

RETRACTABLE TECHNOLOGIES INC
Form 10-K
March 31, 2009
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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, 2008

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)

Texas

75-2599762

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(State or other jurisdiction of incorporation or organization)

(I.R.S. Employer Identification No.)

511 Lobo Lane

Little Elm, Texas 75068-0009

(Address of principal executive offices)

(972) 294-1010

Registrant's telephone number, including area code

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

Title of each class
Common

Name of each exchange on which registered
NYSE Alternext, US, 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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, 2008 was \$15,047,254.72, assuming a price of \$1.48 and volume of 10,167,064.

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 equity, as of the latest practicable date. As of March 2, 2009, there were 23,800,064 shares of our Common Stock issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

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

None except exhibits.

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RETRACTABLE TECHNOLOGIES, INC.

FORM 10-K

For the Fiscal Year Ended December 31, 2008

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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 and the viability of our patents), our ability to maintain favorable supplier arrangements and relationships, our receipt of royalties from Baiyin Tonsun Medical Device Co., Ltd. (BTMD), the impact of dramatic increases in demand, our ability to quickly increase capacity, 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 Description

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 needle products (consisting of 1cc tuberculin, insulin, and allergy antigen VanishPoint® syringes; 0.5cc, 3cc, 5cc, and 10cc 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 syringe 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 reduces the risk of infection resulting from IV line contamination.

Advantages of our VanishPoint® safety needle 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 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 five percent 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.

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See Patents, Trademarks, Licenses, and Proprietary Rights for a more detailed discussion. We and Thomas J. 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 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 is for patent infringement, antitrust practices, and false advertising.

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 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 reduces the risk of infection resulting from IV line contamination.

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 1cc tuberculin; insulin; allergy antigen VanishPoint® syringes; 0.5cc, 3cc, 5cc, and 10cc VanishPoint® syringes; the VanishPoint® blood collection tube holder; the VanishPoint® IV safety catheter; and a small diameter tube adapter. We are also selling autodisable syringes in the international market. We also received a Notice of Substantial Equivalence for our Patient Safe syringe, which reduces the risk of infection resulting from IV line contamination.

We began marketing the Patient Safe syringe in 2008.

In the September 2003 issue of *Health Devices*, ECRI listed three syringes with the highest possible rating: our VanishPoint® syringe, New Medical Technology's (NMT) safety syringe, and BD's Integra syringe. 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.

Syringe sales comprised 98.8%, 98.0%, and 98.6% of revenues in 2006, 2007, and 2008.

Principal Markets

Our products are sold to and used by healthcare providers primarily in the United States (with 16.7% of revenues in 2008 generated from sales outside the United States) 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.

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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 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 manufacturers often enter into long-term exclusive contracts which can prohibit 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 calls on target markets that are users of these products. 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.

We have numerous agreements with organizations for the distribution of our products in foreign markets. Sales to these markets decreased from 18.4% to 16.7% of revenues due to lower volumes and lower average prices in 2007 and 2008, respectively. The total population of Western Europe exceeds 310 million, and the recognition for the urgency of safe needle devices in parts of Europe has followed the United States model. In France, England, Germany, and Italy, organized healthcare worker unions have taken action to force hospitals and government agencies to place safety as a priority. 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 is uncertain.

As a result of the introduction of VanishPoint® syringes through the PEPFAR initiative, African countries have begun to procure products outside of the US-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 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

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United States 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. We are producing catheters with a wide range of needle sizes and have an increased number of sizes available for the Patient Safe syringe.

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. Some suppliers increased their prices generally due to the higher costs of petroleum products in 2008.

Patents, Trademarks, Licenses, and Proprietary Rights

We and Thomas J. 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 Thomas J. 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 five percent 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 by Mr. Shaw and his former wife.

We have the right and obligation to obtain protection of the invention, 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 selective 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

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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 Patient Safe syringe and Port Prep.

We have a patent infringement claim pending against BD involving four patents, a case involving two patents against Occupational and Medical Innovations Limited (OMI), and a case involving two patents against Safety Medical International (SMI). There are also two patent infringement claims pending against us. These claims are 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.

We currently obtain roughly 74.0% 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 0.5cc, autodisable, 5cc and 10cc syringes which comprised about 4.6% of our 2008 revenues.

We had a Licensing Agreement with BTMD which expired on May 13, 2008. Royalties that were expected in 2008 and 2007 were not received due to the time needed to build the factory, assembly equipment, and the related infrastructure as well as the need of BTMD to meet the requisite Chinese government requirements. The facility has been completed and BTMD is in the process of meeting Chinese government requirements. We still continue to expect royalty payments although we are unable to predict the date we will begin to receive such royalties. Royalties should begin once we have an effective agreement, Chinese government requirements are met, and BTMD is able to produce and sell products.

Seasonal Effect on Business

We have generally experienced higher syringe sales during the last half of the year which we believe is due to flu season.

Working Capital Practices

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

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

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Inventories are valued at the lower of cost or market, with cost being determined using a standard cost method, which approximates 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 carry backs.

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 2008 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

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customer may return incorrect shipments within 10 days following arrival at the distributor's facility. In all such cases the distributor must obtain an authorization code from us and affix the code to the returned product. We will not accept returned goods without a returned goods authorization number. We may refund the customer's money or replace the product.

Our 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 one percent 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 overstocked product must be returned to us in our saleable case cartons which are unopened and untampered, with no broken or re-taped seals; v) 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 products less a 10% restocking fee which will be assessed against distributor's subsequent purchase of product; vi) distributor must obtain an authorization code from our distribution department and affix the code to the returned product; and vii) 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

One distributor, McKesson and its affiliates, accounted for an aggregate of 16.8% of our revenue in 2008. We have numerous other distributors that sell our products in the U.S. and internationally.

Backlog Orders

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

Government Funding of Research and Right to License

Thomas J. Shaw developed his initial version of a safety syringe with the aid of grants by the National Institute of Drug Abuse, a subsidiary of the National Institutes of Health. As a result, the federal government has the right, where the public interest justifies it, to disperse the technology to multiple manufacturers so that this early version of a safety syringe could be made widely available to the public. However, the earlier design of 1991 was a bulkier, less effective, and more expensive version of the current VanishPoint® 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®.

Competitive Conditions

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.

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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 product sales accounted for approximately 22% of BD's total 2008 sales. BD currently manufactures the SafetyLok, a syringe that utilizes a tubular plastic sheath that must be manually slid over the needle after an injection, and the SafetyGlide, a needle which utilizes a hinged lever to cover the needle tip. BD also manufactures a safety blood collection and hypodermic needle that utilizes the Eclipse needle cover. BD also manufactures a 3cc and 1cc retracting needle product based on a license agreement with Specialized Health Products International, Inc. (formerly the Med-Design Corporation). The Integra, a retractable syringe offered by BD, does not offer a full product line and cannot be used with highly viscous medication due to leakage (as described on their labels). The introduction of this syringe has had little impact on our sales due to BD's historic market dominance. BD's Vacutainer® blood collection products are commonly used as industry jargon to refer to blood collection products in general.

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

Founded in 1974, 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 both hands to remain safely out of harm's way. BD's Integra operates in a similar way but may have to be removed from the patient in order to have retraction of the needle occur.

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.

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Our products have consistently received high quality ratings. In the September 2003 issue of *Health Devices*, ECRI Institute (ECRI) listed three syringes with the highest possible rating: our VanishPoint® syringe, NMT s safety syringe, and BD s Integra syringe. 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.

In the October 1999 issue of *Health Devices*, our VanishPoint® blood collection tube holder was one of the two blood collection devices that was given ECRI s highest possible award. The other was the Bio-Plexus Punctur-Guard (when used with a disposable holder). ECRI listed the same two products for their highest rating in 2000 and in 2001.

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Our safety needle products also 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. 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. Licensing agreements could provide entry into new markets and generate additional revenue.

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.

Research and Development

We spent \$958,798; \$1,071,143; and \$1,066,068 in fiscal 2006, 2007, and 2008 respectively, on research and development. Costs in 2008 were primarily for validation testing and development work for the safety catheter as well as higher compensation costs. 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 sold for recycling. We also grind dirty plastics, syringes, and needles for disposal by Waste Management. All other nonhazardous waste produced is considered municipal solid waste and sent to a sanitary landfill by Waste Management.

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

Employees

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As of March 2, 2009, we had 144 full-time employees, six part-time employees, and four independently contracted consultants. Of the 144 full-time employees, six persons were engaged in research and development activities, 57 persons were engaged in manufacturing and engineering, 16 persons were engaged in quality assurance and regulatory affairs, 36 persons were engaged in sales and marketing, 28 persons were engaged in general and administrative functions, and one person 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.

Table of ContentsFinancial 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.

| | 2008 | | 2007 | | 2006 |
|---------------------|---------------|----|-------------|----|-------------|
| Domestic sales | \$ 23,244,370 | \$ | 21,461,717 | \$ | 22,240,347 |
| International sales | 4,654,948 | | 4,828,003 | | 3,084,172 |
| Total sales | \$ 27,899,318 | \$ | 26,289,720 | \$ | 25,324,519 |
| Long-lived assets | | | | | |
| Domestic | \$ 14,435,667 | \$ | 11,483,423 | \$ | 12,212,140 |
| Foreign | \$ | \$ | \$ | \$ | \$ |

We have no sales in any foreign country that exceeds 3% of revenue.

Available Information

Our internet address is www.vanishpoint.com. We make our filings with the U.S. Securities and Exchange Commission (the SEC) available via our website. Upon request, we will be pleased to deliver written copies of our filings free of charge.

Item 1A. Risk Factors.

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 the major syringe manufacturer in the U.S., BD. We believe that its monopolistic business practices continue despite its paying us \$100 million to settle a prior lawsuit for anticompetitive practices, business disparagement, and tortious interference. 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 use of safe needle devices. In June 2007, we sued BD alleging infringement of three patents and violations by BD of the federal and state antitrust laws, and of the Lanham Act. We subsequently dropped one patent claim from the lawsuit. In April 2008, we sued BD for infringement of a newly issued patent that was

subsequently consolidated with the other patent case.

Our Cash Position Is Decreasing and Legal Expenses Are Increasing

Due to our operating losses and currently increasing legal fees, our cash position declined \$7.2 million as of December 31, 2008. Our litigation efforts will continue to require a significant amount of cash until the issues are resolved. Our lawsuit against BD is currently scheduled for trial in October 2009. After conclusion of the trial, legal expenses are expected to decrease significantly for the patent infringement cases.

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 cost cutting measures to reduce cash requirements. Such measures could

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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 incurred net operating losses through all fiscal quarters of 2008. 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

We are currently involved in multiple patent disputes. 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. BD also offers a retractable syringe. 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.

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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 0.5cc insulin syringe and the 5cc and 10cc syringes and increase domestic production for the 1cc and 3cc syringes to avoid a disruption in supply. As of December 31, 2008, approximately 74.0% of our production was provided by Double Dove.

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 26.0%) 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 35.7% and 11.8%, respectively, of the outstanding Common Stock as of March 2, 2009. 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 23,800,064 shares of Common Stock outstanding as of March 2, 2009, executive officers and Directors own or control 11,337,000 (47.6%) 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 Alternext US, LLC (NYSE Alternext) (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 Sometimes Decreases Below NYSE Alternext Continued Listing Standards

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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 Alternext 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 Alternext. The NYSE Alternext 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 Alternext, 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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Oil Prices and Transportation Costs May Increase Our Costs

As our products are made from petroleum products, fluctuations in the costs of oil and transportation may have an impact on our costs. Increases in costs may not be recoverable through price increases of our products.

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 \$245,958 for 2008 which brings the balance to \$499,966.

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 products liability coverage with St. Paul Insurance Company covering up to \$1,000,000 per occurrence, with coverage up to \$2,000,000 in the aggregate. Each claim is subject to a \$25,000 deductible. Additionally, we have additional product liability protection under an Umbrella Liability Policy. This policy provides an additional \$10,000,000 per occurrence and aggregate limits in the event claims exceed the primary commercial general liability policy limit. 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

Item 1A. Risk Factors.

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produced approximately 26.0% of the units that were sold in 2008. 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 0.5cc, 5cc, and 10cc syringes which are sold principally in the international market. In that event, we would attempt to engage another manufacturer. We are currently utilizing less than 25% of our current 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 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 one percent, 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.

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On August 29, 2008, we obtained a \$4,210,000 straight line of credit from Lewisville State Bank, a division of 1st International Bank. The purpose of the line of credit was to expand the warehouse, including additional office space, and construct a new Controlled Environment. The maturity date is February 28, 2010. The interest rate is WSJPR plus 0.25%. We may prepay the line of credit without penalty. The construction project has been substantially completed. We expect to replace our note with permanent financing in the second quarter.

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

Item 3. Legal Proceedings.

On August 12, 2005, we filed a lawsuit against Abbott Laboratories (Abbott) in the United States 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 attorney s 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. Some discovery has already taken place (related to the hearings addressing the prior motion to compel arbitration) and additional discovery is underway. The District Court has issued a scheduling order calling for trial in January 2010.

In August 2006, we were sued by OMI in Federal Court of Australia, alleging that two letters written to OMI by outside counsel contained unjustified threats of patent infringement, but seeking no damages. OMI later amended its complaint to seek a declaratory judgment that OMI does not infringe Australian Patent No. 701878, again seeking no damages. Following a one-day trial in June 2007, the Court held that one of the two letters written by outside counsel contained a threat of patent infringement, and awarded costs to OMI. Following a one-day trial in June 2008, the Court issued a declaratory judgment in August 2008 stating that OMI s syringe does not infringe our Australian patent no. 701878 but also awarding costs to us. We and OMI subsequently agreed that each party will bear its own costs, and the matter was settled in October 2008.

In April 2008, we sued OMI in the United States District Court for the Eastern District of Texas, Tyler Division, alleging that OMI has infringed two U.S. patents that are not at issue in the Australian litigation (6,572,584 and 7,351,224). We also allege theft of confidential information, intentional interference with contracts and engaging in false advertising that wrongfully disparages and mischaracterizes our syringe products. We further allege that OMI made false allegations regarding the source of origin of its safety syringe products being offered in the U.S. We seek injunctive relief, unspecified damages (including treble damages) and reimbursement of attorneys fees in the suit. OMI has counterclaimed against us, seeking declaratory judgments of non-infringement and invalidity of our asserted patents. OMI is not seeking monetary damages. Trial is set for December 2009 and discovery is ongoing.

In June 2007, we sued BD in the United States 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. We and Thomas J. Shaw, a co-plaintiff, are seeking injunctive relief, unspecified monetary damages and reimbursement of attorneys fees in the suit. BD counterclaimed for non-infringement and invalidity of the asserted patents. In January 2008, the Court severed the patent claims from the other claims pending resolution of the patent dispute, which is set for trial in October 2009. In April 2008, we and Thomas J. Shaw sued BD in the United States District Court

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for the Eastern District of Texas, Marshall Division, alleging infringement of another recently issued patent (7,351,224), and seeking injunctive relief, unspecified monetary damages (including treble damages) and reimbursement of attorneys fees. BD counterclaimed for non-infringement and invalidity of the asserted patent. We and Thomas J. Shaw moved to consolidate this case with the other patent case against BD that was pending in Marshall and the Court granted our motion, consolidating this case with our above-stated case filed in June 2007. The Court issued its claim construction order in this matter on January 4, 2009.

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 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. 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 March 2008, MedSafe Technologies LLC (MedSafe) initially sued us and BD in the United States District Court for the District of South Carolina, Greenville Division, alleging infringement of a MedSafe patent (6,074,370) and seeking injunctive relief and unspecified monetary damages. We counterclaimed for declarations of non-infringement, invalidity, and unenforceability of the asserted patent. BD subsequently settled with MedSafe. Effective December 22, 2008, we resolved our litigation with MedSafe by entering into a PATENT LICENSE/ASSIGNMENT AND SETTLEMENT AGREEMENT with MedSafe and Syringe Development Partners, LLC; William B.S. Pressly, Sr.; Charles A Vaughn, Sr.; G. Samuel Brockway; and Thomas R. Ellis (collectively, the MedSafe Plaintiffs) (the MedSafe Settlement Agreement). This MedSafe Settlement Agreement ends the patent infringement litigation between us and MedSafe.

In September 2008, we and Thomas J. Shaw sued 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 against us, seeking declaratory judgments of non-infringement and invalidity of the asserted patents. SMI is not seeking monetary damages. No trial date has been set and discovery has not yet commenced.

Item 4. Submission of Matters to a Vote of Security Holders.

No matters were submitted to a vote during the fourth quarter of 2008.

PART II

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

MARKET INFORMATION

Item 1A. Risk Factors.

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Our Common Stock has been listed on the NYSE Alternext under the symbol RVP since May 4, 2001. Shown below are the high and low sales prices of our Common Stock as reported by the NYSE Alternext for each quarter of the last two fiscal years:

| 2008 | High | Low |
|----------------|-------------|------------|
| Fourth Quarter | \$1.46 | \$0.45 |
| Third Quarter | \$1.60 | \$1.20 |
| Second Quarter | \$1.68 | \$1.22 |
| First Quarter | \$2.00 | \$1.30 |

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| 2007 | High | Low |
|----------------|-------------|------------|
| Fourth Quarter | \$2.12 | \$1.40 |
| Third Quarter | \$2.60 | \$1.72 |
| Second Quarter | \$3.06 | \$2.25 |
| First Quarter | \$3.48 | \$2.70 |

SHAREHOLDERS

As of March 2, 2009, there were 23,800,064 shares of Common Stock held by 261 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, 2008, an aggregate of \$13,883,000 in preferred dividends were 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.

RECENT SALES OF UNREGISTERED SECURITIES

In the first quarter of 2008, three accredited investors converted 44,650 shares of Preferred Stock into Common Stock on a one for one basis for no additional consideration, as reported in our Form 10-Q quarterly report filed with the SEC which is available on EDGAR. There were no sales of unregistered securities in the second, third, or fourth quarters of 2008.

PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

The following table shows purchases of equity securities by the issuer in 2008. No purchases were made by affiliated purchasers in 2008.

| Period | Total number of shares (or units purchased) | Average price paid per share (or unit) | Total number of shares (or units) purchased as part of publicly announced plans or programs | Maximum number (or approximate dollar value) of shares (or units) that may yet be purchased under the plans or programs |
|-------------------|---|---|--|--|
| November 18, 2008 | Options to purchase an aggregate of 1,925,365 shares ⁽¹⁾ | N/A | Options to purchase an aggregate of 1,925,365 shares | 0 |

(1) We offered, pursuant to Section 3(a)(9) of the Securities Act of 1933 to exchange certain outstanding eligible options for new options. Such new options were granted under our 2008 Stock Option Plan. The offer was made on the terms and subject to the conditions described in the Offer to Exchange Stock Options dated October 17, 2008 (the Exchange Offer). The Exchange Offer expired at 5:00 p.m., Central Standard Time, on November 18, 2008. Eligible participants (totaling 103 persons) tendered, and

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we accepted for cancellation, eligible options to purchase an aggregate of 1,925,365 shares of our Common Stock representing 99.4% of the total shares of Common Stock underlying options eligible to exchange in the Exchange Offer. We issued new options to purchase an aggregate of 962,683 shares of Common Stock in exchange for the cancellation of the tendered options.

Item 6. Selected Financial Data.

The following selected financial data are 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, 2005 and 2004 and the Balance Sheet data as of December 31, 2006, 2005, and 2004 have been derived from our audited financial statements, which are not included herein.

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

| | As of and for the Years Ended December 31, | | | | | | | | |
|---|---|----|-------------|----|-------------|----|-------------|----|-------------|
| | 2008 | | 2007 | | 2006 | | 2005 | | 2004 |
| Sales, net | \$ 27,899 | \$ | 26,290 | \$ | 20,897 | \$ | 21,157 | \$ | 21,136 |
| Reimbursed discounts | | | | | 4,427 | | 3,078 | | 386 |
| Total sales | 27,899 | | 26,290 | | 25,324 | | 24,235 | | 21,522 |
| Cost of sales | 19,673 | | 18,300 | | 17,778 | | 15,429 | | 16,411 |
| Gross profit | 8,226 | | 7,990 | | 7,546 | | 8,806 | | 5,111 |
| Total operating expenses | 18,671 | | 17,936 | | 14,261 | | 11,683 | | 13,110 |
| Loss from operations | (10,445) | | (9,946) | | (6,715) | | (2,877) | | (7,999) |
| Interest income | 855 | | 1,870 | | 1,976 | | 1,373 | | 475 |
| Interest expense, net | (54) | | (326) | | (411) | | (340) | | (243) |
| Litigation settlements, net | | | | | | | | | 74,635 |
| Net income (loss) before income taxes | (9,644) | | (8,402) | | (5,150) | | (1,844) | | 66,868 |
| Provision (benefit) for income taxes | | | (1,454) | | (1,280) | | (606) | | 12,177 |
| Net income (loss) | (9,644) | | (6,948) | | (3,870) | | (1,238) | | 54,691 |
| Preferred Stock dividend requirements | (1,373) | | (1,399) | | (1,451) | | (1,503) | | (1,993) |
| Earnings (loss) applicable to common shareholders | \$ (11,017) | \$ | (8,347) | \$ | (5,321) | \$ | (2,741) | \$ | 52,698 |
| Earnings (loss) per share basic | \$ (0.46) | \$ | (0.35) | \$ | (0.23) | \$ | (0.12) | \$ | 2.33 |
| Earnings (loss) per share diluted | \$ (0.46) | \$ | (0.35) | \$ | (0.23) | \$ | (0.12) | \$ | 2.08 |
| Weighted average shares outstanding | 23,794,566 | | 23,727,029 | | 23,591,999 | | 23,332,277 | | 22,600,166 |

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| | As of and for the Years Ended December 31, | | | | |
|---|--|-----------|-----------|-----------|-----------|
| | 2008 | 2007 | 2006 | 2005 | 2004 |
| Current assets | \$ 43,614 | \$ 51,916 | \$ 57,781 | \$ 61,485 | \$ 64,674 |
| Current liabilities | \$ 10,238 | \$ 8,786 | \$ 6,891 | \$ 5,458 | \$ 7,852 |
| Property, plant, and equipment, net | \$ 14,436 | \$ 11,483 | \$ 12,212 | \$ 11,926 | \$ 11,057 |
| Total assets | \$ 58,539 | \$ 64,330 | \$ 70,795 | \$ 73,756 | \$ 76,123 |
| Long-term debt, net of current maturities | \$ 6,096 | \$ 3,747 | \$ 4,137 | \$ 4,351 | \$ 3,535 |
| Stockholders' equity | \$ 42,206 | \$ 51,761 | \$ 59,710 | \$ 63,235 | \$ 63,665 |
| Redeemable Preferred Stock (in shares) | 2,285,266 | 2,329,916 | 2,441,166 | 2,498,666 | 2,572,116 |
| Cash dividends per common share | \$ | \$ | \$ | \$ | \$ |
| Gross profit margin | 29.5% | 30.4% | 29.8% | 36.3% | 23.7% |

* Events that could positively affect the trends indicated above include receipt of royalties from BTMD, continued reductions in manufactured costs, continued increasing average sales prices, and the gaining of market access. Future interest income trends may negatively affect the trends indicated above due to possibly continuing low interest rates, lower cash balances, as will our investment of our cash in U.S. Treasury bills and other U.S. government backed securities. Furthermore, 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.

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 and the viability of our patents), our ability to maintain favorable supplier arrangements and relationships, receive royalties from BTMD, the impact of dramatic increases in demand, our ability to quickly increase capacity, 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, the Patient Safe syringe, which reduces the risk of infection resulting from IV line contamination, entered the market in 2008. Safety syringes comprised 98.6% of our sales in 2008.

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, who dominates the market. We believe that its monopolistic business practices continue despite its paying \$100 million in 2004 to settle a prior lawsuit with us for anticompetitive practices, business disparagement, and tortious interference. 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, the federal and state legislation requiring the use of safe needle devices, and various Senate Subcommittee hearings on Group Purchasing Organizations.

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

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product internationally. 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 is uncertain.

As a result of the introduction of VanishPoint® syringes through the PEPFAR initiative, African countries have begun to procure products outside of the US-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.

Additionally, an Australian distributor was awarded a one-year contract in March 2007 to supply our VanishPoint® automated retraction syringes to all of Queensland Health's 202 acute care facilities. Queensland Health is a department within the government of Queensland, Australia. The contract was renewed for an additional two years. VanishPoint® products are distributed in Australia by Brisbane-based Scientific Educational Supplies Pty Ltd. 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 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 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 manufactured cost. Double Dove manufactured, in 2008, approximately 74.0% of the units we produced. These purchases have improved profit margins in spite of limited revenues. The cost of production per unit has generally declined as volumes increased. Double Dove increased the prices in the fourth quarter of 2008 to us by \$0.005 per unit. Product cost reductions could be adversely affected by increased material and transportation costs. 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 0.5cc insulin syringe, the 5cc and 10cc syringes and the autodisable syringe which altogether comprised about 4.6% of our 2008 revenues.

We had a Licensing Agreement with BTMD which expired on May 13, 2008. As a result of the expiration of the contract, we recognized \$100,000 of prepaid royalty income in the second quarter of 2008 as other income. Royalties that were expected in 2008 and 2007 were not received due to the time needed to build the factory, assembly equipment, and the related infrastructure as well as the need of BTMD to meet the requisite Chinese government requirements. The facility has been completed and BTMD is in the process of meeting Chinese government requirements. We still continue to expect royalty payments although we are unable to predict the date we will begin to receive such royalties.

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We should begin earning royalties once we have an effective agreement, Chinese government requirements are met, and BTMD is able to produce and sell products.

Historically, unit sales have increased in the latter part of the year due, in part, to the demand for syringes during the flu season.

With increased volumes, our manufacturing unit costs have generally tended to decline. Factors that could affect our unit costs, in addition to Double Dove's recent increase in unit costs of \$0.005, include 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 have substantially completed the expansion of an existing warehouse. This expansion will increase our warehouse area, provide for additional office space, and add a second Controlled Environment.

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LIQUIDITY AND FUTURE CAPITAL REQUIREMENTS

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 private placements, loans, and litigation settlements. We were capitalized with approximately \$52,600,000 raised from six separate private placement offerings. We raised \$47,375,600 in cash from the private sales of an aggregate of 11,710,221 shares of Convertible Preferred Stock. In addition, we obtained a cancellation of \$3,679,284 in debt and \$1,550,000 in Accounts payable in exchange for Series V Class B Convertible Preferred Stock.

We obtained \$3,910,000 in 2000 from bank loans of which \$3,435,000 has been repaid and \$475,000 was refinanced with a new note for \$2,500,000 with Lewisville State Bank, a division of 1st International Bank. Additionally, we received a Small Business Administration loan of \$1,000,000 in 1996 to pay for portions of automated assembly equipment, multi-cavity molds, and other equipment. This loan has been repaid. Furthermore, we borrowed \$5,000,000 in 2000 under our Credit Agreement with Abbott. In October 2002 we repaid the Abbott note with proceeds from a new note from Katie Petroleum, Inc. for \$3,000,000 and a portion of the proceeds from a private placement. In 2008, we received a construction line of credit for up to \$4,210,000 to fund an expansion of our warehouse.

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 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.

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 26.0%) 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. Double Dove increased their prices to us by \$0.005 per unit in the fourth quarter of 2008. The number of units produced by the Company versus manufactured in China can have a significant effect on the carrying costs of inventory as well as Cost of sales. We will continue to evaluate the appropriate mix of products manufactured domestically and those manufactured in China to achieve economic benefits as well as to maintain our domestic manufacturing capability. Currently, approximately 26.0% 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.

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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.

Licensing Agreement

We had a Licensing Agreement with BTMD which expired on May 13, 2008. As a result of the expiration of the contract, we recognized \$100,000 of prepaid royalty income in the second quarter of 2008 as other income. Royalties that were expected in 2008 and 2007 were not received due to the time needed to build the factory, assembly equipment, and the related infrastructure as well as the need of BTMD to meet the requisite Chinese government requirements. The facility has been completed and BTMD is in the process of meeting Chinese government requirements. We still continue to expect royalty payments, although we are unable to predict the date we will begin to receive such royalties. We should begin earning royalties once we have an effective agreement, Chinese government requirements are met, and BTMD is able to produce and sell products.

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 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.

CAPITAL RESOURCES

In 2006, we invested \$500,000 in a limited liability company (LLC). We exercised our option and our funds were returned in 2008.

Material Commitments for Expenditures

We have substantially completed expansion of our warehouse (including additional warehouse space, additional office space, and a new Controlled Environment). We are funding this expansion with a construction line of credit from Lewisville State Bank, a division of 1st International Bank, for approximately \$4.2 million, secured by a second lien deed on the land and existing buildings. Draws under the construction line of credit, which have totaled approximately \$2.8 million at the end of the year, are expected to be replaced by permanent financing in the second quarter of 2009.

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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 2008, 2007 or 2006. Dollar amounts have been rounded for ease of reading.

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 1cc syringe increased 22.7% and 3cc 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.

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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 \$5.9 million for 2008 due principally to our losses. The effect of non-cash expenses and the change in working capital was a positive \$3.7 million. Investing activities utilized \$1.9 million in cash.

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*Comparison of Year Ended
December 31, 2007, and Year Ended December 31, 2006*

Revenues increased due principally to increased sales in the international market. Domestic sales were 81.6% of revenues with international sales comprising the remainder. Unit sales of the 1cc syringe increased 7.3% and 5cc unit sales increased 30.6%. Unit sales of all products increased 7.5%. The discount reimbursements ended in 2006. The discount reimbursement program expired after the settlement agreement under which it was established provided for a total of \$8.0 million in reimbursements. We had recognized \$8.0 million in cumulative discount reimbursements by the third quarter of 2006. Sales to three distributors accounted for 36.5% and 31.3% of our revenues in 2007 and 2006, respectively.

Cost of sales as a percentage of revenues decreased slightly due to higher volumes offset by the lower average selling price principally in the international sales. The increased volume of production resulted in a lower unit cost. Royalty expenses were flat.

As a result, gross profits increased and gross profit margins increased slightly from 29.8% in 2006 to 30.4% in 2007.

Operating expenses increased from the prior year primarily due to increases in General and administrative costs.

Sales and marketing expenses declined due primarily to decreased marketing and trade show expense. Increased compensation and consulting costs were mitigated by reductions in stock option expenses and travel and entertainment.

Research and development costs were somewhat higher. We had increases in engineering costs due principally to validation testing and the development work on the IV safety catheter and higher compensation costs.

General and administrative costs increased due principally to higher legal expenses. Compensation costs, outside accounting costs, and distribution fees also increased. Stock option expenses, shareholder expenses, consulting and training decreased. Legal costs concerning the litigation against BD comprise the largest amount of legal fees and have a significant effect on our expenses. Our lawsuit against BD is currently scheduled for trial in October 2009. After conclusion of the trial, legal expenses are expected to decrease significantly. The legal costs incurred in 2007 with regard to the Abbott litigation are lower than those in 2006. We expect such costs to continue until the litigation is resolved. We also have higher litigation expenses concerning OMI. We had decreases in taxes other than income taxes in 2007. We awarded merit increases to our employees in 2006. We donated product in an international humanitarian effort in 2006. There have been no stock options awarded since 2004; therefore, this expense continues to decline as the costs become fully amortized with virtually none recorded in 2007. We also increased our allowance for bad debt.

Preferred Stock dividend requirements declined due to conversion of Preferred Stock into Common Stock. The dividend arrearage at December 31, 2007, on all classes of Preferred Stock was approximately \$12,500,000.

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

Provision for income tax benefits consists primarily of the settlement in our favor of a state tax audit. We also have a valuation reserve for all deferred taxes, with the exception of deferred taxes on the beneficial conversion feature associated with our note payable to Katie Petroleum.

Cash flow from operations was negative for 2007 due principally to the loss for the year. The effect of non-cash expenses and the change in working capital were a positive \$2.7 million.

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OFF-BALANCE SHEET ARRANGEMENTS

None.

CONTRACTUAL OBLIGATIONS

Contractual Obligations and Commercial Commitments

The following chart summarizes our material obligations and commitments to make future payments under contracts for long-term debt as of December 31, 2008:

| 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 | \$6,642,854 | \$543,748 | \$3,129,735 | \$510,126 | \$2,459,245 |

The presentation of contractual obligations of long-term debt includes assumptions regarding our ability to replace a construction loan with permanent financing.

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

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.

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

Our 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 one percent 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.

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 Total sales.

Inventories

Inventories are valued at the lower of cost or market, with cost being determined using a standard cost method, which approximates 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. We do not expect the eventual liability for marketing fees, if any, to exceed the amount accrued.

Reimbursed Discounts

We received reimbursed discounts from one of the settlement agreements reached in our previous federal antitrust lawsuit, *Retractable Technologies, Inc. v. BD, et al.* Payments under the discount reimbursement program were recognized upon invoicing of amounts due under the agreement, provided collection was reasonably assured. Such amounts are presented in the Statements of Operations as a separate component of

revenues. All funds available under the discount reimbursement program were recognized by the third quarter of 2006.

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 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, 2008 AND 2007

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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, 2008 and 2007, 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, 2008. 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, 2008 and 2007, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2008 in conformity with accounting principles generally accepted in the United States of America. 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, 2008 included in Item 9A of the Company's December 31, 2008 Form 10-K and, accordingly, we do not express an opinion thereon.

Dallas, Texas
March 31, 2009

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

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

| | December 31, | |
|---|---------------------|---------------|
| | 2008 | 2007 |
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 33,283,740 | \$ 40,507,431 |
| Accounts receivable, net of allowance for doubtful accounts of \$499,966 and \$254,008, respectively | 3,288,942 | 1,667,636 |
| Inventories, net | 6,641,532 | 7,037,129 |
| Income taxes receivable | | 2,345,041 |
| Other current assets | 400,113 | 358,807 |
| Total current assets | 43,614,327 | 51,916,044 |
| Property, plant, and equipment, net | 14,435,667 | 11,483,423 |
| Intangible assets, net | 470,115 | 424,560 |
| Other assets | 18,750 | 505,899 |
| Total assets | \$ 58,538,859 | \$ 64,329,926 |
| LIABILITIES AND STOCKHOLDERS EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 6,144,435 | \$ 5,535,365 |
| Current portion of long-term debt | 451,865 | 387,906 |
| Accrued compensation | 650,704 | 539,330 |
| Marketing fees payable | 1,419,760 | 1,419,760 |
| Accrued royalties to shareholders | 620,987 | 619,304 |
| Other accrued liabilities | 949,770 | 263,339 |
| Current deferred tax liability | | 20,626 |
| Total current liabilities | 10,237,521 | 8,785,630 |
| Long-term debt, net of current maturities | 6,095,535 | 3,747,259 |
| Long-term deferred tax liability | | 36,200 |
| Total liabilities | 16,333,056 | 12,569,089 |
| 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 553,500 shares (liquidation preference of \$6,077,500 and \$6,088,500) | 552,500 | 553,500 |
| Series V, Class B; issued 2,416,221 shares; outstanding: 1,238,821 and 1,282,471 shares, respectively (liquidation preference of \$5,450,812 and \$5,642,872, respectively) | 1,238,821 | 1,282,471 |
| Common Stock, no par value; authorized: 100,000,000 shares; issued and outstanding: 23,800,064 and 23,755,414 shares, respectively | | |
| Additional paid-in capital | 53,952,183 | 53,818,987 |
| Retained deficit | (14,031,646) | (4,388,066) |
| Total stockholders equity | 42,205,803 | 51,760,837 |
| Total liabilities and stockholders equity | \$ 58,538,859 | \$ 64,329,926 |

See accompanying notes to financial statements

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

| | Years Ended December 31, | | |
|--|---------------------------------|----------------|----------------|
| | 2008 | 2007 | 2006 |
| Sales, net | \$ 27,899,318 | \$ 26,289,720 | \$ 20,897,207 |
| Reimbursed discounts | | | 4,427,312 |
| Total sales | 27,899,318 | 26,289,720 | 25,324,519 |
| Cost of Sales | | | |
| Costs of manufactured product | 17,504,842 | 16,212,609 | 15,684,450 |
| Royalty expense to shareholders | 2,168,268 | 2,087,596 | 2,093,822 |
| Total cost of sales | 19,673,110 | 18,300,205 | 17,778,272 |
| Gross profit | 8,226,208 | 7,989,515 | 7,546,247 |
| Operating expenses: | | | |
| Sales and marketing | 4,835,272 | 5,299,157 | 5,545,500 |
| Research and development | 1,066,068 | 1,071,143 | 958,798 |
| General and administrative | 12,769,774 | 11,565,144 | 7,756,647 |
| Total operating expenses | 18,671,114 | 17,935,444 | 14,260,945 |
| Loss from operations | (10,444,906) | (9,945,929) | (6,714,698) |
| Interest and other income | 855,685 | 1,870,512 | 1,976,406 |
| Interest expense, net | (54,359) | (326,304) | (411,154) |
| Loss before income taxes | (9,643,580) | (8,401,721) | (5,149,446) |
| Benefit for income taxes | | (1,453,617) | (1,279,962) |
| Net loss | (9,643,580) | (6,948,104) | (3,869,484) |
| Preferred Stock dividend requirements | (1,373,019) | (1,399,062) | (1,451,321) |
| Net loss applicable to common shareholders | \$ (11,016,599) | \$ (8,347,166) | \$ (5,320,805) |
| Loss per share | \$ (0.46) | \$ (0.35) | \$ (0.23) |
| Weighted average common shares outstanding | 23,794,566 | 23,727,029 | 23,591,999 |

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, 2005 | 171,000 | \$171,000 | 255,200 | \$255,200 | 135,245 | \$135,245 | 556,000 | \$556,000 | 1,381,221 | \$1,381,221 | 23,511,884 | \$ |
| Conversion of Preferred Stock into Common Stock | (7,000) | (7,000) | (30,500) | (30,500) | | | (2,500) | (2,500) | (17,500) | (17,500) | 57,500 | |
| Recognition of stock option exercise | | | | | | | | | | | 74,780 | |
| Recognition of stock option compensation | | | | | | | | | | | | |
| Net loss | | | | | | | | | | | | |
| 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 | |
| | | | | | | | (1,000) | (1,000) | (43,650) | (43,650) | 44,650 | |

Conversion of
Preferred Stock
into Common
Stock

Recognition of
stock option
compensation

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| | <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> |
| Recognition of beneficial conversion feature | | | | | | | | | | | | |
| 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 | \$ |

See accompanying notes to financial statements

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

| | Additional Paid-in Capital | Retained Earnings (Deficit) | Total |
|--|---|--|---------------|
| Balance as of December 31, 2005 | \$ 54,307,053 | \$ 6,429,522 | \$ 63,235,241 |
| Conversion of Preferred Stock into Common Stock | 57,500 | | |
| Recognition of stock option exercise | 74,780 | | 74,780 |
| Recognition of stock option compensation | 269,775 | | 269,775 |
| Net loss | | (3,869,484) | (3,869,484) |
| 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 |

See accompanying notes to financial statements

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

| | Years Ended December 31, | | |
|---|---------------------------------|----------------|----------------|
| | 2008 | 2007 | 2006 |
| Cash flows from operating activities: | | | |
| Net loss | \$ (9,643,580) | \$ (6,948,104) | \$ (3,869,484) |
| Adjustments to reconcile net loss to net cash used by operating activities: | | | |
| Depreciation and amortization | 1,397,333 | 1,430,072 | 1,426,748 |
| Capitalized interest | (236,960) | (177,086) | (135,857) |
| Stock option compensation | 32,629 | 6,478 | 372,298 |
| Provision for inventory valuation | | 155,600 | (61,296) |
| Provision for doubtful accounts | 224,633 | 169,223 | 65,362 |
| Accreted interest | 54,387 | 120,486 | 138,155 |
| Deferred income taxes | | | 534,065 |
| (Increase) decrease in assets: | | | |
| Inventories | 395,597 | (806,949) | (3,026,759) |
| Accounts receivable | (1,845,939) | 119,897 | 1,382,790 |
| Income taxes receivable | 2,345,041 | 10,691 | (1,794,670) |
| Other current assets | (41,306) | (91,100) | 194,443 |
| Other assets | (12,725) | | |
| Increase (decrease) in liabilities: | | | |
| Accounts payable | 609,070 | 1,287,735 | 1,902,016 |
| Other accrued liabilities | 798,578 | 506,386 | (481,842) |
| Net cash used by operating activities | (5,923,242) | (4,216,671) | (3,354,031) |
| Cash flows from investing activities: | | | |
| Purchase of property, plant and equipment | (2,343,556) | (464,415) | (1,530,357) |
| Investment in LLC | 497,690 | | (500,000) |
| Acquisitions of patents, trademarks, licenses, and intangibles | (89,152) | (188,168) | (4,576) |
| Net cash used by investing activities | (1,935,018) | (652,583) | (2,034,933) |
| Cash flows from financing activities: | | | |
| Repayments of long-term debt and notes payable | (489,160) | (384,460) | (385,062) |
| Proceeds from long-term debt | 1,123,729 | | |
| Proceeds from the exercise of stock options | | | 74,780 |
| Payment of Preferred Stock dividends | | (1,053,544) | |
| Net cash provided (used) by financing activities | 634,569 | (1,438,004) | (310,282) |
| Net decrease in cash and cash equivalents | (7,223,691) | (6,307,258) | (5,699,246) |
| Cash and cash equivalents at: | | | |
| Beginning of period | 40,507,431 | 46,814,689 | 52,513,935 |
| End of period | \$ 33,283,740 | \$ 40,507,431 | \$ 46,814,689 |

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| | 2008 | | 2007 | | 2006 |
|--|--------------|----|-------------|----|-------------|
| Supplemental schedule of cash flow information: | | | | | |
| Interest paid | \$ 236,932 | \$ | 382,901 | \$ | 425,429 |
| Income taxes paid | \$ | \$ | \$ | \$ | 45,893 |
| Supplemental schedule of noncash investing and financing activities: | | | | | |
| Debt assumed to construct a warehouse | \$ 1,723,277 | \$ | \$ | \$ | |

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® 0.5cc insulin syringe; 1cc tuberculin, insulin, and allergy antigen syringes; the 0.5cc, 3cc, 5cc, and 10cc syringes; the autodisable syringe; 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 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 a standard cost method, which approximates 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, 2008, 2007, and 2006, the Company capitalized interest of approximately \$237,000; \$177,000; and \$136,000. 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 fair value of financial instruments is determined by reference to various market data and other valuation techniques as appropriate. The Company believes that the fair values of financial instruments approximates their recorded values.

Concentration risks

The Company's financial instruments exposed to concentrations of credit risk consist primarily of cash, cash equivalents, and accounts receivable. Cash balances, some of which exceed federally insured limits, are maintained in financial institutions; however, Management believes the institutions are of high credit quality. The majority of accounts receivable are due from companies which are well-established

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entities. As a consequence, Management considers any exposure from concentrations of credit risks to be limited. The Company had a high concentration of sales with one significant customer. For the year ended December 31, 2008, the aforementioned customer accounted for \$4,679,478, or 16.8% of net sales.

Considering the current economic climate, the Company increased its Provision for doubtful accounts by approximately \$246,000 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 obtains roughly 74.0% of its finished products through Double Dove, a Chinese manufacturer. In the event that the Company becomes unable to purchase such product from Double Dove, the Company would need to find an alternate supplier for its 0.5cc insulin syringe, its 5cc and 10cc syringes and its autodisable syringe and increase domestic production for 1cc and 3cc syringes to avoid a disruption in supply.

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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 one percent 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 Total 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. Abbott filed an answer and counterclaim July 15, 2008. See Note 5 **COMMITMENTS AND CONTINGENCIES-Litigation** for further discussion.

Reimbursed Discounts

The Company received reimbursed discounts from one of the settlement agreements reached in its previous federal antitrust lawsuit, *Retractable Technologies, Inc. v. Becton Dickinson and Co. (BD) et al.* Payments under the discount reimbursement program were recognized upon invoicing of amounts due under the agreement provided collection was reasonably assured. Such amounts are presented in the Statements of

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Operations as a separate component of revenues. All funds available under the discount reimbursement program were recognized by the third quarter of 2006.

Income taxes

The Company provides for deferred income taxes in accordance with SFAS No. 109, *Accounting for Income Taxes* (SFAS 109). SFAS 109 requires an asset and liability approach for financial accounting and reporting for income taxes 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.

Earnings per share

The Company has adopted SFAS No. 128, *Earnings Per Share*, which establishes standards for computing and presenting earnings per share. Basic earnings per share is computed 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 as the Company is in a loss position 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, 2008, 2007 and 2006 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

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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 may 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 one year. Options issued to non-employee Directors vested immediately.

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.

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The Company's share-based payments are accounted for in accordance with the provisions of SFAS No. 123 (Revised 2004) (SFAS 123 R), *Share-Based Payment*, using the fair value method. The Company records share-based compensation expense on a straight-line basis over the requisite service period. In accordance with the disclosure requirements of SFAS No. 123 R, the Company incurred the following share-based compensation costs:

| | 2008 | Years ended December 31, | | 2006 |
|----------------------------|------------|--------------------------|----|---------|
| | | 2007 | | |
| Cost of sales | \$ (1,797) | \$ 6,648 | \$ | 67,561 |
| Sales and marketing | (2,156) | 3,086 | | 101,608 |
| Research and development | (281) | (7,863) | | 12,418 |
| General and administrative | 36,863 | 4,607 | | 190,711 |
| | \$ 32,629 | \$ 6,478 | \$ | 372,298 |

Options awarded to employees are amortized over twelve months. The Company amortized one month's expense in the fourth quarter. Non-employee Directors' option expense was all expensed in the fourth quarter. The Company recognized a credit for the cancelled options in the fourth quarter, resulting in a net credit to stock option expense for employees of \$7,651.

Recent Pronouncements

In April 2008, the Financial Accounting Standards Board (FASB) issued FASB Staff Position (FSP) FAS 142-3, *Determination of the Useful Life of Intangible Assets* . 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 SFAS 141R, and other GAAP. This FSP is effective for financial statements issued for fiscal years and interim periods beginning after December 15, 2008. Early adoption of the standard is prohibited. FAS 142-3 is effective on January 1, 2009. We are currently evaluating the impact of FAS 142-3, and have not yet determined the impact, if any, that the adoption of FSP FAS 142-3 will have on the Company's financial statements.

3. INVENTORIES

Inventories consist of the following:

| | Year ended December 31, | |
|----------------|-------------------------|--------------|
| | 2008 | 2007 |
| Raw materials | \$ 1,885,158 | \$ 1,743,990 |
| Finished goods | 4,961,975 | 5,498,739 |

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| | | |
|-------------------|--------------|--------------|
| Inventory reserve | 6,847,133 | 7,242,729 |
| | (205,600) | (205,600) |
| | \$ 6,641,533 | \$ 7,037,129 |

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Property, plant, and equipment consist of the following:

| | December 31, | |
|---|---------------------|---------------|
| | 2008 | 2007 |
| Land | \$ 261,893 | \$ 261,893 |
| Buildings and building improvements | 5,319,732 | 5,314,725 |
| Production equipment | 14,270,577 | 14,169,902 |
| Office furniture and equipment | 1,825,781 | 1,729,199 |
| Construction in progress | 6,287,503 | 2,185,976 |
| Automobiles | 102,321 | 102,321 |
| | 28,067,807 | 23,764,016 |
| Accumulated depreciation and amortization | (13,632,140) | (12,280,593) |
| | \$ 14,435,667 | \$ 11,483,423 |

Depreciation expense for the years ended December 31, 2008, 2007, and 2006 was \$1,351,547; \$1,370,228; and \$1,380,047, respectively.

5. INTANGIBLE ASSETS

Intangible assets consist of the following:

| | December 31, | |
|--------------------------|---------------------|-------------|
| | 2008 | 2007 |
| License agreement | \$ 500,000 | \$ 500,000 |
| Trademarks and patents | 508,743 | 419,591 |
| | 1,008,743 | 919,591 |
| Accumulated amortization | (538,628) | (495,031) |
| | \$ 470,115 | \$ 424,560 |

In 1995, the Company entered into a license agreement with the Chief Executive Officer of the Company for the exclusive right to manufacture, market, and distribute products utilizing automated retraction technology. This license agreement was amended July 3, 2008 to include certain additional patent applications owned by such officer in the definition of "Patent Properties" so that such additional patent applications would be covered by the license. This technology is the subject of various patents and patent applications owned by such officer of the Company. The initial licensing fee of \$500,000 is being amortized over 17 years. The license agreement also provides for quarterly payments of a 5% royalty fee on gross sales. The royalty fee expense is recognized in the period in which it is earned. Royalty fees of \$2,168,268; \$2,087,596; and \$2,093,822 are included in Cost of sales for the years ended December 31, 2008, 2007, and 2006, respectively. Royalties payable under this agreement aggregated \$620,987 and \$619,304 at December 31, 2008 and 2007, respectively. Gross sales upon which royalties are based were \$43,365,361; \$41,751,897; and \$42,026,447 for 2008, 2007, and 2006, respectively.

Amortization expense for the years ended December 31, 2008, 2007, and 2006, was \$43,597; \$43,454; and \$41,657, respectively. Future amortization expense for the years 2009 through 2013 is estimated to be \$53,000 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.

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| | December 31, | |
|---|------------------------|--------------|
| | 2008 | 2007 |
| Long-term debt consists of the following: | | |
| Note payable to Katie Petroleum. Interest accrues at prime plus 1%, which was 5.0% and 8.50%, at December 31, 2008 and 2007, 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 is 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. | \$ 1,437,977 | \$ 1,735,392 |
| 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, 2008 and 2007 was 4.25% and 7.50%, respectively, and is 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. 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. | 2,241,145 | 2,362,852 |
| 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. | 12,711 | 23,793 |
| Note payable to GMAC. Sixty (60) monthly payments at \$427. Interest is zero percent. Collateralized by a 2005 Chevrolet van. | 8,561 | 13,128 |
| Construction line of credit 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 bears interest at WSJPR plus 0.25%. Payments are interest only and the line of credit matures in February 2010. The line of credit is secured by the Company's land and buildings. The Company has obtained an intent to refinance this line of credit with Lewisville State Bank. Terms of the refinanced loan are expected to be principal and interest payments of approximately \$35,000 based on a 21 year amortization and maturing in 10 years. | 2,847,006 6,547,400 | 4,135,165 |
| Less: current portion | (451,865) | (387,906) |
| | \$ 6,095,535 | \$ 3,747,259 |

The aggregate maturities of long-term debt as of December 31, 2008, are as follows:

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| | | |
|------------|----|-----------|
| 2009 | \$ | 451,865 |
| 2010 | | 5,365,563 |
| 2011 | | 403,687 |
| 2012 | | 326,285 |
| 2013 | | |
| Thereafter | \$ | 6,547,400 |

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8. COMMITMENTS AND CONTINGENCIES

Litigation

On August 12, 2005, the Company filed a lawsuit against Abbott in the United States 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. The Company is seeking damages which it estimates to be in millions of dollars of lost profits, out of pocket expenses, and other damages. In addition, the Company is seeking punitive damages, pre- and post-judgment interest, and attorney's 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. Some discovery has already taken place (related to the hearings addressing the prior motion to compel arbitration) and additional discovery is underway. The District Court has issued a scheduling order calling for trial in January 2010.

In August 2006, the Company was sued by Occupational and Medical Innovations Limited (OMI) in Federal Court of Australia, alleging that two letters written to OMI by outside counsel contained unjustified threats of patent infringement, but seeking no damages. OMI later amended its complaint to seek a declaratory judgment that OMI does not infringe Australian Patent No. 701878, again seeking no damages. Following a one-day trial in June 2007, the Court held that one of the two letters written by outside counsel contained a threat of patent infringement, and awarded costs to OMI. Following a one-day trial in June 2008, the Court issued a declaratory judgment in August 2008 stating that OMI's syringe does not infringe the Australian patent no. 701878 but also awarding costs to the Company. The Company and OMI subsequently agreed that each party will bear its own costs, and the matter was settled in October 2008.

In April 2008, the Company sued OMI in the United States District Court for the Eastern District of Texas, Tyler Division, alleging that OMI has infringed two U.S. patents that are not at issue in the Australian litigation (6,572,584 and 7,351,224). The Company also alleges theft of confidential information, intentional interference with contracts and engaging in false advertising that wrongfully disparages and mischaracterizes the Company's syringe products. The Company further alleges that OMI made false allegations regarding the source of origin of its safety syringe products being offered in the U.S. The Company seeks injunctive relief, unspecified damages (including treble damages) and reimbursement of attorneys fees in the suit. OMI has counterclaimed against the Company, seeking declaratory judgments of non-infringement and invalidity of the asserted patents. OMI is not seeking monetary damages. Trial is set for December 2009 and discovery is ongoing.

In June 2007, the Company sued Becton Dickinson and Company (BD) in the United States 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. The Company and an officer, a co-plaintiff, are seeking injunctive relief, unspecified monetary damages and reimbursement of attorneys fees in the suit. BD counterclaimed for non-infringement and invalidity of the asserted patents. In January 2008, the Court severed the patent claims from the other claims pending resolution of the patent dispute, which is set for trial in October 2009. In April 2008, the Company and that same officer sued BD in the United States District Court for the Eastern District of Texas, Marshall Division, alleging infringement of another recently issued patent (7,351,224), and seeking injunctive relief, unspecified monetary damages (including treble damages) and reimbursement of attorneys fees. BD counterclaimed for non-infringement and invalidity of the asserted patent. The Company and officer moved to consolidate this case with the other patent case against BD that was pending in Marshall and the Court granted the Company's motion, consolidating this case with the above-stated case filed in June 2007. The Court issued its claim construction order in this matter on January 4, 2009.

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In September 2007, BD and MDC Investment Holdings, Inc. (MDC) sued the Company in the United States District Court for the Eastern District of Texas, Texarkana Division, initially alleging that the Company is infringing two U.S. patents of MDC (6,179,812 and 7,090,656) that are licensed to BD. BD and MDC seek injunctive relief and unspecified damages. The Company counterclaimed for declarations of non-infringement, invalidity and unenforceability of the asserted patents. The plaintiffs subsequently dropped allegations with regard to patent no. 7,090,656 and the Company subsequently dropped its counterclaims for unenforceability of the asserted patents. 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 March 2008, MedSafe Technologies LLC (MedSafe) initially sued the Company and BD in the United States District Court for the District of South Carolina, Greenville Division, alleging infringement of a MedSafe patent (6,074,370) and seeking injunctive relief and unspecified monetary damages. The Company counterclaimed for declarations of non-infringement, invalidity, and unenforceability of the asserted patent. BD subsequently settled with MedSafe. Effective December 22, 2008, the Company resolved its litigation with MedSafe by entering into a PATENT LICENSE/ASSIGNMENT AND SETTLEMENT AGREEMENT with MedSafe and Syringe Development Partners, LLC; William B.S. Pressly, Sr.; Charles A Vaughn, Sr.; G. Samuel Brockway; and Thomas R. Ellis (collectively, the MedSafe Plaintiffs) (the MedSafe Settlement Agreement). The MedSafe Settlement Agreement ends the patent infringement litigation between the Company and MedSafe.

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 against the Company, seeking declaratory judgments of non-infringement and invalidity of the asserted patents. SMI is not seeking monetary damages. No trial date has been set and discovery has not yet commenced.

9. INCOME TAXES

The provision for income taxes consists of the following:

| | 2008 | For the Years Ended December 31, | | 2006 |
|--|-------------|---|----|-------------|
| | | 2007 | | |
| Current tax provision (benefit) | | | | |
| Federal | \$ | \$ (143,459) | \$ | (1,696,318) |
| State | | (1,310,158) | | (117,709) |
| Total current provision (benefit) | | (1,453,617) | | (1,814,027) |
| Deferred tax provision (benefit) | | | | |
| Federal | | | | 458,232 |
| State | | | | 75,833 |
| Total deferred tax provision (benefit) | | | | 534,065 |
| Total income tax provision (benefit) | \$ | \$ (1,453,617) | \$ | (1,279,962) |

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.

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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 \$13,935,832 in tax benefits attributable to carry back 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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| | December 31, | |
|---|---------------------|--------------|
| | 2008 | 2007 |
| Deferred tax assets | | |
| Net operating loss carryforwards | \$ 5,285,164 | \$ 1,871,316 |
| Accrued expenses and reserves | 1,261,168 | 1,204,160 |
| Employee option expense | 31,669 | 484,212 |
| Inventory | 435,578 | 402,405 |
| Non-employee option expense | 198,425 | 313,557 |
| Deferred tax assets | 7,212,004 | 4,275,650 |
| Deferred tax liabilities | | |
| Property and equipment | (1,178,618) | (1,341,293) |
| Beneficial conversion feature of debt - current | | (20,626) |
| Beneficial conversion feature of debt - long term | | (36,200) |
| Deferred tax liabilities | (1,178,618) | (1,398,119) |
| Net deferred assets | 6,033,386 | 2,877,531 |
| Valuation allowance | (6,033,386) | (2,934,357) |
| Net deferred tax liabilities | \$ | \$ (56,826) |

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

| | December 31, | | |
|--|---------------------|-------------|-------------|
| | 2008 | 2007 | 2006 |
| 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 | 32.1 | 27.2 | 10.7 |
| Permanent differences | 0.4 | 1.0 | 4.0 |
| Cancellation of options under Exchange Offer | 5.4 | | |
| State tax refund | | (12.0) | |
| Return to accrual adjustments | | 3.2 | |
| Other | | 1.2 | (1.7) |
| Effective tax (benefit) rate | % | (17.3)% | (24.9)% |

In June 2006, the Financial Accounting Standards Board (FASB) issued Financial Interpretation No. 48, *Accounting for Income Tax Uncertainties* (FIN 48). FIN 48 is effective for years beginning after December 15, 2006. FIN 48 prescribes a recognition threshold and measurement attribute for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 requires that a company evaluate whether it is more-likely-than-not that a tax position will be sustained based upon the technical merits of the position. Measurement of the tax position is based upon the largest amount of benefit that is greater than 50% likely of being realized upon ultimate settlement. The Company adopted FIN 48 on January 1, 2007. FIN 48 had no material effect on the financial statements upon adoption. During 2007, the Company reserved approximately \$100,000 for state nexus issues. During 2008, the Company also recorded a state tax receivable of approximately \$100,000 attributable to amended returns.

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, 2005, 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.

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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.

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, 2008 and 2007, respectively. 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, 2008 and 2007 approximately \$108,000 and \$36,000, 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 2008. 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, 2008 and 2007. 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, 2008 and 2007, approximately \$331,000 and \$111,000, 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 2008. 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, 2008 and 2007, respectively. 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

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December 31, 2008 and 2007, approximately \$3,117,000 and \$2,985,000, 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 2008. 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 and 553,500 shares outstanding at December 31, 2008 and 2007, respectively. 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, 2008 and 2007, approximately \$7,030,000 and \$6,478,000, 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, 1,000 shares of Series IV Class B Stock were converted into Common Stock in 2008. 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 and 1,282,471 outstanding at December 31, 2008 and 2007, respectively. Holders of Series V Class B Stock are entitled to receive a cumulative annual dividend of \$0.32 per share, payable quarterly, if declared by the Board of Directors. Holders of Series V Class B Stock generally have no voting rights. At December 31, 2008 and 2007, approximately \$3,297,000 and \$2,898,000, 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, 43,650 shares of Series V Class B Stock were converted into Common Stock in 2008. 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

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after distribution obligations to Series I Class B Stock, Series II Class B Stock, Series III Class B Stock, and Series IV Class B Stock have been satisfied and prior to any distribution to the holders of the Common Stock.

Common stock

The Company is authorized to issue 100,000,000 shares of no par value Common Stock, of which 23,800,064 and 23,755,414 shares were issued and outstanding at December 31, 2008 and 2007, respectively.

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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 years ended December 31, 2007 and 2006, the Company paid \$14,500 and \$34,800, respectively, under this lease. This lease term expired in June 2007.

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, 2008, 2007, and 2006 totaled \$98,401; \$129,618; and \$91,883, respectively.

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

During the years ended December 31, 2008, 2007, and 2006, the Company paid \$40,191; \$30,397; and \$24,162, 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. The 1999 Plan and 2008 Plan are the only plans with stock options currently being awarded. The Company has reserved an aggregate 7,000,000 shares of Common Stock for issuance upon the exercise of options under these plans. We do not intend to issue any options under the 1999 Stock Option Plan.

On September 26, 2008, the Company's shareholders approved the Exchange Offer whereby employees, including executive officers, and Directors may 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 one year. Options issued to non-employee Directors vested immediately.

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.

A committee of independent Directors appointed by the Board of Directors administers all plans and recommends to the Board exercise prices at which options are granted. 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.

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Employee options

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

| | 2008 | | Years Ended December 31, 2007 | | 2006 | |
|--|-------------|---------------------------------|----------------------------------|---------------------------------|-----------|---------------------------------|
| | Shares | Weighted Average Exercise Price | Shares | Weighted Average Exercise Price | Shares | Weighted Average Exercise Price |
| Outstanding at beginning of period | 2,187,455 | \$ 8.80 | 2,417,295 | \$ 8.58 | 2,495,125 | \$ 8.38 |
| Granted | 962,683 | 1.30 | | | | |
| Exercised | | | | | (49,780) | (1.00) |
| Forfeited | (2,092,875) | (8.79) | (229,840) | (6.50) | (28,050) | (4.47) |
| Outstanding at end of period | 1,057,263 | \$ 1.99 | 2,187,455 | \$ 8.80 | 2,417,295 | \$ 8.58 |
| Exercisable at end of period | 147,580 | \$ 6.25 | 2,187,455 | \$ 8.80 | 2,325,770 | \$ 8.57 |
| Weighted average fair value of options granted during period | | \$ 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 percent; risk free interest rate of 2.83 percent; 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 or 2006.

The following table summarizes information about Director, officer, and employee options outstanding under the aforementioned plans at December 31, 2008:

| Exercise Prices | Shares Outstanding | Weighted Average Remaining Contractual Life | Shares Exercisable |
|-----------------|--------------------|---|--------------------|
| \$ 10.00 | 58,500 | 0.89 | 58,500 |
| \$ 6.90 | 15,080 | 3.75 | 15,080 |
| \$ 8.65 | 4,700 | 4.48 | 4,700 |
| \$ 7.50 | 15,000 | 0.36 | 15,000 |

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| | | | | |
|----|------|---------|------|--------|
| \$ | 8.87 | 1,300 | 5.36 | 1,300 |
| \$ | 1.30 | 962,683 | 9.89 | 53,000 |

The Company recorded \$98,473 (offset by a credit of \$65,844 for surrendered stock options); \$6,478; and \$372,298 as stock-based compensation expense in 2008, 2007, and 2006, respectively. The total intrinsic value of options exercised was \$0; \$0; and \$207,924 in 2008, 2007, and 2006, respectively. The aggregate intrinsic value of options outstanding at December 31, 2008 was \$0. The total compensation cost related to non-vested stock options to be recognized in the future was \$635,511 at December 31, 2008.

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

| | 2008 | | Years Ended December 31, 2007 | | 2006 | |
|--|----------|--|----------------------------------|--|----------|--|
| | Shares | Weighted Average Exercise Price | Shares | Weighted Average Exercise Price | Shares | Weighted Average Exercise Price |
| Outstanding at beginning of period | 549,700 | \$ 8.69 | 579,700 | \$ 8.50 | 607,200 | \$ 8.16 |
| Granted | | | | | | |
| Exercised | | | | | (25,000) | (1.00) |
| Forfeited | (95,000) | (10.00) | (30,000) | (5.00) | (2,500) | (1.00) |
| Outstanding at end of period | 454,700 | \$ 8.41 | 549,700 | \$ 8.69 | 579,700 | \$ 8.50 |
| Exercisable at end of period | 454,700 | \$ 8.41 | 549,700 | \$ 8.69 | 579,700 | \$ 8.50 |
| Weighted average fair value of options granted during period | | \$ | | \$ | | \$ |

No options were issued in 2008, 2007 or 2006.

The following table summarizes information about non-employee options outstanding under the aforementioned plans at December 31, 2008:

| Exercise Prices | Shares Outstanding | Weighted Average Remaining Contractual Life | Shares Exercisable |
|-----------------|--------------------|---|--------------------|
| \$10.00 | 222,200 | 1.16 | 222,200 |
| \$6.90 | 232,500 | 3.75 | 232,500 |

13. LITIGATION SETTLEMENTS

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Effective December 22, 2008, the Company resolved its litigation with MedSafe by entering into a PATENT LICENSE/ASSIGNMENT AND SETTLEMENT AGREEMENT with MedSafe and Syringe Development Partners, LLC; William B.S. Pressly, Sr.; Charles A Vaughn, Sr.; G. Samuel Brockway; and Thomas R. Ellis (collectively, the MedSafe Plaintiffs) (the MedSafe Settlement Agreement). This MedSafe Settlement

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Agreement ends the patent infringement litigation between the Company and MedSafe.

14. 401(k) PLAN

The Company implemented an employee savings and retirement plan (the 401(k) Plan) in 2005 that is intended to be a tax-qualified plan covering substantially all employees. Under the terms of the 401(k) Plan, employees may elect to contribute up to 90% of their compensation, or the statutory prescribed limit, if less. The Company may, at its discretion, match employee contributions. The Company made matching contributions of approximately \$122,000; \$111,000; and \$0 in 2008, 2007, and 2006, respectively.

15. BUSINESS SEGMENTS

| | 2008 | | 2007 | | 2006 |
|---------------------|---------------|----|-------------|----|-------------|
| Domestic sales | \$ 23,244,370 | \$ | 21,461,717 | \$ | 22,240,347 |
| International sales | 4,654,948 | | 4,828,003 | | 3,084,172 |
| Total sales | \$ 27,899,318 | \$ | 26,289,720 | \$ | 25,324,519 |
| Long-lived assets | | | | | |
| Domestic | \$ 14,435,667 | \$ | 11,483,423 | \$ | 12,212,140 |
| Foreign | \$ | \$ | \$ | \$ | |

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 United States currency.

SELECTED QUARTERLY FINANCIAL DATA - UNAUDITED

The selected quarterly financial data for the periods ended December 31, 2008 and 2007, 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)
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 |

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| | | | | | | | | |
|--|----|------------|----|------------|----|------------|----|------------|
| 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% |

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

| | 2007 | | | |
|--|------------|------------|------------|------------|
| | Quarter 1 | Quarter 2 | Quarter 3 | Quarter 4 |
| Sales, net | \$ 5,774 | \$ 5,275 | \$ 8,040 | \$ 7,201 |
| Cost of sales | 4,514 | 3,132 | 5,853 | 4,801 |
| Gross profit | 1,260 | 2,143 | 2,187 | 2,400 |
| Total operating expenses | 4,000 | 4,101 | 4,616 | 5,219 |
| Loss from operations | (2,740) | (1,958) | (2,429) | (2,819) |
| Interest income | 541 | 448 | 521 | 360 |
| Interest expense, net | (77) | (94) | (86) | (69) |
| Loss before income taxes | (2,276) | (1,604) | (1,994) | (2,528) |
| Benefit for income taxes | | | (1,406) | (48) |
| Net loss | (2,276) | (1,604) | (588) | (2,480) |
| Preferred stock dividend requirements | (355) | (349) | (348) | (347) |
| Net loss applicable to common shareholders | \$ (2,631) | \$ (1,953) | \$ (936) | \$ (2,827) |
| Net loss per share - basic and diluted | \$ (0.11) | \$ (0.08) | \$ (0.04) | \$ (0.12) |
| Weighted average shares outstanding | 23,677,644 | 23,731,664 | 23,745,206 | 23,754,581 |
| Profit margin | 21.8% | 40.6% | 27.2% | 33.3% |

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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 paragraph (b) of Rule 13a-15 or Rule 15d-15 of the Securities Exchange Act of 1934 (the Exchange Act) and on March 30, 2009, 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) or Rule 15d-15(e). The CEO and CFO concluded, as of December 31, 2008 (the end of the period covered by the report), based on the evaluation of these controls and procedures required by paragraph (b) of Rule 13a-15 or Rule 15d-15 that our disclosure controls and procedures are effective to ensure that information required to be disclosed in our periodic reports is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms.

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 Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Management used the *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) to evaluate the effectiveness of our internal control over financial reporting as required by paragraph (c) of Rule 13a-15 or Rule 15d-15. Management, with the participation of our CEO and CFO, concluded that our internal control over financial reporting as of December 31, 2008, 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 Securities and Exchange Commission 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 2008 or subsequent to December 31, 2008, in our internal control over financial reporting or in any other factor that has materially affected or is reasonably likely to materially affect our internal control over financial reporting.

Item 9B. Other Information.

We will hold our annual meeting on September 25, 2009, at the Little Elm City Hall; 100 West Eldorado Parkway; Little Elm, Texas, 75068. Beginning this year, we will provide proxy disclosures to our shareholders utilizing the new notice and access method. Accordingly, shareholders will no longer receive a Proxy Statement and proxy card in the mail. Instead they will receive a short one page notice with the information allowed by the SEC which will give the shareholders the web address where a copy of the Proxy Statement and related materials may be found. Upon reaching such address, the shareholder may read or print the documents and may (after submitting their account number) vote their shares.

Prior to the annual meeting, we expect to solicit the preferred shareholders to amend the various Certificates of Designation to allow purchases of stock ranking junior to the preferred stock while dividends are in arrears.

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The bylaws allow for uncertificated shares. If any shareholder is interested in holding their shares in electronic form only (which the Company does not recommend) you may initiate that process by contacting Mr. Douglas Cowan at the Company.

Mr. Thomas Shaw's Employment Agreement was amended in 2008 to avoid adverse tax consequences to Mr. Shaw created by passage of the American Jobs Creation Act of 2004. A summary of the existing terms of such agreement may be found in **Item 11 COMPENSATION DISCUSSION AND ANALYSIS-Compensation Pursuant to Employment Agreement.**

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 terms.

| Name | Age | Position | Term as Director Expires |
|------------------------------|------------|--|---------------------------------|
| EXECUTIVES | | | |
| Thomas J. Shaw | 58 | Chairman, President, Chief Executive Officer, and Class 2 Director | 2010 |
| Douglas W. Cowan | 65 | Vice President, Chief Financial Officer, Treasurer, and Class 2 Director | 2010 |
| Kathryn M. Duesman | 46 | Executive Director, Global Health | N/A |
| Russell B. Kuhlman | 55 | Vice President, Sales | N/A |
| Michele M. Larios | 42 | Vice President, General Counsel, and Secretary | N/A |
| Lawrence G. Salerno | 48 | Director of Operations | N/A |
| Steven R. Wisner | 51 | Executive Vice President, Engineering & Production and Class 2 Director | 2010 |
| INDEPENDENT DIRECTORS | | | |
| Marco Laterza | 61 | Class 1 Director | 2009 |
| Amy Mack | 41 | Class 1 Director | 2009 |
| Marwan Saker | 53 | Class 2 Director | 2010 |
| Clarence Zierhut | 80 | Class 2 Director | 2010 |
| SIGNIFICANT EMPLOYEES | | | |
| Shayne Blythe | 40 | Director of Sales and Marketing Logistics | N/A |
| John W. Fort III | 40 | Director of Accounting | N/A |
| James A. Hoover | 61 | Director of Quality Assurance | N/A |

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| | | | |
|---------------|----|----------------------------------|-----|
| R. John Maday | 48 | Production Manager | N/A |
| Jules Millogo | 48 | Medical Director | N/A |
| Judy Ni Zhu | 50 | 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. 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.

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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. He is responsible for our financial, accounting, risk management, and forecasting functions. Mr. Cowan has a Bachelor of Business Administration from Texas Technological College. He is a CPA licensed in Texas.

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 nonpublic 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 Ms. Lillian E. Salerno, a shareholder 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. 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. 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 Chief Financial Officer for EZ Blue Software Corporation, a 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

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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. 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. Since 1983, Mr. Saker has served as Chief Executive Officer of Sovana, Inc., an export management company that supplies agricultural equipment and supplies to overseas markets. Since 2000, he has served as Director of Consolidated Food Concepts Inc. Since 1986, he has served as President of International Exports & Consulting Inc., an export management, consulting, and distribution company. Since 2000, he has served as Vice President of Hanneke Corp., an overseas sourcing company. From 1998 to 2001, he served as a Member of My Investments, LLC, an equity investment company. Since 1999, he has served as President of Saker Investments Inc., a company that manages an investment portfolio. Since 1998, he has served as a General Partner of Maya Investments, Ltd., an investment management limited partnership. He also serves as a Member of MMDA, LLC, a real estate development company. He is also involved with Fig Land Development. 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 offices in Irving, Texas.

Clarence Zierhut has served on our Board of Directors since April 1996. 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 3cc syringe and other SBIR grant projects. Ms. Blythe has a Bachelors of Business Administration in management from the American International 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 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

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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 25 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.

Dr. Jules Millogo has served as our Medical Director since May 2007. His duties include representing us at scientific forums and working with the Ministries of Health and international organizations on developing injection safety and health workers safety standards and policies. From 2004 to April 2007 Dr. Millogo was employed by John Snow, Inc. as the Project Director for the Washington-based Making Medical Injections Safer Project (MMIS), a \$150 million project funded by the U.S. government to decrease unsafe injections and the medical transmission of HIV/AIDS, and hepatitis B and C as part of the U.S. President Emergency Plan for AIDS Relief (PEPFAR which was administered by PATH). Under his leadership, the MMIS Project trained more than 100,000 health workers in safer injection practices and donated more than 100 million safety syringes to high HIV prevalence countries in Africa and the Caribbean. From 2001 to 2004 Dr. Millogo was a technical advisor for John Snow, Inc. Dr. Millogo's experience includes working in several African and Asian countries under the World Health Organization. Dr. Millogo holds a Master's of Science in Epidemiology of Communicable Diseases from the University College of London, UK, and a MD from the University of Ouagadougou, Burkina Faso. Dr Millogo is fluent in French, English, and several African languages.

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 3cc 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 3cc 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 3cc 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 other than as set forth above.

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INVOLVEMENT IN CERTAIN LEGAL PROCEEDINGS

None of the above persons or any business in which such person was an executive officer have been involved in a bankruptcy petition, been subject to a criminal proceeding (excluding traffic violations and other minor offenses), been subject to any order enjoining or suspending their involvement in any type of business, or been found by a court or administrative body to have violated a securities law.

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 percent of a registered class of our equity securities to file with the SEC initial reports of beneficial ownership (Form 3) and reports of changes in beneficial ownership (Forms 4 and 5) of our Common Stock and our other equity

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securities. Officers, Directors, and greater than 10 percent shareholders are required by the SEC's regulations to furnish us with copies of all Section 16(a) reports they file.

Ms. Michele M. Larios, an executive officer, filed a Form 5 on an untimely basis. The Form 5 addressed a bona fide gift (her two children's receipt of 500 shares each of Common Stock).

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.

We have posted a copy of the code on our website at 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 Alternext rules and Item 7(d)(3)(iv) of Schedule 14A under the Exchange Act.

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 Alternext.

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 four basic components:

base salary;

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

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

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

Why We Choose to Pay Each Element of Our Compensation Program

Base Salary

We choose to pay a significant component of our compensation in base salary due to the fact that our financial performance is constrained by the monopolistic activities of BD. 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 its paying \$100 million to settle a prior lawsuit with us in 2004 for anticompetitive practices, business disparagement, and tortious interference. 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.

Cash Bonuses

From time to time and when our cash reserves allow (taking into account the continued need to compete in this monopolistic environment and the continued need for significant cash reserves) we grant cash bonuses in order to reward significant efforts or the accomplishment of short-term goals. The last bonuses were granted in 2003. The CEO has never been granted any bonuses of any kind.

Long-Term Incentives: Stock Options

Long-term incentives are provided through grants of stock options primarily under our 2008 Stock Option Plan. 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 not been reviewed annually. Under the terms of Mr. Shaw's employment agreement, his compensation is reviewed annually.

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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.

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.

Periodic Cash Bonuses

For 2008, we did not grant bonuses to our executive officers. These bonuses, when paid, are paid on a discretionary basis, as determined by the Compensation and Benefits Committee. Factors considered by the Compensation and Benefits Committee in determining discretionary cash bonuses are personal performance, level of responsibility, and many of the same factors considered by the Compensation and Benefits Committee and discussed above when it reviews and sets base salaries, except with a greater focus on the prior fiscal year. The Compensation and Benefits Committee also considers our need to retain cash in deciding whether to grant cash bonuses.

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 2006 or 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. Options are generally granted to regular full-time employees and officers. However, no options have ever been granted to Thomas J. Shaw, the Company's President and CEO.

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

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Directors. However, the committee can grant options on its own initiative.

Once the dollar amount of options to be granted is approved, 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. Currently, we are using the binomial model, but we may use other methods in the future as more appropriate methods are developed.

Options to executive officers are approved by the Compensation and Benefits Committee and then the Board of Directors individually and without regard to a formula. However, the committee can grant options on its own initiative.

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With regard to past grants, after the aggregate number of shares underlying the options to be granted was determined, we allocated the options to our various departments 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 past grants, each option generally became exercisable after three years, contingent upon the employee's continued employment with us. The exception is options issued to Officers and Directors pursuant to the Exchange Offer, which vested 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.

We offered to exchange certain outstanding eligible options for new options, on the terms and subject to the conditions described in the Exchange Offer. The Exchange Offer expired at 5:00 p.m., Central Standard Time, on November 18, 2008. Eligible participants (totaling 103) tendered, and we accepted for cancellation, eligible options to purchase an aggregate of 1,925,365 shares of our Common Stock representing 99.4% of the total shares of Common Stock underlying options eligible to exchange in the Exchange Offer. 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 the tendered options. The exercise price per share of each new option granted in the Offer was \$1.30, which was \$0.20 higher than the last sales price of our Common Stock as reported by the NYSE Alternext on November 18, 2008. Options issued to employees vest in one year. Options issued to non-employee Directors vested immediately.

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 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. 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

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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. At such times that any of these factors make it inadvisable to increase salaries or grant bonuses, 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.

Factors We Consider in Determining to Change Compensation Materially

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

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

How Amounts Realized from Past Compensation Affect Other Elements of Compensation

We are very aware that the vast majority of options granted to our executives are significantly out of the money and that they may remain so until we are able to obtain real access to the market. This is currently even true of the options issued pursuant to the Exchange Offer which occurred in November 2008, which, among its other purposes, was intended to rectify the fact that options were underwater. Accordingly, future compensation will likely continue to be dominated by base salary as well as periodic bonuses when possible.

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 Financial Accounting Standard (FAS) 123(R). We expense all of our option costs as we do the costs of salaries and 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 Hedging Stock Ownership

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 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.

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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. In the event that a proposal is affirmed, the proposal is then recommended to the entire Board of Directors for a vote unless the committee decides to act on its own initiative.

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.

The new 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 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 Consumer Price Index ("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.

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

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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 shall mean 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, 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.

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.

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If Shaw is terminated without cause and not at his implicit request, 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 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 percent or more of the total possible voting power of the stock of the Company (assuming the immediate conversion of all then outstanding convertible preferred stock) or (ii) the date a majority of members of the Board of Directors is replaced during any 12-month period by Directors whose appointment or election is not endorsed by a majority of the members of the Company's Board of Directors before the date of the appointment or election. 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 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 Shaw is entitled to salary through the date of termination, salary for 24 months, reimbursement of expenses and applicable benefits.

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

Mr. Shaw has agreed to a one-year non-compete, not to hire or attempt to hire employees for one year, and 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.

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 | | | | | |
|---------------------------------------|-------------|--------------------|------------------------------|------------------------------------|-------------------|
| Name and Principal Position | Year | Salary (\$) | Option Awards(1) (\$) | All Other Compensation (\$) | Total (\$) |
| Thomas J. Shaw | 2006 | 400,000 | | | 400,000 |

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| | | | | | |
|-------------------------------|------|---------|--------|----------|---------|
| President and CEO | 2007 | 400,000 | | 4,200(2) | 404,200 |
| (principal executive officer) | 2008 | 416,548 | | 4,600(2) | 421,148 |
| Douglas W. Cowan | 2006 | 290,130 | 58,372 | | 348,502 |
| Vice President, CFO | 2007 | 290,109 | 778 | 4,200(2) | 295,087 |
| (principal financial officer) | 2008 | 290,000 | 6,460 | 4,600(2) | 301,060 |
| Steven R. Wisner | 2006 | 290,000 | 8,367 | 6,750(3) | 305,117 |
| Executive Vice President, | 2007 | 290,000 | 758 | 4,200(2) | 294,958 |
| Engineering and Production | 2008 | 290,020 | 6,694 | 4,600(2) | 301,314 |
| Michele M. Larios | 2006 | 351,299 | 58,265 | | 409,564 |
| Vice President, | 2007 | 350,000 | 797 | 4,200(2) | 354,997 |

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| Name and Principal Position | Year | Salary (\$) | Option Awards(1) (\$) | All Other Compensation (\$) | Total (\$) |
|------------------------------------|-------------|------------------------|--------------------------------------|--|-----------------------|
| General Counsel | 2008 | 350,540 | 6,843 | 4,600(2) | 361,983 |
| Russell B. Kuhlman | 2006 | 132,593 | 36,615 | | 169,208 |
| Vice President, Sales | 2007 | 134,779 | 369 | 2,695(2) | 137,843 |
| | 2008 | 140,000 | 4,019 | 2,800(2) | 146,819 |

(1) The fair value of each option grant 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 percent; risk free interest rate of 4.89 percent; and an expected life of 9.0 years. No options were issued in 2005, 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.

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 percent; risk free interest rate of 2.83 percent; 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.

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

(3) This amount constitutes the excess market value of the underlying shares of an exercised stock option over the exercise price.

GRANTS OF PLAN-BASED AWARDS

The following Grants of Plan-Based Awards for 2008 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 2008

| Name | Grant Date | Estimated Future Payouts Under Equity Incentive Plan Awards Target #(1) | 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(2) |
|----------------|-----------------------|--|---|---|--|
| Thomas J. Shaw | | | | | |

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President and CEO
(principal executive officer)

| | | | | | |
|--|----------|--------|--------|------|----------|
| Douglas W. Cowan Vice President, CFO (principal financial officer) | 11/18/08 | 90,909 | 11,091 | 1.30 | \$77,752 |
|--|----------|--------|--------|------|----------|

| | | | | | |
|---|----------|--------|-------|------|----------|
| Steven R. Wisner Executive Vice President, Engineering and Production | 11/18/08 | 90,909 | 9,791 | 1.30 | \$76,761 |
|---|----------|--------|-------|------|----------|

| | | | | | |
|---|----------|--------|-------|------|----------|
| Michele M. Larios Vice President, General Counsel | 11/18/08 | 90,909 | 6,141 | 1.30 | \$73,978 |
|---|----------|--------|-------|------|----------|

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| Name | Grant Date | Estimated Future Payouts Under Equity Incentive Plan Awards Target # ⁽¹⁾ | 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 | 11/18/08 | 63,450 | | 1.30 | \$48,366 |

(1) These options were granted under the 2008 Stock Option Plan in exchange for other options pursuant to our Exchange Offer.

(2) The fair value of the new options issued under the Exchange Offer was determined utilizing the binomial model for pricing stock options. The incremental value of the new options over the tendered options was based on the difference between the grant date fair value of the new options and the fair value of the tendered options immediately before the exchange. The tendered options were valued using the binomial model. The incremental values are equal to the following: \$68,400 for Mr. Cowan; \$74,417 for Mr. Wisner; \$64,639 for Ms. Larios; and \$42,270 for Mr. Kuhlman.

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 in this Item 11 for terms of our only employment agreement in effect.

There was not a re-pricing of options or other award in the last fiscal year, but there was an exchange of options pursuant to our Option Exchange Plan, whereby we offered to exchange certain outstanding eligible options for new options, on the terms and subject to the conditions described in the Exchange Offer. The exercise price was arbitrarily chosen as the higher of: 1) the last sales price of our Common Stock as reported on the NYSE Alternext on the date of grant rounded to the next highest dime or 2) \$1.30. The options were exchanged on a two for one basis. The new options effectively restarted the ten year termination date, re-started a one-year vesting period, reduced the number of shares eligible for purchase by one half and reduced the exercise price to \$1.30.

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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, 2008.

| Name | Outstanding Equity Awards at 2008 Fiscal Year End | | | |
|---|---|---|----------------------------|------------------------|
| | Number of Securities Underlying Unexercised Options | Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Options | Option Exercise Price (\$) | Option Expiration Date |
| Thomas J. Shaw President, CEO (principal executive officer) | | (#)(1) | | |
| Douglas W. Cowan Vice President, CFO (principal financial officer) | 11,091 | 90,909 | 1.30 | 11/18/18 |
| Steven R. Wisner Executive Vice President, Engineering and Production | 9,791 | 90,909 | 1.30 | 11/18/18 |
| Michele M. Larios Vice President, General Counsel | 6,141 | 90,909 | 1.30 | 11/18/18 |
| Russell B. Kuhlman Vice President, Sales | | 63,450 | 1.30 | 11/18/18 |

1) These options will vest on November 18, 2009, 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

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 90% of their compensation, or the statutory prescribed limit, if less. We may, at our discretion, match employee contributions. We made matching contributions of approximately \$122,000 and \$111,000 in 2008 and 2007, respectively. There were no matching contributions in 2006. \$21,095 and \$19,600 of these matching contributions were to executive officers in 2008 and 2007, respectively.

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.

SUMMARY OF PAYMENTS UPON TERMINATION OR CHANGE IN CONTROL**ASSUMING OCCURRENCE AS OF DECEMBER 31, 2008(1)**

| Payment Triggering Event | Salary Through Trigger Event Date | Amounts Owed Under Benefit Plans(2) | Reimbursement of Expenses | Undiscounted Salary For a Period of 24 Months | Payment Equal to 90 Days Salary | Value of Payments(3) |
|--|--|--|----------------------------------|--|--|-----------------------------|
| Death | x | x | x | | | |
| Disability | x | x | x | 833,096 | | 833,096 |
| Termination With Cause | x | | x | | | |
| Termination Without Cause | x | x | x | 833,096 | | 833,096 |
| Resignation (Other Than After a Change in Control) | x | x | x | | 102,710 | 102,710 |
| Resignation (After a Change in Control) | x | x | x | 833,096 | | 833,096 |

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(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 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.

(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, 2008. 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 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:

DIRECTOR COMPENSATION TABLE FOR 2008

| Name(1) | Fees Earned or Paid in Cash (\$) | Option Awards (\$)(2) | All Other Compensation (\$) | Total (\$) |
|------------------|---|----------------------------------|--|-----------------------|
| Marco Laterza | \$3,500 | | | \$3,500 |
| Amy Mack | \$3,000 | | \$20,875(5) | \$23,875 |
| Marwan Saker | \$1,500 | \$30,780(3) | | \$32,280 |
| Clarence Zierhut | \$3,500 | \$9,500(4) | | \$13,000 |

(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.

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(2) These options were issued in exchange for older stock options pursuant to the Exchange Offer. The incremental fair value of such options as of the exchange date was \$29,858 and \$8,590 for Marwan Saker and Clarence Zierhut, respectively. After the exchange of options under this offer the aggregate number of option awards and awards outstanding for Messrs. Saker and Zierhut as of December 31, 2008, was 40,500 and 12,500, respectively. Such awards authorized the purchase of 40,500 and 12,500 shares of Common Stock for Messrs. Saker and Zierhut, respectively.

(3) The grant date fair value of these options is \$0.76 for each option. Mr. Saker has options for the purchase of 40,500 shares of Common Stock outstanding as of December 31, 2008.

(4) The grant date fair value of these options is \$0.76 for each option. Mr. Zierhut has options for the purchase of 12,500 shares of Common Stock outstanding as of December 31, 2008.

(5) Ms. Mack's company was paid these funds for participating in clinical trials in 2008.

Narrative Explanation of Director Compensation Table for 2008

In 2008 we paid each non-employee Director a fee of \$500 per meeting and reimbursed travel expenses. In the past, we have granted to each Director (except Mr. Shaw) stock options for Common Stock. Mr. Laterza and

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Ms. Mack have also not yet been granted options. We do not pay any additional amounts for committee participation or special assignment.

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 the **Compensation Pursuant to Employment Agreement**, set forth above for an in depth summary of the terms of such agreement.

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 at the time of their service on the committee 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 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 402, has recommended to the Board of Directors that the COMPENSATION DISCUSSION AND ANALYSIS be included in this report.

CLARENCE ZIERHUT
MARCO LATERZA
AMY MACK

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, 2008:

Equity Compensation Plan Information

| Plan category | Number of securities to be issued upon exercise of outstanding options, warrants and rights (a) | Weighted average exercise price of outstanding options, warrants and rights (b) | Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column(a)) (c) |
|--|--|--|---|
| Equity compensation plans approved by security holders | 1,286,963 | \$3.40 | 2,037,317 |
| Equity compensation plans not approved by security holders* | 225,000 | \$6.90 | |
| Total | 1,511,963 | \$3.92 | 2,037,317 |

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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.

In connection with a Consulting Agreement with International Export and Consulting, we issued an individual option plan for the purchase of 61,000 shares of Common Stock to Marwan Saker. The option was exercisable at \$10.00 and would have expired in 2010. This option was exchanged for options issued under the 2008 Stock Option Plan which was approved by the shareholders.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS

The following table sets forth certain information regarding the beneficial ownership of our capital stock as of March 2, 2009, for each person known by us to own beneficially 5 percent 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.

| Title of Class | Name and Address of Beneficial Owner | Amount and Nature of Beneficial Ownership | Percent of Class(1) |
|-----------------------|---|--|----------------------------|
| Common Stock | Thomas J. Shaw(2) 511 Lobo Lane P.O. Box 9 Little Elm, TX 75068-0009 | 11,380,000 | 47.6%(2) |
| | Suzanne M. August(3) 5310 Buena Vista Drive Frisco, TX 75034 | 2,800,000 | 11.7%(3) |
| | Lillian E. Salerno(4) 432 Edwards Lewisville, TX 75067 | 2,243,500 | 9.4% |
| | Signia Capital Management, LLC(5) 108 N. Washington St., Ste. 305 Spokane, Washington 99201 | 1,941,861 | 8.1% |
| | | 1,273,600 | 5.3% |

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Lloyd I. Miller, III(6)
4550 Gordon Drive
Naples, FL 34102

Class B Stock

| | | |
|--------------------|--------|------|
| Thomas J. Shaw | 80,000 | 3.5% |
| Lillian E. Salerno | 12,500 | 1% |

(1) The percentages of Common Stock are based on 23,892,564 shares of Common Stock equivalents consisting of 23,800,064 shares of Common Stock outstanding and 92,500 shares of Preferred Stock convertible by the above persons within 60 days of this report. The percentages of Class B Stock are based on 2,285,266 shares of Class B Stock outstanding.

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(2) 80,000 of the shares identified as Common Stock are preferred shares which are eligible for conversion into Common Stock within 60 days of this report. 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 Common Stock equivalents and 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. See footnote 2 for a more detailed explanation. Accordingly, they are also included in the Common Stock equivalents and percentages for Thomas Shaw in the above table.

(4) 12,500 of the shares identified as Common Stock are Class B preferred shares which are eligible for conversion into Common Stock within 60 days of this report.

(5) The number of shares held by this entity was obtained from a Schedule 13G/A filed on February 13, 2009. Pursuant to the Schedule 13G/A, Signia Capital Management, LLC has sole voting power for 512,122 of the shares and sole dispositive power for a total of 1,941,861 shares (inclusive of the sole voting power shares).

(6) The number of shares held by this entity was obtained from a Schedule 13G filed on January 30, 2009. Pursuant to the Schedule 13G, Lloyd I. Miller has sole voting and dispositive power for 208,300 of the shares, and shared voting and dispositive power for 1,065,300 shares.

SECURITY OWNERSHIP OF MANAGEMENT AND DIRECTORS

The following table sets forth certain information regarding the beneficial ownership of our capital stock as of March 2, 2009, for each Named Executive Officer (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.

| Title of Class | Name of Beneficial Owner | Amount and Nature of Beneficial Ownership | Percent of Class(1) |
|----------------|--|--|------------------------|
| Common Stock | | | |
| As a Group | Named Executive Officers and Directors | 12,188,200 | 49.4% |
| As Individuals | Thomas J. Shaw(2) | 11,380,000 | 46.2% |
| | Marwan Saker(3) | 395,500 | 1.6% |
| | Clarence Zierhut(4) | 22,500 | <1% |
| | Douglas W. Cowan(5) | 102,000 | <1% |
| | Steven R. Wisner(6) | 105,700 | <1% |
| | Russell B. Kuhlman(7) | 64,450 | <1% |

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| | | | |
|----------------|------------------------|---------|-------|
| | Michele M. Larios(8) | 108,050 | <1% |
| | Marco Laterza | 10,000 | <1% |
| | | | |
| Class B Stock | | | |
| As a Group | Officers and Directors | 435,000 | 19.0% |
| As Individuals | Thomas J. Shaw | 80,000 | 3.5% |
| | Marwan Saker | 355,000 | 15.5% |

(1) The percentages of Common Stock are based on 24,651,264 shares of Common Stock equivalents consisting of 23,800,064 shares of Common Stock outstanding; 435,000 shares of Preferred Stock convertible by the above persons and options for the purchase of 416,200 shares of Common Stock obtainable by the above persons within 60 days of this report. The percentages of Class B stock are based on 2,285,266 shares of Class B Stock outstanding.

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(2) 80,000 of the shares identified as Common Stock are preferred shares which are eligible for conversion into Common Stock within 60 days of this report. 2,800,000 of the shares are Common Stock shares 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 Common Stock equivalents and percentages in the above table.

(3) 355,000 shares identified as Common Stock are preferred shares which are eligible for conversion into Common Stock within 60 days of this report. 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 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 40,500 shares identified as Common Stock are shares obtainable through the exercise of options held by Mr. Saker within 60 days of this report.

(4) 12,500 of these shares identified as Common Stock are shares acquirable by the exercise of stock options within 60 days of this report.

(5) These shares identified as Common Stock are shares acquirable by the exercise of stock options within 60 days of this report.

(6) 100,700 of these shares identified as Common Stock are shares acquirable by the exercise of stock options within 60 days of this report.

(7) 63,450 of these shares identified as Common Stock are shares acquirable by the exercise of stock options within 60 days of this report.

(8) 97,050 of these shares identified as Common Stock are shares acquirable by the exercise of stock options within 60 days of this report.

There are no arrangements, the operation of which would result in a change in control of the Company, other than the fact that Ms. August's shares shall cease to be controlled by Mr. Shaw under their Voting Agreement upon their sale to a third party.

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

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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 who beneficially owned 35.7 percent of the outstanding Common Stock (and controlled another 11.8 percent pursuant to a Voting Agreement with Ms. Suzanne August) as of July 28, 2008, 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. In addition, Mr. Shaw and Ms. August, together, receive an aggregate 5 percent royalty on gross sales of all licensed products sold to customers over the life of the Technology Licensing Agreement. A royalty of \$2,166,585 and \$1,471,046 was paid in 2008 and 2007, respectively. Royalties of \$620,987 were paid through February 10, 2009.

We have an oral consulting agreement with MediTrade International Corporation, a company controlled by Ms. Lillian Salerno, a shareholder who ceased to be a 10% shareholder in 2008. It is paid \$7,500 per month plus expenses. In 2008 and 2007, it was paid aggregate consideration of \$98,401 and \$129,618, respectively.

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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 Alternext. Our current independent Directors are Messrs. Clarence Zierhut, Marwan Saker, and Marco Laterza, and Ms. Amy Mack.

The Board of Directors, in reviewing the independence of its members, further considered the fact that we paid Ms. Mack's company \$4,500 in 2007 and \$20,875 in 2008 for conducting clinical trials. The Board of Directors determined that her independence was not compromised by such transactions.

Item 14. Principal Accounting Fees and Services.

AUDIT FEES

The aggregate fees billed by CF & Co. for professional services rendered for the audit of our annual financial statements for 2008 and 2007 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 \$195,700 and \$174,583, respectively.

AUDIT RELATED FEES

The aggregate fees billed by CF & Co. for professional services rendered for the audit of our 401(k) plan for 2008 and 2007 were \$11,500 and \$13,500, respectively.

TAX FEES

The aggregate fees billed by CF & Co. for preparation of federal and state income tax returns and tax consulting costs related to notices from taxing authorities for 2008 and 2007 were \$91,520 and \$149,291, respectively.

PRE-APPROVAL POLICIES AND PROCEDURES

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The engagement of CF & Co. was entered into pursuant to the approval policies and procedures of the Audit Committee. Before CF & Co. 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, 2008, 2007, and 2006:

| | Balance at beginning of period | Additions | Deductions | Balance at end of period |
|---|---|------------------|-------------------|-------------------------------------|
| Provision for Inventories Fiscal year ended 2006 | \$ 111,296 | \$ | \$ 61,296 | \$ 50,000 |

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| | Balance at beginning of period | | Additions | | Deductions | | Balance at end of period |
|---|---|----|------------------|----|-------------------|----|-------------------------------------|
| Fiscal year ended 2007 | \$ 50,000 | \$ | 155,600 | \$ | | \$ | 205,600 |
| Fiscal year ended 2008 | \$ 205,600 | \$ | | \$ | | \$ | 205,600 |
| Provision for Accounts Receivables | | | | | | | |
| Fiscal year ended 2006 | \$ 267,174 | \$ | | \$ | 180,144 | \$ | 87,030 |
| Fiscal year ended 2007 | \$ 87,030 | \$ | 166,978 | \$ | | \$ | 254,008 |
| Fiscal year ended 2008 | \$ 254,008 | \$ | 245,958 | \$ | | \$ | 499,966 |
| Deferred Tax Valuation | | | | | | | |
| Fiscal year ended 2006 | \$ 99,280 | \$ | 541,143 | \$ | | \$ | 640,423 |
| 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 |
| Provision for Rebates | | | | | | | |
| Fiscal year ended 2006 | \$ 2,443,960 | \$ | 20,329,974 | \$ | 20,061,184 | \$ | 2,712,750 |
| 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 |

(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

| Exhibit No. | Description of Document |
|------------------------|--|
| 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** |
| 3(ii) | Third Amended and Restated Bylaws of RTI*** |
| 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***** |
| 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**** |

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| Exhibit No. | Description of Document |
|------------------------|---|
| 10.8 | First Amendment to 1999 Stock Option Plan |
| 10.9 | Retractable Technologies, Inc. 2008 Stock Option Plan |
| 23 | Consent of Independent Registered Public Accounting Firm |
| 24 | Power of Attorney |
| 31.1 | Certification of Principal Executive Officer |
| 31.2 | Certification of Principal Financial Officer |
| 32 | Section 1350 Certifications |
| * | 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 |
| | Filed herewith |
| | 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 |
| (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, 2009

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, 2009

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

March 31, 2009

/s/ Clarence Zierhut
Clarence Zierhut
Director

March 31, 2009

/s/ Amy Mack
Amy Mack
Director

March 31, 2009

/s/ Marco Laterza

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Marco Laterza
Director

March 31, 2009

*
Marwan Saker
Director

March 31, 2009

* By: /s/ Marco Laterza
Marco Laterza
Attorney-in-fact