

RETRACTABLE TECHNOLOGIES INC  
Form 10-K  
March 31, 2010  
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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, 2009

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 000-30885

**Retractable Technologies, Inc.**

(Exact name of registrant as specified in its charter)

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

**972-294-1010**

Registrant's telephone number, including area code

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

<b>Title of each class</b>	<b>Name of each exchange on which registered</b>
Common	NYSE Amex LLC

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

**Preferred Stock**

(Title of class)

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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, 2009 was \$11,059,334.10, assuming a closing price of \$0.90 and outstanding shares held by non-affiliates of 12,288,149.

### 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, 2010, there were 23,825,149 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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FORM 10-K

For the Fiscal Year Ended December 31, 2009

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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 (as it affects our costs as well as market access), our ability to maintain favorable supplier arrangements and relationships, our ability to receive royalties from Baiyin Tonsun Medical Device Co., Ltd. ( BTMD ), 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 VanishPoint® safety products (consisting of 1mL tuberculin, insulin, and allergy antigen VanishPoint® syringes; 0.5mL, 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 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 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. Patient Safe®'s unique luer guard reduces the risk of luer tip contact contamination and the risk of contamination of intravenous fluid.

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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 and Thomas J. Shaw, our Founder and CEO, entered into a Technology License Agreement dated effective as of the 23rd day of June 1995, whereby Mr. Shaw granted us a worldwide exclusive license to manufacture, market, sell, and distribute Licensed Products and Improvements until the expiration of the last Licensed Patents unless sooner terminated under certain conditions without right to sublicense. Licensed Products, Improvements, and Licensed Patents are all terms that are extensively defined in the Technology License Agreement. In exchange, we paid a \$500,000 initial licensing fee and a 5% royalty on gross sales after returns of Licensed Products. Mr. Shaw entered into an agreement whereby Ms. Suzanne August, his former spouse, is entitled to \$100,000 per quarter payable out of any royalties. See Patents, Trademarks, Licenses, and Proprietary Rights for a more detailed discussion. 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

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certain additional patent applications (addressing non-syringe patents) owned by Mr. Shaw in 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.

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

Our products have been and continue to be distributed nationally through numerous distributors. However, we have been blocked from access to the market by exclusive marketing practices engaged in by BD which dominates 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. On November 9, 2009, the jury returned a verdict finding that all three patents were valid and infringed.

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 are focusing on methods of upgrading our manufacturing capability and efficiency in order to enable us to offer our technology at a reduced price. We believe our current capitalization provides the resources necessary to implement these changes and improve our manufacturing capacity and efficiency, thereby reducing our unit cost.

We have developed and are developing new safety medical products, some of which do not utilize our patented retraction technology. The Patient Safe® syringe is one such product. This product is uniquely designed to reduce the risk of bloodstream infections resulting from catheter hub contamination. Patient Safe®'s unique luer guard reduces the risk of luer tip contact contamination and the risk of contamination of intravenous fluid.

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; 3mL, 5mL, and 10mL VanishPoint® syringes; the VanishPoint® blood collection tube holder; the VanishPoint® IV safety catheter; small diameter tube adapter and the Patient Safe® syringe, which is uniquely designed to reduce the risk of bloodstream infections resulting from catheter hub contamination. Patient Safe®'s unique luer guard reduces the risk of luer tip contact contamination and the risk of contamination of intravenous fluid. We are also selling autodisable syringes in the international market.



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In the August 2007 issue of *Health Devices*, ECRI listed two syringes with the highest possible rating: our VanishPoint® syringe and BD's Integra syringe. A jury returned a verdict in November 2009 finding that all three patents asserted by us against BD are valid and infringed by BD (with regard to its Integra product).

Syringe sales comprised 98.0%; 98.6%; and 98.9% of revenues in 2007, 2008, and 2009.

### Principal Markets

Our products are sold to and used by healthcare providers primarily in the U.S. (with 11.6% of revenues in 2009 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 syringe and needle device market continues to be a market in transition. The nature of the products comprising the market is slowly changing from standard to safety devices. The impetus for the change to safety devices is the risk that is carried with each needlestick injury which includes the transmission of over 20 bloodborne

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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, many 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 long-term exclusive 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 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 exhibits at related tradeshow 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, long-term exclusive 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 Patient Safe®, catheters, and blood tube holders.

We have numerous agreements with organizations for the distribution of our products in foreign markets. The total population of Western Europe is almost 400 million, and the recognition for the urgency of safe needle devices in parts of Europe has followed the U.S. model. The European Hospital and Healthcare Employers' Association (HOSPEEM) and the European Federation of Public Services Union (EPSU) have entered into an agreement to help prevent needlestick injuries among hospital staff. The European Commission has issued a proposal for a council directive to implement the agreement. Regions within Asia, South America, and Africa are also recognizing the need for our products. Beginning in 2004, we were given an award (from PATH) to supply syringes to various African countries under the President's Emergency Plan for AIDS relief (PEPFAR). Awards increased significantly from 2004 to 2007. The continuation of PEPFAR has been reauthorized by Congress through 2013. However, funding for the procurement of safety syringes in this program has not occurred to date.

As a result of the introduction of VanishPoint® syringes through the PEPFAR initiative, African countries have begun to procure products outside of the U.S.-funded program. In 2007, the Director General of Nigeria's National Agency for Food and Drug Administration and Control (NAFDAC), endorsed automated retraction syringes for use throughout Nigeria. We are currently selling syringes to a Nigerian distributor for use in that country. At the end of 2008, the Deputy Prime Minister of Namibia also publically endorsed automated retraction syringes as a public intervention that would protect health workers and save their patient's lives.

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

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afforded by our products; (f) supply product through GPOs and Integrated Delivery Networks where possible; (g) 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 patented 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 suppliers include Magor Mold, Inc., Helix Medical (formerly APEC), Channel Prime Alliance, Exacto Spring Corporation, Sterigenics, and ISPG.

Patents, Trademarks, Licenses, and Proprietary Rights

We and Mr. Shaw 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 are 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 principal syringe patent in the U.S., as well as its foreign counterpart, will expire in May 2015. 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. We have applied for a trademark for the Port Prep.

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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 2009 we obtained roughly 67.5% 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 3.8% of our 2009 revenues.

We previously entered into a License Agreement with BTMD as of May 13, 2005. That license expired on May 13, 2008 (prior to the manufacture and delivery of any products). Nevertheless, BTMD continued to work toward completing the facility and gaining the necessary approvals in order to manufacture and sell products. The facility has been completed and BTMD has met Chinese government requirements. BTMD received a Registration Certificate for Medical Device on August 24, 2009. Production efforts are currently underway and are being tested. We entered into a new agreement (effective as of July 1, 2009) with BTMD along similar terms as the prior agreement. This agreement expires on July 1, 2010 which may automatically extend under certain conditions. Such terms include granting to BTMD a limited exclusive license to manufacture and a limited exclusive right to sell syringes in the People's Republic of China ( PRC ) having retractable needles that incorporate our technology. This License Agreement is subject to the Technology License Agreement dated June 23, 1995 between Mr. Thomas J. Shaw, our founder and CEO, as licensor, and the Company, as licensee (as amended). Accordingly, Mr. Shaw will receive 5% of the licensing proceeds we receive. BTMD has agreed to manufacture and sell these products in the PRC and to pay us a quarterly royalty of two and one-half cents per unit on 3mL and 5mL syringes and a royalty of three and one-half cents per unit on 0.5mL, 1mL, and 10mL syringes. The obligation to pay the royalties continues even if any and all of our patent rights in the PRC are found to be invalid or unenforceable for any reason. We still continue to expect royalty payments although we are unable to predict the date we will begin to receive such royalties.

Flu and Swine Flu Impact

Historically, unit sales have increased in the latter part of the year due, in part, to the demand for syringes during the flu season. We expect the H1N1 virus ( Swine Flu ) to have a longer worldwide immunization duration than the seasonal flu. 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. Sales to the DHHS comprised 52.0% and 24.4% of our revenues for the three months and twelve months ended December 31, 2009, respectively. This program, which was estimated to run from August 2009 through March 2010, ended in December 2009. Our revenue increased 142.1% in the fourth quarter principally due to the DHHS contract. We do not know if there will be a similar program in 2010.

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

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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. A reserve is established for any excess or obsolete inventories.

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.

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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 2009 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, a copy of which was attached as Exhibit no. 6.3 to our Form 10-SB filed on June 23, 2000. 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 minus a restocking fee of 10% and all applicable freight charges.

Our international contracts do not provide for any returns.

Our return policy also provides that a customer may return product that is overstocked. Overstocking returns are limited to two times in each 12 month period up to 1% of distributor's total purchase of products for the prior 12 month period 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 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 manufacturer.

Dependence on Major Customers

Two customers, DHHS and McKesson, accounted for an aggregate of 38.4% of our revenue in 2009. We have numerous other customers and distributors that sell our products in the U.S. and internationally. The DHHS program, which was estimated to run from August 2009 through March 2010, ended in December 2009. We do not know if there will be a similar program in 2010.

Two customers, DHHS and Cardinal Health, comprised 68.4% of our accounts receivable at December 31, 2009.

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.

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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.

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 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 11.6% of revenues in 2009 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. Our price per unit is competitive or even lower than the competition once all the costs 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. We sued Occupational and Medical Innovations Limited ( OMI ) in April 2008 and separately sued BD in June 2007 for claims of patent infringement (See **Item 3. Legal Proceedings**), and in December 2009 and November 2009, respectively, such companies were found to infringe our patents. These judgments could increase demand for our product. However, there is no assurance when or if such increase will occur.

We have three major competitors: BD, Covidien Ltd. (formerly known as Tyco Healthcare which was spun off from Tyco International) ( Covidien ), and Terumo Medical Corp. ( Terumo ).

Founded in 1897, BD is headquartered in New Jersey. BD's safety-engineered device sales accounted for approximately 23% of BD's total 2009 sales. BD currently manufactures the SafetyLok<sup>®</sup>, a syringe that utilizes a tubular plastic sheath that must be manually slid over the needle after an injection, and the SafetyGlide<sup>®</sup>, 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<sup>®</sup> needle cover. BD also manufactured a 3mL and 1mL retracting needle product based on a license agreement with Specialized Health Products International, Inc. (formerly the Med-Design Corporation). The Integra<sup>®</sup>, a retractable syringe offered by BD, was the subject product in a patent infringement case in which a jury found in our favor. A final judgment has not been entered. See **Item 3. Legal Proceedings**. The introduction of this syringe had little impact on our sales due to BD's historic market dominance. BD's Vacutainer<sup>®</sup> blood collection products are commonly used as industry jargon to refer to blood collection products in general.

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Sherwood Medical Co. ( Sherwood ) was acquired by Tyco International. Sherwood is now part of Covidien. Covidien manufactures various safety syringes and needles.

Terumo was the first company to sell disposable syringes in Japan. Today, Terumo manufactures standard syringes, blood collection tube holders, safety syringes, and blood collection devices. It operates internationally and has sales in more than 150 countries.

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 in order for the safety mechanism to be activated. 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

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both hands to remain safely out of harm's way. If the Integra™ is removed from the market, VanishPoint® will be the only fully passive retractable syringe being manufactured in commercial quantities in the U.S.

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 the 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 are focusing on methods of upgrading our manufacturing capability and efficiency in order to enable us to compete by offering our technology at a reduced price. We believe our current capitalization provides the resources necessary to implement these changes and improve our manufacturing capacity and efficiency, thereby reducing our unit cost.

Our products have consistently received high quality ratings. In the August 2007 issue of *Health Devices*, ECRI listed two syringes with the highest possible rating: our VanishPoint® syringe and BD's Integra syringe. BD's Integra syringe has been found to infringe on our patents. See **Item 3. Legal Proceedings**.

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 such as our purchases from Double Dove have increased our manufacturing capacity with little or no capital outlay and provide a competitive cost.

Our competitive weaknesses include our current lack of market share because 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. Demand for our products could decrease due to the sale of the Integra, a retractable syringe manufactured by BD, which dominates the market and has a wider range of product offerings and more capital resources. However, a jury has returned a verdict that the Integra infringes our patents.

Research and Development

We spent \$1,071,143; \$1,066,068; and \$1,030,622 in fiscal 2007, 2008, and 2009, respectively, on research and development. Costs in 2009 were primarily for compensation and validation. 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 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 (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 Waste Management.

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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, 2010, we had 159 full-time employees, 5 part-time employees, and 3 independently contracted consultants. Of the 159 full-time employees, 4 persons were engaged in research and development activities, 86 persons were engaged in manufacturing and engineering, 16 persons were engaged in quality assurance and regulatory affairs, 22 persons were engaged in sales and marketing, 29 persons were engaged in general and administrative functions, and 2 persons in facilities. No employees are covered by collective bargaining agreements. We are dependent upon a number of management and technical personnel, and the loss of services of one or more of such employees could have a material adverse effect on us. Our President and Chief Executive Officer, Thomas J. Shaw, has an employment contract that will end on December 31, 2010 which contains an automatic and continuous renewal provision for consecutive two-year periods.

Financial Information About Geographic Areas

We have no 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>2009</b>		<b>2008</b>		<b>2007</b>
Domestic sales	\$	34,466,797	\$	23,244,370	\$	21,461,717
International sales		4,515,040		4,654,948		4,828,003
Total sales	\$	38,981,837	\$	27,899,318	\$	26,289,720
Long-lived assets						
Domestic	\$	13,961,445	\$	14,435,667	\$	11,483,423
Foreign	\$	272,736	\$		\$	

We have no sales in any foreign country that exceeds 5% of revenue. 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

## Edgar Filing: RETRACTABLE TECHNOLOGIES INC - Form 10-K

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.**





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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.

### 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 believe that its monopolistic business practices continue despite: (i) its paying \$100 million in 2004 to settle a prior lawsuit with us for anticompetitive practices, business disparagement, and tortious interference and (ii) the fact that a jury returned a verdict in November 2009 finding that all three patents asserted by us against BD are valid and infringed by BD (with regard to its IntegraTM product).

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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.

Our Cash Position Is Decreasing and Legal Expenses Are Increasing

Due to our operating losses and increased legal fees, our cash position declined \$15.2 million as of December 31, 2009 as compared to December 31, 2008. Our litigation efforts will continue to require a significant amount of cash until the issues are resolved.

In the event we continue to have only limited market access, the cash provided by the prior litigation settlements and generated from operations becomes insufficient, and royalties from BTMD are not forthcoming, we would take additional cost cutting measures to reduce cash requirements. Such measures could result in reduction of units being produced, reduction of workforce, reduction of salaries of officers and other nonhourly employees, and deferral of royalty payments.

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 patents protecting our revolutionary spring action syringe will expire beginning in May 2015. 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

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We were involved in two patent disputes both of which the jury found in our favor. Further, we have been sued by BD for patent infringement. See **Item 3. Legal Proceedings** for more information. 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

The three leading manufacturers of hypodermic syringes and blood collection products are BD, Covidien, and Terumo. All three companies offer both standard syringes and at least one safety syringe alternative.

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BD also offers a retractable syringe which was found by a jury to infringe on our patents. See **Item 3. Legal Proceedings**. These 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.

The Majority of Our International Sales Are Filled Using One Supplier

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. As of December 31, 2009, approximately 67.5% of our production was provided by Double Dove. 11.6% of our sales in 2009 were international.

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 (as opposed to 32.0%) of the 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 Chairman of the Board, and Ms. Suzanne August own 36.5% and 11.8%, respectively, of the outstanding Common Stock as of March 1, 2010. The shares held by Ms. August are controlled by Mr. Shaw pursuant to a Voting Agreement, which terminates upon sale of all the shares for value or if terminated by both parties in writing. 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. Of the 23,825,149 shares of Common Stock outstanding as of March 1, 2010, executive officers, affiliates, and Directors own or control 11,537,000 (48.4%) of the shares of outstanding Common Stock, not including Common Stock equivalents such as preferred shares and options.

We Have Limited Access to the Capital Markets

The volume of trading in our Common Stock on the NYSE Amex LLC ( 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 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. In addition, entities that were given such notices under the American Stock Exchange standards were generally given up to 18 months to execute a plan to bring themselves into compliance with the listing standards.

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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. The Provision for doubtful accounts increased by \$182,000 for 2009 which brings the balance to \$681,966.

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 in the event of product failure or claim of harm caused by product operation. Product failure could result in injury to the patient and could expose healthcare workers to the risk of blood borne pathogens. If any of our products prove to be defective, we may be required to recall those products. We do not have recall insurance.

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. We have product liability coverage with St. Paul Insurance Company covering up to \$11,000,000 per occurrence, with coverage up to \$11,000,000 in the aggregate. Each claim is subject to a \$25,000 deductible. We have not had any product liability claims.

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

Not applicable and none.

**Item 2. Properties.**

Our 22,500 square foot 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 32.0% of the units that were sold in 2009. We placed a 47,250 square foot warehouse in service in March 2005 and expanded it (by an additional 47,250 feet) in 2009. 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 which are sold principally in the international market. In that event, we would attempt to engage another manufacturer. We are currently utilizing approximately 51% of our current U.S. productive capacity.

We obtained a loan from 1st International Bank ( 1st International ) for \$2,500,000, secured by the land and existing buildings, which provided funding for the construction of the 47,250 square foot warehouse placed in service in 2005. The proceeds from the loan were used to pay off the remaining \$475,000 of the revolving credit agreement with 1st International in addition to funding the warehouse and related infrastructure. The

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payments for the permanent funding are based on a twenty-year amortization with a five-year maturity. Interest rates are based on the amount of funds kept on deposit with the bank. Accordingly, interest will vary from the Wall Street Journal Prime Rate (the WSJPR ) to the WSJPR plus 1%, with floors that may range from 4.25% to 6.50%. Compensating balances at 1st International affecting the interest rate will range from \$0 to \$500,000. This loan had a maturity date in late March 2010. We anticipate refinancing this loan.

On August 29, 2008, we obtained a \$4,210,000 interim construction loan from Lewisville State Bank, a division of 1st International Bank. The purpose of the loan was to expand the warehouse, including additional office space, and construct a new Controlled Environment. The interest rate was WSJPR plus 0.25%. The loan was renewed on December 10, 2009 with a 20 year amortization and 10 year maturity. The interest rate is 5.968%. The construction project has been completed.

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

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**Item 3. Legal Proceedings.**

On August 12, 2005, we filed a lawsuit against Abbott Laboratories ( Abbott ) in the U.S. District Court in the Eastern District of Texas, Texarkana Division. We are alleging fraud and breach of contract in connection with the National Marketing and Distribution Agreement dated as of May 4, 2000, which was terminated on October 15, 2003. We are seeking damages which we estimate to be in millions of dollars of lost profits, out of pocket expenses, and other damages. In addition, we are seeking punitive damages, pre- and post-judgment interest, and attorneys fees. Following Abbott s unsuccessful attempt to get the case dismissed and ordered to arbitration, Abbott filed an answer and counterclaim on July 15, 2008, alleging several breaches of contract, breach of implied warranty of merchantability, and breach of express warranty, seeking in excess of \$6,000,000 in compensatory damages as well as seeking attorneys fees. We deny the validity of Abbott s counterclaims. Discovery has already taken place and is substantially completed. The District Court has issued a revised scheduling order calling for trial in May 2010.

In April 2008, we sued OMI in the U.S. District Court for the Eastern District of Texas, Tyler Division, alleging that OMI had infringed two U.S. patents (6,572,584 and 7,351,224). We also alleged theft of confidential information, intentional interference with contracts, and engaging in false advertising that wrongfully disparaged and mischaracterized our syringe products. We further alleged that OMI made false allegations regarding the source of origin of its safety syringe products being offered in the U.S. On December 18, 2009, the jury delivered a verdict in our favor on our patent infringement and misappropriation of trade secrets claims against OMI. On March 4, 2010, the Court entered a final judgment and ordered that we recover damages and prejudgment interest from OMI based on OMI s misappropriation of trade secrets in the amount of \$3,153,575. In addition, the Court entered a permanent injunction enjoining OMI, its manufacturers, distributors and service providers from infringing our patent no. 6,572,584, by making, importing, selling, or using any of OMI s syringes in the U.S. and its territories. OMI has entered into an administrative proceeding in Australia which is the equivalent of bankruptcy and has filed a similar proceeding in the Eastern District of Texas, which make the actual recovery of the damages unlikely.

In June 2007, we sued BD in the U.S. District Court for the Eastern District of Texas, Marshall Division, alleging infringement of three patents (5,578,011; 5,632,733; and 6,090,077) and violations by BD of the federal and state antitrust laws, and of the Lanham Act. We subsequently dropped the 5,578,011 patent allegations from the lawsuit. In January 2008, the Court severed the patent claims from the other claims pending resolution of the patent dispute. In April 2008, we and Thomas J. Shaw sued BD in the U.S. District Court for the Eastern District of Texas, Marshall Division, alleging infringement of another recently issued patent (7,351,224). BD counterclaimed for non-infringement and invalidity of the asserted patent. The Court consolidated this case with the above-stated case filed in June 2007. On November 9, 2009, the jury returned a verdict finding that the patents asserted by us were valid and infringed by BD and awarded \$5,000,000 in damages. No final judgment has been entered in this case. We are seeking injunctive relief.

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. No trial date has been set.

In September 2008, we and Thomas J. Shaw sued Safety Medical International ( SMI ) in the United States District Court for the Eastern District of Texas, Tyler Division, alleging infringement of U.S. patent nos. 6,572,584 and 7,351,224, and seeking injunctive relief, unspecified monetary damages, and reimbursement of attorneys fees. SMI has counterclaimed, seeking declaratory judgments of non-infringement and invalidity of the asserted patents. SMI is not seeking monetary damages. SMI has filed for bankruptcy, and this lawsuit, including all claims and counterclaims, was dismissed as a result of those proceedings, which have concluded.





Table of Contents**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, 2010, was \$1.48 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>2009</b>	<b>High</b>	<b>Low</b>
Fourth Quarter	\$2.13	\$1.35
Third Quarter	\$2.95	\$0.68
Second Quarter	\$0.98	\$0.60
First Quarter	\$0.90	\$0.43
<b>2008</b>	<b>High</b>	<b>Low</b>
Fourth Quarter	\$1.46	\$0.45
Third Quarter	\$1.60	\$1.20
Second Quarter	\$1.68	\$1.22
First Quarter	\$2.00	\$1.30

## SHAREHOLDERS

As of March 1, 2010, there were 23,825,149 shares of Common Stock held by 262 shareholders of record not including shareholders who beneficially own Common Stock held in nominee or street name.

## DIVIDENDS

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, 2009, there was an aggregate of \$15.3 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, 2004 to December 31, 2009, 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, 2004, and that all dividends are reinvested.

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RECENT SALES OF UNREGISTERED SECURITIES

None

PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

No repurchases were made in the fourth quarter of 2009.

**Item 6. Selected Financial Data.**



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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, 2006 and 2005 and the Balance Sheet data as of December 31, 2007, 2006, and 2005 have been derived from our audited financial statements, which are not included herein.

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

	<b>As of and for the Years Ended December 31,</b>				
	<b>2009</b>	<b>2008</b>	<b>2007</b>	<b>2006</b>	<b>2005</b>
Sales, net	\$ 38,982	\$ 27,899	\$ 26,290	\$ 20,897	\$ 21,157
Reimbursed discounts				4,427	3,078
Total sales	38,982	27,899	26,290	25,324	24,235
Cost of sales	25,466	19,673	18,300	17,778	15,429
Gross profit	13,516	8,226	7,990	7,546	8,806
Total operating expenses	26,812	18,671	17,936	14,261	11,683
Loss from operations	(13,296)	(10,445)	(9,946)	(6,715)	(2,877)
Interest income	58	855	1,870	1,976	1,373

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	As of and for the Years Ended December 31,					
	2009	2008	2007	2006	2005	
Interest expense, net	(22)	(54)	(326)	(411)	(340)	
Loss before income taxes	(13,260)	(9,644)	(8,402)	(5,150)	(1,844)	
Benefit for income taxes	(3,838)		(1,454)	(1,280)	(606)	
Net loss	(9,422)	(9,644)	(6,948)	(3,870)	(1,238)	
Preferred Stock dividend requirements	(1,371)	(1,373)	(1,399)	(1,451)	(1,503)	
Earnings (loss) applicable to common shareholders	\$ (10,793)	\$ (11,017)	\$ (8,347)	\$ (5,321)	\$ (2,741)	
Earnings (loss) per share basic and diluted	\$ (0.45)	\$ (0.46)	\$ (0.35)	\$ (0.23)	\$ (0.12)	
Weighted average shares outstanding	23,806,533	23,794,566	23,727,029	23,591,999	23,332,277	
Current assets	\$ 39,262	\$ 43,614	\$ 51,916	\$ 57,781	\$ 61,485	
Current liabilities	\$ 13,196	\$ 10,238	\$ 8,786	\$ 6,891	\$ 5,458	
Property, plant, and equipment, net	\$ 14,234	\$ 14,436	\$ 11,483	\$ 12,212	\$ 11,926	
Total assets	\$ 53,941	\$ 58,539	\$ 64,330	\$ 70,795	\$ 73,756	
Long-term debt, net of current maturities	\$ 4,825	\$ 6,096	\$ 3,747	\$ 4,137	\$ 4,351	
Stockholders' equity	\$ 35,920	\$ 42,206	\$ 51,761	\$ 59,710	\$ 63,235	
Redeemable Preferred Stock (in shares)	2,285,266	2,285,266	2,329,916	2,441,166	2,498,666	
Cash dividends per common share	\$	\$	\$	\$	\$	
Gross profit margin	34.7%	29.5%	30.4%	29.8%	36.3%	

\* Events that could affect the trends indicated above include receipt of royalties from BTMD, continued reductions in manufacturing costs, continued increasing average sales prices, the gaining of market access, and protection of our patents. We have been successful in protecting our patents, most recently against BD and OMI. (see **Item 3. Legal Proceedings**). 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 DHHS comprised 52.0% and 24.4% of our revenues for the three months and twelve months ended December 31, 2009, respectively. This program, which was estimated to run from August 2009 through March 2010, ended in December 2009. We do not know if there will be a similar program in 2010.

**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 (as it affects our costs as well as market access), our ability to maintain favorable supplier arrangements and relationships, our ability to receive royalties from BTMD, our ability to quickly



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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. We currently provide other safety medical products in addition to safety syringe products. One such product is the Patient Safe® syringe, which is uniquely designed to reduce the risk of bloodstream infections resulting from catheter hub contamination. Patient Safe®'s unique luer guard reduces the risk of luer tip contact contamination and the risk of contamination of intravenous fluid. Safety syringes comprised 98.9% of our sales in 2009.

Historically, unit sales have increased in the latter part of the year due, in part, to the demand for syringes during the flu season. We expect the Swine Flu to have a longer worldwide immunization duration than the seasonal flu. In the third quarter of 2009, we were awarded a contract by the 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. Sales to the DHHS comprised 52.0% and 24.4% of our revenues for the three months and twelve months ended December 31, 2009, respectively. This program, which was estimated to run from August 2009 through March 2010, ended in December 2009. Our revenue increased 142.1% in the fourth quarter principally due to the DHHS contract. We do not know if there will be a similar program in 2010.

Our products have been and continue to be distributed nationally through numerous distributors. However, we have been blocked from access to the market by exclusive marketing practices engaged in by BD, which dominates the market. We believe that its monopolistic business practices continue despite: (i) its paying \$100 million in 2004 to settle a prior lawsuit with us for anticompetitive practices, business disparagement, and tortious interference and (ii) the fact that a jury returned a verdict in November 2009 finding that all three patents asserted by us against BD are valid and infringed by BD (with regard to its Integra™ product). Although we have made limited progress in some areas, such as the alternate care and international markets, our volumes are not as high as they should be given the nature and quality of our products and the federal and state legislation requiring the use of safe needle devices.

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

We sued OMI in April 2008 and separately sued BD in June 2007 for claims of patent infringement (see **Item 3. Legal Proceedings**), and in December 2009 and November 2009, respectively, such companies were found to infringe our patents. These judgments could increase demand for our product. However, there is no assurance when or if such increase will occur.

Beginning in 2004, we were given an award (from PATH) to supply syringes to various African countries under the President's Emergency Plan for AIDS relief (PEPFAR). Awards increased significantly from 2004 to 2007. The continuation of PEPFAR has been reauthorized by Congress through 2013. However, funding for the procurement of safety syringes in this program has not occurred to date.

As a result of the introduction of VanishPoint® syringes through the PEPFAR initiative, African countries have begun to procure products outside of the U.S.-funded program. In 2007, the Director General of Nigeria's National Agency for Food and Drug Administration and Control (NAFDAC), endorsed automated retraction syringes for use throughout Nigeria. We are currently selling syringes to a Nigerian distributor for use in that country. At the end of 2008, the Deputy Prime Minister of Namibia also publically endorsed automated retraction syringes as a public intervention that would protect health workers and save their patient's lives.

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The number of international distributors continues to increase.

In the event we continue to have only limited market access, the cash provided by the litigation settlements and generated from operations becomes insufficient, and royalties from BTMD are not forthcoming, we would take additional cost cutting measures to reduce cash requirements. Such measures could result in the reduction of units being produced, the reduction of workforce, the reduction of salaries of officers and other nonhourly employees, and the deferral of royalty payments. We took such actions at the end of the second quarter of 2009.

At the end of the second quarter of 2009, we announced that in the interest of the long-term survival of the Company we would reorganize some of the Company's functions and implement staff reductions, all in order to minimize our cash expenditures and conserve our resources. Our workforce was reduced by 16% on July 1, 2009. However, due to the expected increase in production from sales to DHHS, we increased the workforce at the Little Elm facility beginning in the latter part of the third quarter of 2009. The rehiring only slightly affected our prior estimate that annual compensation costs and related expenses would be reduced by \$2.1 million annually due to the layoffs. An anticipated reduction of inventory was estimated (at the time of the announcement) to result in a minimum of \$1.0 million reduction in cash outlays over the subsequent twelve months. However, due to the orders from the DHHS, that particular initiative is on hold. Our President and CEO, Thomas J. Shaw, waived future royalty payments beginning July 1, 2009, for an aggregate savings of \$1.0 million which affected royalty payments (not expenses) in the third and fourth quarter of 2009. Salaries for all personnel above a certain salary level were cut by 10% in 2009 (subject to contract rights). Such reduction, along with discontinuing the 401(k) matching, was estimated to save \$600,000. We expect to save an additional \$1.6 million by the following actions: moving most, if not all, of the molding of piece parts back to Little Elm; reducing professional fees; and various other cost cutting measures. Professional fees have been reduced and we have begun additional molding in Little Elm. These measures will remain in place as long as Management deems them necessary.

We recorded a \$200,000 charge in the second quarter of 2009 for severance pay offered to the terminated employees. All severance payments were paid in the third quarter of 2009. We incurred a noncash expense of \$2.1 million related to the issuance of stock options, most of which will be fully amortized by the third quarter of 2010. We wrote off approximately \$2.6 million in development costs related to the catheters.

We are focusing on methods of upgrading our manufacturing capability and efficiency in order to reduce costs. We believe our current capitalization provides the resources necessary to implement some of these changes and improve our manufacturing capacity and efficiency, thereby reducing our unit cost.

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 2009, Double Dove manufactured approximately 67.5% of the units we produced. The cost of production per unit has generally declined as volumes increased. We believe we could make up any long-term disruption in these supplies by utilizing more of the capacity at the Little Elm facility, except for the 0.5mL insulin syringe, the 5mL and 10mL syringes, and the autodisable syringe which altogether comprised about 3.8% of our 2009 revenues.

We previously entered into a License Agreement with BTMD as of May 13, 2005. That license expired on May 13, 2008 (prior to the manufacture and delivery of any products). Nevertheless, BTMD continued to work toward completing the facility and gaining the necessary approvals in order to manufacture and sell products. The facility has been completed and BTMD has met Chinese Government requirements. BTMD received a Registration Certificate for Medical Device on August 24, 2009. Production efforts are currently underway and are being tested. We entered into a new agreement (effective as of July 1, 2009) with BTMD along similar terms as the prior agreement. This agreement expires on July 1, 2010 which may automatically extend under certain conditions. Such terms include granting to BTMD a limited exclusive license to manufacture and a limited exclusive right to sell syringes in the PRC having retractable needles that incorporate our technology. This

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License Agreement is subject to the Technology License Agreement dated June 23, 1995 between Mr. Thomas J. Shaw, our founder and CEO, as licensor, and the Company, as licensee (as amended). Accordingly, Mr. Shaw will receive 5% of the licensing proceeds we receive. BTMD has agreed to manufacture and sell these products in the PRC and to pay us a quarterly royalty of two and one-half cents per unit on 3mL and 5mL syringes and a royalty of three and one-half cents per unit on 0.5mL, 1mL, and 10mL syringes. The obligation to pay the royalties continues even if

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any and all of our patent rights in the PRC are found to be invalid or unenforceable for any reason. We still continue to expect royalty payments although we are unable to predict the date we will begin to receive such royalties.

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.

We completed the expansion of an existing warehouse in the first quarter of 2009. This expansion increased our warehouse area, provided for additional office space, and added a second Controlled Environment. The additional Controlled Environment will enable us to do more molding in-house.

**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.

Historical Sources of Liquidity

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

Internal Sources of Liquidity

*Margins and Market Access*

To 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 anti-trust 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 are focusing on methods of upgrading our manufacturing capability and efficiency in order to reduce costs. We believe our current capitalization provides the resources necessary to implement some of these changes and improve our manufacturing capacity and efficiency, thereby reducing our unit cost.

In the third quarter of 2009, we were awarded a contract by the 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. Sales to the DHHS comprised 52.0% and 24.4% of our revenues for the three months and twelve months ended December 31, 2009, respectively. This program, which was estimated to run from August 2009 through March 2010, ended in December 2009. Our revenue increased 142.1% in the fourth quarter principally due to the DHHS contract. We do not know if there will be a similar program in 2010.

Beginning in early 2004, we began to receive shipment of product from Double Dove which enabled us to lower our unit 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 32.0%) 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 as domestic costs, such as indirect labor and overhead, remain relatively constant. The number of units produced by the Company versus manufactured in China can have a significant effect on the carrying costs of inventory as well as Cost of sales. We will continue to evaluate the appropriate mix of products manufactured domestically and those manufactured in China to achieve economic

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benefits as well as to maintain our domestic manufacturing capability. Currently, approximately 32.0% of our products are produced domestically.

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

*Seasonality*

Historically, unit sales have increased in the latter part of the year due, in part, to the demand for syringes during the flu season. We expect the Swine Flu to have a longer worldwide immunization duration than the seasonal flu.

*Licensing Agreement*

We previously entered into a License Agreement with BTMD as of May 13, 2005. That license expired on May 13, 2008 (prior to the manufacture and delivery of any products). Nevertheless, BTMD continued to work toward completing the facility and gaining the necessary approvals in order to manufacture and sell products. The facility has been completed and BTMD has met Chinese government requirements. BTMD received a Registration Certificate for Medical Device on August 24, 2009. Production efforts are currently underway and are being tested. We entered into a new agreement (effective as of July 1, 2009) with BTMD along similar terms as the prior agreement. This agreement expires on July 1, 2010 which may automatically extend under certain conditions. Such terms include granting to BTMD a limited exclusive license to manufacture and a limited exclusive right to sell syringes in the PRC having retractable needles that incorporate our technology. This License Agreement is subject to the Technology License Agreement dated June 23, 1995 between Mr. Thomas J. Shaw, our founder and CEO, as licensor, and the Company, as licensee (as amended). Accordingly, Mr. Shaw will receive 5% of the licensing proceeds we receive. BTMD has agreed to manufacture and sell these products in the PRC and to pay us a quarterly royalty of two and one-half cents per unit on 3mL and 5mL syringes and a royalty of three and one-half cents per unit on 0.5mL, 1mL, and 10mL syringes. The obligation to pay the royalties continues even if any and all of our patent rights in the PRC are found to be invalid or unenforceable for any reason. We still continue to expect royalty payments although we are unable to predict the date we will begin to receive such royalties.

*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. We obtained a loan from 1st International for \$2,500,000, secured by the land and existing buildings, which provided funding for the construction of the 47,250 square foot warehouse placed in service in 2005. This loan had a maturity date in late March 2010. We anticipate refinancing this loan.



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**CAPITAL RESOURCES**

Material Commitments for Expenditures

On August 29, 2008, we obtained a \$4,210,000 interim construction loan from Lewisville State Bank, a division of 1st International Bank. The purpose of the loan was to expand the warehouse, including additional office space, and construct a new Controlled Environment. The interest rate was WSJPR plus 0.25%. The loan was renewed on December 10, 2009 with a 20 year amortization and 10 year maturity. The interest rate is 5.968%. The construction project has been completed.

Trends in Capital Resources

Interest expense will increase due to the recent loan of approximately \$4.2 million, but will be somewhat mitigated by lower borrowing rates if current conditions in the credit markets continue. Interest income may be negatively affected by lower interest rates and our prior movement of cash to U.S. Treasury bills and other U.S. government backed securities. Although we believe that we have granted credit to credit-worthy firms, current economic conditions may affect the timing and/or collectability of some accounts.

**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 2009, 2008, or 2007. Dollar amounts have been rounded for ease of reading.

*Comparison of Year Ended*

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

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

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

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

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

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

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

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

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

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Interest income decreased due to lower interest rates and lower cash balances. Interest expense decreased due to capitalized interest. Interest expense is expected to increase in 2010 due to completion of significant capital projects in 2009 for which interest was being capitalized.

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

*Comparison of Year Ended*

*December 31, 2008, and Year Ended December 31, 2007*

Revenues increased 6.1%, due principally to higher average sales prices and greater volumes. Domestic sales were 83.3% of revenues with international sales comprising the remainder. Unit sales of the 1mL syringe increased 22.7% and 3mL unit sales decreased 4.0%. Unit sales of all products increased 3.1%. Domestic unit sales as well as average sales prices increased. International unit sales and average selling prices declined. Sales to one distributor accounted for 17.1% and 13.7% of our revenues in 2008 and 2007, respectively.

Cost of sales increased due to higher manufacturing costs and higher volumes. Royalty expenses were higher due to an increase in gross revenues.

As a result, gross profit margins declined from 30.4% in 2007 to 29.5% in 2008.

Operating expenses increased from the prior year due to higher general and administrative expenses mitigated by lower Sales and marketing and Research and development costs.

Sales and marketing expenses decreased due primarily to reduced travel and entertainment, trade shows and market expense, compensation and office supplies. Consulting expense also decreased.

Research and development costs were flat. We had decreases in engineering costs due principally to higher costs of validation and engineering samples offset by higher compensation costs.

General and administrative costs increased due principally to increased legal costs (including a settlement of litigation whereby we obtained a patent license/assignment), office expenses, compensation, property taxes and freight costs. Travel and entertainment costs and fees to distributors decreased.

Preferred Stock dividend requirements decreased due to conversion of Preferred Stock to Common Stock. The dividend arrearage at December 31, 2008, on all classes of Preferred Stock was approximately \$13.9 million.

Interest income decreased due to lower interest rates and cash balances. Interest expense decreased due to lower interest rates mitigated by higher debt balances and capitalized interest, principally due to the construction of the warehouse.

Other accrued liabilities increased due to prepayments from international customers.

Cash flow from operations was a negative \$5.7 million for 2008 due principally to our losses. The effect of non-cash expenses and the change in working capital was a positive \$4.0 million. Investing activities utilized \$2.2 million in cash.

#### OFF-BALANCE SHEET ARRANGEMENTS

None.

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## CONTRACTUAL OBLIGATIONS

Contractual Obligations and Commercial Commitments

The following chart summarizes our material obligations and commitments to make future payments under contracts for long-term debt as of December 31, 2009:

Contractual Obligations	Total	Payments Due by Period			
		Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
Long-term debt, including current maturities	\$ 7,505,789	\$ 2,659,573	\$ 988,749	\$ 273,366	\$ 3,584,101

These amounts do not reflect the effect of the beneficial conversion feature 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.

**Revenue Recognition**

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Revenue is recognized for sales to distributors when title and risk of ownership passes to the distributor, generally upon shipment. 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. 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 individual distributors' accounts receivable balances for financial reporting purposes. The resulting net balance is reflected in accounts receivable or accounts payable, as appropriate. The terms and conditions of contractual pricing allowances are governed by contracts between us and our distributors. Revenue for shipments directly to end-users is recognized when title and risk of ownership passes from us. Any product shipped or distributed for evaluation purposes is expensed.

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 minus a 10% restocking fee and all applicable freight charges.

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

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Our international Distribution Agreements do not provide for any returns.

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

**Inventories**

Inventories are valued at the lower of cost or market, with cost being determined using actual average cost. A reserve is established for any excess or obsolete inventories.

**Marketing Fees**

Under a sales and marketing agreement with Abbott, we paid marketing fees until we terminated the contract for breach. The contracted services were to include participation in promotional activities, development of educational and promotional materials, representation at trade shows, clinical demonstrations, inservicing and training, and tracking reports detailing the placement of our products to end-users. Marketing fees were accrued at the time of the sale of product to Abbott. These fees were paid after Abbott provided us a tracking report of product sales to end-users. These costs were included in Sales and marketing expense in the Statements of Operations. No marketing fees have been accrued since October 15, 2003, the date the National Marketing and Distribution Agreement with Abbott was terminated. We filed suit against Abbott in August 2005 for breach of contract and trial is scheduled for May 2010. We do not expect the eventual liability for marketing fees, if any, to exceed the amount accrued.

**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 losses in 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, 2009 AND 2008**

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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, 2009 and 2008, 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, 2009. 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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes 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, 2009 and 2008, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2009 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.

We were not engaged to examine management's assertion about the effectiveness of the Company's internal control over financial reporting as of December 31, 2009 included in Item 9A of the Company's December 31, 2009 Form 10-K and, accordingly, we do not express an opinion thereon.

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

Dallas, Texas  
March 31, 2010

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	<b>December 31,</b>	
	<b>2009</b>	<b>2008</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 18,126,084	\$ 33,283,740
Accounts receivable, net of allowance for doubtful accounts of \$681,966 and \$499,966, respectively	9,948,210	3,288,942
Inventories, net	6,907,369	6,641,532
Income taxes receivable	3,655,637	
Other current assets	624,393	400,113
Total current assets	39,261,693	43,614,327
Property, plant, and equipment, net	14,234,181	14,435,667
Intangible assets, net	426,675	470,115
Other assets	18,750	18,750
Total assets	\$ 53,941,299	\$ 58,538,859
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 6,997,310	\$ 6,144,435
Current portion of long-term debt	2,628,652	451,865
Accrued compensation	561,484	650,704
Marketing fees payable	1,419,760	1,419,760
Accrued royalties to shareholders	843,327	620,987
Other accrued liabilities	745,460	949,770
Total current liabilities	13,195,993	10,237,521
Long-term debt, net of current maturities	4,824,833	6,095,535
Total liabilities	18,020,826	16,333,056
Stockholders equity:		
Preferred Stock \$1 par value:		
Class B; authorized: 5,000,000 shares		
Series I, Class B; issued: 1,000,000 shares; outstanding: 144,000 and 144,000 shares, respectively (liquidation preference of \$900,000 and \$900,000 respectively)	144,000	144,000
Series II, Class B; issued: 1,000,000 shares; outstanding: 219,700 and 219,700, respectively (liquidation preference of \$2,746,250 and \$2,746,250, respectively)	219,700	219,700
Series III, Class B; issued: 1,160,445 shares; 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; issued: 1,133,800 shares; outstanding: 552,500 and 552,500 shares (liquidation preference of \$6,077,500 and \$6,077,500, respectively)	552,500	552,500
Series V, Class B; issued 2,416,221 shares; outstanding: 1,238,821 and 1,238,821 shares, respectively (liquidation preference of \$5,450,812 and \$5,450,812, respectively)	1,238,821	1,238,821
Common Stock, no par value; authorized: 100,000,000 shares; issued and outstanding: 23,825,149 and 23,800,064 shares, respectively		
Additional paid-in capital	57,089,153	53,952,183
Retained deficit	(23,453,946)	(14,031,646)
Total stockholders equity	35,920,473	42,205,803
Total liabilities and stockholders equity	\$ 53,941,299	\$ 58,538,859

See accompanying notes to financial statements



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

	<b>Years Ended December 31,</b>		
	<b>2009</b>	<b>2008</b>	<b>2007</b>
Sales, net	\$ 38,981,837	\$ 27,899,318	\$ 26,289,720
Cost of Sales			
Costs of manufactured product	22,659,437	17,504,842	16,212,609
Royalty expense to shareholders	2,806,223	2,168,268	2,087,596
Total cost of sales	25,465,660	19,673,110	18,300,205
Gross profit	13,516,177	8,226,208	7,989,515
Operating expenses:			
Sales and marketing	4,372,163	4,835,272	5,299,157
Research and development	1,030,622	1,066,068	1,071,143
General and administrative	18,814,392	12,769,774	11,565,144
Impairment of assets	2,594,602		
Total operating expenses	26,811,779	18,671,114	17,935,444
Loss from operations	(13,295,602 )	(10,444,906 )	(9,945,929 )
Interest and other income	57,604	855,685	1,870,512
Interest expense, net	(21,892 )	(54,359 )	(326,304 )
Loss before income taxes	(13,259,890 )	(9,643,580 )	(8,401,721 )
Benefit for income taxes	(3,837,590 )		(1,453,617 )
Net loss	(9,422,300 )	(9,643,580 )	(6,948,104 )
Preferred Stock dividend requirements	(1,370,868 )	(1,373,019 )	(1,399,062 )
Net loss applicable to common shareholders	\$ (10,793,168 )	\$ (11,016,599 )	\$ (8,347,166 )
Loss per share	\$ (0.45 )	\$ (0.46 )	\$ (0.35 )
Weighted average common shares outstanding	23,806,533	23,794,566	23,727,029

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, 2006	164,000	\$164,000	224,700	\$224,700	135,245	\$135,245	553,500	\$553,500	1,363,721	\$ 1,363,721	23,644,164	\$
Conversion of Preferred Stock into Common Stock	(20,000)	(20,000)	(5,000)	(5,000)	(5,000)	(5,000)			(81,250)	(81,250)	111,250	
Recognition of stock option compensation												
Dividends declared and paid on Series I Class B Preferred Stock												
Dividends declared and paid on Series II Class B Preferred Stock												
Net loss												
Balance as of December 31, 2007	144,000	144,000	219,700	219,700	130,245	130,245	553,500	553,500	1,282,471	1,282,471	23,755,414	
Conversion of Preferred Stock into Common Stock							(1,000)	(1,000)	(43,650)	(43,650)	44,650	
Recognition of stock option compensation												
Net loss												
Balance as of December 31, 2008	144,000	144,000	219,700	219,700	130,245	130,245	552,500	552,500	1,238,821	1,238,821	23,800,064	

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Recognition  
of stock  
option  
exercise

25,085

Royalty  
waiver

Recognition  
of stock  
option  
compensation

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	\$
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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, 2006	\$ 54,709,108	\$ 2,560,038	\$ 59,710,312
Conversion of Preferred Stock into Common Stock	111,250		
Recognition of stock option compensation	52,173		52,173
Dividends declared and paid on Series I Class B Preferred Stock	(262,819)		(262,819)
Dividends declared and paid on Series II Class B Preferred Stock	(790,725)		(790,725)
Net loss		(6,948,104)	(6,948,104)
Balance as of December 31, 2007	53,818,987	(4,388,066)	51,760,837
Conversion of Preferred Stock into Common Stock	44,650		
Recognition of stock option compensation	88,546		88,546
Net loss		(9,643,580)	(9,643,580)
Balance as of December 31, 2008	53,952,183	(14,031,646)	42,205,803
Recognition of stock option exercise	25,610		25,610
Royalty waiver	1,000,000		1,000,000
Recognition of stock option compensation	2,111,360		2,111,360
Net loss		(9,422,300)	(9,422,300)
Balance as of December 31, 2009	\$ 57,089,153	\$ (23,453,946)	\$ 35,920,473

See accompanying notes to financial statements

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

	<b>Years Ended December 31,</b>		
	<b>2009</b>	<b>2008</b>	<b>2007</b>
<b>Cash flows from operating activities:</b>			
Net loss	\$ (9,422,300)	\$ (9,643,580)	\$ (6,948,104)
Adjustments to reconcile net loss to net cash used by operating activities:			
Depreciation and amortization	1,396,793	1,397,333	1,430,072
Stock option compensation	2,111,360	32,629	6,478
Provision for inventory valuation			155,600
Provision for doubtful accounts	182,000	224,633	169,223
Impairment of assets	2,594,602		
Accreted interest	43,151	54,387	120,486
(Increase) decrease in assets:			
Inventories	(265,837)	395,597	(806,949)
Accounts receivable	(6,841,268)	(1,845,939)	119,897
Income taxes receivable	(3,655,637)	2,345,041	10,691
Other current assets	(224,280)	(41,306)	(91,100)
Other assets		(12,725)	
Increase (decrease) in liabilities:			
Accounts payable	852,875	609,070	1,287,735
Other accrued liabilities	1,015,505	798,578	506,386
Increase (decrease) in income taxes payable	(86,695)		
Net cash used by operating activities	(12,299,731)	(5,686,282)	(4,039,585)
<b>Cash flows from investing activities:</b>			
Purchase of property, plant, and equipment	(2,383,867)	(2,580,516)	(641,501)
Investment in LLC		497,690	
Acquisitions of patents, trademarks, licenses, and intangibles		(89,152)	(188,168)
Net cash used by investing activities	(2,383,867)	(2,171,978)	(829,669)
<b>Cash flows from financing activities:</b>			
Repayments of long-term debt and notes payable	(499,668)	(489,160)	(384,460)
Proceeds from long-term debt		1,123,729	
Proceeds from the exercise of stock options	25,610		
Payment of Preferred Stock dividends			(1,053,544)
Net cash provided (used) by financing activities	(474,058)	634,569	(1,438,004)
Net decrease in cash and cash equivalents	(15,157,656)	(7,223,691)	(6,307,258)
Cash and cash equivalents at:			
Beginning of period	33,283,740	40,507,431	46,814,689
End of period	\$ 18,126,084	\$ 33,283,740	\$ 40,507,431
<b>Supplemental schedule of cash flow information:</b>			
Interest paid	\$ 184,018	\$ 236,932	\$ 382,901
Income taxes paid	\$	\$	\$
<b>Supplemental schedule of noncash investing and financing activities:</b>			

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

See accompanying notes to financial statements

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**NOTES TO FINANCIAL STATEMENTS**

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

**Business of the Company**

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

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Accounting estimates**

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

**Cash and cash equivalents**

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

**Accounts receivable**

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

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

### **Inventories**

Inventories are valued at the lower of cost or market, with cost being determined using actual average cost. A reserve is established for any excess or obsolete inventories.

### **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, 2009, 2008, and 2007, the Company capitalized interest of approximately \$205,000; \$237,000; and \$177,000. 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:

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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.

**Reclassifications**

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

**Intangible assets**

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

**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



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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. Two customers, DHHS and Cardinal Health, comprised 68.4% of the Company's accounts receivable at December 31, 2009. The Company had a high concentration of sales with two significant customers. For the year ended December 31, 2009, the aforementioned customers accounted for \$15.0 million, or 38.4% of net sales. Sales to the DHHS comprised 52.0% and 24.4% of the Company's revenues for the three months and twelve months ended December 31, 2009, respectively. This program, which was estimated to run from August 2009 through March 2010, ended in December 2009. The Company does not know if there will be a similar program in 2010.

Considering the current economic climate, the Company increased its Provision for doubtful accounts by approximately \$182,000 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 67.5% of its finished products in 2009 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

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supplier for its 0.5mL insulin syringe, its 5mL and 10mL syringes, and its autodisable syringe and increase domestic production for 1mL and 3mL syringes to avoid a disruption in supply.

**Revenue recognition**

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

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

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

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

**Marketing fees**

Under a sales and marketing agreement with Abbott Laboratories (Abbott), the Company paid marketing fees until the Company terminated the contract for breach. The contracted services were to include participation in promotional activities, development of educational and promotional materials, representation at trade shows, clinical demonstrations, inservicing and training, and tracking reports detailing the placement of the Company's products to end-users. Marketing fees were accrued at the time of the sale of product to Abbott. These fees were paid after Abbott

provided the Company a tracking report of product sales to end-users. These costs were included in Sales and marketing expense in the Statements of Operations. No marketing fees have been accrued since October 15, 2003, the date the National Marketing and Distribution Agreement with Abbott was terminated. The Company filed suit against Abbott in August 2005 for breach of contract. The District Court has issued a scheduling order calling for trial in May 2010. See Note 8 **COMMITMENTS AND CONTINGENCIES** for further discussion.

### **Litigation Proceeds**

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

### **Income taxes**

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

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The Company provides for deferred income taxes through utilizing an asset and liability approach for financial accounting and reporting based on the tax effects of differences between the financial statement and tax bases of assets and liabilities, based on enacted rates expected to be in effect when such differences reverse in future periods. Deferred tax assets are periodically reviewed for realizability. The Company had sufficient taxable income from prior carryback years to realize all of its taxable losses through December 31, 2006. Taxable losses for 2007 and thereafter are subject to loss carryforwards. 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. Under recent tax law changes, companies are allowed to carry back taxable losses from either 2008 or 2009. The Company will file for a tax refund utilizing its 2009 taxable losses which will result in a minimum of a \$3.7 million refund.

**Earnings per share**

The Company computes basic earnings per share 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. The Company's potentially dilutive Common Stock equivalents, consisting of options, convertible debt, and convertible Preferred Stock, are all antidilutive for all periods presented. Accordingly, basic loss per share is equal to diluted earnings per share. Annual cumulative preferred dividends have been added to net losses for the years ended December 31, 2009, 2008 and 2007 to arrive at net loss per share.

**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**

On September 26, 2008, the Company's shareholders approved the 2008 Stock Option Plan and also approved an Offer to Exchange Stock Options (the Exchange Offer) whereby employees, including executive officers, and Directors exchanged certain outstanding underwater options for options issued under the 2008 Stock Option Plan. Pursuant to the Exchange Offer, eligible participants (totaling 103) tendered, and the Company accepted for cancellation, eligible options to purchase an aggregate of 1,925,365 shares of the Company's Common Stock representing 99.4% of the total shares of Common Stock underlying options eligible to exchange in the Exchange Offer. 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 vested after one year. Options issued to non-employee Directors vested immediately.

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Prior to 2008, the Company had issued options under three stock-based Director, independent contractor and employee compensation plans as well as several individual option agreements. Two of these plans and one individual option agreement have terminated and the unissued and unsold stock under these terminated plans has been deregistered pursuant to Post-Effective Amendment No. 1 to Form S-8 Registration Statement, filed December 2, 2008. As earlier mentioned, in 2008, the 2008 Stock Option Plan was approved and options have been issued under it pursuant to the Exchange Offer. 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.

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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:

	2009	Years Ended December 31, 2008	2007
Cost of sales	\$ 317,644	\$ (1,797)	\$ 6,648
Sales and marketing	242,509	(2,156)	3,086
Research and Development	47,168	(281)	(7,863)
General and administrative	1,504,039	36,863	4,607
	\$ 2,111,360	\$ 32,629	\$ 6,478

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

**Recent Pronouncements**

In June 2009, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standard (SFAS) No. 168, *The FASB Accounting Standards Codification™ and the Hierarchy of Generally Accepted Accounting Principles – a replacement of FASB Statement No. 162* (SFAS 168) (FASB ASC 105-10). SFAS 168 replaces all previously issued accounting standards and establishes the *FASB Accounting Standards Codification™* (FASB ASC or the Codification) as the source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in the preparation of financial statements in conformity with U.S. GAAP. SFAS 168 is effective for all interim and annual periods ending after September 15, 2009. The FASB ASC is not intended to change existing U.S. GAAP. The adoption of this pronouncement only resulted in changes to the Company's financial statement disclosure references. As such, the adoption of this pronouncement had no effect on the Company's financial position, results of operations, or cash flows.

In order to facilitate the transition to the FASB ASC, the Company has elected to show all references to FASB ASC within this report on Form 10-K along with a parenthetical reference to the previous accounting standard.

In April 2008, the FASB issued FASB Staff Position (FSP) FAS 142-3, *Determination of the Useful Life of Intangible Assets* included in the Codification under FASB ASC 350. This FSP amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under FASB Statement No. 142, *Goodwill and Other Intangible Assets* (SFAS 142). The intent of this FSP is to improve the consistency between the useful life of a recognized intangible asset under SFAS 142 and the period of expected cash flows used to measure the fair value of the asset under the Business Combinations Topic of the Codification and other GAAP. FSP FAS 142-3 was effective for the Company beginning January 1, 2009. The adoption of FSP FAS 142-3 did not have a material impact on the Company's financial position, results of operations, or cash flows.

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In May 2009, the FASB issued SFAS No. 165, *Subsequent Events*, included in the Codification under FASB ASC 855, which establishes general standards of accounting for and disclosure of events occurring after the

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balance sheet date, but before the financial statements are issued or available to be issued. In February 2010, FSAB ASC 855 was amended, removing certain disclosure requirements for public companies that conflicted with certain SEC disclosure requirements. Adoption of this standard and its amendment did not have a material 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>2009</b>	<b>2008</b>
Raw materials	\$ 2,424,818	\$ 1,885,158
Finished goods	4,688,151	4,961,974
	7,112,969	6,847,132
Inventory reserve	(205,600)	(205,600)
	\$ 6,907,369	\$ 6,641,532

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

Property, plant, and equipment consist of the following:

	<b>December 31,</b>	
	<b>2009</b>	<b>2008</b>
Land	\$ 261,893	\$ 261,893
Buildings and building improvements	11,079,905	5,319,732
Production equipment	14,428,077	14,270,577
Office furniture and equipment	2,148,622	1,825,781
Construction in progress	1,198,856	6,287,503
Automobiles	102,321	102,321
	29,219,674	28,067,807
Accumulated depreciation	(14,985,493)	(13,632,140)
	\$ 14,234,181	\$ 14,435,667

Depreciation expense for the years ended December 31, 2009, 2008, and 2007 was \$1,353,353; \$1,351,547; and \$1,370,228, respectively.

**5. INTANGIBLE ASSETS**

Intangible assets consist of the following:



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	<b>December 31,</b>	
	<b>2009</b>	<b>2008</b>
License agreement	\$ 500,000	\$ 500,000
Trademarks and patents	508,743	508,743
	1,008,743	1,008,743
Accumulated amortization	(582,068)	(538,628)
	\$ 426,675	\$ 470,115

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

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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 \$2,806,223; \$2,168,268; and \$2,087,596 are included in Cost of sales for the years ended December 31, 2009, 2008, and 2007, respectively. Royalties payable under this agreement aggregated \$843,327 and \$620,987 at December 31, 2009 and 2008, respectively. Gross sales upon which royalties are based were \$56,124,453; \$43,365,361; and \$41,751,897 for 2009, 2008, and 2007, respectively.

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, 2009, 2008, and 2007, was \$43,440; \$43,597; and \$43,454, respectively. Future amortization expense for the years 2010 through 2014 is estimated to be \$43,000 per year.

**6. OTHER ASSETS**

In 2006, the Company invested \$500,000 in a limited liability company. The Company exercised its option to have that investment returned. The investment was returned in April 2008.

**7. LONG-TERM DEBT**

	<b>2009</b>	<b>December 31,</b>	<b>2008</b>
Long-term debt consists of the following:			
Note payable to Katie Petroleum. Interest accrues at prime plus 1%, which was 4.25% and 5.0%, at December 31, 2009 and 2008, respectively. Interest only was payable monthly through February 1, 2004. The original amount of the note of \$3,000,000 was discounted for presentation purposes by \$299,346 for stock options issued in conjunction with the debt and \$412,500 for the intrinsic value of a beneficial conversion feature of the debt. Beginning March 1, 2004, the loan has been payable in equal installments of principal and interest payments (except for changes in the interest rate) of approximately \$37,000 and matures on September 30, 2012. Guaranteed by an officer. Approximately \$163,736 of the principal payment was converted into 40,934 shares of Common Stock as of March 1, 2006. Not otherwise collateralized. Convertible into Common Stock at \$4.00 per share at the option of the holder.	\$ 1,097,112	\$	1,437,977
Note payable to 1st International Bank for \$2,500,000. The proceeds from the loan paid off the remaining \$475,000 of a revolving credit agreement and funded a warehouse and related infrastructure. Payments were interest only during the first 12 months. After 12 months, payments are based on a 20-year amortization with a five-year maturity on March 29, 2010. The interest rate at December 31, 2009 and 2008 was 4.25% and 4.25%, respectively, and is based on the amount of funds kept on deposit with the bank.	2,141,998		2,241,145

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Accordingly, interest will vary from the Wall Street Journal Prime Rate (the WSJPR ) to the WSJPR plus 1%, with floors that may range from 4.25% to 6.50%. Compensating balances at 1st International affecting the interest rate will range from \$0 to \$500,000. The Company had in excess of \$500,000 on deposit with 1st International Bank throughout the year. The note is secured by the Company's land and buildings.

Note payable to DaimlerChrysler Services North America LLC. Sixty (60) monthly payments at \$1,009. Interest is 5.49%. Collateralized by a 2005 Freightliner truck.	1,005	12,711
Note payable to GMAC. Sixty (60) monthly payments at \$427. Interest is zero percent. Collateralized by a 2005 Chevrolet van.	3,762	8,561

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	2009	2008
Interim construction loan from Lewisville State Bank, a division of 1st International Bank, for a maximum of \$4,210,000, which provided funding for the expansion of the warehouse, additional office space, and a new Controlled Environment. The note bore interest at WSJPR plus 0.25%. The loan was renewed on December 10, 2009 with a 20 year amortization and 10 year maturity. The loan is secured by the Company's land and buildings. The interest rate is 5.968%.	4,209,608 7,453,485	2,847,006 6,547,400
Less: current portion	(2,628,652)	(451,865)
	\$ 4,824,833	\$ 6,095,535

The aggregate maturities of long-term debt as of December 31, 2009, are as follows:

2010	\$ 2,628,652
2011	519,611
2012	447,755
2013	132,504
2014	140,862
Thereafter	3,584,101
	\$ 7,453,485

**8. COMMITMENTS AND CONTINGENCIES**

On August 12, 2005, the Company filed a lawsuit against Abbott in the U.S. District Court in the Eastern District of Texas, Texarkana Division. The Company is alleging fraud and breach of contract in connection with the National Marketing and Distribution Agreement dated as of May 4, 2000, which was terminated on October 15, 2003. It is seeking damages which it estimates to be in millions of dollars of lost profits, out of pocket expenses, and other damages. In addition, it is seeking punitive damages, pre- and post-judgment interest, and attorneys' fees. Following Abbott's unsuccessful attempt to get the case dismissed and ordered to arbitration, Abbott filed an answer and counterclaim on July 15, 2008, alleging several breaches of contract, breach of implied warranty of merchantability, and breach of express warranty, seeking in excess of \$6,000,000 in compensatory damages as well as seeking attorneys' fees. The Company denies the validity of Abbott's counterclaims. Discovery has already taken place and is substantially completed. The District Court has issued a revised scheduling order calling for trial in May 2010.

In April 2008, the Company sued Occupational and Medical Innovations Limited ( OMI ) in the U.S. District Court for the Eastern District of Texas, Tyler Division, alleging that OMI had infringed two U.S. patents (6,572,584 and 7,351,224). The Company also alleged theft of confidential information, intentional interference with contracts, and engaging in false advertising that wrongfully disparaged and mischaracterized the syringe products. The Company further alleged that OMI made false allegations regarding the source of origin of its safety syringe products being offered in the U.S. On December 18, 2009, the jury delivered a verdict in the Company's favor on the patent infringement and misappropriation of trade secrets claims against OMI. On March 4, 2010, the Court entered a final judgment and ordered that the Company recover damages and prejudgment interest from OMI based on OMI's misappropriation of trade secrets in the amount of \$3,153,575. In addition, the Court entered a permanent injunction enjoining OMI, its manufacturers, distributors and service providers from infringing patent no. 6,572,584, by making, importing, selling or using any of OMI's syringes in the U.S. and its territories. OMI has entered into an administrative proceeding in Australia which is the equivalent of bankruptcy and has filed a similar proceeding in the Eastern District of Texas, which make the actual recovery of the damages unlikely.

In June 2007, the Company sued Becton Dickinson and Company ( BD ) in the U.S. District Court for the Eastern District of Texas, Marshall Division, alleging infringement of three patents (5,578,011; 5,632,733; and 6,090,077) and violations by BD of the federal and state antitrust laws, and of the Lanham Act. The Company subsequently dropped the 5,578,011 patent allegations from the lawsuit. In January 2008, the Court

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severed the patent claims from the other claims pending resolution of the patent dispute. In April 2008, the Company and the officer sued BD in the U.S. District Court for the Eastern District of Texas, Marshall Division, alleging infringement of another recently issued patent (7,351,224). BD counterclaimed for non-infringement and invalidity of the asserted patent. The Court consolidated this case with the above-stated case filed in June 2007. On November 9, 2009, the jury returned a verdict finding that the patents asserted by the Company were valid and infringed by BD and awarded \$5,000,000 in damages. No final judgment has been entered in this case. The Company is seeking injunctive relief.

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. No trial date has been set.

In September 2008, the Company and an officer sued Safety Medical International ( SMI ) in the United States District Court for the Eastern District of Texas, Tyler Division, alleging infringement of U.S. patent nos. 6,572,584 and 7,351,224, and seeking injunctive relief, unspecified monetary damages, and reimbursement of attorneys' fees. SMI has counterclaimed, seeking declaratory judgments of non-infringement and invalidity of the asserted patents. SMI is not seeking monetary damages. SMI has filed for bankruptcy, and this lawsuit, including all claims and counterclaims, was dismissed as a result of those proceedings, which have concluded.

**9. INCOME TAXES**

The provision for income taxes consists of the following:

	<b>For the Years Ended December 31,</b>		
	<b>2009</b>	<b>2008</b>	<b>2007</b>
Current tax provision (benefit)			
Federal	\$ (3,655,637)	\$	\$ (143,459)
State	(181,953)		(1,310,158)
Total current provision (benefit)	(3,837,590)		(1,453,617)
Deferred tax provision (benefit)			
Federal			
State			
Total deferred tax provision (benefit)			
Total income tax provision (benefit)	\$ (3,837,590)	\$	\$ (1,453,617)

The Company recognized a tax benefit in 2007 primarily due to the net effect of a state tax refund for prior years that had not been previously recognized.

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

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

The Company has \$14,277,070 in tax benefits attributable to carryback losses for federal tax purposes. The loss carryforwards will begin to expire in 2027 for federal tax purposes and will begin to expire for state tax purposes in 2012.

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	<b>December 31,</b>	
	<b>2009</b>	<b>2008</b>
Deferred tax assets		
Net operating loss carryforwards	\$ 5,414,579	\$ 5,285,164
Accrued expenses and reserves	1,045,120	1,240,050
Employee stock option expense	422,476	31,669
Inventory	242,807	435,578
Non-employee stock option expense	183,570	198,425
Charitable contribution carryforwards	26,164	21,118
Deferred tax assets	7,334,716	7,212,004
Deferred tax liabilities		
Property and equipment	(687,512)	(1,178,618)
Deferred tax liabilities	(687,512)	(1,178,618)
Net deferred assets	6,647,204	6,033,386
Valuation allowance	(6,647,204)	(6,033,386)
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>2009</b>	<b>December 31, 2008</b>	<b>2007</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 (decrease) in valuation allowance	4.6	32.1	27.2
Permanent differences	3.0	0.4	1.0
Cancellation of options under Exchange Offer		5.4	
State tax refund and accruals	(0.8)		(12.0)
Return to accrual adjustments	0.5		3.2
Other	1.6		1.2
Effective tax (benefit) rate	(29.0)	%	(17.3)%

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, 2006, remain subject to examination by the Internal Revenue Service. The Company's state and local income tax returns are subject to examination by the respective state and local authorities over various statutes of limitations, most ranging from three to five years from the date of filing.

**10. STOCKHOLDERS' EQUITY****Preferred Stock**

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



Class B

The Company has authorized 5,000,000 shares of \$1 par value Class B Stock which have been allocated among Series I, II, III, IV, and V in the amounts of 144,000; 219,700; 130,245; 552,500; and 1,238,821 shares, respectively. The remaining 2,714,734 authorized shares have not been assigned a series.

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Series I Class B

There were 1,000,000 shares of \$1 par value Series I Class B Convertible Preferred Stock ( Series I Class B Stock ) issued and 144,000 outstanding at December 31, 2009 and 2008. Holders of Series I Class B Stock are entitled to receive a cumulative annual dividend of \$.50 per share, payable quarterly if declared by the Board of Directors. In 2004, the Company paid \$2,550,000 in dividends. In 2007, the Company paid \$262,819 in dividends. At December 31, 2009 and 2008 approximately \$180,000 and \$108,000, respectively, of dividends which had not been declared were in arrears.

Series I Class B Stock is redeemable after three years from the date of issuance at the option of the Company at a price of \$7.50 per share, plus all accrued and unpaid dividends. Each share of Series I Class B Stock may, at the option of the stockholder, be converted to one share of Common Stock after three years from the date of issuance or in the event the Company files an initial registration statement under the Securities Act of 1933. Pursuant to these terms, no shares of Series I Class B Stock were converted into Common Stock in 2009. In the event of voluntary or involuntary dissolution, liquidation, or winding up of the Company, holders of Series I Class B Stock then outstanding are entitled to \$6.25 per share, plus all accrued and unpaid dividends prior to any distributions to holders of Series II Class B Convertible Preferred Stock ( Series II Class B Stock ), Series III Class B Convertible Preferred Stock ( Series III Class B Stock ), Series IV Class B Convertible Preferred Stock ( Series IV Class B Stock ), Series V Class B Convertible Preferred Stock ( Series V Class B Stock ), or Common Stock.

Series II Class B

There were 1,000,000 shares of \$1 par value Series II Class B Stock issued and there were 219,700 shares outstanding at December 31, 2009 and 2008. 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 2004, the Company paid \$4.6 million in dividends. In 2007, the Company paid \$790,725 in dividends. At December 31, 2009 and 2008, approximately \$551,000 and \$331,000 respectively, of dividends which had not been declared were in arrears.

Series II Class B Stock is redeemable after three years from the date of issuance at the option of the Company at a price of \$15.00 per share plus all accrued and unpaid dividends. Each share of Series II Class B Stock may, at the option of the stockholder, be converted to one share of Common Stock after three years from the date of issuance or in the event the Company files an initial registration statement under the Securities Act of 1933. Pursuant to these terms, no shares of Series II Class B Stock were converted into Common Stock in 2009. In the event of voluntary or involuntary dissolution, liquidation, or winding up of the Company, holders of Series II Class B Stock then outstanding are entitled to \$12.50 per share, plus all accrued and unpaid dividends, after distribution obligations to holders of Series I Class B Stock have been satisfied and prior to any distributions to holders of Series III Class B Stock, Series IV Class B Stock, Series V Class B Stock, or Common Stock.

Series III Class B

There were 1,160,445 shares of \$1 par value Series III Class B Stock issued and 130,245 shares outstanding at December 31, 2009 and 2008. 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, 2009 and 2008, approximately \$3,246,000 and \$3,117,000, respectively, of dividends which have not been

declared were in arrears.

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

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2009. In the event of voluntary or involuntary dissolution, liquidation, or winding up of the Company, holders of Series III Class B Stock then outstanding are entitled to \$12.50 per share, plus all accrued and unpaid dividends, after distribution obligations to Series I Class B Stock and Series II Class B Stock have been satisfied and prior to any distributions to holders of Series IV Class B Stock, Series V Class B Stock, or Common Stock.

Series IV Class B

There were 1,133,800 shares issued and 552,500 shares outstanding at December 31, 2009 and 2008. Holders of Series IV Class B Stock are entitled to receive a cumulative annual dividend of \$1.00 per share, payable quarterly, if declared by the Board of Directors. Holders of Series IV Class B Stock generally have no voting rights. At December 31, 2009 and 2008, approximately \$7,583,000 and \$7,030,000, respectively, of dividends which have not been declared were in arrears.

Series IV Class B Stock is redeemable after three years from the date of issuance at the option of the Company at a price of \$11.00 per share plus all accrued and unpaid dividends. Each share of Series IV Class B Stock may, at the option of the stockholder any time subsequent to three years from date of issuance, be converted into one share of Common Stock, or in the event the Company files an initial registration statement under the Securities Act of 1933. Pursuant to these terms, no shares of Series IV Class B Stock were converted into Common Stock in 2009. In the event of voluntary or involuntary liquidation, dissolution, or winding up of the Company, holders of Series IV Class B Stock then outstanding are entitled to receive liquidating distributions of \$11.00 per share, plus accrued and unpaid dividends after distribution obligations to Series I Class B Stock, Series II Class B Stock, and Series III Class B Stock have been satisfied and prior to any distribution to holders of Series V Class B Stock, or Common Stock.

Series V Class B

There were 2,416,221 shares issued and 1,238,821 outstanding at December 31, 2009 and 2008. Holders of Series V Class B Stock are entitled to receive a cumulative annual dividend of \$0.32 per share, payable quarterly, if declared by the Board of Directors. Holders of Series V Class B Stock generally have no voting rights. At December 31, 2009 and 2008, approximately \$3,693,000 and \$3,297,000, respectively, of dividends which have not been declared were in arrears.

Series V Class B Stock is redeemable after two years from the date of issuance at the option of the Company at a price of \$4.40 per share plus all accrued and unpaid dividends. Each share of Series V Class B Stock may, at the option of the stockholder any time subsequent to the date of issuance, be converted into Common Stock. Pursuant to the terms of the certificate of designation, no shares of Series V Class B Stock were converted into Common Stock in 2009. In the event of voluntary or involuntary liquidation, dissolution, or winding up of the Company, holders of Series V Class B Stock then outstanding are entitled to receive liquidating distributions of \$4.40 per share, plus accrued and unpaid dividends after distribution obligations to Series I Class B Stock, Series II Class B Stock, Series III Class B Stock, and Series IV Class B Stock have been satisfied and prior to any distribution to the holders of the Common Stock.

**Common stock**

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The Company is authorized to issue 100,000,000 shares of no par value Common Stock, of which 23,825,149 and 23,800,064 shares were issued and outstanding at December 31, 2009 and 2008, respectively.

### 11. RELATED PARTY TRANSACTIONS

The Company had a lease with Mill Street Enterprises ( Mill Street ), a sole proprietorship owned by a person, who ceased to be a 10% shareholder in 2008, for offices and storage in Lewisville, Texas. During the year ended December 31, 2007, the Company paid \$14,500 under this lease. This lease term expired in June 2007.

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The Company paid MediTrade International Corporation, a company controlled by a person, who ceased to be a 10% shareholder in 2008 on a month-to-month consulting agreement whereby MediTrade is paid \$7,500 per month plus expenses. Total amounts paid to MediTrade for the years ending December 31, 2009, 2008, and 2007 totaled \$111,883.57; \$98,401; and \$129,618, respectively.

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

During the years ended December 31, 2009, 2008, and 2007, the Company paid \$50,793; \$40,191; and \$30,397, respectively, to family members of its Chief Executive Officer for various consulting services.

## **12. STOCK OPTIONS**

### **Stock options**

Prior to 2008, the Company had three stock option plans that provided for the granting of stock options to officers, employees, and other individuals. Two of those plans have terminated. A 2008 Stock Option Plan was approved for the granting of stock options to employees, Directors, and consultants. During 1999, the Company approved the 1999 Stock Option Plan. Options for the purchase of 131,880 shares of Common Stock granted under the 1999 Stock Option Plan are outstanding. The 1999 Stock Option Plan terminated pursuant to its terms in 2009. The 2008 Plan is the only plan with stock options currently being awarded. The Company has reserved an aggregate 3,000,000 shares of Common Stock for issuance upon the exercise of options under the 2008 Stock Option Plan.

On September 26, 2008, the Company's shareholders approved an Exchange Offer whereby employees, including executive officers, and Directors could exchange certain outstanding underwater options for options issued under the 2008 Stock Option Plan. Pursuant to the Exchange Offer, eligible participants (totaling 103) tendered, and the Company accepted for cancellation, eligible options to purchase an aggregate of 1,925,365 shares of the Company's Common Stock representing 99.4% of the total shares of Common Stock underlying options eligible to exchange in the Exchange Offer. 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 vest in mid 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 Company also had options for common shares outstanding under the 1996 Incentive Stock Option Plan and the 1996 Stock Option Plan for Directors and Other Individuals through November 2008. The two 1996 plans and all options issued thereunder have terminated or have been exchanged for options granted under the 2008 Plan.

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 vest over periods up to three years from the date of grant and generally expire ten years after the date of grant. Unvested options issued under the 2008 Stock Option Plan expire immediately after termination of employment.

**Employee options**

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

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	Years Ended December 31,					
	2009		2008		2007	
Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	
Outstanding at beginning of period	1,057,263	\$ 1.99	2,187,455	\$ 8.80	2,417,295	\$ 8.58
Granted	4,796,425	0.81	962,683	1.30		
Exercised	(5,085)	(1.30)				
Forfeited	(127,075)	(4.99)	(2,092,875)	(8.79)	(229,840)	(6.50)
Outstanding at end of period	5,721,528	\$ 0.94	1,057,263	\$ 1.99	2,187,455	\$ 8.80
Exercisable at end of period	1,137,403	\$ 1.44	147,580	\$ 6.25	2,187,455	\$ 8.80
Weighted average fair value of options granted during period		\$ 0.59		\$ 0.76		\$

The fair value of each 2008 option grant is estimated on the date of grant using the binomial option pricing model with the following weighted average assumptions used for grants in 2008: no dividend yield; expected volatility of 67.53%; risk free interest rate of 2.83%; and an expected life of 8.61 to 8.69 years. The options were issued under the 2008 Stock Option Plan. No options were issued in 2007.

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.

The following table summarizes information about Director, officer, and employee options outstanding under the aforementioned plans at December 31, 2009:

Exercise Prices	Shares Outstanding	Weighted Average Remaining Contractual Life	Shares Exercisable
\$ 10.00	17,100	0.84	17,100
\$ 6.90	15,080	2.75	15,080
\$ 8.65	2,400	3.48	2,400
\$ 8.87	700	4.36	700
\$ 1.30	902,123	8.89	902,123
\$ 0.81	4,784,125	9.54	200,000





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

	2009		Years Ended December 31, 2008		2007	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at beginning of period	454,700	\$ 8.41	549,700	\$ 8.69	579,700	\$ 8.50
Granted	90,000	0.84				
Exercised	(20,000)	(0.95)				
Forfeited	(133,100)	(10.00)	(95,000)	(10.00)	(30,000)	(5.00)
Outstanding at end of period	391,600	\$ 6.52	454,700	\$ 8.41	549,700	\$ 8.69
Exercisable at end of period	391,600	\$ 6.52	454,700	\$ 8.41	549,700	\$ 8.69
Weighted average fair value of options granted during period		\$ 0.61		\$		\$

The fair value of each 2009 grant is estimated on the date of the grant using the Black Scholes pricing model with the following assumptions: expected volatility of 67.53%, risk free interest rate of 3.35%, and an expected life of 8.61 years. These options were issued under the 2008 Stock Option Plan. No options were issued in 2008 or 2007.

The following table summarizes information about non-employee options outstanding under the aforementioned plans at December 31, 2009:

Exercise Prices	Shares Outstanding	Weighted Average Remaining Contractual Life	Shares Exercisable
\$ 10.00	89,100	0.58	89,100
\$ 6.90	232,500	2.75	232,500
\$ 0.81	70,000	9.55	70,000

The Company recorded \$2,111,360; \$98,473 (offset by a credit of \$65,844 for surrendered stock options); and \$6,478 as stock-based compensation expense in 2009, 2008, and 2007, respectively. The total intrinsic value of options exercised was \$16,388; \$0; and \$0 in 2009, 2008, and 2007, respectively. The aggregate intrinsic value of options outstanding and of options exercisable at December 31, 2009 was

approximately \$4.3 million and \$531,000, respectively. The total compensation cost related to non-vested stock options to be recognized in the future was \$1,346,587 at December 31, 2009.

**13. 401(k) PLAN**

The Company implemented an employee savings and retirement plan (the 401(k) Plan ) in 2005 that is intended to be a tax-qualified plan covering substantially all employees. Under the terms of the 401(k) Plan, employees may elect to contribute up to 88% of their compensation, or the statutory prescribed limit, if less. The Company may, at its discretion, match employee contributions. The Company made matching

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contributions of approximately \$76,643, \$122,000, and \$111,000 in 2009, 2008 and 2007, respectively. In the third quarter of 2009, the Company discontinued contributions until further notice.

**14. BUSINESS SEGMENTS**

	<b>2009</b>		<b>2008</b>		<b>2007</b>	
Domestic sales	\$	34,466,797	\$	23,244,370	\$	21,461,717
International sales		4,515,040		4,654,948		4,828,003
Total sales	\$	38,981,837	\$	27,899,318	\$	26,289,720
Long-lived assets						
Domestic	\$	13,961,445	\$	14,435,667	\$	11,483,423
Foreign	\$	272,736	\$		\$	

The Company does not operate in separate reportable segments. The Company has no long-lived assets in foreign countries. Shipments to international customers generally require a prepayment either by wire transfer or an irrevocable confirmed letter of credit. The Company does extend credit to international customers on some occasions depending upon certain criteria, including, but not limited to, the credit worthiness of the customer, the stability of the country, banking restrictions, and the size of the order. All transactions are in U.S. currency.

**SELECTED QUARTERLY FINANCIAL DATA - UNAUDITED**

The selected quarterly financial data for the periods ended December 31, 2009 and 2008, 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>2009</b>							
	<b>Quarter 1</b>		<b>Quarter 2</b>		<b>Quarter 3</b>		<b>Quarter 4</b>	
Sales, net	\$	5,258	\$	5,753	\$	10,752	\$	17,219
Cost of sales		4,029		3,413		7,817		10,207
Gross profit		1,229		2,340		2,935		7,012
Total operating expenses		5,271		5,121		6,484		9,936
Loss from operations		(4,042)		(2,781)		(3,549)		(2,924)
Interest and other income		29		11		14		4
Interest expense, net								(22)
Benefit for income taxes		105				100		3,633
Net income (loss)		(3,908)		(2,770)		(3,435)		691
Preferred stock dividend requirements		(343)		(343)		(343)		(342)
Earnings (loss) applicable to common shareholders	\$	(4,251)	\$	(3,113)	\$	(3,778)	\$	349
Net earnings (loss) per share - basic and diluted	\$	(0.18)	\$	(0.13)	\$	(0.16)	\$	0.01
Weighted average shares outstanding		23,800,064		23,800,064		23,803,397		23,822,607
Profit margin		23.4%		40.7%		27.3%		40.7%



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

	2008			
	Quarter 1	Quarter 2	Quarter 3	Quarter 4
Sales, net	\$ 5,315	\$ 6,474	\$ 8,997	\$ 7,113
Cost of sales	4,029	3,498	6,871	5,275
Gross profit	1,286	2,976	2,126	1,838
Total operating expenses	4,362	4,028	4,306	5,975
Loss from operations	(3,076)	(1,052)	(2,180)	(4,137)
Interest and other income	254	241	159	202
Interest expense, net	(41)	(22)	(14)	23
Net loss	(2,863)	(833)	(2,035)	(3,912)
Preferred stock dividend requirements	(345)	(343)	(343)	(342)
Loss applicable to common shareholders	\$ (3,208)	\$ (1,176)	\$ (2,378)	\$ (4,254)
Net loss per share basic and diluted	\$ (0.13)	\$ (0.05)	\$ (0.10)	\$ (0.18)
Weighted average shares outstanding	23,778,072	23,800,064	23,800,064	23,800,064
Profit margin	24.2%	46.0%	23.6%	25.8%

Major variances in the third quarter results for 2009 compared to 2008 are due to higher revenues due to the DHHS contract and higher litigation costs in 2009.

Fourth quarter results for 2009, when compared to 2008, were affected by a dramatic increase in revenues due to the DHHS contract. Operating expenses increased primarily due to the recognition of an impairment cost of \$2.6 million and additional litigation costs of \$2.1 million. Net income was positively affected in 2009 for a tax benefit of \$3.6 million related to the carryback of the 2009 net operating loss for federal taxes.

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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, 2009, 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, 2009, was effective. No material weaknesses in our internal control over financial reporting were identified by Management.

This annual report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to temporary rules of the SEC that permit us to provide only Management's report in this annual report.

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 2009 or subsequent to December 31, 2009 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.

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**Item 9B. Other Information.**

Effective December 20, 2009, the Board of Directors approved changes to the Charters for the Audit Committee, Compensation and Benefits Committee, and Nominating Committee as well as changes to our Code of Business Conduct and Ethics, all of which are posted on our website at [www.vanishpoint.com](http://www.vanishpoint.com). A summary of the material changes is set forth below.

The Audit Committee Charter was amended primarily to reflect the new name change for the NYSE Amex LLC as well as to change reference to various accounting standards as required by changing rules. It was also amended to disclose our current process for receipt, retention, and treatment of complaints regarding accounting, internal accounting controls, or auditing matters and the confidential submission by employees of such concerns. A copy of the charter is attached hereto as Exhibit No. 99.1.

The Compensation and Benefits Committee Charter was amended primarily to reflect the new name for the NYSE Amex LLC and also to clarify that the CEO's compensation is set solely by the Committee. A copy of the charter is attached hereto as Exhibit No. 99.2.

The Nominating Committee Charter was amended to reflect the new name change for the NYSE Amex LLC. A copy of the charter is attached hereto as Exhibit No. 99.3.

The Code of Business Conduct and Ethics was amended to reflect the new name change for the NYSE Amex LLC and also primarily to add our Insider Trading Policy as it currently stands. Other minor changes were also made. A copy of the amended code is incorporated herein as Exhibit No. 14.

On January 22, 2010, we held the rescheduled meeting of preferred shareholders for those series that did not obtain quorum at the initial Special Meeting (Series I – IV Class B Convertible Preferred Stock). The Series II and III Class B Convertible Preferred Shareholders obtained quorum at this rescheduled meeting. The proposals submitted for their approval were those relating to an amendment of the applicable certificates of designation. Previously, the various certificates of designation provided that, if dividends were in arrears on the preferred stock, there were certain prohibitions on acquisitions for consideration by the Company of stock ranking junior to such stock except on certain terms. One of the limitations was that no acquisitions for consideration could be made unless the acquisition involved the acquisition of all of the preferred stock (upon a 50% vote) or unless the preferred stock was converted into or exchanged into stock of the Company ranking junior to the preferred stock as to dividends and upon liquidation. The proposed amendments deleted these requirements and specifically provided that the Company can purchase any of its shares ranking junior to the preferred stock (including Common shares) on any terms it fixes, even where a dividend upon shares of the preferred stock is in arrears, so long as: (A) the cash assets of the Company as of its latest reporting period equal or exceed \$40,000,000 or (B) if the cash assets of the Company as of its latest reporting period were less than \$40,000,000, the amount of funds utilized to purchase such shares within the next quarter do not exceed 25% of the value of the cash assets as of the previous reporting period. The Series II Class B Convertible Preferred Shareholders rejected this proposal. The Series III Class B Convertible Preferred Shareholders approved this proposal. The Series V Class B Convertible Preferred Shareholders approved a similar proposal at the prior Special Meeting. The meeting of the Series I Class B Convertible Preferred Shareholders has been permanently adjourned. The meeting of the Series IV Class B Convertible Preferred Shareholders has been adjourned until June 11, 2010 at 10:00 a.m. Central time.

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Articles of Amendment were filed on October 16, 2009 with the Texas Secretary of State amending the Articles of Incorporation to reflect the prior approval of the proposal by the Series V Class B Convertible Preferred Stock.

### PART III

#### **Item 10. Directors, Executive Officers and Corporate Governance.**

The following table sets forth information concerning our Directors, executives, and certain of our significant employees as of the date of this report. Our Board of Directors consists of a total of seven (7) members, two (2) members of which are Class 1 Directors and five (5) of which are Class 2 Directors which serve for two-year

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terms. At our 2010 Annual Meeting, we will be soliciting the election of four Class 2 Directors and one Class 1 Director so that the Board will be more evenly split with four Class 2 Directors and three Class 1 Directors.

Name	Age	Position	Term as Director Expires
<b>EXECUTIVES</b>			
Thomas J. Shaw	59	Chairman, President, Chief Executive Officer, and Class 2 Director	2010
Douglas W. Cowan	66	Vice President, Chief Financial Officer, Treasurer, and Class 2 Director	2010
Kathryn M. Duesman	47	Executive Director, Global Health	N/A
Russell B. Kuhlman	56	Vice President, Sales	N/A
Michele M. Larios	43	Vice President, General Counsel, and Secretary	N/A
Lawrence G. Salerno	49	Director of Operations	N/A
Steven R. Wisner	52	Executive Vice President, Engineering & Production and Class 2 Director	2010
<b>INDEPENDENT DIRECTORS</b>			
Marco Laterza	62	Class 1 Director	2011
Amy Mack	42	Class 1 Director	2011
Marwan Saker	54	Class 2 Director	2010
Clarence Zierhut	81	Class 2 Director	2010
<b>SIGNIFICANT EMPLOYEES</b>			
Shayne Blythe	41	Director of Sales and Marketing Logistics	N/A
John W. Fort III	41	Director of Accounting	N/A
James A. Hoover	62	Director of Quality Assurance	N/A
R. John Maday	49	Production Manager	N/A
Judy Ni Zhu	51	Research and Development Manager	N/A

### **Executives**

Thomas J. Shaw, our Founder, has served as Chairman of the Board, President, Chief Executive Officer, and Director since our inception. We believe it is appropriate for Mr. Shaw to continue to serve as a Director and as the Chairman of the Board because of his deep knowledge of the strengths and weaknesses of our products (as their primary inventor) and of the Company (as its Founder). Further, his strategic knowledge of the Company and its competitive environment arising from his ongoing services as its CEO is vital to the successful supervision of the Company by the Board of Directors. Finally, Mr. Shaw's educational background in both Engineering and Accounting is helpful to Board deliberations. In addition to his duties overseeing our Management, he continues to lead our design team in product development of other medical safety devices that utilize, among other things, his unique patented friction ring technology. Mr. Shaw has over 25 years of 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. Mr. Shaw received a Bachelor of Science in Civil Engineering from the University of Arizona and a Master of Science in Accounting from the University of North Texas.

Douglas W. Cowan is a Vice President and our Chief Financial Officer, Treasurer, 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

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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. Mr. Cowan also serves as a Director of Cowan Technologies, Inc., a private computer consulting company. Mr. Cowan has a Bachelor of Business Administration from Texas Technological College. He is a CPA licensed in Texas.

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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. Ms. Duesman is a 1985 graduate of Texas Woman's University with a Bachelor of Science in Nursing. Ms. Duesman's clinical background as a registered nurse includes diagnostic, acute, and home healthcare nursing.

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. Mr. Kuhlman is also Vice President of Kuhlman & Kuhlman, Inc., a private real estate management company. He has a sales background in the medical service industry that includes his most recent work for ICU Medical (formerly Bio-Plexus), a medical device manufacturing company, from 1994 to 1997, where he developed strategic marketing plans for new safety products. Prior to his work there, Mr. Kuhlman worked as Director of Sales and Marketing for Ryan Winfield Medical, Inc., a medical device manufacturing company, from 1989 to 1994, where he launched several new products, developed strategic sales territories, and was the trainer for Sales and Regional Managers. Mr. Kuhlman also worked for BD Vacutainer® Systems, a medical products company, in several territories from 1980 to 1989, where he was recognized as the National Sales Representative for the year 1987. Mr. Kuhlman holds a Bachelor of Science in Finance from the University of Tennessee.

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, quality assurance, human resource, and regulatory functions. In addition to working on legal matters and with outside counsel, Ms. Larios works with legislators on pertinent issues and relevant legislation. Ms. Larios received a Bachelor of Arts in Political Science from Saint Mary's College in Moraga, California, and a Juris Doctorate from Pepperdine University School of Law in Malibu, California.

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. Mr. Salerno received his Bachelor of Science in Economics from the University of North Texas.

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 and his comprehensive overview of all of the Company's operations. 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, and international sales. Mr. Wisner has over 30 years of experience in product design, development, and manufacturing. Mr. Wisner holds a Bachelor of Science in Computer Engineering from Iowa State University.

**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

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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



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development stage, software 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. Mr. Laterza received his Bachelors of Business Administration in Accounting from Pace University in 1972. He is a CPA and has received a Certificate of Educational Achievement in Personal Financial Planning from the American Institute of CPAs.

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 over ten years of experience as a nurse (the primary retail user of our products) as well as her experience in running her own company. Further, she contributes to the diversity of experience on our Board. Since 2003, she has owned and operated SPA 02, a medical spa. Since April of 2000, she has owned and operated (and served as Chief Nursing Officer for) EmergiStaff & Associates, a nursing staffing company, in Dallas, Texas. She served as a registered nurse from August 1997 to the date she began EmergiStaff & Associates. She obtained her Bachelor of Science degree from Texas A&M University in College Station, Texas in 1991 and an Associate degree in Nursing from El Centro College in Dallas, Texas in 1994. She is a registered nurse in Texas.

Marwan Saker joined our Board of Directors in June 2000. We believe it is appropriate that Mr. Saker continue to serve as a Director due to over a decade of experience in international business as well as his specific expertise in issues relating to international distribution. Mr. Saker's experience as a business owner competing internationally provides additional necessary insight to our Board. Since 1983, Mr. Saker has served as Chief Executive Officer of Sovana, Inc., a private export management company that supplies agricultural equipment and supplies to overseas markets. Since 2000, he has served as Director of Consolidated Food Concepts Inc., a private company. Since 1986, he has served as President of International Exports & Consulting Inc., a private export management, consulting, and distribution company. Since 2000, he has served as Vice President of Hanneke Corp., a private overseas sourcing company. From 1998 to 2001, he served as a Member of My Investments, LLC, a private equity investment company. Since 1999, he has served as President of Saker Investments Inc., a private company that manages an investment portfolio. Since 1998, he has served as a General Partner of Maya Investments, Ltd., a private investment management limited partnership. He also serves as a Member of MMDA, LLC, a private real estate development company. He is also involved with Fig Land Development, a private 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. He has offices in Irving, Texas.

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. Finally, Mr. Zierhut has valuable experience and insight arising out of the successful running of his own small company. Mr. Zierhut founded an industrial design firm in 1955, Zierhut Design, now Origin Design, that develops new products from concept through final prototypes. He ceased management of the company for a period of time but has since resumed his executive duties. 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. He received a Bachelor of Arts from Art Center College of Design in Los Angeles, California.

**Significant Employees**

Shayne Blythe has been with us for over ten years 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. Prior to joining us, Ms. Blythe assisted Mr. Shaw with the original 3mL syringe and other SBIR grant projects. Ms. Blythe has a Bachelors of Business Administration in management from the American Intercontinental University.

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

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interim reviews by our independent accountants, as well as our cost accounting and forecasting functions. Prior to joining us, he served as the Manager of Financial Planning for the product-marketing department of Excel Communications. Mr. Fort also served as the Manager of Budgeting and Projections for Snelling and Snelling, Inc., an international personnel services firm. Mr. Fort holds a Bachelor of Business Administration in Accounting from Tarleton State University.

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. Mr. Hoover joined us after working for Sherwood for 26 years. During his tenure with Sherwood, a medical device manufacturing company, he gained hands-on experience in all aspects of the medical device manufacturing process. Mr. Hoover began his career with Sherwood as a materials handler and worked his way up through a series of positions with added responsibilities to his final position there as Production Manager of Off-Line Molding, Operating Room/Critical Care. In this capacity, he managed several departments, ran several product lines, and hired and supervised over 200 employees. While at Sherwood, he also gained experience with one of the country's first safety syringes, the Monoject®.

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 over 27 years of manufacturing experience in both class II and III medical devices. He spent three years with Mentor Corp. supervising two production departments and 13 years with Sherwood in which he gained hands-on experience in all aspects of medical device manufacturing including managing the Kit and Packaging department with over 225 employees. Mr. Maday's formal training includes FDA and Total Quality Management Systems and he is certified as a Black Belt of Six Sigma Methodology.

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. Ms. Zhu received her Bachelor of Science from Northwest Polytechnic University in Xian, China, and her Master of Engineering from the University of Texas at Arlington. Ms. Zhu has assisted in design modifications for the 3mL syringe, which have maximized both product reliability and production efficiency. She also designed and developed a manual needle assembly machine and an automatic lubricating and capping system for the 3mL syringe and developed and assisted in the design of automated blood collection tube holder assembly equipment. Ms. Zhu has collaborated with Ms. Duesman and Mr. Shaw in the filing of several patent applications.

**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)

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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. 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;
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.

The Code of Business Conduct and Ethics was amended in 2009 to reflect the new name change for the NYSE Amex and also primarily to add our Insider Trading Policy as it currently stands. Other minor changes were also made. A copy of the amended code 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.

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 Messrs. Clarence Zierhut, Marco Laterza, and Marwan Saker. 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 it is 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:

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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 three basic components:

base salary;

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. We have been blocked from access to the market by exclusive marketing practices engaged in by BD who

dominates the market. We believe that its monopolistic business practices continue despite: (i) its paying \$100 million to settle a prior lawsuit with us in 2004 for anticompetitive practices, business disparagement, and tortious interference and (ii) the fact that a jury returned a verdict in November 2009 finding that all three patents asserted by us against BD are valid and infringed by 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.

#### *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. In the past, when there is a review of executive compensation, we have retained an outside consulting firm, Trinity Executive Recruiters, Inc., to provide benchmarks for similar compensation given the multiple and varied positions each executive fulfills as well as our size and the hostile environment in which we operate.

#### *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.



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These base salaries are reviewed periodically and may be adjusted based upon the factors discussed in the previous sentence, 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%. This included all Executive Officers. 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 had also been previously cut by 10%) by \$11,254.04 for 2010.

*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 2007. We 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 tendered options pursuant to an Exchange Offer in 2008. We issued incentive stock options (ISOs) for the purchase of 269,956 shares of Common Stock and Non Qualified Stock Options (NQSOs) for the purchase of 229,494 shares of Common Stock to Executive Officers and Directors under the 2008 Stock Option Plan in July 2009. Options are generally granted to regular full-time employees and officers except to our CEO.

In 2009, the Compensation and Benefits Committee granted the first 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. The committee took into consideration, among other things, the following benefits received and to be received by the Company in consideration for the grant of the option:

Mr. Shaw has been the primary developer of all of the Company's products and is crucial to the recent development of a number of new products that are capable of expanding the Company's product line both inside and (eventually) outside of the syringe market;

Mr. Shaw's active participation and continuation with the Company is crucial for the success of the Company in breaking into the market through its several ongoing lawsuits. Mr. Shaw's participation was crucial in obtaining the Company's prior litigation settlements for tens of millions of dollars;

Mr. Shaw had his salary reduced by 10% beginning on August 1, 2009;

Mr. Shaw only had a substantive pay raise three times since the Company's incorporation in 1994;

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Mr. Shaw has never before been granted options despite the fact it is a standard compensation practice for a person in his position; and

Mr. Shaw has never before been granted a bonus despite the fact it is a standard compensation practice for a person in his position.

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

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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 was, from time to time, further reviewed by each department's management if they believed certain employees were not awarded an appropriate number of options, which Management would consider.

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 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.

**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.

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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 from time to time (the last time in 2003) 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.

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**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 incented 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.

**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, individual's contribution to the Company's 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.

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

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 positions which are currently fulfilled by various members of our executive team. These benchmarks 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. Such proposal is then submitted to the Compensation and Benefits Committee for its approval.

**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 ends December 31, 2010 that 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, the Compensation and Benefits Committee increased his salary by \$11,254.04.



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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.

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.

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

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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.

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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 to 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) with Management, and, based on the review and discussions referred to in paragraph (e)(5)(i)(A) of Item 407, 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

## SUMMARY OF TOTAL COMPENSATION

The following Summary Compensation Table sets forth the total compensation paid or accrued by us over the prior three 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 2007-2009

<b>Name and Principal Position</b>	<b>Year</b>	<b>Salary (\$)</b>	<b>Option Awards(1) (\$)</b>	<b>All Other Compensation (\$)</b>	<b>Total (\$)</b>
Thomas J. Shaw	2007	400,000		4,200(2)	404,200
President and CEO	2008	416,548		4,600(2)	421,148
(principal executive officer)	2009	399,887	1,762,500	4,808(2)	2,167,195
Douglas W. Cowan	2007	290,109	778	4,200(2)	295,087
Vice President, CFO	2008	290,000	6,460	4,600(2)	301,060
(principal financial officer)	2009	278,289	57,575	3,346(2)	339,210

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Steven R. Wisner	2007	290,000	758	4,200(2)	294,958
Executive Vice President,	2008	290,020	6,694	4,600(2)	301,314
Engineering and Production	2009	278,289	13,806	3,123(2)	295,218
Michele M. Larios	2007	350,000	797	4,200(2)	354,997
Vice President,	2008	350,540	6,843	4,600(2)	361,983
General Counsel	2009	336,676	89,858	4,047(2)	430,581
Russell B. Kuhlman	2007	134,779	369	2,695(2)	137,843
Vice President, Sales	2008	140,000	4,019	2,800(2)	146,819
	2009	133,769	14,688	1,606(2)	150,063

(1) Except for the option granted to Mr. Shaw, all options issued during or after 2008 were granted under the 2008 Stock Option Plan, a copy of which is incorporated herein as

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Exhibit No. 10.9. Options issued prior to 2008 were issued under either the 1996 Incentive Stock Option Plan, the 1996 Stock Option Plan for Directors and Other Individuals, or under the 1999 Stock Option Plan. The employees who had such options were permitted to exchange them for options granted under the 2008 Stock Option Plan pursuant to an Exchange Offer in 2008.

The fair value of each option grant prior to 2008 was estimated on the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions used for grants in 2004: no dividend yield; expected volatility of 37%; risk free interest rate of 4.89%; and an expected life of 9.0 years. No options were issued in 2006 or 2007. Options granted before 2008 were issued under the 1999 Stock Option Plan, a copy of which Plan and amendment were filed as exhibits to our Form 10-SB filed on June 23, 2000 and our Form 10-KSB filed on March 31, 2003, respectively. Option award expense for grants issued before 2008 were fully amortized by the first quarter of 2007.

Option award expense for 2008 is that portion of the fair value of the options issued under the Exchange Offer in 2008. The expense for the options issued under the Exchange Offer was fully amortized in 2009. The fair value of each 2008 option grant was estimated on the date of grant using the binomial option pricing model with the following weighted average assumptions used for grants in 2008: no dividend yield; expected volatility of 67.53%; risk free interest rate of 2.83%; and an expected life of 8.61 to 8.69 years. The options were issued under the 2008 Stock Option Plan, a copy of which Plan was filed as Appendix B to our definitive Schedule 14A filed on August 19, 2008.

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 Mr. Shaw, the options were issued under the 2008 Stock Option Plan.

(2) This amount was compensation pursuant to our matching contributions to the 401(k) plan.

GRANTS OF PLAN-BASED AWARDS

The following Grants of Plan-Based Awards for 2009 Table sets forth information regarding grants of awards made under any plan to each named executive officer in the last completed fiscal year.

**Grants of Plan-Based Awards for 2009**

Name	Grant Date	Estimated Future Payouts Under Equity Incentive Plan Awards Target #	All Other Option Awards: Number of Shares of Stocks or Units #	Exercise or base price of option awards \$/share	Grant date fair value of stock and option awards
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Thomas J. Shaw President and CEO (principal executive officer)	7/15/09		3,000,000	\$0.81	\$ 1,762,500
Douglas W. Cowan Vice President, CFO (principal financial officer)	7/15/09	98,000		\$0.81	\$ 57,575
Steven R. Wisner Executive Vice President, Engineering and Production	7/15/09	23,500		\$0.81	\$ 13,806
Michele M. Larios Vice President, General Counsel	7/15/09	123,456	29,494	\$0.81	\$ 89,858

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Name	Grant Date	Estimated Future Payouts Under Equity Incentive Plan Awards Target #	All Other Option Awards: Number of Shares of Stocks or Units #	Exercise or base price of option awards \$/share	Grant date fair value of stock and option awards
Russell B. Kuhlman Vice President, Sales	7/15/09	25,000		\$0.81	\$ 14,688

**Narrative Disclosure to Summary Compensation Table and Grants of Plan-Based Awards Table**

Please see **Compensation Pursuant to Employment Agreement** and POTENTIAL PAYMENTS UPON TERMINATION OR CHANGE IN CONTROL below for terms of our only employment agreement in effect.

The material terms of awards reported in the Grants of Plan-Based Awards Table include that such options vest on July 15, 2010 (assuming the recipient is still employed by us) and expire on July 15, 2019. All options granted to Named Executive Officers in 2009 have an exercise price per share equal to the close of business stock price on July 15, 2009 (\$0.81). The Compensation and Benefits Committee approved the grant of these stock options on July 15, 2009. All options (except to Mr. Shaw) were granted under the 2008 Stock Option Plan, a copy of which Plan was filed as Appendix B to our definitive Schedule 14A filed on August 19, 2008. Mr. Shaw's stock option was granted outside of any plan under similar terms and conditions as those set forth under the 2008 Stock Option Plan, with the exception that Mr. Shaw's option terminates after 10 years and not five years from the date of grant. (See Exhibit No. 10.10) Mr. Shaw's stock option was approved by shareholders at the annual meeting in 2009.

The ratios of salary and bonus to total compensation for 2009, for each Named Executive Officer is as follows:

Thomas J. Shaw	18.5%
Steven R. Wisner	94.3%
Douglas W. Cowan	82.0%
Michele M. Larios	78.2%
Russell Kuhlman	89.1%

**OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END**

The following Outstanding Equity Awards at Fiscal Year-End Table sets forth information regarding unexercised options held by the principal executive officer, the principal financial officer, and the three highest paid additional executive officers as of December 31, 2009.





Table of Contents**Outstanding Equity Awards at 2009 Fiscal Year End**

Name	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable(1)	Option Awards	Option Exercise Price (\$)	Option Expiration Date
			Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)(2)		
Thomas J. Shaw President, CEO (principal executive officer)		3,000,000		0.81	7-15-19
Douglas W. Cowan Vice President, CFO (principal financial officer)	102,000		98,000	1.30 0.81	11-18-18 7-15-19
Steven R. Wisner Executive Vice President, Engineering and Production	100,700		23,500	1.30 0.81	11-18-18 7-15-19
Michele M. Larios Vice President, General Counsel	97,050	29,494	123,456	1.30 0.81 0.81	11-18-18 7-15-19 7-15-19
Russell B. Kuhlman Vice President, Sales	63,450		25,000	1.30 0.81	11-18-18 7-15-19

(1) These options will vest on July 15, 2010, assuming the recipient is still employed by us.

(2) These options will vest on July 15, 2010, assuming the recipient is still employed by us.

**PENSION BENEFITS**

We do not have a pension plan other than the 401(k) plan which is available to all employees the first of the month after 90 days of service.

**401(k) Plan**

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We 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. We may, at our discretion, match employee contributions. We made matching contributions of approximately \$76,643 and \$122,000 in 2009 and 2008, respectively. \$16,930 and \$21,095 of these matching contributions were to executive officers in 2009 and 2008, respectively. We suspended matching contributions beginning August 1, 2009 until further notice.

### POTENTIAL PAYMENTS UPON TERMINATION OR CHANGE IN CONTROL

The following table identifies the types and amounts of payments that shall be made to Mr. Thomas Shaw, our CEO, in the event of a termination of his employment or a change in control per his Employment Agreement. Such payments shall be made by us and shall be one-time, lump sum payments except as indicated below.

Table of Contents**SUMMARY OF PAYMENTS UPON TERMINATION OR CHANGE IN CONTROL****ASSUMING OCCURRENCE AS OF DECEMBER 31, 2009(1)**

<b>Payment Triggering Event</b>	<b>Salary Through Trigger Event Date</b>	<b>Amounts Owed Under Benefit Plans(2)</b>	<b>Reimbursement of Expenses</b>	<b>Undiscounted Salary For a Period of 24 Months</b>	<b>Payment Equal to 90 Days Salary</b>	<b>Value of Payments(3)</b>
Death	x	x	x			
Disability	x	x	x	750,270		750,270
Termination With Cause	x		x			
Termination Without Cause	x	x	x	750,270		750,270
Resignation (Other Than After a Change in Control)	x	x	x		92,499	92,499
Resignation (After a Change in Control)	x	x	x	750,270		750,270

(1) The above payments would be paid under Mr. Shaw's agreement at certain times. Any payments arising as a result of disability or resignation would be paid not sooner than six months and one day from the termination date but not later than seven months from the termination date. Any payments arising as a result of death would be paid no later than the 90th day following the death. Payments arising as a result of termination with cause or termination without cause would be paid not later than the 30th day following the date of termination except that any amount due in excess of an amount equal to the lesser of two times annual compensation or two times the limit on compensation under section 401(17) of the Internal Revenue Code of 1986 such amount in excess shall be paid no earlier than six months and one day after the date of termination but in no event later than seven months after the date of termination. Under Mr. Shaw's agreement, Mr. Shaw has agreed to a one-year non-compete, not to hire or attempt to hire employees for one year, and to 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. However, it is not clear that the above payments are conditioned on the performance of these contractual obligations.

(2) Mr. Shaw participates in our benefit plans which do not discriminate in scope, terms, or operation in favor of executive officers. Such plans are generally available to all salaried employees. Accordingly, the value of such payments is not included in the "Value of Payments" column.

(3) This value does not include payments under our benefit plans for reasons set forth in footnote 2 above. In addition, this value assumes that the triggering event occurred on December 31, 2009. Authorized payments under the Employment Agreement are also capped to one dollar less than the amount that would cause Mr. Shaw to be the recipient of a parachute payment under Section 280G(b) of the Internal Revenue Code.

## COMPENSATION OF DIRECTORS

The following table identifies the types and amounts of compensation earned by our Directors (with the exception of those that are named Executive Officers as described in footnote 1 to the table) in the last Fiscal Year:

Table of Contents**DIRECTOR COMPENSATION TABLE FOR 2009**

Name(1)	Fees Earned or Paid in		Option Awards (\$)(2)	All Other Compensation (\$)	Total (\$)
	Cash (\$)				
Marco Laterza	\$ 3,000	\$	29,280	\$	32,280
Amy Mack	\$ 2,500	\$	29,280	9,940(3)	41,720
Marwan Saker	\$ 3,000	\$	29,280	\$	32,280
Clarence Zierhut	\$ 3,000	\$	29,280	\$	32,280

(1) Messrs. Thomas J. Shaw, Douglas W. Cowan, and Steven Wisner are Named Executive Officers who are also Directors. Their compensation is reflected in the Summary Compensation and other tables presented earlier.

(2) Aggregate shares underlying options granted to each Director are as follows:

Thomas J. Shaw	3,000,000
Steven R. Wisner	124,200
Douglas W. Cowan	200,000
Marco Laterza	50,000
Clarence Zierhut	62,500
Marwan Saker	90,500
Amy Mack	50,000

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.

(3) Ms. Mack's company was paid these funds for participating in clinical trials in 2009.

**Narrative Explanation of Director Compensation Table for 2009**

In 2009 we paid each non-employee Director a fee of \$500 per meeting and reimbursed travel expenses. We have granted to each Director stock options for Common Stock. We do not pay any additional amounts for committee participation or special assignment.

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Generally, employee Directors are compensated on an at-will basis as discussed in the COMPENSATION DISCUSSION AND ANALYSIS. However, one employee, Mr. Thomas J. Shaw, our President and CEO, is compensated pursuant to an employment agreement. Please see **Compensation Pursuant to Employment Agreement**, set forth above for an in depth summary of the terms of such agreement.

### Compensation Committee Interlocks and Insider Participation

The Compensation and Benefits Committee is currently composed of Messrs. Clarence Zierhut and Marco Laterza and Ms. Amy Mack. Each of these members of this committee is an independent Board member and none have ever been employees.

There are no interlocking Directors or executive officers between us and any other company. Accordingly, none of our executive officers or Directors served as a Director or executive officer for another entity one of whose executives or Directors served on our Board of Directors.

### COMPENSATION POLICIES AND PRACTICES AS THEY RELATE TO RISK MANAGEMENT

We do not believe that risk-taking incentives are created by our compensation policies. We do not have business units. We believe that our compensation expense is a reasonable percentage of revenues overall. We have not set specific performance criteria for the award of bonuses. Salaries are awarded based on skill, experience, and our overall revenues. Non-cash awards to employees are made periodically in the form of stock options, which we believe align the employees' interests with those of stockholders. We review our compensation policies and practices as they relate to risk management objectives if compensation amounts are materially amended or if our risk

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profile changes. No changes to our compensation policies and practices have been implemented as a result of changes to our risk profile.

**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.**

## EQUITY COMPENSATION PLAN INFORMATION

The following table sets forth information relating to our equity compensation plans as of December 31, 2009:

**Equity Compensation Plan Information**

<b>Plan category</b>	<b>Number of securities to be issued upon exercise of outstanding options, warrants and rights</b> (a)	<b>Weighted average exercise price of outstanding options, warrants and rights</b> (b)	<b>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column(a))</b> (c)
Equity compensation plans approved by security holders	5,888,128 \$	1.08	150,892
Equity compensation plans not approved by security holders*	225,000 \$	6.90	0
Total	6,113,128 \$	1.29	150,892

\* We authorized the issuance of an individual option plan for the purchase of 200,000 shares of Common Stock to Jimmie Shiu, M.D., for his past services in introducing us to purchasers of various series of Preferred Stock as well as for introducing us to Mr. Jack Jackson, who controlled Katie Petroleum. The option is exercisable at \$6.90 per share and will terminate in 2012.

We authorized the issuance of an individual option plan for the purchase of 25,000 shares of Common Stock to Mr. Harry Watson for his past services in assisting us in protecting our intellectual property. The option is exercisable at \$6.90 per share and will terminate in 2012.

The Compensation and Benefits Committee authorized (and the shareholders approved) a grant of an option for the purchase of 3,000,000 shares of Common Stock to our CEO, Thomas J. Shaw. The option is exercisable at a price of \$0.81 per share, the market price on the date of grant. The option will terminate in 2019.

**SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS**

The following table sets forth certain information regarding the beneficial ownership of our capital stock as of March 1, 2010, for each person known by us to own beneficially 5% or more of the voting capital stock. Except pursuant to applicable community property laws, each shareholder identified in the table possesses sole voting and investment power with respect to his or her shares, except as noted below.



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<b>Title of Class</b>	<b>Name and Address of Beneficial Owner</b>	<b>Amount and Nature of Beneficial Ownership</b>	<b>Percent of Class (1)</b>
Common Stock	Thomas J. Shaw(2)	14,580,000	54.2%
	511 Lobo Lane		
	P.O. Box 9		
	Little Elm, TX 75068-0009		
	Suzanne M. August(3)	2,800,000	11.8%
	5793 Lois Lane		
	Plano, TX 75024		
	Lillian E. Salerno(4)	1,968,500	8.3%
	432 Edwards		
	Lewisville, TX 75067		
Class B Stock	Lloyd I. Miller, III(5)	1,224,075	5.1%
	4550 Gordon Drive		
	Naples, FL 34102		
	Thomas J. Shaw	80,000	3.5%
Lillian E. Salerno	12,500	<1%	

(1) The Percent of Class is calculated for the Common Stock class by dividing each beneficial owner's Amount of Beneficial Ownership, as shown in the table above, by the sum of the total outstanding Common Stock (23,825,149 shares) plus that beneficial owner's stock equivalents (options and/or preferred stock), if any. The Percent of Class is calculated for the Class B stock by dividing each beneficial owner's Amount of Beneficial Ownership, as shown in the table above, by the total outstanding Class B shares (2,285,266 shares).

(2) 3,000,000 of the shares identified as Common Stock are shares acquirable through the exercise of a stock option beginning on July 15, 2010. 80,000 of the shares identified as Common Stock are preferred shares which are eligible for conversion into Common Stock. 2,800,000 of the shares are owned by Ms. Suzanne August (see footnote 3) but are controlled by Mr. Shaw pursuant to a Voting Agreement. These shares are permanently controlled by Mr. Shaw until such time as they are sold by Ms. August. These shares are included in calculating Mr. Shaw's percentages in the above table.

(3) Ms. August's 2,800,000 shares are controlled by Mr. Thomas J. Shaw pursuant to a Voting Agreement. Accordingly, they are also included in the Common Stock equivalents and percentages for Mr. Shaw in the above table.

(4) 12,500 of the shares identified as Common Stock are preferred shares which are eligible for conversion into Common Stock and 25,000 shares identified as Common Stock are shares which are obtainable by the exercise of options.

(5) The number of shares held by this person was obtained from a Schedule 13G/A filed on February 8, 2010. Pursuant to the Schedule 13G/A, Lloyd I. Miller has sole voting and dispositive power for 303,300 of the shares, and shared voting and dispositive power for 920,775 shares.

Table of Contents**SECURITY OWNERSHIP OF MANAGEMENT AND DIRECTORS**

The following table sets forth certain information regarding the beneficial ownership of our capital stock as of March 1, 2010, for each Named Executive Officer specified by Item 402 of Regulation S-K (i.e., our CEO, CFO, and three other highest paid officers) and Director of the Company. Except pursuant to applicable community property laws or as otherwise discussed below, each shareholder identified in the table possesses sole voting and investment power with respect to his or her shares.

<b>Title of Class</b>	<b>Name of Beneficial Owner</b>	<b>Amount and Nature of Beneficial Ownership</b>	<b>Percent of Class(1)</b>
Common Stock			
As a Group	Named Executive Officers and Directors	15,887,650	59.6%
As Individuals	Thomas J. Shaw(2)	14,580,000	54.2%
	Marwan Saker(3)	445,500	1.8%
	Clarence Zierhut(4)	72,500	<1%
	Douglas W. Cowan(5)	200,000	<1%
	Steven R. Wisner(6)	129,200	<1%
	Russell B. Kuhlman(7)	89,450	<1%
	Michele M. Larios(8)	261,000	1.1%
	Marco Laterza(9)	60,000	<1%
	Amy Mack(10)	50,000	<1%
Class B Stock			
As a Group	Named Executive Officers and Directors	435,000	19.0%
As Individuals	Thomas J. Shaw	80,000	3.5%
	Marwan Saker	355,000	15.5%

(1) The Percent of Class is calculated for the individuals holding Common Stock by dividing each beneficial owner's Amount of Beneficial Ownership, as shown in the table above, by the sum of the total outstanding Common Stock (23,825,149 shares) plus that beneficial owner's stock equivalents (options and/or preferred stock), if any. The Percent of Class is calculated for the As a Group rows by totaling all of the Percent of Class percentages appearing in the chart for individuals for each relevant class. The Percent of Class is calculated for the Class B stock by dividing each beneficial owner's Amount of Beneficial Ownership, as shown in the table above, by the total outstanding Class B shares (2,285,266 shares).

(2) 3,000,000 of the shares identified as Common Stock are shares acquirable through the exercise of a stock option beginning on July 15, 2010. 80,000 of the shares identified as Common Stock are preferred shares which are eligible for conversion into Common Stock. 2,800,000 of the shares are owned by Ms. Suzanne August but are controlled by Mr. Shaw pursuant to a Voting Agreement. These shares are permanently controlled by Mr. Shaw until such time as they are sold by Ms. August. These shares are included in calculating Mr. Shaw's percentages in the above table.

(3) 355,000 shares identified as Common Stock are preferred shares which are eligible for conversion into Common Stock. The shares are held as follows: Saker Investments holds 15,500 shares of Series IV Class B Convertible Preferred Stock and 25,000 shares of Series V Class B Convertible Preferred Stock, Sovana Cayman Islands, Inc. holds 300,000 shares of Series IV Class B Convertible Preferred Stock, and My Investments Co. LLC holds 14,500 shares of Series IV Class B Convertible Preferred Stock. Mr. Saker is an Officer or Director and shareholder for each of these companies. The remaining 90,500 shares identified as Common Stock are shares currently obtainable through

the exercise of options held by Mr. Saker.

- (4) 62,500 of these shares identified as Common Stock are shares acquirable by the exercise of stock options.

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(5) 102,000 of these shares identified as Common Stock are shares acquirable by the exercise of stock options and the remainder vest in July 2010.

(6) 100,700 of these shares identified as Common Stock are shares acquirable by the exercise of stock options and options for the purchase of 23,500 shares vest in July 2010.

(7) 63,450 of these shares identified as Common Stock are shares acquirable by the exercise of stock options and options for the purchase of 25,000 vest in July 2010.

(8) 97,050 of these shares identified as Common Stock are shares acquirable by the exercise of stock options and options for the purchase of 152,950 shares vest in July 2010.

(9) 50,000 of these shares identified as Common Stock are shares acquirable by the exercise of stock options.

(10) These shares identified as Common Stock are shares acquirable by the exercise of stock options.

There are no arrangements, the operation of which would result in a change in control of the Company, other than:

1. Ms. August's shares shall cease to be controlled by Mr. Shaw under their Voting Agreement upon their sale to a third party; and

2. Mr. Shaw was granted an option for the purchase of 3,000,000 shares of Common Stock. Mr. Shaw is able to control 54.2% of the currently outstanding shares of the Common Stock and would control 44.6% of the Common Stock assuming the exercise of all outstanding options and conversion of all outstanding preferred shares and convertible loans.

**Item 13. Certain Relationships and Related Transactions, and Director Independence**



Related Party Transactions

We believe that all of the transactions set forth below were made on terms no less favorable to us than could have been obtained from unaffiliated third parties. In accordance with our Audit Committee Charter, the Audit Committee has reviewed and approved all related party transactions. In particular, the Audit Committee reviews all proposed transactions where the amount involved meets or exceeds \$120,000.

Thomas J. Shaw, our President and Chief Executive Officer, beneficially owned 36.5% of the outstanding Common Stock (and controlled another 11.8% pursuant to a Voting Agreement with Ms. Suzanne August) as of March 1, 2010. In 1995, Mr. Shaw was paid a licensing fee of \$500,000 (amortized over 17 years) by us for the exclusive worldwide licensing rights to manufacture, market, sell, and distribute retractable medical safety products. A royalty of 5% of gross sales of all licensed products sold to customers over the life of the Technology Licensing Agreement is paid. Of this royalty, Ms. Suzanne August, the former spouse of Mr. Shaw, is entitled to \$100,000 per quarter. Mr. Shaw receives the remainder of this royalty. A royalty of \$1,183,883 and \$1,766,585 was paid to Thomas J. Shaw in 2009 and 2008, respectively. Ms. August received \$400,000 in 2009 and 2008. Royalties of \$843,327 were paid to Mr. Shaw and Ms. August from January 1, 2010 through March 1, 2010. In the third quarter of 2009, the Company announced several cost cutting initiatives to conserve its cash. As part of those initiatives, Mr. Shaw waived \$1,000,000 in royalty payments, most of which affect cash outlays in 2009.

Director Independence

The Board of Directors has the responsibility for establishing corporate policies and for our overall performance, although it is not involved in day-to-day operations. Currently, a majority (four of seven) of the Directors serving on our Board of Directors are independent Directors as defined in Section 121(A) of the listing standards of the NYSE Amex. Our current independent Directors are Messrs. Clarence Zierhut, Marwan Saker, and Marco Laterza, and Ms. Amy Mack. Each of our committees is constituted solely by independent Directors.

The Board of Directors, in reviewing the independence of its members, further considered the fact that we paid Ms. Mack's company \$9,940 in 2009 and \$20,875 in 2008 for conducting clinical trials. The Board of Directors determined that her independence was not compromised by such transactions.

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**Item 14. Principal Accounting Fees and Services.**

AUDIT FEES

The aggregate fees billed by CF & Co., L.L.P. for professional services rendered for the audit of our annual financial statements for 2009 and 2008 and the reviews of the financial statements included in our Forms 10-Q or services normally provided by the accountant in connection with statutory and regulatory filings for those fiscal years were \$257,085 and \$195,700, respectively.

AUDIT RELATED FEES

The aggregate fees billed by CF & Co., L.L.P. for professional services rendered for the audit of our 401(k) plan for 2009 and 2008 were \$11,500 and \$11,500, respectively.

TAX FEES

The aggregate fees billed by CF & Co., L.L.P. for preparation of federal and state income tax returns and tax consulting costs related to notices from taxing authorities for 2009 and 2008 were \$64,929 and \$91,520, respectively.

PRE-APPROVAL POLICIES AND PROCEDURES

The engagement of CF & Co., L.L.P. was entered into pursuant to the approval policies and procedures of the Audit Committee. Before CF & Co., L.L.P. was engaged to render services the engagement was approved by the Audit Committee. The engagement is for audit and tax services which were detailed separately. The Audit Committee implemented its approval procedures, i.e., they were not delegated to any other party. All of the services provided were pre-approved by the Audit Committee.

**PART IV**





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

- (a) (1) All financial statements: See Retractable Technologies, Inc. Index to Financial Statements on Page F-2.
- (2) Those financial statement schedules required to be filed by Item 8 of this form, and by paragraph (b) below. Schedule II-Schedule of Valuation and Qualifying Accounts for the years ended December 31, 2009, 2008, and 2007:

	<b>Balance at beginning of period</b>		<b>Additions</b>		<b>Deductions</b>		<b>Balance at end of period</b>
Provision for Inventories							
Fiscal year ended 2007	\$ 50,000	\$	155,600	\$		\$	205,600
Fiscal year ended 2008	\$ 205,600	\$		\$		\$	205,600
Fiscal year ended 2009	\$ 205,600	\$		\$		\$	205,600
Provision for Accounts Receivables							
Fiscal year ended 2007	\$ 87,030	\$	166,978	\$		\$	254,008
Fiscal year ended 2008	\$ 254,008	\$	245,958	\$		\$	499,966
Fiscal year ended 2009	\$ 499,966	\$	182,000	\$		\$	681,966
Deferred Tax Valuation							
Fiscal year ended 2007	\$ 640,423	\$	3,026,509	\$		\$	3,666,932
Fiscal year ended 2008	\$ 3,666,932	\$	2,366,454	\$		\$	6,033,386

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	<b>Balance at beginning of period</b>		<b>Additions</b>		<b>Deductions</b>		<b>Balance at end of period</b>
Fiscal year ended 2009	\$ 6,033,386	\$	613,818	\$		\$	6,647,204
Provision for Rebates			<b>(A)</b>		<b>(B)</b>		
Fiscal year ended 2007	\$ 2,712,750	\$	15,329,840	\$	13,404,097	\$	4,638,493
Fiscal year ended 2008	\$ 4,638,493	\$	13,625,257	\$	14,395,904	\$	3,867,846
Fiscal year ended 2009	\$ 3,867,846	\$	16,554,163	\$	14,365,035	\$	6,056,974

(A) Represents estimated rebates deducted from gross revenues

(B) Represents rebates credited to the distributor

(3) Exhibits:

The following exhibits are filed herewith or incorporated herein by reference to exhibits previously filed with the SEC.

(b) Exhibits

<b>Exhibit No.</b>	<b>Description of Document</b>
3(i)	Third Amended and Restated Articles of Incorporation of RTI filed on November 1, 2004* as amended by that Statement of Change of Registered Office/Agent** and by that certain Articles of Amendment Pursuant to Article 4.04 of the Texas Business Corporation Act filed on October 16, 2009 o. See Exhibit no. 4.
3(ii)	Third Amended and Restated Bylaws of RTI***
4	Third Amended and Restated Articles of Incorporation of RTI filed on November 1, 2004* as amended by that Statement of Change of Registered Office/Agent** and by that certain Articles of Amendment Pursuant to Article 4.04 of the Texas Business Corporation Act filed on October 16, 2009 o. See Exhibit no. 3(i).
10.1	Sample United States Distribution Agreement****
10.2	Sample Foreign Distribution Agreement****
10.3	Employment Agreement between RTI and Thomas J. Shaw dated as of January 1, 2008 (This is a management compensation contract.) ***
10.4	Technology License Agreement between Thomas J. Shaw and RTI dated the 23rd day of June 1995*****

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- 10.5 First Amendment to Technology License Agreement between Thomas J. Shaw and RTI dated the 3rd day of July, 2008
- 10.6 Loan Agreement among RTI, Katie Petroleum and Thomas J. Shaw as of the 30th day of September, 2002 and Promissory Note
- 10.7 RTI s 1999 Stock Option Plan\*\*\*\*
- 10.8 First Amendment to 1999 Stock Option Plan
- 10.9 Retractable Technologies, Inc. 2008 Stock Option Plan

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<b>Exhibit No.</b>	<b>Description of Document</b>
10.10	Thomas J. Shaw Nonqualified Stock Option Agreement Issued Outside of Any Plan oo
10.11	Voting Agreement Between Thomas J. Shaw and Suzanne August dated November 8, 2006 ooo
14	Retractable Technologies, Inc. Code of Business Conduct and Ethics oooo
23	Consent of Independent Registered Public Accounting Firm oo
31.1	Certification of Principal Executive Officer oo
31.2	Certification of Principal Financial Officer oo
32	Section 1350 Certifications oo
99.1	Retractable Technologies, Inc. Audit Committee Charter oo
99.2	Retractable Technologies, Inc. Compensation and Benefits Committee Charter oo
99.3	Retractable Technologies, Inc. Nominating Committee Charter oo
<hr style="width: 25%; margin-left: 0;"/>	
*	Incorporated herein by reference to RTI s Form 10-Q filed on November 14, 2005
**	Incorporated herein by reference to RTI s Form 10-K filed on March 31, 2008
***	Incorporated herein by reference to RTI s Form 10-Q filed on November 14, 2008
****	Incorporated herein by reference to RTI s Registration Statement on Form 10-SB filed on June 23, 2000
	Incorporated herein by reference to RTI s Form 10-K filed on March 31, 2009
	Incorporated herein by reference to RTI s Form 8-K filed on October 10, 2002
	Incorporated herein by reference to RTI s Form 10-KSB filed on March 31, 2003
	Incorporated herein by reference to RTI s definitive Schedule 14A filed on August 19, 2008
o	Incorporated herein by reference to RTI s Form 10-Q filed on November 16, 2009
oo	Filed herewith
ooo	Incorporated herein by reference to RTI s Schedule TO filed on October 17, 2008
oooo	Incorporated herein by reference to RTI s Form 8-K filed on February 19, 2010
(c)	Excluded Financial Statement Schedules: None



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**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

RETRACTABLE TECHNOLOGIES, INC.  
(Registrant)

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

Date: March 31, 2010

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

/s/ Steven R. Wisner  
Steven R. Wisner  
Executive Vice President, Engineering &  
Production and Director

March 31, 2010

/s/ Douglas W. Cowan  
Douglas W. Cowan  
Vice President, Chief Financial Officer, Treasurer,  
and Director

March 31, 2010

/s/ Clarence Zierhut  
Clarence Zierhut  
Director

March 31, 2010

/s/ Amy Mack  
Amy Mack  
Director

March 31, 2010

/s/ Marco Laterza

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Marco Laterza  
Director

March 31, 2010

/s/ Marwan Saker  
Marwan Saker  
Director

March 31, 2010