, Texas as well as utilizing manufacturers in China. The Company obtained roughly 85.1% and 81.7% of its products in the first nine months of 2018 and 2017, respectively, from its Chinese manufacturers. Purchases from Chinese manufacturers aggregated 79.9% and 80.1% of products in the three month periods ended September 30, 2018 and 2017, respectively. In the event that the Company becomes unable to purchase products from its Chinese manufacturers, the Company would need to find an alternate manufacturer for its blood collection set, IV catheter, Patient Safe® syringe, 0.5mL insulin syringe, 0.5mL autodisable syringe, and 2mL, 5mL, and 10mL syringes and would increase domestic production for the 1mL and 3mL syringes and EasyPoint® needles.

Revenue recognition

Revenue is recognized for sales when title and risk of ownership passes to the customer, generally upon shipment. When title and risk of ownership have passed to the customer, the Company has satisfied all performance obligations to the customer. Payments from customers with approved credit terms are typically due 30 days from the invoice date. 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 Condensed Balance Sheets and deducted from Revenues in the Condensed Statements of Operations. Accounts payable included estimated contractual allowances for \$3,443,368 and \$4,115,628 as of September 30, 2018 and December 31, 2017, 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. End-users do not receive any contractual allowances on their purchases. Any product shipped or distributed for evaluation purposes is expensed.

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The Company provides product warranties that: i) the products are fit for medical use as generally defined within the boundaries of United States FDA approval; ii) the products are not defective; and iii) the products will conform to the descriptions set forth in their respective labeling, provided that they are used in accordance with such labeling and the Company's written directions for use. The Company has historically not incurred significant warranty claims.

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The Company's domestic return 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'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.

Disaggregated information of revenue recognized from contracts with customers is as follows:

For the three months ended September 30, 2018:					
Geographic Segment	Syringes	Blood Collection Products	EasyPoint® Needles	Other Products	Total Product Sales
U.S. sales	\$ 6,454,432	\$ 466,392	\$ 1,803,904	\$ 22,968	\$ 8,747,696
North and South America sales (excluding U.S.)	803,414	240			803,654
Other international sales	290,760	12,490		8,672	311,922
Total	\$ 7,548,606	\$ 479,122	\$ 1,803,904	\$ 31,640	\$ 9,863,272

For the three months ended September 30, 2017:					
Geographic Segment	Syringes	Blood Collection Products	EasyPoint® Needles	Other Products	Total Product Sales
U.S. sales	\$ 7,019,389	\$ 309,012	\$ 1,016,226	\$ 14,220	\$ 8,358,847
North and South America sales (excluding U.S.)	1,896,492	1,700		2,700	1,900,892
Other international sales	117,447	30,800		4,050	152,297
Total	\$ 9,033,328	\$ 341,512	\$ 1,016,226	\$ 20,970	\$ 10,412,036

For the nine months ended September 30, 2018:					
Geographic Segment	Syringes	Blood Collection Products	EasyPoint® Needles	Other Products	Total Product Sales
U.S. sales	\$ 18,097,760	\$ 991,318	\$ 2,519,973	\$ 55,988	\$ 21,665,039
North and South America sales (excluding U.S.)	2,595,634	8,805	252	900	2,605,591
Other international sales	682,134	36,024	456	21,825	740,436
Total	\$ 21,375,528	\$ 1,036,147	\$ 2,520,681	\$ 78,713	\$ 25,011,066

For the nine months ended September 30, 2017:					
Geographic Segment	Syringes	Blood Collection Products	EasyPoint® Needles	Other Products	Total Product Sales
U.S. sales	\$ 18,260,242	\$ 821,869	\$ 1,232,979	\$ 46,757	\$ 20,361,847
North and South America sales (excluding U.S.)	3,531,574	2,944		193,934	3,728,452

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Other international sales	829,680	42,954		18,900	891,534
Total	\$ 22,621,496	\$ 867,767	\$ 1,232,979	\$ 259,591	\$ 24,981,833

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Income taxes

The Tax Cuts and Job Act (the Act) was enacted on December 22, 2017, and the U.S. federal corporate tax rate was reduced from 35% to 21%. U.S. generally accepted accounting principles require companies to account for the effects of changes in income tax rates and laws in the period the change is enacted. Financial results, including provisional amounts, have been calculated for the income tax effects of the change. The U.S. Securities and Exchange Commission issued Staff Accounting Bulletin 118 (SAB 118) allowing companies to use provisional estimates to record the effects of the Act. SAB 118, as codified by Financial Accounting Standards Board (FASB) Accounting Standards Update (ASU) 2018-05 Income Taxes (Topic 740): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118 (SEC Update), allows companies to complete accounting for these effects no later than one year from the enactment date of the Act. During the quarter ended September 30, 2018, the Company completed its analysis of the provisional estimates made to record the effects of the Act. There were no adjustments made to previously recorded amounts.

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 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. Such expenses are not material.

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 93,125 shares of Common Stock underlying issued and outstanding stock options for the three months ended September 30, 2017 as their effect was antidilutive. The calculation of diluted EPS excluded 6,126 and 128,540 shares of Common Stock underlying issued and outstanding stock options for the nine months ended September 30, 2018 and September 30, 2017, respectively, as their effect was antidilutive. The potential dilution, if any, is shown on the following schedule:

	Three Months Ended September 30, 2018	Three Months Ended September 30, 2017	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017
Net loss	\$ (63,417)	\$ (66,626)	\$ (1,190,407)	\$ (2,605,917)
Preferred dividend requirements	(176,249)	(176,249)	(528,747)	(528,747)
Loss applicable to common shareholders after assumed conversions	\$ (239,666)	\$ (242,875)	\$ (1,719,154)	\$ (3,134,664)
Average common shares outstanding	32,666,454	32,166,454	32,666,454	31,722,010
	32,666,454	32,166,454	32,666,454	31,722,010

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Average common and common
equivalent shares outstanding
assuming dilution

Basic loss per share	\$	(0.01)	\$	(0.01)	\$	(0.05)	\$	(0.10)
Diluted loss per share	\$	(0.01)	\$	(0.01)	\$	(0.05)	\$	(0.10)

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

Research and development costs

Research and development costs are expensed as incurred.

Share-based compensation

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

	Three Months Ended September 30, 2018	Three Months Ended September 30, 2017	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017
Cost of sales	\$	\$ 74,683	\$	\$ 270,800
Sales and marketing		38,578		143,255
Research and development		12,458		45,174
General and administrative		56,832		193,633
	\$	\$ 182,551	\$	\$ 652,862

Insurance Proceeds

Receipts from insurance up to the amount of any loss recognized by the Company are considered recoveries. Any such recoveries are recorded when they are received. Insurance recoveries are not recognized as a component of earnings (loss) from operations until all repairs are made.

Recently Adopted Pronouncements

In November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash. These amendments require that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. As a result, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The amendments do not provide a definition of restricted cash or restricted cash equivalents. The updated guidance was effective for the

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Company's quarter ended March 31, 2018. The adoption of ASU 2016-18 did not have a material effect on the Company's financial statements as the Company currently holds no restricted cash or restricted cash equivalents.

In August 2016, the FASB issued ASU 2016-15, Statement of Cash Flows (Topic 230), Classification of Certain Cash Receipts and Payments (ASU 2016-15), clarifying guidance on the classification of certain cash receipts and payments in the statement of cash flows. This ASU was effective for the Company's quarter ended March 31, 2018. The adoption of ASU 2016-15 did not have a material impact on the Company's financial statements.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers, as well as several subsequently issued clarifying amendments, 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. The ASU, as amended, 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

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contract. ASU No. 2014-09 allows for either full retrospective or modified retrospective adoption. The ASU, as amended, was effective commencing with the Company's quarter ended March 31, 2018. The Company adopted this amended guidance on a Modified Retrospective basis in the first quarter of 2018. The adoption of the ASU, as amended, had no impact on the opening balance of retained earnings. The Company applied the guidance of ASU No. 2014-09, as amended, to those contracts that were not completed as of January 1, 2018. In implementing the guidance of ASU 2014-09, as amended, the Company applied the practical expedients of FASB ASU No. 2016-12 Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients. Under ASU 2016-12, the Company applies the guidance of ASU 2014-09, as amended, to a portfolio of contracts with similar characteristics, as opposed to individual contracts, as applying the guidance to the portfolio does not materially differ from applying the guidance to individual contracts. In addition, the Company accounts for shipping and handling as activities to fulfill the promise to transfer goods to a customer as opposed to a performance obligation. Historically, freight and handling activities billed to customers have not been material.

In August 2018, the Securities and Exchange Commission (SEC) adopted amendments to certain disclosure requirements in Securities Act Release No. 33-10532, Disclosure Update and Simplification. The amendments were effective November 5, 2018. The amendments eliminate or revise several redundant or duplicative requirements between SEC rules and GAAP, including the elimination of the disclosure of the ratio of earnings to fixed charges and the presentation of dividends per share on the face of the statement of operations for interim periods. Among the amendments is the requirement to present the changes in shareholders' equity in the interim financial statements (either in a separate statement or footnote) in quarterly reports on Form 10-Q. The amendments are effective for all filings made on or after November 5, 2018. In light of the timing of effectiveness of the amendments and proximity of effectiveness to the filing date for most filers' quarterly reports, the SEC staff has indicated that it would not object if the filer's first presentation of the changes in shareholders' equity is included in its Form 10-Q for the quarter that begins after the effective date of the amendments. The Company has elected to adopt the provisions of Securities Act Release No. 33-10532 for the quarter ended September 30, 2018 and has presented condensed statements of changes in stockholders' equity for the periods ended September 30, 2018 and 2017 in this quarterly report on Form 10-Q.

Recently Issued Pronouncements

In June 2016, the FASB issued Accounting Standards Update 2016-13, Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments. Among other things, these amendments require the measurement of all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions, and reasonable and supportable forecasts. Many of the loss estimation techniques applied today will still be permitted, although the inputs to those techniques will change to reflect the full amount of expected credit losses. This ASU is effective for the Company's quarter ending March 31, 2020 with early application permitted for the Company's quarter ending March 31, 2019. The Company is currently assessing the impact that adoption of this guidance will have on its financial statements and related disclosures.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842), as well as several subsequently issued clarifying amendments. Under the ASU, as amended, lessees will be required to recognize the following for all leases (with the exception of short-term leases) at the commencement date: (1) a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis; and (2) a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. Under the guidance, lessor accounting is largely unchanged. The lease guidance simplified the accounting for sale and leaseback transactions primarily because lessees must recognize lease assets and lease liabilities. In July 2018, the FASB issued ASU 2018-10, Codification Improvements to Topic 842, Leases. This amendment clarifies Topic 842 and corrected unintended application of guidance and is effective concurrent with Topic 842 or upon issuance if Topic 842 was early adopted. In August 2018, the FASB issued ASU 2018-11, Leases (Topic 842): Targeted Improvements. This amendment provides additional transition options allowing entities to recognize a cumulative effect adjustment to the opening balance of retained earnings in the period of adoption rather than the earliest period presented and provides a practical expedient to lessors to elect, by class of underlying assets, to account for non-lease and lease

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components as a single arrangement. The Company intends to adopt the provisions of ASU 2018-11 through a cumulative effect adjustment. Topic 842, and its subsequent amendments, is effective for the Company's quarter ending March 31, 2019, with early adoption permitted. The Company is currently evaluating the various accounting policy elections associated with this ASU, as amended, including transition methods and practical expedients, identifying contracts for evaluation, and reviewing contracts to determine if they contain leases. While the Company is currently evaluating the timing and impact of adopting ASU 2016-02, as amended, the Company anticipates recording lease assets and liabilities less than \$250,000 on its Condensed Balance Sheets, with no material impact to its Condensed Statements of Operations or to its accumulated deficit. However, the ultimate impact of adopting ASU 2016-02 will depend on the Company's lease portfolio as of the adoption date. The Company expects to complete these procedures before the end of the year and determine any transition adjustments.

In August 2018, the FASB issued ASU 2018-15, Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That is a Service Contract (a Consensus of the FASB Emerging Issues Task Force). This amendment requires that implemented costs incurred in a hosting arrangement that is a service contract should be accounted for in accordance with ASC 350-40. Accordingly, costs incurred during the preliminary project and post-implementation stages are expensed and costs associated with the application development phase are capitalized. The amendment also requires that capitalized costs be amortized over the term of the hosting arrangement and that capitalized costs should be evaluated for impairment. The amendment is effective for annual periods beginning after December 15, 2019 and interim periods within those annual periods. The Company is currently assessing the impact that adoption of this ASU will have on its financial statements and related disclosures.

3. INVENTORIES

Inventories consist of the following:

	September 30, 2018	December 31, 2017
Raw materials	\$ 1,467,431	\$ 1,511,339
Finished goods	6,512,470	5,289,761
	7,979,901	6,801,100
Inventory reserve	(594,488)	(594,939)
	\$ 7,385,413	\$ 6,206,161

4. INCOME TAXES

The Company's effective tax rate on the net earnings (loss) before income taxes was 0.0% for the nine months ended September 30, 2018 and September 30, 2017. For the three months ended September 30, 2018 and September 30, 2017, the Company's effective tax rate on the net earnings (loss) before income taxes was 0.0% and (0.4)%, respectively.

5. OTHER ACCRUED LIABILITIES

Other accrued liabilities consist of the following:

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	September 30, 2018	December 31, 2017
Prepayments from customers	\$ 440,528	\$ 355,742
Accrued property taxes	331,284	14,681
Accrued professional fees	233,153	231,826
Other accrued expenses	41,515	55,674
Total	\$ 1,046,480	\$ 657,923

Table of Contents**6. COMMITMENTS AND CONTINGENCIES**

In May 2010, the Company and an officer's suit against Becton, Dickinson and Company ("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 including, among other things, a requirement to notify certain customers and others regarding misleading disclosures. In connection with BD's subsequent appeal, on December 2, 2016, the United States Court of Appeals for the Fifth Circuit overturned the antitrust damages. The finding of false advertising liability was affirmed and the case was remanded to the Eastern District of Texas for a redetermination as to the amount of damages to which the Company is entitled. On August 17, 2017, District Court for the Eastern District of Texas issued the Court's Final Judgment ordering that the Company take nothing in its suit against BD and dismissing the case. The Company filed a notice of Appeal with the United States Court of Appeals for the Fifth Circuit on November 3, 2017. Briefing for the appeal was completed by the parties on May 2, 2018 and oral argument occurred on October 3, 2018.

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 preceding paragraph. The case remains stayed as a result of the ongoing proceedings regarding the Lanham Act claims in the separate proceeding described above.

7. BUSINESS SEGMENT

The Company does not operate in separate reportable segments. 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. Revenues by geography are as follows:

	Three Months Ended September 30, 2018	Three Months Ended September 30, 2017	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017
U.S. sales	\$ 8,747,696	\$ 8,358,847	\$ 21,665,039	\$ 20,361,847
North and South America sales (excluding U.S.)	803,654	1,900,892	2,605,591	3,728,452
Other international sales	311,922	152,297	740,436	891,534
Total sales	\$ 9,863,272	\$ 10,412,036	\$ 25,011,066	\$ 24,981,833

Long-lived assets by geography are as follows:

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	September 30, 2018		December 31, 2017	
Long-lived assets				
U.S.	\$	10,856,824	\$	11,215,583
International		119,526		137,619
Total	\$	10,976,350	\$	11,353,202

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8. DIVIDENDS

The Company declared dividends in 2017 in the amounts of \$12,313 and \$42,800 paid to Series I Class B and Series II Class B Preferred Stockholders, respectively, on January 6, 2017, April 24, 2017, July 20, 2017, and October 20, 2017. The Company declared dividends in 2018 in the amounts of \$12,313 and \$42,800 paid to Series I Class B and Series II Class B Preferred Stockholders, respectively, on January 19, 2018, April 24, 2018, July 20, 2018, and October 23, 2018.

9. PRIVATE PURCHASE

The Company approved three of its executive officers to purchase shares directly from the Company. Thomas J. Shaw, CEO, exercised his purchase rights on January 12, 2017, buying two million shares at market price for an aggregate purchase price of \$1.78 million, and he exercised the remainder of his purchase rights on August 23, 2017 by purchasing one million shares at market price for aggregate consideration of \$570,100. Mr. Cowan, CFO, and Ms. Larios, Vice President and General Counsel, are authorized to purchase 500,000 shares each at market price any time prior to December 9, 2018. The approximate dollar value of these potential future purchases cannot be predicted.

10. BONUSES

In February of 2017, Mr. Cowan and Ms. Larios were each granted cash bonuses of \$250,000. Ms. Larios received her bonus in the first quarter of 2017. Mr. Cowan received his bonus in the fourth quarter of 2017.

11. STORM DAMAGE AND INSURANCE PROCEEDS

On March 26, 2017, a hail storm passed through Little Elm, Texas, resulting in damage to the Company's two buildings. During April 2017, the Company performed an inspection of its facilities and determined that possible roof damage had been sustained. In late April 2017, the Company's insurance carrier inspected the two buildings and confirmed that damage occurred from the hail storm. This damage was principally to the roofs of the buildings but also many of the HVAC units and a wall alongside one of the buildings were also damaged.

The Company's insurance carrier has assessed damages of \$1,009,960 and the Company's deductible is \$5,000. The Company received these funds from its carrier in the second quarter of 2017. Repairs commenced during the third quarter of 2017. The Company expects that all repairs will be completed in the fourth quarter.

During 2017, the Company incurred and recognized \$538,667 in repairs due to the storm damage. Repairs during the first nine months of 2018 were \$203,289. This repair expense was offset by the insurance proceeds, resulting in no impact to the Statement of Operations. These costs and offsets are included in General and administrative expense in the Statement of Operations. The remaining insurance proceeds are expected to be recognized as income in the fourth quarter of 2018.

12. LONG-TERM DEBT

On April 10, 2018, the Company renewed its loan with American First National Bank, which renewal included a ten-year extension of the Company's promissory note in the original principal amount of approximately \$4.21 million (\$3.03 million at date of renewal) and converted the interest rate to an adjustable interest rate equal to the prime rate plus 0.25%. The note matures on April 10, 2028 and is secured by the Company's land and buildings. The interest rate was 5.5% at September 30, 2018.

The following chart summarizes the Company's obligations under this note to make future payments as of September 30, 2018 for years ending December 31:

2018	\$	63,102
2019		246,995
2020		260,202
2021		273,703
2022		287,905
Thereafter		1,807,208
	\$	2,939,115

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13. SUBSEQUENT EVENTS

On November 8, 2018, the Company terminated the employment approximately 20 employees earning total annual compensation of approximately \$1.1 million. Some of these positions may be filled in the future. Under the proposed severance agreements, severance costs are expected to be a maximum of \$250 thousand.

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, potential tariffs, our ability to maintain liquidity, our maintenance of patent protection, the impact of current and future Court decisions regarding current litigation, our ability to maintain favorable third party manufacturing and supplier arrangements and relationships, foreign trade risk, 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 impact 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 85.5% of our sales in the first nine months of 2018. We also manufacture and market the EasyPoint® needle, 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 associated with catheter hub contamination.

In the second quarter of 2016, we began selling the EasyPoint® needle. EasyPoint® needles made up 4.9% of revenues in the first nine months of 2017 and 10.1% of our revenues in the first nine months of 2018. The EasyPoint® needle is a retractable needle that can be used with Luer lock syringes, Luer slip syringes, and prefilled syringes to give injections. The EasyPoint® needle can also be used to aspirate fluids and collect blood.

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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 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.

We have reported in the past that our progress is limited principally due to the practices engaged in by BD, the dominant maker and seller of disposable syringes. We initiated an antitrust and false advertising lawsuit in 2007 against BD. Although a district court judgment in 2015 awarded us approximately \$340 million in antitrust

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damages from BD and the Fifth Circuit affirmed a finding of false advertising liability against BD, we were ultimately awarded a take nothing judgment in August 2017 and the case was dismissed. We appealed that ruling, briefing has been completed, and oral arguments occurred October 3, 2018.

Our litigation expenses were significantly less in 2017 than in prior years. In the first nine months of 2018, our legal expenses, including litigation expenses, were significantly lower as compared to the first nine months of 2017. We have expanded our sales and marketing staff in an effort to gain market share. Costs related to additional compensation, bonuses to Ms. Larios and Mr. Cowan, and stock option expense related to options granted in 2016 were amortized in 2017 and affect comparability to 2017.

In January 2018, Congress imposed another two-year moratorium on the 2.3% medical device excise tax imposed by Internal Revenue Code section 4191. Thus, the medical device excise tax is not expected to go into effect until January 1, 2020.

On November 8, 2018, we terminated the employment of approximately 20 employees earning total annual compensation of approximately \$1.1 million. Some of these positions may be filled in the future. Under the proposed severance agreements, severance costs are expected to be a maximum of \$250 thousand.

In 2016, we granted a right to three of our executive officers to purchase shares directly from the Company. Thomas J. Shaw exercised such right on January 12, 2017, buying two million shares at market price for an aggregate purchase price of \$1.78 million and purchased one million shares at market price on August 23, 2017 for an aggregate purchase price of \$570,100.

We received approximately \$1 million from our insurance carrier in the second quarter of 2017 and the majority of these funds have been used to repair our buildings from earlier storm damage. The remaining insurance proceeds are expected to be recognized as income in the fourth quarter of 2018.

In the second quarter of 2018, the Company renewed its loan with American First National Bank, which renewal included a ten-year extension of the Company's promissory note in the original principal amount of approximately \$4.21 million and converted the interest rate to an adjustable interest rate equal to the prime rate plus 0.25%.

Product purchases from our Chinese manufacturers have enabled us to increase manufacturing capacity with little capital outlay and have provided a competitive manufacturing cost. In the first nine months of 2018, our Chinese manufacturers produced approximately 85.1% of our products. In the event that we become unable to purchase products from our Chinese manufacturers, we would need to find an alternate manufacturer for the blood collection set, IV catheter, Patient Safe® syringe, 0.5mL insulin syringe, 0.5mL autodisable syringe, and 2mL, 5mL, and 10mL syringes and we would increase domestic production for the 1mL and 3mL syringes. New import tariffs on Chinese products could materially adversely affect us. As of the date of this filing, syringes are not included among the Chinese products on which the United States has proposed tariffs.

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In 1995, we entered into a license agreement with Thomas J. Shaw for the exclusive right to manufacture, market, and distribute products utilizing his patented automated retraction technology and other patented 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.

With increased volumes, our manufacturing unit costs have generally tended to decline. Factors that could affect our unit costs include possible tariffs, 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.

RESULTS OF OPERATIONS

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, 2018 or 2017.

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Comparison of Three Months Ended September 30, 2018 and September 30, 2017

Domestic sales accounted for 88.7% and 80.3% of the revenues for the three months ended September 30, 2018 and 2017, respectively. Domestic revenues increased 4.7% principally due to sales of EasyPoint® needles. Domestic unit sales increased 19.7%. Domestic unit sales were 85.8% of total unit sales for the three months ended September 30, 2018. International revenue and unit sales decreased 45.7% and 49.6%, respectively, due to decreased volumes. Our international orders may be subject to significant fluctuation over time. Overall unit sales increased 0.2%.

The Cost of manufactured product decreased by 1.6% principally due to lower average cost. 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 1.9% due to higher gross sales.

Gross profit decreased 14.2% primarily due to lower average sales prices.

Operating expenses decreased 13.3%. The decrease was due to lower legal expenses, lower travel and entertainment costs, and lower employee costs.

Our operating loss was \$60,226 compared to an operating loss for the same period last year of \$32,858 due primarily to lower gross profit mitigated by lower operating expenses.

Our effective tax rate on the net loss before income taxes was 0.0% and (0.4)% for the three months ended September 30, 2018 and September 30, 2017, respectively.

Comparison of Nine Months Ended September 30, 2018 and September 30, 2017

Domestic sales accounted for 86.6% and 81.5% of the revenues for the nine months ended September 30, 2018 and 2017, respectively. Domestic revenues increased 6.4% principally due to sales of EasyPoint® needles. Domestic unit sales increased 14.2%. Domestic unit sales were 81.3% of total unit sales for the nine months ended September 30, 2018. International revenue and unit sales decreased 27.6% and 26.4%, respectively, due to decreased volumes. Our international orders may be subject to significant fluctuation over time. Overall unit sales increased 3.6%.

The Cost of manufactured product was flat due to higher volumes offset by lower average costs. 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 5.0% due to higher gross sales.

Gross profit decreased 0.9% primarily due to slightly higher royalty costs.

Operating expenses decreased 13.7%. The decrease was due to lower legal expenses, bonuses paid in 2017, lower employee cost, reduction in share-based compensation, and lower travel and entertainment costs.

Our operating loss was \$1.2 million compared to an operating loss for the same period last year of \$2.5 million due primarily to lower operating expenses.

Our effective tax rate on the net loss before income taxes was 0.0% for the nine months ended September 30, 2018 and September 30, 2017.

Discussion of Balance Sheet and Statement of Cash Flow Items

Cash comprised 36.8% of total assets at September 30, 2018. Working capital was \$17.4 million at September 30, 2018, a decrease of \$1.3 million from December 31, 2017.

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Cash flow used by operations was \$440 thousand for the nine months ended September 30, 2018 due primarily to increased inventory.

We also received approximately \$1.0 million in 2017 from our insurance carrier which has been used to repair damage to our buildings from a hail storm. We expect that all repairs will be completed and approved by our insurance adjuster during the fourth quarter of 2018. The remaining insurance proceeds are expected to be recognized as income in the fourth quarter of 2018.

LIQUIDITY

At the present time, Management does not intend to publicly raise equity capital. Due to the funds received from prior litigation and direct purchases of our stock, 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.

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.

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 14.9%) of our products in the U.S. or find other manufacturers. This could temporarily increase unit costs as we ramp up domestic production.

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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. Some international sales of our products are shipped directly from China to the customer. 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.

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 legal costs and we continue to evaluate these costs. We terminated approximately 20 employees in the fourth quarter of 2018 which may reduce future costs, although some of the positions may be filled in the future. In the future, if such cost cutting measures prove insufficient, we may reduce the number of units being produced, further reduce the workforce, reduce the salaries of officers and other employees, and/or defer royalty payments. Some increases in compensation were made in 2017 due to hiring additional sales personnel and nonrecurring bonuses made to two officers.

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External Sources of Liquidity

We have obtained several loans since our inception, which have, together with the proceeds from the sales of equities and litigation efforts, enabled us to pursue development and production of our products. 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 public sale of equity. We granted a right to three of our executive officers to engage in private purchases of stock at market prices. Thomas J. Shaw exercised such right on January 12, 2017, buying two million shares at market price for an aggregate purchase price of \$1.78 million and purchased one million shares at market price on August 23, 2017 for an aggregate purchase price of \$570,100.

CAPITAL RESOURCES

There were no material commitments for capital expenditures in the third quarter of 2018.

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, 2018, our disclosure controls and procedures were effective.

Changes in Internal Control Over Financial Reporting

There have been no changes during the third quarter of 2018 or subsequent to September 30, 2018 in our internal control over financial reporting that has materially affected or is reasonably likely to materially affect our internal control over financial reporting.

PART II OTHER INFORMATION

Item 1. Legal Proceedings.

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 our Risk Factors as set forth in our most recent annual and quarterly reports which are available on EDGAR.

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

None.

Item 3. Defaults Upon Senior Securities.

Working Capital Restrictions and Limitations on the Payment of Dividends

The Company declared a dividend to the Series I Class B and Series II Class B Convertible Preferred Shareholders in the aggregate amount of \$55,113. This dividend was paid on October 23, 2018.

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.

Series I Class B Convertible Preferred Stock

For the nine months ended September 30, 2018, no dividends were in arrears.

Series II Class B Convertible Preferred Stock

For the nine months ended September 30, 2018, no dividends were in arrears.

Series III Class B Convertible Preferred Stock

For the nine months ended September 30, 2018, the amount of dividends in arrears was \$96,934 and the total arrearage was \$4,243,000 as of September 30, 2018.

Series IV Class B Convertible Preferred Stock

For the nine months ended September 30, 2018, the amount of dividends in arrears was \$256,875 and the total arrearage was \$6,398,000 as of September 30, 2018.

Series V Class B Convertible Preferred Stock

For the nine months ended September 30, 2018, the amount of dividends in arrears was \$9,600 and the total arrearage was \$1,006,000 as of September 30, 2018.

Item 5. Other Information.

Our next annual meeting of shareholders will be held on May 7, 2019, rather than in September. As a result, the deadlines for receipt of shareholder proposals and director nominations set forth in our proxy statement relating to the meeting held September 7, 2018 must be revised. Both such deadlines for the next annual meeting of shareholders will be January 2, 2019.

Item 6. Exhibits.

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

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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, 2018, formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Balance Sheets as of September 30, 2018 and December 31, 2017, (ii) Condensed Statements of Operations for the three months and nine months ended September 30, 2018 and 2017, (iii) Condensed Statements of Cash Flows for the nine months ended September 30, 2018 and 2017 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 14, 2018

RETRACTABLE TECHNOLOGIES, INC.
(Registrant)

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