RETRACTABLE TECHNOLOGIES INC
Form 10-K/A
February 27, 2008

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K/A

(Mark One)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2006

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission file number 000-30885

Retractable Technologies, Inc.

(Name of registrant as specified 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** (Address of principal executive offices)	**75068-0009** (Zip Code)

Registrant s telephone number, including area code **(972) 294-1010**

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

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

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

Preferred Stock

(Title of Class)

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K/A or any amendment to this Form 10-K/A. o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act (check one):

Large accelerated filer o Accelerated filer o Non-accelerated filer x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act) Yes o No x

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to

the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant s most recently completed second fiscal quarter. The aggregate market value of the common equity held by non-affiliates is $36,649,107, assuming a price of $3.70, which was computed with reference to the closing price as of June 30, 2006.

APPLICABLE ONLY TO REGISTRANTS INVOLVED IN BANKRUPTCY PROCEEDINGS DURING THE PRECEDING FIVE YEARS

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Section 12, 13, or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. Yes o No o

(APPLICABLE ONLY TO CORPORATE REGISTRANTS)

Indicate the number of shares outstanding of each of the registrant s classes of common equity, as of the latest practicable date. As of March 1, 2007, there were 23,674,164 shares of our Common Stock issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None except exhibits

EXPLANATORY NOTE

This amendment to the Annual Report of Retractable Technologies, Inc. for the fiscal year 2006 filed on Form 10-K/A is being filed primarily: 1) to amend **Item 9A. Controls and Procedures** to provide greater detail regarding the disclosed material weakness discovered regarding the initial booking of a significant entry in the wrong period and 2) to amend Exhibit No. 31.2 to re-insert the introductory language to paragraph 4 which was inadvertently deleted from the certification.

This Form 10-K/A has also been amended where necessary to reflect material events that have occurred subsequent to April 2, 2007, including but not limited to, the conclusion of the 2007 fiscal year, the termination of a lease from an affiliate, changes in key employees, subsequent litigation filed by us against Becton, Dickinson & Company (BD) and by BD and MDC Investment Holdings, Inc. against us, our annual meeting, the resignation of an independent Director, and the appointment of an independent Director.

TABLE OF CONTENTS

PART I

PART II

PART III

PART IV

PART I

Item 1. Business.

DESCRIPTION OF BUSINESS

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. The IV catheter also operates with a friction ring mechanism whereby the needle is retracted after insertion of the catheter into the patient. We introduced an IV safety catheter in the first quarter of 2006. 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 . Mr. Shaw entered into an agreement whereby Suzanne August, his former spouse, is entitled to $100,000 per quarter out of any royalty payments. See Patents, Licenses 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.

We have been manufacturing and marketing our products into the market place since 1997. 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 Company, Inc. (BD) who dominates our market.

We continue to attempt to gain access to the market through our sales efforts, our innovative technology, and introduction of new products. We are focusing on methods of upgrading our manufacturing capability and efficiency in order to enable us to offer our technology at a reduced price. We believe our current capitalization provides the resources necessary to implement these changes and greatly improve our manufacturing capacity and efficiency, thereby reducing our unit cost.

Principal Products

Our products with Notice of Substantial Equivalence to the FDA include the VanishPoint® IV Safety Catheter, 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. Syringe sales comprised 97.5%, 98.6%, and 98.8% of revenues in 2004, 2005, and 2006.

We also have begun selling allergy trays with 25 syringes per tray. The trays accounted for approximately 1.4% of U.S. sales in 2006. The tray design eliminates the need to individually unwrap each syringe.

We introduced the IV safety catheter into the market in the first quarter of 2006. We have completed the construction of automated assembly equipment in the first quarter of 2007 and we expect it will be placed in service in the second quarter of 2007.

Our products (without Notice of Substantial Equivalence to the FDA) also include a dental syringe, a butterfly IV, and an autodisable syringe. 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.

Principal Markets

The VanishPoint® syringe and needle device products are sold to and used by healthcare providers primarily in the United States (with 12.2% of revenues in 2006 generated from sales outside the United States) which include, but are not limited to, acute care hospitals, alternate care facilities, doctors offices, clinics, emergency centers, surgical centers, convalescent hospitals, Veterans Administration facilities, military organizations, public health facilities, and prisons.

The syringe and needle device market continues to be a market in transition. The nature of the products comprising the market is slowly changing from standard to safety devices. The impetus for the change to safety devices is the risk that is carried with each needlestick injury which includes the transmission of over 20 bloodborne pathogens, including the human immunodeficiency virus (HIV, which causes AIDS), hepatitis B, and hepatitis C. Because of the occupational and public health hazards posed by conventional disposable syringes, public health policy makers, domestic organizations and government agencies have been involved in the effort to get more effective safety needle products to healthcare workers. Federal legislation was signed into law on November 6, 2000, by former President Clinton. This legislation, which became effective for most states on April 12, 2001, now requires safety needle products be used for the vast majority of procedures. However, even with this requirement, many hospitals are neglecting to follow the law intended to protect healthcare workers.

According to Greystone Associates, the worldwide market for safety syringes was a little over $1 billion in 2003 and is projected to be approximately $1.6 billion by 2007. The safety syringe market made up approximately 43% of the total 2003 syringe market and is expected to make up 57% of the market in 2007.

Methods of Marketing and Distribution

Under the current supply chain system in the U.S. acute care market, the vast majority of decisions relating to the contracting for and purchasing of medical supplies are made by the representatives of group purchasing organizations (GPOs) rather than the end-users of the product (nurses,

doctors, and testing personnel). The GPOs and manufacturers often enter into long-term exclusive contracts which can prohibit entry in the marketplace by competitors.

We distribute our products throughout the 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, blood collection tube holders and IV safety catheters. 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 acute care and alternate care sites and speak directly with the decision-makers of these facilities. We employ trained

clinicians, including registered nurses and/or medical technologists that educate healthcare providers and healthcare workers on the use of safety devices through exhibits at related tradeshows and publications of relevant articles in trade journals and magazines. These nurses provide clinical support to customers. In addition to marketing our products, the network demonstrates the safety and cost effectiveness of the VanishPoint® automated retraction products to customers.

In the needle and syringe market, the market share leader, BD, has utilized, among other things, long-term exclusive contracts which have restricted our entry into the market.

We have numerous agreements with organizations for the distribution of our products in foreign markets. Sales to these markets increased from 7.9% to 12.2% of revenues in 2006. The total population of Western Europe exceeds 310 million, and the recognition for the urgency of safe needle devices in parts of Europe has followed the United States model. In France, England, Germany, and Italy, organized healthcare worker unions have taken action to force hospitals and government agencies to place safety as a priority. Regions within Asia and Africa are also recognizing the need for our products. Beginning in 2004, we were awarded a federal contract to supply syringes to various African countries. The 2004 award from PATH was for 1,530,000 units. The 2005 award was for 11,700,000 units. The 2006 award was for 16,400,000 units. All awards were filled over multiple quarters due principally to logistical requirements for the orders. We are hopeful that these awards will continue although there is currently no funding to continue this program.

Key components of our strategy to increase our market share are to: (a) focus on methods of upgrading our manufacturing capability and efficiency in order to enable us to offer products at a reduced price and improved profit margins; (b) continue marketing emphasis in the U.S.; (c) continue to add Veterans Administration facilities, health departments, emergency medical services, federal prisons, long-term care and home healthcare facilities as customers; (d) 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; (e) supply product through GPOs and Integrated Delivery Networks where possible; (f) consider possibilities for future licensing agreements and joint venture agreements for the manufacture and distribution of safety products in the United States and abroad; (g) introduce new products where market access is possible; and (h) continue to increase international sales.

Status of New Products

We have patented and are in the process of developing additional safety needle products. Such products include a ½ cc insulin syringe, an autodisposable syringe, a dental syringe, and a winged butterfly IV for which we have developed early stage prototypes. We have preproduction prototypes for our autodisable syringe. Our limited access to the market has slowed the introduction of these products into the market. We launched an IV safety catheter in the first quarter of 2006.

Competitive Conditions

We believe VanishPoint® products continue to be the most effective safety devices in today s market. Our products include passive safety activation, require less disposal space, and are activated while in the patient. The Company has three major competitors: BD, Tyco, and Terumo.

Founded in 1897, BD is headquartered in New Jersey. BD s safety-engineered device sales accounted for approximately 11.3 percent of BD s total 2006 sales. BD currently manufactures the SafetyLok, a syringe that utilizes a tubular plastic sheath that must be manually slid over the needle after an injection, and the SafetyGlide, a needle which utilizes a hinged lever to cover the needle tip. BD also manufactures a safety blood collection and hypodermic needle that utilizes the Eclipse needle cover. BD also manufactures a 3cc and 1cc retracting needle product based on a license agreement with Specialized Health Products International, Inc. (formerly the Med-Design Corporation). The Integra, a retractable syringe offered by BD, does not offer a full product line and cannot be used with highly viscous medication due to leakage (as described on their labels). The introduction of this syringe has had little impact on our sales due to BD s historic market dominance. BD s Vacutainer® blood collection products are commonly used as industry jargon to refer to blood collection products in general.

Sherwood 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. Sherwood also manufactures the Magellan safety syringe, a product similar to the BD SafetyGlide.

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

Both BD s SafetyLok® and Sherwood s Monoject® safety syringes require the use of two hands and several extra steps to activate the tubular plastic shield which must be slid and locked into place to protect the needle. These products must be removed from the patient in order for the safety mechanism to be activated. In contrast, use of the VanishPoint® syringe is identical to that of a standard syringe until the end of an injection, when the automated retraction mechanism retracts the needle directly from the patient safely into the barrel of the syringe. This allows both hands to remain safely out of harm s way. BD s Integra operates in a similar way but may have to be removed from the patient in order to have retraction of the needle occur.

BD and 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. BD may be able to use its resources to improve its products through research or acquisitions or develop new products, which may compete more effectively with our products. We continue to attempt to gain access to the market through our sales efforts and our innovative technology. We are focusing on methods of upgrading our manufacturing capability and efficiency in order to enable us to compete by offering our technology at a reduced price. We believe our current capitalization provides the resources necessary to implement these changes and greatly improve our manufacturing capacity and efficiency, thereby reducing our unit cost.

Our competitive strengths include that the VanishPoint® syringe is one of four syringes given the highest possible rating by ECRI. 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 increased by existing legislation and other legislative and investigative efforts. Outsourcing arrangements such as our purchases from Double Dove have increased our manufacturing capacity with little or no capital outlay and provide a competitive cost. Licensing agreements such as the one with Baiyin Tonsun Medical Device Co., Ltd. (BTMD) could provide entry into new markets and generate additional revenue. A discussion of the BTMD agreement can be found elsewhere herein.

Our competitive weaknesses include our current lack of market share because two 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 may be 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 manufactured by BD, which dominates the market. Although, to date, the introduction of the Integra has not noticeably impacted our sales, BD 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, Sterigenics, and ISPG. We have also received shipments of product from Double Dove since early 2004.

Dependence on Major Customers

Two distributors accounted for an aggregate of 31.3% of our revenue in 2006. We have numerous other distributors that sell our products in the U.S. and internationally.

Backlog Orders

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

Patents, Licenses, 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 Lic 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 licensing fee and agreed to pay a 5 percent royalty on gross sales after returns. The license terminates upon expiration of the last licensed patents unless sooner terminated under certain circumstances. The licensing fees have been paid in accordance with this agreement with the exception of $1,500,000 in fees which were waived by Mr. Shaw and his wife.

We have the right and obligation to obtain protection of the invention, including prosecution of patent properties. The license unilaterally changes to a nonexclusive license in the event of a hostile takeover. Also, if Mr. Shaw involuntarily loses control of the Company, the license becomes a nonexclusive license and a right to information.

We have sought foreign patent protection through the Patent Cooperation Treaty and have filed applications for regional and national patent protection in selective countries 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, IV safety catheters, winged IV sets, syringes, and blood collection tube holders. In addition, we have multiple applications for patents currently pending. The principal syringe patents in the U.S., as well as their foreign counterparts, will expire in May 2015.

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

There are currently no patent infringement claims pending against the VanishPoint® retraction technology other than those set forth in **Item 3. Legal Proceedings**. We have decided, on the advice of patent counsel, not to purchase patent insurance because it would require inappropriate disclosure of information that is currently proprietary and confidential.

We currently obtain roughly 72.8% of our finished products through Double Dove, a Chinese manufacturer. We believe we could make up any long-term disruption in these supplies by utilizing more

of the capacity at the Little Elm facility, except for 5cc and 10cc syringes which comprised about 5.8% of our 2006 revenues.

We have a Licensing Agreement with Baiyin Tonsun Medical Device Co., Ltd. (BTMD) which expires on May 13, 2008. Royalties that were expected in 2007 were not received due to the time needed to build the factory, assembly equipment, and the related infrastructure as well as the need of BTMD to meet the requisite government requirements. The facility has been completed and BTMD is in the process of meeting government requirements. We are in the process of formally extending our agreement with BTMD. Accordingly, although we still continue to expect royalty payments we are unable to predict the date we will begin to receive such royalties. Royalties will begin once government requirements are met and BTMD is able to produce and sell products.

Seasonal Effect on Business

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

Working Capital Practices

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

Our credit policy has provided for negligible reserve requirements on our Accounts Receivable. Outstanding accounts are reviewed regularly and reserves provided for potential write off, if applicable.

Inventories are valued at lower of cost or market. We maintain a reserve for potential write-downs or write offs, and obsolete inventory is written off.

Receivables are established for federal and state taxes where we have determined we are entitled to a refund for overpayments of estimated taxes or loss carry backs.

Accounts payable and other short-term liabilities include amounts that we believe we have an obligation for at the end of year. These included charges for goods or services received in 2006 but not billed to us at the end of the year. It also included estimates of potential liabilities such as rebates and other fees.

Our domestic return policy is set forth in our standard Distribution Agreement, a copy of which is incorporated by reference in Exhibit number 10.1. This policy provides that a customer may return incorrect shipments within 10 days following arrival at the distributor s facility. In all such cases the distributor must obtain an authorization code from us and affix the code to the returned product. We will not accept returned goods without a returned goods authorization number. We may refund the customer s money or replace the product.

Our international contracts do not provide for any returns.

Our return policy also provides that a customer may return product that is overstocked. Overstocking returns are limited to two times in each twelve month period up to 1% of distributor s total purchase of products for the prior twelve month period upon the following terms: i) an overstocked product is that portion of distributor s inventory of the product (individual catalog number) which exceeds distributor s sales volume for the product during the preceding four months; ii) distributor must not have taken delivery of the product which is overstocked (individual catalog number) during the preceding four months, iii) overstocked product held by distributor in excess of twelve (12) months from the date of original invoice will not be eligible for return; iv) the overstocked product must be returned to us in our saleable case cartons which are unopened and untampered, with no broken or re-taped seals; v) distributor will be granted a credit which may be used only to purchase other products from us, the credit to be in the amount of the invoice price of the returned products less a 10% restocking fee which will be assessed against distributor s subsequent purchase of product; vi) distributor must obtain an authorization code from our distribution department and affix the code to the returned product; and vii) distributor shall bear the cost of shipping the returned products to us. All product overstocks and returns are subject to inspection and acceptance by manufacturer.

Regulatory Status and Effect of Regulation

We and our products are regulated by the FDA. The syringe and the IV safety catheter are Class II medical devices which require assurance by the manufacturer that the device is safe and effective and that they meet 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) the VanishPoint® blood collection tube holder and small tube adapter. In September 2005, the FDA granted permission to market our IV safety catheter in interstate commerce.

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 2005 after which the auditor determined No Action Indicated.

TUV-USA, a member of the TUV Nord Group, 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 13485:2000, CAN/CSA:13485:1996 and EN 13485:2000 in August 2004. We have since received certification to the most current version of these standards. In addition, the VanishPoint product line was certified for a CE Mark by TUV-USA. The CE Mark authorizes us to sell in the European Union. TUV-USA performs annual surveillance audits to ensure our compliance with ENISO 13485:2003, CAN/CSA: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.

Research and Development

We spent $626,941, $934,209, and $958,798 in fiscal 2004, 2005, and 2006 respectively, on research and development. Costs in 2006 were primarily for compensation, validation and engineering costs, and consulting costs. Our ongoing research and development activities are performed by an internal research and development staff. This team of engineers is developing process improvements for current and future automated machines. Products currently in development by our internal team include the winged butterfly IV, the dental syringe, a ½ cc insulin syringe and an autodisable syringe. Our limited access to the market has slowed the introduction of these products into the market. Possible future products include all needle medical devices to which the automated retraction mechanism can be applied.

Environmental Compliance

We believe that we do not incur material costs in connection with compliance with environmental laws. We are considered a Conditionally Exempt Small Quantity Generator because we generate less than 100 kilograms (220 lbs.) of hazardous waste per month. Therefore, we are exempt from the reporting requirements set forth by the Texas Commission on Environmental Quality. The waste that is generated at our facility is primarily made up of flammable liquids and paint-related waste and is sent for fuel blending

by Safety Kleen. This fuel blending process completely destroys our waste and satisfies our cradle-to-grave responsibility.

Other nonhazardous production waste includes clean polypropylene regrind that is sold for recycling. 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 Stericycle.

Employees

As of March 1, 2007, we had 146 full-time employees, 5 part-time employees, and 6 independently contracted consultants. Of the 146 full-time employees, 5 persons were engaged in research and development activities, 61 persons were engaged in manufacturing and engineering, 18 persons were engaged in quality assurance and regulatory affairs, 42 persons were engaged in sales and marketing, 19 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 with an initial term that ended on September 2002 that contains an automatic and continuous renewal provision for consecutive two-year periods.

FINANCIAL INFORMATION

We have no long-lived assets in foreign countries. Shipments to international customers generally require a prepayment either by wire transfer or an irrevocable confirmed letter of credit. We do extend credit to international customers on some occasions depending upon certain criteria, including, but not limited to, the credit worthiness of the customer, the stability of the country, banking restrictions, and the size of the order. All transactions are in United States currency.

		2006		2005		2004
Domestic sales	$	22,240,347	$	22,310,150	$	20,193,999
International sales		3,084,172		1,924,866		1,327,701
Total sales	$	25,324,519	$	24,235,016	$	21,521,700
Long-lived assets						
Domestic	$	12,212,140	$	11,925,976	$	11,056,865
Foreign	$		$		$	

Please see the financial statements in Item 8 for information about our revenues, profits and losses for the last three years, and total assets for the last two years.

Item 1A. Risk Factors.

You should carefully consider the following material risks facing the Company. If any of these risks occur, our business, results of operations or financial condition could be materially adversely affected.

The Majority of our International Sales are Filled using one Supplier

Most international sales are filled by production from Double Dove. In the event that we were unable to purchase such product from Double Dove, we would need to find an alternate supplier for the 5 cc and 10 cc syringes and increase domestic production for 1 cc and 3 cc syringes to avoid a disruption in supply. Currently, approximately 72.8% of our production is provided by Double Dove.

Our Cash Position is Decreasing

Due to continuing barriers to the market place, coupled with the completion of the discount reimbursement program and increases in accounts receivable and inventory, mitigated by an increase in accounts payable, the Company s cash position declined $5.7 million. The negative impact in the third and fourth quarter of the ending of the discount reimbursement program is approximately $6.0 million.

In the event we continue to have only limited market access and the cash provided by the litigation settlements and generated from operations becomes insufficient and royalties from BTMD are not forthcoming, 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.

We Compete in a Monopolistic Marketplace

We operate in an environment that is dominated by the major syringe manufacturer in the United States, BD. We believe that its monopolistic business practices continue despite its paying the Company $100 million to settle a lawsuit for anticompetitive practices, business disparagement, and tortious interference. Although we made limited progress in some areas, such as the alternate care and international markets, our volumes are not as high as they should be given the nature and quality of our product, the federal and state legislation requiring use of safe needle devices, and the Senate Subcommittee hearings on GPOs.

We Have Generally Been Unable to Gain Sufficient Market Access to Achieve Profitable Operations

We have incurred net operating losses in all fiscal quarters of 2006 and may experience operating losses in the future. If we are unable to gain sufficient market access and market share, we may be unable to continue to finance research and development as well as support operations and expansion of production.

Our Patent Protection Is Aging

Our main competitive strength is our technology. As it ages (and the associated patent life expires), our competitive position in the marketplace will weaken. The initial patents protecting our revolutionary spring action syringe will expire beginning in May 2015. Patent life may be extended, not through the original patents, but related improvements. Eventually, however, our patent protection may decrease and we will be vulnerable to other competitors utilizing our technology.

We Are Vulnerable to New Technologies

Because we have a narrow focus on a particular product line and technology (retractable needles), we are vulnerable to the development of superior competing products and to changes in technology which could eliminate or reduce the need for our products. If a superior technology is created, the demand for our products could greatly diminish.

We May Lack Future Financial Resources to Capture Increased Market Share

The three leading manufacturers of hypodermic syringes and blood collection products are BD with a worldwide market share in the safety syringe market of approximately 68 percent, Sherwood with approximately 18 percent, and Terumo with a market share of approximately 4 percent. All three companies offer both standard syringes and at least one safety syringe alternative. BD also offers a retractable syringe. BD and Sherwood have greater financial resources, larger and more established sales and marketing and distribution organizations, and greater market influence, including long-term contracts with GPOs. These competitors may be able to use these resources to improve their products through research and acquisitions or develop new products, which may compete more effectively with our products.

If our competitors choose to use their resources to create products superior to ours, we may be unable to sell our products and the ability of our company to continue would be weakened.

Fluctuations in Supplies of Inventory Could Temporarily Increase Costs

Fluctuations in the cost and availability of raw materials and inventory and the ability to maintain favorable supplier arrangements and relationships could result in the need to manufacture all (as opposed to 27.2%) of the products in the United States. This could temporarily increase unit costs as we ramp up domestic production.

We Face Inherent Product Liability Risks

As a manufacturer and provider of safety needle products, we face an inherent business risk of exposure to product liability claims in the event of product failure or claim of harm caused by product operation. Product failure could result in injury to the patient or loss of blood and could expose healthcare workers to the risk of blood borne pathogens. If any of our products prove to be defective, we may be required to recall those products. If a product liability claim is made and damages are in excess of our product liability coverage, our competitive position could be weakened by the amount of money we could be required to pay to compensate those injured by our products. We have products liability coverage with St. Paul Insurance Company covering up to $1,000,000 per occurrence, with coverage up to $2,000,000 in the aggregate. Each claim is subject to a $25,000 deductible. Additionally, we have additional products liability protection under an Umbrella Liability Policy. This policy provides an additional $10,000,000 per occurrence and aggregate limits in the event claims exceed the primary commercial general liability policy limit. We have not had any product liability claims.

We Have Limited Access to the Capital Markets

The volume of trading in our Common Stock on the American Stock Exchange (the AMEX) is low. Accordingly, it is unclear if there is any significant market for our shares. This may reduce our ability to raise cash through public or private offerings in the future.

Our Company Is Controlled by Two Shareholders

Thomas J. Shaw, our President and a Director, Ms. Suzanne August, and Lillian E. Salerno, a consultant to the Company, own 35.8%, 11.8%, and 10.5%, respectively, of the Common Stock as of March 1, 2007. The shares held by Ms. August are controlled by Mr. Shaw pursuant to a voting agreement, which terminates upon sale of all the shares for value or if terminated by both parties in writing. These shareholders will, therefore, have the ability to direct our operations and financial affairs and to substantially influence the election of members of our Board of Directors. The interests of these persons may not always coincide with the Company s interests or the interests of other stockholders. This concentration of ownership, for example, may have the effect of delaying, deferring or preventing a change in control of the Company, impeding a merger, consolidation, takeover or other business combination involving the Company or discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of the Company, which in turn could materially adversely affect the market price of the Common Stock. Of the 23,674,164 shares of Common Stock outstanding as of March 1, 2007, Officers and Directors owned 12,761,500 of the shares.

Current Investigations Could Result in Beneficial Legislation Increasing Our Access to the Hospital Market

On March 15, 2006, the Senate Judiciary Subcommittee on Antitrust, Competition Policy and Consumer Rights held its fourth hearing on the anti-competitive practices of GPOs. As the Senate s four-year inquiry has revealed, these purchasing cartels, in collusion with the dominant medical supply manufacturers, have harmed competition, stifled innovation, and increased the cost of healthcare. Senate testimony, government studies, and media reports have exposed a long list of abuses, including conflicts of interest, kickbacks, sole-source and long-term contracts, and other exclusionary practices that have kept patients and healthcare workers in GPO-member hospitals from gaining access to better, safer, and more

cost-effective medical products. The U. S. Department of Justice and the Connecticut Attorney General are also conducting wide-ranging criminal investigations of GPO practices and have issued subpoenas to many of the nation s largest medical suppliers, GPOs, and hospital systems.

Item 1B. Unresolved Staff Comments.

Not applicable

Item 2. Properties.

Our 22,500 square foot headquarters is located at 511 Lobo Lane, on 35 acres, which we own, overlooking Lake Lewisville in Little Elm, Texas. The building is a modular portion of a larger planned building for which the engineering design has been finalized which could be expanded with minimal disruption of production. The headquarters are in good condition and house our administrative offices and manufacturing facility. We put a 45,000 square foot warehouse in service in March 2005. The manufacturing facility produced approximately 27.2% of the units that were sold in 2006. In the event of a disruption in service of our outside supplier, we believe we could produce quantities sufficient to meet demand under current circumstances except for demand for 5cc and 10cc syringes which are sold principally in the international market. In that event, we would attempt to engage another manufacturer.

The Company obtained a loan from 1st International Bank (st International) for $2,500,000, secured by the land and existing buildings, which provided interim funding for the construction of the 45,000 square foot warehouse. The proceeds from the loan were used to pay off the remaining $475,000 of the revolving credit agreement with 1st International in addition to funding the new warehouse and related infrastructure. Payments on the note were interest only during the first twelve months. The payments for the permanent funding are based on a twenty-year amortization with a five-year maturity. Interest rates are based on the amount of funds kept on deposit with the bank. Accordingly, interest will vary from the Wall Street Journal Prime Rate (the WSJPR) to the WSJPR plus 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, molding equipment, 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.

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

Item 3. Legal Proceedings.

On August 12, 2005, we filed a lawsuit against Abbott Laboratories Inc. in the United States District Court in the Eastern District of Texas, Texarkana Division. We are alleging fraud and breach of contract in connection with the National Marketing and Distribution Agreement dated as of May 4, 2000 which was terminated on October 15, 2003. We are seeking damages which we estimate to be in millions of dollars of lost

profits, out of pocket expenses and other damages. In addition, we are seeking punitive damages, pre-judgment and post-judgment interest and attorney s fees. Abbott has appealed a trial court determination that the dispute does not need to be decided by arbitration. Oral argument is scheduled for March 3, 2008.

In August 2006, we were sued by Occupational and Medical Innovations Limited (OMI) in Federal Court of Australia, alleging that two letters written to OMI by our outside counsel contained unjustified threats. OMI is not seeking monetary damages in the action, but was awarded its costs. The Court subsequently held that one of the letters written by outside counsel contained an unjustified threat. OMI amended its complaint to seek a declaratory judgment that OMI s syringe does not infringe RTI s Australian patents. Trial of that claim is set for April 2008.

On June 15, 2007, we filed a lawsuit against BD in the United States District Court for the Eastern District of Texas, Marshall Division. We are alleging antitrust violations, violations of the Lanham Act and patent infringement. Please see Exhibit No. 99 to our Form 8-K filed on June 19, 2007 for details regarding the factual basis underlying the action as well as the relief sought. BD has counterclaimed for a declaration that our patents are invalid and unenforceable. All other claims have been stayed until resolution of the patent claims. The patent case is set for trial in March 2009.

On September 6, 2007, BD and MDC Investment Holdings, Inc. filed a complaint against us in the United States District Court for the Eastern District of Texas, Texarkana Division. Plaintiffs allege that our VanishPoint® product line infringes U.S. patent nos. 6,179,812 and 7,090,656. Plaintiffs seek a declaration of infringement, an injunction against further infringement, compensatory damages (with interest), the costs of the litigation, and such other relief as the Court deems just and proper. We have counterclaimed for a declaration that the asserted patents are invalid and unenforceable. We believe that we have meritorious defenses to such allegations and we intend to defend this lawsuit vigorously. No trial date has been set.

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

No matters were submitted to a vote during the fourth quarter of 2006.

PART II

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

MARKET INFORMATION

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

	Common Stock	
	High	**Low**
2006		
Fourth Quarter	$ 3.44	$ 2.20
Third Quarter	$ 3.96	$ 3.16
Second Quarter	$ 4.02	$ 3.22
First Quarter	$ 4.11	$ 3.45
2005		
Fourth Quarter	$ 4.83	$ 3.51
Third Quarter	$ 6.49	$ 2.65
Second Quarter	$ 4.04	$ 2.60
First Quarter	$ 4.80	$ 3.70

SHAREHOLDERS

As of March 1, 2007, there were 23,674,164 shares of Common Stock held by 297 shareholders of record not including shareholders who beneficially own Common Stock held in nominee or street name.

DIVIDENDS

We have not ever declared or paid any dividends on the Common Stock. We have no current plans to pay any cash dividends on the Common Stock. We intend to retain all earnings, except those required to be paid to the holders of the Preferred Stock, to support operations and future growth.

The Board of Directors declared a dividend on the Series I and II Class B Convertible Preferred Stock in 2004. The cumulative dividend arrearage through June 30, 2004, on the Series I and II Class B Convertible Preferred Stock of $7,118,583 was paid on August 27, 2004, to the holders of record as of August 17, 2004. As of December 31, 2006, $12,163,000 in dividends were in arrears on the Class B stock. Dividends may not be paid on the Common Stock until all dividends on the Preferred Stock have been paid.

On March 27, 2007, the Board of Directors declared a dividend on the Series I and Series II Class B Convertible Preferred Stock to be paid on July 24, 2007 to Shareholders of Record on July 2, 2007. Arrearages will be paid through June 30, 2007 in the amount of $1.1 million.

EQUITY COMPENSATION PLAN INFORMATION

See **Item 12 Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters** for a chart describing compensation plans under which equity securities are authorized.

RECENT SALES OF UNREGISTERED SECURITIES

Sales of unregistered securities in the first and second quarters of 2006 were reported in the Company s Form 10-Q quarterly reports filed with the United States Securities and Exchange Commission (the Commission) which are available via EDGAR. There were no sales of unregistered securities in the third or fourth quarter.

PERFORMANCE GRAPH

The following graph compares the cumulative total return for our Common Stock from December 31, 2001, (the year in which the Company became a public company) to December 31, 2006, to the total returns for the Russell Microcap and Becton Dickinson (BD), a peer issuer. The graph assumes an investment of $100 in Common Stock and in the Russell Microcap index as of January 1, 2001, and that all dividends are reinvested.

The comparisons in the graph are required by the SEC. You should be careful about drawing any conclusions from the data contained in the graph, because past results do not necessarily indicate future performance. The information contained in this graph shall not be deemed to be soliciting material or filed with the SEC or subject to the liabilities of Section 18 of the Exchange Act, except to the extent that we specifically incorporate it by reference into a document filed under the Securities Act of 1933, as amended or the Exchange Act.

Item 6. Selected Financial Data.

The following selected financial data are qualified by reference to, and should be read in conjunction with, our audited financial statements and the notes to those statements and Management s Discussion and Analysis of Financial Condition and Results of Operations appearing elsewhere herein. The selected Statement of Operations data presented below for the years ended December 31, 2003 and 2002, and the Balance Sheet data as of December 31, 2004, 2003, and 2002, have been derived from our audited financial statements, which are not included herein.

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

	As of and for the Years Ended December 31,				
	2006	**2005**	**2004**	**2003**	**2002**
Sales, net	$ 20,898	$ 21,157	$ 21,136	$ 19,078	$ 20,316
Reimbursed discounts	4,427	3,078	386		
Total sales	25,325	24,235	21,522	19,078	20,316
Cost of sales	17,779	15,429	16,411	14,654	15,472
Gross profit	7,546	8,806	5,111	4,424	4,844
Total operating expenses	14,260	11,683	13,110	10,327	11,234
Loss from operations	(6,714)	(2,877)	(7,999)	(5,903)	(6,390)
Interest income	1,976	1 ,373	475	45	10
Interest expense, net	(411)	(340)	(243)	(308)	(446)
Litigation settlements, net			74,635	13,880	
Net income (loss) before income taxes	(5,149)	(1,844)	66,868	7,714	(6,826)
Provision (benefit) for income taxes	(1,280)	(605)	12,177	266	
Net income (loss)	(3,869)	(1,239)	54,691	7,448	(6,826)
Preferred Stock dividend requirements	(1,451)	(1,503)	(1,993)	(2,560)	(2,266)
Earnings (loss) applicable to common shareholders	$ (5,320)	$ (2,742)	$ 52,698	$ 4,888	$ (9,092)
Earnings (loss) per share basic	$ (0.23)	$ (0.12)	$ 2.33	$ 0.23	$ (0.45)
Earnings (loss) per share diluted	$ (0.23)	$ (0.12)	$ 2.08	$ 0.20	$ (0.45)
Weighted average shares outstanding	23,591,999	23,332,277	22,600,166	21,001,004	20,300,454
Current assets	$ 57,780	$ 61,485	$ 64,674	$ 13,497	$ 7,065
Current liabilities	$ 6,891	$ 5,458	$ 7,852	$ 5,773	$ 8,021
Property, plant, and equipment, net	$ 12,212	$ 11,926	$ 11,057	$ 9,679	$ 10,515
Total assets	$ 70,794	$ 73,756	$ 76,123	$ 23,631	$ 18,059
Long-term debt	$ 4,399	$ 4,646	$ 3,807	$ 2,934	$ 3,441
Stockholders equity	$ 59,746	$ 63,625	$ 63,665	$ 15,135	$ 7,437
Redeemable Preferred Stock (in shares)	2,441,166	2,498,666	2,572,116	3,591,216	5,379,366
Cash dividends per common share	$	$	$	$	$
Gross profit margin	29.8%	36.3%	23.7%	23.2%	23.8%

Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operation.

FORWARD-LOOKING STATEMENT WARNING

Certain statements included by reference in this filing containing the words could, may, believes, anticipates, intends, expects, and simila
words constitute forward-looking

statements within the meaning of the Private Securities Litigation Reform Act. Any forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements. Such factors include, among others, the impact of dramatic increases in demand, our ability to quickly increase capacity in the event of a dramatic increase in demand, our ability to access the market, our ability to decrease production costs, our ability to continue to finance research and development as well as operations and expansion of production, the recently increased interest of larger market players, specifically BD, in providing safety needle devices, and other factors listed in **Item 1A Risk Factors**. Given these uncertainties, undue reliance should not be placed on forward-looking statements.

OVERVIEW

We have been manufacturing and marketing our products into the marketplace since 1997. Our products have been and continue to be distributed nationally through numerous distributors. However, we have been blocked from access to the market by exclusive marketing practices engaged in by BD who dominates the market. We believe that their monopolistic business practices continue despite their paying $100 million to settle a lawsuit with the Company for anticompetitive practices, business disparagement, and tortious interference. Although we made limited progress in some areas, such as the alternate care and international markets, our volumes are not as high as they should be given the nature and quality of our product, the federal and state legislation requiring use of safe needle devices, and the Senate Subcommittee hearings on GPOs. We continue to pursue various strategies to have better access to the hospital market, as well as other markets, including attempting to gain access to the market through our sales efforts and innovative technology.

We are focusing on methods of upgrading our manufacturing capability and efficiency in order to enable us to offer our technology at a reduced price. We believe our current capitalization provides the resources necessary to implement these changes, improve profit margins, and greatly improve our manufacturing capacity and efficiency, thereby reducing our unit cost. We are also marketing more products internationally. Beginning in 2004, we were awarded a federal contract to supply syringes to various African countries. The 2004 award from PATH was for 1,530,000 units. The 2005 award was for 11,700,000 units. The 2006 award was for 16,400,000 units. All awards were filled over multiple quarters due principally to logistical requirements for the orders. We are hopeful that these awards will continue although there is currently no funding to continue this program. We continue to produce syringes and blood collection tube holders in Little Elm, Texas.

Additionally, the Company was awarded a one-year contract to supply its VanishPoint® automated retraction syringes to all of Queensland Health s 202 acute care facilities. Queensland Health is a department within the government of Queensland, Australia. The contract is effective immediately and renewable for two years. VanishPoint® products are distributed in Australia by Brisbane-based Scientific Educational Supplies Pty Ltd.

Product purchases from Double Dove have enabled us to increase manufacturing capacity with little capital outlay and provided a competitive manufactured cost. These purchases have enabled improved profit margins in spite of limited revenues. The cost of production per unit has generally declined as volumes increased. We currently obtain roughly 72.8% of our finished products through Double Dove, a Chinese manufacturer. We believe we could make up any long-term disruption in these supplies by utilizing more of the capacity at the Little Elm facility, except for 5cc and 10cc syringes which comprised about 5.8% of our 2006 revenues.

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

produce and sell products.

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

RESULTS OF OPERATIONS

The following discussion contains trend information and other forward-looking statements that involve a number of risks and uncertainties. Our actual future results could differ materially from our historical results of operations and those discussed in the forward-looking statements. All period references are to our fiscal years ended December 2006, 2005 or 2004. Dollar amounts have been rounded for ease of reading.

Comparison of Year Ended
December 31, 2006, and Year Ended December 31, 2005

Revenues increased 4.5%, due principally to increased sales in the alternate care and international markets. Domestic sales were 87.8% of revenues with international sales comprising the remainder. Unit sales of the 1cc syringe increased 39.1% and 3cc unit sales increased 19.7%. Unit sales of all products increased 32.6%. The hospital market continues to lag despite very favorable promotional pricing under the discount program. The increase in discount reimbursements in 2006 is due principally to the reduction of the promotional prices initiated in April 2005, resulting in larger reimbursements, mitigated by the ending of the reimbursement of the discounts in the third quarter of 2006. The discount reimbursement program expired since the settlement agreement under which it was established provided for a total of $8.0 million in reimbursements. We had recognized $8.0 million in cumulative discount reimbursements in the third quarter of 2006. Sales to two distributors accounted for 31.3% and 34.8% of our revenues in 2006 and 2005, respectively.

Cost of sales as a percentage of revenues increased due to the lower average selling price resulting from the ending of the discount reimbursement program mitigated by higher volumes of product produced and sold. The increased volume of production resulted in a lower unit cost. The effect of the reduction in staff in August 2005 also contributed to the lower unit cost in 2006. Royalty expenses were higher due to an increase in gross revenues.

As a result, gross profits decreased, and gross profit margins declined from 36.3% in 2005 to 29.8% in 2006.

Operating expenses increased from the prior year due to increases in sales and marketing costs and general and administrative costs.

Sales and marketing expenses increased as we continued to grow our sales force, resulting in higher compensation costs, marketing and promotional costs, and travel and entertainment. We also had increased consulting expense mitigated by a reduction in stock option expense. We expect sales and marketing costs will continue to increase as we work to get our products into U.S. hospitals and in the international market.

Research and development costs were flat. We had increases in consulting costs and decreases in engineering costs due principally to validation testing and the development work on the IV safety catheter in 2005. We began marketing the IV safety catheter in the first quarter of 2006. We anticipate that until we reach economies of scale in manufacturing this product, we will incur losses on its sale.

General and administrative costs increased due principally to higher legal costs, compensation costs, consulting, and taxes other than income taxes. Decreases in expenses include stock option expense, shareholder expenses, outside accounting costs, severance pay and training. The legal costs incurred in 2006 in regard to the Abbott Laboratories litigation are higher than those in 2005. We expect such costs to continue until the litigation is resolved. We also have litigation expenses concerning OMI, an Australian company, which is discussed elsewhere herein. Compensation costs increased as officers and other salaries were brought into a more appropriate range in 2005, the full effect being reflected in 2006. The Company also awarded merit increases to our employees in 2006. Consulting costs increased due to our continuing

efforts to penetrate U.S. and international markets. We had increases in taxes other than income taxes in 2006. We donated product in an international humanitarian effort in 2006. There have been no stock options awarded since 2004, therefore this expense continues to decline as the costs become fully amortized.

Preferred Stock dividend requirements declined due to conversion of Preferred Stock into Common Stock. The dividend arrearage at December 31, 2006, on all classes of Preferred Stock was approximately $12,200,000.

Interest income increased due to higher interest rates. Interest expense increased due to higher interest rates mitigated by lower debt balances.

Provision for income tax benefits consists primarily of federal tax subject to carry back provisions. State income taxes are also subject to the various states carry back rules. The Company also has a valuation reserve for all deferred taxes, with the exception of deferred taxes on the beneficial conversion feature associated with its note payable to Katie Petroleum, Inc.

Cash flow from operations was negative for 2006 due principally to the loss for the year. The effect of non-cash expenses and the change in working capital were a positive $500,000. Investing activities utilized $2.0 million in cash.

Comparison of Year Ended
December 31, 2005, and Year Ended December 31, 2004

Revenues increased, due principally to increased sales in the alternate care and international market. Domestic sales were 92.1% of revenues with international sales comprising the remainder. Unit sales of the 1cc syringe increased 20.9% and 3cc unit sales increased 12.7%. Unit sales of all products increased 19.1%. The hospital market continued to lag despite very favorable promotional pricing under the discount reimbursement program. The increase in discount reimbursements in 2005 was due principally to the reduction of the promotional prices in April 2005. We recognized $3.5 million in discount reimbursements through December 31, 2005. Sales to two distributors accounted for 34.8% of our revenues in 2005 and sales to one distributor accounted for 16.6% of our revenues in 2004.

Cost of sales as a percentage of revenues improved as higher volumes of product were produced and sold. The increased volume resulted in a lower unit cost of production. The effect of the reduction in staff in August 2005 also contributed to the lower unit cost. Royalty expenses declined due to a reduction in gross revenues.

Operating expenses decreased from the prior year due to decreases in general and administrative costs, mitigated by increases in sales and marketing costs as well as an increase in research and development costs.

Sales and marketing expenses increased as we continued to grow our sales force, resulting in higher compensation and travel expense. This increase in sales and marketing costs was mitigated by a reduction in consulting expenses.

Research and development costs increased due principally to validation testing and the development work on the IV safety catheter. We began marketing the IV safety catheter in the first quarter of 2006. We also anticipate that until we reach economies of scale in manufacturing this product, we will incur losses on its sale.

General and administration costs decreased significantly due principally to lower legal costs incurred in 2005. The legal costs incurred in 2005 in regard to the Abbott Laboratories litigation were substantially less than the legal costs we incurred for the BD and NMT litigation in 2004. However, we expect such costs to increase as our litigation against Abbott continues.

Preferred Stock dividend requirements declined due to conversions of Preferred Stock into Common Stock. The dividend arrearage at December 31, 2005, on all classes of Preferred Stock was approximately $10,700,000.

Interest income increased due to a higher average outstanding cash balance and higher interest rates. Interest expense increased due to higher debt balances incurred for the warehouse financing and higher interest rates.

Provision for income tax benefits consisted primarily of federal tax subject to carry back provisions. State income taxes were also subject to the various states carry back rules.

Cash flow from operations was negative for 2005 due principally to the loss for the year and changes in working capital.

SIGNIFICANT ACCOUNTING POLICIES

We consider the following to be our 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.

Accounts Receivable

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

Revenue Recognition

Revenue is recognized for sales to distributors when title and risk of ownership passes to the distributor, generally upon shipment. Revenue is recorded on the basis of sales price to distributors, less contractual pricing allowances. Contractual pricing allowances consist of (i) rebates granted to distributors who provide tracking reports which show, among other things, the facility that purchased the products, and (ii) a provision for estimated contractual pricing allowances for products that the Company has not received tracking reports. Rebates are recorded when issued and are applied against the customer s receivable balance. The provision for contractual pricing allowances is reviewed at the end of each quarter and adjusted for changes in levels of products for which there is no tracking report. Additionally, if it becomes clear that tracking reports will not be provided by individual distributors, the provision is further adjusted. The estimated contractual allowance is netted against individual distributors accounts receivable balances for financial reporting purposes. The resulting net balance is reflected in accounts receivable or accounts payable, as appropriate. The terms and conditions of contractual pricing allowances are governed by contracts between the Company and its distributors. 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.

Inventories

Inventories are valued at the lower of cost or market, with cost being determined using a standard cost method, which approximates average cost. Provision is made for any excess or obsolete inventories.

Marketing Fees

Under a sales and marketing agreement with Abbott, the Company paid marketing fees until the Company terminated the contract for breach. The contracted services were to include participation in promotional activities, development of educational and promotional materials, representation at trade shows, clinical demonstrations, inservicing and training, and tracking reports detailing the placement of our products to end-users. Marketing fees were accrued at the time of the sale of product to Abbott. These fees were paid after Abbott provided us a tracking report of product sales to end-users. These costs were included in Sales and marketing expense in the Statements of Operations. No marketing fees have been accrued since October 15, 2003, the date the National Marketing and Distribution Agreement with Abbott was terminated.

Litigation Proceeds

Proceeds from litigation settlements in our federal antitrust lawsuit, Retractable Technologies, Inc. v. BD, et al. were recognized when realized. Generally, realization was not reasonably assured and expected until proceeds were collected. Such amounts were net of attorneys fees, court costs, legal expenses, and amounts payable under the Covenant Not to Sue. Liability for attorneys fees was not incurred until proceeds were collected.

Reimbursed Discounts

The Company received reimbursed discounts from one of the settlement agreements reached in its federal antitrust lawsuit, Retractable Technologies, Inc. v. BD, et al. Payments under the discount reimbursement program were recognized upon delivery of the product, provided collection was reasonably assured. Such amounts are presented in the Statements of Operations as a separate component of revenues. The program reimbursed $8.0 million for discounts, the limit provided by the settlement agreement. This limit was reached during the third quarter of 2006 and negatively affected profit margin for the third and fourth quarters. The discount program ended on December 31, 2006.

LIQUIDITY AND FUTURE CAPITAL REQUIREMENTS

Historical Sources of Liquidity

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

We obtained $3,910,000 in 2000 from bank loans of which $3,435,000 has been repaid and $475,000 was refinanced with a new note with 1st International. Additionally, we received a Small Business Administration loan of $1,000,000 in 1996 to pay for portions of automated assembly equipment, multi-cavity molds, and other equipment. This loan has been repaid. Furthermore, we borrowed $5,000,000 in 2000 under our Credit Agreement with Abbott Laboratories. In October 2002 we repaid the Abbott Laboratories note with proceeds from a new note from Katie

Petroleum, Inc. (Katie Petroleum) for $3,000,000 and a portion of the proceeds from a private placement.

We obtained a loan from 1st International for $2,500,000 for interim and long-term financing of our warehouse. Principal and interest payments began in the first part of 2005. See Note 7 to the Financial Statements for a discussion of the terms of the note.

Internal Sources of Liquidity

Beginning in early 2004 we began to receive shipment of product from Double Dove, a Chinese manufacturer. Fluctuations in the cost and availability of raw materials and inventory and the ability to maintain favorable supplier arrangements and relationships could result in the need to manufacture all (as opposed to 27.2%) of the products in the United States. This could temporarily increase unit costs as we ramp up domestic production.

To achieve break even quarters we need minimal access to hospital markets which has been difficult to obtain due to the monopolistic marketplace which was the subject of our antitrust lawsuit against BD. We will continue to attempt to gain access to the market through our sales efforts and innovative technology. We are focusing on methods of upgrading our manufacturing capability and efficiency in order to enable us to offer our technology at a reduced price. We believe our current capitalization provides the resources necessary to implement these changes and greatly improve our manufacturing capacity and efficiency, thereby reducing our unit cost.

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

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

At the present time Management does not intend to raise equity capital. Due to the litigation settlements, we have sufficient cash reserves and intend to rely on operations, cash reserves, and debt financing as the primary ongoing sources of cash.

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

The Company had a reduction in force in August 2005.

External Sources of Liquidity

We have obtained several loans over the past seven years, which have, together with proceeds from the sales of equities and litigation settlements, enabled us to pursue development and production of our products. Currently we believe we could obtain additional funds through loans if needed. Furthermore, the shareholders have previously authorized an additional 5,000,000 shares of a Class C stock that could, if necessary, be authorized and 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, 2006:

	Payments Due by Period				
Contractual Obligations	**Total**	**2007**	**2008-2009**	**2010-2011**	**Thereafter**
Long-Term Debt Obligations	$ 4,669,468	$ 382,397	$ 873,976	$ 3,057,707	$ 355,388
Capital Lease Obligations					
Operating Lease Obligations	17,400	17,400			
Purchase Obligations					
Other Long-Term Liabilities Reflected on Balance Sheet					
Total Contractual Cash Obligations	$ 4,686,868	$ 399,797	$ 873,976	$ 3,057,707	$ 355,388

Material Commitments for Expenditures

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

We had $1.5 million in capital expenditures in 2006 and $2.0 million in 2005. The Company invested $500,000 in a limited liability company (LLC) in which we will be a minority interest holder. The funds are held in escrow until the LLC has raised the majority of its capital. The Company has the option to have its investment returned. The purpose of this project is to provide information and insight to the public regarding healthcare. Capital expenditures in 2007 are dependent upon several factors, including, but not limited to, projects to decrease production costs, the introduction of new products, and access to debt financing.

On March 27, 2007, the Board of Directors declared a dividend on the Series I and Series II Class B Convertible Preferred Stock that was paid on July 24, 2007 to Shareholders of Record on July 2, 2007. Arrearages were paid through June 30, 2007 in the amount of $1.1 million.

OFF-BALANCE SHEET ARRANGEMENTS

We have no off-balance sheet transactions.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We believe that our market risk exposures are immaterial as we do not have instruments for trading purposes and reasonable possible near-term changes in market rates or prices will not result in material near-term losses in earnings.

Item 8. Financial Statements and Supplementary Data.

RETRACTABLE TECHNOLOGIES, INC.

FINANCIAL STATEMENTS AND
REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

DECEMBER 31, 2006 AND 2005

RETRACTABLE TECHNOLOGIES, INC.

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders
of Retractable Technologies, Inc.

We have audited the accompanying balance sheets of Retractable Technologies, Inc. as of December 31, 2006 and 2005, and the related statements of operations, changes in stockholders equity, and cash flows for each of the three years in the period ended December 31, 2006. Our audits also included the financial statement schedule of Retractable Technologies, Inc., listed in Item 15(a). These financial statements and financial statement schedule are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Retractable Technologies, Inc. as of December 31, 2006 and 2005, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2006 in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

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

Dallas, Texas
April 2, 2007, except for Note 8
as to which the date is February 27, 2008

RETRACTABLE TECHNOLOGIES, INC.

BALANCE SHEETS

	December 31,	
	2006	**2005**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 46,814,689	$ 52,513,935
Accounts receivable, net of allowance for doubtful accounts of $87,030 and $267,174, respectively	1,956,756	3,404,908
Inventories, net	6,385,780	3,297,726
Income taxes receivable	2,355,732	561,062
Current deferred tax asset		1,245,508
Other current assets	267,707	462,150
Total current assets	57,780,664	61,485,289
Property, plant, and equipment, net	12,212,140	11,925,976
Intangible assets, net	279,846	316,926
Other assets	522,294	27,334
Total assets	$ 70,794,944	$ 73,755,525
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 4,247,630	$ 2,345,613
Current portion of long-term debt	261,905	295,417
Accrued compensation	472,573	388,726
Marketing fees payable	1,419,760	1,419,760
Accrued royalties to shareholder	2,755	540,888
Other accrued liabilities	440,253	467,812
Current deferred tax liability	45,697	
Total current liabilities	6,890,573	5,458,216
Long-term debt, net of current maturities	4,137,231	4,350,625
Long-term deferred tax liability	56,828	711,443
Total liabilities	11,084,632	10,520,284
Stockholders equity:		
Preferred Stock $1 par value:		
Class B; authorized: 5,000,000 shares		
Series I, Class B; issued: 1,000,000 shares; outstanding: 164,000 and 171,000 shares, respectively (liquidation preference of $1,025,000 and $1,068,750, respectively)	164,000	171,000
Series II, Class B; issued: 1,000,000 shares; outstanding 224,700 and 255,200 shares, respectively (liquidation preference of $2,808,750 and $3,190,000, respectively)	224,700	255,200
Series III, Class B; issued: 1,160,445 shares; outstanding: 135,245 and 135,245 shares, respectively (liquidation preference of $1,690,563 and $1,690,563, respectively)	135,245	135,245
Series IV, Class B; issued: 1,133,800 shares; outstanding 553,500 and 556,000 shares, respectively (liquidation preference of $6,088,500 and $6,116,000, respectively)	553,500	556,000
Series V, Class B; issued 2,416,221 shares; outstanding: 1,363,721 and 1,381,221 shares, respectively (liquidation preference of $6,000,372 and $6,077,372, respectively)	1,363,721	1,381,221
Common Stock, no par value; authorized: 100,000,000 shares; issued and outstanding: 23,644,164 and 23,511,884 shares, respectively		
Additional paid-in capital	54,709,108	54,307,053
Retained earnings	2,560,038	6,429,522
Total stockholders equity	59,710,312	63,235,241
Total liabilities and stockholders equity	$ 70,794,944	$ 73,755,525

See accompanying notes to financial statements

RETRACTABLE TECHNOLOGIES, INC.

STATEMENTS OF OPERATIONS

	Years Ended December 31,		
	2006	**2005**	**2004**
Sales, net	$ 20,897,207	$ 21,156,666	$ 21,135,943
Reimbursed discounts	4,427,312	3,078,350	385,757
Total sales	25,324,519	24,235,016	21,521,700
Cost of Sales			
Costs of manufactured product	15,684,450	13,713,675	14,564,404
Royalty expense to shareholder	2,093,822	1,715,024	1,846,195
Total cost of sales	17,778,272	15,428,699	16,410,599
Gross profit	7,546,247	8,806,317	5,111,101