

RETRACTABLE TECHNOLOGIES INC
Form 10KSB
March 31, 2005
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-KSB

(Mark One)

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

For the fiscal year ended December 31, 2004

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)

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Texas
(State or other jurisdiction of
incorporation or organization)

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

511 Lobo Lane

Little Elm, Texas
(Address of principal executive offices)

75068-0009
(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 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.

State issuer's revenues for its most recent fiscal year. \$21,135,943

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was sold, or the average bid and asked price of such common equity, as of a specified date within the past 60 days. (See definition of affiliate in Rule 12b-2 of the Exchange Act.) The aggregate market value of the common equity held by non-affiliates is \$36,637,912 which was computed with reference to the closing price as of March 1, 2005.

(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 1, 2005 there were 23,204,498 shares of our Common Stock issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None except exhibits

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

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PART I

Item 1. Description of Business

BUSINESS DEVELOPMENT

General Description

We design, develop, manufacture, and market innovative patented safety needle devices for the healthcare industry. Our VanishPoint® products utilize a unique friction ring mechanism patented by Thomas J. Shaw, our Founder, President, and Chief Executive Officer. VanishPoint® products are designed specifically to prevent needlestick injuries and to prevent reuse. The friction ring mechanism permits the automated retraction of the syringe needle into the barrel of the syringe, directly from the patient, after delivery of the medication is completed. The VanishPoint® blood collection tube holder utilizes the same mechanism to retract the needle after blood has been drawn from the patient. Closure of an attached end cap of the blood collection tube holder causes the needle to retract directly from the patient into the closed tube holder. Advantages of our products include protection from needlestick injuries, prevention of cross contamination through reuse, and reduction of disposal and other associated costs. Federal regulation now requires the use of safe needle devices. We have an exclusive license from Thomas J. Shaw, our President and Chief Executive Officer, for the patent rights for our safety needle products.

We and Thomas J. Shaw entered into a Technology License Agreement dated effective as of the 23rd day of June 1995, whereby Mr. Shaw granted us a worldwide exclusive license to manufacture, market, sell, and distribute Licensed Products and Improvements until the expiration of the last to expire of the last Licensed Patents unless sooner terminated under certain conditions without right to sublicense. Licensed Products, Improvements, and Licensed Patents are all terms that are extensively defined in the Technology License Agreement. In exchange, we paid Mr. Shaw a \$500,000 initial licensing fee and a 5 percent royalty on gross sales after returns of Licensed Products. See Patents and Proprietary Rights for a more detailed discussion. Our goal is to become a leading provider of automated retraction safety devices.

Development of the Company

While owning and operating Checkmate Engineering, a sole proprietorship, Thomas J. Shaw, our President and Chief Executive Officer, developed and patented the idea and early prototypes of the syringe that were to become the VanishPoint® safety syringe. On May 9, 1994, the Company was incorporated in Texas to design, develop, manufacture, and market medical safety devices for the healthcare industry.

We received our ISO 9001:1994 recertification in July 1998, and the VanishPoint® syringe received its CE Mark on July 31, 1998. In July 2001, we received re-certification to ISO 9001:1994 and the CE Mark. In August 2004, we received certification to ISO 13485:2000, CAN/CSA:13485:1996 and EN 13485.2000. These standards replace the ISO 9001:1994 for Quality Management Systems. The 13485:2000 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.

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We have been manufacturing and marketing our products into the market place since 1997. In May 2000 we signed a National Marketing and Distribution Agreement with Abbott Laboratories. We

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terminated this agreement in October 2003. Our products have been and continue to be distributed nationally through numerous distributors. However, we have been blocked from access to the market by exclusive marketing practices engaged in by Becton Dickinson and Company, Inc. (BD) who dominates our market.

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

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

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. We also have begun selling allergy trays with 25 syringes per tray. The tray design eliminates the need to individually unwrap each syringe. Our products (without Notice of Substantial Equivalence to the FDA) also include a dental syringe, a butterfly IV, a self retracting IV catheter introducer, and an auto-disable 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. The VanishPoint® blood collection tube holder received Risk and Insurance magazine's 1997 Top of the Line Award for excellence.

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

Market Overview

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

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

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Marketing and Distribution

Under the current supply chain system in the U.S. acute care market, the vast majority of decisions relating to the contracting for and purchase of medical supplies are made by the representatives of group purchasing organizations (GPOs) rather than the end-users of the product (nurses, doctors, and testing personnel). The GPOs and manufacturers often enter into long-term exclusive contracts which can prohibit entry in the marketplace by competitors. According to *The Role of Group Purchasing Organizations in the US Health Care System*, a report prepared by Muse & Associates for the Health Industry Group Purchasing Association (HIGPA), the potential hospital marketplace for medical/surgical equipment and supplies in 1998 and 1999 was \$32.8 billion and \$34.1 billion, respectively. According to information posted on HIGPA 's website about 72 percent of these hospital expenditures are channeled through GPOs. In the needle and syringe market, the market share leader, BD, has utilized, among other things, long-term exclusive contracts which have restricted our entry into the market.

We distribute our products throughout the United States and its territories through general line and specialty distributors. We also utilize international distributors. We have developed a national direct marketing network in order to market our products to health care customers and their purchaser representatives. Our marketers make calls on target markets that are users of syringes and blood collection tube holders. Our marketers make contact with all of the departments that affect the decision-making process for safety products, including the purchasing agents. They call on acute care and alternate care sites and talk directly with the decision-makers of these facilities. We employ trained clinicians, including registered nurses and/or medical technologists, that educate healthcare providers and healthcare workers on the use of safety devices through exhibits at related tradeshow and publications of relevant articles in trade journals and magazines. These nurses provide clinical support to customers. In addition to marketing our products, the network demonstrates the safety and cost effectiveness of the VanishPoint® automated retraction products to customers.

We have numerous agreements with organizations for the distribution of our products in foreign markets. Sales to these markets increased in 2004. The total population of Western Europe exceeds 310 million, and the recognition for the urgency of safe needle devices in parts of Europe has echoed the United States model. In France, England, Germany, and Italy, organized healthcare worker unions have taken action to force hospitals and government agencies to place safety as a priority. Regions within Asia and Africa are also recognizing the need for our products. In 2004, we were awarded a federal contract to supply syringes to five African countries. Even though the contract was less than \$1,000,000, the Company is hopeful that the contract will provide increased access to this federal 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; (b) continue marketing emphasis in the U.S. which has implemented the requirements outlined by safe needle legislation; (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; and (h) continue to increase international sales.

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, a catheter introducer and an auto-disable syringe. Our limited access to the market has slowed the introduction of these products into the market.

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Competition

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

Founded in 1897, BD is headquartered in New Jersey. BD's safety-engineered syringe and needle products sales accounted for approximately 15 percent of BD's total 2003 sales. BD currently manufactures the SafetyLok® syringe that utilizes a tubular plastic sheath that must be manually slid over the needle after an injection, and the SafetyGlide, a syringe which utilizes a hinged lever to cover the needle tip. BD also manufactures a safety blood collection needle that utilizes the Eclipse needle cover. BD's Vacutainer® blood collection products are commonly used as industry jargon to refer to blood collection products in general. BD manufactures a 3cc and 1cc retracting needle product based on a license agreement with Med-Design. The impact of BD's new Integra syringe is yet to be determined. However, at this time, it does not offer a full product line and cannot be used with highly viscous medication due to leakage (as described on their labels).

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

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

Our competitive strengths include that the VanishPoint® syringe is one of four syringes given the highest possible rating by ECRI (formerly Emergency Care Research Institute). Our blood collection tube holder is one of only two safety products given the highest possible rating. Our products also have an

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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 efforts. Outsourcing arrangements such as our agreement with Double Dove have increased our manufacturing capacity with little or no capital outlay and provides a competitive cost.

Our competitive weaknesses include our current lack of market share (less than 1 percent) 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 by BD, which dominates the market, 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, Nipro Corporation and ISPG. We began to receive shipment of product under our agreement with Double Dove, a Chinese manufacturer, in 2004.

Dependence on Major Customers

One distributor accounted for 16.6% of our unit sales in 2004. We have numerous other distributors that sell our products in the U.S. and internationally.

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 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. In addition, we have filed applications for national patents in selective countries where we believe the VanishPoint® syringe can be utilized most.

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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 trademark protection for the phrase "The New Standard for Safety."

There are currently no patent infringement claims pending against the VanishPoint[®] retraction technology. We have decided, on the advice of patent counsel, not to purchase patent insurance because it would require inappropriate disclosure of information that is currently proprietary and confidential.

Regulatory Status and Effect of Regulation

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

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

RWTUV-USA, a subsidiary of TUV Essen Germany, performs our quality management system certification. We were originally certified to ISO 9001:1994 in 1997 and received annual surveillance audits, maintaining that certification until March of 2004 with no major non-conformances. We received certification to ISO 13485:2000, CAN/CSA:13485:1996 and EN 13485.2000 in August 2004. In addition, the VanishPoint product line was certified for a CE Mark by RWTUV. The CE Mark authorizes us to sell in the European Union. RWTUV performs annual surveillance audits to ensure our compliance with ISO 13485:2000, CAN/CSA:13485:1996 and EN 13485.2000 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

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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 \$561,135 and \$626,941 in fiscal 2003 and 2004, respectively, on research and development. Costs in 2004 were primarily for compensation and experimental parts. 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

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currently in development by our internal team include the winged butterfly IV, the catheter introducer, and the dental syringe. Our limited access to the market has slowed the introduction of these products into the market. Possible future products include all needle medical devices to which the automated retraction mechanism can be applied.

Environmental Compliance

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

Other nonhazardous production waste includes clean polypropylene regrind that is sold for recycling. The Company also grinds dirty plastics, syringes, and needles for disposal by Waste Management. All other nonhazardous waste produced is considered municipal solid waste and sent to a sanitary landfill by Waste Management.

We also produce small amounts of regulated biohazardous waste from contaminated sharps and laboratory wastes. This waste is sent for incineration by American 3CI.

Employees

As of March 1, 2005, we had 148 full-time employees, 2 part-time employees, and 1 independently contracted consultant. Of the 148 full-time employees, 5 persons were engaged in research and development activities, 65 persons were engaged in manufacturing and engineering, 26 persons were engaged in quality assurance and regulatory affairs, 22 persons were engaged in sales and marketing, 29 persons were engaged in general and administrative functions, and 1 person in facilities. No employees are covered by collective bargaining agreements. We are dependent upon a number of key management and technical personnel, and the loss of services of one or more key employees could have a material adverse effect on us. Our President and Chief Executive Officer, Thomas J. Shaw, has an employment contract that ended on September 2002 with an automatic and continuous renewal for consecutive two-year periods.

Item 2. Description of Property

Our 22,500 square foot headquarters is located at 511 Lobo Lane, on 35 acres, which we own, overlooking Lake Lewisville in Little Elm, Texas. The building is a modular portion of a larger planned building for which the engineering design has been finalized. The headquarters are in good condition and house our administrative offices and manufacturing facility. We have completed construction of a 45,000 square foot warehouse and put it in service in March 2005.

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The Company has obtained a loan from 1st International Bank ("1 International ") for \$2,500,000 (the "New Loan "), 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 new note were interest only during the first twelve months. The payments for the permanent funding will be based on a twenty-year amortization with a five year maturity. Interest rates will be based on the amount of funds kept on deposit with the bank. Accordingly, interest will vary from the WSJPR to the WSJPR plus 1 percent, with floors that may range from 4.25 percent to 6.50 percent. Compensating balances at 1st International affecting the interest rate will range from \$0 to \$500,000.

Additional capital expenditures may include additional assembly lines, 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.

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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 holding more than 10% of the Common Stock. 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. This lease is expected to terminate in the second quarter.

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, GE Capital Modular Space, and 1st International as the loss payees.

We do not hold any real estate or related securities for investment purposes or engage in real estate activities. It is not our policy to acquire assets primarily for possible capital gain or primarily for income. However, there are no limitations on the percentage of assets which may be invested in any one type of investment and our policies may be changed without a vote of the shareholders.

Item 3. Legal Proceedings

We are not a party to any material legal proceeding.

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

No matters were submitted to a vote during the fourth quarter of 2004.

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 high and 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:

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	<u>Common Stock</u>	
	<u>High</u>	<u>Low</u>
2004		
Fourth Quarter	\$ 5.24	\$ 3.55
Third Quarter	\$ 9.16	\$ 4.50
Second Quarter	\$ 7.75	\$ 5.20
First Quarter	\$ 8.89	\$ 5.82
2003		
Fourth Quarter	\$ 6.98	\$ 5.75
Third Quarter	\$ 8.25	\$ 6.00
Second Quarter	\$ 9.50	\$ 2.90
First Quarter	\$ 5.00	\$ 2.99

SHAREHOLDERS

As of March 1, 2005, there were 23,204,498 shares of Common Stock held by 342 shareholders of record not including shareholders who beneficially own Common Stock held in nominee or street name.

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DIVIDENDS

We have not ever declared or paid any dividends on the Common Stock. We have no current plans to pay any cash dividends on the Common Stock. We intend to retain all earnings, except those required to be paid to the holders of the Preferred Stock, to support operations and future growth. The Board of Directors declared a dividend on the Series I and II Class B Convertible Preferred Stock. The dividend arrearage through June 30, 2004, on the Series I and II Class B Convertible Preferred Stock of \$7,118,583 was paid on August 27, 2004, to the holders of record as of August 17, 2004. As of December 31, 2004, \$9,209,000 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.

EQUITY COMPENSATION PLAN INFORMATION

See **Item 11 Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters** for a chart describing compensation plans under which equity securities are authorized.

RECENT SALES OF UNREGISTERED SECURITIES

Sales of unregistered securities in the first three quarters of 2004 were reported in the Company's Form 10-QSB quarterly reports filed with the United States Securities and Exchange Commission (the "Commission") which are available via Edgar. There were no sales in the fourth quarter of 2004.

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

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 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. Our agreement with Double Dove has enabled us to increase manufacturing capacity with little or no capital outlay and provided a competitive manufactured cost. 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 are also marketing more product internationally.

Historically, unit sales have increased in the latter part of the year due, in part, to the demands for syringes during the flu season. As a result of the severe flu vaccine shortage in 2004, management believes

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that our sales in the third and fourth quarter of 2004 were negatively affected by customers that would have ordered product but for the shortage. Management further anticipates that not all product that was ordered in the latter part of 2004 was used as a result of the vaccine shortage. Accordingly, management anticipates that sales in the first and possibly second quarter of 2005 may be negatively impacted as well until current customer inventories are depleted.

SELECTED FINANCIAL DATA

The following selected financial data for fiscal years ended December 31, 2004, and 2003, 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,	
	2004	2003
Sales, net	\$ 21,135,943	\$ 19,078,332
Reimbursed discounts	385,757	
Total sales	21,521,700	19,078,332
Cost of sales	16,410,599	14,654,006
Gross margin	5,111,101	4,424,326
Operating expenses		
Sales and marketing	3,648,454	3,374,212
Research and development	626,941	561,135
General and administrative	8,834,527	6,391,931
Total operating expenses	13,109,922	10,327,278
Loss from operations	(7,998,821)	(5,902,952)
Interest income	475,121	44,553
Interest expense, net	(243,922)	(307,142)
Litigation settlement, net	74,635,362	13,879,511
Net income before income taxes	66,867,740	7,713,970
Provision for income taxes	12,176,345	265,473
Net income	54,691,395	7,448,497
Preferred stock dividend requirement	(1,993,516)	(2,560,723)

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Earnings applicable to Common Stockholders	\$ 52,697,879	\$ 4,887,774
Earnings per share - basic	\$ 2.33	\$ 0.23
Earnings per share - diluted	\$ 2.08	\$ 0.20
Weighted average common shares outstanding	22,600,166	21,001,004

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The following discussion contains trend information and other forward-looking statements that involve a number of risks and uncertainties. Our actual future results could differ materially from our historical results of operations and those discussed in the forward-looking statements. All period references are to our fiscal year ended December 2004 or 2003. Variances have been rounded for ease of reading.

Comparison of Year Ended

December 31, 2004, and Year Ended December 31, 2003

Net sales were \$21,135,943 and \$19,078,332 for the years ended December 31, 2004, and December 31, 2003, respectively. Unit sales increased 23.8 percent. The increase in net sales of \$2,057,611, or 10.8 percent, was due principally to increased sales in the alternate care market and international sales. Domestic sales comprised 94.0% of our revenues whereas international sales accounted for the remaining 6.0%. Discount reimbursements in 2004 were \$358,757. Unit sales of the 1cc syringe increased 21.1 percent, 3cc sales increased 13.0 percent. Sales to one distributor in 2004 accounted for 16.6 percent of the revenues.

Cost of sales increased from \$14,654,006 in 2003 to \$16,410,599, in 2004, an increase of \$1,756,593, or 12.0 percent. \$1,543,000 of the increase is due to additional products being sold and the purchases from China. The remaining increase is additional royalty expense of \$369,000 mitigated by reduced insurance costs of \$65,000, decreased supplies and testing costs of \$65,000, and other reduced costs of \$25,000.

Sales and marketing expenses increased to \$3,648,454 in 2004 from \$3,374,212 in 2003, an increase of \$274,000. Labor costs increased \$422,000 mitigated by the 2003 bonuses of \$108,000. Labor costs increased due to additional sales and marketing employees. Other increases in expense include travel and entertainment of \$182,000, administrative fees paid under GPO contracts \$102,000, stock option expense of \$99,000, consulting costs of \$78,000, advertising costs of \$65,000, meetings and trade show expense of \$54,000, and various other office expenses and freight comprising the remainder. The increase was mitigated by the reduction in marketing fees of \$680,000 due to the termination of the Abbott Agreement.

Research and development expense increased from \$561,135 in 2003 to \$626,941 in 2004. Increases in labor costs of \$106,000, offset by 2003 bonuses of \$25,000, lower consulting cost of \$84,000, and an increase in experimental parts of \$62,000 account for most of the change.

General and administrative costs increased \$2,442,596, or 38.2 percent, from 2003 to 2004. Increases include higher legal expenses of \$1,919,000 principally due to the Becton Dickinson litigation. Legal fees for patents also increased \$322,000. Labor costs increased \$310,000, offset by the 2003 bonuses of \$226,000, stock option expense increased \$123,000, taxes other than income taxes increased \$327,000 due primarily to property taxes, and accounting fees increased \$54,000 due to the increased complexity of the Company and the effect of Sarbanes Oxley. Insurance cost, principally liability insurance, declined \$66,000 due principally to changing market conditions.

Effective July 2, 2004, the Company entered into a Settlement Agreement and Release with BD. The Company received \$65.1 million of the proceeds which is net of attorneys' fees and expenses. Approximately \$3.4 million was paid to Thomas J. Shaw, President and CEO, under a Covenant Not to Sue.

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Effective as of April 27, 2004, the Company and Thomas J. Shaw entered into a Settlement Agreement and Release with New Medical Technology, Inc. et. al. (NMT). NMT is enjoined from importing the NMT Safety Syringe into the United States and from making, using, selling, or offering to sell the NMT Safety Syringe within the United States until the lapse or expiration of the subject patents. Additionally, NMT paid \$1,000,000.00 to the Company.

In 2003, the Company reached settlement agreements with three of the defendants in its federal antitrust lawsuit, Retractable Technologies, Inc. v. BD et al. As part of the settlements, the Company received \$8,051,250 in 2004 as payment under the financial terms of these settlement agreements which is

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net of attorneys' fees, court costs, legal expenses, and a payment to Mr. Thomas J. Shaw of \$423,750 pursuant to the Covenant Not to Sue. See **Note 12 LITIGATION SETTLEMENTS** of the Notes to Financial Statements for a discussion of these settlements.

Provision for income tax consists primarily of federal income tax. The Company utilized all of its net operating loss carryforward for federal and state tax purposes.

Preferred stock dividend requirements were \$1,993,516 for 2004 compared to \$2,560,723 in 2003, a decrease of \$567,207. The decrease is due to the conversion of preferred stock, principally Series IV Stock and Series V Stock, resulting in fewer preferred shares outstanding.

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

As a result of the litigation settlement proceeds, the Company is in a profitable position for 2003 and 2004.

Cash flow from operating activities improved from \$8,085,125 to \$56,479,136, an improvement of \$48,421,011. The principal factor in the improvement was the proceeds from the litigation settlements. Inventories increased \$198,000 and property, plant and equipment increased \$2,437,847 principally due to construction of the warehouse. Accounts payable and income taxes payable increased \$1,067,000 and \$1,136,135, respectively. Accrued royalties declined \$652,617. The Company paid \$7,118,583 in dividends on the Series I and Series II preferred stock.

The proceeds from litigation provided significant improvements to the Company's balance sheet, particularly with the increase in cash. Conversion of 1,019,100 shares of preferred stock reduced our dividend requirements in 2004 by \$567,000.

We began construction of a warehouse in 2004 which was completed in the first quarter of 2005. The interim and long-term financing was provided by a loan from 1st International.

Comparison of Year Ended

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

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

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of other products. Sales under the Abbott Agreement accounted for 26.4 percent of 2003 revenues and 49.0 percent of 2002 revenues. Sales to other distributors in 2003 increased to 73.6 percent compared to 51.0 percent in 2002. The Abbott Agreement was terminated October 15, 2003.

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

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

Sales and marketing expenses decreased to \$3,374,212 in 2003 from \$4,042,081 in 2002, a decrease of \$668,000. As a percentage of revenues, sales and marketing expenses decreased from 19.9 percent in 2002 to 17.7 percent in 2003. The decrease was attributable to the reduction in marketing fees of \$1.4 million due to the termination of the Abbott Agreement mitigated by the decrease in revenues

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discussed earlier. The decreased marketing fees were offset by increases in labor costs of \$120,000, bonuses of \$108,000, stock option expense of \$84,000, travel and entertainment expense of \$152,000, meetings and trade show expense of \$53,000, samples and promotional materials of \$52,000, and various other office expenses and freight comprising the remainder.

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

The Company reached settlement agreements with three of the defendants in its federal antitrust lawsuit, Retractable Technologies, Inc. v. BD et al. As part of the settlements, the litigation against Premier, Novation, and TYCO has been dismissed. The Company received \$13,879,511 as the initial payment under the financial terms of these settlement agreements which is net of attorneys' fees, court costs, legal expenses, and a payment to Mr. Thomas J. Shaw of \$728,609 pursuant to the Covenant Not to Sue. See **Note 12 LITIGATION SETTLEMENTS** of the Notes to Financial Statements for a discussion of settlements relating to the antitrust lawsuit.

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

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

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

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

SIGNIFICANT ACCOUNTING POLICIES

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

Revenue Recognition

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

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Marketing Fees

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

Litigation Proceeds

Proceeds from litigation settlements in the Company's federal antitrust lawsuit, Retractable Technologies, Inc. v. Becton Dickinson & Co., et al. are recognized when realizable. Generally, realization is not reasonably assured and expected until proceeds are collected. Such amounts are net of attorneys' fees, court costs, legal expenses, and amounts payable under the Covenant Not to Sue. Liability for attorneys' fees is not incurred until proceeds are collected.

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

Stock-Based Compensation

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

LIQUIDITY AND FUTURE CAPITAL REQUIREMENTS

Historical Sources of Liquidity

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We have historically funded operations primarily from proceeds from private placements and loans. We were capitalized with approximately \$52,600,000 raised from six separate private placement offerings. 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. In October 2002 we repaid the Abbott note with proceeds from a new note from Katie Petroleum for \$3,000,000 and a portion of the proceeds from a private placement.

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

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Internal Sources of Liquidity

In early 2004 we began to receive shipment of product under our agreement with Double Dove, a Chinese manufacturer. We believe as we receive greater quantities our profit margins could increase. To achieve our break even quarter we would need minimal access to hospital markets which has been difficult to obtain due to the monopolistic marketplace which was the subject of our antitrust lawsuit against BD. We will continue to attempt to gain access to the market through our sales efforts and innovative technology. We are focusing on methods of upgrading our manufacturing capability and efficiency in order to enable us to offer our technology at a reduced price. We believe our current capitalization provides the resources necessary to implement these changes and greatly improve our manufacturing capacity and efficiency, thereby reducing our unit cost.

Historically, unit sales have increased in the latter part of the year due, in part, to the demand for syringes during the flu season. As a result of the severe flu vaccine shortage, management believes that our sales in the third and fourth quarter of 2004 were negatively affected by customers that would have ordered product but for the shortage. Management further anticipates that not all product that was ordered in the latter part of 2004 was used as a result of the vaccine shortage. Accordingly, management anticipates that sales in the first and possibly second quarter of 2005 may be negatively impacted as well until current customer inventories are depleted.

Our primary sources of ongoing liquidity are sales of product and, historically, litigation proceeds, sales of stock and loans. At the present time Management does not intend to raise additional equity capital in 2005. Due to the recent 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 becomes insufficient to support operations, the Company would take cost cutting measures to reduce cash requirements. Such measures could result in reduction of units being produced, reduction of workforce, reduction of salaries of officers and other nonhourly employees, and deferral of royalty payments to Thomas Shaw.

External Sources of Liquidity

We have obtained several loans over the past six years, which have, together with proceeds from sales of equities, enabled us to pursue development and production of our products. Currently we believe we could obtain additional funds through loans if needed. Furthermore, the shareholders have 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, 2004:

Contractual Obligations	Payments Due by Period				
	Total	2005	2006-2007	2008-2009	Thereafter
Long-Term Debt	\$ 4,299,730	\$ 361,969	\$ 782,072	\$ 814,589	\$ 2,341,100
Capital Lease Obligations	17,128	10,992	6,136	0	0
Operating Lease Obligations	11,600	11,600	0	0	0
Total Contractual Cash Obligations	\$ 4,328,458	\$ 384,561	\$ 788,208	\$ 814,589	\$ 2,341,100

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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 \$2,437,847 in capital expenditures in 2004 and \$385,921 in 2003. We anticipate capital expenditures of approximately \$1,500,000 in 2005 primarily for completion of the warehouse construction and purchase of other capital assets.

OFF BALANCE SHEET TRANSACTIONS

We have no off-balance sheet transactions.

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Item 7. Financial Statements

RETRACTABLE TECHNOLOGIES, INC.

FINANCIAL STATEMENTS AND

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

DECEMBER 31, 2004 AND 2003

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RETRACTABLE TECHNOLOGIES, INC.

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders

of Retractable Technologies, Inc.

We have audited the accompanying balance sheets of Retractable Technologies, Inc. as of December 31, 2004 and 2003, 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, 2004. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits 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, 2004 and 2003, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2004 in conformity with accounting principles generally accepted in the United States of America.

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

CF & Co., L.L.P.

Dallas, Texas

March 30, 2005

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	December 31,	
	2004	2003
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 55,868,526	\$ 8,155,621
Accounts receivable, net of allowance for doubtful accounts of \$196,320 and \$146,452, respectively	1,864,514	1,170,231
Inventories, net	3,778,949	3,976,584
Prepaid income taxes	1,349,144	
Current deferred tax asset	1,887,347	
Other current assets	296,683	194,310
Total current assets	65,045,163	13,496,746
Property, plant, and equipment, net	11,056,865	9,678,826
Intangible assets, net	358,659	394,369
Other assets	34,005	60,565
Total assets	\$ 76,494,692	\$ 23,630,506
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	\$ 3,402,037	\$ 2,335,389
Current portion of long-term debt	271,842	210,681
Accrued compensation	322,861	231,959
Marketing fees payable	1,419,760	1,419,760
Accrued royalties	504,016	1,156,633
Other accrued liabilities	118,832	152,800
Income taxes payable	1,813,084	265,473
Total current liabilities	7,852,432	5,772,695
Long-term debt, net of current maturities	3,535,410	2,723,001
Long-term deferred tax liability	1,442,145	
Total liabilities	12,829,987	8,495,696
Stockholders equity:		
Preferred stock \$1 par value:		
Class B; authorized: 5,000,000 shares		
Series I, Class B; issued: 1,000,000 shares; outstanding: 199,400 and 229,400 shares, respectively (liquidation preference of \$1,246,250 and \$1,433,750, respectively)	199,400	229,400
Series II, Class B; issued: 1,000,000 shares; outstanding 289,000 and 418,500 shares, respectively (liquidation preference of \$3,612,500 and \$5,231,250 respectively)	289,000	418,500
Series III, Class B; issued: 1,160,445 shares; outstanding: 137,745 and 145,245 shares, respectively (liquidation preference of \$1,721,813 and \$1,815,563 respectively)	137,745	145,245

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Series IV, Class B; issued: 1,133,800 shares; outstanding 556,000 and 1,066,000 shares, respectively (liquidation preference of \$6,116,000 and \$11,726,000, respectively)	556,000	1,066,000
Series V, Class B; issued 2,416,221 shares; outstanding: 1,389,971 and 1,732,071 shares, respectively (liquidation preference of \$6,115,872 and \$7,621,112 respectively)	1,389,971	1,732,071
Common Stock, no par value; authorized: 100,000,000 shares; issued and outstanding: 23,201,998 and 22,141,964, respectively		
Additional paid-in capital	53,424,744	51,448,561
Retained earnings (deficit)	7,667,845	(39,904,967)
	<hr/>	<hr/>
Total stockholders' equity	63,664,705	15,134,810
	<hr/>	<hr/>
Total liabilities and stockholders' equity	\$ 76,494,692	\$ 23,630,506
	<hr/>	<hr/>

See accompanying notes to the financial statements

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

	Years Ended December 31,		
	2004	2003	2002
Sales, net	\$ 21,135,943	\$ 19,078,332	\$ 20,316,299
Reimbursed discounts	385,757		
Total sales	21,521,700	19,078,332	20,316,299
Cost of sales	16,410,599	14,654,006	14,990,932
Product recall and recovery			481,637
Gross margin	5,111,101	4,424,326	4,843,730
Operating expenses:			
Sales and marketing	3,648,454	3,374,212	4,042,081
Research and development	626,941	561,135	337,930
General and administrative	8,834,527	6,391,931	4,534,217
Debt conversion expense			2,319,073
Total operating expenses	13,109,922	10,327,278	11,233,301
Loss from operations	(7,998,821)	(5,902,952)	(6,389,571)
Interest income	475,121	44,553	10,035
Interest expense, net	(243,922)	(307,142)	(446,392)
Litigation settlements, net	74,635,362	13,879,511	
Net income (loss) before income taxes	66,867,740	7,713,970	(6,825,928)
Provision for income taxes	12,176,345	265,473	
Net income (loss)	54,691,395	7,448,497	(6,825,928)
Preferred stock dividend requirements	(1,993,516)	(2,560,723)	(2,266,250)
Earnings (loss) applicable to common shareholders	\$ 52,697,879	\$ 4,887,774	\$ (9,092,178)
Earnings (loss) per share - basic	\$ 2.33	\$ 0.23	\$ (0.45)
Earnings (loss) per share - diluted	\$ 2.08	\$ 0.20	\$ (0.45)
Weighted average common shares outstanding	22,600,166	21,001,004	20,300,454

See accompanying notes to the financial statements

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RETRACTABLE TECHNOLOGIES, INC.

STATEMENTS OF CHANGES OF STOCKHOLDERS EQUITY

	Series A		Series I Class B		Series II Class B		Series III Class B		Series IV Class B		Series V Class B		Common	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount
Balance as of December 31, 2001	1,101,500	\$ 1,101,500	261,900	\$ 261,900	431,000	\$ 431,000	158,245	\$ 158,245	1,066,000	\$ 1,066,000		\$	20,262,600	\$
Issued Preferred Series V, Class B shares 2,022,012 shares, \$1 par (net of stock issuance costs of \$296,088)											2,022,012	2,022,012		
Conversion of Preferred Stock into Common Stock	(45,500)	(45,500)	(2,500)	(2,500)			(7,500)	(7,500)						55,500
Recognition of stock option compensation														
Stock options given in connection with issuance of \$3,000,000 note payable														
Stock options given in connection with stock subscriptions for 525,000 Preferred Series V, Class B shares														
Stock options given in connection with conversion of \$3,679,284 of debt														
Issued 394,209 additional shares of Preferred Series V, Class B shares in connection											394,209	394,209		

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with conversion of \$3,679,284 of debt														
Beneficial conversion feature of \$3,000,000 note payable														
Implied dividend for beneficial conversion feature of Preferred Series V, Class B shares														
Forgiveness of royalties due to an officer														
Net loss														
Balance as of December 31, 2002	1,056,000	1,056,000	259,400	259,400	431,000	431,000	150,745	150,745	1,066,000	1,066,000	2,416,221	2,416,221	20,318,100	
Conversion of debt into Common Stock													35,714	
Conversion of preferred Stock into Common Stock	(1,056,000)	(1,056,000)	(30,000)	(30,000)	(12,500)	(12,500)	(5,500)	(5,500)			(684,150)	(684,150)	1,788,150	
Recognition of stock option compensation														
Dividends declared and paid on Series A Preferred Stock														
Net income														
Balance as of December 31, 2003			229,400	229,400	418,500	418,500	145,245	145,245	1,066,000	1,066,000	1,732,071	1,732,071	22,141,964	
Conversion of debt into Common Stock													40,934	
Conversion of Preferred Stock into Common Stock			(30,000)	(30,000)	(129,500)	(129,500)	(7,500)	(7,500)	(510,000)	(510,000)	(342,100)	(342,100)	1,019,100	
Recognition of stock option compensation														
Dividends declared and paid on Series I Class B Stock														
Dividends declared and paid on Series II Class B														

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Stock

Net Income

Balance as of December 31, 2004		199,400	\$ 199,400	289,000	\$ 289,000	137,745	\$ 137,745	556,000	\$ 556,000	1,389,971	\$ 1,389,971	23,201,998
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See accompanying notes to the financial statements

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

	Additional Paid-in Capital	Retained Earnings	Total
	<u> </u>	<u> </u>	<u> </u>
Balance as of December 31, 2001	\$ 37,671,513	\$ (40,527,536)	\$ 162,622
Issued Preferred Series V, Class B shares 2,022,012 shares, \$1 par (net of stock issuance costs of \$296,088)	8,663,051		10,685,063
Conversion of Preferred Stock into Common Stock	55,500		
Recognition of stock option compensation	48,926		48,926
Stock options given in connection with issuance of \$3,000,000 note payable	299,346		299,346
Stock options given in connection with Issuance of 525,000 Preferred Series V, Class B shares	209,572		209,572
Stock options given in connection with conversion of \$3,679,284 of debt	440,000		440,000
Issued 394,209 additional shares of Preferred Series V, Class B shares in connection with conversion of \$3,679,284 of debt	1,427,036		1,821,245
Beneficial conversion feature of \$3,000,000 note payable	412,500		412,500
Implied dividend for beneficial conversion feature of Preferred Series V, Class B shares	(1,316,267)		(1,316,267)
Forgiveness of royalties due to an officer	1,500,000		1,500,000
Net loss		(6,825,928)	(6,825,928)
	<u> </u>	<u> </u>	<u> </u>
Balance as of December 31, 2002	49,411,177	(47,353,464)	7,437,079
Conversion of debt into Common Stock	249,998		249,998
Conversion of Preferred Stock into Common Stock	1,788,150		
Recognition of stock option compensation	458,324		458,324
Dividends declared and paid on Series A Preferred Stock	(459,088)		(459,088)
Net income		7,448,497	7,448,497
	<u> </u>	<u> </u>	<u> </u>
Balance as of December 31, 2003	51,448,561	(39,904,967)	15,134,810
Conversion of debt into Common Stock	163,736		163,736
Conversion of Preferred Stock into Common Stock	1,019,100		
Recognition of stock option compensation	793,347		793,347
Dividends declared and paid on Series I Stock		(2,550,338)	(2,550,338)
Dividends declared and paid on Series II Stock		(4,568,245)	(4,568,245)
Net income		54,691,395	54,691,395
	<u> </u>	<u> </u>	<u> </u>
Balance as of December 31, 2004	\$ 53,424,744	\$ 7,667,845	\$ 63,664,705
	<u> </u>	<u> </u>	<u> </u>

See accompanying notes to the financial statements

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

	Years Ended December 31,		
	2004	2003	2002
Cash flows from operating activities:			
Net income (loss)	\$ 54,691,395	\$ 7,448,497	\$ (6,825,928)
Adjustments to reconcile net income (loss) to net cash provided (used) by operating activities:			
Depreciation and amortization	1,294,297	1,308,624	1,328,700
Capitalized interest	(52,788)	(26,924)	(25,796)
Stock option compensation	793,347	458,324	48,927
Provision for doubtful accounts	146,049	100,352	12,498
Accreted interest	101,120	101,119	
Deferred income taxes	(445,202)		
Waiver of vacation pay			(100,937)
Debt conversion expense			2,319,073
Change in assets and liabilities:			
(Increase) decrease in inventories	197,635	(1,197,029)	439,232
(Increase) decrease in accounts and note receivable	(840,332)	1,396,282	(1,094,338)
(Increase) decrease in prepaid income taxes	(1,349,144)		
(Increase) decrease in other current assets	(75,817)	87,443	88,430
Increase (decrease) in accounts payable	1,066,648	(1,894,008)	1,909,280
Increase (decrease) in marketing fees payable		(454,811)	(642,770)
Increase (decrease) in other accrued liabilities	(595,683)	464,783	1,000,163
Increase (decrease) in income taxes payable	1,547,611	265,473	
Net cash provided (used) by operating activities	<u>56,479,136</u>	<u>8,058,125</u>	<u>(1,543,466)</u>
Cash flows from investing activities:			
Purchase of property, plant and equipment	(2,437,847)	(385,921)	(71,314)
Acquisition of patents, trademarks, licenses and intangibles		(24,713)	(59,903)
Net cash used by investing activities	<u>(2,437,847)</u>	<u>(410,634)</u>	<u>(131,217)</u>
Cash flows from financing activities:			
Repayments of long-term debt and notes payable	(159,802)	(374,899)	(5,552,527)
Proceeds from long-term debt	950,000		3,000,000
Proceeds from the sale of Preferred Stock			4,435,600
Payment of Preferred Stock dividends	(7,118,582)	(459,088)	
Offering expenses related to Preferred Stock issuances			(86,517)
Net cash provided (used) by financing activities	<u>(6,328,384)</u>	<u>(833,987)</u>	<u>1,796,556</u>
Net increase in cash and cash equivalents	47,712,905	6,813,504	121,873
Cash and cash equivalents at:			
Beginning of period	8,155,621	1,342,117	1,220,244

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End of period	\$ 55,868,526	\$ 8,155,621	\$ 1,342,117
Supplemental schedule of cash flow information:			
Interest paid	\$ 202,572	\$ 257,986	\$ 460,159
Income taxes paid	\$ 12,439,212	\$	\$
Supplemental schedule of noncash investing and financing activities:			
Debt assumed to acquire assets	\$ 121,837	\$ 16,264	\$
Closing costs rolled into long-term debt	\$ 24,154	\$	\$
Conversion of long-term debt into Common Stock	\$ 163,740	\$ 249,998	\$
Forgiveness of royalties by an officer	\$	\$	\$ 1,500,000
Conversion of accounts payable into Preferred Stock	\$	\$	\$ 1,550,000
Conversion of long-term debt into Preferred Stock	\$	\$	\$ 3,679,284
Stock issuance costs paid in stock options	\$	\$	\$ 209,572
Loan origination fee paid in stock options	\$	\$	\$ 299,346
Beneficial conversion feature of Preferred Stock issued	\$	\$	\$ 1,316,267
Beneficial conversion feature of a \$3,000,000 note payable	\$	\$	\$ 412,500
Implied dividends from beneficial conversion feature	\$	\$	\$ (1,316,267)

See accompanying notes to the financial statements

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NOTES TO FINANCIAL STATEMENTS

1. BUSINESS OF THE COMPANY

Retractable Technologies, Inc. (the Company) was incorporated in Texas on May 9, 1994, to design, develop, manufacture and market safety syringes and other safety medical products for the healthcare profession. The Company began to develop its manufacturing operations in 1995. The Company's manufacturing and administrative facilities are located in Little Elm, Texas. The Company's primary products are the VanishPoint® syringe in the 1cc, 3cc, 5cc and 10cc sizes and blood collection tube holders. The Company has conducted preliminary clinical evaluations and worked with national distributors to encourage healthcare facilities to transition from the use of standard syringes to the VanishPoint® syringe.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Accounting estimates

The preparation of financial statements in conformity with United States generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ significantly from those estimates.

Cash and cash equivalents

For purposes of reporting cash flows, cash and cash equivalents include unrestricted cash and investments with original maturities of three months or less.

Accounts receivable

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

Inventories

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

Property, plant and equipment

Property, plant and equipment are stated at cost. Expenditures for maintenance and repairs are charged to operations as incurred. Cost includes major expenditures for improvements and replacements which extend useful lives or increase capacity and interest cost associated with significant capital additions. For the years ended December 31, 2004, 2003, and 2002, the Company capitalized interest of approximately \$53,000, \$27,000, and \$26,000, respectively. Gains or losses from property disposals are included in income.

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

Production equipment	3 to 13 years
Office furniture and equipment	3 to 10 years
Building	39 years
Building improvements	15 years
Automobiles	7 years

Long-lived assets

The Company assesses the recoverability of long-lived assets using an assessment of the estimated undiscounted future cash flows related to such assets. In the event that assets are found to be carried at amounts which are in excess of estimated gross future cash flows, the assets will be adjusted for impairment to a level commensurate with a discounted cash flow analysis of the underlying assets.

Reclassifications

Certain prior year amounts have been reclassified to conform with the current year's presentation.

Intangible assets

Intangible assets are stated at cost and consist primarily of patents, a license agreement granting exclusive rights to use patented technology, and trademarks which are amortized using the straight-line method over 17 years.

Financial instruments

The fair value of financial instruments is determined by reference to various market data and other valuation techniques as appropriate. The Company believes that the fair value of financial instruments approximates their recorded values.

Concentrations of credit risk

The Company's financial instruments exposed to concentrations of credit risk consist primarily of cash, cash equivalents and accounts receivable. Cash balances, some of which exceed the federally insured limits, are maintained in financial institutions; however, management believes the

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institutions are of high credit quality. The majority of accounts receivable are due from companies which are well-established entities. As a consequence, management considers any exposure from concentrations of credit risks to be limited. The Company had a high concentration of sales with two significant customers. For the year ended December 31, 2004, the aforementioned customers accounted for \$6,112,892, or 28.4%, of net sales, and their aggregated accounts receivable balance at December 31, 2004, was \$236,478.

Revenue recognition

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

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Marketing fees

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

Litigation Proceeds

Proceeds from litigation settlements in the Company's federal antitrust lawsuit, Retractable Technologies, Inc. v. Becton Dickinson & Co., et al. are recognized when realizable. Generally, realization is not reasonably assured and expected until proceeds are collected. Such amounts are net of attorneys' fees, court costs, legal expenses, and amounts payable under the Covenant Not to Sue. Liability for attorneys' fees is not incurred until proceeds are collected.

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

Income taxes

The Company provides for deferred income taxes in accordance with Statement of Financial Accounting Standard No. 109, *Accounting for Income Taxes* (SFAS 109). SFAS 109 requires an asset and liability approach for financial accounting and reporting for income taxes based on the tax effects of differences between the financial statement and tax bases of assets and liabilities, based on enacted rates expected to be in effect when such basis differences reverse in future periods. Deferred tax assets are periodically reviewed for realizability. Valuation allowances are recorded when realizability of deferred tax assets is not likely.

Earnings per share

The Company has adopted Statement of Financial Accounting Standards No. 128, *Earnings Per Share*, which establishes standards for computing and presenting earnings per share. Basic earnings per share is computed by dividing net earnings for the period (adjusted for any cumulative dividends for the period) by the weighted average number of common shares outstanding during the period. The Company's potentially dilutive Common Stock equivalents, consist of options, convertible debt and convertible Preferred Stock and are dilutive or antidilutive in different periods as shown in the schedule below:

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	Years Ended December 31,		
	2004	2003	2002
Net Income (loss)	\$ 54,691,395	\$ 7,448,497	\$ (6,825,928)
Preferred stock dividend requirements	(1,993,516)	(2,560,723)	(2,266,250)
Earnings (loss) available to common shareholders	52,697,879	4,887,774	(9,092,178)
Effect of dilutive securities:			
Preferred stock dividend requirements	1,993,516		
Convertible debt interest and loan fees	(351,860)	(454,379)	
Earnings (loss) available to common shareholders after assumed conversions	\$ 54,339,535	\$ 4,433,395	\$ (9,092,178)
Average common shares outstanding	22,600,166	21,001,004	20,300,454
Dilutive stock equivalents from stock options	269,016	292,528	
Shares issuable upon conversion of Preferred Stock	2,572,116		
Shares issuable upon conversion of convertible debt	685,855	750,000	
Average common and common equivalent shares outstanding assuming dilution	26,127,153	22,043,532	20,300,454
Basic earnings (loss) per share	\$ 2.33	\$ 0.23	\$ (0.45)
Diluted earnings (loss) per share	\$ 2.08	\$ 0.20	\$ (0.45)

Research and development costs

Research and development costs are expensed as incurred.

Stock-based compensation

The Company has three stock-based director, officer and employee compensation plans which are described more fully in Note 11. Prior to 2002, the Company accounted for those plans under the recognition and measurement provisions (intrinsic value method) of APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and related Interpretations. Effective January 1, 2002, the Company adopted the fair value recognition provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*, prospectively to all director, officer and employee awards granted, modified, or settled after December 31, 2001. Awards under the Company's plans vest over periods up to three years. Therefore, the cost related to stock-based compensation included in the determination of net income for 2002 and 2003 is less than what would have been recognized if the fair value method had been applied to all awards since the original effective date of SFAS No. 123. SFAS No. 123 indicates that the fair value method is the preferable method of accounting. The following table indicates the effect on net income and earnings per share if the fair value method had been applied to all outstanding and unvested awards in each period.

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	Year Ended December 31,		
	2004	2003	2002
Net income (loss), as reported	\$ 54,691,395	\$ 7,448,497	\$ (6,825,928)
Add: Stock-based employee compensation expense included in reported net income, net of related tax effects	759,203	458,324	38,323
Deduct: Total stock-based employee compensation expense determined by fair value based method for all awards, net of related tax effects	(759,203)	(566,779)	(185,072)
Pro forma net income	\$ 54,691,395	\$ 7,340,042	\$ (6,972,677)
Earnings (loss) per share (basic)-as reported	\$ 2.33	\$ 0.23	\$ (0.45)
Earnings (loss) per share (diluted)-as reported	\$ 2.08	\$ 0.20	\$ (0.45)
Earnings (loss) per share (basic)-pro forma	\$ 2.33	\$ 0.23	\$ (0.46)
Earnings (loss) per share (diluted)-pro forma	\$ 2.08	\$ 0.20	\$ (0.46)

Recent Pronouncements

In December 2004, the FASB issued SFAS No. 123 (revised 2004), *Share Based Payment* (SFAS No. 123(R)). SFAS No. 123(R) supercedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and amends SFAS No. 95, *Statement of Cash Flows*. Generally, the approach in SFAS No. 123(R) is similar to the approach described in SFAS No. 123. SFAS No. 123(R) must be adopted by our Company by the third quarter of 2005. Currently, our Company uses the Black-Scholes model to estimate the value of stock options granted to employees and is evaluating option valuation models, including the Black-Scholes model to determine which model the Company will utilize upon adoption of SFAS No. 123(R). Our Company plans to adopt SFAS No. 123(R) using the modified-prospective method. We do not anticipate that adoption of SFAS No. 123(R) will have a material impact on our Company's stock-based compensation expense.

In November 2004, the FASB issued SFAS No. 151, *Inventory Costs*, an amendment of ARB No. 43, Chapter 4, *Inventory Pricing*, to clarify that abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage), should be expensed as incurred and not included in overhead. In addition, this Statement requires the allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. The provisions in SFAS No. 151 are effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The Company is currently assessing the impact of SFAS No. 151 on its financial statements.

In December 2004, the FASB issued Staff Position No. FAS 109-1, Application of FASB Statement No. 109, *Accounting for Income Taxes*, to the tax Deduction on Qualified Production Activities Provided by the American Jobs Creation Act of 2004 (the Act) that provides a tax deduction on qualified production activities. Accordingly FASB indicated that this deduction should be accounted for as a special deduction in accordance with FASB Statement No. 109. The Company will comply with the provisions of FSP 109-1 effective January 1, 2005, and does not believe that the adoption of this FASB Staff Position will have a material impact on the Company's financial statements.

Table of Contents**Index to Financial Statements****3. INVENTORIES**

Inventories consist of the following:

	December 31,	
	2004	2003
Raw materials	\$ 763,664	\$ 884,986
Finished goods	3,112,604	3,188,917
	<u>3,876,268</u>	<u>4,073,903</u>
Inventory reserve	(97,319)	(97,319)
	<u>\$ 3,778,949</u>	<u>\$ 3,976,584</u>

4. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consist of the following:

	December 31,	
	2004	2003
Land	\$ 261,893	\$ 261,893
Building and building improvements	1,896,188	1,883,259
Production equipment	13,491,629	13,284,593
Office furniture and equipment	997,943	782,273
Construction in progress	2,617,991	417,000
Automobiles	21,858	21,858
	<u>19,287,502</u>	<u>16,650,876</u>
Accumulated depreciation and amortization	(8,230,637)	(6,972,050)
	<u>\$ 11,056,865</u>	<u>\$ 9,678,826</u>

Acquisition costs of production equipment financed through capital leases were \$45,000 and \$1,257,307 at December 31, 2004 and 2003, respectively. Accumulated amortization on these leases was \$12,404 and \$778,171 at December 31, 2004 and 2003, respectively.

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Depreciation expense and capital lease amortization expense for the years ended December 31, 2004, 2003 and 2002 was \$1,258,587, \$1,265,762, and \$1,275,594, respectively.

5. INTANGIBLE ASSETS

Intangible assets consist of the following:

	December 31,	
	2004	2003
License agreement	\$ 500,000	\$ 500,000
Trademarks and patents	226,847	226,847
	726,847	726,847
Accumulated amortization	(368,188)	(332,478)
	\$ 358,659	\$ 394,369

In 1995, the Company entered into the license agreement with an officer of the Company for the exclusive right to manufacture, market and distribute products utilizing automated retraction technology. This technology is the subject of various patents and patent applications owned by an officer of the Company. The initial licensing fee of \$500,000 is being amortized over 17 years. The license agreement also provides for quarterly payments of a 5% royalty fee to the officer on gross sales. The

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royalty fee expense is recognized in the period in which it is earned. Royalty fees of \$1,846,195, \$1,477,213, and \$1,483,727 are included in cost of sales for the years ended December 31, 2004, 2003 and 2002, respectively. Accrued royalties under this agreement aggregated \$504,016 and \$1,156,633 at December 31, 2004 and 2003, respectively.

During 2002, the officer and his wife forgave \$1.5 million of the royalties payable under a licensing agreement which was recorded as additional paid in capital.

Amortization expense for the years ended December 31, 2004, 2003 and 2002, was \$35,710, \$42,862, and \$53,106, respectively. Future amortization expense for the years 2005 through 2009 is estimated to be \$42,000 per year.

6. LONG-TERM DEBT

	<u>December 31,</u>	
	<u>2004</u>	<u>2003</u>
Long-term debt consists of the following:		
Note payable to Katie Petroleum. Interest accrues at prime plus 1%, 6.25% and 5.00% at December 31, 2004 and 2003, respectively. Interest only was payable monthly through February 1, 2004. The original amount of the note of \$3,000,000 was discounted for presentation purposes by \$299,346 for stock options issued in conjunction with the debt and \$412,500 for the intrinsic value of a beneficial conversion feature of the debt. Beginning March 1, 2004, the loan is payable in equal installments of principal and interest payments (except for changes in the interest rate) of approximately \$37,000 and being fully paid on September 30, 2012. Guaranteed by an officer. Approximately \$413,738 of the initial principal payment was converted into 103,435 shares of Common Stock as of March 1, 2005. Not otherwise collateralized. Convertible into Common Stock at \$4.00 per share at the option of the holder.	\$ 2,233,812	\$ 2,389,273
Note payable to 1st International Bank for \$2,500,000. The proceeds from the loan paid off the remaining \$475,000 of the revolving credit agreement and funded a new warehouse and related infrastructure. Payments are interest only during the first twelve months. After twelve months, payments are based on a twenty-year amortization with a five year maturity. The interest rate at December 31, 2004, was 5.25% and is based on the amount of funds kept on deposit with the bank. Accordingly, interest will vary from the Wall Street Journal Prime rate (the WSJPR) to the WSJPR plus one 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. The Company had in excess of \$500,000 on deposit with 1st International Bank throughout the year. Subsequent to December 31, 2004, the Company drew down the remaining balance of the credit agreement.	1,449,154	
Note payable to 1st International Bank. Interest only payments. Interest at prime plus 2%; 6.00% on December 31, 2003. Collateralized by accounts receivable. Guaranteed by an officer. Subsequent to December 31, 2003, the note was paid with the proceeds of a new loan agreement discussed above.		475,000
Note payable to CitiCorp. Vendor Finance; Interest at 4.2%; Collateralized by software; Payable in eight quarterly principal and interests payments of \$15,955.	107,158	
Capital lease obligations payable in monthly installments ranging from approximately \$1,000 to \$5,000 through June, 2006. Interest at rates from 10.04% to 14.87%. Collateralized by certain machinery and equipment. Guaranteed by an officer.	17,128	64,004

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Other		5,405
	<u>3,807,252</u>	<u>2,933,682</u>
Less: current portion	(271,842)	(210,681)
	<u>\$ 3,535,410</u>	<u>\$ 2,723,001</u>

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The aggregate maturities of long-term debt as of December 31, 2004 are as follows:

2005	\$ 271,842
2006	316,041
2007	269,929
2008	353,452
2009	378,637
Thereafter	2,217,351
	<u>\$ 3,807,252</u>

7. COMMITMENTS AND CONTINGENCIES

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

8. INCOME TAXES

The provision for income taxes consists of the following:

	<u>For the Years Ended December 31,</u>		
	<u>2004</u>	<u>2003</u>	<u>2002</u>
Current tax provision			
Federal	\$ 10,785,856	\$ 173,542	\$
State	1,835,691	91,931	
	<u>12,621,547</u>	<u>265,473</u>	
Total current provision			
Deferred tax provision (benefit)			
Federal	(399,126)		
State	(46,076)		
	<u>(445,202)</u>		
Total deferred tax provision (benefit)			
Total income tax provision	<u>\$ 12,176,345</u>	<u>\$ 265,473</u>	<u>\$</u>

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The Company's income tax benefit of net operating loss carry forwards utilized in 2004 aggregated \$12.1 million for current federal income taxes and \$7.5 million for current state income taxes. The income tax benefit of net operating loss carryforwards utilized in 2003 aggregated \$3.1 million for current federal income taxes and \$200,000 for current state income taxes. As of December 31, 2004, the Company has utilized all of its net operating loss carry forwards.

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Deferred taxes are provided for those items reported in different periods for income tax and financial reporting purposes. The tax effects of temporary differences that give rise to significant portions of the deferred tax assets and liabilities are presented below:

	December 31,	
	2004	2003
Current deferred tax assets:		
Net operating loss carry forwards	\$	\$ 13,143,516
Non-employee option expense	673,434	476,486
Employee option expense	57,778	192,375
Inventory	193,437	181,762
Alternative minimum tax credit		173,542
Accrued expenses and reserves	962,698	1,205,568
Total current deferred tax assets	1,887,347	15,373,249
Non current deferred tax liabilities:		
Property and equipment	1,442,145	1,693,358
Valuation allowance		(13,679,891)
Net deferred tax assets	\$ 445,202	\$

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

	December 31,		
	2004	2003	2002
Income tax (benefit) at the federal statutory rate	35.0%	35.0%	(35.0)%
State tax (benefit), net of federal (benefit)	2.9	0.8	(2.9)
Increase (decrease) in valuation allowance	(19.8)	(41.8)	25.3
Permanent differences	0.5	0.2	10.2
Other	(0.3)	8.0	2.4
Effective tax (benefit) rate	18.3%	2.2 %	%

9. STOCKHOLDERS EQUITY**Preferred stock**

The Company has one class of preferred stock outstanding: Class B Convertible Preferred Stock (Class B Stock). The Class B Stock has five series: Series I, Series II, Series III, Series IV, and Series V.

Class B

The Company has authorized 5,000,000 shares of \$1 par value Class B Convertible Preferred Stock which have been allocated among Series I, II, III, IV and V in the amounts of 199,400; 289,000; 137,745; 556,000; and 1,389,971 shares, respectively. The remaining 2,427,884 authorized shares have not been assigned a series.

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Series I Class B

There were 1,000,000 shares of \$1 par value Series I Class B Convertible Preferred Stock (Series I Class B Stock) issued and 199,400 and 229,400 shares outstanding at December 31, 2004 and 2003, respectively. Holders of Series I Class B Stock are entitled to receive a cumulative annual dividend of \$.50 per share, payable quarterly if declared by the board of directors. At December 31, 2004 and 2003 approximately \$50,000 and \$2,561,000, respectively, of dividends which have not been declared were in arrears.

Series I Class B Stock is redeemable after three years from the date of issuance at the option of the Company at a price of \$7.50 per share, plus all accrued and unpaid dividends. Each share of Series I Class B Stock may, at the option of the stockholder, be converted to one share of Common Stock after three years from the date of issuance or in the event the Company files an initial registration statement under the Securities Act of 1933. Pursuant to these terms, a total of 30,000 shares of Series I Class B Stock were converted into Common Stock in 2004. In the event of voluntary or involuntary dissolution, liquidation or winding up of the Company, holders of Series I Class B Stock then outstanding are entitled to \$6.25 per share, plus all accrued and unpaid dividends prior to any distributions to holders of Series II Class B Convertible Preferred Stock (Series II Class B Stock), Series III Class B Convertible Preferred Stock (Series III Class B Stock), Series IV Class B Convertible Preferred Stock (Series IV Class B Stock), Series V Class B Convertible Preferred Stock (Series V Class B Stock) or Common Stock.

Series II Class B

There were 1,000,000 shares of \$1 par value Series II Class B Stock issued and there were 289,000 and 418,500 shares outstanding at December 31, 2004 and 2003. Holders of Series II Class B Stock are entitled to receive a cumulative annual dividend of \$1.00 per share, payable quarterly if declared by the board of directors. Holders of Series II Class B Stock generally have no voting rights until dividends are in arrears and unpaid for twelve consecutive quarters. In such case, the holders of Series II Class B Stock have the right to elect one-third of the board of directors of the Company. At December 31, 2004 and 2003, approximately \$167,000 and \$4,487,000, respectively, of dividends which have not been declared were in arrears.

Series II Class B Stock is redeemable after three years from the date of issuance at the option of the Company at a price of \$15.00 per share plus all accrued and unpaid dividends. Each share of Series II Class B Stock may, at the option of the stockholder, be converted to one share of Common Stock after three years from the date of issuance or in the event the Company files an initial registration statement under the Securities Act of 1933. Pursuant to these terms, 129,500 shares of Series II Class B Stock were converted into Common Stock in 2004. In the event of voluntary or involuntary dissolution, liquidation or winding up of the Company, holders of Series II Class B Stock then outstanding are entitled to \$12.50 per share, plus all accrued and unpaid dividends, after distribution obligations to holders of Series I Class B Stock have been satisfied and prior to any distributions to holders of Series III Class B Stock, Series IV Class B Stock, Series V Class B Stock or Common Stock.

Series III Class B

There were 1,160,445 shares of \$1 par value Series III Class B Stock issued and 137,745 and 145,245 shares outstanding at December 31, 2004 and 2003, respectively. Holders of Series III Class B Stock are entitled to receive a cumulative annual dividend of \$1.00 per share, payable quarterly if declared by the board of directors. At December 31, 2004 and 2003, approximately \$2,582,000 and \$2,440,000, respectively, of dividends which have not been declared were in arrears.

Series III Class B Stock is redeemable after three years from the date of issuance at the option of the Company at a price of \$15.00 per share, plus all accrued and unpaid dividends. Each share of Series III Class B Stock may, at the option of the stockholder, be converted to one share of Common Stock

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after three years from the date of issuance or in the event the Company files an initial registration statement under the Securities Act of 1933. Pursuant to these terms, 7,500 shares of Series III Class B Stock were converted into Common Stock in 2004. In the event of voluntary or involuntary dissolution, liquidation or winding up of the Company, holders of Series III Class B Stock then outstanding are entitled to \$12.50 per share, plus all accrued and unpaid dividends, after distribution obligations to Series I Class B Stock and Series II Class B Stock have been satisfied and prior to any distributions to holders of Series IV Class B Stock, Series V Class B Stock or Common Stock.

Series IV Class B

There were 1,133,800 shares issued and 556,000 and 1,066,000 shares outstanding at December 31, 2004 and 2003, respectively. Holders of Series IV Class B Stock are entitled to receive a cumulative annual dividend of \$1.00 per share, payable quarterly, if declared by the board of directors. Holders of Series IV Class B Stock generally have no voting rights. At December 31, 2004 and 2003, approximately \$4,813,000 and \$3,932,000 respectively of dividends which have not been declared were in arrears.

Series IV Class B Stock is redeemable after three years from the date of issuance at the option of the Company at a price of \$11.00 per share plus all accrued and unpaid dividends. Each share of Series IV Class B Stock may, at the option of the stockholder any time subsequent to three years from date of issuance, be converted into one share of Common Stock, or in the event the Company files an initial registration statement under the Securities Act of 1933. Pursuant to these terms, 510,000 shares of Series IV Class B Stock were converted into Common Stock in 2004. In the event of voluntary or involuntary liquidation, dissolution or winding up of the Company, holders of Series IV Class B Stock then outstanding are entitled to receive liquidating distributions of \$11.00 per share, plus accrued and unpaid dividends after distribution obligations to Series I Class B Stock, Series II Class B Stock, and Series III Class B Stock have been satisfied and prior to any distribution to holders of Series V Class B Stock or Common Stock.

Series V Class B

There were 2,416,221 shares issued and 1,389,971 and 1,732,071 outstanding at December 31, 2004 and 2003, respectively. Series V Class B Stock ranks senior to the Company's Common Stock with respect to dividends and upon liquidation, dissolution, or winding up, but secondary to the Company's Series I Class B Stock, Series II Class B Stock, Series III Class B Stock, and Series IV Class B Stock. Holders of Series V Class B Stock are entitled to receive a cumulative annual dividend of \$0.32 per share, payable quarterly, if declared by the board of directors. Holders of Series V Class B Stock generally have no voting rights. At December 31, 2004 and 2003, approximately \$1,597,000 and \$1,098,000, respectively, of dividends which have not been declared were in arrears.

Series V Class B Stock is redeemable after two years from the date of issuance at the option of the Company at a price of \$4.40 per share plus all accrued and unpaid dividends. Each share of Series V Class B Stock may, at the option of the stockholder any time subsequent to the date of issuance, be converted into Common Stock. Pursuant to the terms of the certificate of designation, 342,100 shares of Series V Class B Stock were converted into Common Stock in 2004. In the event of voluntary or involuntary liquidation, dissolution, or winding up of the Company, holders of Series V Class B Stock then outstanding are entitled to receive liquidating distributions of \$4.40 per share, plus accrued and unpaid dividends after distribution obligations to Series I Class B Stock, Series II Class B Stock, Series III Class B Stock and Series IV Class B Stock have been satisfied and prior to any distribution to the holders of the Common Stock.

Common stock

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The Company is authorized to issue 100,000,000 shares of no par value Common Stock, of which 23,201,998 and 22,141,964 shares are issued and outstanding at December 31, 2004 and 2003, respectively.

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10. RELATED PARTY TRANSACTIONS

The Company has a lease with Mill Street Enterprises (Mill Street), a sole proprietorship owned by a former Board member, for sales and marketing offices in Lewisville, Texas. During the years ended December 31, 2004, 2003 and 2002, the Company paid \$37,700, \$34,800, and \$34,800, respectively, under this lease. This lease will be terminated in the second quarter of 2005.

During the years ended December 31, 2004, 2003 and 2002, the Company paid \$13,578 and \$15,238 and \$10,412, respectively, to family members of its chief executive officer for various consulting services.

The Company had a consulting agreement with MediTrade International Corporation, a company controlled by Lillian E. Salerno, a 10% shareholder. The contract was terminated on February 28, 2005. Ms. Salerno was paid \$16,667 per month and reimbursed for business expenses incurred on behalf of the Company, not to exceed \$5,000 per month without prior approval for the term of the contract. During the years ended December 31, 2004, 2003, and 2002 the Company paid \$304,282, \$253,952, and \$201,120, respectively, under this agreement.

The Company has a license agreement with an officer of the Company. See Note 5. An officer of the Company has a Covenant Not to Sue Agreement with the Company. See Note 12.

11. STOCK OPTIONS

Stock options

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

The Company also has options for common shares outstanding under the 1996 Incentive Stock Option Plan and the 1996 Stock Option Plan for Directors and Other Individuals. A committee appointed by the Board of Directors administers all plans and determines exercise prices at which options are granted. Shares exercised come from the Company's authorized but unissued Common Stock. The options vest over periods up to three years from the date of grant and generally expire ten years after the date of grant. All unvested options issued under the plans expire three months after termination of employment or service to the Company.

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

Years Ended December 31,

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	2004		2003		2002	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at beginning of period	2,589,160	\$ 8.36	1,748,780	\$ 8.21	1,191,280	\$ 8.90
Granted	131,775	8.61	897,300	\$ 8.65	589,580	6.90
Exercised						
Forfeited	(86,050)	(8.36)	(56,920)	\$ (8.59)	(32,080)	(9.71)
Outstanding at end of period	2,634,885	\$ 8.37	2,589,160	\$ 8.36	1,748,780	\$ 8.21
Exercisable at end of period	1,295,030	\$ 8.74	1,293,580	\$ 8.78	901,505	\$ 8.44
Weighted average fair value of options granted during period		\$ 2.02		\$ 2.42		\$ 0.07

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The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions used for grants in 2004, 2003 and 2002: no dividend yield; expected volatility of 37%, 1.30% and 1.57%, respectively; risk free interest rates of 4.89%, 3.53% and 4.00%, respectively; and expected lives of 9.0, 9.3 and 10.0 years, respectively.

The following table summarizes information about director, officer and employee options outstanding under the aforementioned plans at December 31, 2004:

<u>Exercise Prices</u>	<u>Shares Outstanding</u>	<u>Weighted Average Remaining Contractual Life</u>	<u>Shares Exercisable</u>
\$ 1.00	60,280	1.32	60,280
\$ 5.00	152,300		