

RETRACTABLE TECHNOLOGIES INC

Form 10KSB/A

September 14, 2004

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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**Form 10KSB-A**  
**Amendment No. 1**

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(Mark One)

**ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2003

**TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 000-30885

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**Retractable Technologies, Inc.**

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(Name of small business issuer in its charter)

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

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

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

**75068-0009**  
(Zip Code)

Issuer's telephone number (972) 294-1010

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**Securities registered under Section 12(b) of the Exchange Act:**

<b>Title of each class</b>	<b>Name of each exchange on which registered</b>
<b>Common</b>	<b>The American Stock Exchange</b>

**Securities registered under Section 12(g) of the Exchange Act:**

**Preferred Stock**

(Title of Class)

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Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 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 .

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B contained in this form and no disclosure will be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10KSB-A or any amendment to this Form 10KSB-A.

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State issuer's revenues for its most recent fiscal year. \$19,078,332

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 sold, or the average bid and asked price of such common equity, as of a specified date within the past 60 days. (See definition of affiliate in Rule 12b-2 of the Exchange Act.) The aggregate market value of the common equity held by non-affiliates is \$51,762,599 which was computed with reference to the closing price as of August 2, 2004.

**(ISSUERS INVOLVED IN BANKRUPTCY PROCEEDINGS DURING THE PAST FIVE YEARS)**

Check whether the issuer has filed all documents and reports required to be filed by Section 12, 13, or 15(d) of the Exchange Act after the distribution of securities under a plan confirmed by a court. Yes  No

**(APPLICABLE ONLY TO CORPORATE REGISTRANTS)**

State the number of shares outstanding of each of the issuer's classes of common equity, as of the latest practicable date. As of August 2, 2004, there were 22,580,679 shares of our Common Stock issued and outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

None except exhibits

Transitional Small Business Disclosure Format (Check one): Yes  No

**EXPLANATORY NOTE**

This Amendment No. 1 to the Annual Report on Form 10-KSB of Retractable Technologies, Inc. (the Company) for the fiscal year ended December 31, 2003 is being filed primarily for the purpose of amending and revising Items 3 (Legal Proceedings), 6 (Comparison of Year Ended December 31, 2003 and Year Ended December 31, 2002 and Significant Accounting Policies), and 7 (Summary of Significant Accounting Policies and Notes 13 and 14).

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In connection with a Peer Review request of the Company's independent accountant, the Company is amending its Annual Report on Form 10-KSB to provide additional information concerning the aggregate payments to the Company and its attorneys resulting from the settlement agreements entered into with Premier Inc.; Premier Purchasing Partners, L.P.; VHA, Inc.; Novation, L.L.C.; Tyco International (US) Inc.; and Tyco Healthcare Group L.P. (the GPO Settlements) as well as certain additional consideration to be received under the GPO Settlements relating to the facilitation of the sale of the Company's products to Premier and Novation member facilities.

This Form 10KSB-A has also been updated to reflect material events that have occurred subsequent to March 31, 2004, including, but not limited to, our settlements with Becton Dickinson and Company, Inc. and New Medical Technology, Inc. and affiliates.

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**PART I**

**Item 1. Description of Business**

BUSINESS DEVELOPMENT

General Description

We design, develop, manufacture, and market innovative patented safety needle devices for the healthcare industry. Our VanishPoint® products utilize a unique friction ring mechanism patented by Thomas J. Shaw, our Founder, President, and Chief Executive Officer. VanishPoint® 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 tube holder. Advantages of our products include protection from needlestick injuries, prevention of cross contamination through reuse, and reduction of disposal and other associated costs. Federal regulation now requires the use of safe needle devices. We have an exclusive license from Thomas J. Shaw, our President and Chief Executive Officer, for the patent rights for our safety needle products.

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 to expire 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 Mr. Shaw a \$500,000 initial licensing fee and a 5 percent royalty on gross sales after returns of Licensed Products. See Patents and Proprietary Rights for a more detailed discussion. Our goal is to become a leading provider of automated retraction safety devices.

Development of the Company

While owning and operating Checkmate Engineering, a sole proprietorship, Thomas J. Shaw, our President and Chief Executive Officer, developed and patented the idea and early prototypes of the syringe that were to become the VanishPoint® safety syringe. On May 9, 1994, the Company was incorporated in Texas to design, develop, manufacture, and market medical safety devices for the healthcare industry. In April 1995, Mr. Shaw, who owned all 1,000 of the then issued and outstanding shares of the Common Stock, exchanged all 1,000 shares then outstanding for 14,000,000 shares of Common Stock. In May 1996, Mr. Shaw transferred 2,800,000 shares of the 14,000,000 then issued and outstanding Common Stock to Lillian E. Salerno, a former Director.

We received our ISO 9001:1994 recertification in July 1998, and the VanishPoint® syringe received its CE Mark on July 31, 1998. In July 2001, we received re-certification to ISO 9001:1994 and the CE Mark. In March of 2004, we received certification to ISO 13485:2003. This standard replaces the ISO 9001:1994 for Quality Management Systems. The 13485:2003 standard is a model created by the International Organization for Standardization (ISO), an international agency consisting of almost 100 member countries that provides guidance in the development and

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implementation of an effective quality management system through a series of five international standards. This model is used by organizations to certify their quality system from initial design and development of a desired product or service through production, installation, and servicing. The CE mark allows us to sell our products in Europe.

We have been manufacturing and marketing our products into the market place since 1997. In May 2000 we signed a national marketing and distribution agreement with Abbott Laboratories. We terminated this agreement in October 2003. Our products have been and continue to be distributed nationally through numerous distributors. However, we have been blocked from access to the market by

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exclusive marketing practices engaged in by Becton Dickinson and Company, Inc. ( BD ) who dominates our market. As a result of the anticompetitive practices of BD we entered into litigation as discussed in **Item 3. Legal Proceedings** and Notes 13 and 14 of the financial statements. This litigation resulted in settlements with all parties.

We continue to attempt to gain access to the market through our sales efforts and our innovative technology. 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 greatly improve our manufacturing capacity and efficiency, thereby reducing our unit cost.

We have not been involved in any bankruptcy or similar proceedings and have not merged or consolidated a significant amount of assets other than in the ordinary course of business except as discussed above.

## BUSINESS OF RTI

### Principal Products

Our products with Notice of Substantial Equivalence to the FDA include 1cc tuberculin, insulin, and allergy antigen VanishPoint® syringes; 3cc, 5cc, and 10cc VanishPoint® syringes; and the VanishPoint® blood collection tube holder and small tube adapter. Our products (without Notice of Substantial Equivalence to the FDA) also include a dental syringe, a full displacement syringe, a butterfly IV, and a self retracting IV catheter introducer. From 1999 to 2001 and in 2003 ECRI (formerly known as the Emergency Care Research Institute), a recognized authority in evaluating medical devices, awarded the VanishPoint® syringe and blood collection tube holder its highest possible rating. The VanishPoint® blood collection tube holder received Risk and Insurance magazine's 1997 Top of the Line Award for excellence.

Our 1cc VanishPoint® tuberculin, insulin, and allergy antigen syringes which reached the market in the first quarter of 2001, are being produced in various needle lengths and gauges and packaging styles. The 3cc VanishPoint® syringe reached the market in the first quarter of 1997. It is available in various needle lengths and gauges. The 5cc and 10cc VanishPoint® syringes are being produced in various needle lengths and gauges and are currently being sold in limited quantities.

The manufacture and sale of medical devices entails an inherent risk of liability in the event of product failure or claim of harm caused by the product's operation. In March, 1998, the Journal of Healthcare Safety, Compliance and Infection Control published a survey of 26 medical facilities having used a total of 86,000 3cc syringes, during which no needlestick injuries from using the VanishPoint® syringes were reported.

### Market Overview



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The VanishPoint® syringe and needle device products are sold to and used by healthcare providers (primarily in the United States with limited 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.

The syringe and needle device market continues to be a market in transition. The nature of the products comprising the market is 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 and 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 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.

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#### 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 purchase 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. According to *The Role of Group Purchasing Organizations in the US Health Care System*, a report prepared by Muse & Associates for the Health Industry Group Purchasing Association ( HIGPA ), the potential hospital marketplace for medical/surgical equipment and supplies in 1998 and 1999 was \$32.8 billion and \$34.1 billion, respectively. HIGPA and other industry representatives estimate that 80 percent of these hospital expenditures were channeled through GPOs. 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 distribute our products throughout the United States 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 syringes and blood collection tube holders. Our marketers make contact with all of the departments that affect the decision-making process for safety products, including the purchasing agents. They call on alternate care sites and talk directly with the decision-makers of the facility. 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 tradeshows and publications of relevant articles in trade journals and magazines. These nurses provide clinical support to customers. In addition to marketing our products, the network demonstrates the safety and cost effectiveness of the VanishPoint® automated retraction products to customers.

We have numerous agreements with organizations for the distribution of our products in foreign markets. Sales to these markets are limited at this time, as the marketing efforts are in their early stages. The total population of Western Europe exceeds 310 million, and the recognition for the urgency of safe needle devices in parts of Europe has echoed 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 and Africa are also recognizing the need for our products. We currently are pursuing marketing opportunities within these areas.

Key components of our strategy to increase our market share are to: (a) continue marketing emphasis in the U.S. which has implemented the requirements outlined by safe needle legislation; (b) continue to add Veterans Administration facilities, health departments, emergency medical services, federal prisons, long-term care and home healthcare facilities as customers; (c) 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 VanishPoint® products; (d) supply product through GPOs and Integrated Delivery Networks where possible; (e) explore possibilities for future licensing agreements and joint venture agreements for the manufacture and distribution of safety products in the United States and abroad; (f) introduce new products; (g) focus on methods of upgrading our manufacturing capability and efficiency in order to enable us to offer products at a reduced price, and (h) continue to increase international sales, particularly in Europe, where safety legislation appears to be moving parallel to the United States, with a one to two-year lag time.

#### Status of Publicly Announced Products

We have patented and are in the process of developing additional safety needle products. Such products include a dental syringe, winged butterfly IV, and a catheter introducer. Our limited access to the market has slowed the introduction of these products into the market.



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#### Competition

We believe VanishPoint® syringes continue to be the most effective safety syringes in today's market. Our syringes include passive safety activation, require less disposal space, and are activated while in the patient.

Founded in 1897, BD is headquartered in New Jersey. BD's safety-engineered syringe and needle products sales accounted for approximately 14.2 percent of BD's total 2002 sales. BD currently manufactures the SafetyLok® syringe that utilizes a tubular plastic sheath that must be manually slid over the needle after an injection, and the SafetyGlide, a syringe which utilizes a hinged lever to cover the needle tip. BD also manufactures a safety blood collection tube holder that utilizes the SafetyLok sheath. BD's Vacutainer® blood collection tube holder is commonly used as industry jargon to refer to blood collection tube holders in general. BD has begun manufacture of a 3cc retracting needle product based on a license agreement with Med-Design. The impact of BD's new Integra syringe is yet to be determined. However, at this time, it does not offer a full product line and cannot be used with highly viscous medication due to leakage (as described on their labels).

Sherwood was acquired by Tyco International Ltd., a company headquartered in Bermuda. Sherwood manufactures the Monoject®, a safety syringe that utilizes a sheath similar to the BD SafetyLok syringe.

Founded in 1974, Terumo was the first company to sell disposable syringes in Japan. Today Terumo manufactures standard syringes and blood collection tube holders, operates internationally, and has sales in some 120 countries.

Both BD's SafetyLok and Sherwood'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. 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 Sherwood have controlling 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 with GPOs described earlier. The current conditions have restricted competition in the needle and syringe market. As a result, we filed a lawsuit in the United States District Court for the Eastern District of Texas against BD and certain GPOs which resulted in settlements with all parties. See **Item 3. Legal Proceedings**. 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 and our innovative technology. 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 greatly improve our manufacturing capacity and efficiency, thereby reducing our unit cost.

In addition to BD and Sherwood, there are companies that manufacture needlestick injury prevention products that our products will compete against for market share. Among those companies are: Bio-Plexus, Inc. ( Bio-Plexus ), Smiths Industries Medical Systems ( SIMS ), and Sterimatic, Ltd. Bio-Plexus utilizes a recessed internal hollow blunt safety technology where the internal blunt is advanced and locked into place beyond the sharp outer tip of the needle. SIMS utilizes a patented sheath whereupon completion of the procedure, the healthcare worker presses the sheath against a hard surface to lock the needle into the sheath. Sterimatic, Ltd. manufactures a syringe with a plastic sleeve that covers the

needle after injection.

Our competitive strengths include that the VanishPoint® syringe is one of four syringes given the highest possible rating by ECRI (formerly Emergency Care Research Institute). Our blood collection tube

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holder is one of only two safety products given the highest possible rating. Our 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 dramatically increased by legislation encouraging the use of safety syringes. Outsourcing arrangements such as our agreement with Double Dove could increase our manufacturing capacity with little or no capital outlay and provide a competitive cost. Marketability of our products could depend, in part, on our ability to meet a dramatic and sudden increase in demand and on our ability to quickly find additional production capacity through licensing agreements and joint ventures, the purchase of appropriate facilities, or manufacturing and storage services.

Our competitive weaknesses include our current lack of market share (less than 1 percent) because three well-established companies control most of the 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 is higher. However, 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. Demand for our products could decrease due to the introduction of the Integra, a retractable syringe by BD, which dominates the market, and has a wider range of product offerings, and more capital resources.

### Principal Suppliers and Sources 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. Our suppliers include Magor Mold, Inc., APEC, Multivac, Inc., Exacto Spring Corporation, Ion Beam Applications, Inc. (IBA, formerly Sterigenics), and Nipro Corporation and ISPG. We have begun to receive shipment of product under our agreement with Double Dove, a Chinese manufacturer.

### Dependence on Major Customers

Abbott purchases comprised 43.8 percent and 22.4 percent of our unit sales in 2002 and 2003, respectively. Unit sales to distributors other than Abbott were 56.2 percent and 77.6 percent of sales in 2002 and 2003, respectively. The agreement with Abbott to market into the U.S. acute care market was terminated in 2003. The Company now utilizes its other distributors to supply that market.

Two other distributors each accounted for 10% or more of our unit sales and 24.7 percent in the aggregate in 2003.

### Patents and Proprietary Rights

Thomas J. Shaw and the Company entered into a Technology License Agreement dated effective as of the 23<sup>rd</sup> day of June, 1995, 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

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unassembled, which comprise an invention described in Licensed Patents , and improvements thereof including any and all Products which employ the inventive concept disclosed or claimed in the Licensed Patents .

In exchange, we paid Mr. Shaw a \$500,000 initial licensing fee which was fully paid in 1997. Furthermore, we agreed to pay a 5 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 wife.

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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 have sought foreign patent protection through the Patent Cooperation Treaty and have filed applications for regional and national patent protection in selective countries. In addition, we have filed applications for national patents in selective countries where we believe the VanishPoint® syringe can be utilized most.

We hold numerous United States patents related to our automated retraction technology, including patents for dental syringes, catheter introducers, winged IV sets, syringes, and blood collection tube holders. In addition, we have multiple applications for patents currently pending.

We have also registered the following trade names and trademarks: VanishPoint®, VanishPoint® logos, RT with a circle mark, the Spiral Logo used in packaging our products, and the color coded spots on the ends of our syringes. We also have applications pending for trademark protection for the phrase the new standard for safety.

There are currently no patent infringement claims pending against the VanishPoint® retraction technology. 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.

### Regulatory Status and Effect of Regulation

We and our products are regulated by the FDA. The syringe is a Class II medical device which requires assurance by the manufacturer that the device is safe and effective and that it meets certain performance standards. The FDA issued its Notice of Substantial Equivalence declaring the VanishPoint® syringe products to be substantially equivalent to a legally marketed predicate device (i.e., granted us permission to market our safety syringes in interstate commerce) for the 3cc VanishPoint® syringe in December 1995; for the 5cc and 10cc VanishPoint® syringes in May 1997; for the 1cc allergy and insulin syringes in November 1997; for the 1cc VanishPoint® tuberculin syringe in February 1998; and for the VanishPoint® blood collection tube holder and small tube adapter in August 1997.

In addition to the Notice of Substantial Equivalence, we must register with the FDA on an annual basis and provide the FDA with a list of commercially distributed products. Texas has similar registration requirements. The FDA tries to inspect all medical device manufacturing facilities at least once every two years to determine the extent to which they are complying with Quality System Regulation. The most recent inspection occurred in July 2003 after which the auditor determined No Action Indicated.

RWTUV-USA, a subsidiary of TUV Essen Germany, performs our quality management system certification. We were originally certified to ISO 9001:1994 in 1997 and received annual surveillance audits, maintaining that certification until March of 2004 with no major non-conformances. We received certification to ISO 13485:2003 in March of 2004. In addition, the VanishPoint product line was certified for a CE Mark by RWTUV. The CE Mark authorizes us to sell in the European Union. RWTUV performs annual surveillance audits to ensure our compliance with ISO 13485:2003 and the Medical Device Directive, 93/42/EEC.



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 the safety syringe can be made widely available to the public. However, the funding

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was only used to develop and patent the earlier syringe design as of 1991. That syringe was a bulkier, less effective, and more expensive version of the current product. Accordingly and on the advice of counsel, Management believes that the risk of the government demanding manufacture of this alternative product is minimal.

### Research and Development

We spent \$337,930 and \$561,135 in fiscal 2002 and 2003, respectively, on research and development. The \$561,135 was spent primarily on consulting for research samples and experimental parts and increased compensation costs. Our ongoing research and development activities are performed by an internal research and development staff. This team of engineers developed automated line assembly for the syringe and blood collection tube holder and established processes to meet regulatory requirements. Products currently in development by our internal team include the winged butterfly IV, the catheter introducer, and the dental syringe. Our limited access to the market has slowed the introduction of these products into the market. Possible future products include all needle medical devices to which the automated retraction mechanism can be applied.

### 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 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 to Penn Tex Plastics for recycling. The Company also grinds 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 American 3CI.

### Employees

As of August 18, 2004, we had 160 full-time employees, two part-time employees, and one independently contracted consultant. Of the 160 full-time employees, five persons were engaged in research and development activities, 70 persons were engaged in manufacturing and engineering, 28 persons were engaged in quality assurance and regulatory affairs, 22 persons were engaged in sales and marketing, 34 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 key management and technical personnel, and the loss of services of one or more key employees could have a material adverse effect on us. Our President and Chief Executive Officer, Thomas J. Shaw, has an employment contract that ended on September 2002 with an automatic and continuous renewal for consecutive two-year periods.

**Item 2. Description of Property**

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 building is a modular portion of a larger planned building for which the engineering design has been finalized. The headquarters are in good condition and house our administrative offices and manufacturing facility. Our current expansion plans do not include going outside the 35 acres on which the headquarters is located. The Board of Directors has authorized the expenditure of \$2 million for the construction of a warehouse.

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The Company has received a loan from 1<sup>st</sup> International Bank ( "1 International " ) for \$2,500,000 (the "New Loan " ) which will provide funding for the construction. The initial proceeds from the loan were used to pay off the remaining \$475,000 of the revolving credit agreement with 1<sup>st</sup> International and fund the new warehouse and related infrastructure. Payments on the new note will be interest only during the first twelve months. Afterwards, payments will be based on a twenty-year amortization with a five year maturity. Interest rates will be based on the amount of funds kept on deposit with the bank. Accordingly, interest will vary from the WSJPR to the WSJPR plus 1 percent, with floors that may range from 4.25 percent to 6.50 percent. Compensating balances at 1<sup>st</sup> International affecting the interest rate will range from \$0 to \$500,000.

A 45,000 square foot warehouse is under construction at an estimated cost of approximately \$2.5 million which was funded by a loan from 1<sup>st</sup> International. Additional capital expenditures may include additional assembly lines, manufacturing space, warehousing and related infrastructure. The expansion could include those products that have been developed but not yet marketed, as well as expanding manufacturing capacity for existing products.

We also lease Suites 618, 620, 622, and 628 S. Mill Street, Lewisville, Texas, as well as storage stalls located at 102 E. Purnell, Lewisville, Texas, from Mill Street Enterprises, a sole proprietorship owned by Lillian E. Salerno, a 10 percent shareholder and consultant to the Company. This lease is for over 4,000 square feet of office space in good condition. The lease is for a five-year period beginning in July 2002 at a monthly rate of \$2,900. This space is used to store office documents and for general office and marketing purposes.

In the opinion of Management, all the properties and equipment are suitable for their intended use and are adequately covered by an insurance policy which lists Balboa Capital, American Express, GE Capital Modular Space, Fleet Capital, and 1<sup>st</sup> International as the loss payees.

We do not hold any real estate or related securities for investment purposes or engage in real estate activities. It is not our policy to acquire assets primarily for possible capital gain or for income.

### **Item 3. Legal Proceedings**

#### Antitrust Suit

On January 29, 2001, we filed a lawsuit in the United States District Court for the Eastern District of Texas, Texarkana Division styled *Retractable Technologies, Inc. v. Becton Dickinson & Company ( "BD " ), Tyco International (U.S.), Inc., Tyco Healthcare Group, L.P., Novation, L.L.C., VHA, Inc., Premier, Inc., and Premier Purchasing Partners, L.P.*, Cause No. 501CV036. We alleged violations of state and federal antitrust acts, tortious interference with prospective business relationships, business disparagement, and common law conspiracy. These violations were based on our belief that the defendants combined or conspired to eliminate or lessen competition and to acquire and maintain monopoly power among hospitals and healthcare technology providers. We were seeking the following damages: an injunction enjoining the defendants from continuing the unlawful conduct alleged and from entering into any other combination, conspiracy, or agreement having similar purposes or effect and for actual damages, punitive damages, treble damages, costs of suit including reasonable attorneys' fees, pre-judgment and post-judgment interest at the maximum possible rate, and such other relief as we were entitled.

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In the second quarter of 2003 the Company reached settlement agreements with Premier Inc.; Premier Purchasing Partners, L.P.; VHA, Inc.; Novation, L.L.C.; Tyco International (US) Inc.; and Tyco Healthcare Group L.P. in the Antitrust Lawsuit. As part of the settlements, the litigation against Premier, VHA, Novation, and Tyco has been dismissed.

Although specific terms are confidential, the agreements include cash payments and other financial consideration as well as provisions that are intended to facilitate the sale of our VanishPoint® products to Premier and Novation member facilities. In exchange for the settlement provisions, we have agreed to give up our claims against these companies.

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The initial cash payment of \$29,125,000 was paid in 2003. The total cash payment in April 2004 was \$14,125,000.

The Company received net cash payments of \$13,879,511 and \$8,051,250 from the cash payments above in 2003 and 2004, respectively. These proceeds were net of attorneys' fees, court costs, legal expenses, and amounts paid to Mr. Shaw.

Pursuant to a Covenant Not to Sue agreement entered into on September 19, 2001, between the Company and Thomas J. Shaw, individually, Mr. Shaw received \$728,609 of the initial cash payment in 2003 and \$423,750 of the cash payment in 2004.

The total attorneys' fees, court costs, and legal expenses were \$14,516,880 paid in May 2003, \$4,250,000 paid in December 2003 and \$5,650,000 paid in April 2004.

As part of the settlement agreements, a discount reimbursement program of \$8,000,000, which is net of legal fees, was established whereby the Company shall be provided quarterly reimbursements for certain discounts given to participating facilities. The Company will offer certain discounts to participating facilities and will be reimbursed for such discounts. The Company received \$10,132 and \$21,254 in the first quarter and second quarter of 2004, respectively, under this program. These payments are recognized upon delivery of products provided collection is reasonably assured.

The case against BD had been rescheduled for a July 6, 2004, trial date. Effective July 2, 2004, we entered into a Settlement Agreement and Release with BD (the Settlement Agreement). Pursuant to the Settlement Agreement, BD was obligated to deliver within two (2) business days, One Hundred Million Dollars (\$100,000,000.00) into the registry of the Court. This amount was received on July 7, 2004. The Company received \$65.1 million of the proceeds which is net of attorneys' fees and expenses estimated not to exceed \$31.5 million and \$3.4 million to be paid to Thomas J. Shaw, President and Chief Executive Officer, under a Covenant not to Sue.

### Patent Infringement Suit

On February 1, 2002, we filed a patent infringement lawsuit alleging willful and intentional infringement of two patents directed to syringes having retractable needles in the United States District Court for the Eastern District of Texas, Sherman Division, styled *Retractable Technologies, Inc. and Thomas J. Shaw v. New Medical Technology, Inc.; New Medical Technology, Ltd.; and NMT Group PLC*, Cause No. 4:02-CV-34 (the Infringement Lawsuit). The defendants counterclaimed, alleging noninfringement and invalidity of the patents. On February 18, 2003, we and Thomas J. Shaw filed an additional complaint against the same defendants, alleging infringement of a third syringe patent. The two actions were consolidated and the trial was set for June of 2004.

Effective as of April 27, 2004, we and Thomas J. Shaw entered into a Settlement Agreement and Release (the NMT Settlement Agreement) with New Medical Technology, Inc.; New Medical Technology, LTD. and NMT Group PLC (collectively NMT). Pursuant to the NMT Settlement Agreement, the parties have agreed to and did file a Stipulation and Consent Judgment (the Consent Judgment) in full settlement of the claims raised in the infringement Lawsuit. The Consent Judgment asserts that NMT manufactured the NMT Safety Syringe and imported and sold it in the United States until it ceased the offer and sale of these products in 2003. The Consent Judgment includes admissions that the NMT Safety Syringe infringed the subject patents which were valid and enforceable. The Consent Judgment enjoins NMT and all parties acting in concert

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with them from importing the NMT Safety Syringe into the United States and from making, using, selling, or offering to sell the NMT Safety Syringe within the United States until the lapse or expiration of all the subject patents.

Within three days of the entry of the Consent Judgment, NMT was required to cause the delivery of One Million Dollars (\$1,000,000.00) to the Company. This amount was received by the Company on April 30, 2004. This amount is an amount arrived at by compromise for purposes of settling the Infringement Lawsuit. NMT has agreed to release the Company and Mr. Shaw from all claims asserted in

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the Infringement Lawsuit and any other claims which existed as of April 27, 2004, but did not release any claim they may have in any action brought by the Company or Mr. Shaw in any jurisdiction outside the United States in relation to the sale of the NMT Safety Syringe made by NMT outside the United States.

In exchange, we and Mr. Shaw have released NMT from any causes of action which could have been brought in the infringement lawsuit and any other claims which existed as of April 27, 2004, except that this release in no way applies to: 1) BD or any subsidiary or affiliate, 2) Abbott Laboratories or any subsidiary or affiliate, 3) any claim that we or Mr. Shaw may have under any patents against the syringe technology advertised by NMT as Second Generation , 4) any claim under any patent against any medical product of NMT other than the NMT Safety Syringe or 5) any claim that we or Mr. Shaw may have against NMT in any jurisdiction outside the United States for infringement of any patent issued by any country or region other than the States.

We are not a party to any other material legal proceeding.

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

The business of the Series II Class B Convertible Preferred ( Series II ) Stockholders intended to be addressed at the 2003 Annual Meeting (the Annual Meeting ) of Retractable Technologies, Inc., originally scheduled for September 19, 2003, was adjourned and rescheduled for November 21, 2003, because quorum requirements were not met. The purpose of the meeting was the election by the Series II shareholders of three Series II Directors. Of the 418,500 shares of Series II Stock entitled to vote, more than the 209,250 shares required to constitute a quorum were represented in person or by proxy at the rescheduled November 21, 2003, meeting. The election of three Series II Directors was put to a vote by the holders of the Series II stock present in person or by proxy and the results were as follows:

<u>NOMINEE</u>	<u>FOR</u>	<u>WITHHELD</u>
Kenneth W. Biermacher, Esq.	162,200	10,000
Timothy G. Greene, Esq.	167,200	10,000
John J. McDonald, Jr.	203,200	10,000
Herbert A. Wilson	51,000	0

Accordingly, Kenneth W. Biermacher, Timothy G. Greene, and John J. McDonald, Jr. were elected as Series II Directors to serve until the 2004 annual meeting. As of their election, the Board of Directors consisted of:

Thomas J. Shaw	Class 2 Director
Steven R. Wisner	Class 2 Director
Russell B. Kuhlman	Class 1 Director
Douglas W. Cowan	Class 2 Director
Clarence Zierhut	Class 2 Director
Marwan Saker	Class 2 Director
Kenneth W. Biermacher	Series II Director*
Timothy G. Greene	Series II Director*



John J. McDonald

Series II Director\*

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\* See **Item 9 Directors, Executive Officers, Promoters, and Control Persons; Compliance with Section 16(a) of the Exchange Act** for a discussion regarding the ending of the terms of the Series II Directors as of August 27, 2004.

No other matters were voted on at the November 21, 2003, meeting.

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## MARKET INFORMATION

Our Common Stock has been listed on The American Stock Exchange (the AMEX ) since May 4, 2001. Shown below is the closing high and closing low sales price of our Common Stock as reported by the AMEX for each quarter of the last two fiscal years since the Common Stock began trading on the AMEX:

	<u>Common Stock</u>	
	<u>High</u>	<u>Low</u>
2003		
Fourth Quarter	\$ 6.81	\$ 5.79
Third Quarter	\$ 8.17	\$ 6.11
Second Quarter	\$ 9.44	\$ 2.90
First Quarter	\$ 4.80	\$ 3.00
2002		
Fourth Quarter	\$ 4.75	\$ 3.60
Third Quarter	\$ 5.35	\$ 3.65
Second Quarter	\$ 6.69	\$ 3.70
First Quarter	\$ 5.95	\$ 4.10

## SHAREHOLDERS

As of August 2, 2004, there were 22,580,679 shares of Common Stock held by 360 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, to support operations and future growth. The Board of Directors declared a dividend on the Series I and II Class B Convertible Preferred Stock. The dividend arrearage through June 30, 2004, on the Series I and II Class B Convertible Preferred Stock of \$7,118,583 was paid on August 27, 2004, to the holders of record as of August 17, 2004. As of June 30, 2004, \$8,347,000 in dividends were in arrears on the Series III, IV and V Class B stock. Dividends may not

be paid on the Common Stock until all dividends on the Preferred Stock have been paid.

#### EQUITY COMPENSATION PLAN INFORMATION

See **Item 11 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

Sales of unregistered securities in the first three quarters of 2003 were reported in the Company's Form 10-QSB quarterly reports filed with the United States Securities and Exchange Commission (the Commission) and available via Edgar.

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**Item 6. Management's Discussion and Analysis or Plan of Operation**

OVERVIEW

We have been manufacturing and marketing our products into the marketplace since 1997. In May 2000 we signed a national marketing and distribution agreement with Abbott Laboratories. We terminated this agreement in October 2003. 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. As a result of the anticompetitive practices of BD we entered into litigation as discussed in **Item 3. Legal Proceedings** and Notes 13 and 14 to the financial statements. This litigation resulted in settlements with all parties. We continue to attempt to gain access to the market through our sales efforts and innovative technology. 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 greatly improve our manufacturing capacity and efficiency, thereby reducing our unit cost.

FORWARD-LOOKING STATEMENT WARNING

Certain statements included by reference in this filing containing the words believes, anticipates, intends, expects, and similar such 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, the impact of dramatic increases in demand, our ability to quickly increase capacity in the event of a dramatic increase in demand, our ability to access the market, our ability to decrease production costs, our ability to continue to finance research and development as well as operations and expansion of production, and the recently increased interest of larger market players, specifically BD, in providing safety needle devices. Given these uncertainties, undue reliance should not be placed on forward-looking statements.

SELECTED FINANCIAL DATA

The following selected financial data for fiscal years ended December 31, 2003, and 2002, is derived from financial statements, which were audited by independent accountants. The data should be read in conjunction with the audited financial statements and selected notes and the following discussion of results of operations.

CONDENSED STATEMENTS OF OPERATIONS

Year Ended December 31,	
2003	2002

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Sales, net	\$ 19,078,332	\$ 20,316,299
Cost of sales	14,654,006	14,990,932
Product recall and recovery		481,637
	<u>4,424,326</u>	<u>4,843,730</u>
Gross margin		
Operating expenses		
Sales and marketing	3,374,212	4,042,081
Research and development	561,135	337,930
General and administrative	6,391,931	4,534,217
Debt conversion expense		2,319,073
	<u>10,327,278</u>	<u>11,233,301</u>
Total operating expenses		
Loss from operations	(5,902,952)	(6,389,571)
Interest income (expense), net	(262,589)	(436,357)
Litigation settlement, net	13,879,511	
	<u>7,713,970</u>	<u>(6,825,928)</u>
Net income (loss) before income taxes		
Provision for income taxes	265,473	
	<u>7,448,497</u>	<u>(6,825,928)</u>
Net income (loss)		
Preferred stock dividend requirement	(2,560,723)	(2,266,250)
	<u>\$ 4,887,774</u>	<u>\$ (9,092,178)</u>
Earnings (loss) applicable to Common Stockholders		
Earnings (loss) per share - basic	\$ 0.23	\$ (0.45)
Earnings (loss) per share - diluted	\$ 0.20	\$ (0.45)
Weighted average common shares outstanding	<u>21,001,004</u>	<u>20,300,454</u>

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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 year ended December 2003 or 2002. Variances have been rounded for ease of reading.

*Comparison of Year Ended*

*December 31, 2003, and Year Ended December 31, 2002*

Net sales were \$19,078,332 and \$20,316,299 for the years ended December 31, 2003, and December 31, 2002, respectively. Unit sales increased 1.4 percent. The decrease in revenues of \$1,237,967, or 6.1 percent, was due principally to the unit sales price to Abbott being higher than the unit sales price to other distributors and the termination of the National Marketing and Distribution Agreement with Abbott Laboratories (the Abbott Agreement). The incrementally higher unit sales prices attributable to Abbott are offset by the marketing fees accrued for Abbott which are included in sales and marketing expense. Unit sales of the 1cc syringe increased 7.0 percent which was mitigated by a decrease in unit sales of other products. Sales under the Abbott Agreement accounted for 26.4 percent of 2003 revenues and 49.0 percent of 2002 revenues. Sales to other distributors in 2003 increased to 73.6 percent compared to 51.0 percent in 2002. The Abbott Agreement was terminated October 15, 2003.

Cost of sales decreased from \$14,990,932 in 2002 to \$14,654,006 in 2003, a decrease of 2.2 percent. The improvement of cost of sales is attributable to better operating efficiencies offset by bonuses of \$258,000, stock option expense of \$80,000, and repairs of \$205,000. Also included in the 2003 costs was an increase of \$193,000 principally related to samples and testing of product from China.

Research and development expense increased from \$337,930 in 2002 to \$561,135 in 2003. Increases in labor costs of \$52,000, bonuses of \$25,000, consulting of \$84,000, and experimental parts and samples of \$58,000 account for most of the increase.

Sales and marketing expenses decreased to \$3,374,212 in 2003 from \$4,042,081 in 2002, a decrease of \$668,000. As a percentage of revenues, sales and marketing expenses decreased from 19.9 percent in 2002 to 17.7 percent in 2003. The decrease was attributable to the reduction in marketing fees of \$1.4 million due to the termination of the Abbott Agreement mitigated by the decrease in revenues discussed earlier. The decreased marketing fees were offset by increases in labor costs of \$120,000, bonuses of \$108,000, stock option expense of \$84,000, travel and entertainment expense of \$152,000, meetings and trade show expense of \$53,000, samples and promotional materials of \$52,000, and various other office expenses and freight comprising the remainder.

General and administrative costs increased \$1,857,714, or 41.0 percent, from 2002 to 2003. Increases include increased legal fees of \$590,000 principally due to the NMT litigation offset by decreased fees related to the Sortimat litigation, labor costs of \$411,000, bonuses of \$226,000, and stock option expense of \$239,000. We increased the bad debt reserve by \$73,000, insurance costs increased \$40,000, and taxes increased \$25,000. These increases were offset by reduction in accounting fees of \$46,000, advertising of \$37,000, and shareholder expense of \$30,000.

The Company reached settlement agreements with three of the defendants in its federal antitrust lawsuit, Retractable Technologies, Inc. v. BD et al. As part of the settlements, the litigation against Premier, Novation, and TYCO has been dismissed. The Company received \$13,879,511 as the initial payment under the financial terms of these settlement agreements which is net of attorneys' fees, court



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costs, legal expenses, and a payment to Mr. Thomas J. Shaw of \$728,609 pursuant to the Covenant Not to Sue. See **Item 3. Legal Proceedings** and **Notes 13 Litigation Settlements** and **14 Subsequent Events** of the Notes to Financial Statements for a discussion of settlements relating to the antitrust lawsuit.

Preferred stock dividend requirements were \$2,560,723 for 2003 compared to \$2,266,250 in 2002, an increase of \$294,473. The increase is due to the Series V Stock being outstanding for all of 2003, mitigated by the conversion of all of the remaining Series A stock and conversion of 684,500 shares of Series V Stock.

As a result of the litigation settlement proceeds, the Company is in a profitable position for 2003.

Cash flow from operating activities improved from a negative \$1,543,466 to a positive \$8,058,125, an improvement of \$9,601,591. The principal factor in the improvement was the proceeds from the litigation settlements. The decrease in accounts receivable improved cash flow by \$1,396,282. The principal factors reducing the Company's cash flow were the increase in inventories of \$1,197,029 and the decrease in payables of \$1,884,036. The Company spent \$385,921 for capital items.

The proceeds from litigation provided significant improvements to the Company's balance sheet, particularly with the increase in cash and the decrease in current liabilities. Conversion of all of the Series A Stock and 732,150 shares of various series of Class B stock provided an increase in additional paid-in capital and a reduction in the Company's annual preferred dividend requirements of \$379,000.

We are constructing a warehouse which is being funded by a loan from 1<sup>st</sup> International as discussed earlier.

*Comparison of Year Ended*

*December 31, 2002, and Year Ended December 31, 2001*

Net sales were \$20,316,299 and \$16,145,635 for the years ended December 31, 2002, and December 31, 2001, respectively. The increase of \$4,170,664 or 25.8 percent, was due principally to an increase in the sales of \$4,200,000 and \$2,000,000 for the 1cc syringe and 3cc syringe, respectively. These increases were offset by a decrease in revenues of \$1,900,000 for the 5cc syringes, 10cc syringes, and blood collection tube holders. Sales under the Abbott Agreement accounted for 49.0 percent of 2002 revenues and 55.2 percent of 2001 revenues. Sales to other distributors in 2002 increased 43.3 percent compared to 2001. Syringe revenues increased \$4,800,000, or 32.0 percent, and blood collection tube holder revenues decreased \$636,000, or 57.0 percent.

Cost of sales increased from \$13,322,965 in 2001 to \$14,990,932 in 2002, or an increase of \$1,667,967, or 12.5 percent. Cost of sales as a percentage of revenues decreased from 82.5 percent to 73.9 percent. The improvement of Cost of sales as a percentage of revenue is attributable to better operating efficiencies achieved at higher production volumes. Other factors included in Cost of sales are increases in royalty expense of \$304,000 and depreciation of \$144,000. Decreases include a reduction in repairs of \$271,000, product testing of \$70,000, and consulting of \$41,000.



The Company recorded an expense of \$481,637 in the second quarter of 2002 related to a recall and recovery of certain lots of blood collection tube holders. The Company found that, in limited lots, upon testing some blood collection tube holders retracted prior to activation. The premature retraction occurred during use as well as during shipping and handling. The Company has addressed the premature retraction through the manufacturing and design process.

Research and development expense decreased from \$756,542 in 2001 to \$337,930 in 2002. Reductions in labor costs of \$194,000, consulting of \$154,000, and experimental parts of \$48,000 account for most of the decrease. The reduction was due to costs associated with the 1cc syringe incurred when production began in 2001.

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Sales and marketing expenses decreased to \$4,042,081 in 2002 from \$4,066,433 in 2001, a de minimus change. As a percentage of revenues, sales and marketing expenses decreased from 25.2 percent in 2001 to 19.9 percent in 2002. Marketing fees to distributors increased \$247,000 due to the increase in revenues. The increased marketing fees were offset by decreases in travel and entertainment expense of \$97,000, office expense of \$24,000, telephone expense of \$26,000, and trade show expense of \$31,000.

General and administrative costs increased \$384,828, or 9.3 percent, from 2001 to 2002. Increases include increased legal fees of \$525,000, insurance costs of \$96,000, option expense of \$49,000 and property tax of \$38,000. These increases were offset by reduction in accounting fees of \$137,000, wages of \$123,000, office expense of \$89,000, and advertising of \$51,000.

In 2002, the Company converted a \$2,500,000 note and \$1,179,284 of the real estate note, to shares of Series V Stock of the Company. The Company recorded an expense of \$2,319,073. This expense consisted of \$1,821,246 attributable to the value of the shares issued in addition to the original conversion terms of the note, \$440,000 is attributable to stock options issued in connection with the conversion of the debt, and the write-off of unamortized debt expense of \$57,827. The expense associated with the additional shares issued and the stock options were increases to additional paid-in-capital. See Note 7 to the Financial Statements for additional information.

Preferred stock dividend requirements were \$2,266,250 for 2002 compared to \$2,023,954 in 2001, an increase of \$242,296. The increase is due to the issuance of Series V Stock in 2002.

Cash flow from operating activities improved from a negative \$3,672,828 to a negative \$1,543,466, an improvement of \$2,129,362. The Company's net loss was \$389,351 less than the previous year, but the loss for 2002 included a noncash charge for debt conversion expense of \$2,319,073. Other positive factors affecting cash flow include an increase in payables of \$1,909,280, an increase in other accrued liabilities of \$1,000,163, and a decrease in inventories of \$439,232. Negative factors include an increase in accounts receivable of \$1,094,338 and a decrease in marketing fees of \$642,770. The Company spent \$131,217 for capital items.

Finance activities provided significant changes to the Company's balance sheet, including the sale of the Series V Stock offering, providing approximately \$9,700,000 in equity. We used \$2,000,000 of the proceeds of the Series V Stock offering and the proceeds from a \$3,000,000 loan from Katie Petroleum to retire the \$5,000,000 note from Abbott. We exchanged 919,821 shares of Series V Stock to retire \$3,679,284 of long-term debt. We exchanged 387,500 shares of Series V Stock to reduce payables by \$1,550,000. Thomas Shaw and his wife, Suzanne August, forgave \$1,500,000 in royalties in 2002.

## **SIGNIFICANT ACCOUNTING POLICIES**

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

### **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. Revenues on sales to distributors are recorded net of contractual pricing allowances. Revenue for shipments directly to end-users is recognized when title and risk of ownership passes from the Company. Any product shipped or distributed for evaluation purposes is expensed.

#### **Marketing Fees**

The Company paid Abbott marketing fees for services they provided. 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 are accrued at the time of the sale of

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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.

### **Litigation Proceeds**

Proceeds from litigation settlements with Premier Inc.; Premier Purchasing Partners, L.P.; VHA, Inc.; Novation, L.L.C.; Tyco International (US) Inc.; and Tyco Healthcare Group L.P. in the Company's federal antitrust lawsuit, *Retractable Technologies, Inc. v. Becton Dickinson & Co., et al.* are recognized when realizable. Generally, realization is not reasonably assured and expected until proceeds are collected. Such amounts are net of attorneys' fees, court costs, legal expenses, and amounts payable under the Covenant Not to Sue. Liability for attorneys' fees is not incurred until proceeds are collected.

Payments under the discount reimbursement program will be recognized upon delivery of the product provided collection is reasonably assured. Such amounts will be presented in the Statements of Operations as a separate component of revenues.

### **Stock-Based Compensation**

Prior to 2002, the Company accounted for stock-based compensation under the recognition and measurement provisions (intrinsic value method) of APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and related Interpretations. Effective January 1, 2002, the Company adopted the fair value recognition provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*, prospectively to all director, officer, and employee awards granted, modified, or settled after December 31, 2001. The prospective method is one of the alternative transition methods provided in FAS 148. Awards under the Company's plans vest over periods up to three years. Therefore, the cost related to stock-based compensation included in the determination of net income for 2002 and 2003 is less than would have been recognized if the fair value method had been applied to all awards since the original effective date of SFAS No. 123. SFAS No. 123 indicates that the fair value method is the preferable method of accounting.

## LIQUIDITY AND FUTURE CAPITAL REQUIREMENTS

### Historical Sources of Liquidity

We have historically funded operations primarily from proceeds from private placements and loans. We were capitalized with approximately \$52,600,000 raised from six separate private placement offerings. As of September 30, 1995, we sold 5,000,000 shares of Series A Stock at \$1 per share, for an aggregate of \$5,000,000. As of October 31, 1996, we sold 1,000,000 shares of Series I Class B Stock at \$5 per share for an aggregate of \$5,000,000. As of January 31, 1998, we sold 1,000,000 shares of Series II Class B Stock at \$10 per share for an aggregate of \$10,000,000. As of September 30, 1999, we sold 1,160,200 shares of Series III Class B Stock at \$10 per share for an aggregate of \$11,602,000. As of May 4, 2000, we sold 1,133,800 shares of Series IV Class B Stock at \$10 per share for an aggregate of \$11,338,000. As of December 31, 2002, we sold 2,416,221 shares of Series V Class B Stock at \$4 per share. Of the \$12,802,396 raised in this offering, \$4,435,600 was in cash; \$3,679,284 was in exchange for loans payable to Katie Petroleum; \$1,550,000 was in exchange of accounts payable; \$1,821,245 of debt

conversion cost; and recognized beneficial conversion feature aggregating \$1,316,267.

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 with 1<sup>st</sup> International. 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 for \$3,000,000 and a portion of the proceeds from the Series V Class B offering.

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The Company has executed a loan from 1<sup>st</sup> International for \$2,500,000. See Note 7 to Financial Statements for a discussion of the terms of the note.

### Internal Sources of Liquidity

We believe we can achieve our break even quarter utilizing our existing equipment. In early 2004 we began to receive shipment of product under our agreement with Double Dove, a Chinese manufacturer. We believe as we receive greater quantities our profit margins could increase. To achieve our break even quarter we would need minimal access to hospital markets which has been difficult to obtain due to the monopolistic marketplace which was the subject of our antitrust lawsuit against BD. We will continue to attempt to gain access to the market through our sales efforts and innovative technology. 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 greatly improve our manufacturing capacity and efficiency, thereby reducing our unit cost.

Our primary sources of liquidity are sales of product, proceeds from litigation settlements, and, historically, sales of stock and loans. At the present time Management does not intend to raise additional equity capital in 2004. Due to the recent litigation settlements, we have sufficient cash reserves and intend to rely on operations as the primary ongoing source of cash.

Sales revenues decreased 6.1 percent from 2002 to 2003. Abbott purchases comprised 49.0 percent and 26.4 percent of our net revenues in 2002 and 2003, respectively. Unit sales to Abbott decreased from 43.8 percent in 2002 to 22.4 percent in 2003. Abbott distributed and marketed our products into the acute care market. However, the National Marketing and Distribution Agreement with Abbott was terminated on October 15, 2003. Other distributors now provide product to the acute care market. Unit sales to customers other than Abbott were 56.2 percent and 77.6 percent of sales in 2002 and 2003, respectively. Two other distributors accounted for 19.6 percent and 24.7 percent of sales in 2002 and 2003, respectively.

Sales revenues decreased 3.2 percent from the six months ended June 30, 2003 to the six months ended June 30, 2004. Abbott purchases comprised 51.7 percent and zero percent of our net revenues for the six months ended June 30, 2003 and 2004, respectively. For the same six month periods, unit sales increased 8.0 percent. Unit sales to Abbott during the same periods decreased from 47.2 percent to zero percent. Unit sales to customers other than Abbott during the same periods were 52.8 percent and 100.0 percent of sales, respectively.

In the event we continue to have only limited market access and cash generated from operations becomes insufficient to support operations, the Company would take cost cutting measures to reduce cash requirements. Such measures could result in reduction of units being produced, reduction of workforce, reduction of salaries of officers and other nonhourly employees, and deferral of royalty payments to Thomas Shaw.

### External Sources of Liquidity

We have obtained several loans over the past six years, which have, together with proceeds from sales of equities, enabled us to pursue development and production of our products. Currently we believe we could obtain additional funds through loans if needed. Furthermore, the shareholders have authorized an additional 5,000,000 shares of a Class C stock that could, if necessary, be used to raise funds through the sale of

equity.

**Table of Contents****Index to Financial Statements****Contractual Obligations and Commercial Commitments**

The following chart summarizes all of our material obligations and commitments to make future payments under contracts such as debt and lease agreements as of December 31, 2003:

<b>Contractual Obligations</b>	<b>Payments Due by Period</b>				
	<b>Total</b>	<b>2004</b>	<b>2005-2006</b>	<b>2007-2008</b>	<b>Thereafter</b>
Long-Term Debt	\$ 3,480,405	\$ 264,924	\$ 640,643	\$ 707,357	\$ 1,867,481
Capital Lease Obligations	64,004	46,876	17,128	0	0
Operating Lease Obligations	121,800	34,800	69,600	17,400	0
<b>Total Contractual Cash Obligations</b>	<b>\$ 3,666,209</b>	<b>\$ 346,600</b>	<b>\$ 727,371</b>	<b>\$ 724,757</b>	<b>\$ 1,867,481</b>

**Material Commitments for Expenditures**

Assuming we are able to access the market, we may obtain additional capital to fund capital expenditures and working capital needs. Management would fund these expenditures through debt and equity offerings. Capital expenditures could include additional assembly lines, manufacturing space, warehousing, and related infrastructure. The expansion could include those products that have been developed but not yet marketed, as well as expanding manufacturing capacity for existing products.

We had \$385,921 in capital expenditures in 2003 and \$552,341 in capital expenditures for the six months ended June 30, 2004. We anticipate capital expenditures of approximately \$3,000,000 in 2004 primarily for the construction of a warehouse.

**OFF BALANCE SHEET TRANSACTIONS**

We have no off-balance sheet transactions.



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**Item 7. Financial Statements**

**RETRACTABLE TECHNOLOGIES, INC.**

**FINANCIAL STATEMENTS AND**

**REPORTS OF INDEPENDENT ACCOUNTANTS**

**DECEMBER 31, 2003 AND 2002**

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**RETRACTABLE TECHNOLOGIES, INC.**

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**Report of Independent Accountants**

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, 2003 and 2002, and the related statements of operations, changes in stockholders' equity, and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. The financial statements of Retractable Technologies, Inc. for the year ended December 31, 2001 were audited by other auditors whose report dated March 28, 2002 expressed an unqualified opinion on those statements.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. 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, 2003 and 2002, and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 2, the Company has limited access to the hospital market. The Company's plans with respect to market access and liquidity are also set forth in Note 2.

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

CF & CO., L.L.P.

Dallas, Texas

March 29, 2004 except for Note 14,

as to which the dates are April 6, 2004,

April 27, 2004, July 2, 2004 and July 20, 2004



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**Report of Independent Accountants**

To the Board of Directors and

the Stockholders of Retractable Technologies, Inc.

In our opinion, the balance sheet as of December 31, 2001 and the related statements of operations, of changes in stockholders' equity and of cash flows for each of the two years in the period ended December 31, 2001, present fairly, in all material respects, the financial position, results of operations and cash flows of Retractable Technologies, Inc. at December 31, 2001 and for each of the two years in the period ended December 31, 2001, in conformity with accounting principles generally accepted in the United States of America. These financial statements 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 of these statements in accordance with auditing standards generally accepted in the United States of America, which 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, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

As discussed in Note 2, the Company has had limited access to the hospital market. The Company's plans with respect to market access and liquidity are also set forth in Note 2. Also, see Note 7 for discussion of classification of note payable to Abbott Laboratories (Note references are to 2001 Annual Report on Form 10-KSB).

/s/ PricewaterhouseCoopers LLP

PricewaterhouseCoopers LLP

Dallas, Texas

March 28, 2002

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**Table of Contents****Index to Financial Statements****RETRACTABLE TECHNOLOGIES, INC.****BALANCE SHEETS**

	<b>December 31,</b>	
	<b>2003</b>	<b>2002</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 8,155,621	\$ 1,342,117
Accounts receivable, net of allowance for doubtful accounts of \$146,452 and \$73,294, respectively	1,170,231	2,666,866
Inventories, net	3,976,584	2,779,554
Other current assets	194,310	276,524
<b>Total current assets</b>	<b>13,496,746</b>	<b>7,065,061</b>
Property, plant, and equipment, net	9,678,826	10,515,480
Intangible assets, net	394,369	405,641
Other assets	60,565	72,671
<b>Total assets</b>	<b>\$ 23,630,506</b>	<b>\$ 18,058,853</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 2,335,389	\$ 4,229,396
Current portion of long-term debt	210,681	840,899
Accrued compensation	231,959	328,717
Marketing fees payable	1,419,760	1,874,571
Accrued royalties	1,156,633	602,777
Other accrued liabilities	152,800	145,116
Income taxes payable	265,473	
<b>Total current liabilities</b>	<b>5,772,695</b>	<b>8,021,476</b>
Long-term debt, net of current maturities	2,723,001	2,600,298
Stockholders equity:		
Preferred stock \$1 par value:		
Series A; authorized and issued: 5,000,000 shares; outstanding: none and 1,056,000 shares, respectively (liquidation preference of none and \$1,584,000)		1,056,000
Class B; authorized: 5,000,000 shares		
Series I, Class B; issued: 1,000,000 shares; outstanding: 229,400 and 259,400 shares, respectively (liquidation preference of \$1,433,750 and \$1,621,250, respectively)	229,400	259,400
Series II, Class B; issued: 1,000,000 shares; outstanding 418,500 and 431,000 shares, respectively (liquidation preference of \$5,231,250 and \$5,387,500, respectively)	418,500	431,000
Series III, Class B; issued: 1,160,445 shares; outstanding: 145,245 and 150,745 shares, respectively (liquidation preference of \$1,815,563 and \$1,884,313, respectively)	145,245	150,745
Series IV, Class B; issued: 1,133,800 shares; outstanding 1,066,000 shares (liquidation preference of \$11,726,000)	1,066,000	1,066,000
	1,732,071	2,416,221

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Series V, Class B; issued 2,416,221 shares; outstanding: 1,732,071 and 2,416,221 shares, respectively (liquidation preference of \$7,621,112 and \$10,631,372, respectively)

Common Stock, no par value; authorized: 100,000,000 shares; issued and outstanding: 22,141,964 and 20,318,100, respectively

Additional paid-in capital	51,448,561	49,411,177
Accumulated deficit	(39,904,967)	(47,353,464)
	<hr/>	<hr/>
Total stockholders equity	15,134,810	7,437,079
	<hr/>	<hr/>
Total liabilities and stockholders equity	\$ 23,630,506	\$ 18,058,853
	<hr/>	<hr/>

See accompanying notes to the financial statements

**Table of Contents****Index to Financial Statements****RETRACTABLE TECHNOLOGIES, INC.****STATEMENTS OF OPERATIONS**

	Years Ended December 31,		
	2003	2002	2001
Sales, net	\$ 19,078,332	\$ 20,316,299	\$ 16,145,635
Cost of sales	14,654,006	14,990,932	13,322,965
Product recall and recovery		481,637	
Gross margin	4,424,326	4,843,730	2,822,670
Operating expenses:			
Sales and marketing	3,374,212	4,042,081	4,066,433
Research and development	561,135	337,930	756,542
General and administrative	6,391,931	4,534,217	4,149,389
Debt conversion expense		2,319,073	
Deferred IPO expenses			563,912
Total operating expenses	10,327,278	11,233,301	9,536,276
Loss from operations	(5,902,952)	(6,389,571)	(6,713,606)
Interest income	44,553	10,035	51,943
Interest expense, net	(307,142)	(446,392)	(553,617)
Litigation settlement, net	13,879,511		
Net income (loss) before income taxes	7,713,970	(6,825,928)	(7,215,280)
Provision for income taxes	265,473		
Net income (loss)	7,448,497	(6,825,928)	(7,215,280)
Preferred stock dividend requirements	(2,560,723)	(2,266,250)	(2,023,954)
Earnings (loss) applicable to common shareholders	\$ 4,887,774	\$ (9,092,178)	\$ (9,239,234)
Earnings (loss) per share -basic	\$ 0.23	\$ (0.45)	\$ (0.47)
Earnings (loss) per share -diluted	\$ 0.20	\$ (0.45)	\$ (0.47)
Weighted average common shares outstanding	21,001,004	20,300,454	19,774,006

See accompanying notes to the financial statements





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	Series A		Series I Class B		Series II Class B		Series III Class B		Series IV Class B		Series V Class B		Common	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount
Balance as of December 31, 2000	1,826,500	\$ 1,826,500	366,400	\$ 366,400	489,250	\$ 489,250	158,245	\$ 158,245	1,066,000	\$ 1,066,000		\$	19,365,850	\$
Conversion of Preferred Stock into Common Stock	(725,000)	(725,000)	(104,500)	(104,500)	(58,250)	(58,250)								887,750
Exercise of stock options														9,000
Net loss														
Balance as of December 31, 2001	1,101,500	\$ 1,101,500	261,900	\$ 261,900	431,000	\$ 431,000	158,245	\$ 158,245	1,066,000	\$ 1,066,000		\$	20,262,600	\$
Issued Preferred Series V, Class B shares 2,022,012 shares, \$1 par (net of stock issuance costs of \$296,088)											2,022,012	2,022,012		
Conversion of Preferred Stock into Common Stock	(45,500)	(45,500)	(2,500)	(2,500)			(7,500)	(7,500)						55,500
Recognition of stock option compensation														
Stock options given in connection with issuance of \$3,000,000 note payable														
Stock options given in connection with stock subscriptions for 525,000														

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Preferred Series V, Class B shares														
Stock options given in connection with conversion of \$3,679,284 of debt													394,209	394,209
Issued 394,209 additional shares of Preferred Series V, Class B shares in connection with conversion of \$3,679,284 of debt													394,209	394,209
Beneficial conversion feature of \$3,000,000 note payable														
Implied dividend for beneficial conversion feature of Preferred Series V, Class B shares														
Forgiveness of royalties due to an officer														
Net loss														
Balance as of December 31, 2002	1,056,000	\$ 1,056,000	259,400	\$ 259,400	431,000	\$ 431,000	150,745	\$ 150,745	1,066,000	\$ 1,066,000	2,416,221	\$ 2,416,221	20,318,100	\$
Conversion of debt into Common Stock														35,714
Conversion of preferred Stock into Common Stock	(1,056,000)	(1,056,000)	(30,000)	(30,000)	(12,500)	(12,500)	(5,500)	(5,500)			(684,150)	(684,150)	1,788,150	
Recognition of stock option compensation														
Dividends declared and paid on Series A Preferred Stock														
Net income														
Balance as of December 31, 2003		\$	229,400	\$ 229,400	418,500	\$ 418,500	145,245	\$ 145,245	1,066,000	\$ 1,066,000	1,732,071	\$ 1,732,071	22,141,964	\$

See accompanying notes to the financial statements

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	<b>Additional Paid-in Capital</b>	<b>Unearned Compensation</b>	<b>Accumulated Deficit</b>	<b>Total</b>
Balance as of December 31, 2000	\$ 36,774,763	\$	\$ (33,312,256)	\$ 7,368,902
Conversion of Preferred Stock into Common Stock	887,750			
Exercise of stock options	9,000			9,000
Net loss			(7,215,280)	(7,215,280)
Balance as of December 31, 2001	\$ 37,671,513	\$	\$ (40,527,536)	\$ 162,622
Issued Preferred Series V, Class B shares 2,022,012 shares, \$1 par (net of stock issuance costs of \$296,088)	8,663,051			10,685,063
Conversion of Preferred Stock into Common Stock	55,500			
Recognition of stock option compensation	48,926			48,926
Stock options given in connection with issuance of \$3,000,000 note payable	299,346			299,346
Stock options given in connection with Issuance of 525,000 Preferred Series V, Class B shares	209,572			209,572
Stock options given in connection with conversion of \$3,679,284 of debt	440,000			440,000
Issued 394,209 additional shares of Preferred Series V, Class B shares in connection with conversion of \$3,679,284 of debt	1,427,036			1,821,245
Beneficial conversion feature of \$3,000,000 note payable	412,500			412,500
Implied dividend for beneficial conversion feature of Preferred Series V, Class B shares	(1,316,267)			(1,316,267)
Forgiveness of royalties due to an officer	1,500,000			1,500,000
Net loss			(6,825,928)	(6,825,928)
Balance as of December 31, 2002	\$ 49,411,177	\$	\$ (47,353,464)	\$ 7,437,079
Conversion of debt into Common Stock	249,998			249,998
Conversion of Preferred Stock into Common Stock	1,788,150			
Recognition of stock option compensation	458,324			458,324
Dividends declared and paid on Series A Preferred Stock	(459,088)			(459,088)
Net income			7,448,497	7,448,497
Balance as of December 31, 2003	\$ 51,448,561	\$	\$ (39,904,967)	\$ 15,134,810

See accompanying notes to the financial statements



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	<b>Years Ended December 31,</b>		
	<b>2003</b>	<b>2002</b>	<b>2001</b>
<b>Cash flows from operating activities:</b>			
Net income (loss)	\$ 7,448,497	\$ (6,825,928)	\$ (7,215,280)
Adjustments to reconcile net income (loss) to net cash provided (used) by operating activities:			
Depreciation and amortization	1,308,624	1,328,700	1,196,120
Capitalized interest	(26,924)	(25,796)	(152,559)
Stock option compensation	458,324	48,927	
Provision for doubtful accounts	100,352	12,498	3,117
Accreted interest	101,119		
Waiver of vacation pay		(100,937)	
Debt conversion expense		2,319,073	
Change in assets and liabilities:			
(Increase) decrease in inventories	(1,197,029)	439,232	(1,643,150)
(Increase) decrease in accounts receivable	1,396,282	(1,094,338)	737,111
(Increase) decrease in other current assets	87,443	88,430	256,654
Increase (decrease) in accounts payable	(1,894,008)	1,909,280	2,049,293
Increase (decrease) in marketing fees payable	(454,811)	(642,770)	580,269
Increase (decrease) in income taxes payable	265,473		
Increase (decrease) in other accrued liabilities	464,783	1,000,163	515,597
Net cash provided (used) by operating activities	<u>8,058,125</u>	<u>(1,543,466)</u>	<u>(3,672,828)</u>
<b>Cash flows from investing activities:</b>			
Purchase of property, plant and equipment	(385,921)	(71,314)	(782,130)
Acquisition of patents, trademarks, licenses and intangibles	(24,713)	(59,903)	(54,678)
Net cash used by investing activities	<u>(410,634)</u>	<u>(131,217)</u>	<u>(836,808)</u>
<b>Cash flows from financing activities:</b>			
Repayments of long-term debt and notes payable	(374,899)	(5,552,527)	(506,802)
Proceeds from long-term debt		3,000,000	2,500,000
Proceeds from the sale of Preferred Stock		4,435,600	
Payment of Preferred Stock dividends	(459,088)		
Proceeds from the exercise of stock options			9,000
Offering expense related to Preferred Stock issuances		(86,517)	
Net cash provided (used) by financing activities	<u>(833,987)</u>	<u>1,796,556</u>	<u>2,002,198</u>
Net increase (decrease) in cash and cash equivalents	6,813,504	121,873	(2,507,438)
Cash and cash equivalents at:			
Beginning of period	1,342,117	1,220,244	3,727,682

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End of period	\$ 8,155,621	\$ 1,342,117	\$ 1,220,244
Supplemental schedule of cash flow information:			
Interest paid	\$ 257,986	\$ 460,159	\$ 747,452
Supplemental schedule of noncash investing and financing activities:			
Equipment acquired through capital lease obligation	\$	\$	\$ 45,000
Assets acquired through debt	\$ 16,264	\$	\$ 75,451
Forgiveness of royalties by an officer	\$	\$ 1,500,000	\$
Conversion of accounts payable into Preferred Stock	\$	\$ 1,550,000	\$
Conversion of long-term debt into Common Stock	\$ 249,998	\$	\$
Conversion of long-term debt into Preferred Stock	\$	\$ 3,679,284	\$
Stock issuance costs paid in stock options	\$	\$ 209,572	\$
Loan origination fee paid in stock options	\$	\$ 299,346	\$
Beneficial conversion feature of Preferred Stock issued	\$	\$ 1,316,267	\$
Beneficial conversion feature of a \$3,000,000 note payable	\$	\$ 412,500	\$
Implied dividends from beneficial conversion feature	\$	\$ (1,316,267)	\$

See accompanying notes to the financial statements

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**NOTES TO FINANCIAL STATEMENTS**

**1. BUSINESS OF THE COMPANY**

Retractable Technologies, Inc. (the Company) was incorporated in Texas on May 9, 1994, to design, develop, manufacture and market 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 are the VanishPoint® syringe in the 1cc, 3cc, 5cc and 10cc sizes and blood collection tube holders. The Company has conducted preliminary clinical evaluations and worked with national distributors to encourage healthcare facilities to transition from the use of standard syringes to the VanishPoint® syringe.

**2. LIQUIDITY, CAPITAL RESOURCES AND MANAGEMENT'S PLANS**

The Company has been successful in raising funds through private equity financing totaling approximately \$52.6 million, including approximately \$5.5 million in conversion of debt and accounts payable, over the last eight and one-half years.

Positive factors that affected the Company in 2003 were:

\$250,000 in debt was converted into Common Stock

Stockholders' equity increased from \$7.4 million at December 31, 2002 to \$15.1 million at December 31, 2003

Working capital improved from a negative \$1.0 million at December 31, 2002 to a positive \$7.7 million at December 31, 2003

Litigation settlements provided cash of \$13.9 million

All of the Series A Stock was converted into Common Stock of the Company and all dividends in arrears to the Series A shareholders were paid.

Over 700,000 shares of Class B Stock were converted into Common Stock.

However, the environment facing the Company continued to be difficult in 2003. Noteworthy conditions are:

Because the Company's efforts to penetrate the market have been severely restricted, the Company filed a lawsuit in 2001 in the United States District Court for the Eastern District of Texas against Becton Dickinson & Co. (BD), et al. The suit alleges violation of state and federal antitrust laws, tortious interference, business disparagement and common law conspiracy. All

defendants except BD settled in 2003. The case is scheduled for trial in July 2004.

The Company has incurred substantial losses from operations in every fiscal year since inception. For the years ended December 31, 2003, 2002, and 2001, the Company incurred a loss from operations of approximately \$5.9 million, \$6.4 million, and \$6.7 million, respectively.

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As of December 31, 2003, and 2002, the Company had accumulated deficits of approximately \$39.9 million and \$47.4 million, respectively.

The National Marketing and Distribution Agreement (the Agreement) the Company had with Abbott Laboratories (Abbott) was terminated as of October 15, 2003. The Company had a high concentration of sales with this significant customer. Sales to other distributors are expected to replace those lost from the termination of the Abbott Agreement. Cash and cash equivalents balances at December 31, 2003 are expected to be sufficient for 2004 operating needs. Management expects to reach a break even point when the Company has more access to the market. Failure to generate sufficient revenues or raise additional capital could have a material adverse effect on the Company's ability to continue as a going concern and to achieve its intended business objectives beyond 2004. In the event the Company cannot generate sufficient revenues or raise additional capital, management has committed to undertake actions to preserve liquidity including, but not limited to, eliminating research and development expenditures, deferral of royalty payments to a Company officer (Note 6) and salary reductions.

**3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Accounting estimates**

The preparation of financial statements in conformity with United States generally accepted accounting principles 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 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. Provision is made 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, 2003, 2002, and 2001, the Company capitalized interest of approximately \$27,000, \$26,000, and \$153,000, respectively. Gains or losses from property disposals are included in income.

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

Production equipment	3 to 13 years
Office furniture and equipment	3 to 10 years
Building	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 value of financial instruments approximates their recorded values.

**Concentrations of credit risk**

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 the federally insured limits, are maintained in financial institutions; however, management believes the

institutions are of high credit quality. The majority of accounts receivable are due from companies which are well-established entities. As a consequence, management considers any exposure from concentrations of credit risks to be limited. The Company had a high concentration of sales with three significant customers. For the year ended December 31, 2003, the aforementioned customers accounted for \$9,320,000, or 48.9%, of net sales, and their aggregated accounts receivable balance at December 31, 2003, was \$371,587.

#### **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. Revenues on sales to distributors are recorded net of contractual pricing allowances. Revenue for shipments directly to end-users is recognized when title and risk of ownership passes from the Company. Any product shipped or distributed for evaluation purposes is expensed.

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#### **Marketing fees**

The Company paid Abbott marketing fees for services they provided. 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 are 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.

#### **Litigation Proceeds**

Proceeds from litigation settlements with Premier Inc.; Premier Purchasing Partners, L.P.; VHA, Inc.; Novation, L.L.C.; Tyco International (US) Inc.; and Tyco Healthcare Group L.P. in the Company's federal antitrust lawsuit, Retractable Technologies, Inc. v. Becton Dickinson & Co., et al. are recognized when realizable. Generally, realization is not reasonably assured and expected until proceeds are collected. Such amounts are net of attorneys' fees, court costs, legal expenses, and amounts payable under the Covenant Not to Sue. Liability for attorneys' fees is not incurred until proceeds are collected.

Payments under the discount reimbursement program will be recognized upon delivery of the product, provided collection is reasonably assured. Such amounts will be presented in the Statements of Operations as a separate component of revenues.

#### **Income taxes**

The Company provides for deferred income taxes in accordance with Statement of Financial Accounting Standard 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 basis differences reverse in future periods. Deferred tax assets are periodically reviewed for realizability. Valuation allowances are recorded when realizability of deferred tax assets is not likely.

#### **Earnings per share**

The Company has adopted Statement of Financial Accounting Standards 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 weighted average number of shares outstanding was 21,001,004; 20,300,454; and 19,774,006, for the periods ended December 31, 2003, 2002 and 2001, respectively. The Company's potentially dilutive Common Stock equivalents, options and convertible debt, are dilutive for the year ended December 31, 2003, and antidilutive of the prior year periods as the Company was in a loss position. The Company's Common Stock equivalents, consisting of convertible Preferred Stock are antidilutive for all periods presented. Cumulative preferred dividends of approximately \$2,600,000; \$2,300,000; and \$2,000,000, have been added to net income (losses) for the years ended December 31, 2003, 2002 and 2001,

respectively, to arrive at earnings (loss) per share.

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	Years Ended December 31,		
	2003	2002	2001
Net Income (loss)	\$ 7,448,497	\$ (6,825,928)	\$ (7,215,280)
Preferred stock dividend requirements	(2,560,723)	(2,266,250)	(2,023,954)
Earnings (loss) available to common shareholders	4,887,774	(9,092,178)	(9,239,234)
Effect of dilutive securities: convertible debt interest and loan fees	(454,379)		
Earnings (loss) available to common shareholders after assumed conversions	\$ 4,433,395	\$ (9,092,178)	\$ (9,239,234)
Average common shares outstanding	21,001,004	20,300,454	19,774,006
Dilutive stock equivalents from stock options	292,528		
Shares issuable upon conversion of convertible debt	750,000		
Average common and common equivalent shares outstanding assuming dilution	22,043,532	20,300,454	19,774,006
Basic earnings (loss) per share	\$ 0.23	\$ (0.45)	\$ (0.47)
Diluted earnings (loss) per share	\$ 0.20	\$ (0.45)	\$ (0.47)

**Research and development costs**

Research and development costs are expensed as incurred.

**Stock-based compensation**

The Company has three stock-based director, officer and employee compensation plans which are described more fully in Note 12. Prior to 2002, the Company accounted for those plans under the recognition and measurement provisions (intrinsic value method) of APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and related Interpretations. Effective January 1, 2002, the Company adopted the fair value recognition provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*, prospectively to all director, officer and employee awards granted, modified, or settled after December 31, 2001. Awards under the Company's plans vest over periods up to three years. Therefore, the cost related to stock-based compensation included in the determination of net income for 2002 and 2003 is less than what would have been recognized if the fair value method had been applied to all awards since the original effective date of SFAS No. 123. SFAS No. 123 indicates that the fair value method is the preferable method of accounting. The following table indicates the effect on net income and earnings per share if the fair value method had been applied to all outstanding and unvested awards in each period.

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	Year Ended December 31,		
	2003	2002	2001
Net income (loss), as reported	\$ 7,448,497	\$ (6,825,928)	\$ (7,215,280)
Add: Stock-based employee compensation expense included in reported net income, net of related tax effects	458,324	38,323	
Deduct: Total stock-based employee compensation expense determined by fair value based method for all awards, net of related tax effects	(566,779)	(185,072)	(205,692)
<b>Pro forma net income</b>	<b>\$ 7,340,042</b>	<b>\$ (6,972,677)</b>	<b>\$ (7,420,972)</b>
Earnings (loss) per share (basic)-as reported	\$ 0.23	\$ (0.45)	\$ (0.47)
Earnings (loss) per share (diluted)-as reported	\$ 0.20	\$ (0.45)	\$ (0.47)
Earnings (loss) per share (basic)-pro forma	\$ 0.23	\$ (0.46)	\$ (0.48)
Earnings (loss) per share (diluted)-pro forma	\$ 0.20	\$ (0.46)	\$ (0.48)

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**Table of Contents****Index to Financial Statements****Recent Pronouncements**

In December 2003, the Financial Accounting Standards Board ( FASB ) issued a revision to the Statement of Financial Accounting Standards No. 132 (revised 2003), *Employer's Disclosures About Pensions and other Postretirement Benefits* ( SFAS 132(R) ). The revisions to SFAS 132(R) require disclosures regarding an employer's percentages of plan assets, description of investing strategies and descriptions used to determine the overall expected rate of return on assets in the employer's pension or defined benefit plans. The expanded disclosure requirements for domestic plans are effective for interim periods beginning after December 15, 2003. The Company does not have a pension, defined benefit plan or any future postretirement obligations. Therefore, the requirements contained within SFAS 132(R) have no impact to the Company.

On May 31, 2003, the FASB issued Statement No. 150, *Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity* ( SFAS 150 ). SFAS 150 establishes standards for how an issuer classifies and measures in its statement of financial position certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument within its scope as a liability (or an asset in some circumstances) because that financial instrument embodies an obligation of the issuer. SFAS 150 is effective at the beginning of the first interim period beginning after June 15, 2003. The Company does not have any financial instruments that fall under the guidance of SFAS 150 and, therefore, the adoption did not have any effect on its financial position or results of operations.

On July 31, 2003, the Emerging Issue task Force ( EITF ) discussed Issue No. 03-7, *Accounting for the Settlement of the Equity-Settled Portion of a Convertible Debt Instrument that Permits or Requires the Conversion Spread to Be Settled in Stock* (Instrument C of Issue 90-19) . The Task Force revised the consensus in EITF Issue No. 90-19, *Convertible Bonds With Issuer Option to Settle for Cash Upon Conversion* . EITF Issue No. 03-7 is effective for reporting periods beginning after August 13, 2003. The Company does not have any debt instruments that fall under the guidance of EITF Issue No. 03-7 and, therefore, adoption will not have any effect on its financial position or results of operations.

On July 30, 2002, the FASB issued Statement No. 146, *Accounting for Costs Associated with Exit or Disposal Activities* ( FAS 146 ). FAS 146 requires companies to recognize costs associated with exit or disposal activities when they are incurred rather than at the date of commitment to an exit or disposal plan. FAS 146 is to be applied prospectively to exit or disposal activities initiated after December 31, 2002. The Company did not commence any exit or disposal activities in 2003 and there are no exit or disposal activities currently planned.

**4. INVENTORIES**

Inventories consist of the following:

	<b>December 31,</b>	
	<b>2003</b>	<b>2002</b>
Raw materials	\$ 884,986	\$ 941,512
Finished goods	3,188,917	1,935,361
	<b>4,073,903</b>	<b>2,876,873</b>
Inventory reserve	(97,319)	(97,319)

	<u>\$ 3,976,584</u>	<u>\$ 2,779,554</u>
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Property, plant and equipment consist of the following:

	December 31,	
	2003	2002
Land	\$ 261,893	\$ 261,893
Building and building improvements	1,883,259	1,879,027
Production equipment	13,284,593	13,150,258
Office furniture and equipment	782,273	671,304
Construction in progress	417,000	237,427
Automobiles	21,858	21,858
	<u>16,650,876</u>	<u>16,221,767</u>
Accumulated depreciation and amortization	(6,972,050)	(5,706,287)
	<u>\$ 9,678,826</u>	<u>\$ 10,515,480</u>

Acquisition costs of production equipment financed through capital leases were \$1,257,307 at December 31, 2003 and 2002. Accumulated amortization on these leases was \$778,171 and \$692,434 at December 31, 2003 and 2002, respectively.

Depreciation expense and capital lease amortization expense for the years ended December 31, 2003, 2002 and 2001 was \$1,265,762, \$1,275,594, and \$1,142,017 respectively.

**6. INTANGIBLE ASSETS**

Intangible assets consist of the following:

	December 31,	
	2003	2002
License agreement	\$ 500,000	\$ 500,000
Trademarks and patents	226,847	216,151
	<u>726,847</u>	<u>716,151</u>
Accumulated amortization	(332,478)	(310,510)

\$ 394,369	\$ 405,641
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In 1995, the Company entered into the license agreement with an officer of the Company for the exclusive right to manufacture, market and distribute products utilizing automated retraction technology. This technology is the subject of various patents and patent applications owned by an 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 to the officer on gross sales. The royalty fee expense is recognized in the period in which it is earned. Royalty fees of \$1,477,213, \$1,483,727, and \$1,179,657, are included in cost of sales for the years ended December 31, 2003, 2002 and 2001, respectively. Accrued royalties under this agreement aggregated \$1,156,633 and \$602,777 at December 31, 2003 and 2002, respectively.

During 2002, the officer and his wife forgave \$1.5 million of the royalties payable under a licensing agreement.

Amortization expense for the years ended December 31, 2003, 2002 and 2001, was \$42,862, \$53,106, and \$54,103, respectively. Future amortization expense for the years 2004 through 2008 is estimated to be \$43,000 per year.

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	<b>December 31,</b>	
	<b>2003</b>	<b>2002</b>
Long-term debt consists of the following:		
Note payable to Katie Petroleum. Interest accrues at prime plus 1%, 5.00% and 5.25% at December 31, 2003 and 2002, respectively. Interest only is 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) beginning March 1, 2004 and being fully paid on September 30, 2012. Guaranteed by an officer. Approximately \$23,000 of the initial principal payment was converted into 5,770 shares of Common Stock as of March 1, 2004. Not otherwise collateralized. Convertible into Common Stock at \$4.00 per share at the option of the holder.	\$ 2,389,273	\$ 2,288,154
Note payable to 1 <sup>st</sup> International Bank. Interest only payments. Interest at prime plus 2%; 6.00% and 6.25% on December 31, 2003 and 2002. Collateralized by accounts receivable. Guaranteed by an officer. Subsequent to December 31, 2003, the note was paid with the proceeds of a new loan agreement discussed below.	475,000	500,000
Capital lease obligations payable in monthly installments ranging from approximately \$1,000 to \$5,000 through June, 2006. Interest at rates from 10.04% to 14.87%. Collateralized by certain machinery and equipment. Covenants require the Company to maintain a minimum tangible net worth and a specific ratio of total liabilities to tangible net worth. Guaranteed by an officer.	64,004	229,521
Note payable to 1 <sup>st</sup> International Bank. The remaining balance of \$250,003 was converted into 35,714 shares of Common Stock on July 15, 2003. \$1,179,284 was converted into 294,821 shares of Series V, Class B Convertible Preferred Stock ( Series V Stock ) in 2002. Loan modified in 2002 to interest only payments. Interest adjustable annually, prime plus 1%; 5.25% on December 31, 2002. Collateralized by land and building, and guaranteed by an officer. This note was purchased by Katie Petroleum, Inc. on November 12, 2001 and was convertible into Common Stock at \$7 per share.		250,003
Small Business Administration note payable to Texas Bank for a maximum of \$1,000,000, all of which was drawn during 1997. Payable in monthly principal and interest installments of approximately \$16,000. Interest at prime plus 1.5%; 5.75% and on December 31, 2002; adjustable quarterly. Matured on July 1, 2003. Collateralized by equipment. Guaranteed by an officer.		106,406
Note payable to AFCO. Payable in monthly principal and interest installments of approximately \$13,700. Interest at 7.084%. Paid off in May 2003.		67,113
Other	5,405	
	<u>2,933,682</u>	<u>3,441,197</u>
Less: current portion	<u>(210,681)</u>	<u>(840,899)</u>
	<u>\$ 2,723,001</u>	<u>\$ 2,600,298</u>

The aggregate maturities of long-term debt as of December 31, 2003 are as follows:

2004	\$ 210,681
2005	222,263
2006	233,269
2007	243,801
2008	321,186
Thereafter	1,702,482
	<hr/>
	\$ 2,933,682
	<hr/>

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Subsequent to December 31, 2003, the Company executed a loan from 1<sup>st</sup> International Bank for \$2,500,000. The proceeds from the loan paid off the remaining \$475,000 of the revolving credit agreement and will fund a new warehouse and related infrastructure. Payments on the new note will be interest only during the first twelve months. After twelve months, payments will be based on a twenty-year amortization with a five year maturity. The exact terms will be 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 percent to 6.50 percent. Compensating balances at 1<sup>st</sup> International affecting the interest rate will range from \$0 to \$500,000.

In 2002, the debt held by Katie Petroleum, Inc. aggregating \$3,679,284 was exchanged into Series V Stock at a rate of \$4 per share. The debt had a stated conversion feature of \$7 per share of Common Stock. The Series V Stock can be immediately convertible to Common Stock. Therefore, the additional shares issued for the conversion were valued at the market price of the Common Stock at the time of the conversion and recorded as debt conversion expense of \$1,821,246. Additional debt conversion expense consisted of \$440,000 for options issued to purchase 100,000 shares of Common Stock issued in connection with the conversion and \$57,827 attributable to the write-off of unamortized debt expense. Both the expense of additional shares of stock issued and the stock options were increases to stockholders' equity.

The Company entered into an agreement in 2002 with Katie Petroleum, Inc. and its affiliates whereby they purchased 525,000 shares of Series V Stock at a price of \$2.1 million and loaned the Company \$3.0 million. The Company used \$5 million of the proceeds to retire the note payable to Abbott Laboratories (Abbott) on October 7, 2002. The Company also authorized options to purchase 136,439 shares of its Common Stock in connection with these transactions.

**8. COMMITMENTS AND CONTINGENCIES**

The Company is involved in various legal proceedings which have arisen in the ordinary course of business. Management believes that any liabilities arising from these claims and contingencies would not have a material adverse effect on the Company's annual results of operations or financial condition.

**9. INCOME TAXES**

The provision for income taxes consists of the following:

	<b>For the Years Ended December 31,</b>		
	<b>2003</b>	<b>2002</b>	<b>2001</b>
Current tax provision			
Federal, alternative minimum tax	\$ 173,542	\$	\$
State	91,931		
Total current provision	265,473		
Deferred tax provision (benefit)			
Total income tax provision (benefit)	\$ 265,473	\$	\$



The Company did not provide any current or deferred income tax provision or benefit for 2002 and 2001 because it had experienced net operating losses from its inception to December 31, 2002. The income tax benefit of net operating loss carryforwards utilized in 2003 aggregated \$3.1 million for current federal income taxes and \$200,000 for current state income taxes. At December 31, 2003 and 2002 the

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Company had available federal and state net operating loss carry forwards of approximately \$34.7 million and \$43.3 million, respectively. The federal net operating loss carry forwards will begin to expire in 2012. The state net operating loss carry forwards began expiring in 2000.

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:

	December 31,	
	2003	2002
Deferred tax assets:		
Net operating loss carry forwards	\$ 13,143,516	\$ 16,434,304
Non-employee option expense	476,486	476,486
Employee option expense	192,375	18,556
Inventory	181,762	99,457
Intangible assets	2,328	2,328
Alternative minimum tax credit	173,542	
Accrued expenses and reserves	1,205,568	1,084,871
<b>Total deferred tax assets</b>	<b>15,375,577</b>	<b>18,116,002</b>
Deferred tax liabilities:		
Property and equipment	(1,695,686)	(1,214,271)
<b>Valuation allowance</b>	<b>(13,679,891)</b>	<b>(16,901,731)</b>
<b>Net deferred tax assets</b>	<b>\$</b>	<b>\$</b>

Management believes that, based on the history of the losses and other factors, the weight of available evidence indicates that it is more likely than not that the Company will not be able to realize its net deferred tax assets, therefore a full valuation reserve has been recorded. Management evaluates on a periodic basis the recoverability of deferred tax assets and the valuation allowance. At such time as it is determined that it is more likely than not that deferred tax assets are realizable the valuation allowance will be reduced.

A reconciliation of income taxes based on the federal statutory rate and the provision for income taxes, had one been provided, is summarized as follows:

	December 31,		
	2003	2002	2001
Income tax (benefit) at the federal statutory rate	35.0%	(35.0)%	(35.0)%
State tax (benefit), net of federal (benefit)	0.8	(2.9)	(2.8)

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Increase (decrease) in valuation allowance	(41.8)	25.3	39.1
Permanent differences	0.2	10.2	0.2
Other	8.0	2.4	(1.5)
Effective tax (benefit) rate	2.2%	%	%

**10. STOCKHOLDERS EQUITY**

**Preferred stock**

The Company has two classes of preferred stock: Series A and Class B. The Class B Preferred Stock has five series: Series I, Series II, Series III, Series IV, and Series V.

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#### Series A

The Company authorized 5,000,000 shares of \$1 par value Series A Convertible Preferred Stock ( Series A Stock ) in April 1995. Holders of Series A Stock were entitled to receive a cumulative annual cash dividend of \$.12 per share, payable quarterly if declared by the board of directors. Holders of Series A Stock generally have no voting rights until dividends are in arrears and unpaid for twelve consecutive quarters. In such case, the holders of Series A Stock have the right to elect one-third of the board of directors of the Company.

Series A Stock was redeemable after three years from the date of issuance at the option of the Company at a price of \$1.70 per share, plus all accrued and unpaid dividends. Each share of Series A Stock could have been converted to one share of Common Stock after three years from the date of issuance at the option of the shareholder. Pursuant to these terms, a total of 10,000 shares of Series A Stock were converted into Common Stock in 2003 prior to the redemption discussed below. In the event of voluntary or involuntary dissolution, liquidation or winding up of the Company, holders of Series A Stock then outstanding were entitled to \$1.50 per share plus all accrued and unpaid dividends, prior to any distributions to holders of Class B preferred stock or of Common Stock.

During the second quarter of 2003, the Company called the remaining 1,046,000 shares of Series A Stock for redemption at \$1.70 per share plus unpaid dividends in accordance with the certificate of designation. All of the Series A shareholders, at their option, converted their Series A stock into Common Stock on a one-for-one basis as provided in the certificate of designation. The Company paid approximately \$460,000 in accumulated and unpaid dividends. The conversion of these remaining Series A Stock resulted in an annualized decrease of \$125,520 in preferred dividend requirements. The Company does not intend to reissue any of the Series A Stock.

#### Class B

The Company has authorized 5,000,000 shares of \$1 par value Class B Convertible Preferred Stock which have been allocated among Series I, II, III, IV and V in the amounts of 229,400; 418,500; 145,245; 1,066,000 and 1,732,071 shares, respectively. The remaining 1,408,784 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 229,400 and 259,400 shares outstanding at December 31, 2003 and 2002, 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. At December 31, 2003 and 2002 approximately \$2,561,000 and \$2,435,000, respectively, of dividends which have 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, a total of 30,000 shares of Series I Class B Stock were converted into Common Stock in 2003. 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

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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.

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**Series II Class B**

There were 1,000,000 shares of \$1 par value Series II Class B Stock issued and there were 418,500 and 431,000 shares outstanding at December 31, 2003 and 2002. 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. Since December 31, 2000, dividends were in arrears for twelve consecutive quarters. Accordingly, the Series II shareholders have directors on the Board. At December 31, 2003 and 2002, approximately \$4,487,000 and \$4,063,000, respectively, of dividends which have 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, 12,500 shares of Series II Class B Stock were converted into Common Stock in 2003. 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 145,245 and 150,745 shares outstanding at December 31, 2003 and 2002, 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 December 31, 2003 and 2002, approximately \$2,440,000 and \$2,292,000, 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, 5,500 shares of Series III Class B Stock were converted into Common Stock in 2003. 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 1,066,000 shares outstanding at December 31, 2003 and 2002. 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, 2003 and 2002, approximately \$3,932,000 and \$2,866,000 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

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initial registration statement under the Securities Act of 1933. 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**

On April 17, 2002, the Company issued two Private Placement Memoranda offering up to 1,250,000 shares of its \$1.00 par value Series V Class B Stock at \$4.00 per share. A Regulation D offering comprised 1,000,000 of the shares and a Regulation S offering made up the remaining 250,000 shares. The terms of both offerings were similar. The Regulation D offering was amended to increase the shares being offered from 1,000,000 shares to 1,403,034 shares. The Company sold 583,900 shares for \$2,335,600 in cash and 387,500 shares for \$1,550,000 in cancelled accounts payable. No shares were sold in the Regulation S offering.

In a separate private offering in 2002, the Company issued 919,821 shares to Katie Petroleum ( Katie ) in exchange for cancellation of \$2,500,000 in debt under a working capital loan and \$1,179,284 of the outstanding amount payable on a real estate note.

In another private offering with Katie in 2002 the Company sold 525,000 shares of Series V Stock at \$4.00 per share for total proceeds of \$2,100,000.

In total, the Company raised \$4,435,600 in cash, exchanged stock for \$1,550,000 in accounts payable, exchanged stock for \$3,679,284 and 2,416,221 in debt and \$1,821,245 of debt conversion cost and recognized the intrinsic value of a beneficial conversion feature aggregating \$1,316,267. The Company sold or exchanged 2,416,221 shares of Series V Stock for gross proceeds of \$12,802,396. As of December 31, 2003 and 2002 there were 1,732,071 and 2,416,221 shares issued and outstanding, respectively.

Series V Class B Stock ranks senior to the Company's Common Stock with respect to dividends and upon liquidation, dissolution, or winding up, but secondary to the Company's Series I Class B Stock, Series II Class B Stock, Series III Class B Stock, and Series IV Class B Stock. 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, 2003 and 2002, approximately \$1,098,000 and \$357,000, 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, 684,150 shares of Series V Class B Stock were converted into Common Stock in 2003. In the event of voluntary or involuntary liquidation, dissolution, or winding up of the Company, holders of Series V Class B Stock then outstanding are entitled to receive liquidating distributions of \$4.40 per share, plus accrued and unpaid dividends after distribution obligations to Series I Class B Stock, Series II Class B Stock, Series III Class B Stock and Series IV Class B Stock have been satisfied and prior to any distribution to the holders of the Common Stock.

**Common stock**

The Company is authorized to issue 100,000,000 shares of no par value Common Stock, of which 22,141,964 and 20,318,100 shares are issued and outstanding at December 31, 2003 and 2002, respectively.

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**11. RELATED PARTY TRANSACTIONS**

The Company has a lease with Mill Street Enterprises ( Mill Street ), a sole proprietorship owned by a former Board member, for sales and marketing offices in Lewisville, Texas. During the years ended December 31, 2003, 2002 and 2001, the Company paid \$34,800, \$34,800, and \$34,800, respectively, under this lease. The future lease commitment is \$34,800 per year through December 31, 2006 and \$17,400 for the year ended December 31, 2007.

During the years ended December 31, 2003, 2002 and 2001, the Company paid \$15,238, \$10,412, and \$12,070, respectively, to family members of its chief executive officer for various consulting services.

The Company has a consulting agreement with MediTrade International Corporation, a company controlled by Lillian E. Salerno, a 10% shareholder. The contract was amended on August 23, 2000 and expired on May 31, 2001. The contract is now on a month-to-month basis. MediTrade has agreed to establish contacts with major European entities to develop marketing and distribution channels as well as licensing agreements. Ms. Salerno will be paid \$16,667 per month and reimbursed for business expenses incurred on behalf of the Company, not to exceed \$5,000 per month without prior approval for the term of the contract. During the years ended December 31, 2003, 2002, and 2001 the Company paid \$253,952, \$201,120, and \$304,812, respectively, under this agreement.

The Company entered into a Consulting Agreement on March 15, 2000, with International Export and Consulting where International Export and Consulting agreed to advise the Company with respect to selection of an international distribution network, potential strategic partners, and future licensing for VanishPoint® technology in the Middle East. In exchange, the Company agreed to pay a consulting fee in the amount of \$2,000 a month for ten months as well as issue nonqualified stock options for 61,000 shares of Common Stock at an exercise price of \$10 per share. The Company expensed approximately \$115,000 related to the options issued. Marwan Saker, a principal in International Export and Consulting, is a director of the Company. During the years ended December 31, 2003, 2002, and 2001, the Company paid \$0, \$0, and \$2,000, respectively, under this agreement.

The Company has a license agreement with an officer of the Company. See Note 6. An officer of the Company has a Covenant Not to Sue Agreement with the Company. See Notes 13 and 14.

**12. STOCK OPTIONS**

**Stock options**

The Company has three stock option plans that provide for the granting of stock options to officers, employees and other individuals. During 1999, the Company approved the 1999 Stock Option Plan. The 1999 Plan is the only plan with stock options currently being awarded. The Company has reserved 4,000,000 shares of Common Stock for use upon the exercise of options under this plan.

The Company also has options for common shares outstanding under the 1996 Incentive Stock Option Plan and the 1996 Stock Option Plan for Directors and Other Individuals. A committee appointed by the Board of Directors administers all plans and determines exercise prices at which

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options are granted. Shares exercised 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. All unvested options issued under the plans expire three months after termination of employment or service to the Company.

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

	Years Ended December 31,					
	2003		2002		2001	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at beginning of period	1,748,780	\$ 8.21	1,191,280	\$ 8.90	1,390,705	\$ 8.91
Granted	897,300	\$ 8.65	589,580	6.90		
Exercised					(2,500)	(1.00)
Forfeited	(56,920)	\$ (8.59)	(32,080)	(9.71)	(196,925)	(9.05)
Outstanding at end of period	2,589,160	\$ 8.36	1,748,780	\$ 8.21	1,191,280	\$ 8.90
Exercisable at end of period	1,293,580	\$ 8.78	901,505	\$ 8.44	650,780	\$ 7.99
Weighted average fair value of options granted during period		\$ 2.42		\$ 0.07		\$

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions used for grants in 2003 and 2002: no dividend yield; expected volatility of 1.30% and 1.57%, respectively; risk free interest rates of 3.53% and 4.0%, respectively; and expected lives of 9.3 and 10.0 years, respectively.

The following table summarizes information about director, officer and employee options outstanding under the aforementioned plans at December 31, 2003:

Exercise Prices	Shares Outstanding	Weighted Average Remaining Contractual Life	Shares Exercisable
\$ 1.00	60,280	2.32	60,280
\$ 5.00	152,300	3.32	152,300
\$ 10.00	924,000	5.91	924,000
\$ 6.90	566,380	8.76	32,000
\$ 8.65	886,200	8.78	125,000

**Non-employee options**

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Options were granted to non-employees during the years ended December 31 as follows:

	Years Ended December 31,					
	2003		2002		2001	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at beginning of period	847,139	\$ 6.17	378,200	\$ 8.95	381,200	\$ 8.80
Granted			468,939	3.93	3,500	10.00
Exercised					(6,500)	(1.00)
Forfeited	(3,500)	\$ (10.00)				
Outstanding at end of period	843,639	\$ 6.15	847,139	\$ 6.17	378,200	\$ 8.95
Exercisable at end of period	843,639	\$ 6.15	799,137	\$ 5.94	234,700	\$ 8.31
Weighted average fair value of options granted during period		\$ -		\$ 1.94		\$ 0.89

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Included in the outstanding options at December 31, 2001 are options for the purchase of 15,000 shares of Common Stock that were granted to a non-employee for prior services performed. This individual became an employee of the Company during 2001.

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions used for grants in 2002: and 2001: no dividend yield; expected volatility of 1.64% and 30%, respectively; risk-free interest rates of 3.50%, and 4.40%, respectively; and expected lives of 8.5 and 2 years, respectively.

The following table summarizes information about non-employee options outstanding under the aforementioned plan at December 31, 2003:

<u>Exercise Prices</u>	<u>Shares Outstanding</u>	<u>Weighted Average Remaining Contractual Life</u>	<u>Shares Exercisable</u>
\$ 1.00	263,939	1.70	263,939
\$ 5.00	30,000	3.36	30,000
\$ 10.00	317,200	6.11	317,200
\$ 6.90	232,500	8.76	232,500

**13. LITIGATION SETTLEMENTS**

In the second quarter of 2003 the Company reached settlement agreements with Premier Inc.; Premier Purchasing Partners, L.P.; VHA, Inc.; Novation, L.L.C.; Tyco International (US) Inc.; and Tyco Healthcare Group L.P. in its federal antitrust lawsuit, Retractable Technologies, Inc. v. Becton Dickinson & Co. et al. As part of the settlements, the litigation against Premier, VHA, Novation, and Tyco has been dismissed.

Although specific terms are confidential, the agreements include cash payments and other financial consideration as well as provisions that are intended to facilitate the sale of our VanishPoint® products to Premier and Novation member facilities. In exchange for the settlement provisions, we have agreed to give up our claims against these companies.

The initial cash payment of \$29,125,000 was paid in 2003. The Company received net cash payments of \$13,879,511 of the cash payment in 2003. These proceeds were net of attorneys' fees, court costs, legal expenses, and amounts paid to Mr. Shaw.

Pursuant to a Covenant Not to Sue agreement entered into on September 19, 2001, between the Company and Thomas J. Shaw, individually, Mr. Shaw received \$728,609 of the initial cash payment in 2003.

Total attorneys' fees, court costs, and legal expenses were \$14,516,880 paid in May 2003 and \$4,250,000 paid in December 2003.

As part of the settlement agreements, a discount reimbursement program of \$8,000,000, which is net of legal fees, was established whereby the Company shall be provided quarterly reimbursements for certain discounts given to participating facilities. The Company will offer certain discounts to participating facilities and will be reimbursed for such discounts. These payments will be recognized upon delivery of products provided collection is reasonably assured. No reimbursements were recorded as of December 31, 2003.

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These agreements leave Becton Dickinson & Co. ( B-D ), the dominant U.S. maker of syringes and other needle products, as the sole remaining defendant in the case, which is currently scheduled for trial on July 6, 2004, in federal court in Texarkana, Texas. Among other allegations, the Company asserts in the lawsuit that B-D has acquired and maintained monopoly power among hospitals and healthcare providers to eliminate or lessen competition.

**14. SUBSEQUENT EVENTS**

In April 2004 \$14,125,000 was paid into the registry of the court under the terms of settlement agreements reached in the second quarter of 2003 with Premier Inc; Premier Purchasing Partners, L.P.; VHA, Inc.; Novation, L.L.C.; Tyco International (US) Inc; and Tyco Healthcare Group L.P. in its federal antitrust lawsuit, Retractable Technologies, Inc. v. Becton Dickinson & Co. ( BD ) et al. The Company received \$8,051,250 in connection with this payment. The amount received by the Company is net of attorneys' fees, court costs, legal expenses, and the amount paid to Mr. Shaw.

Pursuant to a Covenant Not to Sue agreement, Mr. Shaw received \$423,750 as a result of this payment to the Company under the settlement agreements.

The Company's litigation attorneys received \$5,650,000 of the April payment.

The Company received \$10,132 in the first quarter and \$21,254 in the second quarter of 2004 under the discount reimbursement program.

Effective as of April 27, 2004, the Company and Thomas J. Shaw entered into a Settlement Agreement and Release (the NMT Settlement Agreement ) with New Medical Technology, Inc.; New Medical Technology, LTD. and NMT Group PLC (collectively NMT ). Pursuant to the NMT Settlement Agreement NMT and all parties acting in concert with them are enjoined from importing the NMT Safety Syringe into the United States and from making, using, selling, or offering to sell the NMT Safety Syringe within the United States until the lapse or expiration of the subject patents. In addition and within three days of the entry of a Stipulation and Consent Judgment, NMT shall cause the delivery of One Million Dollars (\$1,000,000.00) to the Company.

Effective July 2, 2004, the Company entered into a Settlement Agreement and Release with BD (the Settlement Agreement ). Pursuant to the Settlement Agreement, BD was obligated to deliver within two (2) business days, One Hundred Million Dollars (\$100,000,000.00) into the registry of the Court. This amount was received on July 7, 2004. The Company received \$65.1 million of the proceeds which is net of attorney fees and expenses estimated not to exceed \$31.5 million and approximately \$3.4 million to be paid to Thomas J. Shaw, President and CEO, under a Covenant Not to Sue.

On July 20, 2004 the Board of Directors declared a dividend payable August 27, 2004 to shareholders of record as of August 17, 2004. The dividend pays the arrearage of \$2,550,338 on the Series I Class B stock and arrearage of \$4,568,245 on the Series II Class B stock from date of original issue to conversion or June 30, 2004, whichever is appropriate.



**Table of Contents****Index to Financial Statements****Item 8. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

The Company dismissed PricewaterhouseCoopers LLP ( PWC ) as its independent accountants effective as of June 24, 2002, upon the recommendation of the Audit Committee and the approval of the Board of Directors. The Board of Directors authorized and the Company appointed the firm of CF & Co, L.L.P. to serve as the Company's independent accountants for the years ended December 31, 2002 and 2003.

**Item 8A. 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 26, 2004, 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) and determined that, as of December 31, 2003, and based on the evaluation of these controls and procedures as required by paragraph (b) of 13a-15 or 15d-15 there were no significant deficiencies in these procedures. The CEO and CFO determined that our disclosure controls and procedures are effective.

Also, the CEO and CFO did not identify any deficiencies or material weaknesses in our internal controls, nor did they identify fraud that involved our management or any other employee who had a significant role in our internal controls. They did not find any deficiencies or weaknesses which would require changes to be made or corrective actions to be taken related to our internal controls. There have been no material changes during the fourth quarter of 2003 or subsequent to December 31, 2003, in our internal controls over financial reporting or in any other factor that has materially affected or is reasonably likely to materially affect our internal controls over financial reporting.

**PART III****Item 9. Directors, Executive Officers, Promoters, and Control Persons; Compliance with Section 16(a) of the Exchange Act**

The following table sets forth information concerning our Directors, executive officers, and certain of our significant employees as of August 2, 2004. Our Board of Directors consists of a total of nine (9) members, four (4) members of which are generally Class 1 Directors and five (5) of which are generally Class 2 Directors which serve for two-year terms. Because of dividend default voting rights, Series II Class B Shareholders had the right to fill one-third (1/3) of the Board seats. Due to dividend default voting rights of the Series II Class B Shareholders, three (3) of the Class 1 Director seats were filled by Series II Directors. However, the Board of Directors has declared and paid a dividend, of all amounts in arrears as of June 30, 2004, to the Series I and Series II Class B Shareholders. Accordingly, as of August 27, 2004, the dividend payment date, the terms of the Series II Directors terminated and the Board seats reverted to Class 1 Director seats. The three (3) vacancies will be filled by Directors appointed by the remaining Board members. Management intends to recommend that the vacancies be filled by independent Directors. Such appointed Directors will serve until the Class 1 Directors are up for election at the 2005 annual meeting of shareholders.

<u>Name</u>	<u>Age</u>	<u>Position</u>	<u>Term as Director Expires</u>
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**EXECUTIVES**

Thomas J. Shaw	54	Chairman, President, Chief Executive Officer, and Class 2 Director	2004
Steven R. Wisner	46	Executive Vice President, Engineering & Production and Class 2 Director	2004
Lawrence G. Salerno	44	Director of Operations	N/A
James A. Hoover	56	Production Manager	N/A
Russell B. Kuhlman	50	Vice President, Sales, and Class 1 Director	2005
Kathryn M. Duesman	41	Director of Clinical Services	N/A
Douglas W. Cowan	61	Vice President, Chief Financial Officer, Treasurer, and Class 2 Director	2004
Michele M. Larios	38	Vice President, General Counsel, and Secretary	N/A

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<b>Name</b>	<b>Age</b>	<b>Position</b>	<b>Term as Director Expires</b>
<b>INDEPENDENT DIRECTORS</b>			
Clarence Zierhut	75	Class 2 Director	2004
Marwan Saker	48	Class 2 Director	2004
<b>SIGNIFICANT EMPLOYEES</b>			
Phillip L. Zweig	57	Communications Director	N/A
Judy Ni Zhu	45	Research and Development Manager	N/A
Weldon G. Evans	62	Manager of Manufacturing Engineering	N/A
Roni Diaz	33	Director of Regulatory Affairs	N/A
Timothy E. Poquette	49	Quality Assurance Manager	N/A
John W. Fort III	36	Director of Accounting	N/A

**EXECUTIVES**

Thomas J. Shaw, the Founder of the Company, has served as Chairman of the Board, President, Chief Executive Officer, and Director since the Company's inception. In addition to his duties overseeing the management of the Company, he continues to lead our design team in product development of other medical safety devices that utilize 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.

Steven R. Wisner joined us in October 1999 as Executive Vice President, Engineering and Production and Director. Mr. Wisner's responsibilities include the management of engineering, production, quality assurance, Chinese operations, and international sales. Mr. Wisner has over 25 years of experience in product design and development. Before joining us, Mr. Wisner was the Director of Operations for Flextronics International in Richardson, Texas, an electronic manufacturing services company, from May 1998 to October 1999, where he had complete responsibility for taking product ideas from the concept stage through full design and into the manufacturing process. Mr. Wisner worked as Design Services Manager at Altatron Technologies, an electronic manufacturing service company, from August 1997 to May 1998, and as Director of Engineering with Responsive Terminal Systems, a medical reporting device manufacturing company, from 1984 to 1997. While working at Texas Instruments, a leading electronics manufacturing company, from 1982 to 1984, Mr. Wisner was the team leader of a product development that successfully integrated several thousand personal computers into the worldwide Texas Instruments data network. As a project leader with Mostek Corporation, a semiconductor manufacturing company, from 1980 to 1982, he oversaw the development of automated manufacturing control systems for semiconductor assembly. Mr. Wisner began his engineering career with Rockwell-Collins, an avionics division of Rockwell International, in 1977, where he was involved in the design of flight navigation equipment, including the first GPS (Global Positioning System). Mr. Wisner holds a Bachelor of Science in Computer Engineering from Iowa State University.

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 VanishPoint® products, as well as all product development, Quality Assurance, and process development projects. In addition, he supervised all aspects of the construction of our facilities in Little Elm, Texas. Mr. Salerno is the brother of Lillian E. Salerno, a shareholder holding more than 10 percent of the Common Stock, former Director and consultant to the Company.

James A. Hoover joined us in February 1996 and is our Production Manager. He is responsible for supervision of the production of our products. Mr. Hoover has also developed and implemented FDA required procedures and has been involved in the FDA inspection process. Mr. Hoover

joined us after working for Sherwood for 26 years. During his tenure with Sherwood, a medical device manufacturing company, he gained hands-on experience in all aspects of the medical device manufacturing process. Mr. Hoover began his career with Sherwood as a materials handler and worked his way up through a series of positions with added responsibilities to his final position there as Production Manager of Off-Line Molding,

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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®.

Russell B. Kuhlman joined us in February 1997 and is our Vice President, Sales and a Director. Mr. Kuhlman joined the Board of Directors in 2001. 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 the VanishPoint® product line. Mr. Kuhlman is respected throughout the industry and is a main contributor to the safety effort in this country. He has a sales background in the medical service industry that includes his most recent work for 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 the Houston Territory 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.

Kathryn M. Duesman, RN, joined us in 1996 and currently serves as the Director of Clinical Affairs and Marketing. She provides clinical expertise on existing VanishPoint® products as well as those in development. She has been instrumental in developing training and marketing materials and has spoken and been published on needle safety issues. Ms. Duesman has provided needle safety training to healthcare organizations, schools of nursing and government agencies. In 1996, Ms. Duesman served as a Registered Nurse ( RN ) at Denton Community Hospital. From 1995 to part of 1996, Ms. Duesman served as a RN at Pilot Point Home Health, an agency for home healthcare. From 1992 to 1995, Ms. Duesman served as a RN for Denton Community Hospital. 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.

Douglas W. Cowan is a Vice President and our Chief Financial Officer, Treasurer, and a Director. Mr. Cowan joined the Company as Chief Financial Officer and was elected to the Board of Directors in 1999. He is responsible for the financial, accounting, risk management and forecasting functions of the Company. Mr. Cowan has a Bachelor of Business Administration from Texas Technological College. He is a CPA licensed in Texas.

Michele M. Larios joined us in February 1998 and currently serves as a Vice President, the General Counsel and as Secretary of the Company. Ms. Larios is responsible for the legal and legislative, human resource and regulatory functions of the Company. 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.

**INDEPENDENT DIRECTORS**

Clarence Zierhut has served on our Board of Directors since April 1996. Since 1955, Mr. Zierhut has operated an industrial design firm, Zierhut Design, now Origin Design that develops new products from concept through final prototypes. 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 Laboratories, Gould, and McDonnell Douglas. He received a Bachelor of Arts from Art Center College of Design in Los Angeles, California.

Marwan Saker first 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



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equipment and supplies to overseas markets. Since 2000, he has served as Director of Consolidated Food Concepts Inc. From 1991 to 2001, Mr. Saker served as a Director of Meridian Marketing & Logistics Inc., an international transportation and home furnishing distribution company. 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. Mr. Saker has acted as a representative for United States 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 Dallas, Texas.

**SIGNIFICANT EMPLOYEES**

Phillip L. Zweig joined us in December 1999 as Communications Director. Mr. Zweig is a prize winning financial journalist who has worked as a staff reporter at The American Banker, The Wall Street Journal, Bloomberg Business News, and other media organizations. From 1993 to 1998, he served as Corporate Finance Editor at Business Week where he wrote a major article on the Company. Before joining us, he worked as a freelance financial writer and editorial consultant. His clients included Andersen Consulting and Boston Consulting Group. Mr. Zweig received a Bachelor of Arts in Behavioral Psychology from Hamilton College and a Master of Business Administration from the Baruch College Graduate School of Business.

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 with Checkmate Engineering, an engineering firm, as a design engineer 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 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.

Weldon G. Evans joined us in October 2000 as Manager of Manufacturing Engineering. His responsibilities include the support of new product development and current production, as well as the creation of new and improved manufacturing processes. Prior to joining us, he served as a senior project engineer with BD, a medical technology company, from 1973 to 2000. He received a Bachelor of Science degree in Mechanical Engineering and a Master of Science degree in Engineering Administration from Southern Methodist University. Mr. Evans is a member of Pi Tau Sigma National Honorary Mechanical Engineering Society and the American Society of Mechanical Engineering.

Roni Diaz is our Director of Regulatory Affairs. She joined us in March 2001 as Manager of Regulatory Affairs. Her responsibilities include development and implementation of company regulatory and quality policies, communication with FDA, European and other medical regulatory authorities, implementation of ISO 9001 and other necessary quality system certifications, obtaining CE mark approvals, generating and maintaining technical files, routine regulatory reports, and regulatory licensures applications and renewals. Prior to joining us, Ms. Diaz served as a Regulatory/Clinical Project Manager for MedTrials, a medical device and pharmaceutical consulting firm. From 1996-1999, she worked for Arthrocare, a medical device manufacturer, as a regulatory/clinical affairs associate. She received a Bachelor of Science degree in Health Sciences from San Jose State University. Ms. Diaz is a member of the Regulatory Affairs Professional Society and holds a Regulatory Affairs Certification.

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Timothy E. Poquette joined us in May 2000 as Quality Engineer and assumed the responsibilities of Quality Assurance Manager in July 2001. In this capacity, he is responsible for Quality Engineering and

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Assessment. Mr. Poquette holds an AAS in Chemical Technologies from Hartford State Technical College and is certified in quality engineering and quality management by the American Society for Quality. His professional experience includes 25 years of employment in the specialty chemical, pharmaceutical and medical device industries; before joining us, he served as supervisor of the QA Chemistry and Microbiology laboratories for the Oral Pharmaceuticals division of Colgate Palmolive.

John W. Fort III is our Director of Accounting. Mr. Fort joined us in March of 2000 as 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, coordination of the annual audits, and interim reviews by our independent accountants, as well as the cost accounting and forecasting functions of the Company. 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.

**FAMILY RELATIONSHIPS**

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

**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.

**DIRECTORSHIPS IN OTHER COMPANIES**

No Directors hold Directorships in reporting companies other than as set forth above.

**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 Commission initial reports of beneficial ownership (Form 3) and reports of changes in beneficial ownership (Forms 4 and 5) of our Common Stock and our other equity securities. Officers, Directors, and greater than 10 percent shareholders are required by the Commission's regulations to furnish us with copies of all Section 16(a) reports they file.

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To our knowledge based solely on a review of Forms 3 and 4 provided to us, all Directors, Officers, and holders of more than 10 percent of our equity securities registered pursuant to Section 12 of the Securities Exchange Act filed reports required by Section 16(a) of the Exchange Act as of December 31, 2003, with the exception of Lillian Salerno, a 10 percent shareholder. Ms. Salerno failed to timely file a Form 4 in December 2003 regarding the sale of 10,000 shares of Common Stock due to new electronic filing requirement difficulties.

### CODE OF ETHICS

Effective as of March 9, 2004, we have adopted a code of ethics that applies to all employees, including, but not limited to, the Company's principal executive and financial officers, a copy of which is attached hereto and incorporated herein as Exhibit No. 14. Our Code of Business Conduct and Ethics is designed to deter wrongdoing and to promote:

1. Honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interests between personal and professional relationships;

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2. Full, fair, accurate, timely, and understandable disclosure in reports and documents that we file with, or submit to, the Commission and in 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](http://www.vanishpoint.com). Any amendment to this code or waiver of its application to the principal executive officer, principal financial officer, accounting officer, or controller or similar person shall be disclosed to investors by means of a Form 8-K filing with the Commission. 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 and Marwan Saker. As of August 27, 2004, the Audit Committee has one vacancy.

**Audit Committee Financial Expert**

Mr. John J. McDonald served as the Company's designated Audit Committee Financial Expert. Due to the payment of dividends to the Series II Class B stockholders on August 27, 2004, the terms of the three Series II Directors (including Mr. McDonald) terminated. The Board of Directors is currently considering independent candidates to fill the three vacancies. At such time as the vacancies are filled, the Company will announce its designated Audit Committee Financial Expert. Each of the members of the Audit Committee are independent as determined by The AMEX rules and Item 7(d)(30)(iv) of Schedule 14A under the Exchange Act.

COMPENSATION AND BENEFITS COMMITTEE

We have a separately designated standing Compensation and Benefits Committee consisting of Clarence Zierhut. As of August 27, 2004, the Compensation and Benefits Committee has two vacancies.

NOMINATING COMMITTEE

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We have a separately designated standing Nominating Committee consisting of Marwan Saker. As of August 27, 2004, the Nominating Committee has two vacancies.

### DISCLOSURE REPRESENTATIVE

Mr. Timothy G. Greene had been designated as our Disclosure Representative. Mr. Greene's term as a Series II Director terminated on August 27, 2004. The Company will announce the new Disclosure Representative when appointed. Communications intended for the Board of Directors should be addressed to the Disclosure Representative and sent to 511 Lobo Lane, Little Elm, Texas 75068-0009.

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The following summary compensation table sets forth the total annual compensation paid or accrued by us to or for the account of the Chief Executive Officer and four additional executive officers whose total cash compensation exceeded \$100,000 for any of the past three fiscal years:

SUMMARY COMPENSATION TABLE

Name and Principal Position	Year	Annual Compensation		Other Annual Compen- sation(\$)	Long-Term Compensation			All Other Compen- sation (\$)
		Salary(\$)	Bonus(\$)		Awards		Payout(s)	
					Restricted Stock Award(s) (\$)	Securities Underlying Options/ SARs (#)	LTIP Payouts (\$)	
Thomas J. Shaw, President and CEO	2001	250,016						
	2002	250,016						
	2003	250,016						
Steven R. Wisner, Executive Vice President, Engineering and Production	2001	150,010	0			0		
	2002	150,010	0			20,000		
	2003	191,544	40,200			12,500		
Douglas W. Cowan, Vice President, Chief Financial Officer, and Treasurer	2001	142,501	5,000			0		
	2002	142,501	0			25,000		
	2003	187,501	37,400			125,000		
Michele M. Larios, Vice President, General Counsel, and Secretary	2001	120,016	0			0		
	2002	122,437	28,500			25,000		
	2003	183,462	62,100			124,600		
Russell B. Kuhlman,								

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Vice President, Sales	2001	105,019	0	0
	2002	105,019	1,000	20,000
	2003	105,020	24,700	79,400

The following sets forth the total individual grants of stock options and freestanding stock appreciation rights ( SARs ) made by us to persons listed in the above Summary Compensation Table during the last completed fiscal year:

**Option/SAR Grants in Last Fiscal Year\***

Individual Grants

<u>Name</u>	<u>Number of Securities Underlying Options/SARs Granted (#)</u>	<u>Percent of Total Options/SARs Granted to Employees in Fiscal Year</u>	<u>Exercise or Base Price (\$/Sh)</u>	<u>Expiration Date</u>
Thomas J. Shaw	0	N/A	N/A	N/A
Steven R. Wisner	12,500	1.6%	\$ 8.65	6/23/13
Douglas W. Cowan	125,000	16.2%	\$ 8.65	6/23/13
Michele M. Larios	124,600	16.1%	\$ 8.65	6/23/13
Russell B Kuhlman	79,400	10.3%	\$ 8.65	6/23/13

\* The options were issued under the 1999 Stock Option Plan as amended which is incorporated herein by reference to Exhibit No. 3.12 of the Company's registration Statement on Form 10-SB filed on June 23, 2000, and Exhibit No. 10.13 of the Company's Form 10-KSB filed on March 31, 2003. These options are exercisable 3 years after the date of grant.



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The following sets forth information regarding the exercise of options by the above executives and the year-end value of their unexercised options:

**Aggregate Option/SAR Exercises in Last Fiscal Year and FY-End Option/SAR Values**

Name	Shares	Value	Number of Securities Underlying	Value of Unexercised in-the-
	Acquired on Exercise (#)	Realized (\$)	Unexercised Options/SARs at FY-End (#) Exercisable/Unexercisable	Money Options/SARs at FY-End (\$) Exercisable/Unexercisable
Thomas J. Shaw	0	0	0	0
Steven R. Wisner	0	0	167,500/32,500	\$ 7,000/0
Douglas W. Cowan	0	0	50,000/150,000	0
Michele M. Larios	0	0	50,400/149,600	0
Russell B. Kuhlman	0	0	50,600/99,400	0

**COMPENSATION OF DIRECTORS**

We pay each non-employee Director a meeting fee of \$250 for each Board meeting attended. In the past, the Company has granted to each Director (except Mr. Shaw) stock options for Common Stock. We do not pay any additional amounts for committee participation or special assignment. Each independent Director received a one-time stipend of \$5,000 in addition to the per meeting payment.

**EMPLOYMENT AGREEMENT**

There are no other employment agreements in place involving other Officers or Directors, except as set forth below:

**Thomas J. Shaw**

We have a written employment agreement with Thomas J. Shaw, our President and Chief Executive Officer, for an initial period of three years which ended September 2002 that automatically and continuously renews for consecutive two-year periods. The agreement is terminable either by us or Thomas J. Shaw upon 30 days written notice. The agreement provides for an annual salary of at least \$150,000 with an annual salary increase equal to no less than the percentage increase in the Consumer Price Index during the previous calendar year. Thomas J. Shaw's salary shall be reviewed by the Board of Directors each January, which shall make such increases as it considers appropriate. Thomas J. Shaw is also entitled to participate in all executive bonuses as the Board of Directors, in its sole discretion, shall determine.

Under the employment agreement, we will also provide certain fringe benefits, including, but not limited to, participation in pension plans, profit-sharing plans, employee stock ownership plans, stock appreciation rights, hospitalization and health insurance, disability and life insurance, paid vacation, and sick leave. We also reimburse him for any reasonable and necessary business expenses, including travel and entertainment expenses, necessary to carry on his duties. Pursuant to the employment agreement, we have agreed to indemnify Thomas J. Shaw for all legal expenses and liabilities incurred with any proceeding involving him by reason of his being an officer or agent. We have further agreed to pay reasonable attorney fees and expenses in the event that, in Thomas J. Shaw's sole judgment, he needs to retain counsel or otherwise expend his personal funds for his defense.

Thomas J. 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 of the Company. Furthermore, Mr. Shaw has the right to resign in the event that there is a change in control which is defined as a change in the majority of directors within any 12 month period without two-thirds approval of the shares outstanding and entitled to vote, or a merger where less than 50 percent of the outstanding stock survives and a majority of the Board of Directors remains, or the sale of substantially all of our assets, or any other person acquires more than 50 percent of the voting capital. Mr. Shaw retained the right to participate in other businesses as long as they do not compete with us and so long as he devotes the necessary working time to the Company.

Table of ContentsIndex to Financial Statements**Item 11. 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, 2003:

<u>Plan category</u>	<u>Number of securities to be issued upon exercise of outstanding options, warrants, and rights</u>	<u>Weighted average exercise price of outstanding options, warrants, and rights</u>	<u>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))</u>
	(a)	(b)	(c)
Equity compensation plans approved by security holders	2,971,360	\$ 8.43	2,028,640
Equity compensation plans not approved by security holders*	522,439	\$ 3.88	N/A
<b>Total</b>	<b>3,493,799</b>	<b>N/A</b>	<b>2,028,640</b>

\* In conjunction with a \$3 million Loan Agreement and the purchase of 525,000 Series V shares by Katie Petroleum, we issued options for the purchase of 136,439 shares of Common Stock of the Company at an exercise price of \$1 per share to Katie Petroleum and two affiliates. The options were exercisable immediately and expire on September 30, 2005.

In conjunction with a \$2.5 million working capital loan, purchase of our real estate note and a \$1,000,000 construction loan (which was never drawn on) we issued options to Katie Petroleum for the purchase of 100,000 shares of Common Stock of the Company at an exercise price of \$1 per share. The options were exercisable immediately and expire on June 21, 2005.

We authorized the issuance of an option for the purchase of 200,000 shares of Common Stock to Jimmie Shiu, M.D., for his past services in introducing the Company to purchasers of various series of Preferred Stock as well as for introducing the Company to Katie Petroleum. The option is exercisable at \$6.90 per share and will terminate in 10 years.

We authorized the issuance of an option for the purchase of 25,000 shares of Common Stock to Harry Watson for his past services in assisting the Company in protecting its intellectual property. The option is exercisable at \$6.90 per share and will terminate in 10 years.

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In connection with a Consulting Agreement with International Export and Consulting, we issued options for the purchase of 61,000 shares of Common Stock to Marwan Saker, a Director.

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## SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS

The following table sets forth certain information regarding the beneficial ownership of our capital stock as of August 2, 2004, for: (a) each person known by us to own beneficially 5 percent or more of the voting capital stock, and (b) each Director and executive officer (earning in excess of \$100,000 annually) who owns capital stock. Except pursuant to applicable community property laws and except as otherwise indicated, each shareholder identified in the table possesses sole voting and investment power with respect to his or her shares.

<u>Title of Class</u>	<u>Name and Address of Beneficial Owner</u>	<u>Amount and Nature of Beneficial Ownership</u>	<u>Percent of Class<sup>(1)</sup></u>
<b>Common Stock</b>			
As a Group	Officers and Directors		
	511 Lobo Lane, P.O. Box 9		
	Little Elm, TX 75068-0009	12,138,000	46.1%
As Individuals	Thomas J. Shaw <sup>(2)</sup>	11,280,000	42.8%
	Lillian E. Salerno <sup>(3)</sup>	2,794,500	10.6%
	Marwan Saker <sup>(4)</sup>	461,000	1.7%
	Russell B. Kuhlman <sup>(5)</sup>	50,600	Less than 1%
	Clarence Zierhut <sup>(6)</sup>	66,000	Less than 1%
	Douglas W. Cowan <sup>(7)</sup>	50,000	Less than 1%
	Steve R. Wisner <sup>(8)</sup>	170,000	1%
	Michele M. Larios <sup>(9)</sup>	60,400	Less than 1%
<b>Series I-V Class B Stock</b>			
As a Group	Officers and Directors		
	511 Lobo Lane, P.O. Box 9		
	Little Elm, TX 75068-0009	447,500	14.1%
As Individuals	Thomas J. Shaw	80,000	2.5%
	Marwan Saker	355,000	11.2%
	Lillian E. Salerno	12,500	Less than 1%

- (1) The percentages of each class are based on 26,352,795 shares of Common Stock equivalents consisting of 22,580,679 shares of Common Stock outstanding, 3,181,616 shares of Preferred Stock convertible and options for the purchase of 590,500 shares of Common Stock obtainable within 60 days of this Report.
- (2) 80,000 of the 11,280,000 shares identified as Common Stock are preferred shares which are eligible for conversion into Common Stock within 60 days of the Report.
- (3) Lillian Salerno is a holder of more than 5 percent of the Company's voting stock. All other persons listed in the table are Officers or Directors of the Company. Furthermore, 12,500 of the shares identified as Common Stock are preferred shares which are eligible for conversion into Common Stock within 60 days of the Report.
- (4) 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 Stock and 25,000 shares of Series V Stock, Sovana Cayman Islands, Inc. holds 300,000 shares of Series IV Stock, and My Investments holds 14,500 shares of Series IV Stock. Mr. Saker is an Officer or Director and shareholder for each of these companies. The remaining 106,000 shares identified as Common Stock are shares exercisable through the exercise of options held by Mr. Saker within 60 days of the Report.

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

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- (6) These shares identified as Common Stock are shares acquirable by the exercise of stock options within 60 days of the Report.
- (7) These shares identified as Common Stock are shares acquirable by the exercise of stock options within 60 days of the Report.
- (8) 167,500 of these shares identified as Common Stock are shares acquirable by the exercise of stock options within 60 days of the Report.
- (9) 50,400 of the shares identified as Common Stock are shares acquirable by the exercise of stock options within 60 days of the Report.

There are no arrangements the operation of which would result in a change in control of the Company.

**Item 12. Certain Relationships and Related 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.

Thomas J. Shaw, our President and Chief Executive Officer who beneficially owned 49.6 percent of the outstanding Common Stock as of August 2, 2004, 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 receives a 5 percent royalty on gross sales of all licensed products sold to customers over the life of the technology licensing agreement. Mr. Shaw was paid a royalty of \$400,000 and \$923,357 for 2002 and 2003, respectively. Mr. Shaw, in 2003, received a total of \$728,609 from the proceeds of some of the settlements relating to an antitrust lawsuit styled *Retractable Technologies, Inc. v. Becton Dickinson & Co., Tyco International (U.S.), Inc., Tyco Healthcare Group, L.P., Novation, L.L.C., VHA, Inc, Premier, Inc., and Premier Purchasing Partners, L.P.* pursuant to the terms of the Covenant Not to Sue. Mr. Shaw and his wife waived royalties of \$1.5 million in 2002.

Lillian E. Salerno, a consultant for the Company, a 10 percent shareholder, and former Director, d/b/a Mill Street Enterprises ( Mill Street ), a sole proprietorship, leases offices at 618, 620, 622, and 628 S. Mill Street, in Lewisville, Texas, to us for our marketing and sales department. This lease is for a five-year period beginning in July 2002 at a monthly rate of \$2,900. Lease payments of \$34,800 and \$34,800 were paid in 2002 and 2003, respectively.

The Company has a consulting agreement with MediTrade International Corporation, a company controlled by Lillian E. Salerno. The contract was amended on August 23, 2000, and expired on May 31, 2001. The contract is now on a month-to-month basis. MediTrade has agreed to establish contacts with major European entities to develop marketing and distribution channels as well as licensing agreements. MediTrade is paid \$16,667 per month and reimbursed for business expenses incurred on behalf of the Company, not to exceed \$5,000 per month without prior approval for the term of the contract. During the years ended December 31, 2003 and 2002, the Company paid \$253,952 and \$201,120 respectively, under this agreement.

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**Item 13. Exhibits and Reports on Form 8-K**

(a) EXHIBITS

<b>Exhibit No.</b>	<b>Description of Document</b>
3(i)	Second Amended and Restated Articles of Incorporation of RTI filed August 14, 2000, as amended *
3(ii)	Amended and Restated Bylaws of RTI dated as of the 12th day of July, 2004 ***** **
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 September 28, 1999 ***
10.4	Technology License Agreement between Thomas J. Shaw and RTI dated the 23rd day of June 1995 ***
10.5	Loan Agreement Between RTI and Katie Petroleum, dated November 12, 2001, with the following exhibits: Note, Security Agreement, Construction Loan Agreement, Real Estate Lien Note, Guaranty, and Deed of Trust *** ** *
10.6	Consulting Agreement entered into on August 23, 2000, between RTI and Lillian Salerno dba Medi-Trade International **
10.7	First Amendment to Loan Agreement and Loan Documents and Note Modification Agreement entered into Between Katie Petroleum and RTI effective as of the 21st day of June 2002 *****
10.8	Loan Agreement Among RTI, Katie Petroleum and Thomas J. Shaw as of the 30th day of September, 2002 and Promissory Note *** **
10.9	Royalty Waiver Agreement entered into among Retractable Technologies, Inc., Thomas J. Shaw, and Suzanne M. August effective as of June 21, 2002 *** **
10.10	RTI s 1999 Stock Option Plan ***
10.11	First Amendment to 1999 Stock Option Plan *
10.12	1996 Incentive Stock Option Plan of RTI ***
10.13	1996 Stock Option Plan for Directors and Other Individuals ***
10.14	Settlement Agreement and Release by and among RTI, Thomas J. Shaw, New Medical Technology, Inc., New Medical Technology, LTD and NMT Group PLC dated effective as of April 27, 2004***** **
10.15	Covenant Not to Sue between Thomas J. Shaw and Retractable Technologies, Inc. ***** **
10.16	Settlement Agreement and Release between Retractable Technologies, Inc. and Becton Dickinson and Company, Inc. dated effective July 2, 2004 ***** **



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<b><u>Exhibit No.</u></b>	<b><u>Description of Document</u></b>
14	Retractable Technologies, Inc. Code of Business Conduct and Ethics **** ** and **** **
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-KSB filed on March 31, 2003
**	Incorporated herein by reference to RTI s Registration Statement on Form 10SB-A filed on October 25, 2000
***	Incorporated herein by reference to RTI s Registration Statement on Form 10-SB filed on June 23, 2000
****	Incorporated herein by reference to RTI s Form 8-K filed on July 10, 2002
*** **	Incorporated herein by reference to RTI s Form 10-QSB filed on August 14, 2002
*** **	Incorporated herein by reference to RTI s Form 8-K filed on October 10, 2002
*** ** *	Incorporated herein by reference to RTI s Form 10-QSB filed on November 14, 2001
**** **	Incorporated herein by reference to RTI s Form 10-KSB filed on March 30, 2004
**** **	Incorporated herein by reference to RTI s Form 8-K filed on January 29, 2004
**** ** *	Incorporated herein by reference to RTI s Form 8-K filed on July 6, 2004
**** ** **	Incorporated herein by reference to RTI s Form 10-QSB filed on August 16, 2004
**** ** **	Filed herewith

**(b) REPORTS ON FORM 8-K**

On December 18, 2003, we filed a Form 8-K with an item 5 disclosure that we issued a press release entitled RTI Reports Fully Diluted Earnings per Share of \$0.30 for the Nine Months Ended September 30, 2003. The press release contained copies of the Condensed Balance Sheets for September 30, 2003 and December 31, 2002 and Condensed Statements of Operations for the three and nine month periods ended September 30, 2002 and 2003.

**Item 14. Principal Accountant Fees and Services****AUDIT FEES**

The aggregate fees billed by CF & Co., L.L.P. for professional services rendered for the audit of the Company s annual financial statements for 2003 and the reviews of the financial statements included in the Company s Forms 10-QSB were \$115,415.

**TAX FEES**

The aggregate fees billed by CF & Co., L.L.P. for tax return preparation were \$10,000.

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PRE-APPROVAL POLICIES AND PROCEDURES

All of the non-audit related services were pre-approved by the Audit Committee.

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SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

RETRACTABLE TECHNOLOGIES, INC.  
(Registrant)

By: /s/ Thomas J. Shaw

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THOMAS J. SHAW  
CHAIRMAN, PRESIDENT, AND  
CHIEF EXECUTIVE OFFICER

Date: September 10, 2004

In accordance with the Exchange Act, 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

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

09/10/04

/s/ Russell B. Kuhlman

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Russell B. Kuhlman  
Vice President, Sales and Director

09/14/04

/s/ Douglas W. Cowan

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

09/10/04

*/s/ Clarence Zierhut*

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Clarence Zierhut  
Director

09/14/04

*/s/ Marwan Saker*

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Marwan Saker  
Director

09/13/04