

RETRACTABLE TECHNOLOGIES INC  
Form 10-K/A  
June 09, 2011  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-K/A**

Amendment No. 1

(Mark One)

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

For the fiscal year ended December 31, 2010

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES 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)

|  |  |
|--|--|
| <b>Texas</b><br>(State or other jurisdiction of<br>incorporation or organization)            | <b>75-2599762</b><br>(I.R.S. Employer<br>Identification No.) |
| <b>511 Lobo Lane</b><br><b>Little Elm, Texas</b><br>(Address of principal executive offices) | <b>75068-0009</b><br>(Zip Code)                              |

**972-294-1010**

Registrant's telephone number, including area code

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Name of each exchange on which registered |
|---------------------|---|
| Common              | NYSE Amex LLC                             |

Securities registered pursuant to Section 12(g) of the Act:

**Preferred Stock**

(Title of class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

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

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Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of the Form 10-K or any amendment to the Form 10-K.

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 <input type="radio"/>  | Accelerated filer <input type="radio"/>                    |
| Non-accelerated filer <input type="radio"/><br>(Do not check if a smaller reporting company) | Smaller reporting company <input checked="" type="radio"/> |

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

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter. The aggregate market value of the common equity held by non-affiliates as of June 30, 2010 was \$18,574,972.50, assuming a closing price of \$1.61 and outstanding shares held by non-affiliates of 11,537,250.

### APPLICABLE ONLY TO REGISTRANTS INVOLVED IN BANKRUPTCY

#### PROCEEDINGS DURING THE PRECEDING FIVE YEARS:

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Section 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 REGISTRANTS)

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date. As of May 25, 2011, there were 24,000,914 shares of our Common Stock issued and outstanding.

#### DOCUMENTS INCORPORATED BY REFERENCE

List hereunder the following documents if incorporated by reference and the Part of the Form 10-K (e.g., Part I, Part II, etc.) into which the document is incorporated: (1) Any annual report to security holders; (2) Any proxy or information statement; and (3) Any prospectus filed pursuant to Rule 424(b) or (c) under the Securities Act of 1933. The listed documents should be clearly described for identification purposes (e.g., annual report to security holders for fiscal year ended December 24, 1980).

None except exhibits.



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**Explanatory Note**

We are filing this Amendment No. 1 to our Annual Report on Form 10-K for the year ended December 31, 2010 which was filed with the U.S. Securities and Exchange Commission on March 31, 2011. The primary purposes of this Amendment No. 1 are to: 1) reclassify royalties of \$116,671 paid in connection with litigation settlement payments as a reduction to Litigation settlements, net and a reduction to Royalty expense to shareholders shown under Cost of Sales to conform to the presentation used in our previous filings as well as our Form 10-Q for the quarter ended March 31, 2011; 2) correct the values for raw materials and finished goods (which values were inadvertently substituted for one another) in Note 3 to the financial statements in Item 8 of Part II; and 3) correct the dates on which the Directors' terms expire in Item 10 of Part III. No other material changes have been made. The complete text of Items 7 and 8 of Part II and Item 10 of Part III are set forth herein. Certain exhibits and signatures are also provided.

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**RETRACTABLE TECHNOLOGIES, INC.**

**FORM 10-K/A**

**For the Fiscal Year Ended December 31, 2010**

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**SIGNATURE**

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**Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operation.**

FORWARD-LOOKING STATEMENT WARNING

Certain statements included by reference in this filing containing the words could, may, believes, anticipates, intends, expects, and similar words constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act. Any forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements. Such factors include, among others, our ability to maintain liquidity, our maintenance of patent protection, the impact of current litigation, our ability to maintain favorable supplier arrangements and relationships, our ability to quickly increase capacity in response to an increase in demand, our ability to access the market, our ability to maintain or lower production costs, our ability to continue to finance research and development as well as operations and expansion of production, the increased interest of larger market players, specifically BD, in providing devices to the safety market, and other factors referenced in **Item 1A. Risk Factors** of the Form 10-K. Given these uncertainties, undue reliance should not be placed on forward-looking statements.

OVERVIEW

We have been manufacturing and marketing our products into the marketplace since 1997. We currently provide other safety medical products in addition to safety syringe products. One such product is the Patient Safe® syringe, which is uniquely designed to reduce the risk of bloodstream infections resulting from catheter hub contamination. Safety syringes comprised 97.3% of our sales in 2010.

Historically, unit sales have increased in the latter part of the year due, in part, to the demand for syringes during the flu season. In 2009, we had a contract to provide DHHS with syringes to be used in the U.S. efforts to provide swine flu vaccinations. This contract was material for 2009 and affects comparability to 2009 financial data.

Our products have been and continue to be distributed nationally through numerous distributors. However, we have been blocked from access to the market by exclusive marketing practices engaged in by BD, which dominates the market. We believe that its monopolistic business practices continue despite: (i) its paying \$100 million in 2004 to settle a prior lawsuit with us for anticompetitive practices, business disparagement, and tortious interference and (ii) the fact that its Integra products were found to infringe our products in May 2010. The Court's injunction in this case was stayed pending appeal. Although we have made limited progress in some areas, such as the alternate care and international markets, our volumes are not as high as they should be given the nature and quality of our products and the federal and state legislation requiring the use of safe needle devices.

We continue to pursue various strategies to have better access to the hospital market, as well as other markets, including attempting to gain access to the market through our sales efforts, our innovative technology, introduction of new products, and, when necessary, litigation. We are also marketing more products internationally.

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In the event we continue to have only limited market access and the cash provided by the litigation settlements and generated from operations becomes insufficient, we would take additional cost cutting measures to reduce cash requirements. Such measures could result in the reduction of units being produced, the reduction of workforce, the reduction of salaries of officers and other nonhourly employees, and the deferral of royalty payments. We took such actions at the end of the second quarter of 2009.

At the end of the second quarter of 2009, we announced that in the interest of the long-term survival of the Company we would reorganize some of the Company's functions and implement staff reductions, all in order to minimize our cash expenditures and conserve our resources. Our workforce was reduced by 16% on July 1, 2009. However, due to the increase in production from sales to DHHS, we increased the workforce at the Little Elm facility beginning in the latter part of the third quarter of 2009. Salaries for all personnel above a certain salary level were cut by 10% in 2009. Although certain salary reductions remain in place, we granted payments to our employees to offset such salary reductions in 2010. As a result of the cost cutting measures, compensation costs for 2010 included in Operating expenses were reduced by \$800,000.

Our litigation costs for 2010 were approximately \$5.1 million less than the prior year. Additional reductions in expenses in 2010 as compared to 2009 include reductions of \$771,000 for stock option expense, \$178,000 for travel and entertainment, \$173,000 for consulting, \$77,000 in 401(k) expense, and \$48,000 for marketing expense.

We are bringing additional molding operations to Little Elm as a cost saving measure. We continue to focus on methods of upgrading our manufacturing capability and efficiency in order to reduce costs.

Effective July 12, 2010, we entered into a settlement agreement with Abbott and Hospira. Pursuant to this settlement agreement, we received \$6 million in the third quarter of 2010 and Abbott waived its rights to a



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marketing fee of \$1,419,760 and any Series IV Class B preferred stock dividends. Additionally, we granted Hospira an exclusive one-year option to negotiate a licensing agreement for certain uses of our Patient Safe® syringe. It has not exercised its option. As part of the option fee, we have received from Hospira two payments of \$2 million each in the fourth quarter of 2010 and first quarter of 2011 and expect another two payments of \$2 million each in the second and third quarters of 2011, for a total of \$8 million. In the third quarter of 2010, we granted bonuses to certain officers and employees in recognition of work leading to the Abbott settlement.

In the second quarter of 2010, we reached an agreement with our counsel, Locke Lord Bissell & Liddell, regarding future litigation expenditures that caps certain of our litigation costs in exchange for a contingent fee interest. We believe this agreement serves both our short-term and long-term interests and will reduce the legal fee component of our General and administrative costs and will impact our cash flow in a positive manner.

Product purchases from Double Dove, a Chinese manufacturer, have enabled us to increase manufacturing capacity with little capital outlay and have provided a competitive manufacturing cost. In 2010, Double Dove manufactured approximately 64.1% of the units we produced. The cost of production per unit has generally declined as volumes increased. We believe we could make up any long-term disruption in these supplies by utilizing more of the capacity at the Little Elm facility, except for the 0.5mL insulin syringe, the 5mL and 10mL syringes, and the autodisable syringe which altogether comprised about 8.4% of our 2010 revenues.

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.

**RESULTS OF OPERATIONS**

The following discussion contains trend information and other forward-looking statements that involve a number of risks and uncertainties. Our actual future results could differ materially from our historical results of operations and those discussed in the forward-looking statements. All period references are to our fiscal years ended December 2010, 2009, or 2008. Dollar amounts have been rounded for ease of reading.

*Comparison of Year Ended*

*December 31, 2010 and Year Ended December 31, 2009*

Revenues decreased 7.1%, due principally to the effect of the DHHS contract in 2009. Domestic sales were 81.7% of revenues with international sales comprising the remainder. Unit sales decreased 7.4%. Domestic unit sales decreased 16.8% and average sales prices increased 3.2%. International unit sales increased 31.2% and average international selling prices increased.

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Cost of sales decreased due to lower volume of product sold. Royalty expenses increased due to higher gross sales as well as net litigation proceeds.

As a result, gross profit margins decreased slightly from 34.7% in 2009 to 34.6% in 2010.

Operating expenses decreased 28.4% from the prior year due to lower litigation costs, lower compensation costs (\$800,000), lower stock option expense (\$771,000), and lower travel and entertainment costs (\$178,000). Our litigation costs for 2010 were approximately \$5.1 million less than the prior year. Lower litigation costs are the result of an agreement between us and our counsel to cap certain litigation fees. Additional reductions in expenses in 2010 as compared to 2009 include reductions of \$173,000 for consulting, \$77,000 in 401(k) expense, and \$48,000 for marketing expense.

In 2010, we recognized impairment charges of \$365,295 for costs associated with research and development activities compared to impairment charges of \$2.6 million in 2009 associated with catheter production equipment.

Operating loss was \$6.7 million in 2010 compared to an operating loss in 2009 of \$13.3 million.

Interest income decreased due to lower interest rates. Interest expense increased due to higher average loan balances and a reduction in capitalized interest.

Litigation settlements, net reflects cash proceeds of \$8.0 million from Hospira and a waiver of \$1.4 million in marketing fees payable to Abbott. A receivable from Abbott for \$144 thousand was also waived. Royalties of \$116,671 were paid as a result of the settlement.

Benefit for income taxes consists principally of additional refunds due for our 2009 federal tax return reduced by \$130 thousand due in Alternative Minimum Tax for 2010.

Cash flow from operations was \$8.7 million for 2010 due principally to litigation settlements and improved results from operations.

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*Comparison of Year Ended*

*December 31, 2009 and Year Ended December 31, 2008*

Revenues increased 39.7%, due principally to sales under the DHHS contract. Domestic sales were 88.4% of revenues with international sales comprising the remainder. Without the DHHS contract, our revenues would have increased 5.6%, with domestic revenues increasing 7.3% and international revenues declining 3.0%. Unit sales of the 1mL syringe increased 17.1% and 3mL unit sales increased 54.3%. Unit sales of all products increased 27.3%. Domestic unit sales as well as average sales prices increased. International unit sales decreased slightly and average selling prices increased. Sales to two customers accounted for 38.4% of our revenues in 2009. Only one of these two customers was a customer in 2008, and such customer accounted for 17.1% of our revenues in 2008.

Cost of sales increased due to greater volumes. Royalty expenses were higher due to higher gross sales.

As a result, gross profit margins increased from 29.5% in 2008 to 34.7% in 2009.

Operating expenses increased from the prior year due to litigation costs and stock option expense mitigated by the cost cutting measures beginning in the third quarter of 2009.

Sales and marketing expenses decreased due primarily to lower compensation due to staff reduction and reduction in pay, lower advertising expenses, and reduced travel costs. Stock option expense and consulting costs increased.

Research and development costs were lower. We had decreases in engineering costs due principally to reduction in staff and pay as well as lower consulting cost. Stock option expense increased.

General and administrative costs increased due principally to litigation costs and stock option expense. Compensation costs decreased due to staff reductions and reductions in pay.

In the fourth quarter of 2009, we recognized an impairment charge of \$2,594,602 associated with catheter production equipment.

Interest income decreased due to lower interest rates and lower cash balances. Interest expense decreased due to capitalized interest.

The Company recognized a tax benefit in 2009 primarily due to a federal tax carryback related to 2009.

Preferred Stock dividend requirements decreased slightly due to conversion of preferred stock in the first quarter of 2008. The dividend arrearage at December 31, 2009, on all classes of Preferred Stock was approximately \$15.3 million.

Cash flow from operations was a negative \$12.3 million for 2009 due principally to operating losses and increases in receivables. Most of the increase in receivables was related to billings in December 2009 to DHHS and collected in January 2010. The increase in income taxes receivable was related to a refund for carryback of our 2009 net operating loss. We filed for this refund early in the second quarter of 2010 and received the refund in 2010. The effect of non-cash expenses and the change in working capital was a negative \$2.9 million. Investing activities utilized \$2.4 million in cash.

## **LIQUIDITY**

At the present time, Management does not intend to raise equity capital. Due to the funds received from prior litigation settlements, we have sufficient cash reserves and intend to rely on operations, cash reserves, and debt financing as the primary ongoing sources of cash.

Our cash position has improved \$5.1 million, or 28.4%, over 2009. The improvement is directly related to the litigation proceeds paid in 2010 and the effect of cost reduction measures taken in 2009 and 2010. Reduction in litigation costs, particularly from the second quarter of 2010 through the end of the year, were significant. We expect these lower litigation costs and the effect of the cost reductions to continue.

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Historical Sources of Liquidity

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

Internal Sources of Liquidity

*Margins and Market Access*

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

We continue to focus on methods of upgrading our manufacturing capability and efficiency in order to reduce costs.

Fluctuations in the cost and availability of raw materials and inventory and our ability to maintain favorable supplier arrangements and relationships could result in the need to manufacture all (as opposed to 33.4%) of our products in the U.S. This could temporarily increase unit costs as we ramp up domestic production.

The mix of domestic and international sales affects the average sales price of our products. Generally, the higher the ratio of domestic sales to international sales, the higher the average sales price will be. Typically international sales are shipped directly from China to the customer. Purchases of product manufactured in China, if available, usually decrease the average cost of manufacture for all units. Domestic costs, such as indirect labor and overhead, remain relatively constant. The number of units produced by the Company versus manufactured in China can have a significant effect on the carrying costs of inventory as well as Cost of sales. We will continue to evaluate the appropriate mix of products manufactured domestically and those manufactured in China to achieve economic benefits as well as to maintain our domestic manufacturing capability.

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

*Seasonality*

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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. In 2009, we had a contract to provide DHHS with syringes to be used in the U.S. efforts to provide swine flu vaccinations. This contract was material for 2009 and affects comparability to 2009 financial data.

### *Cash Requirements*

Due to funds received from prior litigation settlements, we have sufficient cash reserves and intend to rely on operations, cash reserves, and debt financing as the primary ongoing sources of cash. In the event we continue to have only limited market access and cash generated from operations becomes insufficient to support operations, we would take additional cost cutting measures to reduce cash requirements. Such measures could result in the reduction of units being produced, the reduction of workforce, the reduction of salaries of officers and other nonhourly employees, and the deferral of royalty payments.

### External Sources of Liquidity

We have obtained several loans from our inception, which have, together with the proceeds from the sales of equities and litigation efforts, enabled us to pursue development and production of our products. Given the

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current economic conditions, our ability to obtain additional funds through loans is uncertain. Furthermore, the shareholders previously authorized an additional 5,000,000 shares of a Class C Preferred Stock that could, if necessary, be designated and used to raise funds through the sale of equity. Due to the current market price of our Common Stock, it is unlikely we would choose to raise funds by the sale of equity.

Effective July 12, 2010, we entered into a settlement agreement with Abbott and Hospira. Pursuant to this settlement agreement, we received \$6 million in the third quarter of 2010 and Abbott waived its rights to a marketing fee of \$1,419,760 and any Series IV Class B preferred stock dividends. Additionally, we granted Hospira an exclusive one-year option to negotiate a licensing agreement for certain uses of our Patient Safe® syringe. It has not exercised its option. As part of the option fee, we have received from Hospira two payments of \$2 million each in the fourth quarter of 2010 and first quarter of 2011 and expect another two payments of \$2 million each in the second and third quarters of 2011, for a total of \$8 million.

**CAPITAL RESOURCES**

Material Commitments for Expenditures

In 2011, we purchased molding machines to expand our in-house molding capability and further reduce costs. Financing was completed in the second quarter of 2011 for three molding machines. The purchase and financing for a fourth molding machine is expected to be completed in 2011.

Trends in Capital Resources

Interest expense may increase due to the reduction of capitalized interest at the present time. It may also be affected by additional loans or rising interest rates. Interest income may continue to be negatively affected by lower interest rates and our prior movement of cash to U.S. Treasury bills and other U.S. government backed securities. Although we believe that we have granted credit to credit-worthy firms, current economic conditions may affect the timing and/or collectability of some accounts.

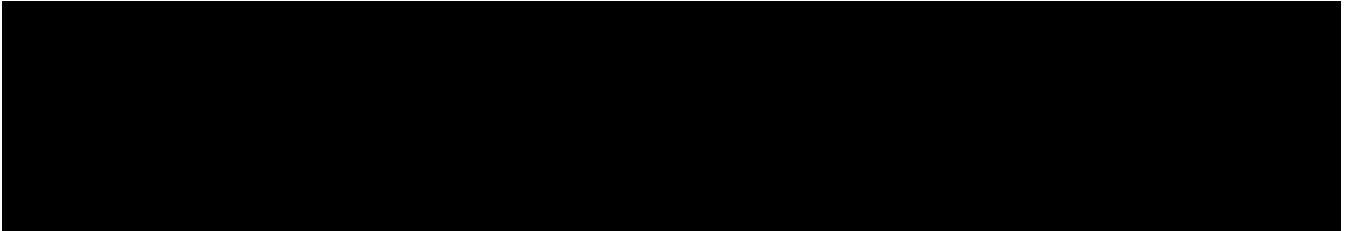
**OFF-BALANCE SHEET ARRANGEMENTS**

None.

**CONTRACTUAL OBLIGATIONS**

Contractual Obligations and Commercial Commitments

The following chart summarizes our material obligations and commitments to make future payments under contracts for long-term debt as of December 31, 2010:



These amounts do not reflect the effect of the beneficial conversion feature of the note payable to Katie Petroleum and therefore will be greater than the amounts in the financial statements.



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SIGNIFICANT ACCOUNTING POLICIES

We consider the following to be our most significant accounting policies. Careful consideration and review is given to these and all accounting policies on a routine basis to ensure that they are accurately and consistently applied.

**Accounts Receivable**

We record trade receivables when revenue is recognized. No product has been consigned to customers. Our allowance for doubtful accounts is primarily determined by review of specific trade receivables. Those accounts that are doubtful of collection are included in the allowance. An additional allowance has been established based on a percentage of receivables outstanding. These provisions are reviewed to determine the adequacy of the allowance for doubtful accounts. Trade receivables are charged off when there is certainty as to their being uncollectible. Trade receivables are considered delinquent when payment has not been made within contract terms.

We require certain distributors to make a prepayment prior to beginning production or shipment of their order. Distributors may apply such prepayments to their outstanding invoices or pay the invoice and continue to carryforward the deposit for future orders. Such amounts are included in Other accrued liabilities on the Balance Sheets and are shown in Note 6, Other Accrued Liabilities.

We record an allowance for estimated returns as a reduction to accounts receivable and gross sales. Historically, returns have been less than 0.5% of net sales.

**Revenue Recognition**

Revenue is recognized for sales when title and risk of ownership passes to the customer, generally upon shipment. Under certain contracts, revenue is recorded on the basis of sales price to distributors, less contractual pricing allowances. Contractual pricing allowances consist of (i) rebates granted to distributors who provide tracking reports which show, among other things, the facility that purchased the products, and (ii) a provision for estimated contractual pricing allowances for products that we have 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 us. 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 us. The provision for contractual pricing allowances is reviewed at the end of each quarter and adjusted for changes in levels of products for which there is no tracking report. Additionally, if it becomes clear that tracking reports will not be provided by individual distributors, the provision is further adjusted. The estimated contractual allowance is netted against the individual distributor's accounts receivable balances for financial reporting purposes. The resulting net balance is reflected in accounts receivable or accounts payable, as appropriate. The terms and conditions of contractual pricing allowances are governed by contracts between us and our distributors. Revenue for shipments directly to end-users is recognized when title and risk of ownership passes from us. 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 us. We have been in discussions with the principal customers that claimed non-contractual rebates. Major customers said they have ceased the practices resulting in claiming non-contractual rebates. The product for which they were claiming rebates was actually product they had not purchased from us. Rebates can only be claimed on purchases made directly from us. We have 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 a reduction of accounts receivable.

Our domestic return policy is set forth in our 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 us and affix the code to the returned product. We will not accept returned goods without a returned goods authorization number. We may refund the customer's money or replace the product.

Our domestic return policy also provides that a customer may return product that is overstocked. Overstocking returns are limited to two times in each 12 month period up to 1% of distributor's total purchase of products for the prior 12 month period. All product overstocks and returns are subject to inspection and acceptance by us.

Our international distribution agreements do not provide for any returns.

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**Inventories**

Inventories are valued at the lower of cost or market, with cost being determined using actual average cost. We compare the average cost to the market price and record 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.

**Marketing Fees**

In prior periods, Marketing fees payable to Abbott were included in current liabilities in the Balance Sheets. In connection with the settlement with Abbott, Marketing fees payable recorded in previous periods will not have to be paid. The reversal of this accrual is included in Litigation settlements, net on the Statements of Operations.

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**Item 8. Financial Statements and Supplementary Data.**

**RETRACTABLE TECHNOLOGIES, INC.**

**FINANCIAL STATEMENTS AND**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

**DECEMBER 31, 2010 AND 2009**

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**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders

of Retractable Technologies, Inc.

We have audited the accompanying balance sheets of Retractable Technologies, Inc. as of December 31, 2010 and 2009, and the related statements of operations, changes in stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2010. Our audits also included the financial statement schedule of Retractable Technologies, Inc., listed in Item 15(a) of the Form 10-K. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Retractable Technologies, Inc. as of December 31, 2010 and 2009, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2010, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

Dallas, Texas  
March 31, 2011

/s/ CF & Co., L.L.P.  
CF & Co., L.L.P.

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|  | <b>December 31,</b> |               |
|--|---------------------|---------------|
|  | <b>2010</b>         | <b>2009</b>   |
| <b>ASSETS</b>  |                     |               |
| Current assets:  |                     |               |
| Cash and cash equivalents  | \$ 23,266,039       | \$ 18,126,084 |
| Accounts receivable, net of allowance for doubtful accounts of \$780,900 and \$681,966, respectively   | 7,582,062           | 9,948,210     |
| Inventories, net   | 8,682,191           | 6,907,369     |
| Income taxes receivable  | 12,031              | 3,655,637     |
| Other current assets   | 681,244             | 624,393       |
| Total current assets   | 40,223,567          | 39,261,693    |
| Property, plant, and equipment, net  | 12,560,592          | 14,234,181    |
| Intangible and other assets, net   | 406,910             | 445,425       |
| Total assets   | \$ 53,191,069       | \$ 53,941,299 |
| <b>LIABILITIES AND STOCKHOLDERS EQUITY</b>   |                     |               |
| Current liabilities:   |                     |               |
| Accounts payable   | \$ 3,847,966        | \$ 6,997,310  |
| Current portion of long-term debt  | 519,611             | 2,628,652     |
| Accrued compensation   | 603,484             | 561,484       |
| Marketing fees payable   |                     | 1,419,760     |
| Accrued royalties to shareholders  | 949,619             | 843,327       |
| Other accrued liabilities  | 3,910,428           | 745,460       |
| Income taxes payable   | 155,000             |               |
| Total current liabilities  | 9,986,108           | 13,195,993    |
| Long-term debt, net of current maturities  | 4,304,460           | 4,824,833     |
| Total liabilities  | 14,290,568          | 18,020,826    |
| Commitments and Contingencies - See Note 8   |                     |               |
| Stockholders' equity:  |                     |               |
| Preferred Stock \$1 par value:   |                     |               |
| Class B; authorized: 5,000,000 shares  |                     |               |
| Series I, Class B; outstanding: 144,000 and 144,000 shares, respectively (liquidation preference of \$900,000 and \$900,000 respectively)          | 144,000             | 144,000       |
| Series II, Class B; outstanding: 219,700 and 219,700, respectively (liquidation preference of \$2,746,250 and \$2,746,250, respectively)           | 219,700             | 219,700       |
| Series III, Class B; outstanding: 130,245 and 130,245 shares, respectively (liquidation preference of \$1,628,063 and \$1,628,063, respectively)   | 130,245             | 130,245       |
| Series IV, Class B; outstanding: 552,500 and 552,500 shares (liquidation preference of \$6,077,500 and \$6,077,500, respectively)                  | 552,500             | 552,500       |
| Series V, Class B; outstanding: 1,232,571 and 1,238,821 shares, respectively (liquidation preference of \$5,423,312 and \$5,450,812, respectively) | 1,232,571           | 1,238,821     |
| Common Stock, no par value; authorized: 100,000,000 shares; issued and outstanding: 23,974,114 and 23,825,149 shares, respectively                 |                     |               |
| Additional paid-in capital   | 57,674,737          | 57,089,153    |
| Retained deficit   | (21,053,252)        | (23,453,946)  |
| Total stockholders' equity   | 38,900,501          | 35,920,473    |
| Total liabilities and stockholders' equity   | \$ 53,191,069       | \$ 53,941,299 |

See accompanying notes to financial statements





Table of Contents**RETRACTABLE TECHNOLOGIES, INC.****STATEMENTS OF OPERATIONS**

|   | <b>Years Ended December 31,</b> |                 |                 |
|---|---------------------------------|-----------------|-----------------|
|   | <b>2010</b>                     | <b>2009</b>     | <b>2008</b>     |
| Sales, net  | \$ 36,219,562                   | \$ 38,981,837   | \$ 27,899,318   |
| Cost of Sales                                     |                                 |                 |                 |
| Costs of manufactured product                     | 20,757,488                      | 22,659,437      | 17,504,842      |
| Royalty expense to shareholders                   | 2,940,948                       | 2,806,223       | 2,168,268       |
| Total cost of sales                               | 23,698,436                      | 25,465,660      | 19,673,110      |
| Gross profit                                      | 12,521,126                      | 13,516,177      | 8,226,208       |
| Operating expenses:                               |                                 |                 |                 |
| Sales and marketing                               | 3,674,168                       | 4,372,163       | 4,835,272       |
| Research and development                          | 885,445                         | 1,030,622       | 1,066,068       |
| General and administrative                        | 14,260,151                      | 18,814,392      | 12,769,774      |
| Impairment of assets                              | 365,295                         | 2,594,602       |                 |
| Total operating expenses                          | 19,185,059                      | 26,811,779      | 18,671,114      |
| Loss from operations                              | (6,663,933)                     | (13,295,602)    | (10,444,906)    |
| Interest and other income                         | 32,324                          | 57,604          | 855,685         |
| Interest expense, net                             | (302,843)                       | (21,892)        | (54,359)        |
| Litigation settlements, net                       | 9,159,089                       |                 |                 |
| Income (loss) before income taxes                 | 2,224,637                       | (13,259,890)    | (9,643,580)     |
| Benefit for income taxes                          | (176,057)                       | (3,837,590)     |                 |
| Net income (loss)                                 | 2,400,694                       | (9,422,300)     | (9,643,580)     |
| Preferred Stock dividend requirements             | (1,370,620)                     | (1,370,868)     | (1,373,019)     |
| Earnings (loss) applicable to common shareholders | \$ 1,030,074                    | \$ (10,793,168) | \$ (11,016,599) |
| Basic earnings (loss) per share                   | \$ 0.04                         | \$ (0.45)       | \$ (0.46)       |
| Diluted earnings (loss) per share                 | \$ 0.04                         | \$ (0.45)       | \$ (0.46)       |
| Weighted average common shares outstanding:       |                                 |                 |                 |
| Basic   | 23,872,783                      | 23,806,533      | 23,794,566      |
| Diluted   | 26,248,874                      | 23,806,533      | 23,794,566      |

See accompanying notes to financial statements

Table of Contents**RETRACTABLE TECHNOLOGIES, INC.****STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY**

|   | <u>Series I Class B</u> |               | <u>Series II Class B</u> |               | <u>Series III Class B</u> |               | <u>Series IV Class B</u> |               | <u>Series V Class B</u> |               | <u>Common</u> |               |
|---|-------------------------|---------------|--------------------------|---------------|---------------------------|---------------|--------------------------|---------------|-------------------------|---------------|---------------|---------------|
|   | <u>Shares</u>           | <u>Amount</u> | <u>Shares</u>            | <u>Amount</u> | <u>Shares</u>             | <u>Amount</u> | <u>Shares</u>            | <u>Amount</u> | <u>Shares</u>           | <u>Amount</u> | <u>Shares</u> | <u>Amount</u> |
| Balance as of December 31, 2007                 | 144,000                 | \$ 144,000    | 219,700                  | \$ 219,700    | 130,245                   | \$ 130,245    | 553,500                  | \$ 553,500    | 1,282,471               | \$ 1,282,471  | 23,755,414    | \$            |
| Conversion of Preferred Stock into Common Stock |                         |               |                          |               |                           |               | (1,000)                  | (1,000)       | (43,650)                | (43,650)      | 44,650        |               |
| Recognition of stock option compensation        |                         |               |                          |               |                           |               |                          |               |                         |               |               |               |
| Net loss  |                         |               |                          |               |                           |               |                          |               |                         |               |               |               |
| Balance as of December 31, 2008                 | 144,000                 | 144,000       | 219,700                  | 219,700       | 130,245                   | 130,245       | 552,500                  | 552,500       | 1,238,821               | 1,238,821     | 23,800,064    |               |
| Recognition of stock option compensation        |                         |               |                          |               |                           |               |                          |               |                         |               |               |               |
| Recognition of stock option exercise            |                         |               |                          |               |                           |               |                          |               |                         |               | 25,085        |               |
| Royalty waiver                                  |                         |               |                          |               |                           |               |                          |               |                         |               |               |               |
| Net loss  |                         |               |                          |               |                           |               |                          |               |                         |               |               |               |
| Balance as of December 31, 2009                 | 144,000                 | 144,000       | 219,700                  | 219,700       | 130,245                   | 130,245       | 552,500                  | 552,500       | 1,238,821               | 1,238,821     | 23,825,149    |               |
| Conversion of Preferred Stock into Common Stock |                         |               |                          |               |                           |               |                          |               | (6,250)                 | (6,250)       | 6,250         |               |
| Recognition of stock option compensation        |                         |               |                          |               |                           |               |                          |               |                         |               |               |               |
| Recognition of stock option exercise            |                         |               |                          |               |                           |               |                          |               |                         |               | 142,715       |               |
| Payment of dividends                            |                         |               |                          |               |                           |               |                          |               |                         |               |               |               |
| Net income                                      |                         |               |                          |               |                           |               |                          |               |                         |               |               |               |
|   | 144,000                 | \$144,000     | 219,700                  | \$219,700     | 130,245                   | \$130,245     | 552,500                  | \$552,500     | 1,232,571               | \$ 1,232,571  | 23,974,114    | \$            |

Balance as of  
December 31,  
2010

See accompanying notes to financial statements

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

|   | <b>Additional<br/>Paid-in<br/>Capital</b> | <b>Retained<br/>Earnings<br/>(Deficit)</b> | <b>Total</b>  |
|---|---|--|---------------|
| Balance as of December 31, 2007                 | \$ 53,818,987                             | \$ (4,388,066)                             | \$ 51,760,837 |
| Conversion of Preferred Stock into Common Stock | 44,650                                    |  |               |
| Recognition of stock option compensation        | 88,546                                    |  | 88,546        |
| Net loss  |   | (9,643,580)                                | (9,643,580)   |
| Balance as of December 31, 2008                 | 53,952,183                                | (14,031,646)                               | 42,205,803    |
| Recognition of stock option compensation        | 2,111,360                                 |  | 2,111,360     |
| Recognition of stock option exercise            | 25,610                                    |  | 25,610        |
| Royalty waiver                                  | 1,000,000                                 |  | 1,000,000     |
| Net loss  |   | (9,422,300)                                | (9,422,300)   |
| Balance as of December 31, 2009                 | 57,089,153                                | (23,453,946)                               | 35,920,473    |
| Conversion of Preferred Stock into Common Stock | 6,250                                     |  |               |
| Recognition of stock option compensation        | 1,340,300                                 |  | 1,340,300     |
| Recognition of stock option exercise            | 115,600                                   |  | 115,600       |
| Payment of dividends                            | (876,566)                                 |  | (876,566)     |
| Net income                                      |   | 2,400,694                                  | 2,400,694     |
| Balance as of December 31, 2010                 | \$ 57,674,737                             | \$ (21,053,252)                            | \$ 38,900,501 |

See accompanying notes to financial statements

Table of Contents**RETRACTABLE TECHNOLOGIES, INC.****STATEMENTS OF CASH FLOWS**

|  | <b>Years Ended December 31,</b> |                |                |
|--|---------------------------------|----------------|----------------|
|  | <b>2010</b>                     | <b>2009</b>    | <b>2008</b>    |
| <b>Cash flows from operating activities:</b>   |                                 |                |                |
| Net income (loss)  | \$ 2,400,694                    | \$ (9,422,300) | \$ (9,643,580) |
| Adjustments to reconcile net income (loss) to net cash provided by (used by) operating activities: |                                 |                |                |
| Depreciation and amortization  | 1,516,226                       | 1,396,793      | 1,397,333      |
| Litigation settlement marketing fees payable   | (1,419,760)                     |                |                |
| Stock option compensation  | 1,340,300                       | 2,111,360      | 32,629         |
| Reserve for non-contractual deductions   | 850,000                         |                |                |
| Provision for doubtful accounts  | 133,990                         | 182,000        | 224,633        |
| Impairment of assets   | 365,295                         | 2,594,602      |                |
| Accreted interest  | 30,920                          | 43,151         | 54,387         |
| (Increase) decrease in assets:   |                                 |                |                |
| Inventories  | (1,774,822)                     | (265,837)      | 395,597        |
| Accounts receivable  | 1,382,158                       | (6,841,268)    | (1,845,939)    |
| Income taxes receivable  | 3,643,606                       | (3,655,637)    | 2,345,041      |
| Other current assets   | (56,851)                        | (224,280)      | (41,306)       |
| Other assets   |                                 |                | (12,725)       |
| Increase (decrease) in liabilities:  |                                 |                |                |
| Accounts payable   | (3,149,344)                     | 852,875        | 609,070        |
| Other accrued liabilities  | 3,313,260                       | 1,015,505      | 798,578        |
| Income taxes payable   | 155,000                         | (86,695)       |                |
| Net cash provided (used) by operating activities   | 8,730,672                       | (12,299,731)   | (5,686,282)    |
| <b>Cash flows from investing activities:</b>   |                                 |                |                |
| Purchase of property, plant, and equipment   | (169,415)                       | (2,383,867)    | (2,580,516)    |
| Investment in LLC  |                                 |                | 497,690        |
| Acquisitions of patents, trademarks, licenses, and intangibles                                     |                                 |                | (89,152)       |
| Net cash used by investing activities  | (169,415)                       | (2,383,867)    | (2,171,978)    |
| <b>Cash flows from financing activities:</b>   |                                 |                |                |
| Repayments of long-term debt and notes payable   | (2,660,336)                     | (499,668)      | (489,160)      |
| Proceeds from long-term debt   |                                 |                | 1,123,729      |
| Proceeds from the exercise of stock options  | 115,600                         | 25,610         |                |
| Payment of Preferred Stock dividends   | (876,566)                       |                |                |
| Net cash provided (used) by financing activities   | (3,421,302)                     | (474,058)      | 634,569        |
| Net increase (decrease) in cash and cash equivalents   | 5,139,955                       | (15,157,656)   | (7,223,691)    |
| Cash and cash equivalents at:  |                                 |                |                |
| Beginning of period  | 18,126,084                      | 33,283,740     | 40,507,431     |
| End of period  | \$ 23,266,039                   | \$ 18,126,084  | \$ 33,283,740  |
| <b>Supplemental schedule of cash flow information:</b>   |                                 |                |                |
| Interest paid  | \$ 321,610                      | \$ 184,018     | \$ 236,932     |
| Income taxes paid  | \$ 16,000                       | \$             | \$             |
| <b>Supplemental schedule of noncash investing and financing activities:</b>                        |                                 |                |                |

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|   |    |    |           |    |           |
|---|----|----|-----------|----|-----------|
| Debt assumed to construct a warehouse   | \$ | \$ | 1,362,602 | \$ | 1,723,277 |
| Forgiveness of royalties by shareholder | \$ | \$ | 1,000,000 | \$ |           |

See accompanying notes to financial statements

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**NOTES TO FINANCIAL STATEMENTS**

**1. BUSINESS OF THE COMPANY AND BASIS OF PRESENTATION**

**Business of the Company**

Retractable Technologies, Inc. (the Company) was incorporated in Texas on May 9, 1994, and designs, develops, manufactures, and markets safety syringes and other safety medical products for the healthcare profession. The Company began to develop its manufacturing operations in 1995. The Company's manufacturing and administrative facilities are located in Little Elm, Texas. The Company's primary products with Notice of Substantial Equivalence to the FDA are the VanishPoint® 0.5mL insulin syringe; 1mL tuberculin, insulin, and allergy antigen syringes; the 0.5mL, 2mL, 3mL, 5mL, and 10mL syringes; the small diameter tube adapter; the blood collection tube holder; the allergy tray; the IV safety catheter; and the Patient Safe® syringe.

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Accounting estimates**

The preparation of financial statements in conformity with U.S. generally accepted accounting principles (GAAP) requires Management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ significantly from those estimates.

**Cash and cash equivalents**

For purposes of reporting cash flows, cash and cash equivalents include unrestricted cash, money market accounts, and investments with original maturities of three months or less.

**Accounts receivable**

The Company records trade receivables when revenue is recognized. No product has been consigned to customers. The Company's allowance for doubtful accounts is primarily determined by review of specific trade receivables. Those accounts that are doubtful of collection are included in the allowance. An additional allowance has been established based on a percentage of receivables outstanding. These provisions are

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reviewed to determine the adequacy of the allowance for doubtful accounts. Trade receivables are charged off when there is certainty as to their being uncollectible. Trade receivables are considered delinquent when payment has not been made within contract terms.

The Company requires certain distributors to make a prepayment prior to beginning production or shipment of their order. Distributors may apply such prepayments to their outstanding invoices or pay the invoice and continue to carryforward the deposit for future orders. Such amounts are included in Other accrued liabilities on the Balance Sheets and are shown in Note 6, Other Accrued Liabilities.

The Company records an allowance for estimated returns as a reduction to Accounts receivable and Gross sales. Historically, returns have been less than 0.5% of net sales.

### **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. For the years



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ended December 31, 2010, 2009, and 2008, the Company capitalized interest of approximately \$50,000; \$205,000; and \$237,000. Gains or losses from property disposals are included in income.

Depreciation and amortization are calculated using the straight-line method over the following useful lives:

|                                |               |
|--------------------------------|---------------|
| Production equipment           | 3 to 13 years |
| Office furniture and equipment | 3 to 10 years |
| Buildings                      | 39 years      |
| Building improvements          | 15 years      |
| Automobiles                    | 7 years       |

**Long-lived assets**

The Company assesses the recoverability of long-lived assets using an assessment of the estimated undiscounted future cash flows related to such assets. In the event that assets are found to be carried at amounts which are in excess of estimated gross future cash flows, the assets will be adjusted for impairment to a level commensurate with a discounted cash flow analysis of the underlying assets.

During 2009, the Company recognized an impairment charge of \$2,594,602 associated with its catheter production equipment. The Company determined it was more cost effective to outsource the majority of this production through overseas manufacturers, and thus the Company's catheter production equipment will be utilized less. Minimal cash flows are expected to be generated by this equipment. Accordingly, the Company reduced the carrying value of the catheter production equipment to an estimated fair value of zero. The Company's management estimated the fair value of the equipment based on guidance established by the *Fair Value Measurements and Disclosures* Topic of the Financial Accounting Standards Board ( FASB ) Accounting Standards Codification ( ASC ). In this instance, the Company's management determined the impairment charge by utilizing observable market data, a Level 2 input under the FASB ASC. A Level 1 input would require quoted prices, which were not available in this matter.

During 2010, the Company recognized impairment charges of \$365,295 on equipment designed in connection with research and development activities. The Company will likely outsource the majority of this production through overseas manufacturers. Minimal cash flows, if any, are expected to be generated by this equipment. Accordingly, the Company reduced the carrying value of this equipment to an estimated fair value of zero. The Company's management estimated the fair value of the equipment based on guidance established by the *Fair Value Measurements and Disclosures* Topic of the FASB ASC. In this instance, the Company's management determined the impairment charge by utilizing observable market data, a Level 2 input under the FASB ASC. A Level 1 input would require quoted prices, which were not available in this matter.

The Company's remaining property, plant, and equipment primarily consists of buildings, land, assembly equipment for syringes, molding machines, molds, office equipment, furniture, and fixtures. There has been no impairment charge against the assembly equipment since the Company continues to manufacture a significant portion of 1cc and 3cc syringes at the Company's Little Elm facility which results in sufficient future cash flows to recoup the net book value of all property, plant, and equipment.

**Reclassifications**

Certain prior year amounts have been reclassified to conform with the current year's presentation.

**Intangible assets**

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

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**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.

**Concentration risks**

The Company's financial instruments exposed to concentrations of credit risk consist primarily of cash, cash equivalents, and accounts receivable. Cash balances, some of which exceed federally insured limits, are maintained in financial institutions; however, Management believes the institutions are of high credit quality. The majority of accounts receivable are due from companies which are well-established entities. As a consequence, Management considers any exposure from concentrations of credit risks to be limited. The Company had a high concentration of sales with three significant customers. For the year ended December 31, 2010, the aforementioned customers accounted for \$13.9 million, or 38.6% of net sales.

Considering the current economic climate, the Company increased its allowance for doubtful accounts by approximately \$98,934 this year.

The Company manufactures syringes in Little Elm, Texas as well as utilizing manufacturers in China. The Company purchases most of its product components from single suppliers, including needle adhesives and packaging materials. There are multiple sources of these materials. The Company obtained roughly 64.1% of its finished products in 2010 through Double Dove, a Chinese manufacturer. In the event that the Company becomes unable to purchase such product from Double Dove, the Company would need to find an alternate supplier for its 0.5mL insulin syringe, its 5mL and 10mL syringes, and its autodisable syringe and increase domestic production for 1mL and 3mL syringes to avoid a disruption in supply.

**Revenue recognition**

Revenue is recognized for sales when title and risk of ownership passes to the customer, generally upon shipment. Under certain contracts, revenue is recorded on the basis of sales price to distributors, less contractual pricing allowances. Contractual pricing allowances consist of: (i) rebates granted to distributors who provide tracking reports which show, among other things, the facility that purchased the products, and (ii) a provision for estimated contractual pricing allowances for products that the Company has not received tracking reports. Rebates are recorded when issued and are applied against the customer's receivable balance. Distributors receive a rebate for the difference between the Wholesale Acquisition Cost and the appropriate contract price as reflected on a tracking report provided by the distributor to the Company. If product is sold by a distributor to an entity that has no contract, there is a standard rebate (lower than a contracted rebate) given to the distributor. One of the purposes of the rebate is to encourage distributors to submit tracking reports to the Company. The provision for contractual pricing allowances is reviewed at the end of each quarter and adjusted for changes in levels of products for which there is no tracking report. Additionally, if it becomes clear that tracking reports will not be provided by individual distributors, the provision is further adjusted. The estimated contractual allowance is netted against the individual distributor's accounts receivable balances for financial reporting purposes.

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The resulting net balance is reflected in accounts receivable or accounts payable, as appropriate. The terms and conditions of contractual pricing allowances are governed by contracts between the Company and its distributors. Revenue for shipments directly to end-users is recognized when title and risk of ownership pass from the Company. Any product shipped or distributed for evaluation purposes is expensed.

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

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claiming non-contractual rebates. The product for which they were claiming rebates was actually product they had not purchased from the Company. 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 a reduction of accounts receivable.

The Company's domestic return policy is set forth in its standard Distribution Agreement. This policy provides that a customer may return incorrect shipments within 10 days following arrival at the distributor's facility. In all such cases the distributor must obtain an authorization code from the Company and affix the code to the returned product. The Company will not accept returned goods without a returned goods authorization number. The Company may refund the customer's money or replace the product.

The Company's domestic return policy also provides that a customer may return product that is overstocked. Overstocking returns are limited to two times in each 12-month period up to 1% of distributor's total purchase of products for the prior 12-month period. All product overstocks and returns are subject to inspection and acceptance by us.

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

**Marketing fees**

In prior periods, Marketing fees payable to Abbott Laboratories (Abbott) were included in current liabilities in the Balance Sheets. In connection with the settlement with Abbott, Marketing fees payable recorded in previous periods will not have to be paid. The reversal of this accrual is included in Litigation settlements, net on the Statements of Operations.

**Litigation Settlements**

Proceeds from litigation settlements are recognized when realizable. Generally, realization is not reasonably assured and expected until proceeds are collected. Pursuant to a settlement agreement among the Company, Abbott, and Hospira, Inc. (Hospira), Hospira delivered \$6 million to the Company in the third quarter of 2010. The Company reduced its litigation settlements by \$144,000 attributable to an unpaid Abbott invoice. Abbott also waived its rights to any Series IV Class B Preferred Stock dividends. Additionally, the Company granted Hospira an exclusive one-year option to negotiate a licensing agreement for certain uses of the Patient Safe® syringe. As part of the \$8.0 million option payment, the Company received a payment of \$2.0 million in the fourth quarter of 2010.

**Income taxes**

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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. Under recent tax law changes, companies are allowed to carry back taxable losses from either 2008 or 2009. The Company filed

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for a tax refund utilizing its 2009 taxable losses which resulted in a \$4.0 million refund received in the third quarter of 2010. The Company has established a valuation allowance for its net deferred tax asset as future taxable income cannot be reasonably assured. Penalties and interest on uncertain tax positions are classified as income taxes in the Statements of Operations.

**Earnings per share**

The Company computes basic earnings per share ( EPS ) by dividing net earnings for the period (adjusted for any cumulative dividends for the period) by the weighted average number of common shares outstanding during the period. Diluted EPS includes the determinants of basic EPS and, in addition, reflects the dilutive effect, if any, of the common stock deliverable pursuant to stock options or common stock issuable upon the conversion of convertible preferred stock and convertible debt. The potential dilution, if any, is shown on the following schedule.

|   | <b>Years Ended December 31,</b> |                 |                 |
|---|---------------------------------|-----------------|-----------------|
|   | <b>2010</b>                     | <b>2009</b>     | <b>2008</b>     |
| Net income (loss)   | \$ 2,400,694                    | \$ (9,422,300)  | \$ (9,643,580)  |
| Preferred dividend requirements   | (1,370,620)                     | (1,370,868)     | (1,373,019)     |
| Earnings (loss) available to common shareholders after assumed conversions  | \$ 1,030,074                    | \$ (10,793,168) | \$ (11,016,599) |
| Average common shares outstanding   | 23,872,783                      | 23,806,533      | 23,794,566      |
| Dilutive stock equivalents from stock options                               | 2,376,091                       |                 |                 |
| Average common and common equivalent shares outstanding - assuming dilution | 26,248,874                      | 23,806,533      | 23,794,566      |
| Basic earnings per share  | \$ 0.04                         | \$ (0.45)       | \$ (0.46)       |
| Diluted earnings per share  | \$ 0.04                         | \$ (0.45)       | \$ (0.46)       |

**Shipping and handling costs**

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

**Research and development costs**

Research and development costs are expensed as incurred.

Table of Contents**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:

|                            | <b>2010</b>  | <b>Years Ended December 31,</b> | <b>2008</b> |
|----------------------------|--------------|---------------------------------|-------------|
|                            |              | <b>2009</b>                     |             |
| Cost of sales              | \$ 182,892   | \$ 317,644                      | \$ (1,797)  |
| Sales and marketing        | 78,343       | 242,509                         | (2,156)     |
| Research and Development   | 28,259       | 47,168                          | (281)       |
| General and administrative | 1,050,806    | 1,504,039                       | 36,863      |
|                            | \$ 1,340,300 | \$ 2,111,360                    | \$ 32,629   |

Options awarded to employees in 2009 and 2008 were amortized over twelve months. The Company amortized one month's expense for options granted in 2008 in the fourth quarter of 2008. The Company expensed five months of expense for options issued in 2009. Non-employee Directors' option expense was all expensed in the third quarter of 2009.

All stock options were fully vested at June 30, 2010; therefore, all stock option expense was fully recognized at June 30, 2010.

**3. INVENTORIES**

Inventories consist of the following:

|                   | <b>Year Ended December 31,</b> |              |
|-------------------|--------------------------------|--------------|
|                   | <b>2010</b>                    | <b>2009</b>  |
| Raw materials     | \$ 1,401,930                   | \$ 2,424,818 |
| Finished goods    | 7,485,861                      | 4,688,151    |
|                   | 8,887,791                      | 7,112,969    |
| Inventory reserve | (205,600)                      | (205,600)    |
|                   | \$ 8,682,191                   | \$ 6,907,369 |

**4. PROPERTY, PLANT, AND EQUIPMENT**



Property, plant, and equipment consist of the following:

|                                     | <b>December 31,</b> |             |
|-------------------------------------|---------------------|-------------|
|                                     | <b>2010</b>         | <b>2009</b> |
| Land                                | \$ 261,893          | \$ 261,893  |
| Buildings and building improvements | 11,093,797          | 11,079,905  |
| Production equipment                | 14,808,055          | 14,428,077  |
| Office furniture and equipment      | 2,260,219           | 2,148,622   |
| Construction in progress            | 486,187             | 1,198,856   |
| Automobiles                         | 102,321             | 102,321     |
|                                     | 29,012,472          | 29,219,674  |

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|                          | <b>2010</b>   |    | <b>2009</b>  |
|--------------------------|---------------|----|--------------|
| Accumulated depreciation | (16,451,880)  |    | (14,985,493) |
|                          | \$ 12,560,592 | \$ | 14,234,181   |

Depreciation expense for the years ended December 31, 2010, 2009, and 2008 was \$1,482,591; \$1,353,353; and \$1,351,547, respectively.

**5. INTANGIBLE ASSETS**

Intangible assets consist of the following:

|                          | <b>December 31,</b> |             |
|--------------------------|---------------------|-------------|
|                          | <b>2010</b>         | <b>2009</b> |
| License agreement        | \$ 500,000          | \$ 500,000  |
| Trademarks and patents   | 508,743             | 508,743     |
|                          | 1,008,743           | 1,008,743   |
| Accumulated amortization | (625,507)           | (582,068)   |
|                          | \$ 383,236          | \$ 426,675  |

In 1995, the Company entered into a license agreement with the Chief Executive Officer of the Company for the exclusive right to manufacture, market, and distribute products utilizing automated retraction technology. This license agreement was amended July 3, 2008 to include certain additional patent applications owned by such officer in the definition of Patent Properties so that such additional patent applications would be covered by the license. This technology is the subject of various patents and patent applications owned by such officer of the Company. The initial licensing fee of \$500,000 is being amortized over 17 years. The license agreement also provides for quarterly payments of a 5% royalty fee on gross sales. The royalty fee expense is recognized in the period in which it is earned. Royalty fees of \$3,057,619; \$2,806,223; and \$2,168,268 are included in Cost of sales for the years ended December 31, 2010, 2009, and 2008, respectively. Royalties payable under this agreement aggregated \$949,619 and \$843,327 at December 31, 2010 and 2009, respectively. Gross sales upon which royalties are based were \$58,795,279; \$56,124,453; and \$43,365,361 for 2010, 2009, and 2008, respectively. Royalties were also paid on litigation proceeds, net of legal fees, and royalties from third parties on a gross amount of \$2.4 million.

In the third quarter of 2009, the Company announced several cost cutting and cash saving initiatives to conserve its cash. As a part of those initiatives, the Chief Executive Officer waived payment to him of \$1,000,000 in royalty fees. Therefore, the royalty fees of \$2,806,223 for 2009 resulted in a cash outlay of \$1,806,223.

Amortization expense for the years ended December 31, 2010, 2009, and 2008, was \$43,440; \$43,440; and \$43,597, respectively. Future amortization expense for the years 2011 through 2015 is estimated to be \$43,000 per year.

**6. OTHER ACCRUED LIABILITIES**

Other accrued liabilities consist of the following:

|                            | <b>December 31,</b> |             |
|----------------------------|---------------------|-------------|
|                            | <b>2010</b>         | <b>2009</b> |
| Prepayments from customers | \$ 3,555,272        | \$ 499,777  |
| Accrued professional fees  | 288,942             | 191,416     |
| Other accrued expenses     | 66,214              | 54,267      |
|                            | \$ 3,910,428        | \$ 745,460  |

The increase in prepayments is attributable primarily to purchases by South American customers.

Table of Contents**7. LONG-TERM DEBT**

|  | <b>December 31,</b> |                    |
|--|---------------------|--------------------|
|  | <b>2010</b>         | <b>2009</b>        |
| Long-term debt consists of the following:  |                     |                    |
| Loan from Lewisville State Bank, a division of 1st International Bank. It has a 20 year amortization and 10 year maturity from December 10, 2009. The loan provided funding for the expansion of the warehouse, additional office space, and a new Controlled Environment. The loan is secured by the Company's land and buildings. The interest rate is 5.968%.   | \$ 4,098,578        | \$ 4,209,608       |
| Note payable to Katie Petroleum. Interest accrues at prime plus 1%, which was 4.25% at December 31, 2010 and 2009. Interest only was payable monthly through February 1, 2004. The original amount of the note of \$3,000,000 was discounted for presentation purposes by \$299,346 for stock options issued in conjunction with the debt and \$412,500 for the intrinsic value of a beneficial conversion feature of the debt. Beginning March 1, 2004, the loan has been payable in equal installments of principal and interest payments (except for changes in the interest rate) of approximately \$37,000 and matures on September 30, 2012. Guaranteed by an officer. Approximately \$163,736 of the principal payment was converted into 40,934 shares of Common Stock as of March 1, 2006. Not otherwise collateralized. Convertible into Common Stock at \$4.00 per share at the option of the holder. | 725,493             | 1,097,112          |
| Note payable to 1st International Bank for \$2,500,000. The proceeds from the loan paid off the remaining \$475,000 of a revolving credit agreement and funded a warehouse and related infrastructure. Payments were interest only during the first 12 months. After 12 months, payments are based on a 20-year amortization with a five-year maturity on March 29, 2010. The interest rate at December 31, 2009 was 4.25% and was based on the amount of funds kept on deposit with the bank. Accordingly, interest varied from the Wall Street Journal Prime Rate (the "WSJPR") to the WSJPR plus 1%, with floors that may have ranged from 4.25% to 6.50%. Compensating balances at 1st International affecting the interest rate ranged from \$0 to \$500,000. The note was secured by the Company's land and buildings.   |                     | 2,141,998          |
| Note payable to GMAC. Sixty (60) monthly payments at \$427. Interest was zero percent. Collateralized by a 2005 Chevrolet van.   |                     | 3,762              |
| Note payable to DaimlerChrysler Services North America LLC. Sixty (60) monthly payments at \$1,009. Interest was 5.49%. Collateralized by a 2005 Freightliner truck.   | 4,824,071           | 1,005<br>7,453,485 |
| Less: current portion  | (519,611)           | (2,628,652)        |
|  | \$ 4,304,460        | \$ 4,824,833       |

The aggregate maturities of long-term debt as of December 31, 2010, are as follows:

|      |            |
|------|------------|
| 2011 | \$ 519,611 |
| 2012 | 447,755    |
| 2013 | 132,504    |
| 2014 | 140,862    |



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|            |    |           |
|------------|----|-----------|
| 2015       |    | 149,744   |
| Thereafter |    | 3,433,595 |
|            | \$ | 4,824,071 |

**8. COMMITMENTS AND CONTINGENCIES**

In June 2010, Becton Dickinson and Company ( BD ) filed an appeal in the U.S. Court of Appeals for the Federal Circuit appealing a final judgment entered on May 19, 2010 for the Company and against BD s counterclaims in patent litigation. Such final judgment ordered that the Company recover \$5,000,000 plus prejudgment interest, and ordered a permanent injunction for BD s 1mL and 3mL Integra syringes until the expiration of certain patents. The permanent injunction was stayed for the longer of the exhaustion of the appeal of the district court s case or twelve months from May 19, 2010. Briefing for the appeal has been completed and oral argument took place March 10, 2011. At this time, a final decision by the appellate court is anticipated to occur in 2011.

In May 2010, the Company and an officer s suit against BD in the U.S. District Court for the Eastern District of Texas, Marshall Division alleging violations of antitrust acts, false advertising, product disparagement, tortious interference, and unfair competition was reopened. The Company and an officer filed a Second Amended Complaint on July 23, 2010 setting forth additional detail regarding the allegations of BD s illegal conduct. BD filed a motion to dismiss and the Court denied that motion in part and granted it in part, granting the Company the right to re-plead certain allegations by May 13, 2011. A scheduling conference was held on January 31, 2011 and a trial date was set for January 10, 2012.

In September 2007, BD and MDC Investment Holdings, Inc. ( MDC ) sued the Company in the United States District Court for the Eastern District of Texas, Texarkana Division, initially alleging that the Company is infringing two U.S. patents of MDC (6,179,812 and 7,090,656) that are licensed to BD. BD and MDC seek injunctive relief and unspecified damages. The Company counterclaimed for declarations of non-infringement, invalidity, and unenforceability of the asserted patents. The plaintiffs subsequently dropped allegations with regard to patent no. 7,090,656 and the Company subsequently dropped its counterclaims for unenforceability of the asserted patents. The Court conducted a claims construction hearing on September 25, 2008 and issued its claims construction order on November 14, 2008. A trial date has been set for February 14, 2012.

In 2011, the Company purchased molding machines to expand its in-house molding capability and further reduce costs. Financing was completed in the second quarter of 2011 for three molding machines. The purchase and financing for a fourth molding machine is expected to be completed in 2011.

**Operating Leases**

During 2010, the Company entered into a non-cancellable operating lease for additional office space. Rent expense under this lease was \$3,495 in 2010. Future annual minimum rental payments as of December 31, 2010 are presented below:

|      |    |        |
|------|----|--------|
| 2011 | \$ | 59,194 |
|------|----|--------|

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|            |    |         |
|------------|----|---------|
| 2012       |    | 60,400  |
| 2013       |    | 61,607  |
| 2014       |    | 62,813  |
| 2015       |    | 59,966  |
| Thereafter |    |         |
| Total      | \$ | 303,980 |

**9. INCOME TAXES**

The provision for income taxes consists of the following:

|  | <b>For the Years Ended December 31,</b> |                |             |
|--|---|----------------|-------------|
|  | <b>2010</b>                             | <b>2009</b>    | <b>2008</b> |
| Current tax provision (benefit)        |   |                |             |
| Federal                                | \$ (204,507)                            | \$ (3,655,637) | \$          |
| State                                  | 28,450                                  | (181,953)      |             |
| Total current provision (benefit)      | (176,057)                               | (3,837,590)    |             |
| Deferred tax provision (benefit)       |   |                |             |
| Federal                                |   |                |             |
| State                                  |   |                |             |
| Total deferred tax provision (benefit) |   |                |             |
| Total income tax provision (benefit)   | \$ (176,057)                            | \$ (3,837,590) | \$          |

The Company recognized a tax benefit in 2009 primarily due to net operating losses incurred in 2009.

The Company recognized a net tax benefit due to an additional refund for net operating losses in 2009 mitigated by Alternative Minimum Tax in 2010.

The Company has \$11,150,486 in tax benefits attributable to carryback losses for federal tax purposes. The loss carryforwards will begin to expire in 2027 for federal tax purposes and will begin to expire for state tax purposes in 2012.

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Deferred taxes are provided for those items reported in different periods for income tax and financial reporting purposes. The tax effects of temporary differences that give rise to significant portions of the deferred tax assets and liabilities are presented below:

|                                       | <b>December 31,</b> |              |
|---------------------------------------|---------------------|--------------|
|                                       | <b>2010</b>         | <b>2009</b>  |
| Deferred tax assets                   |                     |              |
| Net operating loss carryforwards      | \$ 4,228,826        | \$ 5,414,579 |
| Accrued expenses and reserves         | 907,624             | 1,045,120    |
| Employee stock option expense         | 682,810             | 422,476      |
| Inventory                             | 385,856             | 242,807      |
| Non-employee stock option expense     | 81,310              | 183,570      |
| Charitable contribution carryforwards | 26,164              | 26,164       |
| Deferred tax assets                   | 6,312,590           | 7,334,716    |
| Deferred tax liabilities              |                     |              |
| Property and equipment                | (869,908)           | (687,512)    |
| Deferred tax liabilities              | (869,908)           | (687,512)    |
| Net deferred assets                   | 5,442,682           | 6,647,204    |
| Valuation allowance                   | (5,442,682)         | (6,647,204)  |
| Net deferred tax liabilities          | \$                  | \$           |

A reconciliation of income taxes based on the federal statutory rate and the provision (benefit) for income taxes is summarized as follows:

|  | <b>December 31,</b> |             |             |
|--|---------------------|-------------|-------------|
|  | <b>2010</b>         | <b>2009</b> | <b>2008</b> |
| Income tax (benefit) at the federal statutory rate               | 35.0%               | (35.0)%     | (35.0)%     |
| State tax (benefit), net of federal (benefit)                    | 2.9                 | (2.9)       | (2.9)       |
| Increase in valuation allowance                                  |                     | 4.6         | 32.1        |
| Permanent differences  | 9.1                 | 3.0         | 0.4         |
| Cancellation of options under Exchange Offer                     |                     |             | 5.4         |
| Return to accrual adjustments                                    | (15.0)              | (0.3)       |             |
| Alternative minimum tax  | 5.8                 |             |             |
| Release of valuation allowance - Net operating loss carryforward | (45.2)              |             |             |
| Other  | (0.5)               | 1.6         |             |
| Effective tax (benefit) rate                                     | (7.9)%              | (29.0)%     | %           |



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The Company files income tax returns in the U.S. federal jurisdiction and in various state and local jurisdictions. The Company's federal income tax returns for all tax years ended on or after December 31, 2007, remain subject to examination by the Internal Revenue Service. The Company's state and local income tax returns are subject to examination by the respective state and local authorities over various statutes of limitations, most ranging from three to five years from the date of filing.

**10. STOCKHOLDERS EQUITY**

**Preferred Stock**

The Company has one class of Preferred Stock outstanding: Class B Convertible Preferred Stock ( Class B Stock ). The Class B Stock has five series: Series I, Series II, Series III, Series IV, and Series V.

Class B

The Company has authorized 5,000,000 shares of \$1 par value Class B Stock which have been allocated among Series I, II, III, IV, and V in the amounts of 144,000; 219,700; 130,245; 552,500; and 1,232,571 shares, respectively as of December 31, 2010. The remaining 2,720,984 authorized shares have not been assigned a series.

Series I Class B

There were 144,000 shares of \$1 par value Series I Class B Convertible Preferred Stock ( Series I Class B Stock ) outstanding at December 31, 2010 and 2009. Holders of Series I Class B Stock are entitled to receive a cumulative annual dividend of \$.50 per share, payable quarterly if declared by the Board of Directors. In 2010, the Company paid \$216,000 in dividends. At December 31, 2010 and 2009 approximately \$36,000 and \$180,000, respectively, of dividends which had not been declared were in arrears.

Series I Class B Stock is redeemable after three years from the date of issuance at the option of the Company at a price of \$7.50 per share, plus all accrued and unpaid dividends. Each share of Series I Class B Stock may, at the option of the stockholder, be converted to one share of Common Stock after three years from the date of issuance or in the event the Company files an initial registration statement under the Securities Act of 1933. Pursuant to these terms, no shares of Series I Class B Stock were converted into Common Stock in 2010. In the event of voluntary or involuntary dissolution, liquidation, or winding up of the Company, holders of Series I Class B Stock then outstanding are entitled to \$6.25 per share, plus all accrued and unpaid dividends prior to any distributions to holders of Series II Class B Convertible Preferred Stock ( Series II Class B Stock ), Series III Class B Convertible Preferred Stock ( Series III Class B Stock ), Series IV Class B Convertible Preferred Stock ( Series IV Class B Stock ), Series V Class B Convertible Preferred Stock ( Series V Class B Stock ), or Common Stock.

Series II Class B

There were 219,700 shares of \$1 par value Series II Class B Stock outstanding at December 31, 2010 and 2009. Holders of Series II Class B Stock are entitled to receive a cumulative annual dividend of \$1.00 per share, payable quarterly if declared by the Board of Directors. Holders of Series II Class B Stock generally have no voting rights until dividends are in arrears and unpaid for twelve consecutive quarters. In such case, the holders of Series II Class B Stock have the right to elect one-third of the Board of Directors of the Company. In 2010, the Company paid \$660,566 in dividends. At December 31, 2010 and 2009, approximately \$110,000 and \$551,000 respectively, of dividends which had not been declared were in arrears.

Series II Class B Stock is redeemable after three years from the date of issuance at the option of the Company at a price of \$15.00 per share plus all accrued and unpaid dividends. Each share of Series II Class B Stock may, at the option of the stockholder, be converted to one share of Common Stock after three years from the date of issuance or in the event the Company files an initial registration statement under the Securities Act of 1933. Pursuant to these terms, no shares of Series II Class B Stock were converted into Common Stock in

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2010. In the event of voluntary or involuntary dissolution, liquidation, or winding up of the Company, holders of Series II Class B Stock then outstanding are entitled to \$12.50 per share, plus all accrued and unpaid dividends, after distribution obligations to holders of Series I Class B Stock have been satisfied and prior to any distributions to holders of Series III Class B Stock, Series IV Class B Stock, Series V Class B Stock, or Common Stock.

Series III Class B

There were 130,245 shares of \$1 par value Series III Class B Stock outstanding at December 31, 2010 and 2009. Holders of Series III Class B Stock are entitled to receive a cumulative annual dividend of \$1.00 per share, payable quarterly if declared by the Board of Directors. At December 31, 2010 and 2009, approximately \$3,376,000 and \$3,246,000, respectively, of dividends which have not been declared were in arrears.

Series III Class B Stock is redeemable after three years from the date of issuance at the option of the Company at a price of \$15.00 per share, plus all accrued and unpaid dividends. Each share of Series III Class B Stock may, at the option of the stockholder, be converted to one share of Common Stock after three years from the date of issuance or in the event the Company files an initial registration statement under the Securities Act of 1933. Pursuant to these terms, no shares of Series III Class B Stock were converted into Common Stock in 2010. In the event of voluntary or involuntary dissolution, liquidation, or winding up of the Company, holders of Series III Class B Stock then outstanding are entitled to \$12.50 per share, plus all accrued and unpaid dividends, after distribution obligations to Series I Class B Stock and Series II Class B Stock have been satisfied and prior to any distributions to holders of Series IV Class B Stock, Series V Class B Stock, or Common Stock.

Series IV Class B

There were 552,500 shares of \$1 par value Series IV Class B Stock outstanding at December 31, 2010 and 2009. Holders of Series IV Class B Stock are entitled to receive a cumulative annual dividend of \$1.00 per share, payable quarterly, if declared by the Board of Directors. Holders of Series IV Class B Stock generally have no voting rights. At December 31, 2010 and 2009, approximately \$5,982,000 and \$7,583,000, respectively, of dividends which have not been declared were in arrears.

Series IV Class B Stock is redeemable after three years from the date of issuance at the option of the Company at a price of \$11.00 per share plus all accrued and unpaid dividends. Each share of Series IV Class B Stock may, at the option of the stockholder any time subsequent to three years from date of issuance, be converted into one share of Common Stock, or in the event the Company files an initial registration statement under the Securities Act of 1933. Pursuant to these terms, no shares of Series IV Class B Stock were converted into Common Stock in 2010. In the event of voluntary or involuntary liquidation, dissolution, or winding up of the Company, holders of Series IV Class B Stock then outstanding are entitled to receive liquidating distributions of \$11.00 per share, plus accrued and unpaid dividends after distribution obligations to Series I Class B Stock, Series II Class B Stock, and Series III Class B Stock have been satisfied and prior to any distribution to holders of Series V Class B Stock, or Common Stock.

Series V Class B

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There were 1,232,571 and 1,238,821 shares of \$1 par value Series V Class B Stock outstanding at December 31, 2010 and 2009, respectively. Holders of Series V Class B Stock are entitled to receive a cumulative annual dividend of \$0.32 per share, payable quarterly, if declared by the Board of Directors. Holders of Series V Class B Stock generally have no voting rights. At December 31, 2010 and 2009, approximately \$4,090,000 and \$3,693,000, respectively, of dividends which have not been declared were in arrears.

Series V Class B Stock is redeemable after two years from the date of issuance at the option of the Company at a price of \$4.40 per share plus all accrued and unpaid dividends. Each share of Series V Class B Stock may, at the option of the stockholder any time subsequent to the date of issuance, be converted into Common Stock. Pursuant to the terms of the certificate of designation, 6,250 shares of Series V Class B Stock were

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converted into Common Stock in 2010. In the event of voluntary or involuntary liquidation, dissolution, or winding up of the Company, holders of Series V Class B Stock then outstanding are entitled to receive liquidating distributions of \$4.40 per share, plus accrued and unpaid dividends after distribution obligations to Series I Class B Stock, Series II Class B Stock, Series III Class B Stock, and Series IV Class B Stock have been satisfied and prior to any distribution to the holders of the Common Stock.

**Common stock**

The Company is authorized to issue 100,000,000 shares of no par value Common Stock, of which 23,974,114 and 23,825,149 shares were issued and outstanding at December 31, 2010 and 2009, respectively.

**11. RELATED PARTY TRANSACTIONS**

The Company has a license agreement with the Chief Executive Officer of the Company. See Note 5.

During the years ended December 31, 2010, 2009, and 2008, the Company paid \$75,831; \$50,793; and \$40,191, respectively, to family members of its Chief Executive Officer for various consulting services.

During the years ended December 31, 2010, 2009, and 2008, the Company paid \$20,350, \$9,940; and \$20,875, respectively, to a Director's company for participating in clinical trials.

**12. STOCK OPTIONS**

**Stock options**

A 2008 Stock Option Plan was approved for the granting of stock options to employees, Directors, and consultants. During 1999, the Company approved the 1999 Stock Option Plan. Options for the purchase of 25,680 shares of Common Stock granted under the 1999 Stock Option Plan are outstanding. The 1999 Stock Option Plan terminated pursuant to its terms in 2009. The 2008 Plan is the only plan with stock options currently being awarded. The Company has reserved an aggregate 3,000,000 shares of Common Stock for issuance upon the exercise of options under the 2008 Stock Option Plan. Of this amount, options for the purchase of 2,849,108 shares have been issued.

On September 26, 2008, the Company conducted an Exchange Offer whereby employees, including executive officers, and Directors exchanged certain outstanding underwater options for options issued under the 2008 Stock Option Plan. The Company issued new options under the 2008

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Stock Option Plan to purchase an aggregate of 962,683 shares of Common Stock in exchange for the cancellation of the tendered options. Options issued to employees vested in 2010. Options issued to non-employee Directors vested in 2009.

In July 2009, the Company issued options for the purchase of a total of 1,886,425 shares to Directors, Executive Officers, employees, and consultants under the 2008 Stock Option Plan. Of this amount, incentive stock options for the purchase of 269,956 shares of Common Stock and Non-Qualified Stock Options for the purchase of 229,494 shares of Common Stock were issued to Executive Officers and Directors. Additionally, in 2009, an option to purchase Three Million (3,000,000) shares issued to Thomas J. Shaw outside these plans was approved by shareholders.

The Compensation and Benefits Committee administers all plans and determines and/or recommends to the Board exercise prices at which options are granted. All executive compensation, including the granting of stock options, is determined by the Compensation and Benefits Committee. Shares issued upon exercise of options come from the Company's authorized but unissued Common Stock. The options vested over periods up to three years from the date of grant and generally expire ten years after the date of grant. Unvested options issued under the 2008 Stock Option Plan expire immediately after termination of employment.

### **Employee options**

A summary of Director, officer, and employee options granted and outstanding under the Plans is presented below:

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|  | Years Ended December 31, |                                 |           |                                 |             |                                 |
|--|--------------------------|---------------------------------|-----------|---------------------------------|-------------|---------------------------------|
|  | 2010                     |                                 | 2009      |                                 | 2008        |                                 |
|  | Shares                   | Weighted Average Exercise Price | Shares    | Weighted Average Exercise Price | Shares      | Weighted Average Exercise Price |
| Outstanding at beginning of period                           | 5,721,528                | \$ 0.94                         | 1,057,263 | \$ 1.99                         | 2,187,455   | \$ 8.80                         |
| Granted  |                          |                                 | 4,796,425 | 0.81                            | 962,683     | 1.30                            |
| Exercised  | (142,715)                | (0.81)                          | (5,085)   | (1.30)                          |             |                                 |
| Forfeited  | (70,300)                 | (3.09)                          | (127,075) | (4.99)                          | (2,092,875) | (8.79)                          |
| Outstanding at end of period                                 | 5,508,513                | \$ 0.91                         | 5,721,528 | \$ 0.94                         | 1,057,263   | \$ 1.99                         |
| Exercisable at end of period                                 | 5,508,513                | \$ 0.91                         | 1,137,403 | \$ 1.44                         | 147,580     | \$ 6.25                         |
| Weighted average fair value of options granted during period |                          | \$                              |           | \$ 0.59                         |             | \$ 0.76                         |

The fair value of each 2008 option grant is estimated on the date of grant using the binomial option pricing model with the following weighted average assumptions used for grants in 2008: no dividend yield; expected volatility of 67.53%; risk free interest rate of 2.83%; and an expected life of 8.61 to 8.69 years. The options were issued under the 2008 Stock Option Plan.

The fair value of each 2009 grant is estimated on the date of the grant using the Black-Scholes pricing model with the following weighted average assumptions used for grants in 2009: expected volatility of 67.53%, risk free interest rate of 3.35%, and an expected life of 8.61 to 8.69 years. Other than the options issued to the Chief Executive Officer, the options were issued under the 2008 Stock Option Plan. No options were issued in 2010.

The following table summarizes information about Director, officer, and employee options outstanding under the aforementioned plans at December 31, 2010:

| Exercise Prices | Shares Outstanding | Weighted Average Remaining Contractual Life | Shares Exercisable |
|-----------------|--------------------|---|--------------------|
| \$ 6.90         | 15,080             | 1.75  | 15,080             |
| \$ 8.65         | 2,400              | 2.48  | 2,400              |
| \$ 8.87         | 700                | 3.36  | 700                |
| \$ 1.30         | 895,213            | 7.88  | 895,213            |
| \$ 0.81         | 4,595,120          | 8.54  | 4,595,120          |

**Non-employee options**

A summary of options outstanding during the years ended December 31 and held by non-employees is as follows:

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|  | Years Ended December 31, |                                 |           |                                 |          |                                 |
|--|--------------------------|---------------------------------|-----------|---------------------------------|----------|---------------------------------|
|  | 2010                     |                                 | 2009      |                                 | 2008     |                                 |
|  | Shares                   | Weighted Average Exercise Price | Shares    | Weighted Average Exercise Price | Shares   | Weighted Average Exercise Price |
| Outstanding at beginning of period                           | 391,600                  | \$ 6.52                         | 454,700   | \$ 8.41                         | 549,700  | \$ 8.69                         |
| Granted  |                          |                                 | 90,000    | 0.84                            |          |                                 |
| Exercised  |                          |                                 | (20,000)  | (0.95)                          |          |                                 |
| Forfeited  | (89,100)                 | (10.00)                         | (133,100) | (10.00)                         | (95,000) | (10.00)                         |
| Outstanding at end of period                                 | 302,500                  | \$ 5.49                         | 391,600   | \$ 6.52                         | 454,700  | \$ 8.41                         |
| Exercisable at end of period                                 | 302,500                  | \$ 5.49                         | 391,600   | \$ 6.52                         | 454,700  | \$ 8.41                         |
| Weighted average fair value of options granted during period |                          | \$                              |           | \$ 0.61                         |          | \$                              |

The fair value of each 2009 grant is estimated on the date of the grant using the Black Scholes pricing model with the following assumptions: expected volatility of 67.53%, risk free interest rate of 3.35%, and an expected life of 8.61 years. These options were issued under the 2008 Stock Option Plan. No options were issued in 2008 or 2010.

The following table summarizes information about non-employee options outstanding under the aforementioned plans at December 31, 2010:

|    | Exercise Prices | Shares Outstanding | Weighted Average Remaining Contractual Life | Shares Exercisable |
|----|-----------------|--------------------|---|--------------------|
| \$ | 6.90            | 232,500            | 1.75  | 232,500            |
| \$ | 0.81            | 70,000             | 8.54  | 70,000             |

The Company recorded \$1,340,300; \$2,111,360; \$98,473 (offset by a credit of \$65,844 for surrendered stock options); as stock-based compensation expense in 2010, 2009, and 2008, respectively. The total intrinsic value of options exercised was \$124,221; \$16,388; and \$0 in 2010, 2009, and 2008, respectively. The aggregate intrinsic value of options outstanding and of options exercisable at December 31, 2010 was approximately \$4.8 million. The total compensation cost related to non-vested stock options to be recognized in the future was \$0 at December 31, 2010.

**Options Pricing Models Assumptions**

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The expected life and forfeiture rate assumptions are based on the vesting period for each option grant and expected exercise behavior. The assumptions for expected volatility and dividend yield are based on recent historical experience. Risk-free interest rates are set using grant-date U.S. Treasury yield curves for the same periods as the expected term.

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Table of Contents**13. 401(k) PLAN**

The Company implemented an employee savings and retirement plan (the 401(k) Plan ) in 2005 that is intended to be a tax-qualified plan covering substantially all employees. Under the terms of the 401(k) Plan, employees may elect to contribute up to 88% of their compensation, or the statutory prescribed limit, if less. The Company may, at its discretion, match employee contributions. The Company made matching contributions of \$0, \$76,643, and \$122,000 in 2010, 2009 and 2008, respectively. In the third quarter of 2009, the Company discontinued its matching contributions until further notice.

**14. BUSINESS SEGMENTS**

|  | <b>2010</b>   |    | <b>2009</b> |    | <b>2008</b> |
|--|---------------|----|-------------|----|-------------|
| U.S. sales                                     | \$ 29,577,050 | \$ | 34,466,797  | \$ | 23,244,370  |
| North and South America sales (excluding U.S.) | 4,887,073     |    | 1,764,584   |    | 937,698     |
| Other international sales                      | 1,755,439     |    | 2,750,456   |    | 3,717,250   |
| Total sales                                    | \$ 36,219,562 | \$ | 38,981,837  | \$ | 27,899,318  |
| Long-lived assets                              |               |    |             |    |             |
| U.S.   | \$ 12,297,942 | \$ | 13,961,445  | \$ | 14,435,667  |
| International                                  | \$ 262,650    | \$ | 272,736     | \$ |             |

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.

**SELECTED QUARTERLY FINANCIAL DATA - UNAUDITED**

The selected quarterly financial data for the periods ended December 31, 2010 and 2009, have been derived from the Company's unaudited financial statements and include all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the results of the interim periods.

| <b>(In thousands, except for per share and outstanding stock amounts)</b> |                  |    |                  |    |                  |    |                  |
|---|------------------|----|------------------|----|------------------|----|------------------|
| <b>2010</b>   |                  |    |                  |    |                  |    |                  |
|   | <b>Quarter 1</b> |    | <b>Quarter 2</b> |    | <b>Quarter 3</b> |    | <b>Quarter 4</b> |
| Sales, net  | \$ 8,466         | \$ | 7,449            | \$ | 12,235           | \$ | 8,070            |
| Cost of sales   | 5,015            |    | 4,624            |    | 7,018            |    | 7,042            |
| Gross profit  | 3,451            |    | 2,825            |    | 5,217            |    | 1,028            |
| Total operating expenses  | 5,635            |    | 5,854            |    | 4,185            |    | 3,511            |
| Income (loss) from operations   | (2,184)          |    | (3,029)          |    | 1,032            |    | (2,483)          |

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|   |            |            |          |            |
|---|------------|------------|----------|------------|
| Interest and other income                         | 6          | 3          | 10       | 14         |
| Interest expense, net                             | (91)       | (76)       | (70)     | (66)       |
| Litigation settlements, net                       |            |            | 7,259    | 1,900      |
| Benefit (provision) for income taxes              | (2)        | 337        |          | (158)      |
| Net income (loss)                                 | (2,271)    | (2,765)    | 8,231    | (793)      |
| Preferred stock dividend requirements             | (343)      | (343)      | (343)    | (342)      |
| Earnings (loss) applicable to common shareholders | \$ (2,614) | \$ (3,108) | \$ 7,888 | \$ (1,135) |
| Net earnings (loss) per share basic               | \$ (0.11)  | \$ (0.13)  | \$ 0.33  | \$ (0.05)  |

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|   | Quarter 1  | Quarter 2  | Quarter 3  | Quarter 4  |
|---|------------|------------|------------|------------|
| Net earnings (loss) per share diluted         | (0.11) \$  | (0.13) \$  | 0.29       | (0.05)     |
| Weighted average shares outstanding - basic   | 23,825,149 | 23,825,149 | 23,887,028 | 23,953,806 |
| Weighted average shares outstanding - diluted | 23,825,149 | 23,825,149 | 28,767,768 | 23,953,806 |
| Gross profit margin                           | 40.8%      | 37.9%      | 42.6%      | 12.7%      |

(In thousands, except for per share and outstanding stock amounts)  
2009

|   | Quarter 1  | Quarter 2  | Quarter 3  | Quarter 4  |
|---|------------|------------|------------|------------|
| Sales, net  | \$ 5,258   | \$ 5,753   | \$ 10,752  | \$ 17,219  |
| Cost of sales                                     | 4,029      | 3,413      | 7,817      | 10,207     |
| Gross profit                                      | 1,229      | 2,340      | 2,935      | 7,012      |
| Total operating expenses                          | 5,271      | 5,121      | 6,484      | 9,936      |
| Loss from operations                              | (4,042)    | (2,781)    | (3,549)    | (2,924)    |
| Interest and other income                         | 29         | 11         | 14         | 4          |
| Interest expense, net                             |            |            |            | (22)       |
| Benefit for income taxes                          | 105        |            | 100        | 3,633      |
| Net income (loss)                                 | (3,908)    | (2,770)    | (3,435)    | 691        |
| Preferred stock dividend requirements             | (343)      | (343)      | (343)      | (342)      |
| Earnings (loss) applicable to common shareholders | \$ (4,251) | \$ (3,113) | \$ (3,778) | \$ 349     |
| Net earnings (loss) per share basic and diluted   | \$ (0.18)  | \$ (0.13)  | \$ (0.16)  | \$ 0.01    |
| Weighted average shares outstanding               | 23,800,064 | 23,800,064 | 23,803,397 | 23,822,607 |
| Gross profit margin                               | 23.4%      | 40.7%      | 27.3%      | 40.7%      |

Major variances for 2010 compared to 2009 are due to lower revenues in 2010, lower operating costs (particularly litigation costs) in 2010, litigation settlement proceeds received in 2010, impairment charges taken in 2009, and income tax refunds recorded in 2009.

Table of Contents**PART III****Item 10. Directors, Executive Officers and Corporate Governance.**

The following table sets forth information concerning our Directors, executives, and certain of our significant employees as of the date of this report. Our Board of Directors consists of a total of seven (7) members, three (3) members of which are Class 1 Directors and four (4) of which are Class 2 Directors which serve for two-year terms.

| <b>Name</b>                  | <b>Age</b> | <b>Position</b>  | <b>Term as Director Expires</b> |
|------------------------------|------------|--|---------------------------------|
| <b>EXECUTIVES</b>            |            |  |                                 |
| Thomas J. Shaw               | 60         | Chairman, President, Chief Executive Officer, and Class 2 Director                                     | 2012                            |
| Douglas W. Cowan             | 67         | Vice President, Chief Financial Officer, Treasurer, Principal Accounting Officer, and Class 2 Director | 2012                            |
| Kathryn M. Duesman           | 48         | Executive Director, Global Health  | N/A                             |
| Russell B. Kuhlman           | 57         | Vice President, Sales  | N/A                             |
| Michele M. Larios            | 44         | Vice President, General Counsel, and Secretary   | N/A                             |
| Lawrence G. Salerno          | 50         | Director of Operations   | N/A                             |
| Steven R. Wisner             | 53         | Executive Vice President, Engineering & Production and Class 1 Director                                | 2011                            |
| <b>INDEPENDENT DIRECTORS</b> |            |  |                                 |
| Marco Laterza                | 63         | Class 1 Director   | 2011                            |
| Amy Mack                     | 43         | Class 1 Director   | 2011                            |
| Marwan Saker                 | 55         | Class 2 Director   | 2012                            |
| Clarence Zierhut             | 82         | Class 2 Director   | 2012                            |
| <b>SIGNIFICANT EMPLOYEES</b> |            |  |                                 |
| Shayne Blythe                | 42         | Director of Sales and Marketing Logistics  | N/A                             |
| John W. Fort III             | 42         | Director of Accounting   | N/A                             |
| James A. Hoover              | 63         | Director of Quality Assurance  | N/A                             |
| R. John Maday                | 50         | Production Manager   | N/A                             |
| Judy Ni Zhu                  | 52         | Research and Development Manager   | N/A                             |

**Executives**

Thomas J. Shaw, our Founder, has served as Chairman of the Board, President, Chief Executive Officer, and Director since our inception. We believe it is appropriate for Mr. Shaw to continue to serve as a Director and as the Chairman of the Board because of his deep knowledge of the strengths and weaknesses of our products (as their primary inventor) and of the Company (as its Founder). Further, his strategic knowledge of the Company and its competitive environment arising from his ongoing services as its CEO is vital to the successful supervision of the Company by the Board of Directors. Finally, Mr. Shaw's educational background in both Engineering and Accounting is helpful to Board deliberations. In addition to his duties overseeing our Management, he continues to lead our design team in product development of other medical safety devices that utilize, among other things, his unique patented friction ring technology. Mr. Shaw has extensive experience in industrial product design

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and has developed several solutions to complicated mechanical engineering challenges. He has been granted multiple patents and has additional patents pending.

Douglas W. Cowan is a Vice President and our Chief Financial Officer, Treasurer, Principal Accounting Officer, and a Director. Mr. Cowan joined us as Chief Financial Officer and was elected to the Board of Directors

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in 1999. We believe it is appropriate Mr. Cowan continue to serve as a Director due to his level of involvement in the financial state of the Company (as its CFO) as well as his lead role in supervising all internal control and disclosure control procedures and statements. He also serves as the primary contact for investors which enables him to bring their concerns to the Board on appropriate topics as they arise. His expertise as a CPA and experience as the Company's CFO allow him to guide the Board, upon request, with regard to financial matters. He is responsible for our financial, accounting, risk management, and forecasting functions.

Kathryn M. Duesman, RN, joined us in 1996 and currently serves as the Executive Director, Global Health. She provides clinical expertise on existing products as well as those in development. She has been instrumental in developing training and marketing materials and has spoken and been published on safety issues. Ms. Duesman works with international agencies to promote the use of safe technologies in developing countries.

Russell B. Kuhlman joined us in February 1997 and is our Vice President, Sales. Mr. Kuhlman is responsible for management of the sales force and liaison with GPOs and product training for our sales organization, as well as distribution. Mr. Kuhlman's efforts with us have resulted in bringing onboard Specialty Distributors, influencing legislation, and educating influential healthcare representatives about the benefits of our product line. Mr. Kuhlman is respected throughout the industry and is a main contributor to the safety effort in this country.

Michele M. Larios joined us in February 1998 and currently serves as our Vice President, General Counsel, and Secretary. Ms. Larios is responsible for our legal and legislative, human resource, and regulatory functions. In addition to working on legal matters and with outside counsel, Ms. Larios works with legislators on pertinent issues and relevant legislation.

Lawrence G. Salerno has been employed with us since 1995 and has served as Director of Operations for us since 1998. He is responsible for the manufacture of all our products, as well as all product development and process development projects. In addition, he supervises all aspects of the construction and expansion of our facilities in Little Elm, Texas. Mr. Salerno is the brother of a 5% shareholder (and consultant to the Company) who ceased to be a 10% shareholder in 2008.

Steven R. Wisner joined us in October 1999 as Executive Vice President, Engineering and Production and as a Director. We believe it is appropriate that Mr. Wisner continue to serve as a Director due to his extensive experience in operational management. His role in overseeing all engineering, production, and foreign sales allows him to provide timely and insightful guidance regarding the effect of Board decisions on the Company's abilities to meet its goals. Mr. Wisner's responsibilities include the management of engineering, production, Chinese operations, quality assurance, information technology, and international sales. Mr. Wisner has extensive experience in product design, development, and manufacturing.

**Independent Directors**

Marco Laterza joined us as a Director effective as of March 22, 2005. We believe it is appropriate Mr. Laterza continue to serve as a Director because of his skills as a CPA in active practice as well as his decades of experience in advising individuals and entities with regard to corporate planning and financial issues. Such skills and experience provide a valuable contribution in his role as the designated financial expert on the Audit Committee as well as provide valuable independent accounting advice to the Board. Since 1988, Mr. Laterza has owned and operated a public accounting practice. His practice includes corporate, partnership and individual taxation, compilation/review of financial statements,



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financial planning, business consulting, and trusts and estates. From 2004 to the present Mr. Laterza has also served as the Treasurer for EZ Blue Software Corporation, a private software company. Since 2009, Mr. Laterza has served as Vice President of SpectraComp, Corp., a private holding company. Formerly, Mr. Laterza was employed in a number of positions from 1977 to 1985 with El Paso Natural Gas Company eventually serving as its Director of Accounting.

Amy Mack joined us as a Director on November 19, 2007. We believe it is appropriate that Ms. Mack continue as a Board member due both to her experience as a nurse (the primary retail user of our products) as well as her experience in running her own company. Since April of 2000, she has been the Secretary of EmergiStaff & Associates, a nursing agency, in Dallas, Texas.

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Marwan Saker joined our Board of Directors in June 2000. We believe it is appropriate that Mr. Saker continue to serve as a Director due to over a decade of experience in international business as well as his specific expertise in issues relating to international distribution. Mr. Saker's experience as a business owner competing internationally provides additional necessary insight to our Board. Since 1983, Mr. Saker has served as Chief Executive Officer of Sovana, Inc., a private international trade company. Since 1986, he has served as President of International Exports & Consulting Inc., a private export management company acting as sales representative, master franchisee and franchise consultant developing Middle East markets for numerous U.S. manufacturers in agriculture, fast food, home, and contract furnishing industries. Since 1995, he has served as Manager of Hanneke Corp., a private trust. Since 2000, he has served as a Member of My Investments, LLC, a private entity. Since 2002, he has served as President of Saker Investments Inc., a private investment company. He is also President of Figland Development, a private real estate development company. Mr. Saker has acted as a representative for U.S. companies seeking distribution, licensing, and franchising in the Middle East, Europe, and North Africa. Mr. Saker was instrumental in developing successful partnerships in more than 15 countries.

Clarence Zierhut has served on our Board of Directors since April 1996. We believe it is appropriate for Mr. Zierhut to continue to serve as a Director primarily due to his lifetime of experience in conception and development of innovative products as well as his experience in adapting such products to address mass production issues. During his professional career, Mr. Zierhut has created over 3,000 product designs for more than 350 companies worldwide, in virtually every field of manufacturing, and has won many international awards for design excellence. His clients have included Johnson & Johnson, Abbott, Gould, and McDonnell Douglas.

**Significant Employees**

Shayne Blythe has been with us since 2001 and is our Director of Sales and Marketing Logistics. She is responsible for developing and implementing strategic directions, objectives, comprehensive sales and marketing plans, and programs. In addition, she directs and oversees all aspects of the distribution process and customer service policies in order to monitor and maintain customer satisfaction.

John W. Fort III is our Director of Accounting. Mr. Fort joined us in March of 2000 as a Financial Analyst and has served as our Director of Accounting since October of 2002. His primary responsibilities include managing the day-to-day operations of the Accounting and Finance Department and coordination of the annual audits, and interim reviews by our independent accountants, as well as our cost accounting and forecasting functions.

James A. Hoover joined us in February 1996 and is our Director of Quality Assurance. Prior to his becoming Director of Quality Assurance he was Production Manager. He is responsible for our quality assurance functions. Mr. Hoover has also developed and implemented FDA required procedures and has been involved in the FDA inspection process.

R. John Maday joined us in July 1999 and is our Production Manager. He is responsible for supervision of the production of our products. Prior to becoming Production Manager on January 1, 2005, he served as our Production General Supervisor. Mr. Maday has extensive manufacturing experience in both class II and III medical devices.

Judy Ni Zhu joined us in 1995 and is our Research and Development Manager. Her primary focus is on new product development and improvement of current products. Prior to joining us, Ms. Zhu worked as a design engineer with Mr. Shaw on the original 3mL syringe and

other SBIR grant projects.

FAMILY RELATIONSHIPS

There are no family relationships among the above persons except as set forth above.

DIRECTORSHIPS IN OTHER COMPANIES

No Directors hold directorships in reporting companies.

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INVOLVEMENT IN CERTAIN LEGAL PROCEEDINGS

None of the above persons or any business in which such person was an executive officer have been involved in a bankruptcy petition, been subject to a criminal proceeding (excluding traffic violations and other minor offenses), been subject to any order enjoining or suspending their involvement in any type of business, or been party to an alleged violation of a securities law, commodities law, law or regulation respecting financial institutions or insurance companies, law or regulation prohibiting mail or wire fraud, or rules of any organization that has disciplinary authority over its members.

SECTION 16(a) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Section 16 of the Exchange Act requires our Directors, executive officers, and persons who own more than 10% of a registered class of our equity securities to file with the SEC initial reports of beneficial ownership (Form 3) and reports of changes in beneficial ownership (Forms 4 and 5) of our Common Stock and our other equity securities. Officers, Directors, and greater than 10% shareholders are required by the SEC's regulations to furnish us with copies of all Section 16(a) reports they file. Two shareholders each failed to timely file a beneficial ownership report. On February 22, 2011, Steven R. Wisner filed a late Form 5 relating to a transaction on December 2, 2010. On March 2, 2011, Suzanne M. August filed a late Form 4 relating to a transaction on October 28, 2009.

CODE OF ETHICS

Effective as of March 9, 2004, we adopted a code of ethics that applies to all employees, including, but not limited to, our principal executive and financial officers. Our Code of Business Conduct and Ethics is designed to deter wrongdoing and to promote:

1. Honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interests between personal and professional relationships;
2. Full, fair, accurate, timely, and understandable disclosure in reports and documents that we file with, or submit to, the SEC and in our other public communications;
3. Compliance with applicable governmental laws, rules, and regulations;
4. The prompt, internal reporting of violations of the code to an appropriate person or persons identified in the code; and
5. Accountability for adherence to the code.

A copy of the code, as amended in 2009, is incorporated herein as Exhibit No. 14. We have posted a copy of the code on our website at [www.vanishpoint.com/investor.asp](http://www.vanishpoint.com/investor.asp). Please follow the link to Governance then follow the link to Charters, then click on RVP Corporate Code of Conduct. Any amendment to this code or waiver of its application to the principal executive officer, principal financial officer, principal accounting officer, or controller or similar person shall be disclosed to investors by means of a Form 8-K filing with the SEC. We will provide to any person without charge, upon request, a copy of such code of ethics. Such requests should be submitted in writing to Mr. Douglas W.

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Cowan at 511 Lobo Lane, P.O. Box 9, Little Elm, Texas 75068-0009.

AUDIT COMMITTEE

We have a separately-designated standing Audit Committee established in accordance with Section 3(a)(58)(A) of the Exchange Act consisting of Clarence Zierhut, Marco Laterza, and Marwan Saker. Each of the members of the Audit Committee is independent as determined by the NYSE Amex rules.

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Audit Committee Financial Expert

The Board of Directors has determined that we have at least one financial expert serving on the Audit Committee. Mr. Marco Laterza serves as our designated Audit Committee Financial Expert. Mr. Laterza is independent as defined for Audit Committee members by the listing standards of the NYSE Amex.

**PART IV**

**Item 15. Exhibits, Financial Statement Schedules.**

(b) Exhibits

| <b>Exhibit No.</b> | <b>Description of Document</b>                           |
|--------------------|--|
| 23                 | Consent of Independent Registered Public Accounting Firm |
| 31.1               | Certification of Principal Executive Officer             |
| 31.2               | Certification of Principal Financial Officer             |
| 32                 | Section 1350 Certifications                              |

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**SIGNATURE**

Pursuant to the requirements of Section 13 or 15(d) 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.

RETRACTABLE TECHNOLOGIES, INC.  
(Registrant)

By: /s/ Thomas J. Shaw  
THOMAS J. SHAW  
CHAIRMAN, PRESIDENT, AND  
CHIEF EXECUTIVE OFFICER

Date: June 9, 2011