RETRACTABLE TECHNOLOGIES INC
Form 10KSB
March 31, 2003
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-KSB

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

For the fiscal year ended December 31, 2002

[ ] 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. $20,316,299

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 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 $29,973,864, which was computed with reference to the closing price as of March 17, 2003.

(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 17, 2003, there were 20,328,100 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 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 Certificate in July 1998, and the VanishPoint® syringe received its CE Mark Certificate on July 31, 1998. In July 2001, the Company received re-certification of the ISO 9001 and CE Mark. ISO 9001 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.

On May 4, 2000, we entered into an agreement with Abbott Laboratories for an initial five-year term for the marketing and distribution of the Company s products into the U.S. acute care market. See Dependence on Certain Customers.

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We installed our 1cc assembly equipment in the fourth quarter of 2000 and began production in the first quarter of 2001.

We continue to attempt to gain access to the market through our sales efforts and through our litigation against Becton Dickinson and Company (B-D), Tyco International (U.S.), Inc. and Tyco Healthcare Group, L.P. (Tyco), Premier, Inc. and Premier Purchasing Partners, L.P. (Premier), and Novation, L.L.C. (Novation). We believe that if we are successful in getting 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. In 1999, 2000, and 2001, 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 are being produced in various needle lengths and gauges and packaging styles. We began automated assembly of 1cc syringes in the first quarter of 2001 and they are available in commercial quantities. 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. Sales of the VanishPoint® blood collection tube holder and a small tube adapter for use with small sample collection tubes began in the third quarter of 1998.

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 is 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 the following domestic organizations and government

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agencies are involved in the current effort to get more effective safety needle products to healthcare workers:

National Institute of Occupational Safety and Health issued a safety alert calling on employers to adopt safer needles to reduce needlestick injuries. The federal agency is a division of the Centers for Disease Control and Prevention. In its alert, Preventing Needlestick Injuries in Health Care Settings, the National Institute of Occupational Safety and Health provides scientific information about the risk of needlestick injuries. This alert adds momentum to the growing safety movement and supports the rules issued by OSHA, on November 5, 1999.

OSHA issued a Compliance Directive, which instructs OSHA inspectors to cite employers who fail to evaluate and buy the safest needle devices available on the market. The directive states that where engineering controls will reduce employee exposure either by removing, eliminating, or isolating the hazard, they must be used. OSHA has published a revised Bloodborne Pathogens Standard.

The Service Employees International Union (SEIU) has taken a proactive stance with regard to promoting the use of automated retraction needle devices in member hospitals. Events, including introduction of state and federal legislation and protests by SEIU members at San Francisco General Hospital, attest to the type of support from the community that the safety products and VanishPoint® product line, in particular, attract. Members of the SEIU have specifically requested VanishPoint® products in order to make their members aware of the availability of VanishPoint® technology and the need for it at other facilities with union membership. Unionized healthcare workers provide healthcare staffing for 12.5 percent of United States hospital facilities.

Under California s groundbreaking legislation, Cal OSHA mandates healthcare employers to provide their workers with safe needle devices. This action was taken in response to events that transpired at San Francisco General Hospital and pressure from the SEIU and various federal, state, and local elected officials in California who demanded change. Our representatives served on the Advisory Committee for developing the amendments. California was the first state to successfully pass legislation mandating the use of safety needle products. The 1998 California legislation directed Cal OSHA to amend California s bloodborne pathogens standard. This regulation requires the use of needle products that effectively eliminate or reduce injury rates. Employers are also required to create and maintain a log of all needlestick injuries by the type of device and the manufacturer s brand. Noncompliance with this Cal OSHA standard can result in misdemeanor and/or felony charges that carry penalties of up to three years in prison and fines up to $250,000.

Numerous states have now enacted safety needle laws including California, Tennessee, Maryland, Texas, New Jersey, Ohio, West Virginia, Minnesota, Maine, Georgia, New Hampshire, Iowa, Alaska, Connecticut, Oklahoma, Massachusetts, New York, Missouri, Rhode Island, Pennsylvania, and Arkansas. Federal legislation was signed into law on November 6, 2000, by former President Clinton. Federal legislation which became effective for most states on April 12, 2001,

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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 the needle and syringe market, the market share leader, B-D, has utilized long-term exclusive contracts which have restricted our entry into the market.

We distribute our products in the United States and its territories through general line and specialty distributors. We also utilize international distributors. We entered into an agreement with Abbott Laboratories whereby Abbott agreed to act as a nonexclusive marketer and distributor of our 1cc, 3cc, 5cc, and 10cc syringes, blood collection tube holders, and small tube adapters to acute care facilities in the United States. See Dependence on Certain Customers. The Abbott agreement is for an initial five-year term that began in May 2000. We continue to utilize our current general line and specialty distributors in other market segments, such as primary care and alternate care facilities.

We have developed a national direct marketing network in order to market our products to health care customers and their purchaser representatives. We have seven employees located across Texas, Georgia, California, Tennessee, New Jersey, Wisconsin, and Arizona. 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 registered nurses that educate healthcare providers and healthcare workers through accredited continuing education units for in-service training, 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. France has led Western Europe in its recognition of safety and has implemented VanishPoint® blood collection tube holders in several hospitals and clinical laboratories.

Key components of our strategy to increase our market share are to: (a) continue marketing emphasis in states that have implemented safe needle legislation; (b) continue to add Veterans Administration facilities, health departments, emergency medical services, federal prisons, 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 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.

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Several factors could materially affect the marketability of our products. Demand could be dramatically increased by current legislation encouraging the use of safety syringes. Demand could also be increased if we were successful in the antitrust lawsuit we have filed against B-D and others. See **Item 3 Legal Proceedings**. 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.

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 and lack of adequate capitalization 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, B-D is headquartered in New Jersey. B-D s safety-engineered syringe and needle products sales accounted for approximately 14.2 percent of B-D s total 2002 sales. B-D 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. B-D also manufactures a safety blood collection tube holder that utilizes the SafetyLok sheath. B-D s Vacutainer® blood collection tube holder is commonly used as industry jargon to refer to blood collection tube holders in general. B-D has begun manufacture of a 3cc retracting needle product. The impact of B-D s new Integra syringe is yet to be determined. However, at this time, it does not offer a 1cc size and when used with highly viscous medication may leak (as described in their instructions for use). B-D s marketing practice is currently the subject of our litigation. See **Item 3 Legal Proceedings**.

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 B-D SafetyLok syringe and the Magellan®, a safety syringe that utilizes a hinged lever to cover the needle tip.

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 B-D 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.

B-D and Sherwood have controlling market share, greater financial resources, larger and more established sales and 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, the Company filed a lawsuit in the United States District Court for the Eastern District of Texas against B-D; Tyco International (U.S.), Inc.; Tyco Healthcare Group, L.P.; Premier, Inc.; Premier Purchasing Partners, L.P.; V.H.A., Inc.; and Novation L.L.C. The suit alleges violations of state and federal antitrust laws, tortious interference, business disparagement, and common law conspiracy. See **Item 3 - Legal Proceedings**. These competitors may be

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able to use their resources to improve their products through research or acquisitions or develop new products, which may compete more effectively with our products.

In addition to B-D 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 manufactures a syringe that utilizes automated retraction of the used needle within the barrel of the syringe. See **Item 3 - Legal Proceedings**.

Other events that could have an impact on our competitiveness include class action lawsuits by healthcare workers. Class action suits on behalf of healthcare workers have been filed in several states against B-D 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. Our products include design features which prohibit unfortunate and improper reuse.

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, in some instances, 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.

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), Nipro Corporation and ISPG.

Dependence on Major Customers

Abbott purchases comprised 47.4 percent and 43.8 percent of our unit sales in 2001 and 2002, respectively. Unit sales to Abbott increased 14.1 percent from 2001 to 2002. Abbott distributes and markets our products into the acute care market. While the 14.1 percent increase in our sales

to Abbott is significant, inconsistencies in sales growth and timing of orders have made it difficult to plan production requirements in an efficient and cost effective manner.

McKesson accounted for 11.8 percent of unit sales in 2002.

Unit sales to others were 52.6 percent and 56.2 percent of sales in 2001 and 2002, respectively. Unit sales to others increased 31.9 percent from 2001 to 2002. Sales to others consist primarily of sales into the alternate care market.

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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 licensing fee has been paid in accordance with this agreement. Pursuant to a Royalty Waiver Agreement effective as of January 18, 2002, among the Company, Thomas J. Shaw and his wife, Suzanne M. August, Mr. Shaw and his wife agreed to waive payment of royalties in the amount of $1 million payable for sales of Licensed Products during the year 2001. On June 21, 2002, Thomas J. Shaw and his wife, Suzanne M. August, forgave an additional $500,000 of the royalties payable under the licensing agreement. All prior royalties have been paid.

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 which is detailed in the June 1995 license agreement.

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

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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 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 April 2000, after which the auditor determined No Action Indicated.

TUV Essen, a subsidiary of RWTÜV Germany, certified our quality system for ISO 9001: 1994. Since the original certification in 1997, we have undergone annual surveillance audits with no major noncompliances noted. In addition, the VanishPoint® product line was certified for a CE Mark. The CE Mark authorizes us to sell in 18 different countries.

In June 2001, TUV Essen performed a re-certification audit of our quality system and CE Mark (ISO 9001, EN 46001, 93/42/EEC Annex II). We received re-certification in July 2001. The last surveillance audit was performed in March 2002 with no major noncompliances noted.

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.

Research and Development

We spent $899,149, $756,542 and $337,930 in fiscal 2000, 2001, and 2002, respectively, on research and development, primarily on development of prototype molds and manufacturing processes for the following products: 1cc syringe, 3cc syringe, 5cc syringe, 10cc syringe, and the blood collection tube holder. 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 and lack of adequate capitalization 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.

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Employees

As of March 17, 2003, we had 164 full-time employees, two part-time employees, and one independently contracted consultant. Of the 164 full-time employees, four persons were engaged in research and development activities, 82 persons were engaged in manufacturing and engineering, 35 persons were engaged in quality assurance and regulatory affairs, 14 persons were engaged in sales and marketing, 26 persons were engaged in general and administrative functions, and three persons 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. We anticipate that any future development of facilities beyond those 35 acres will be in areas closer to the east and west coast customer bases. The land and building on which the headquarters is located are the subject of a lien by Katie Petroleum, Inc. (Katie Petroleum) as collateral for a loan in the aggregate current principal amount of $250,003 (the Katie Petroleum Loan). The Katie Petroleum Loan provides for monthly payments of accrued interest and a February 18, 2005, maturity date. The interest rate on the Katie Petroleum Loan is prime plus 1 percent. The Katie Petroleum Loan agreement further provides that, as long as preferred stock dividend arrearages exist, the maturity date will be extended on a year to year basis until such time as no arrearages exist. Pursuant to the Katie Petroleum Loan Agreement, the Deed of Trust for this property and a related Assignment of Rents cannot be pledged until the loan is repaid. The loan cannot be prepaid before the preferred stock dividends are paid.

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 shareholder and consultant for 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.

We do not hold any real estate or related securities for investment purposes or engage in real estate activities.

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, Texas Bank, and Katie Petroleum as the loss payees.

Assuming we are able to access the market, we would need to receive additional capital to fund capital expenditures which could include additional assembly lines, manufacturing space, warehousing, and related infrastructure. The expansion could include 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.

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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 (the Federal Court Case) styled *Retractable Technologies, Inc. v. Becton Dickinson and 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. We are seeking the following damages: an injunction enjoining each defendant 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 was scheduled for an April 2003 trial but has been rescheduled for a February 3, 2004, trial date. We have filed a Motion to Reconsider Trial Date requesting the trial be reset on a date beginning in August or September 2003.

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. v. New Medical Technology, Inc.; New Medical Technology, Ltd.; and NMT Group PLC*, Cause No. 4:02-CV-34 (the NMT Defendants). Thomas J. Shaw was subsequently added as a plaintiff in the suit. The defendants counterclaimed, alleging noninfringement and invalidity of the patents. Discovery is underway and trial is set for November 3, 2003. On February 18, 2003, the Company and Thomas J. Shaw filed an additional complaint against the same defendants in this Court, alleging infringement of a third syringe patent. The Company is presently trying to consolidate the two actions. The Company is seeking monetary damages and permanent injunctive relief in both actions.

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 2002 Annual Meeting (the Annual Meeting) of Retractable Technologies, Inc., originally scheduled for September 20, 2002, was adjourned and rescheduled for November 8, 2002, because quorum requirements were not met on September 20, 2002. The purpose of the meeting was the election by the Series II shareholders of three Series II Directors. Of the 431,000 shares of Series II Stock of RTI entitled to vote, less than the 215,500 required to constitute a quorum were represented in person or by proxy at the rescheduled November 8, 2002, meeting. Accordingly, no business of the Series II shareholders could be transacted except for the rescheduling of the Series II shareholder meeting. The Series II shareholders voted in favor of January 24, 2003, as the rescheduled date for the Series II business of the Annual Meeting.

At the January 24, 2003, meeting, 242,000 shares of the 431,000 shares of Series II Stock of the Company entitled to vote were represented in person or by proxy at the Series II Meeting, which was more than the 215,500 required for quorum. 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	AGAINST

Kenneth W. Biermacher	232,000	10,000
Timothy G. Greene	232,000	10,000
John J. McDonald	232,000	10,000

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Accordingly, Kenneth W. Biermacher, Timothy G. Greene, and John J. McDonald were elected as Series II Directors to serve until the 2003 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 January 24, 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
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
2001		
Fourth Quarter	$ 7.40	$ 5.34
Third Quarter	$ 7.00	$ 3.40
Second Quarter	$ 12.75	$ 5.80

SHAREHOLDERS

As of March 17, 2003, there were 20,328,100 shares of Common Stock held by 403 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 the date of this Report, approximately $403,000 in dividends are in arrears on Series A Stock and $12,013,000 in dividends are in arrears on the Class B Preferred Stock. Dividends may not be paid on the Common Stock until all dividends on the Preferred Stock have been paid. Pursuant to the requirements of a loan from

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Texas Bank, we have agreed not to return capital to the shareholders or redeem outstanding shares without the bank s prior consent. We had permission from the bank where necessary, namely, the redemption of Series A Stock and payment of Series A dividends.

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

The following discussion outlines all securities sold by us for cash or services rendered during the fourth quarter of 2002. All of the shares sold or granted were issued pursuant to the authority granted by the private offering exemption outlined in Section 4(2) and Rule 506 of Regulation D under the Securities Act to a limited number of persons and without a view toward distribution.

We sold 27,500 shares of Series V Class B Convertible Preferred Stock (Series V Stock) at $4.00 per share to 3 accredited investors for an aggregate amount of $110,000 in cash. Series V Stock is convertible immediately on a one-to-one basis into shares of Common Stock for no additional consideration.

Sales of unregistered securities in the first three quarters of 2002 were reported in the Company s Form 10-QSB quarterly reports filed with the Commission and are available online via Edgar.

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

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 successfully resolve our litigation with B-D, among others, 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 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, 2002, and 2001, 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,	
	2002	2001
Sales, net	$ 20,316,299	$ 16,145,635
Cost of sales	14,990,932	13,322,965
Product recall and recovery	481,637	