

RETRACTABLE TECHNOLOGIES INC  
Form 10-K  
March 30, 2012  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-K**

(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, 2011

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)

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**Texas**  
(State or other jurisdiction of  
incorporation or organization)

**75-2599762**  
(I.R.S. Employer  
Identification No.)

**511 Lobo Lane**  
**Little Elm, Texas**  
(Address of principal executive offices)

**75068-0009**  
(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**  
**Common**

**Name of each exchange on which registered**  
**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

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 this Form 10-K or any amendment to this Form 10-K.

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Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer, and smaller reporting company in Rule 12b-2 of the Exchange Act:

Large accelerated filer

Accelerated filer

Non-accelerated filer   
(Do not check if a smaller reporting company)

Smaller reporting company

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, 2011 was \$21,060,744, assuming a closing price of \$1.54 and outstanding shares held by non-affiliates of 13,675,808.

### 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 March 1, 2012, there were 25,318,700 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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RETRACTABLE TECHNOLOGIES, INC.

FORM 10-K

For the Fiscal Year Ended December 31, 2011

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**PART I**

FORWARD-LOOKING STATEMENT WARNING

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

**Item 1. Business.**

DESCRIPTION OF BUSINESS

General Development of Business

On May 9, 1994, our company was incorporated in Texas to design, develop, manufacture, and market innovative patented safety medical products for the healthcare industry.

Our goal is to become a leading provider of safety medical products.

Advantages of our VanishPoint® safety products include protection from needlestick injuries, prevention of cross contamination through reuse, and reduction of disposal and other associated costs. Federal regulation now requires the use of safe needle devices. We have developed and are developing new safety medical products, some of which do not utilize our patented retraction technology.

Our VanishPoint® safety products (consisting of 1mL tuberculin, insulin, and allergy antigen VanishPoint® syringes; 0.5mL, 2mL, 3mL, 5mL, and 10mL VanishPoint® syringes; the VanishPoint® blood collection tube holder; autodisable syringe; and the VanishPoint® IV safety catheter) utilize a unique friction ring mechanism patented by Thomas J. Shaw, our Founder, President, and Chief Executive Officer. VanishPoint® safety needle products are designed specifically to prevent needlestick injuries and to prevent reuse. The friction ring mechanism

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permits the automated retraction of the needle into the barrel of the syringe, directly from the patient, after delivery of the medication is completed. The VanishPoint® blood collection tube holder utilizes the same mechanism to retract the needle after blood has been drawn from the patient. Closure of an attached end cap of the blood collection tube holder causes the needle to retract directly from the patient into the closed blood collection tube holder. The IV safety catheter also operates with a friction ring mechanism whereby the needle is retracted after insertion of the catheter into the patient. We also have a Patient Safe® syringe which is uniquely designed to reduce the risk of bloodstream infections resulting from catheter hub contamination.

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 Becton, Dickinson and Company ( BD ) which dominates our market. We initiated a lawsuit in 2007 against BD. The suit was for patent infringement, antitrust practices, and false advertising. The court severed the patent claims from the other claims pending resolution of the patent dispute. In May 2010, the Court determined that BD s Integra products infringed our patents, but the Court s injunction was stayed pending appeal, so the products remain in the market at this time. However, BD voluntarily removed its 1mL syringes from the market. The portion of the suit regarding antitrust and other claims was scheduled to be tried in February 2012; however, in January 2012 the parties agreed to a continuance. Trial is currently anticipated to be scheduled in fall 2012.

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During the last two quarters of 2011, we purchased four new molding machines which provide us with the capability to manufacture all piece parts for our VanishPoint® syringes at our plant in Little Elm. We expect to reduce our unit cost of manufacture.

We continue to attempt to gain access to the market through our sales efforts, our innovative technology, 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.

Effective July 12, 2010, we entered into a settlement agreement with Abbott Laboratories ( Abbott ) and Hospira, Inc. ( Hospira ). In connection with this settlement agreement, we granted Hospira an exclusive one-year option to negotiate a licensing agreement for certain uses of our Patient Safe® syringe. This option expired unexercised in July 2011. We have received the total \$8 million option payment. As part of the settlement, in the third quarter of 2010, Hospira paid us \$6 million and forgave a marketing fee of \$1.4 million. The settlement was reduced by an outstanding invoice due to us for \$144 thousand.

On September 12, 2011, we commenced an offer to purchase all outstanding Class B Convertible Preferred Stock (the Preferred Stock ) for cash and Common Stock (the 2011 Exchange Offer ). As of November 4, 2011, the expiration date of the 2011 Exchange Offer, Preferred Stockholders had tendered a total of 1,246,964 shares of Preferred Stock. A total of \$1,308,275 and 1,246,964 shares of Common Stock were issued as consideration to participating Preferred Stockholders pursuant to the 2011 Exchange Offer. In accordance with the terms of the 2011 Exchange Offer, participating Preferred Stockholders agreed to waive all unpaid dividends in arrears associated with their tendered Preferred Stock, which resulted in a waiver of a total of \$3,539,714 in unpaid dividends in arrears. During the quarter ended December 31, 2011, we engaged in private sales with three Preferred Stockholders which tendered a total of 30,500 shares of Preferred Stock. A total of \$49,000 and 30,500 shares of Common Stock were issued as consideration to the three Preferred Stockholders. In accordance with the terms of the private sales, the three Preferred Stockholders agreed to waive all unpaid dividends in arrears associated with their tendered Preferred Stock, which resulted in a waiver of a total of \$97,079 in unpaid dividends in arrears.

## Financial Information

Please see the financial statements in **Item 8 Financial Statements and Supplementary Data** for information about our revenues, profits and losses for the last three years, and total assets for the last two years.

## Principal Products

Our products with Notice of Substantial Equivalence to the U.S. Food and Drug Administration ( FDA ) and which are currently sold include the 1mL tuberculin; insulin; allergy antigen VanishPoint® syringes; 2mL, 3mL, 5mL, and 10mL VanishPoint® syringes; the VanishPoint® blood collection tube holder; the VanishPoint® IV safety catheter; small diameter tube adapter; the Patient Safe® syringe; and the Patient Safe® Luer Cap. We are also selling autodisable syringes in the international market in addition to our other products.

In the August 2007 issue of *Health Devices*, ECRI listed the VanishPoint® syringe as one of two syringes with the highest possible rating.



Syringe sales comprised 98.9%; 97.3%; and 97.2% of revenues in 2009, 2010, and 2011.

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Principal Markets

Our products are sold to and used by healthcare providers primarily in the U.S. (with 17.0% of revenues in 2011 generated from sales outside the U.S.) which include, but are not limited to, acute care hospitals, alternate care facilities, doctors' offices, clinics, emergency centers, surgical centers, convalescent hospitals, Veterans Administration facilities, military organizations, public health facilities, and prisons.

The need to change to safety devices is due to the risk that is carried with each needlestick injury which includes the potential transmission of over 20 bloodborne pathogens, including the human immunodeficiency virus ( HIV, which causes AIDS), hepatitis B, and hepatitis C. Because of the occupational and public health hazards posed by conventional disposable syringes, public health policy makers, domestic organizations, and government agencies have been involved in the effort to get more effective safety needle products to healthcare workers. Federal legislation was signed into law on November 6, 2000, by former President William Jefferson Clinton. This legislation, which became effective for most states on April 12, 2001, now requires safety needle products be used for the vast majority of procedures. However, even with this requirement, hospitals are neglecting to follow the law intended to protect healthcare workers.

Methods of Marketing and Distribution

Under the current supply chain system in the U.S. acute care market, the vast majority of decisions relating to the contracting for and purchasing of medical supplies are made by the representatives of group purchasing organizations ( GPOs ) rather than the end-users of the product (nurses, doctors, and testing personnel). The GPOs and large manufacturers often enter into contracts which can prohibit or limit entry in the marketplace by competitors.

We distribute our products throughout the U.S. and its territories through general line and specialty distributors. We also utilize international distributors. We have developed a national direct marketing network in order to market our products to health care customers and their purchaser representatives. Our marketers make contact with all of the departments that affect the decision-making process for safety products, including the purchasing agents. They call on acute care and alternate care sites and speak directly with the decision-makers of these facilities. We employ trained clinicians, including registered nurses and/or medical technologists that educate healthcare providers and healthcare workers on the use of safety devices through on-site clinical training, exhibits at related tradeshows, and publications of relevant articles in trade journals and magazines. These nurses provide clinical support to customers. In addition to marketing our products, the network demonstrates the safety and cost effectiveness of the VanishPoint® automated retraction products to customers.

In the needle and syringe market, the market share leader, BD, has utilized, among other things, contracts which have restricted our entry into the market. Other needle related products manufactured by us that are being denied market access as a result of BD's anti-competitive actions include the IV safety catheters and blood collection tube holders.

We have numerous agreements with organizations for the distribution of our products in foreign markets. In Canada, the provinces of Alberta, Manitoba, Ontario, and Saskatchewan have passed laws or regulations regarding healthcare worker safety and the use of safe needle products. In Europe, the European Council adopted a directive requiring the use of safe needle products in EU countries to prevent needlestick injuries. Brazil is the only country in Latin America that has initiated a regulation requiring the use of safe needle products to prevent needlestick injuries. The Australian states of New South Wales, Queensland, and Victoria have guidelines or directives regarding the prevention of

needlestick injuries.

Key components of our strategy to increase our market share are to: (a) defeat monopolistic practices through litigation; (b) focus on methods of upgrading our manufacturing capability and efficiency in order to enable us to reduce costs and improve profit margins; (c) continue marketing emphasis in the U.S.; (d) continue to add Veterans Administration facilities, health departments, emergency medical services, federal prisons, long-term care, and home healthcare facilities as customers; (e) educate healthcare providers, insurers, healthcare workers, government agencies, government officials, and the general public on the reduction of risk and the cost effectiveness afforded by our products; (f) supply product through GPOs and Integrated Delivery Networks where possible; (g)

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consider possibilities for future licensing agreements and joint venture agreements for the manufacture and distribution of safety products in the U.S. and abroad; (h) introduce new products; and (i) increase international sales.

Status of Publicly Announced New Products

We have applied for patent protection and are in the process of developing additional safety medical products which have yet to be announced.

Sources and Availability of Raw Materials

We purchase most of our product components from single suppliers, including needle adhesives and packaging materials. There are multiple sources of these materials. We own the molds that are used to manufacture the plastic components of our products in the U.S. Our current suppliers include Magor Mold, Inc., Channel Prime Alliance, Exacto Spring Corporation, Sterigenics, and Kovacmed.

Patents, Trademarks, Licenses, and Proprietary Rights

We and Thomas J. Shaw, our Founder and CEO, entered into a Technology License Agreement dated effective as of the 23rd day of June 1995 (the Technology License Agreement), whereby Mr. Shaw granted us a worldwide exclusive license and right under the Licensed Patents and Information, to manufacture, market, sell and distribute Licensed Products and Improvements without right to sublicense and subject to such nonexclusive rights as may be possessed by the Federal Government. Licensed Patents, Information, Licensed Products, and Improvements all defined extensively in the Technology License Agreement. We may enter into sublicensing arrangements with Mr. Shaw's written approval of the terms and conditions of the licensing agreement. The Licensed Products include all retractable syringes and retractable fluid sampling devices and components thereof, assembled or unassembled, which comprise an invention described in Licensed Patents, and improvements thereto including any and all Products which employ the inventive concept disclosed or claimed in the Licensed Patents. We and Mr. Shaw entered into the First Amendment to Technology Agreement July 3, 2008, whereby we amended the Technology License Agreement in order to include certain additional patent applications (addressing non-syringe patents) owned by Mr. Shaw to the definition of Patent Properties as set forth in the Technology License Agreement so that such additional patent applications would be covered by the license granted by Mr. Shaw to us.

In exchange for the Technology License Agreement, we negotiated a licensing fee and agreed to pay a 5% royalty on gross sales after returns. The license terminates upon expiration of the last licensed patents unless sooner terminated under certain circumstances. The licensing fees have been paid in accordance with this agreement with the exception of \$1,500,000 in fees which were waived in 2002 and \$1,000,000 in fees which were waived in 2009.

We have the right and obligation to obtain protection of the inventions, including prosecution of patent properties. The license unilaterally changes to a nonexclusive license in the event of a hostile takeover. Also, if Mr. Shaw involuntarily loses control of the Company, the license becomes a nonexclusive license and a right to information.

We seek foreign patent protection through the Patent Cooperation Treaty and have filed applications for regional and national patent protection in selected countries where we believe our products can be utilized most.

We hold numerous U.S. patents related to our automated retraction technology, including patents for IV safety catheters, winged IV sets, syringes, dental syringes, and blood collection tube holders. In addition, we have multiple applications for patents currently pending. The initial revolutionary spring action syringe patents will expire beginning in May 2015. However, a significant patent will not expire until August 2016. We have also registered the following trade names and trademarks: VanishPoint®, VanishPoint® logos, RT with a circle mark, the Spiral Logo used in packaging our products, and the color coded spots on the ends of our syringes. We also have trademark protection for the phrase The New Standard for Safety.

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We are involved in patent litigation detailed in **Item 3. Legal Proceedings**. We have decided, on the advice of patent counsel, not to purchase patent insurance because it would require inappropriate disclosure of information that is currently proprietary and confidential.

In 2011 we obtained roughly 67.1% of our finished products through Double Dove, a Chinese manufacturer. 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 0.5mL, autodisable, 5mL, and 10mL syringes which comprised about 9.1% of our 2011 revenues.

Seasonality

Historically, unit sales have increased in the latter part of the year due, in part, to the demand for syringes during the flu season. In the third quarter of 2009, we were awarded a contract by the Department of Health and Human Services ( DHHS ) to supply a portion of the safety engineered syringes to be used in the U.S. efforts to vaccinate the U.S. population against the swine flu. The impact on us was material in 2009. Sales to the DHHS comprised 24.4% of our revenues for the twelve months ended December 31, 2009.

Working Capital Practices

Cash and cash equivalents include unrestricted cash and investments with original maturities of three months or less.

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.

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.

Receivables are established for federal and state taxes where we have determined we are entitled to a refund for overpayments of estimated taxes or loss carrybacks.

Accounts payable and other short-term liabilities include amounts that we believe we have an obligation for at the end of year. These included charges for goods or services received in 2011 but not billed to us at the end of the year. It also included estimates of potential liabilities such as

rebates and other fees.

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 generally provides that a customer may return product that is overstocked. Overstocking returns are limited to two times in each 12 month period up to 1% of distributor's total purchase of products for the prior 12 month period upon the following terms: i) an overstocked product is that portion of distributor's inventory of the product which exceeds distributor's sales volume for the product during the preceding four months; ii) distributor must not have taken delivery of the product which is overstocked during the preceding four months; iii) overstocked product held by distributor in excess of 12 months from the date of original invoice will not be eligible for return; iv) the product must have an expiration date of at least 24 months from the date of return; v) the overstocked product must be returned to us in our saleable case cartons which are unopened and

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untampered, with no broken or re-taped seals; vi) distributor will be granted a credit which may be used only to purchase other products from us, the credit to be in the amount of the invoice price of the returned product less a 10% restocking fee which will be assessed against distributor's subsequent purchase of product; vii) distributor must obtain an authorization code from our distribution department and affix the code to the returned product; and viii) distributor shall bear the cost of shipping the returned products to us. All product overstocks and returns are subject to inspection and acceptance by us.

Our international contracts do not provide for any returns.

Dependence on Major Customers

Four customers accounted for an aggregate of 50.6% of our revenue in 2011. We have numerous other customers and distributors that sell our products in the U.S. and internationally.

Backlog Orders

Order backlog is not material to our business inasmuch as orders for our products generally are received and filled on a current basis, except for items temporarily out of stock.

Government Funding of Research and Right to License

Thomas J. Shaw developed his initial version of a safety syringe with the aid of grants by the National Institute of Drug Abuse, a subsidiary of the National Institutes of Health. As a result, the federal government has the right, where the public interest justifies it, to disperse the technology to multiple manufacturers so that this early version of a safety syringe could be made widely available to the public. However, the earlier design of 1991 was a bulkier, less effective, and more expensive version of the current VanishPoint® syringe product. Accordingly, Management believes that the risk of the government demanding manufacture of this alternative product is minimal. The VanishPoint® syringe design was only partly funded with grant money and the product, as sold, incorporates technology for which the government has no rights. Therefore the government has no right to allow others to manufacture the VanishPoint® syringe.

Government Approval and Government Regulations

For all products manufactured for sale in the domestic market we have given notice of intent to market to the FDA and the devices were shown to be substantially equivalent to the predicate devices for the stated intended use.



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For all products manufactured for sale in the foreign market, we hold a certificate of Quality System compliance with ISO 13485. We also have approval to label products for sale into European Union countries with a CE Mark. We will continue to comply with the regulatory regulations of all countries in which our products are registered for sale.

### Competitive Conditions

Our products are sold to and used by healthcare providers primarily in the U.S. (with 17.0% of revenues in 2011 generated from sales outside the U.S.) which include, but are not limited to, acute care hospitals, alternate care facilities, doctors' offices, clinics, emergency centers, surgical centers, convalescent hospitals, Veterans Administration facilities, military organizations, public health facilities, and prisons.

We compete primarily on the basis of product performance and quality. We believe our competitive advantages include, but are not limited to, our leadership in quality and innovation. We believe our products continue to be the most effective safety devices in today's market. Our syringe products include passive safety activation, require less disposal space, and are activated while in the patient, effectively reducing exposure to the contaminated needle. Our price per unit is competitive or even lower than the competition once all the costs

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incurred during the life cycle of a syringe are considered. Such life cycle costs include disposal costs, testing and treatment costs for needlestick injuries, and treatment for contracted illnesses through needlestick injuries.

Major domestic competitors include BD and Covidien Ltd. ( Covidien ). Terumo Medical Corp. ( Terumo ), Smiths Medical, and B Braun are additional competitors with smaller market share.

Founded in 1897, BD is headquartered in New Jersey. BD's safety-engineered device sales accounted for approximately 24% of BD's total 2011 sales. Included as safety-engineered devices manufactured by BD are the SafetyLok, a syringe that utilizes a tubular plastic sheath that must be manually slid over the needle after an injection, and the SafetyGlide, a needle which utilizes a hinged lever to cover the needle tip. BD also manufactures a safety blood collection and hypodermic needle that utilizes the Eclipse needle cover. BD also manufactured the Integra 3mL retracting needle product. BD's Vacutainer® blood collection products are commonly used as industry jargon to refer to blood collection products in general.

Both BD's SafetyLok and Covidien's Monoject® safety syringes require the use of two hands and several extra steps to activate the tubular plastic shield which must be slid and locked into place to protect the needle. These products must be removed from the patient prior to activation, resulting in exposure to the contaminated needle. In contrast, use of the VanishPoint® syringe is identical to that of a standard syringe until the end of an injection, when the automated retraction mechanism retracts the needle directly from the patient safely into the barrel of the syringe. This allows both hands to remain safely out of harm's way.

BD and Covidien have controlling U.S. market share; greater financial resources; larger and more established sales, marketing, and distribution organizations; and greater market influence, including long-term and/or exclusive contracts. The current conditions have restricted competition in the needle and syringe market. BD may be able to use its resources to improve its products through research or acquisitions or develop new products, which may compete more effectively with our products.

We continue to attempt to gain access to the market through our sales efforts, our innovative technology, 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.

Our safety needle products have an advantage over non-retracting safety needles because minimal training and changes to practitioners' normal routines are required. Use of our products also prohibits unfortunate and improper reuse. Several factors could materially and beneficially affect the marketability of our products. Demand could be increased by existing legislation and other legislative and investigative efforts. Licensing agreements could provide entry into new markets and generate additional revenue. Further, outsourcing arrangements could increase our manufacturing capacity with little or no capital outlay and provide a competitive cost.

Two well-established companies control most of the U.S. market. Our competitive position is also weakened by the method that providers use for making purchasing decisions and the fact that our initial price per unit for our safety needle products may be higher.

Research and Development

We spent \$1,030,622; \$885,445; and \$815,018 in fiscal 2009, 2010, and 2011 respectively, on research and development. Costs in 2011 were primarily for samples, testing, and compensation. Our ongoing research and development activities are performed by an internal research and development staff. This team of engineers is developing process improvements for current and future automated machines. Our limited access to the market has slowed the introduction of products. Possible future products include other needle medical devices to which the automated retraction mechanism can be applied as well as other safety medical devices.

Environmental Compliance

We believe that we do not incur material costs in connection with compliance with environmental laws. We are considered a Conditionally Exempt Small Quantity Generator because we generate less than 100 kilograms

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(220 lbs.) of hazardous waste per month. Therefore, we are exempt from the reporting requirements set forth by the Texas Commission on Environmental Quality. The waste that is generated at our facility is primarily made up of flammable liquids and paint-related waste and is sent for fuel blending by Safety Kleen. This fuel blending process completely destroys our waste and satisfies our cradle-to-grave responsibility.

Other nonhazardous production waste includes clean polypropylene regrind that is recycled. All other nonhazardous waste produced is considered municipal solid waste and sent to a sanitary landfill by CWD.

We also produce small amounts of regulated biohazardous waste from contaminated sharps and laboratory wastes. This waste is sent for incineration by Stericycle.

Employees

As of March 1, 2012, we had 148 employees. 144 of such employees were full time employees.

Financial Information About Geographic Areas

We have 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. We do 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. We attribute sales to countries based on the destination of shipment.

	<b>2011</b>		<b>2010</b>		<b>2009</b>
U.S. sales	\$ 26,655,781	\$	29,577,050	\$	34,466,797
North and South America sales (excluding U.S.)	4,736,356		4,887,073		1,764,584
Other international sales	710,159		1,755,439		2,750,456
Total sales	\$ 32,102,296	\$	36,219,562	\$	38,981,837
Long-lived assets					
U.S.	\$ 12,412,502	\$	12,297,942	\$	13,961,445
International	\$ 241,354	\$	262,650	\$	272,736

Most international sales are filled by production from Double Dove. In the event that we become unable to purchase such product from Double Dove, we would need to find an alternate supplier for the 0.5mL insulin syringe, the 0.5mL autodisable syringe, and the 5mL and 10mL syringes. We would increase domestic production for the 1mL and 3mL syringes to avoid a disruption in supply.

Available Information

We make available, free of charge on our website ([www.vanishpoint.com](http://www.vanishpoint.com)), our Form 10-K Annual Report and Form 10-Q Quarterly reports and current reports on Form 8-K (and any amendments to such reports) as soon as reasonably practical after such reports are filed.

**Item 1A. Risk Factors.**

We could be subject to complex and costly regulatory activities. Our business could suffer if we or our suppliers encounter manufacturing problems. We could be subject to risks associated with doing business outside of the U.S. Current or worsening economic conditions may adversely affect our business and financial condition.

You should carefully consider the following material risks facing us. If any of these risks occur, our business, results of operations, or financial condition could be materially affected.

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We Compete in a Monopolistic Marketplace

We operate in an environment that is dominated by BD, the major syringe manufacturer in the U.S. We have sued BD alleging violations of antitrust acts, false advertising, product disparagement, tortious interference, and unfair competition. It is anticipated that this suit will be scheduled to be tried in fall 2012.

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 Have Generally Been Unable to Gain Sufficient Market Access to Achieve Profitable Operations

We have a history of incurring net operating losses. We may experience operating losses in the future. If we are unable to gain sufficient market access and market share, we may be unable to continue to finance research and development as well as support operations and expansion of production.

We Are Dependent on Our Aging Patent Protection

Our main competitive strength is our technology. We are dependent on our patent rights, and if our patent rights are invalidated or circumvented, our business would be adversely affected. Patent protection is considered, in the aggregate, to be of material importance in our marketing of products in the U.S. and in most major foreign markets. Patents covering products that we have introduced normally provide market exclusivity, which is important for the successful marketing and sale of our products.

As our technology ages (and the associated patent life expires), our competitive position in the marketplace will weaken. The initial revolutionary spring action syringe patents will expire beginning in May 2015. However, a significant patent will not expire until August 2016. Patent life may be extended, not through the original patents, but through related improvements. Our ability to improve these patents is uncertain. Eventually, however, our patent protection may decrease and we will be vulnerable to other competitors utilizing our technology.

Our Patents Are Subject to Litigation

We have been sued by BD and MDC Investment Holdings, Inc. for patent infringement. There is currently no trial date set for this litigation. Patent litigation and challenges involving our patents are costly and unpredictable and may deprive us of market exclusivity for a patented product or, in some cases, third party patents may prevent us from marketing and selling a product in a particular geographic area.

We Are Vulnerable to New Technologies

Because we have a narrow focus on particular product lines and technology (currently predominantly retractable needle products), we are vulnerable to the development of superior competing products and to changes in technology which could eliminate or reduce the need for our products. If a superior technology is created, the demand for our products could greatly diminish.

Our Competitors Have Greater Resources

Our competitors have greater financial resources, larger and more established sales and marketing and distribution organizations, and greater market influence, including long-term contracts. These competitors may be able to use these resources to improve their products through research and acquisitions or develop new products, which may compete more effectively with our products. If our competitors choose to use their resources to create products superior to ours, we may be unable to sell our products and our ability to continue operations would be weakened.

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The Majority of Our International Sales Are Filled Using One Supplier

Most international syringe sales are filled by production from Double Dove. In the event that we become unable to purchase such product from Double Dove, we would need to find an alternate supplier for the 0.5mL insulin syringe, the 0.5mL autodisable syringe, and the 5mL and 10mL syringes. We would increase domestic production for the 1mL and 3mL syringes to avoid a disruption in supply.

Fluctuations in Supplies of Inventory Could Temporarily Increase Costs

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

We Are Controlled by One Shareholder

Thomas J. Shaw, our President and Chief Executive Officer, beneficially owned 30.9% of the outstanding Common Stock (and controlled another 15.0% pursuant to a Voting Agreement with Ms. Suzanne August and trust agreements for the benefit of family members) as of March 1, 2012. Mr. Shaw will, therefore, have the ability to direct our operations and financial affairs and to substantially influence the election of members of our Board of Directors. His interests may not always coincide with our interests or the interests of other stockholders. This concentration of ownership, for example, may have the effect of delaying, deferring, or preventing a change in control, impeding a merger, consolidation, takeover, or other business combination involving us, or discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us, which in turn could materially adversely affect the market price of our Common Stock.

We Have Limited Access to the Capital Markets

The volume of trading in our Common Stock on the NYSE Amex LLC (the NYSE Amex ) (formerly the American Stock Exchange) is low. Accordingly, it is unclear if there is any significant market for our shares. This may reduce our ability to raise cash through public or private offerings in the future.

Our Stock Price Is Low

Our stock price may be deemed to have been selling for a substantial period of time at a low price per share which may result in our receipt of a notification from the NYSE Amex that a reverse split is necessary. We have received no such notification. When a company receives such a notification, failure to effect a reverse stock split may result in suspension or removal from trading on the NYSE Amex. The NYSE Amex may initiate delisting procedures in its discretion. Delisting of our shares would greatly affect the liquidity of our shares and would reduce our ability



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to raise funds from the sale of equity in the future. However, we believe such delisting application to be unlikely. Furthermore, in the event that we receive a deficiency letter from the NYSE Amex, we will have the right to appeal such determination.

### Current Economic Conditions May Decrease Collectability of Accounts

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.

### We Face Inherent Product Liability Risks

As a manufacturer and provider of safety needle products, we face an inherent business risk of exposure to product liability claims. If a product liability claim is made and damages are in excess of our product liability coverage, our competitive position could be weakened by the amount of money we could be required to pay to compensate those injured by our products. In the event of a recall, we do not have recall insurance.

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**Item 1B. Unresolved Staff Comments.**

Not applicable and none.

**Item 2. Properties.**

Our headquarters is located at 511 Lobo Lane, on 35 acres, which we own, overlooking Lake Lewisville in Little Elm, Texas. The headquarters are in good condition and house our administrative offices and manufacturing facility. The manufacturing facility produced approximately 32.4% of the units that were manufactured in 2011. In the event of a disruption in service of our outside supplier, Double Dove, we believe we could produce quantities sufficient to meet demand under current circumstances except for demand for 0.5mL, 5mL, and 10mL syringes. In that event, we would attempt to engage another manufacturer. The 5mL and 10mL syringes are sold principally in the international market. In 2011, we utilized approximately one-third of our current U.S. productive capacity.

A \$4,210,000 loan to expand our warehouse was renewed on December 10, 2009 with a 20 year amortization and 10 year maturity. The interest rate is 5.968%.

In the opinion of Management, the property and equipment are suitable for their intended use and are adequately covered by an insurance policy.

**Item 3. Legal Proceedings.**

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

In May 2010, our 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. We 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 us the right to re-plead certain allegations by May 13, 2011. We and an officer filed a Third Amended Complaint in May 2011, setting forth additional detail regarding the alleged illegal

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conduct by BD. Trial was initially set for February 2012. However, in January 2012 the parties agreed to a continuance to allow the petition for certiorari to be considered. As a result of retirement, a new judge will be assigned. It is currently believed that trial will proceed in the fall of 2012.

In September 2007, BD and MDC Investment Holdings, Inc. ( MDC ) sued us in the United States District Court for the Eastern District of Texas, Texarkana Division, initially alleging that we are 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. We 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 we subsequently dropped our 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. There is currently no trial date set for this case. We have filed a motion for summary judgment that is now pending.

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**Item 4. Mine Safety Disclosures.**

Not applicable.

**PART II**

**Item 5. Market for Registrant's Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities.**

MARKET INFORMATION

Our Common Stock has been listed on the NYSE Amex under the symbol RVP since May 4, 2001. Our closing price on March 1, 2012, was \$1.20 per share. Shown below are the high and low sales prices of our Common Stock as reported by the NYSE Amex for each quarter of the last two fiscal years:

<b>2011</b>	<b>High</b>	<b>Low</b>
Fourth Quarter	\$1.45	\$1.00
Third Quarter	\$1.56	\$1.10
Second Quarter	\$1.78	\$1.30
First Quarter	\$2.25	\$1.38

<b>2010</b>	<b>High</b>	<b>Low</b>
Fourth Quarter	\$1.93	\$1.35
Third Quarter	\$1.88	\$0.83
Second Quarter	\$1.80	\$1.20
First Quarter	\$2.03	\$1.31

SHAREHOLDERS

As of March 1, 2012, there were 25,318,700 shares of Common Stock held by 265 shareholders of record not including shareholders who beneficially own Common Stock held in nominee or street name.

DIVIDENDS

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We have not ever declared or paid any dividends on the Common Stock. We have no current plans to pay any cash dividends on the Common Stock. We intend to retain all earnings, except those required to be paid to the holders of the Preferred Stock as resources allow, to support operations and future growth. Dividends on Common Stock cannot be paid so long as preferred dividends are unpaid. As of December 31, 2011, there was an aggregate of \$10.7 million in preferred dividends in arrears.

### EQUITY COMPENSATION PLAN INFORMATION

See **Item 12 Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters** for a chart describing compensation plans under which equity securities are authorized.

### STOCK PERFORMANCE GRAPH

The following graph compares the cumulative total return for our Common Stock from December 31, 2006 to December 31, 2011, to the total returns for the Russell Microcap® and Becton, Dickinson and Company (or BDX), a peer issuer. The graph assumes an investment of \$100 in the aforementioned equities as of December 31, 2006, and that all dividends are reinvested.

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RECENT SALES OF UNREGISTERED SECURITIES

We exchanged 1,246,964 shares of Common Stock (and cash) for 1,246,964 shares of our Class B Convertible Preferred Stock as of November 4, 2011 pursuant to the 2011 Exchange Offer. We exchanged 30,500 shares of Common Stock (and cash) for 30,500 shares of our Preferred Stock as of December 30, 2011 outside of the 2011 Exchange Offer. The 2011 Exchange Offer was offered to all our Preferred Stockholders. The sales outside of the 2011 Exchange Offer were made to three of our Preferred Shareholders who did not participate in the 2011 Exchange Offer. In accordance with the terms of both exchange transactions, participating Preferred Stockholders agreed to waive all unpaid dividends in arrears associated with their tendered Preferred Stock. Both transactions are exempt from registration under the Securities Act pursuant to Section 3(a)(9) of the Securities Act because the securities were exchanged with existing security holders exclusively where no commission or other remuneration was paid or given directly or indirectly for soliciting such exchange.

PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

No shares or other units of equity securities registered pursuant to Section 12 of the Exchange Act were purchased by us in the fourth quarter of 2011. As discussed above, our Preferred Stock, which is not registered pursuant to Section 12 of the Exchange Act, was purchased by us in the fourth quarter of 2011.

**Item 6. Selected Financial Data.**

The following selected financial data is qualified by reference to, and should be read in conjunction with, our audited financial statements and the notes to those statements and Management's Discussion and Analysis of Financial Condition and Results of Operations appearing elsewhere herein. The selected Statements of Operations data presented below for the years ended December 31, 2008 and 2007 and the Balance Sheet data as of December 31, 2009, 2008, and 2007 have been derived from our audited financial statements, which are not included herein.

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(In thousands except for earnings per share, shares, and percentages)\*

	<b>As of and for the Years Ended December 31,</b>					
	<b>2011</b>	<b>2010</b>	<b>2009</b>	<b>2008</b>	<b>2007</b>	
Sales, net	\$ 32,102	\$ 36,219	\$ 38,982	\$ 27,899	\$ 26,290	
Cost of sales	21,199	23,698	25,466	19,673	18,300	
Gross profit	10,903	12,521	13,516	8,226	7,990	
Total operating expenses	14,993	19,185	26,812	18,671	17,936	
Loss from operations	(4,090)	(6,664)	(13,296)	(10,445)	(9,946)	
Interest income	63	32	58	855	1,870	
Interest expense, net	(241)	(302)	(22)	(54)	(326)	
Litigation settlements, net	5,700	9,159				
Income (loss) before income taxes	1,432	2,225	(13,260)	(9,644)	(8,402)	
Provision (benefit) for income taxes	14	(176)	(3,838)		(1,454)	
Net income (loss)	1,418	2,401	(9,422)	(9,644)	(6,948)	
Preferred Stock dividend requirements	(964)	(1,371)	(1,371)	(1,373)	(1,399)	
Earnings (loss) applicable to common shareholders	\$ 454	\$ 1,030	\$ (10,793)	\$ (11,017)	\$ (8,347)	
Earnings (loss) per share basic	\$ 0.02	\$ 0.04	\$ (0.45)	\$ (0.46)	\$ (0.35)	
Earnings (loss) per share diluted	\$ 0.02	\$ 0.04	\$ (0.45)	\$ (0.46)	\$ (0.35)	
Weighted average shares outstanding basic	24,171,238	23,872,783	23,806,533	23,794,566	23,727,029	
Weighted average shares outstanding diluted	26,354,786	26,248,874	23,806,533	23,794,566	23,727,029	
Current assets	\$ 35,745	\$ 40,224	\$ 39,262	\$ 43,614	\$ 51,916	
Current liabilities	\$ 5,967	\$ 9,986	\$ 13,196	\$ 10,238	\$ 8,786	
Property, plant, and equipment, net	\$ 12,654	\$ 12,561	\$ 14,234	\$ 14,436	\$ 11,483	
Total assets	\$ 48,762	\$ 53,191	\$ 53,941	\$ 58,539	\$ 64,330	
Long-term debt, net of current maturities	\$ 4,143	\$ 4,304	\$ 4,825	\$ 6,096	\$ 3,747	
Stockholders equity	\$ 38,651	\$ 38,901	\$ 35,920	\$ 42,206	\$ 51,761	
Redeemable Preferred Stock (in shares)	1,001,552	2,279,016	2,285,266	2,285,266	2,329,916	
Capital leases						
Cash dividends per common share	\$	\$	\$	\$	\$	
Gross profit margin	34.0%	34.6%	34.7%	29.5%	30.4%	

\* Events that could affect the trends indicated above include continued reductions in manufacturing costs, changing average sales prices, the gaining of market access, and protection of our patents. As our products are made from petroleum products, the changing cost of oil and transportation may have an impact on our costs to the extent increases may not be recoverable through price increases of our products and reductions in oil prices may not quickly affect petroleum product prices. Sales to the Department of Health and Human Services ( DHHS ) comprised 24.4% of our revenues for the twelve months ended December 31, 2009, which affects comparability between 2009 and other years. Receipt of settlement proceeds and option payments from Abbott and Hospira positively affected 2010 and 2011 results. Cost cutting measures implemented at the end of the second quarter of



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2009 and an agreement reached in the second quarter of 2010 with our litigation counsel to cap certain legal fees should both contribute to a lower level of expenses going forward. Our purchase in 2011 of a total of 1,277,464 shares of our Preferred Stock (which purchase required the selling Preferred Stockholder to waive all unpaid dividends in arrears) in exchange for our Common Stock and cash will reduce our Preferred Stock Dividend Requirements going forward.

**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**. 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. Safety syringes comprised 97.2% of our sales in 2011. We also manufacture and market the blood collection tube holder and the IV safety catheter. We currently provide other safety medical products in addition to safety products utilizing retractable technology. One such product is the Patient Safe® syringe, which is uniquely designed to reduce the risk of bloodstream infections resulting from catheter hub contamination.

Historically, unit sales have increased in the latter part of the year due, in part, to the demand for syringes during the flu season. 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 and internationally through numerous distributors. Although we have made limited progress in some areas, such as the alternate care market, our volumes are not as high as they should be given the nature and quality of our products and the federal and state legislation requiring the use of safe needle devices. The alternative care market is composed of alternate care facilities that provide long-term nursing and out-patient surgery, emergency care, and physician services. The fact that our progress is limited is principally due to exclusive marketing practices engaged in by BD, the dominant maker and seller of disposable syringes and other needle products, which practices have blocked us from access to the market. A suit against BD is currently pending alleging violations of state and federal antitrust acts and false advertising. BD has ceased marketing the infringing 1mL Integra syringe.

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

In the event we continue to have only limited market access and the cash provided by the litigation settlements and generated from operations becomes insufficient, we would take additional cost cutting measures to reduce cash requirements. Such measures could result in the reduction of units being produced, the reduction of

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workforce, the reduction of salaries of officers and other nonhourly employees, and the deferral of royalty payments. We took such actions at the end of the second quarter of 2009. Salary reductions put in place in the second quarter of 2009 remain in place.

We are bringing additional molding operations to Little Elm as a cost saving measure. The addition of four molding machines in 2011 is part of that endeavor. 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. In connection with this settlement agreement, we granted Hospira an exclusive one-year option to negotiate a licensing agreement for certain uses of our Patient Safe® syringe. This option expired unexercised in July 2011. We have received the total \$8 million option payment. As part of the settlement, in the third quarter of 2010, Hospira paid us \$6 million and forgave a marketing fee of \$1.4 million. The settlement was reduced by an outstanding invoice due to us for \$144 thousand.

In the second quarter of 2010, we reached an agreement with our counsel, Locke Lord LLP, 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 continue to impact our cash flow in a positive manner.

On September 12, 2011, we commenced the 2011 Exchange Offer. As of November 4, 2011, the expiration date of the 2011 Exchange Offer, Preferred Stockholders had tendered the following number of shares of Preferred Stock: 1) 27,500 shares of Series I Preferred Stock; 2) 41,000 shares of Series II Preferred Stock; 3) no shares of Series III Preferred Stock were exchanged; 4) 5,000 shares of Series IV Preferred Stock; and 5) 1,173,464 shares of Series V Preferred Stock. A total of \$1,308,275 and 1,246,964 shares of Common Stock were issued as consideration to participating Preferred Stockholders pursuant to the 2011 Exchange Offer. In accordance with the terms of the 2011 Exchange Offer, participating Preferred Stockholders agreed to waive all unpaid dividends in arrears associated with their tendered Preferred Stock, which resulted in a waiver of a total of \$3,539,714 in unpaid dividends in arrears.

As of December 30, 2011, we engaged in private sales with three Preferred Stockholders which tendered the following number of shares of Preferred Stock: 1) 13,000 shares of Series I Preferred Stock; 2) 5,000 shares of Series IV Preferred Stock; and 3) 12,500 shares of Series V Preferred Stock. A total of \$49,000 and 30,500 shares of Common Stock were issued as consideration to the three Preferred Stockholders. In accordance with the terms of the private sales, the three Preferred Stockholders agreed to waive all unpaid dividends in arrears associated with their tendered Preferred Stock, which resulted in a waiver of a total of \$97,079 in unpaid dividends in arrears.

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 2011, Double Dove manufactured approximately 67.1% of the units we produced. We believe we could make up any long-term disruption in these purchases by utilizing more of the capacity at the Little Elm facility, except for the 0.5mL insulin syringe, the 5mL and 10mL syringes, and the autodisable syringe which altogether comprised about 9.1% of our 2011 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 2011, 2010, or 2009. Dollar amounts have been rounded for ease of reading.

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*Comparison of Year Ended*

*December 31, 2011 and Year Ended December 31, 2010*

Revenues decreased 11.4%, due principally to lower volume and lower average sales price. Domestic sales were 83.0% of revenues with international sales comprising the remainder. Unit sales decreased 6.3%. Domestic unit sales decreased 1.9% and average sales prices decreased 8.2%. International unit sales decreased 15.8% and average international selling prices decreased 2.7%.

Cost of sales decreased due to lower volumes and lower unit costs. Royalty expenses decreased due to lower gross sales revenues.

As a result, gross profit margins decreased from 34.6% in 2010 to 34.0% in 2011.

Operating expenses decreased 21.9% from the prior year due to lower litigation cost of \$2.9 million, lower stock option expense of \$1.2 million, bonuses paid in 2010 of \$630 thousand, and an impairment charge of \$365 thousand in 2010. Bad debt expense and legal expenses related to patent matters increased. Lower litigation costs are the result of an agreement between us and our counsel to cap certain litigation fees.

Loss from operations was \$4.1 million in 2011 compared to an operating loss in 2010 of \$6.7 million.

Litigation settlements, net reflects cash proceeds of \$6.0 million net of a \$300 thousand royalty payment.

The provision for income taxes consists principally of \$43 thousand of state and local income taxes and a credit to federal income tax of \$29 thousand.

Cash flow from operations was \$5.5 million for 2011 due principally to litigation settlements, a reduction in accounts receivable balances and inventories. A decrease in accrued liabilities and net income, mitigated the increase in cash flow.

*Comparison of Year Ended*

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

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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.

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 of \$800 thousand, lower stock option expense of \$771 thousand, and lower travel and entertainment costs of \$178 thousand. 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 thousand for consulting, \$77 thousand in 401(k) expense, and \$48 thousand for marketing expense.

In 2010, we recognized impairment charges of \$365 thousand 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.

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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.

**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 \$2.4 million, or 10.3%, over 2010. The improvement is related to cash provided by operations, including litigation proceeds, reduced by the purchase of our preferred stock.

Historical Sources of Liquidity

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

Internal Sources of Liquidity

*Margins and Market Access*

To routinely achieve 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 32.4%) 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 us versus manufactured in China can have a significant effect on the carrying costs of inventory as well as Cost of sales. We will continue to evaluate the appropriate mix of products manufactured domestically and those manufactured in China to achieve economic benefits as well as to maintain our domestic manufacturing capability.

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



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*Seasonality*

Historically, unit sales have increased in the latter part of the year due, in part, to the demand for syringes during the flu season. 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 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. In connection with this settlement agreement, we granted Hospira an exclusive one-year option to negotiate a licensing agreement for certain uses of our Patient Safe® syringe. This option expired unexercised in July 2011. We have received the total \$8 million option payment. As part of the settlement, in the third quarter of 2010, Hospira paid us \$6 million and forgave a marketing fee of \$1.4 million. The settlement was reduced by an outstanding invoice due to us for \$144 thousand.

**CAPITAL RESOURCES**

Repurchase of Preferred Shares

On September 12, 2011, we commenced an offer to purchase all outstanding Class B Convertible Preferred Stock (the Preferred Stock ) for cash and Common Stock (the 2011 Exchange Offer ). As of November 4, 2011, the expiration date of the 2011 Exchange Offer, Preferred

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Stockholders had tendered a total of 1,246,964 shares of Preferred Stock. A total of \$1,308,275 and 1,246,964 shares of Common Stock were issued as consideration to participating Preferred Stockholders pursuant to the 2011 Exchange Offer. In accordance with the terms of the 2011 Exchange Offer, participating Preferred Stockholders agreed to waive all unpaid dividends in arrears associated with their tendered Preferred Stock, which resulted in a waiver of a total of \$3,539,714 in unpaid dividends in arrears. During the quarter ended December 31, 2011, we engaged in private sales with three Preferred Stockholders which tendered a total of 30,500 shares of Preferred Stock. A total of \$49,000 and 30,500 shares of Common Stock were issued as consideration to the three Preferred Stockholders. In accordance with the terms of the private sales, the three Preferred Stockholders agreed to waive all unpaid dividends in arrears associated with their tendered Preferred Stock, which resulted in a waiver of a total of \$97,079 in unpaid dividends in arrears.

### Material Commitments for Expenditures

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

### Trends in Capital Resources

#### OFF-BALANCE SHEET ARRANGEMENTS

None.

#### CONTRACTUAL OBLIGATIONS

### Contractual Obligations and Commercial Commitments

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The following chart summarizes our material obligations and commitments to make future payments under contracts for long-term debt as of December 31, 2011:

	<b>Total</b>	<b>Payments Due by Period</b>			<b>More Than 5 Years</b>
		<b>Less Than 1 Year</b>	<b>1-3 Years</b>	<b>3-5 Years</b>	
<b>Contractual Obligations Note</b>					
Long-term debt	\$ 4,767,512	\$ 624,246	\$ 562,149	\$ 308,926	\$ 3,272,191
Operating leases	244,786	60,401	124,419	59,966	
Total	\$ 5,012,298	\$ 684,647	\$ 686,568	\$ 368,892	\$ 3,272,191

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.

## 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 immaterial.

**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

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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.

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

Our international distribution agreements do not provide for any returns.

**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 in 2010.

**Recent Pronouncement**

In June 2011, FASB issued Accounting Standards Update ( ASU ) No. 2011-05, *Presentation of Comprehensive Income*. FASB ASU No. 2011-05 amends existing guidance by allowing two options for presenting the components of net income and other comprehensive income: (1) in a single continuous financial statement: a statement of income and other comprehensive income or (2) in two separate but consecutive financial statements, consisting of an income statement followed by a separate statement of other comprehensive income. Also, items that are reclassified from other comprehensive income to net income must be presented on the face of the financial statements. ASU No. 2011-05 requires retrospective application, and it is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011, with early adoption permitted. We do not expect the adoption of this standard to have an impact on our financial position, results of operations, or cash flows.

**Item 7A. Quantitative and Qualitative Disclosures About Market Risk.**

We believe that our market risk exposures regarding our cash and cash equivalents are immaterial as we do not have instruments for trading purposes. We shifted the bulk of our funds into U.S. Treasury bills and other U.S. government backed securities in April 2008. Additionally, reasonable, possible near-term changes in market rates or prices will not result in material changes in near-term earnings.

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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, 2011 AND 2010**

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**RETRACTABLE TECHNOLOGIES, INC.**

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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, 2011 and 2010, 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, 2011. Our audits also included the financial statement schedule of Retractable Technologies, Inc., listed in Item 15(a). 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 audits 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, 2011 and 2010, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2011, 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.

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

Dallas, Texas  
March 30, 2012

Table of Contents**RETRACTABLE TECHNOLOGIES, INC.****BALANCE SHEETS**

	<b>December 31,</b>	
	<b>2011</b>	<b>2010</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 25,673,263	\$ 23,266,039
Accounts receivable, net of allowance for doubtful accounts of \$2,078,944 and \$780,900, respectively	3,576,411	7,582,062
Inventories, net	6,237,419	8,682,191
Income taxes receivable	39,485	12,031
Other current assets	218,529	681,244
Total current assets	35,745,107	40,223,567
Property, plant, and equipment, net	12,653,856	12,560,592
Intangible and other assets, net	362,976	406,910
Total assets	\$ 48,761,939	\$ 53,191,069
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 3,500,301	\$ 3,847,966
Current portion of long-term debt	620,472	519,611
Accrued compensation	628,794	603,484
Accrued royalties to shareholders	122,239	949,619
Other accrued liabilities	1,065,943	3,910,428
Income taxes payable	29,471	155,000
Total current liabilities	5,967,220	9,986,108
Long-term debt, net of current maturities	4,143,267	4,304,460
Total liabilities	10,110,487	14,290,568
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: 103,500 and 144,000 shares, respectively (liquidation preference of \$646,875 and \$900,000 respectively)	103,500	144,000
Series II, Class B; outstanding: 178,700 and 219,700, respectively (liquidation preference of \$2,233,750 and \$2,746,250, respectively)	178,700	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: 542,500 and 552,500 shares (liquidation preference of \$5,967,500 and \$6,077,500, respectively)	542,500	552,500
Series V, Class B; outstanding: 46,607 and 1,238,821 shares, respectively (liquidation preference of \$205,071 and \$5,423,312, respectively)	46,607	1,232,571
Common Stock, no par value; authorized: 100,000,000 shares; issued and outstanding: 25,318,700 and 23,974,114 shares, respectively		
Additional paid-in capital	57,284,670	57,674,737
Retained deficit	(19,634,770)	(21,053,252)
Total stockholders equity	38,651,452	38,900,501
Total liabilities and stockholders equity	\$ 48,761,939	\$ 53,191,069

See accompanying notes to financial statements



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

	<b>Years Ended December 31,</b>		
	<b>2011</b>	<b>2010</b>	<b>2009</b>
Sales, net	\$ 32,102,296	\$ 36,219,562	\$ 38,981,837
Cost of Sales			
Costs of manufactured product	18,556,257	20,757,488	22,659,437
Royalty expense to shareholders	2,643,209	2,940,948	2,806,223
Total cost of sales	21,199,466	23,698,436	25,465,660
Gross profit	10,902,830	12,521,126	13,516,177
Operating expenses:			
Sales and marketing	3,439,535	3,674,168	4,372,163
Research and development	815,018	885,445	1,030,622
General and administrative	10,738,110	14,260,151	18,814,392
Impairment of assets		365,295	2,594,602
Total operating expenses	14,992,663	19,185,059	26,811,779
Loss from operations	(4,089,833)	(6,663,933)	(13,295,602)
Interest and other income	62,596	32,324	57,604
Interest expense, net	(240,484)	(302,843)	(21,892)
Litigation settlements, net	5,700,000	9,159,089	
Income (loss) before income taxes	1,432,279	2,224,637	(13,259,890)
Provision (benefit) for income taxes	13,797	(176,057)	(3,837,590)
Net income (loss)	1,418,482	2,400,694	(9,422,300)
Preferred Stock dividend requirements	(964,047)	(1,370,620)	(1,370,868)
Earnings (loss) applicable to common shareholders	\$ 454,435	\$ 1,030,074	\$ (10,793,168)
Basic earnings (loss) per share	\$ 0.02	\$ 0.04	\$ (0.45)
Diluted earnings (loss) per share	\$ 0.02	\$ 0.04	\$ (0.45)
Weighted average common shares outstanding:			
Basic	24,171,238	23,872,783	23,806,533
Diluted	26,354,786	26,248,874	23,806,533

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, 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												
Balance as of December 31, 2010	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	
Exchange of Preferred Stock for Common Stock	(40,500)	(40,500)	(41,000)	(41,000)			(10,000)	(10,000)	(1,185,964)	(1,185,964)	1,277,464	
Purchase of Preferred Stock												
Recognition of stock option exercise												67,122

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Payment of  
dividends

Net income

Balance as of  
December 31,  
2011

103,500	\$	103,500	178,700	\$	178,700	130,245	\$	130,245	542,500	\$	542,500	46,607	\$	46,607	25,318,700	\$
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See accompanying notes to financial statements

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

	<b>Additional Paid-in Capital</b>	<b>Retained Earnings (Deficit)</b>	<b>Total</b>
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
Exchange of Preferred Stock for Common Stock	1,277,464		
Purchase of Preferred Stock	(1,357,275)		(1,357,275)
Recognition of stock option exercise	54,369		54,369
Payment of dividends	(364,625)		(364,625)
Net income		1,418,482	1,418,482
Balance as of December 31, 2011	\$ 57,284,670	\$ (19,634,770)	\$ 38,651,452

See accompanying notes to financial statements





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

	<b>Years Ended December 31,</b>		
	<b>2011</b>	<b>2010</b>	<b>2009</b>
<b>Cash flows from operating activities:</b>			
Net income (loss)	\$ 1,418,482	\$ 2,400,694	\$ (9,422,300)
Adjustments to reconcile net income (loss) to net cash provided by (used by) operating activities:			
Depreciation and amortization	1,311,746	1,516,226	1,396,793
Litigation settlement marketing fees payable		(1,419,760)	
Stock option compensation		1,340,300	2,111,360
Provision for inventory valuation	52,835		
Reserve for non-contractual deductions		850,000	
Provision for doubtful accounts	1,298,044	133,990	182,000
Impairment of assets		365,295	2,594,602
Accreted interest	17,610	30,920	43,151
(Increase) decrease in assets:			
Inventories	2,391,937	(1,774,822)	(265,837)
Accounts receivable	2,707,607	1,382,158	(6,841,268)
Income taxes receivable	(27,454)	3,643,606	(3,655,637)
Other current assets	462,715	(56,851)	(224,280)
Increase (decrease) in liabilities:			
Accounts payable	(347,665)	(3,149,344)	852,875
Accrued liabilities, other	(3,646,555)	3,313,260	1,015,505
Income taxes payable	(125,529)	155,000	(86,695)
Net cash provided (used) by operating activities	5,513,773	8,730,672	(12,299,731)
<b>Cash flows from investing activities:</b>			
Purchase of property, plant, and equipment	(826,091)	(169,415)	(2,383,867)
Net cash used by investing activities	(826,091)	(169,415)	(2,383,867)
<b>Cash flows from financing activities:</b>			
Repayments of long-term debt and notes payable	(612,927)	(2,660,336)	(499,668)
Repurchase of Preferred Stock	(1,357,275)		
Proceeds from the exercise of stock options	54,369	115,600	25,610
Payment of Preferred Stock dividends	(364,625)	(876,566)	
Net cash used by financing activities	(2,280,458)	(3,421,302)	(474,058)
Net increase (decrease) in cash and cash equivalents	2,407,224	5,139,955	(15,157,656)
Cash and cash equivalents at:			
Beginning of period	23,266,039	18,126,084	33,283,740
End of period	\$ 25,673,263	\$ 23,266,039	\$ 18,126,084
<b>Supplemental schedule of cash flow information:</b>			
Interest paid	\$ 279,691	\$ 321,610	\$ 184,018
Income taxes paid	\$ 188,754	\$ 16,000	\$
<b>Supplemental schedule of noncash investing and financing activities:</b>			
Debt assumed to construct a warehouse	\$	\$	\$ 1,362,602
Forgiveness of royalties by shareholder	\$	\$	\$ 1,000,000

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Debt assumed for the purchase of molding machines	\$	534,986	\$	\$
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; the Patient Safe® syringe; and the Patient Safe® Luer Cap.

**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 immaterial.

### **Inventories**

Inventories are valued at the lower of cost or market, with cost being determined using actual average cost. The Company compares the average cost to the market price and records the lower value. Management considers such factors as the amount of inventory on hand and in the distribution channel, estimated time to sell such inventory, the shelf life of inventory, and current market conditions when determining excess or

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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 ended December 31, 2011, 2010, and 2009, the Company capitalized interest of approximately \$57,000; \$50,000; and \$205,000. 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 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 1mL 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.

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**Intangible assets**

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

**Financial instruments**

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 4 significant customers. For the year ended December 31, 2011, the aforementioned customers accounted for \$16.2 million, or 50.6% of net sales.

Considering the current economic climate, the Company increased its allowance for doubtful accounts by approximately \$1.3 million 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 67.1% of its finished products in 2011 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**

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



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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 claiming non-contractual rebates. Rebates can only be claimed on purchases made directly from the Company. The Company has established a reserve for the collectability of these non-contractual rebate amounts. The expense for the reserve is recorded in Operating expense, General and administrative. The reserve for such non-contractual deductions is 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 generally provides that a customer may return product that is overstocked. Overstocking returns are limited to two times in each 12-month period up to 1% of distributor's total purchase of products for the prior 12-month period. All product overstocks and returns are subject to inspection and acceptance by the Company.

The Company's international distribution agreements 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 were not required to be paid. The reversal of this accrual is included in Litigation settlements, net on the Statements of Operations in 2010.

**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, which option expired unexercised in July 2011. The Company has received the \$8.0 million option payment. The Company recognizes proceeds from litigation settlements, net of any associated royalty expense.

**Income taxes**

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

The Company provides for deferred income taxes through utilizing an asset and liability approach for financial accounting and reporting based on the tax effects of differences between the financial statement and tax bases of assets and liabilities, based on enacted rates expected to be in effect when such differences reverse in future periods. Deferred tax assets are periodically reviewed for realizability. Under recent tax law changes, companies are allowed to carry back taxable losses from either 2009 or 2010. The Company filed for a tax refund utilizing its 2009 taxable losses which resulted in a \$4.0 million refund

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received in the third quarter of 2010. The Company utilized some of its net operating carry forwards in 2011 and paid Alternative Minimum Tax on its taxable income. The Company has established a valuation allowance for its net deferred tax asset as future taxable income cannot be reasonably assured. Penalties and interest on uncertain tax positions are classified as income taxes in the 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>2011</b>	<b>2010</b>	<b>2009</b>
Net income (loss)	\$ 1,418,482	\$ 2,400,694	\$ (9,422,300)
Preferred dividend requirements	(964,047)	(1,370,620)	(1,370,868)
Effect of dilutive securities:			
Convertible debt interest and loan fees	(10,120)		
Earnings (loss) available to common shareholders after assumed conversions	\$ 444,315	\$ 1,030,074	\$ (10,793,168)
Average common shares outstanding	24,171,238	23,872,783	23,806,533
Dilutive stock equivalents from stock options	2,101,825	2,376,091	
Shares issuable upon conversion of convertible debt	81,723		
Average common and common equivalent shares outstanding - assuming dilution	26,354,786	26,248,874	23,806,533
Basic earnings per share	\$ 0.02	\$ 0.04	\$ (0.45)
Diluted earnings per share	\$ 0.02	\$ 0.04	\$ (0.45)

**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.

**Share-based compensation**

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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:

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	<b>Years Ended December 31,</b>		
	<b>2011</b>	<b>2010</b>	<b>2009</b>
Cost of sales	\$	\$ 182,892	\$ 317,644
Sales and marketing		78,343	242,509
Research and development		28,259	47,168
General and administrative		1,050,806	1,504,039
	\$	\$ 1,340,300	\$ 2,111,360

Options awarded to employees in 2009 were amortized over twelve months. 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.

**Recent Pronouncement**

In June 2011, FASB issued Accounting Standards Update (ASU) No. 2011-05, *Presentation of Comprehensive Income*. FASB ASU No. 2011-05 amends existing guidance by allowing two options for presenting the components of net income and other comprehensive income: (1) in a single continuous financial statement: a statement of income and other comprehensive income or (2) in two separate but consecutive financial statements, consisting of an income statement followed by a separate statement of other comprehensive income. Also, items that are reclassified from other comprehensive income to net income must be presented on the face of the financial statements. ASU No. 2011-05 requires retrospective application, and it is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011, with early adoption permitted. The Company does not expect the adoption of this standard to have an impact on the Company's financial position, results of operations, or cash flows.

**3. INVENTORIES**

Inventories consist of the following:

	<b>Year Ended December 31,</b>	
	<b>2011</b>	<b>2010</b>
Raw materials	\$ 1,282,357	\$ 1,401,930
Finished goods	5,213,497	7,485,861
	6,495,854	8,887,791
Inventory reserve	(258,435)	(205,600)
	\$ 6,237,419	\$ 8,682,191



Table of Contents**4. PROPERTY, PLANT, AND EQUIPMENT**

Property, plant, and equipment consist of the following:

	<b>December 31,</b>	
	<b>2011</b>	<b>2010</b>
Land	\$ 261,893	\$ 261,893
Buildings and building improvements	11,121,552	11,093,797
Production equipment	15,550,226	14,808,055
Office furniture and equipment	2,341,747	2,260,219
Construction in progress	995,810	486,187
Automobiles	102,321	102,321
	30,373,549	29,012,472
Accumulated depreciation	(17,719,693)	(16,451,880)
	\$ 12,653,856	\$ 12,560,592

Depreciation expense for the years ended December 31, 2011, 2010, and 2009 was \$1,267,813; \$1,482,591; and \$1,353,353, respectively.

**5. INTANGIBLE ASSETS**

Intangible assets consist of the following:

	<b>December 31,</b>	
	<b>2011</b>	<b>2010</b>
License agreement	\$ 500,000	\$ 500,000
Trademarks and patents	508,743	508,743
	1,008,743	1,008,743
Accumulated amortization	(678,614)	(625,507)
	\$ 330,129	\$ 383,236

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 \$2,643,209; \$2,940,948; and \$2,806,223 are included in Cost of sales for the years ended December 31, 2011, 2010, and 2009, respectively. Royalties payable under this agreement aggregated \$122,939 and \$949,619 at December 31, 2011 and 2010, respectively. Gross sales upon which royalties are based were \$52,864,158; \$58,795,279; and \$56,124,453 for 2011, 2010, and 2009, respectively. Royalties were also paid on litigation proceeds, net of legal

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fees, on a gross amount of \$2.4 million in 2010 and \$6.0 million in 2011. A small amount of royalties was paid on royalties from a licensing agreement with a third party.

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, 2011, 2010, and 2009, was \$43,934; \$43,440; and \$43,440, respectively. Future amortization expense for the years 2012 through 2016 is estimated to be \$43,933 per year.



Table of Contents**6. OTHER ACCRUED LIABILITIES**

Other accrued liabilities consist of the following:

	<b>December 31,</b>	
	<b>2011</b>	<b>2010</b>
Prepayments from customers	\$ 869,334	\$ 3,555,272
Accrued professional fees	134,790	288,942
Other accrued expenses	61,819	66,214
	<b>\$ 1,065,943</b>	<b>\$ 3,910,428</b>

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

**7. LONG-TERM DEBT**

	<b>December 31,</b>	
	<b>2011</b>	<b>2010</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%.	\$ 3,979,122	\$ 4,098,578
Note payable to Katie Petroleum. Interest accrues at prime plus 1%, which was 4.25% at December 31, 2011 and 2010. 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 (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.	323,118	725,493
Note payable to Deutsche Leasing USA, Inc. The interest rate is 5.57%. The original amount of the note was \$327,726 with a 36 month maturity ending in April 2014. Beginning May 2011, the loan is payable in equal installments of principal and interest of approximately \$9,900. Collateralized by three molding machines. It has a purchase option of \$1.00 at the end of the term.	259,543	
Note payable to Deutsche Leasing USA, Inc. The interest rate is 5.57%. The original amount of the note was \$207,260 with a 36 month maturity ending in November 2014. Beginning December 2011, the loan is payable in equal installments of principal and interest of approximately \$6,300. Collateralized by a molding machine. It has a purchase option of \$1.00	201,956	

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at the end of the term.

	4,763,739	4,824,071
Less: current portion	(620,472)	(519,611)
	\$ 4,143,267	\$ 4,304,460

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The aggregate maturities of long-term debt as of December 31, 2011, are as follows:

2012	\$	620,472
2013		315,086
2014		247,064
2015		149,744
2016		159,182
Thereafter		3,272,191
	\$	4,763,739

**8. COMMITMENTS AND CONTINGENCIES**

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

In May 2010, the Company and an officer s suit against BD in the U.S. District Court for the Eastern District of Texas, Marshall Division alleging violations of antitrust acts, false advertising, product disparagement, tortious interference, and unfair competition was reopened. The Company and an officer filed a Second Amended Complaint on July 23, 2010 setting forth additional detail regarding the allegations of BD s illegal conduct. BD filed a motion to dismiss and the Court denied that motion in part and granted it in part, granting the Company the right to re-plead certain allegations by May 13, 2011. The Company and an officer filed a Third Amended Complaint in May 2011, setting forth additional detail regarding the alleged illegal conduct by BD. Trial was initially set for February 2012. However, in January 2012 the parties agreed to a continuance to allow the petition for certiorari to be considered. As a result of retirement, a new judge will be assigned. It is currently believed that trial will proceed in the fall of 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. There is currently no trial date set for this case. The Company has filed a motion for summary judgment that is now pending.

**Operating Leases**

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During 2010, the Company entered into a non-cancellable operating lease for additional office space. Rent expense under this lease was \$59,195 in 2011. Future annual minimum rental payments as of December 31, 2011 are presented below:

2012	\$	60,401
2013		61,607
2014		62,812
2015		59,966
Thereafter		
Total	\$	244,786

**9. INCOME TAXES**

The provision for income taxes consists of the following:

	<b>For the Years Ended December 31,</b>		
	<b>2011</b>	<b>2010</b>	<b>2009</b>
Current tax provision (benefit)			
Federal	\$ (29,070)	\$ (204,507)	\$ (3,655,637)
State	42,867	28,450	(181,953)
Total current provision (benefit)	13,797	(176,057)	(3,837,590)
Deferred tax provision (benefit)			
Federal			
State			
Total deferred tax provision (benefit)			
Total income tax provision (benefit)	\$ 13,797	\$ (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 \$8,893,855 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.

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:

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	<b>December 31,</b>	
	<b>2011</b>	<b>2010</b>
Deferred tax assets		
Net operating loss carryforwards	\$ 3,372,994	\$ 4,228,826
Accrued expenses and reserves	1,118,679	907,624
Employee stock option expense	682,810	682,810
Inventory	397,449	385,856
Non-employee stock option expense	79,939	81,310
Charitable contribution carryforwards		26,164
Deferred tax assets	5,651,871	6,312,590
Deferred tax liabilities		
Property and equipment	(768,455)	(869,908)
Deferred tax liabilities	(768,455)	(869,908)

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	<b>2011</b>	<b>2010</b>
Net deferred assets	4,883,416	5,442,682
Valuation allowance	(4,883,416)	(5,442,682)
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>2011</b>	<b>December 31, 2010</b>	<b>2009</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
Permanent differences	2.0	9.1	3.0
Return to accrual adjustments	(2.8)	(15.0)	(0.3)
Alternative minimum tax	3.4	5.8	
Release of valuation allowance	(39.0)	(45.2)	
Other	(0.5)	(0.5)	1.6
Effective tax (benefit) rate	1.0%	(7.9)%	(29.0)%

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, 2008, 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. EXCHANGE OF PREFERRED STOCK FOR COMMON STOCK AND CASH

On September 12, 2011, the Company commenced an offer to purchase all outstanding Class B Stock for cash and Common Stock (the 2011 Exchange Offer). As of November 4, 2011, the expiration date of the 2011 Exchange Offer, Preferred Stockholders had tendered the following number of shares of Preferred Stock: 1) 27,500 shares of Series I Class B Stock; 2) 41,000 shares of Series II Class B Stock; 3) no shares of Series III Class B Stock were exchanged; 4) 5,000 shares of Series IV Class B Stock; and 5) 1,173,464 shares of Series V Class B Stock. A total of \$1,308,275 and 1,246,964 shares of Common Stock were issued as consideration to participating Preferred Stockholders pursuant to the 2011 Exchange Offer. In accordance with the terms of the 2011 Exchange Offer, participating Preferred Stockholders agreed to waive all unpaid dividends in arrears associated with their tendered Preferred Stock, which resulted in a waiver of a total of \$3,539,714 in unpaid dividends in arrears.

During the quarter ended December 31, 2011, the Company engaged in private sales with three Preferred Stockholders which tendered the following number of shares of Preferred Stock: 1) 13,000 shares of Series I Class B Stock; 2) 5,000 shares of Series IV Class B Stock; and 3) 12,500 shares of Series V Class B Stock. A total of \$49,000 and 30,500 shares of Common Stock were issued as consideration to the three Preferred Stockholders. In accordance with the terms of the private sales, the three Preferred Stockholders agreed to waive all unpaid dividends in arrears associated with their tendered Preferred Stock, which resulted in a waiver of a total of \$97,079 in unpaid dividends in arrears.

The 2011 Exchange Offer and private sales are summarized in the table below.

	Number of Preferred Stock Shares Tendered by Preferred Stockholders	Cash Outlay by Company	Number of Common Stock Shares Tendered by Company	Accrued Dividends Eliminated	Amount of Annual Dividend Reduction
Series I Class B Stock	40,500	\$ 60,750	40,500	\$	\$ 20,250
Series II Class B Stock	41,000	123,000	41,000		41,000
Series IV Class B Stock	10,000	35,000	10,000	114,575	10,000
Series V Class B Stock	1,185,964	1,138,525	1,185,964	3,478,084	379,508
<b>Total Class B Stock</b>	<b>1,277,464</b>	<b>\$ 1,357,275</b>	<b>1,277,464</b>	<b>\$3,592,659</b>	<b>\$450,758</b>

## 11. STOCKHOLDERS EQUITY

### Preferred Stock

The Company is authorized to issue 5,000,000 shares of Preferred Stock Class A with a par value of One Dollar (\$1.00) per share; 5,000,000 shares of Preferred Stock Class B with a par value of One Dollar (\$1.00) per share; and 5,000,000 shares of Preferred Stock Class C with a par value of One Dollar (\$1.00) per share.

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.

The Class B Stock has been allocated among Series I, II, III, IV, and V in the amounts of 103,500; 178,700; 130,245; 542,500; and 46,607 shares, respectively as of December 31, 2011. The remaining 3,998,448 authorized shares have not been assigned a series.

#### Series I Class B Stock

There were 103,500 and 144,000 shares of \$1 par value Series I Class B Stock outstanding at December 31, 2011 and 2010, respectively. The Company exchanged Common Stock and cash for 27,500 shares of Series I Class B Stock in 2011 pursuant to its Tender Offer Statement on Schedule TO filed on September 12, 2011 (the 2011 Exchange Offer ) and also engaged in a private sale to purchase 13,000 shares of Series I Class B Stock in 2011. Holders of Series I Class B Stock are entitled to receive a cumulative annual dividend of \$0.50 per share, payable quarterly if declared by the Board of Directors. In 2010, the Company paid \$216,000 in dividends. In 2011, the Company paid \$90,000 in dividends. At December 31, 2011 and 2010, approximately \$13,000 and \$36,000, respectively, of dividends which had not been declared were in arrears.



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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 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 2011 or 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 unpaid dividends prior to any distributions to holders of Series II Class B Stock, Series III Class B Stock, Series IV Class B Stock, Series V Class B Stock, or Common Stock.

Series II Class B Stock

There were 178,700 and 219,700 shares of \$1 par value Series II Class B Stock outstanding at December 31, 2011 and 2010, respectively. The Company exchanged Common Stock and cash for 41,000 shares of Series II Class B Stock in 2011 pursuant to its 2011 Exchange Offer. 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. In 2011, the Company paid \$274,625 in dividends. At December 31, 2011 and 2010, approximately \$45,000 and \$110,000, 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 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 2011 or 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 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 Stock

There were 130,245 shares of \$1 par value Series III Class B Stock outstanding at December 31, 2011 and 2010. 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, 2011 and 2010, approximately \$3,366,000 and \$3,236,000, 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 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 2011 or 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 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 Stock

There were 542,500 and 552,500 shares of \$1 par value Series IV Class B Stock outstanding at December 31, 2011 and 2010, respectively. The Company exchanged Common Stock and cash for 5,000 shares of Series

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IV Class B Stock in 2011 pursuant to its 2011 Exchange Offer and also engaged in a private sale to purchase 5,000 shares of Series IV Class B Stock in 2011. 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. At December 31, 2011 and 2010, approximately \$6,338,000 and \$5,903,000, 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 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 2011 or 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, 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 Stock

There were 46,607 and 1,232,571 shares of \$1 par value Series V Class B Stock outstanding at December 31, 2011 and 2010, respectively. The Company exchanged Common Stock and cash for 1,173,464 shares of Series V Class B Stock in 2011 pursuant to its 2011 Exchange Offer and also engaged in a private sale to purchase 12,500 shares of Series V Class B Stock in 2011. 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. At December 31, 2011 and 2010, approximately \$914,000 and \$4,093,000, 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 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 these terms, 6,250 shares of Series V Class B Stock were converted into Common Stock in 2010 and none were converted in 2011. 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 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 25,318,700 and 23,974,114 shares were issued and outstanding at December 31, 2011 and 2010, respectively.

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**12. 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, 2011, 2010, and 2009, the Company paid \$96,787; \$75,831; and \$50,793, respectively, to family members of its Chief Executive Officer for various consulting services.

During the years ended December 31, 2011, 2010, and 2009, the Company paid \$0; \$20,350; and \$9,940, respectively, to a Director's company for participating in clinical trials.

The Chief Executive Officer exchanged his Preferred Stock shares for Common Stock and cash in the fourth quarter of 2011 pursuant to the 2011 Exchange Offer on the same terms as were offered to all Preferred Stockholders. He received 86,607 shares of Common Stock and \$95,843 in exchange for 5,000 shares of Series IV Preferred Stock and 81,607 shares of Series V Preferred Stock, and he waived a total of \$58,110 in unpaid dividends in arrears. The Company's Common Stock had a closing stock price of \$1.39 at November 4, 2011, the expiration date of the 2011 Exchange Offer.

**13. STOCK OPTIONS**

**Stock options**

The Company has approved stock option plans for the granting of stock options to employees, Directors, and consultants. Options for the purchase of 25,680 shares of Common Stock remain outstanding under the 1999 Stock Option Plan, which terminated pursuant to its terms in 2009. Options for the purchase of 2,849,108 shares of Common Stock have been issued under the 2008 Stock Option Plan, which authorized a total of

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3,000,000 shares of Common Stock upon the exercise of stock options. Options for the purchase of 2,485,411 shares under the 2008 Stock Option Plan were outstanding as of December 31, 2011. Options for the purchase of a total of 225,000 shares of Common Stock remain outstanding under individual stock option plans to Dr. Jimmie Shiu and Mr. Harry Watson. Options for the purchase of 3,000,000 shares of Common Stock remain outstanding under an option granted to Mr. Thomas J. Shaw.

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 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, including executive officers, 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:

	Years Ended December 31,					
	2011		2010		2009	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at beginning of period	5,508,513	\$ 0.91	5,721,528	\$ 0.94	1,057,263	\$ 1.99
Granted					4,796,425	0.81
Exercised	(67,122)	(0.81)	(142,715)	(0.81)	(5,085)	(1.30)
Forfeited	(7,800)	(0.85)	(70,300)	(3.09)	(127,075)	(4.99)
Outstanding at end of period	5,433,591	\$ 0.91	5,508,513	\$ 0.91	5,721,528	\$ 0.94

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Exercisable at end of period	5,433,591	\$	0.91	5,508,513	\$	0.91	1,137,403	\$	1.44
Weighted average fair value of options granted during period		\$			\$			\$	0.59

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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 or 2011.

The following table summarizes information about Director, officer, and employee options outstanding under the aforementioned plans at December 31, 2011:

Exercise Prices	Shares Outstanding	Weighted	
		Average Contractual Life	Shares Exercisable
\$ 6.90	15,080	0.75	15,080
\$ 8.65	2,400	1.48	2,400
\$ 8.87	700	2.36	700
\$ 1.30	894,513	6.88	894,513
\$ 0.81	4,520,898	7.54	4,520,898

**Non-employee options**

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

	Years Ended December 31,						
	2011	2010		2009			
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	
Outstanding at beginning of period	302,500	\$ 5.49	391,600	\$ 6.52	454,700	\$ 8.41	
Granted					90,000	0.84	
Exercised					(20,000)	(0.95)	
Forfeited			(89,100)	(10.00)	(133,100)	(10.00)	
Outstanding at end of period	302,500	\$ 5.49	302,500	\$ 5.49	391,600	\$ 6.52	
Exercisable at end of period	302,500	\$ 5.49	302,500	\$ 5.49	391,600	\$ 6.52	
Weighted average fair value of options granted during period		\$		\$		\$ 0.61	

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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 2010 or 2011.

The following table summarizes information about non-employee options outstanding under the aforementioned plans at December 31, 2011:

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Exercise Prices	Shares Outstanding	Weighted Average Remaining Contractual Life	Shares Exercisable
\$ 6.90	232,500	0.75	232,500
\$ 0.81	70,000	7.54	70,000

The Company recorded \$0; \$1,340,300; and \$2,111,360 as stock-based compensation expense in 2011, 2010, and 2009, respectively. The total intrinsic value of options exercised was \$49,626; \$124,221; and \$16,388 in 2011, 2010, and 2009, respectively. The aggregate intrinsic value of options outstanding and of options exercisable at December 31, 2011 was approximately \$1.7 million. There is no compensation cost related to non-vested stock options to be recognized in the future.

**Options Pricing Models Assumptions**

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.

**14. 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 \$76,643 in 2009. In the third quarter of 2009, the Company discontinued its matching contributions until further notice.

**15. BUSINESS SEGMENTS**

	2011	2010	2009
U.S. sales	\$ 26,655,781	\$ 29,577,050	\$ 34,466,797
North and South America sales (excluding U.S.)	4,736,356	4,887,073	1,764,584
Other international sales	710,159	1,755,439	2,750,456
Total sales	\$ 32,102,296	\$ 36,219,562	\$ 38,981,837
Long-lived assets			
U.S.	\$ 12,412,502	\$ 12,297,942	\$ 13,961,445
International	\$ 241,354	\$ 262,650	\$ 272,736

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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.

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The selected quarterly financial data for the periods ended December 31, 2011 and 2010, 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.

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

	<b>2011</b>			
	<b>Quarter 1</b>	<b>Quarter 2</b>	<b>Quarter 3</b>	<b>Quarter 4</b>
Sales, net	\$ 9,748	\$ 7,976	\$ 8,271	\$ 6,108
Cost of sales	6,457	4,840	4,881	5,021
Gross profit	3,291	3,136	3,390	1,087
Total operating expenses	3,391	4,124	3,416	4,063
Income (loss) from operations	(100)	(988)	(26)	(2,976)
Interest and other income	16	18	15	14
Interest expense, net	(57)	(66)	(63)	(56)
Litigation settlements, net	1,900	1,900	1,900	
Provision (benefit) for income taxes	35	17	(2)	(37)
Net income (loss)	1,724	847	1,828	(2,981)
Preferred stock dividend requirements	(342)	(342)	(342)	(230)
Earnings (loss) applicable to common shareholders	\$ 1,382	\$ 505	\$ 1,486	\$ (3,211)
Basic earnings (loss) per share	\$ 0.06	\$ 0.02	\$ 0.06	\$ (0.13)
Diluted earnings (loss) per share	\$ 0.05	\$ 0.02	\$ 0.06	\$ (0.13)
Weighted average shares outstanding - basic	23,986,114	24,004,118	24,027,053	24,667,668
Weighted average shares outstanding - diluted	26,664,597	26,189,076	25,950,804	24,667,668
Gross profit margin	33.8%	39.3%	41.0%	17.8%

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

	<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)
Interest and other income	6	3	10	14
Interest expense, net	(91)	(76)	(70)	(66)
Litigation settlements, net			7,259	1,900
Provision (benefit) 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)

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	<b>Quarter 1</b>	<b>Quarter 2</b>	<b>Quarter 3</b>	<b>Quarter 4</b>
Net earnings (loss) per share basic	\$ (0.11)	\$ (0.13)	\$ 0.33	\$ (0.05)
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%

Major variances for 2011 compared to 2010 are due to lower sales volumes, lower operating expenses, primarily litigation costs and stock option expense, and lower litigation proceeds.

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**Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.**

None.

**Item 9A. Controls and Procedures.**

Disclosure Controls and Procedures

Pursuant to Rule 13a-15(b) under the Securities Exchange Act of 1934 (the Exchange Act), Management, with the participation of our President, Chairman, and Chief Executive Officer, Thomas J. Shaw (the CEO), and our Vice President and Chief Financial Officer, Douglas W. Cowan (the CFO), acting in their capacities as our principal executive and financial officers, evaluated the effectiveness of our disclosure controls and procedures, as defined in Rule 13a-15(e) under the Exchange Act. The term disclosure controls and procedures means controls and other procedures that are designed to ensure that information required to be disclosed by us in our periodic reports is: i) recorded, processed, summarized, and reported within the time periods specified in the Securities and Exchange Commission's (the SEC) rules and forms; and ii) accumulated and communicated to our Management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Based upon this evaluation, the CEO and CFO concluded that, as of December 31, 2011, our disclosure controls and procedures were effective.

Management's Annual Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over our financial reporting as defined in Rule 13a-15(f) under the Exchange Act. The term internal control over financial reporting means a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our Board of Directors, Management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that: (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect our transactions and dispositions of assets; (ii) provide reasonable assurance that our transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of Management and Directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on our financial statements. Management used the *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission to evaluate the effectiveness of our internal control over financial reporting as required by paragraph (c) of Rule 13a-15 under the Exchange Act. Management, with the participation of our CEO and CFO, concluded that our internal control over financial reporting as of December 31, 2011, was effective. No material weaknesses in our internal control over financial reporting were identified by Management.

Our Management, including the CEO and CFO, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all errors and all instances of fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met.

Changes in Internal Control Over Financial Reporting

There have been no changes during the fourth quarter of 2011 or subsequent to December 31, 2011 in our internal control over financial reporting or in any other factor that has materially affected or is reasonably likely to materially affect our internal control over financial reporting.

**Item 9B. Other Information.**

We exchanged 1,246,964 shares of Common Stock (and cash) for 1,246,964 shares of our Class B Convertible Preferred Stock as of November 4, 2011 pursuant to the 2011 Exchange Offer. We exchanged 30,500 shares of Common Stock (and cash) for 30,500 shares of our Preferred Stock as of December 30, 2011 outside of the

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2011 Exchange Offer. The 2011 Exchange Offer was offered to all our Preferred Stockholders. The sales outside of the 2011 Exchange Offer were made to three of our Preferred Shareholders who did not participate in the 2011 Exchange Offer. In accordance with the terms of both exchange transactions, participating Preferred Stockholders agreed to waive all unpaid dividends in arrears associated with their tendered Preferred Stock. Both transactions are exempt from registration under the Securities Act pursuant to Section 3(a)(9) of the Securities Act because the securities were exchanged with existing security holders exclusively where no commission or other remuneration was paid or given directly or indirectly for soliciting such exchange.

**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 currently consists of a total of six (6) members, three (3) members of which are Class 1 Directors and three (3) of which are Class 2 Directors which serve for two-year terms. Marwan Saker served as a Class 2 Director until February 29, 2012.

<b>Name</b>	<b>Age</b>	<b>Position</b>	<b>Term as Director Expires</b>
<b>EXECUTIVES</b>			
Thomas J. Shaw	61	Chairman, President, Chief Executive Officer, and Class 2 Director	2012
Douglas W. Cowan	68	Vice President, Chief Financial Officer, Treasurer, Principal Accounting Officer, and Class 2 Director	2012
Russell B. Kuhlman	58	Vice President, Sales	N/A
Michele M. Larios	45	Vice President, General Counsel, and Secretary	N/A
Steven R. Wisner	54	Executive Vice President, Engineering & Production and Class 1 Director	2013
<b>INDEPENDENT DIRECTORS</b>			
Marco Laterza	64	Class 1 Director	2013
Amy Mack	44	Class 1 Director	2013
Marwan Saker	56	Former Class 2 Director	2012
Clarence Zierhut	83	Class 2 Director	2012
<b>SIGNIFICANT EMPLOYEES</b>			
Kathryn M. Duesman	49	Executive Director, Global Health	N/A
Lawrence G. Salerno	51	Director of Operations	N/A
Shayne Blythe	43	Director of Sales and Marketing Logistics	N/A
John W. Fort III	43	Director of Accounting	N/A
James A. Hoover	64	Director of Quality Assurance	N/A
R. John Maday	51	Production Manager	N/A
Judy Ni Zhu	53	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



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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 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 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.

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 all legal matters, both internally and with outside counsel, Ms. Larios oversees work on any pertinent legislative issues and all relevant regulatory matters.

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, 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.

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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, and she served as the Chief Nursing Officer of EmergiStaff & Associates from 2000 to 2011. From 2003 to 2010, she was the Owner and Aesthetics Nurse Specialist for Spa O2 & Medical Aesthetics. In 2011, she was involved with Report Prep. Ms. Mack's responsibilities included nurse and utilization review, identification and application of evidence based medicine resources to medication and procedure requests, and review of workers' compensation claims.

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Marwan Saker joined our Board of Directors in June 2000 and resigned on February 29, 2012. Mr. Saker served as Chief Executive Officer of Sovana, Inc., a private international trade company. He 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. He served as Manager of Hanneke Corp., a private trust. He served as a Member of My Investments, LLC, a private entity. He served as President of Saker Investments Inc., a private investment company. He was 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**

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.

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.

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.

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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.

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. Based on our review of the forms submitted to us during and with respect to its most recent fiscal year, all of our Directors, executive officers, and 10% shareholders filed all reports timely.

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;

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

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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 and Marco Laterza. Marwan Saker served on the Audit Committee until his resignation on February 29, 2012. Each of the members of the Audit Committee is independent as determined by the NYSE Amex rules.

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.

**Item 11. Executive Compensation.**

COMPENSATION DISCUSSION AND ANALYSIS

**The Objectives of Our Compensation Plan**

Our executive officer compensation program (the Compensation Program) is based on the belief that competitive compensation is essential to attract, retain, motivate, and reward highly qualified and industrious executive officers. Our Compensation Program is intended to accomplish the following:

attract and retain highly talented and productive executive officers;

provide incentives and rewards for superior performance by the executive officers; and

align the interests of executive officers with the interests of our stockholders.

**What the Compensation Program Is Designed to Award**

Our Compensation Program is designed to award both superior long-term performance by our executive officers and their loyalty.

### **Summary of Each Element of Compensation**

To achieve these objectives, the Compensation and Benefits Committee has approved an executive officer compensation program that consists of four basic components:

base salary;

short-term incentive compensation in the form of cash bonuses;

periodic long-term incentive compensation in the form of stock options; and

medical, life, and benefit programs (which are generally available on the same terms to all employees).

### **Why We Choose to Pay Each Element of Our Compensation Program**

#### *Base Salary*

We choose to pay a significant component of our compensation in base salary due to the fact that our financial performance is constrained by the monopolistic activities of BD. Until such time as we believe that we have access to the market, we believe that it is appropriate to weigh our Compensation Program heavily in favor of base salaries rather than in incentive compensation.



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*Cash Bonuses*

From time to time and when our cash reserves allow, we grant cash bonuses in order to reward significant efforts or the accomplishment of short term goals. The Compensation and Benefits Committee granted such bonuses in 2010 to certain executive officers in recognition of the time and effort expended by such executive officers which led to the settlement agreement with Abbott and Hospira. The preparation for the trial and ultimate settlement was an extraordinary time commitment for the executive officers to whom bonuses were granted and resulted in a total of approximately \$14 million paid to us over time. Thomas J. Shaw declined any bonus.

Prior to 2010, the last bonuses were granted in 2003.

*Long-Term Incentives: Stock Options*

Long-term incentives are provided through grants of stock options. The grants are designed to align the interests of executive officers with those of stockholders and to provide each executive officer with a significant incentive to manage from the perspective of an owner with an equity stake in the Company.

**How We Determine the Amount or Formula for Payment in Light of Our Objectives**

Executive compensation remains the same until there is a review of such compensation by the Compensation and Benefits Committee. Compensation, other than that of the Chief Executive Officer, has generally not been reviewed annually. Under the terms of Mr. Shaw's employment agreement, his compensation is reviewed annually.

*Base Salary*

The base salary for each of our executive officers is subjectively determined primarily on the basis of the following factors: experience, individual performance, contribution to our performance, level of responsibility, duties and functions, salary levels in effect for comparable positions within and without our industry, and internal base salary comparability considerations. However, salaries can also be affected by our long-term needs.

These base salaries are reviewed periodically and may be adjusted based upon the factors discussed in the previous paragraph, as well as upon individual performance during the previous fiscal year, changes in the duties, responsibilities and functions of the executive officer, and general changes in the compensation peer group in which we compete for executive talent. The relative weight given to each of these factors in the Compensation and Benefits Committee's recommendation differs from individual to individual, as the Compensation and Benefits Committee deems appropriate.

Beginning August 1, 2009, all employees above a certain salary level had their salaries reduced by 10%. Although certain salary reductions remain in place, we granted payments to our employees to offset such salary reductions in the first and third quarters of 2010. All Executive Officers and other employees' salaries continue to be reduced by 10% from the levels prior to August 2009. However, Mr. Shaw's Employment Agreement provides salary is automatically increased by the percentage increase in the consumer price index (CPI) from the previous year. The Compensation and Benefits Committee decided to increase Mr. Shaw's salary (which has also been cut by 10%) by \$13,904 over his 2011 salary for 2012.

*Cash Bonuses*

The bonuses, when paid, are paid on a discretionary basis as determined by the Compensation and Benefits Committee. Factors considered by the Compensation and Benefits Committee include personal performance, level of responsibility, and the factors used in determination of base salary as stated above, except with a greater focus on the prior fiscal year. The Compensation and Benefits Committee also considers our need to retain cash in deciding whether to grant cash bonuses.

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*Long-Term Incentive: Stock Options*

We have issued stock options to our employees from time to time and may do so in the future. We did not issue any stock options in 2011. Options are generally granted to regular full-time employees and officers except for our CEO.

In 2009, the Compensation and Benefits Committee granted an option to Thomas J. Shaw, our CEO, which option grant was approved by the shareholders later that year. The option was granted outside of any plan and was for the purchase of 3,000,000 shares of Common Stock.

If stock options are to be issued, Management prepares a proposal to the Compensation and Benefits Committee. Considerations by Management in its initial proposal in determining a suitable aggregate fair market value of options to be granted include our financial condition, the number of options already outstanding, and the benefit to the non-executive officer employees. The proposal includes information relating to the expected expense of such grants to be recognized by us, the approximate number of options to be issued, the number of options currently outstanding, the employees to be included, the amount of stock currently outstanding, and the method under which the options would be awarded.

Once the dollar amount of options to be granted is approved by the Compensation and Benefits Committee, Management begins determining the aggregate number of shares underlying options that can be granted under such approval (based on the fair value of an option for the purchase of one underlying share). Factors included in the determination of the value of an option grant for the purchase of one share include current market price of the Company's stock, the proposed exercise price, the proposed expiration date, the volatility of the Company's stock, and the risk free rate. We may retain an independent outside consultant to determine such value. In the past we have utilized the Black-Scholes model as well as the binomial model, but we may use other methods in the future as more appropriate methods are developed.

Management provides the Compensation and Benefits Committee with a proposal regarding option grants to executive officers. If the recommendation is acceptable, the committee grants the options. If the committee feels changes are merited, it grants options on its own terms.

With regard to many past grants, after the aggregate number of shares underlying the options to be granted was determined, we allocated the options to our various departments using a factor based on their annual compensation times their performance rating. The individual employee's allocation factor was the numerator of a fraction. The denominator was the department's sum of all factors (annual compensation times performance ratings of all the eligible employees). The resulting fraction was multiplied by the stock options to be awarded to determine the employee's individual portion of the aggregate approved options. Future grants may be based on the value of contributions to the Company and not necessarily pursuant to any formula.

The allocation may be further reviewed by each department's management if they believed certain employees were not awarded an appropriate number of options. Management would consider any suggestions.

Each stock option grant to employees allows the employee to acquire shares of Common Stock at a fixed price per share (never less than the closing stock price of the Common Stock on the date of grant) for a fixed period (usually ten years). With regard to grants prior to 2009, each

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option generally became exercisable after three years, contingent upon the employee's continued employment with us. The exceptions include options issued to Officers and Directors pursuant to the Exchange Offer, which vested immediately for non-employee Directors and after one year for employees (including employee Directors) and options granted in 2009 which vested in one year for executive officers and immediately for non-employee Directors. Accordingly, generally stock option grants will provide a return to the employee only if the employee remains employed by us during the vesting period, and then only if the market price of the underlying Common Stock appreciates. Future grants may vest over a shorter or longer period.

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**How Each Compensation Element and Decision Fits Into Overall Compensation Objectives**

Our Compensation Program is intended to accomplish the following objectives: 1) attract and retain highly talented and productive executive officers; 2) provide incentives and rewards for superior performance by the executive officers; and 3) align the interests of executive officers with the interests of our stockholders.

We ensure, through periodic retention of compensation consulting experts to provide a benchmark analysis of industry compensation, that overall compensation is sufficient to attract and retain highly talented and productive executive officers. We pay the bulk of our compensation in the form of cash compensation due to the fact that competing in an anti-competitive environment means that results will not always be commensurate with performance. We believe that the performance of our executives has been outstanding. We believe this is especially true given the anti-competitive environment in which we operate. Bonuses are granted occasionally to recognize extraordinary performance and/or extraordinary job requirements. We believe this approach and weighting of compensation elements is necessary to retain our executive talent due to the environment in which we operate.

Periodically, we grant stock options with the intent to provide both an incentive and reward to executive officers for long-term performance and to align the interests of our employees with that of the shareholders.

**Shareholder Advisory Votes**

As a smaller reporting company, we are not yet required to solicit shareholder advisory votes with respect to executive compensation.

**Allocation Between Long-Term/Current and Between Cash/Non-Cash Compensation**

All of our long-term compensation consists of non-cash compensation in the form of stock options. We believe that the granting of stock options incentivizes executives to maximize our long-term strengths as well as our stock price. However, because we are operating in a monopolistic environment and our stock price has little relationship with our performance, the most significant component of compensation is base salary and not stock options. Management is incentivized to maximize shareholder value and will be rewarded if they do so. However, a significant base salary enables us to retain this competent Management despite the current inability to provide valuable equity incentives.

**How Determinations Are Made as to When Awards Are Granted**

Generally, option awards to executive officers are granted by the Compensation and Benefits Committee and for others are granted at the discretion of the Board after recommendation of the Compensation and Benefits Committee or on the committee's own initiative. No awards are granted if the Compensation and Benefits Committee does not support a recommendation.

Unfortunately, our stock price does not always react as expected to our achievements. Accordingly, at times, options have been granted to aid in retaining competent and experienced executives without regard to the then current stock price. However, such options always have exercise prices that are at or above fair market value on the date of grant.

In addition, there is no relationship between the date of grant of options and our possession of material non-public information (i.e., we grant options without regard to whether or not we are in possession of material non-public information as we usually are in possession of such information). Furthermore, it is our policy with regard to options that (although the options could be exercised) the underlying shares could not be sold into the market while the executive was in possession of material non-public information under our insider trading policy. Accordingly, we believe that there is minimal risk of the executive profiting from such material nonpublic information.

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**What Specific Items of Corporate Performance Are Taken Into Account in Setting Compensation Policies and Making Compensation Decisions**

Cash reserves as well as trends in sales and costs are taken into account when considering the advisability of increasing base salaries or granting cash bonuses. However, no specific items of corporate performance are taken into account in setting executive compensation due to the fact that we compete in a monopolistic environment and, therefore, significant achievement or performance is not always correlated with corporate results. At such times that any of these factors make it inadvisable to increase salaries or grant bonuses as advisable, then consideration is given to increasing option awards taking into account the value of prior option awards.

Awards are granted on the basis of historical performance. Accordingly, there is no discretion to change the awards once granted.

**How Compensation Reflects Individual Performance**

Executive compensation is not based on the individual's contribution to specific, quantitative corporate objectives due to the fact that we compete in a monopolistic environment. However, the individual's contribution to our performance is determined pursuant to qualitative factors as discussed above under How We Determine the Amount or Formula for Payment in Light of Our Objectives.

**Factors We Consider in Determining to Change Compensation Materially**

We consider our cash position, current liquidity trends, and the short-term and long-term needs for cash reserves (especially in light of the hostile environment in which we operate) when evaluating whether we can change compensation materially at a given time.

On an individual-by-individual basis, we also consider the value of past option compensation, the competitiveness of that individual's base salary, and that individual's contribution to our goals.

**The Impact of the Accounting and Tax Treatments of Our Types of Compensation**

Stock options granted to executives and other employees are expensed for accounting purposes under the Stock Compensation Topic of the Financial Accounting Standards Board Accounting Standards Codification. We expense all of our option costs as we do the costs of salaries and any periodic bonuses. Accordingly, the impact of tax treatment of various compensation forms does not impact our compensation decisions. Stock option expense is not recognized for tax purposes, except in the case of non-qualified stock options. For non-qualified stock options, the intrinsic value of the option is recognized when the option is exercised.

**Our Policy Regarding Stock Ownership and Hedging**

We do not have a policy regarding stock ownership by executive officers. We prohibit certain stock transactions by employees and Directors, including:

1. Purchases and sales of our stock within a six month period;
2. Short sales of our stock; and
3. Transactions in puts, calls, or other derivative securities involving our stock.

Furthermore, employees and Directors are required to pre-clear any hedging transactions.

**Benchmarking of Our Compensation Program**

In 2003, we hired Trinity Executive Recruiters, Inc. to assist us in providing benchmarks for the salary component of executive compensation by similarly sized companies in similar industries for persons that hold



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positions which are currently fulfilled by various members of our executive team. These benchmarks at least support existing executive compensation.

**The Role of Our Executives and Directors in Determining Compensation**

Management establishes the initial recommendations regarding compensation for all employees, including themselves. The Compensation and Benefits Committee reviews executive compensation changes and the process by which the employees are compensated.

**Compensation Pursuant to Employment Agreement**

We have an Employment Agreement with Mr. Thomas J. Shaw which was modified effective January 1, 2008 to avoid adverse tax consequences to Mr. Shaw created by the passage of the American Jobs Creation Act of 2004. No other executives or Directors are compensated pursuant to employment agreements.

Our Employment Agreement with Mr. Shaw (the "Employment Agreement") provides for an initial period of three years which ended December 31, 2010 and automatically and continuously renews for consecutive two-year periods. The Employment Agreement is terminable either by us or Mr. Shaw upon 30 days' written notice or upon Mr. Shaw's death.

The Employment Agreement provides for an annual salary of at least \$416,399.88 with an annual salary increase equal to no less than the percentage increase in the CPI over the prior year. The Employment Agreement requires that Mr. Shaw's salary be reviewed by the Compensation and Benefits Committee annually, which shall make such increases as it considers appropriate. Mr. Shaw took a 10% salary cut in August of 2009, along with all other executive officers and other employees earning over a certain salary. In 2010, Mr. Shaw received \$41,681.64 to offset his salary reductions through August 20, 2010. In 2012, the Compensation and Benefits Committee increased his salary by \$13,904 over his 2011 salary.

Under the Employment Agreement, we are obligated to provide certain benefits, including, but not limited to, participation in qualified pension plan and profit-sharing plans, participation in the Company's Cafeteria Plan and other such insurance benefits provided to other executives, paid vacation, and sick leave. We are also obligated to furnish him with a cellular telephone and suitable office space as well as reimburse him for any reasonable and necessary out of pocket travel and entertainment expenses incurred by him in carrying out his duties and responsibilities, membership dues to professional organizations, and any business-related seminars and conferences.

Pursuant to the Employment Agreement, we are obligated to indemnify Mr. Shaw for all legal expenses, court costs, and all liabilities incurred in connection with any proceeding involving him by reason of his being an officer, employee, or agent of the Company. We are further obligated to pay reasonable attorney fees and expenses and court and other costs associated with his defense in the event that, in Mr. Shaw's sole judgment, he needs to retain counsel or otherwise expend his personal funds for his defense.

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Upon his death, Mr. Shaw's estate shall be entitled to his salary through the date of death, applicable benefits, and reimbursement of expenses.

We have the right to terminate the Employment Agreement if Mr. Shaw incurs a permanent disability during the term of his employment. A permanent disability means that Mr. Shaw is unable to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment which can be expected to result in death or can be expected to last for a continuous period of not less than 12 months or is, by reason of any medically determinable physical or mental impairment which can be expected to result in death or can be expected to last for a continuous period of not less than 12 months, receiving income replacement benefits for a period of not less than 3 months under an accident and health plan covering employees of the Company. Mr. Shaw shall also be deemed to be disabled if he is determined to be totally disabled by the Social Security Administration. In such event, Mr. Shaw is entitled to his salary through the date of termination, reimbursement of expenses, and salary for a period of 24 months as well as applicable benefits.

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Mr. Shaw's employment may be terminated for cause which is defined to be conviction of a felony which is materially detrimental to the Company, proof, as determined finally by a court of competent jurisdiction of the gross negligence or willful misconduct which is materially detrimental to the Company or proof, as determined finally by a court of competent jurisdiction, of a breach of a fiduciary duty which is materially detrimental to the Company. In such event, he shall be entitled to his salary through the date of termination plus reimbursement of expenses.

If Mr. Shaw is terminated without cause and not at his implicit request, Mr. Shaw shall be entitled to his salary through the date of termination, reimbursement of expenses, his salary for 24 months, as well as applicable benefits.

If Mr. Shaw resigns (other than because of a change in control), he is entitled to his salary through the date of termination, reimbursement of expenses, salary for 90 days, and applicable benefits.

Mr. Shaw has the right under this agreement to resign in the event that there is a change in control. A Change of Control shall be deemed to have occurred on either of the following dates: (i) the date any one person (other than Mr. Shaw), or more than one person acting as a group, acquires (or has acquired during the 12-month period ending on the date of the most recent acquisition by such person or persons) ownership of stock of the Company possessing 30% or more of the total possible voting power of the stock of the Company (assuming the immediate conversion of all then outstanding convertible preferred stock) or (ii) the date a majority of members of the Board of Directors is replaced during any 12-month period by Directors whose appointment or election is not endorsed by a majority of the members of the Company's Board of Directors before the date of the appointment or election. Mr. Shaw further has the right to resign if there is a change in ownership. A change in ownership is defined to have occurred on the date that any one person (other than Mr. Shaw) or more than one person acting as a group acquires ownership of the Company's stock that, together with the stock previously held by such person or group, constitutes more than 50% of the total fair market value or total voting power (assuming the immediate conversion of all then outstanding convertible preferred stock) of the Company. In such event Mr. Shaw is entitled to salary through the date of termination, salary for 24 months, reimbursement of expenses, and applicable benefits.

Mr. Shaw's commitment to the Company may not be construed as preventing him from participating in other businesses or from investing his personal assets as may require occasional or incidental time in the management, conservation, and protection of such investments provided such investments or businesses cannot be construed as being competitive or in conflict with the business of the Company.

Mr. Shaw has agreed to a one-year non-compete, not to hire or attempt to hire employees for one year, and not make known our customers or accounts or to call on or solicit our accounts or customers in the event of termination of his employment for one year unless the termination is without cause or pursuant to a change of control or ownership.

Compensation Committee Report

The Compensation and Benefits Committee has reviewed and discussed the COMPENSATION DISCUSSION AND ANALYSIS required by Item 402(b) of Regulation S-K with Management, and, based on the review and discussions referred to in paragraph (e)(5)(i)(A) of Item 407 of Regulation S-K, has recommended to the Board of Directors that the COMPENSATION DISCUSSION AND ANALYSIS be included in this report on Form 10-K.

CLARENCE ZIERHUT  
MARCO LATERZA  
AMY MACK

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## SUMMARY OF TOTAL COMPENSATION

The following Summary Compensation Table sets forth the total compensation paid or accrued by us over the past three fiscal years to or for the account of the principal executive officer, the principal financial officer, and the three highest paid additional executive officers:

## SUMMARY COMPENSATION TABLE FOR 2009-2011

<b>Name and Principal Position</b>	<b>Year</b>	<b>Salary(1) (\$)</b>	<b>Bonus (\$)</b>	<b>Option Awards(2) (\$)</b>	<b>All Other Compensation(3) (\$)</b>	<b>Total (\$)</b>
Thomas J. Shaw President and CEO (principal executive officer)	2009	399,887		1,762,500	4,808	2,167,195
	2010	427,854				427,854
	2011	392,810				392,810
Michele M. Larios Vice President, General Counsel	2009	336,676		89,858	4,047	430,581
	2010	350,051	200,000			550,051
	2011	315,281				315,281
Douglas W. Cowan Vice President, CFO (principal financial officer, principal accounting officer)	2009	278,289		57,575	3,346	339,210
	2010	290,406	35,000			325,406
	2011	261,051				261,051
Steven R. Wisner Executive Vice President, Engineering and Production	2009	278,289		13,806	3,123	295,218
	2010	290,000	15,000			305,000
	2011	261,000				261,000
Russell B. Kuhlman Vice President, Sales	2009	133,769		14,688	1,606	150,063
	2010	139,992				