RETRACTABLE TECHNOLOGIES INC
Form 10KSB
March 30, 2004
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-KSB

(Mark One)

x 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

Retractable Technologies, Inc.

(Name of small business issuer in its charter)

Texas	**75-2599762**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
511 Lobo Lane	
Little Elm, Texas	**75068-0009**

(Address of principal executive offices) **(Zip Code)**

Issuer s telephone number (972) 294-1010

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

Title of each class	**Name of each exchange on which registered**
Common	The American Stock Exchange

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

Preferred Stock

(Title of Class)

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 x 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 10-KSB or any amendment to this Form 10-KSB. ¨

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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 $50,296,139 which was computed with reference to the closing price as of March 9, 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 March 9, 2004, there were 22,182,734 shares of our Common Stock issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None except exhibits

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

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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 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 exclusive marketing practices engaged in by Becton Dickinson and Co (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 Note 13 of the financial statements. This litigation resulted in settlements in 2003 with all parties except BD.

We continue to attempt to gain access to the market through our sales efforts and through our litigation against BD. We believe that if we are successful in getting

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market access for our products, it would have a significant favorable impact on the Company. See **Item 3. Legal Proceedings.**

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

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.

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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.

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

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the needle and syringe market, the market share leader, BD has utilized 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 trade shows, 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; and (g) 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 inability to access the market has slowed the introduction of these products into the market.

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 , a 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

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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). However, based on BD s exclusive marketing practices and market share dominance BD is likely to continue to block us from free access to the market until the matter is resolved through the current litigation.

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, some safety products, 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. The suit alleges violations of state and federal antitrust laws, tortious interference, business disparagement, and common law conspiracy. 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.

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), Sterimatic, Ltd., and New Medical Technologies, Inc. (NMT). 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. NMT manufactured a syringe that utilized automated retraction of the used needle within the barrel of the syringe. NMT no longer manufactures these products. See **Item 3. Legal Proceedings**.

Other factors affecting our competitiveness include class action lawsuits by healthcare workers. Class action suits on behalf of healthcare workers have been filed in several states against BD and Sherwood, et al. The success of such lawsuits could, obviously, be materially beneficial to any company that provides a safer alternative technology to the standard needle products, which cause as many as 800,000 reported needlestick injuries each year.

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 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. Demand could also be increased if we were successful in the antitrust lawsuit we have filed against BD. See **Item 3. Legal Proceedings**. Outsourcing arrangements

such as our agreement with Double Dove could increase our manufacturing capacity with

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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.

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 23rd 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 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 royalties have been paid in accordance with this agreement with the exception of $1,500,000 which were waived by Mr. Shaw and his wife.

We have the right and obligation to obtain protection of the invention, including prosecution of patent properties. The license unilaterally changes to a nonexclusive license in the event of a hostile

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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. See **Item 3. Legal Proceedings**.

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 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.

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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 inability to access 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 March 9, 2004, we had 168 full-time employees, two part-time employees, and one independently contracted consultant. Of the 168 full-time employees, five persons were engaged in research and development activities, 78 persons were engaged in manufacturing and engineering, 30 persons were engaged in quality assurance and regulatory affairs, 22 persons were engaged in sales and marketing, 32 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.

The Company has received a loan from 1st International Bank (st 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 1st International and fund the new warehouse and related infrastructure. Payments on the new note

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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 1st International affecting the interest rate will range from $0 to $500,000.

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. The amount of capital required would be dependent on our analysis of the extent of the potential market penetration if we were able to compete in a free market environment.

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 1st 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

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, 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 allege violations of state and federal antitrust acts, tortious interference with prospective business relationships, business disparagement, and common law conspiracy. These violations are 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. As of May 7, 2003, we announced we had dismissed our claims against Novation, L.L.C.; VHA Inc.; Premier Inc.; Premier Purchasing Partners, L.P.; Tyco International (US) Inc.; and Tyco Healthcare Group, L.P. pursuant to settlements. We were seeking the following damages: an injunction enjoining BD 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 may be entitled. The case has been rescheduled for a July 6, 2004, trial date. We are still assessing the true extent of damages actually incurred by us as a result of BD s alleged monopolistic activities. We are in the process of researching such damage amounts and cannot state them with certainty at this time.

On February 1, 2002, the Company 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 defendants counterclaimed, alleging noninfringement and invalidity of the patents. On February 18, 2003, the Company and Thomas J. Shaw filed an additional complaint against the same defendants, alleging infringement of a third syringe patent. The two actions have been consolidated and the trial will be set for some time in June of 2004. We are seeking monetary damages and permanent injunctive relief in

both actions.

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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:

NOMINEE	FOR	WITHHELD
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 consists 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

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

PART II

Item 5. Market for Common Equity and Related Stockholder Matters

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:

	Common Stock	
	High	**Low**
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

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SHAREHOLDERS

As of March 9, 2004, there were 22,182,734 shares of Common Stock held by 380 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. As of March 9, 2004, $14,518,000 in dividends is in arrears on the Class B Convertible Preferred 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 Commission and available via Edgar.

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

OVERVIEW

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 exclusive marketing practices engaged in by Becton Dickinson and Co. (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 Note 13 to the financial statements. This litigation resulted in settlements in 2003 with all parties except BD. We continue to attempt to gain access to the market through our sales efforts and through our litigation against BD.

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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 production capacity in the event of a dramatic increase in demand, our ability to access the market, our ability to decrease production costs through our manufacturing agreement with Double Dove, our ability to finance research and development as well as operations and expansion of production through equity and debt financing, as well as sales, and the increased interest of larger market players (specifically BD) in providing safety needle devices such as the competing retractable syringe, the Integra. 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**
Sales, net	$ 19,078,332	$ 20,316,299
Cost of sales	14,654,006	14,990,932
Product recall and recovery		481,637
Gross margin	4,424,326	4,843,730
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
Total operating expenses	10,327,278	11,233,301
Loss from operations	(5,902,952)	(6,389,571)
Interest income (expense), net	(262,589)	(436,357)
Litigation settlement, net	13,879,511	
Net income (loss) before income taxes	7,713,970	(6,825,928)
Provision for income taxes	265,473	

Net income (loss)	7,448,497	(6,825,928)
Preferred stock dividend requirement	(2,560,723)	(2,266,250)
Earnings (loss) applicable to Common Stockholders	$ 4,887,774	$ (9,092,178)
Earnings (loss) per share - basic	$ 0.23	$ (0.45)
Earnings (loss) per share - diluted	$ 0.20	$ (0.45)
Weighted average common shares outstanding	21,001,004	20,300,454

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

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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 $14,608,120, less $728,609 paid to Thomas J. Shaw under the terms of a Covenant Not to Sue, as the initial payment under the financial terms of these settlement agreements.

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

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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 1st 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.

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

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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 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

Revenues 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 collected. Other consideration provided through these settlement agreements will be recognized and disclosed periodically as required by SEC rules and regulations.

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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 bank 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. All but $475,000 of these loans have been repaid. The $475,000 loan will be repaid out of the New Loan with 1st International as discussed below. 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.

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

Current 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 is the subject of our lawsuit discussed in greater detail in **Item 3. Legal Proceedings**. In the event our lawsuit is successfully

resolved, it will likely have a beneficial and material impact on our liquidity and demand for our products.

Our primary source of liquidity is sales of product and, historically, sales of stock and bank 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.

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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.

In the event we continue to have only limited market access and the cash provided by the recent litigation settlements and generated from operations becomes insufficient, 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, we have 1,408,784 shares of Class B stock and 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.

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:

	Payments Due by Period				
Contractual Obligations	**Total**	**2004**	**2005-2006**	**2007-2008**	**Thereafter**
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
Total Contractual Cash Obligations	**$ 3,666,209**	**$ 346,600**	**$ 727,371**	**$ 724,757**	**$ 1,867,481**

Material Commitments for Expenditures

Assuming we are able to access the market, we would need to receive 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. The amount of capital required would be dependent on our analysis of the extent of the potential market penetration if we are able to compete in a free market environment.

We had $385,921 in capital expenditures in 2003. We anticipate capital expenditures of approximately $3,000,000 in 2004.

PLAN OF OPERATION ASSUMING LIMITED ACCESS TO MARKETS

At the present time Management does not intend to raise additional equity capital in 2004. In the event we continue to have only limited market access, we would take cost cutting measures to reduce cash requirements. Such measures could result in reduction of units being produced, reduction of workforce, and

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reduction of salaries of officers and other nonhourly employees and deferral of royalty payments to Thomas Shaw.

OFF BALANCE SHEET TRANSACTIONS

We have no off-balance sheet transactions with the exception of the personal guarantees of Thomas J. Shaw of our debt with Katie Petroleum.

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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 years 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

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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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RETRACTABLE TECHNOLOGIES, INC.

BALANCE SHEETS

	December 31,	
	2003	**2002**
ASSETS		
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
Total current assets	13,496,746	7,065,061
Property, plant, and equipment, net	9,678,826	10,515,480
Intangible assets, net	394,369	405,641
Other assets	60,565	72,671
Total assets	$ 23,630,506	$ 18,058,853
LIABILITIES AND STOCKHOLDERS EQUITY		
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	
Total current liabilities	5,772,695	8,021,476
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
Series V, Class B; issued 2,416,221shares; outstanding: 1,732,071 and 2,416,221 shares, respectively (liquidation preference of $7,621,112 and $10,631,372, respectively)	1,732,071	2,416,221

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)
Total stockholders equity	15,134,810	7,437,079
Total liabilities and stockholders equity	$ 23,630,506	$ 18,058,853

See accompanying notes to the financial statements

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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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RETRACTABLE TECHNOLOGIES, INC.

STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY

	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	Amoun
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 Preferred Series V,														

Class B shares														
Stock options given in connection with conversion of $3,679,284 of debt														
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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RETRACTABLE TECHNOLOGIES, INC.

STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY

	Additional Paid-in Capital	Unearned Compen-sation	Accumulated Deficit	Total
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