SHPI Reports Fourth Quarter and Year-End 2003 Financial Results

Bountiful, Utah – March 24, 2004 - Specialized Health Products International, Inc. (OTCBB: SHPI), a leader in the design and development of medical safety needles, today reported consolidated financial results for the fourth quarter and year-ended December 31, 2003.

Fourth Quarter 2003 Operating Results

- Revenue totaled $1.2 million in fourth quarter 2003, an increase of $472 thousand or 65% as compared to the year-earlier period, and an increase of 15% as compared to the preceding quarter.
- Product sales and royalty revenue accounted for 83% of total revenue in fourth quarter 2003 as compared to 62% in the year-earlier period.
- Gross profit totaled $961 thousand in fourth quarter 2003 (80% gross profit margin), an increase of $321 thousand or 50% as compared to the year-earlier period.
- Operating expense totaled $2.6 million in fourth quarter 2003, an increase of $1.2 million or 91% as compared to the year-earlier period. Fourth quarter operating expense of $2.6 million includes an accrual for patent litigation expense of $1.3 million, which amount is the Company's estimate of the portion of costs associated with pending litigation by BD (Becton, Dickinson & Company) against Tyco Healthcare that Tyco Healthcare will withhold against royalties due SHPI through 2005.
- Excluding the accrual for patent litigation expense, operating expense would have totaled $1.3 million in fourth quarter 2003, a decrease of $62 thousand or 5% as compared to the year-earlier period.
- Net loss totaled $1.6 million in fourth quarter 2003, including the $1.3 million accrual for patent litigation expense. This net loss represents an increase of $916 thousand or 129% as compared to the year-earlier period. Reported net loss per diluted share was $(0.09) for fourth quarter 2003, as compared to $(0.04) for the year-earlier period.
- Excluding the accrual for patent litigation expense, net loss would have totaled $326 thousand in fourth quarter 2003, an improvement of $384 thousand or 54% as compared to the year-earlier period. This relates to a net loss per diluted share of $(0.02) for fourth quarter 2003, as compared to $(0.04) for the year-earlier period.

Full Year 2003 Operating Results

- Revenue totaled $3.6 million in 2003, an increase of $2.0 million or 121% as compared to 2002.
- Product sales and royalty revenue accounted for 77% of total revenue in 2003 as compared to 30% in 2002.
- Gross profit totaled $3.0 million in 2003 (84% gross profit margin), an increase of $1.7 million or 127% as compared to 2002.

- Operating expense totaled $6.2 million in 2003, an increase of $2.3 million or 57% as compared to 2002, including a $1.3 million accrual for patent litigation expense in fourth quarter 2003.
- Excluding the accrual for patent litigation expense, operating expense would have totaled $4.9 million in 2003, an increase of $961 thousand or 24% as compared to 2002, with sales & marketing expense associated with LiftLoc® Safety Infusion Set responsible for 80% of this increase.
- Excluding the accrual for patent litigation expense, research & development accounted for 53% of total operating expense in 2003. Sales & marketing accounted for 24% of total operating expense. General & administrative accounted for 23% of total operating expense.
- Net loss totaled $3.1 million in 2003, an improvement of $2.8 million or 47% as compared to 2002. This net loss comparison includes an accrual of $1.3 million for patent litigation expense in 2003 and a preferred stock deemed dividend related to beneficial conversion feature of $3.3 million in 2002. Reported net loss per diluted share was $(0.18) for 2003, as compared to $(0.33) for 2002.
- Excluding the accrual for patent litigation expense in 2003 and the preferred stock deemed dividend in 2002, net loss would have totaled $1.8 million in 2003, an improvement of $787 thousand or 30% as compared to 2002. This relates to a net loss per diluted share of $(0.10) for 2003, as compared to $(0.15) for 2002.

Jeff Soinski, President and Chief Executive Officer, commented, "In 2003, we achieved our objective of more than doubling revenues versus 2002. We also laid the foundation for future growth, with the:

- Expansion of our distribution network and sales and marketing efforts for LiftLoc® Safety Infusion Set, our first OEM and SHPI-branded product;
- Continued growth of the Monoject Magellan™ safety syringe needle product line spurred by the highly effective marketing efforts of Kendall, a business unit of Tyco Healthcare;
- Early 2003 launch and rapid growth of LuproLoc™, a proprietary safety needle device attached to pre-filled syringes of Lupron Depot® (leuprolide acetate for depot suspension) by TAP Pharmaceutical Products Inc.;
- Filing of 16 additional U.S. and foreign patent applications for SecureLoc™, our second major platform technology;
- Completion of our first major product agreement on the SecureLoc™ technology with BD for safety-engineered spinal and epidural needles;
- Achievement of ISO certification and CE Mark for LiftLoc® to pave the way for the international launch of our manufactured products, including the Canadian launch of LiftLoc® announced earlier this year; and
- Recent launch of the Monoject Magellan™ safety blood collection product line by Kendall."

Mr. Soinski further commented, "In 2004, we expect to report continued steady revenue growth versus our 2003 performance, without significantly increasing operating expense prior to the accrual for patent litigation expense in 2003. Without material adverse

events, which we do not anticipate at this time, we expect to significantly reduce our net loss in 2004 to achieve sustainable profitability by the fourth quarter of this year."

SHPI will conduct a conference call to discuss fourth quarter and year-end 2003 financial results on Thursday, March 25, 2004, at 4:30 p.m. EST. Investors can listen to the conference call live by dialing (800) 450-0788 in the U.S. and (612) 332-0820 internationally. A replay of the call will be available for one week after the event by dialing (800) 475-6701 in the U.S. and (320) 365-3844 internationally and entering access code: 724421.

About Specialized Health Products International, Inc.

SHPI is a leading designer and developer of proprietary safety medical needle products, designed to minimize the risk of accidental needlesticks, which are a leading cause of the spread of blood-borne diseases such as HIV/AIDS, and the hepatitis B and C viruses. SHPI has twenty highly differentiated, patented safety needle technologies that apply to virtually all medical needles used today. SHPI manufactures and markets certain products under its own label. Other products are supplied to third parties on an OEM basis or licensed to leading manufacturers and marketers in the disposable medical products industry. For more information about SHPI, visit the company's web site at www.shpi.com.

This news release contains forward-looking statements within the meaning of the Securities Act of 1933 and the Securities Exchange Act of 1934, as amended. Such statements are subject to risks and uncertainties that could cause actual results to vary materially from those projected in the forward-looking statements. The Company may experience significant fluctuations in future operating results due to a number of economic conditions, risks in product and technology development, the effect of the Company's accounting policies and other risk factors detailed in the Company's SEC filings. These factors and others could cause operating results to vary significantly from those in prior periods and those projected in forward-looking statements. Additional information with respect to these and other factors, which could materially affect the Company and its operations, are included on certain forms the Company files with the Securities and Exchange Commission.

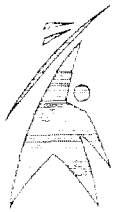
Contact:

Paul S. Evans, SHPI
Telephone: 801-298-3360
Fax: 801-298-1759
pevans@shpi.com

Website: www.shpi.com

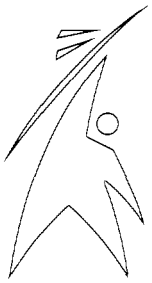
PATIENT # 2357 - JW

HOSPITAL RECORDS	NO. 882357
ATTENTION:	
Healthcare workers suffer an estimated 800,000 injuries from accidental needlesticks annually. That's why we're here.	

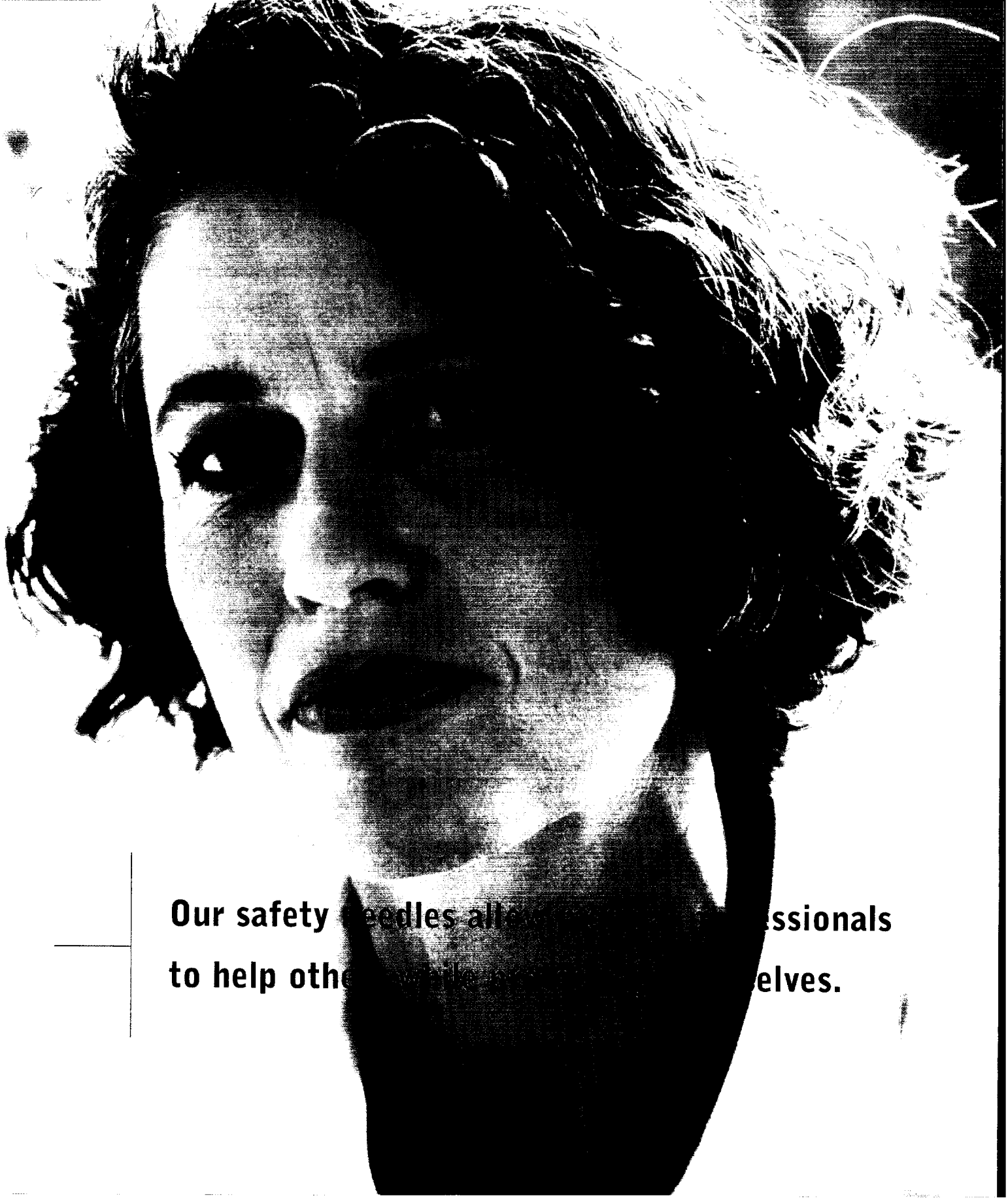


SHPI

SAFETY ENSURES TOMORROW™



Distinguished by a herald's staff with two white ribbons, the Greek messenger of the gods Hermes was an inventive genius at birth. Because he often flew on winged shoes to help others escape from harm, he became known for his helpfulness to mankind. Over the centuries, his staff evolved into the caduceus, the universal medical symbol of the staff with two intertwined snakes.



Our safety needles allow ssionals to help others while protecting themselves.

AN ACCIDENTAL NEEDLESTICK CAN HURT FOR A LIFETIME.

Healthcare is one of the largest industries in the world and grows larger each year. Healthcare worker safety is and will remain a high priority, high profile issue. Healthcare workers in the U.S. use about 6 billion needles and suffer an estimated 800,000 injuries from accidental needlesticks and other sharps annually.[1]

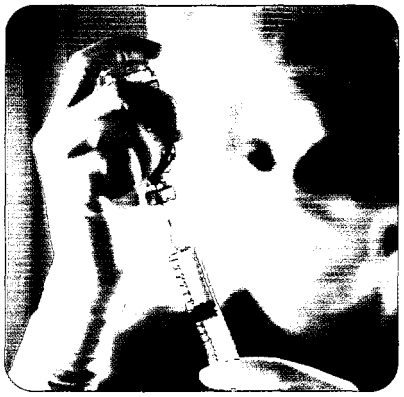
Diseases that can be acquired from such accidents include HIV/AIDS, HBV (Hepatitis B virus), HCV (Hepatitis C virus), diphtheria, gonorrhea, typhus, herpes simplex virus, malaria, syphilis and tuberculosis.

According to the American Hospital Association, a single case of serious blood-borne pathogen infection can cost more than $1 million in expenses for follow-up testing, lost work time and disability payments. $750 million to $1 billion is spent in the U.S. annually on the testing and treatment of accidental needlestick injuries.[2]

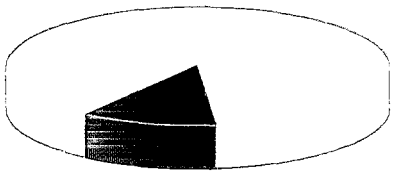
With numbers this tragic and costly, it's easy to see why state and federal legislation have mandated the use of safety medical needles, culminating in the U.S. Needlestick Safety and Prevention Act, effective since April 2001.

While such government regulations are expected to dramatically increase conversions to safety products, the greatest obstacle to conversion may be adequate supply and availability of well-designed and cost-efficient safety products.

[1] Centers for Disease Control and Prevention, *MMWR 46(2): 21-25*
[2] Based upon data in U.S. General Accounting Office Report GAO-01-60R



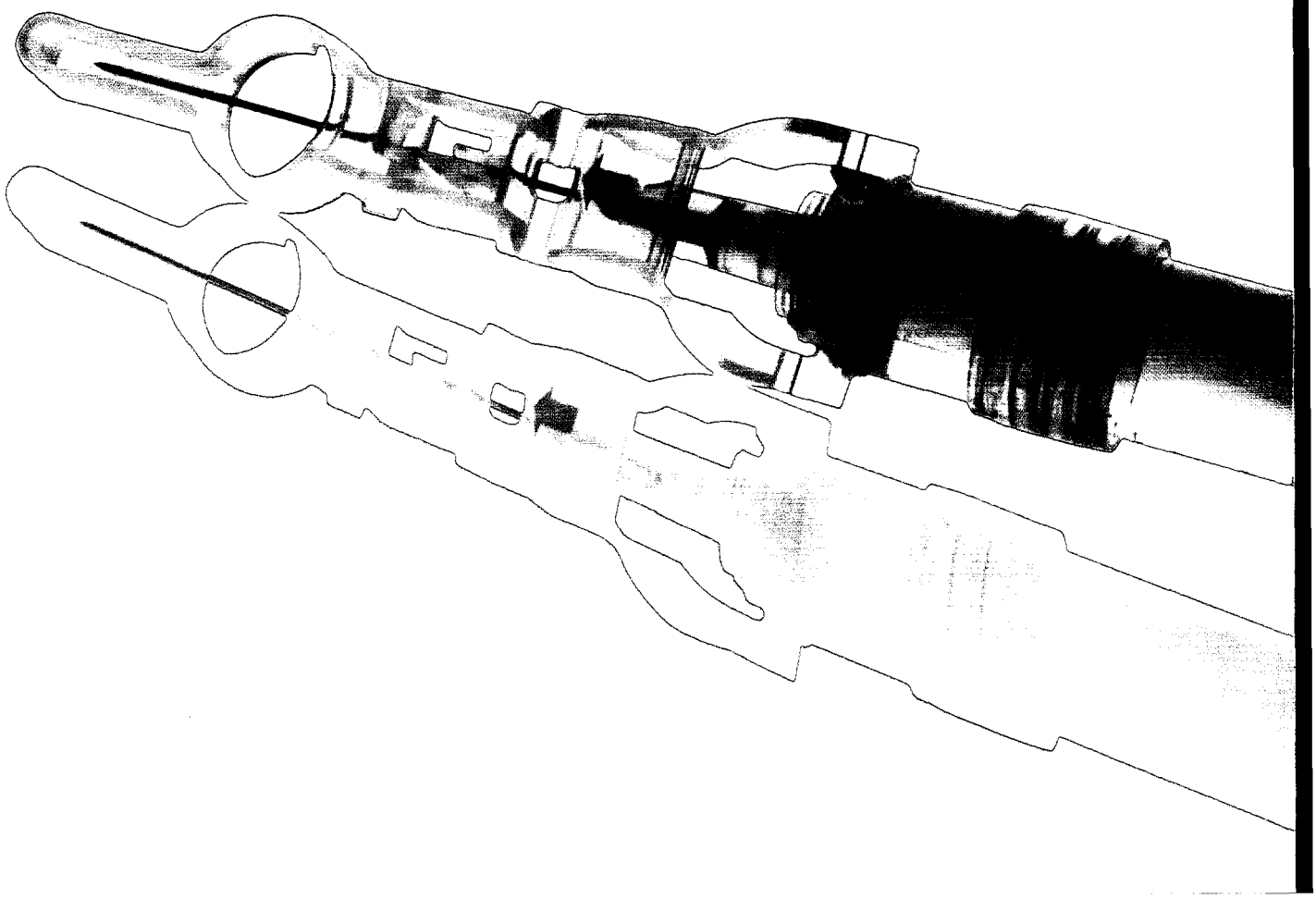
ESTIMATES INDICATE HEALTHCARE WORKERS SUFFER 800,000 ACCIDENTAL NEEDLESTICKS ANNUALLY.



ACCIDENTAL NEEDLESTICKS ACCOUNT FOR 86% OF ALL OCCUPATIONALLY ACQUIRED CASES OF HIV/AIDS.

Source: Centers for Disease Control and Prevention, HIV/AIDS Surveillance Report 8(2): Atlanta, GA 1996

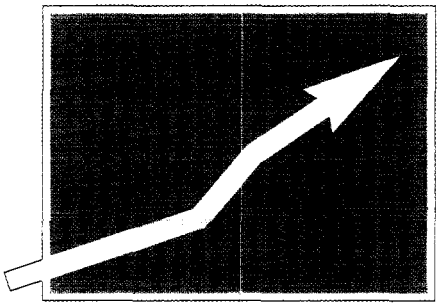
The U.S. Needlestick Safety and Prevention Act requires healthcare employers to review new safety needle products and mandates their usage by employees.



Our Vision: EVERY NEEDLE A SAFE NEEDLE.

CDC REPORTS THAT MORE THAN 80% OF NEEDLESTICK INJURIES CAN BE PREVENTED BY USING SAFETY NEEDLE DEVICES.

Source: U.S. General Accounting Office Report GAO-01-60R



THE DISPOSABLE NEEDLE MARKET IS ESTIMATED TO BE WELL OVER $1 BILLION A YEAR AND GROWING.

Source: Industry Estimates

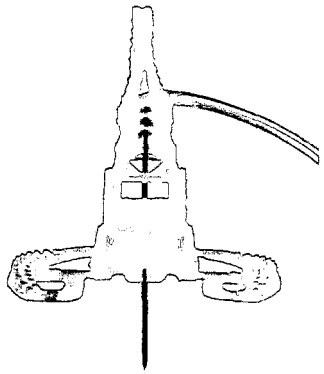
We design and develop cost-effective, innovative safety healthcare products that minimize the risk of accidental needlesticks, which are a leading cause of the spread of blood-borne diseases.

We have 20 highly differentiated, patented safety needle technologies that apply to virtually all medical needles used today. These proprietary technologies are protected by 22 U.S. patents and over 90 U.S. and international patent applications pending.

We manufacture and market certain products under our own label. Other products are supplied to third parties on an OEM basis or licensed to leading manufacturers and marketers in the disposable medical products industry.

There is a significant and growing market opportunity for our innovative and patent-protected safety needle products. The current U.S. market for disposable medical needles is well in excess of $1 billion and growing.

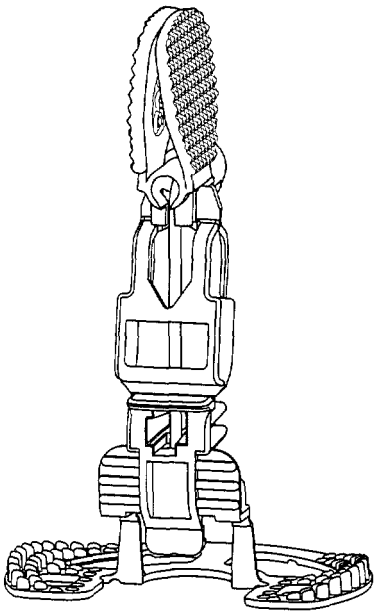
Our Mission: LEADERSHIP



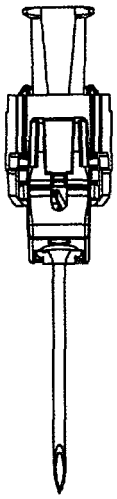
Our mission is to be the leader and innovator in disposable medical safety sharps products, with an initial focus on safety medical needles. Our strategy to achieve this mission involves: 1) capturing significant market share of targeted product segments, 2) broadening existing product lines, and 3) developing new products and seeking additional market opportunities.

We specialize in products that provide the following features and benefits:

- Excellent functionality for the intended medical use.
- Similar or enhanced clinical technique versus conventional products.
- Comparable, improved or additional ancillary clinician or patient benefits (*e.g.*, comfort or convenience).
- Efficient/low cost manufacturability to provide attractive margins at a reasonable price.
- Superior safety technology to prevent accidental exposure to blood borne pathogens.



Our Business Model: PARTNERSHIP



Kendall (Tyco)

Bard

Merit

TAP (Takeda-Abbott)

MANY OF OUR PRODUCTS GO TO MARKET UNDER THE NAMES OF INDUSTRY-LEADING PARTNERS.

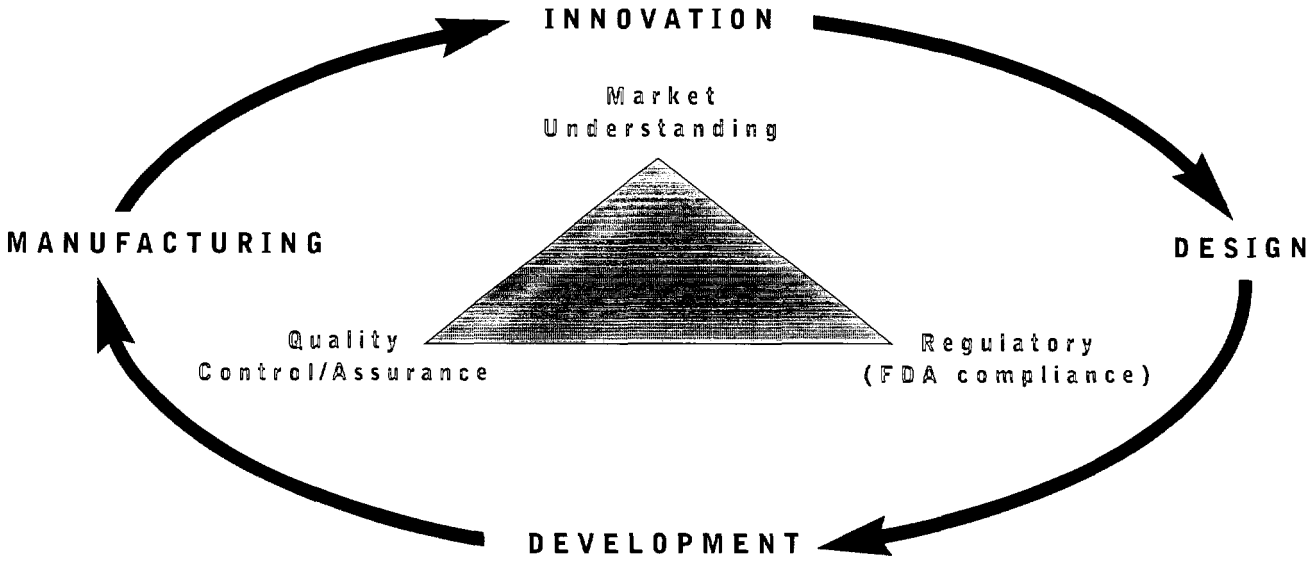
Our business model is to enter into licensing, OEM supply, or distribution agreements for our products, rather than engage in direct sales of products to end-users.

We operate under product agreements relating to specific technologies and product lines with Kendall, a business unit of Tyco Healthcare, TAP Pharmaceutical Products Inc., Merit Medical Systems, Inc. and Bard Access Systems, Inc., a subsidiary of C.R. Bard, Inc.

We have distribution agreements in place with Cardinal Health, Medline Industries, Inc., and Physician Sales and Service, Inc. ("PSS") for products marketed under our own SHPI label. Additional discussions are ongoing with potential partners for other applications of our proprietary technologies.

OEM supply or distribution arrangements are our preferred business relationship for targeted specialty products. Out-licensing opportunities are pursued for high volume product opportunities where efficient and low cost manufacturing is unfeasible at a contract manufacturer, or when a large capital investment is required to scale-up manufacturing.

Our Capabilities: COMPREHENSIVE

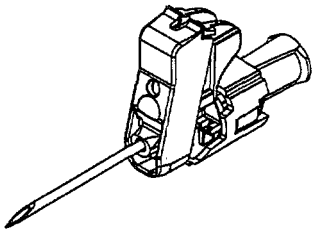


From concept to market, we are fully-equipped to imagine, design, develop and manufacture medical safety products. It all begins with market understanding. Before R&D begins, our world-class specialists interview clinicians, observe their techniques, and develop an intricate understanding of their safety device requirements. This understanding then drives product concept and design.

During the design process, our deep background in regulatory issues, including FDA compliance, ensures that products are ready for market as early as possible. This expertise, along with extensive experience in quality control and assurance, also impacts our efficiency in manufacturing and delivering a quality product from our manufacturing partners.

Once a product is ready to launch, our dedicated sales, marketing and customer service staff stand ready to assist our distributors and strategic partners in their marketing efforts.

Our Products: PATENTED AND EXCLUSIVE



SHPI SAFETY NEEDLE SOLUTIONS

SYRINGE

HUBER

BLOOD COLLECTION

PRE-FILLED SYRINGE

GUIDEWIRE INTRODUCER NEEDLES

IV CATHETER

PICC INTRODUCER NEEDLES

WINGED NEEDLE SETS

EPIDURAL

SPINAL

BIOPSY

PLASMA APHAERESIS SETS

DIALYSIS SETS

OTHER SPECIALTY NEEDLES

Our patent-protected safety needle technologies are the basis for a wide range of safety needle products. These products apply to virtually all medical needles used today.

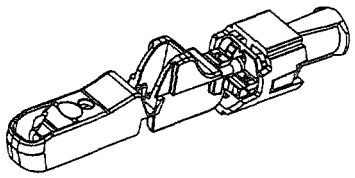
Ongoing research and development are intended to maintain and expand our leadership position in safety needle technologies. The following pages offer a detailed description of our initial safety needle products.

22 U.S. PATENTS

90 U.S. AND INTERNATIONAL PATENTS PENDING

SAFETY SYRINGE NEEDLES

1



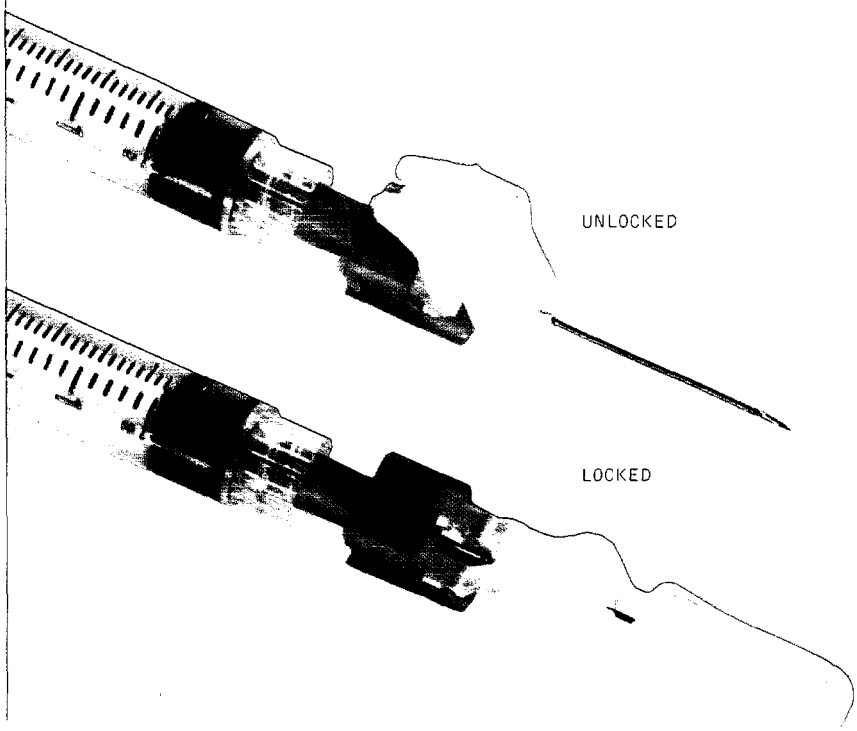
THERE IS SIGNIFICANT RISK OF ACCIDENTAL NEEDLESTICKS DURING SYRINGE NEEDLE USE.

Monoject Magellan™ is a single use, disposable safety syringe needle. This innovative product features engineering controls designed to provide a high level of safety, while conforming to user technique. It is low-cost, intuitive and easy-to-use. The integral safety mechanism is activated by a simple press with the thumb or finger, or by pressing the device against a solid surface such as a counter or tabletop. Monoject Magellan™ is packaged in a sterile, easy-to-open peel pack.

Monoject Magellan™ features include:

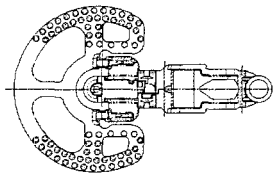
- Easy one-handed activation
  Minimizes training and in-service
- Needle based engineering control
  Promotes clinical flexibility
- Robust safety shield covers entire needle
  Maximizes protection from sharps injury
- Complete 15 SKU product line in a variety of needle lengths and gauges
  Simplifies standardization to safety

Monoject Magellan™ is manufactured and marketed by Kendall, a business unit of Tyco Healthcare and a leading marketer of syringe needles. The Monoject Magellan™ product line competes in the $260 million U.S. safety needle and syringe market.



LIFTLOC® SAFETY HUBER NEEDLES

2



A MAJOR CAUSE OF ACCIDENTAL NEEDLE STICK INJURIES FROM HUBER NEEDLES IS DUE TO THE "REBOUND EFFECT."

LiftLoc® Safety Infusion Set incorporates a Huber type needle into an integral safety needle device. Huber needles are used to access surgically implanted, subcutaneous vascular access ports on a repeated basis. As such, they are hollow-bore and potentially blood-contaminated at the time of removal, with a significant need for an effective safety solution. An estimated 47% of accidental needlestick injuries from Huber needles is due to the "rebound effect,"[1] which occurs during needle withdrawal from the implanted port.

LiftLoc® features a robust safety shield that is deployed as the needle is withdrawn from the port, effectively reducing the risk of accidental needlesticks, including rebound injuries. A unique Patient Comfort Pad™ is packaged with each LiftLoc® set. The Patient Comfort Pad™ is made of breathable felted foam that creates a soft uniform barrier between the Huber needle's wings and the patient's skin. Its use is optional.

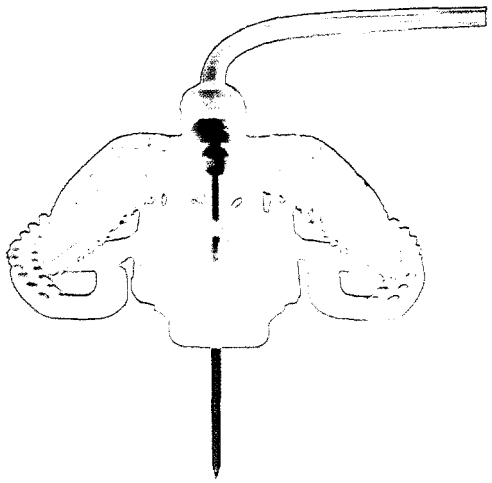
LiftLoc® Safety Infusion Set is the first product to be manufactured under our authority and supervision. And, the first product to be marketed under the SHPI brand.

[1] Janine Jagger, MPH, PhD, *Avoiding rebound injuries from Huber needles.* (nursing precautions), Nursing, April 1999

LiftLoc® Safety Infusion Set is distributed in the hospital market on a private label basis by Bard Access Systems, Inc., a leader in the field of implanted ports. The product line is distributed under the SHPI label by Cardinal Health, Medline Industries, Inc., and Physician Sales and Service, Inc. ("PSS"). LiftLoc® Safety Infusion Set competes in the $46 million U.S. Huber needle market.

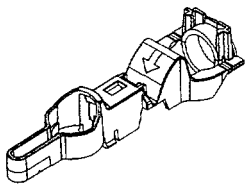
LiftLoc® Safety Infusion Set features include:

- Conforms to current user technique
- Reduces the risk of accidental needlestick injuries
- Non-coring Huber needle
- Capped "Y" site for needleless access
- Low profile, easy-to-dress
- Latex free



PRE-FILLED SYRINGE SAFETY NEEDLE DEVICE

3



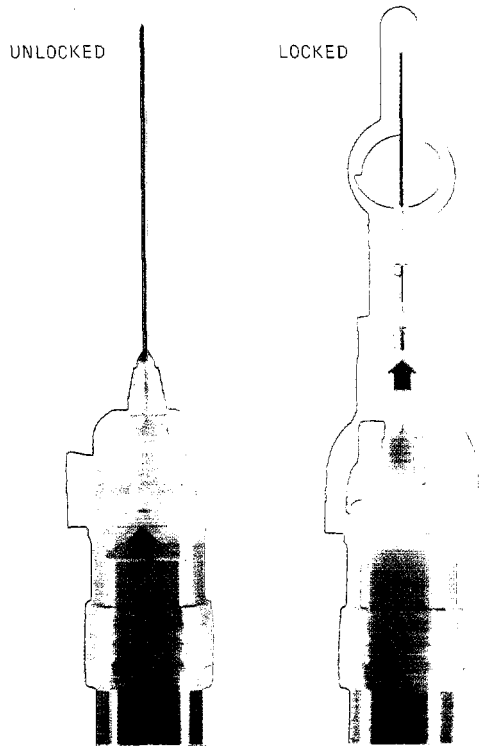
PRE-FILLED SYRINGES ARE A SIGNIFICANT DRUG DELIVERY MODALITY, WITH A STRONG NEED FOR AN EFFECTIVE, COST-EFFICIENT SAFETY NEEDLE SOLUTION.

A wide range of drugs, from high volume vaccines to many of today's newer drugs are delivered via pre-filled syringes. Prefilled syringes are used to deliver drugs in a variety of forms, including liquids, gels, lyophilized (freeze-dried) drugs, or a combination of liquid and dry in a multiple chamber syringe.

We have developed a proprietary safety needle device that is adaptable to a wide variety of pre-filled syringes. This device provides intuitive, one-handed activation. Additionally, the device is designed for easy integration into pharmaceutical manufacturing. Our device can be applied to the pre-filled syringe after filling and before final packaging. This minimizes capital investment and speeds integration.

Lupron Depot® (leuprolide acetate for depot suspension), marketed by TAP Pharmaceutical Products, is the first pharmaceutical product available with our pre-filled syringe safety needle device and the first product in its class to offer an integral safety needle device on pre-filled syringes.

TAP Pharmaceutical Products Inc. (Takeda-Abbott) is the first major pharmaceutical company to attach our innovative safety needle device to its pre-filled syringes. The U.S. market for pre-filled syringes is estimated to be in excess of $100 million annually.



SAFETY BLOOD COLLECTION DEVICES

4

COMBINING A PROPRIETARY SAFETY NEEDLE DEVICE WITH AN INTEGRAL BARREL HELPS PROTECT BOTH THE HEALTHCARE WORKER AND PATIENT.

The present method for drawing blood from patients for blood tests involves insertion of a needle, which is attached to a barrel, into a blood vessel. Blood is then obtained by way of vacuum pressure, most often into a small evacuated tube-like container inserted into the barrel. After blood is drawn, the needle is manually removed from the patient. At this point, the collection tube, barrel and needle are often set aside on a tray or table. Then the needle is usually unscrewed from the barrel and discarded into a sharps container, while the barrel is often used again with another patient (increasing the risk of cross-contamination).

We have developed a family of safety blood collection (phlebotomy) products that have a unique, one-piece injection molded barrel with an integral safety needlestick prevention feature. Since the blood collection barrel is integral to the needle assembly, our safety phlebotomy device ensures that a new barrel is used for each patient. Our product offers easy one-handed activation and has been highly rated in market acceptance studies. The FDA has already granted 510(k) clearance for marketing this device.

The safety blood collection product line will be manufactured and marketed by Kendall, a business unit of Tyco Healthcare. It will compete in the $130 million U.S. blood collection needle market.

SAFETY ANGIOGRAPHIC NEEDLES

5 SAFETY AND INTUITIVE OPERATION FOR THE MILLIONS OF ANGIOGRAPHY PROCEDURES PERFORMED ANNUALLY.

The Majestik™ Shielded Needle is a proprietary safety angiographic needle. Angiographic needles are used to provide vascular access for the introduction of guidewires or other devices during diagnostic or therapeutic procedures, primarily in the fields of cardiology and radiology.

The Majestik™ Shielded Needle is intuitive and easy-to-use. After using the needle, the clinician simply presses a button to mechanically extend a safety shield over the needle. Once the device is locked around the needle, the entire unit is then discarded into an approved sharps container.

The Majestik™ Shielded Needle features include:

- Simple, one-step activation
- 18 gauge 7cm needle
- Top or right orientation
- Normal or ribbed hub
- Integral safety device covers entire needle
- Fits in standard sharps container

Majestik™ Shielded Needle is manufactured and marketed by Merit Medical Systems, Inc., a leading manufacturer and marketer of proprietary disposable products used in cardiology and radiology procedures. Approximately 10 million angiography procedures are performed each year worldwide.

NEW TECHNOLOGY

6

SECURELOC™ TECHNOLOGY ADDS SAFETY TO A WIDE RANGE OF MEDICAL NEEDLES, MANY CURRENTLY WITHOUT A VIABLE SAFETY SOLUTION.

SecureLoc™ technology is an integral safety capsule that automatically senses the end of the needle as it slides down the needle shaft and instantly locks out to encapsulate the needle tip. Activation of a SecureLoc™ device can be active or passive depending upon the product application and/or clinician preference. Our initial product applications of this new platform technology are focused in two major market areas, long specialty needles and safety catheter introducers.

Safety Long Specialty Needles

There is no integral safety alternative available for most long specialty needles.

We have a significant program underway for developing safety long specialty needles based upon the SecureLoc™ technology. These needles are used across a variety of medical disciplines, including anesthesiology, oncology, radiol gy, urology, and cardiology. Initial markets of interest include epidural, spinal, introducer needles, soft tissue and bone biopsy, and others. Together long specialty needles represent a combined market opportunity in excess of $200 million annually in the U.S.

Due to their length, these specialty needles present unique challenges for developing an effective safety system that does not interfere with clinical technique. SecureLoc™ effectively addresses these problems. In addition, SecureLoc™ can be efficiently manufactured and installed onto existing long specialty needles.

Safety Catheter Introducers

The IV catheter market in the U.S. alone represents a $255 million market opportunity.

Catheter introducers are devices that insert catheters into veins or other areas of the body using a catheter insertion needle to allow blood or other fluids to be removed from or delivered into the patient's body. Peripheral IV catheter use presents a risk for clinician exposure to blood-borne pathogens similar to those faced in drawing blood. Inserting a catheter involves a percutaneous (*i.e.*, through the skin) needlestick followed by threading the catheter over the needle into a patient's vein or artery.

We have developed proprietary safety needle products for catheter insertion based upon our SecureLoc™ technology. These products provide passive needle protection in an intuitive design that is integral to the catheter introducer. Clinicians would be able to use our passive safety catheter introducers without modification to their current technique and still have effective protection. Our products also minimize the issue of blood splatter or loss of control as is the case with some of the existing safety catheter introducers.

EXPERIENCED LEADERSHIP

Left to right: Paul Evans, Jeff Soinski, Guy Jordan, Donald Solomon

Our leadership team is highly experienced in both the healthcare and medical safety product sectors. Their brief biographies show we have the entrepreneurial leadership, strategic guidance and industry experience necessary to efficiently realize our full market potential.

Jeffrey Soinski *President and CEO*

Mr. Soinski brings 20 years of general management, business development and marketing experience to SHPI, including several years as the President and CEO of ViroTex Corporation ("ViroTex"), a venture-backed pharmaceutical company focused on the development and commercialization of proprietary drug delivery systems. Mr. Soinski merged ViroTex into Atrix Laboratories, Inc. (Nasdaq: ATRX) in 1998. Prior to joining SHPI, he was the Managing Partner and CEO of Mad Dogs & Englishmen, a marketing communications firm with offices in New York and San Francisco. Mr. Soinski has a BA degree from Dartmouth College.

Guy Jordan *Ph.D., Chairman of the Board*

Dr. Jordan brings a wealth of senior management healthcare experience to SHPI, with a strong focus in the areas of vascular disease and oncology. Dr. Jordan recently retired as Group President for C.R. Bard, Inc. with global operating responsibility for their oncology businesses, geographic responsibility for Canada, Australia, Latin America and Asia Pacific, and functional responsibility for all of Bard's research and development. Prior to joining C.R. Bard in 1986, Dr. Jordan held senior product development positions at American Cyanamid. Dr. Jordan has a Ph.D. degree from Georgetown University and an MBA from Fairleigh Dickinson University.

Donald Solomon *Ph.D., COO, CTO, VP, Director*

Dr. Solomon has over 23 years of medical product experience in research, product development, engineering and manufacturing. Prior to joining SHPI, Dr. Solomon was the Vice President of Research and Development at Johnson & Johnson Medical – Vascular Access. Prior to that he spent 14 years at Becton Dickinson ("BD"), and held positions as Worldwide Director of R&D for BD Pharmaceutical Systems Division based in France, and Director of R&D for Biocompatible Polymer Development at the BD Infusion Therapy Division. Dr. Solomon holds 38 patents and is the author of 52 scientific publications. He received Masters and Ph.D. degrees from Case Institute of Technology at Case Western Reserve University.

Paul Evans *VP, Business Development, General Counsel and Secretary*

Mr. Evans brings a wide range of intellectual property and corporate legal experience to SHPI, having previously served as Vice President, General Counsel for an R&D company, and as a patent attorney with the law firm of Snow, Christensen & Martineau. In addition, Mr. Evans leads the company's business development efforts. Prior to earning his law degree, Mr. Evans worked as a Project/Design Engineer for Morton International (now Autoliv). He holds BS and JD degrees from the University of Utah.

Larry Sheldon *VP, Sales and Marketing*

Mr. Sheldon brings over 24 years of relevant healthcare experience to SHPI, including domestic and international management of sales, marketing, national accounts, and customer service. Most of Mr. Sheldon's experience is from Johnson & Johnson, where he was Vice President, Corporate Distributor Business, responsible for managing distributor relationships for medical/surgical products with annual sales of $1.7 billion. At Johnson & Johnson, Mr. Sheldon held several senior sales management positions in both the Patient Care and Hospital Services divisions. Immediately prior to joining SHPI, Mr. Sheldon was the Sr. VP., Sales & Marketing at Tillotson Healthcare Corporation, a domestic medical and non-medical glove manufacturer. He has a BS degree from Fairleigh Dickinson University.

David Jahns *Director*

Mr. Jahns is a General Partner and principal of Galen Partners. Since joining Galen in 1993, Mr. Jahns has been responsible for making and managing successful investments in several of the firm's portfolio companies. He is an experienced board member and currently serves on the boards of DAOU Systems, Inc. and several of Galen's privately held portfolio companies. Prior to joining Galen, Mr. Jahns worked in the Corporate Finance Division at Smith Barney. Mr. Jahns has an MBA degree from the J. L. Kellogg Graduate School of Management at Northwestern University and a BA degree from Colgate University.

Stuart Randle *Director*

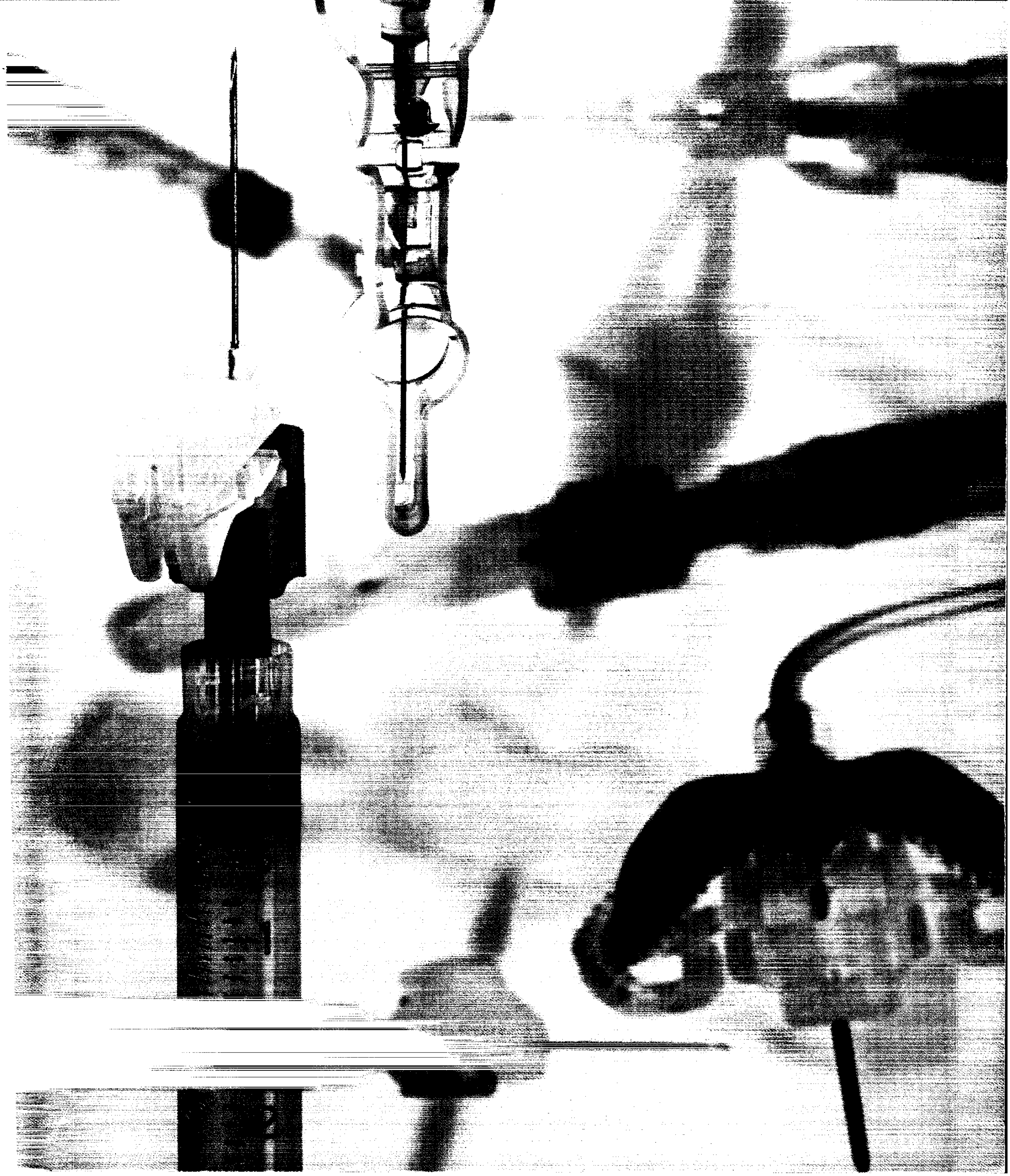
Mr. Randle is the past President and CEO of ACT Medical, Inc., a leading company providing outsourcing services to the medical device, biotech and diagnostic industries. He merged ACT Medical with MedSource Technologies in 2001. Prior to ACT Medical, Mr. Randle was President, Northeast Region, for Allegiance Corporation, a $5 billion medical products distribution and manufacturing company. He is also the past President, New England Region, for Baxter Healthcare Corporation. Mr. Randle has an MBA degree from the J. L. Kellogg Graduate School of Management at Northwestern University and a BS degree from Cornell University.

Stephen Shapiro *Director*

Mr. Shapiro has over 30 years of relevant medical device and equipment industry experience, including executive positions at Union Carbide and Becton Dickinson. In 1982, he joined The Wilkerson Group, a leading management consultancy to the healthcare industry. Mr. Shapiro was Managing Director of The Wilkerson Group at the time of its acquisition by IBM. In 1999, Mr. Shapiro left The Wilkerson Group to focus on sourcing and evaluating investments for two premier healthcare venture capital firms, including Galen Partners. Mr. Shapiro has a BS degree from MIT and an MS degree in biomedical engineering from the University of California, Berkley.

Robert Walker *Director*

Mr. Walker is the past President of the IHC Affiliated Services Division of Intermountain Healthcare, a regional hospital company. He is also former Chairman of the Board of AmeriNet, Inc., a national group purchasing organization for hospitals, clinics, detox/drug centers, emergency, nursing homes, and other healthcare institutions. Mr. Walker is a member of the American Hospital Association and the Hospital Financial Management Association. He has a BS degree in Business Administration from the University of Utah.



SPECIALIZED HEALTH PRODUCTS INTERNATIONAL, INC.

585 WEST 500 SOUTH • BOUNTIFUL, UT 84010

T: 801.298.3360 • F: 801.298.1759 • WWW.SHPI.COM

NASDAQ OTCBB: SHPI

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-KSB

Annual Report Pursuant
to Section 13 or 15(d) of the
Securities Exchange Act of 1934

For the fiscal year ended
December 31, 2003

Commission file number
0-26694

SPECIALIZED HEALTH PRODUCTS INTERNATIONAL, INC.
(Exact name of registrant as specified in its charter)

Delaware	**93-0945003**
(State or other jurisdiction of incorporation)	(IRS Employer Identification No.)
585 West 500 South, Bountiful, Utah 84010	**(801) 298-3360**
(Address of principal executive offices)	(Registrant's telephone number, including area code)

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

Title of each class	Name of each exchange on which registered
Common Stock, $.02 Par Value	None

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

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB. ☒

The issuer's revenue for its most recent fiscal year was $3,606,574

The aggregate market value of the common stock held by non-affiliates (*i.e.*, does not include directors, executive officers or ten percent stockholders identified in Item 11 hereof) of the issuer as of March 22, 2004 was approximately $19,697,884.

As of March 22, 2004, the Company had 17,831,479 shares of common stock outstanding (not including 21,831,369 shares of Series A Preferred stock that are being automatically converted into common stock on a one-for-one basis as described in Item 11).

SPECIALIZED HEALTH PRODUCTS INTERNATIONAL, INC.

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ON FORM 10-KSB
YEAR ENDED DECEMBER 31, 2003

PART I

PART II

PART III

Forward-Looking Statements

When used in this Form 10-KSB, in our filings with the Securities and Exchange Commission ("SEC"), in our press releases or other public or stockholder communications, or in oral statements made with the approval of an authorized executive officer, the words or phrases "would be," "will allow," "intends to," "will likely result," "are expected to," "will continue," "is anticipated," "estimate," "project," or similar expressions are intended to identify "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements specifically include, but are not limited to, launch dates for licensed products; dates upon which we will receive royalty payments; the generation of royalty revenues from our licensees; acceptance of safety products by health care professionals; plans to rely on our joint venture partners to pursue commercialization of licensed products; expectations regarding the ability of our products to compete with the products of our competitors; acceptance of our products by the marketplace as cost-effective; factors affecting the ability of licensees to sell licensed products; sufficiency and timing of available resources to fund operations; plans regarding the raising of capital; the size of the market for safety products; plans regarding sales and marketing; strategic business initiatives; intentions regarding dividends and the launch dates of our licensed products.

We caution readers not to place undue reliance on any forward-looking statements, which speak only as of the date made, are based on certain assumptions and expectations which may or may not be valid or actually occur, and which involve various risks and uncertainties, including but not limited to risk of a lack of demand or low demand for our products or for safety products generally; a determination of one or more licensees to focus their marketing efforts on products other than those licensed from us; the inability to license or enter into joint venture or similar arrangements relating to products that are not being commercialized; competitive products and pricing; delays in introduction of products licensed by us due to manufacturing difficulties or other factors; difficulties in product development, commercialization and technology; changes in the regulation of safety healthcare products; a failure to timely obtain Food and Drug Administration ("FDA") or other necessary approval to sell future products and other risks set forth in Item 6 "Risk Factors" and elsewhere herein. If and when product sales commence, sales may not reach the levels anticipated. As a result, our actual results for future periods could differ materially from those anticipated or projected.

Unless otherwise required by applicable law, we do not undertake, and specifically disclaim any obligation, to update any forward-looking statements to reflect occurrences, developments, unanticipated events or circumstances after the date of such statement.

PART I

Item 1. Description of Business

Overview

We design, develop, manufacture, and license cost-effective, innovative safety healthcare products that minimize the risk of accidental needle sticks, which are a leading cause of the spread of blood-borne diseases such as human immunodeficiency virus and autoimmunodeficiency syndrome ("HIV/AIDS") and hepatitis B virus ("HBV") and hepatitis C virus ("HCV"). We have 20 highly differentiated, patented safety needle technologies. These technologies apply to virtually all medical needles used today including: syringe, pre-filled syringe, IV catheter, guidewire introducer, PICC introducer, blood collection, epidural, spinal, Huber, biopsy, and other specialty needles.

Our business model is to enter into licensing, original equipment manufacturing ("OEM") supply, or distribution agreements for our products, rather than engage in direct sales of products to end-users on our own. We have entered into product agreements relating to specific technologies and product lines with The Kendall Company ("Kendall"), a division of Tyco Healthcare Group LP, Bard Access Systems, Inc. ("Bard"), TAP Pharmaceutical Products Inc. ("TAP"), Merit Medical Systems, Inc. ("Merit"), Exelint International Co. ("Exel") and Becton, Dickinson and Company ("BD"). We have distribution agreements in

place with Cardinal Health ("Cardinal", formerly Allegiance), Medline Industries, Inc. ("Medline"), Physician Sales and Service, Inc. ("PSS"), and several other specialty distributors for products marketed under our own SHPI ("SHPI" is used for Specialized Health Products International, Inc.) label. Additional discussions are ongoing with potential partners for several other product applications of our proprietary technologies.

Our primary objective is to be the leader and innovator in disposable medical safety sharps products, with an initial focus on safety medical needles. We will seek to commercialize products providing the following features and benefits:

- Excellent functionality for the intended medical use;
- Similar or enhanced clinical technique versus conventional product offerings;
- Comparable, improved or additional ancillary patient benefits (*e.g.*, comfort, convenience, etc.);
- Efficient/low cost manufacturability to provide attractive margins at a reasonable price; and
- Superior safety technology to prevent accidental exposure to blood-borne pathogens.

We introduced our first safety needle products into the U.S. market in 2002. Five product lines based upon our proprietary safety needle technologies are currently marketed in the U.S. These products are discussed in detail in the *Our Products* section below and include the following:

- Monoject Magellan™ -- safety syringe needle (Kendall)
- LiftLoc® Safety Infusion Set -- safety Huber needle (Bard and Exel private label and SHPI branded)
- Majestik™ Shielded Needle -- safety angiographic introducer needle (Merit)
- LuproLoc™ -- pre-filled syringe safety needle (TAP)
- Monoject Magellan™ -- safety blood collection device (Kendall)

We see a significant and growing market opportunity for our medical safety needle products. The current U.S. market for disposable medical needles is in excess of $1.4 billion. Most of this market is directly impacted by broad reaching state and federal safety legislation, culminating in the Needlestick Safety and Prevention Act, which was signed into federal law in November 2000, and became effective in April 2001. This law requires healthcare employers to review new safety needle products and mandates their usage by employees. As various government agencies increase their efforts to monitor compliance and better designed safety products become available at reasonable pricing, we anticipate that conversion to safety products will continue to accelerate.

While foreign safety needle legislation lags behind that of the U.S., certain countries, such as Germany, France, Italy, Australia, and Canada are increasing efforts to protect their healthcare workers in a similar manner. As these efforts continue, we expect foreign demand for medical safety needle products to expand.

Our Products

We have 20 highly differentiated, patented safety needle technologies that are the basis for a wide range of safety needle products. These proprietary technologies are protected by 22 U.S. patents and over 90 U.S. patents and international patent applications pending. Our primary research and development, business development and marketing efforts are focused on the following product lines:

Safety Syringe Needles

There is significant risk of accidental needlesticks during syringe needle use. Generally, the use of a needle for a medical procedure involves removing a needle cap just prior to performing the procedure. In the past, medical personnel attempted to achieve protection from accidental needlesticks by replacing the needle cap after performing a procedure, but a high number of accidental needlesticks related to needle cap

replacement resulted in such practices being prohibited by the Centers for Disease Control ("CDC"). Some medical personnel began using needles and syringes having sheaths that could be extended over the exposed needle after a procedure.

Our safety syringe needle eliminates the need to perform dangerous recapping techniques with an integral safety device that covers the needle after use. This innovative product features engineering controls designed to provide a high level of safety while conforming to current user technique. It is low-cost, intuitive, and easy-to-use. The integral safety mechanism is activated by a simple press with the thumb or finger, or by pressing the device against a solid surface such as a counter or tabletop.

A robust product line based upon this proprietary safety syringe needle technology is being manufactured and marketed by Kendall, a division of Tyco Healthcare Group LP and the second leading marketer of syringe needles. In November 1999, we entered into a Development and License Agreement (the "Kendall Agreement") with Kendall relating to the production of a line of safety medical needle products, including six syringe products and five other safety needle products. The Kendall Agreement became effective in March 2000. In April 2000, we received $1,464,956 under the Kendall Agreement. We received an additional $1,000,000 in November 2002 in exchange for our assigning to Kendall the FlexLoc® and ReLoc™ trademarks and two related U.S. patents and their progeny for a technology. The assignment of the patent rights to Kendall provides for our retention of an exclusive, royalty-free worldwide license in a number of strategic product areas. The Kendall Agreement also provides for us to receive development fees and ongoing royalties, including a $500,000 advance royalty payment also received in November 2002.

Kendall initiated its U.S. market launch of a proprietary line of safety syringe needles based upon this technology in the second calendar quarter of 2002, subsequent to receiving 510(k) clearance from the FDA in 2001. Kendall is marketing the product line under the brand name Monoject Magellan™. The Monoject Magellan™ product line includes a wide variety of needle lengths and gauges, and competes in the $260 million U.S. safety needle and syringe market.

Safety Huber Needle Devices

Our LiftLoc® Safety Infusion Set incorporates a Huber type needle into an integral safety needle device. This product is designed for use with a vascular access infusion system (used to infuse fluids, drugs, or for blood sampling) and is specifically designed to access surgically implanted, subcutaneous vascular ports on a repeated basis. Patients with implanted ports require access by Huber needles frequently over six months to a year. A major cause of accidental needlestick injuries to healthcare workers from Huber needles is due to the "rebound effect" which occurs during needle withdrawal from the implanted port. This needle presents a high risk for transmission of blood-borne pathogens, since it is hollow-bore and potentially blood-contaminated at the time of removal.

Our LiftLoc® Safety Infusion Set conforms to current user technique and reduces the risk of accidental needlesticks, including rebound injuries, by locking the needle into a protective sheath as the needle is withdrawn from the port. Each LiftLoc® set is packaged with a unique Patient Comfort Pad™ accessory product. The Patient Comfort Pad™ is made of breathable felted foam that creates a soft uniform barrier between the Huber needle's wings and the patient's skin. Its use is optional.

The LiftLoc® Safety Infusion Set product line is distributed in the hospital market by Bard Access Systems, Inc., a division of C. R. Bard, Inc., a leading multinational developer, manufacturer and marketer of healthcare products in the field of implanted ports that are accessed using Huber needles. In September 2001, we entered into a Distribution Agreement (the "Bard Agreement") with Bard whereby Bard acquired the non-exclusive right to promote, market, distribute and sell the LiftLoc® Safety Infusion Set, which we manufacture, to hospitals and group purchasing organizations. The Bard Agreement excludes alternate site locations, such as homecare services, nursing homes, oncology centers, infusion centers, same day surgery centers, physician offices and clinics, non-hospital pharmacies and pain clinics. Under the terms of the

agreement, we sell finished product to Bard for marketing under Bard's private label. In the second calendar quarter of 2003 we entered into a Distribution Agreement (the "Exel Agreement") with Exel whereby Exel acquired the non-exclusive right to promote, market, distribute and sell LiftLoc® Safety Infusion Set. Under the terms of the agreement, we sell finished product to Exel for marketing under Exel's SecureTouch® private label. Exel is subject to minimum purchase requirements under the terms of the agreement.

We distribute LiftLoc® Safety Infusion Set under the SHPI label through non-exclusive distribution agreements with Cardinal Health, Medline, PSS, Medical Specialties Distributors, Inc. ("Medical Specialties"), Omni Medical Supply, Inc. ("Omni"), Briggs Corporation ("Briggs"), Wolf Medical Supply, Inc. ("Wolf Medical"), and Henry Schein, Inc. ("Henry Schein"), distributors with a strong presence in the oncology, chronic hematology, and long-term intravenous nutritionals markets.. In addition, we have entered into distribution agreements with Medical Mart Supplies Ltd. ("Medical Mart") for the distribution of our LiftLoc® product in Canada and Biometrix Ltd. ("Biometrix") for the distribution of LiftLoc® in Israel. Under the terms of the distribution agreements, LiftLoc® distributors purchase product from us for resale to their end-user customers.

We received 510(k) clearance from the FDA for LiftLoc® Safety infusion Set in 2001, and initiated the U.S. market launch of the product line under our SHPI label in September 2002. Bard initiated its U.S market launch of LiftLoc® Safety Infusion Set under the Bard label in December 2002. The LiftLoc® Safety Infusion Set product line includes a wide variety of needle lengths and gauges. It competes in the $46 million U.S. Huber needle market.

Pre-filled Syringe Safety Needle Device

Pre-filled syringes are a significant drug delivery modality, with a strong need for an effective, cost-efficient safety needle solution. A wide range of drugs, from high volume vaccines to many of today's newer drugs, are delivered via pre-filled syringes. Typically, the pre-filled syringe is made of glass to ensure appropriate shelf life and inertness to the drug. Pre-filled syringes are used to deliver drugs in a variety of forms, including liquids, gels, lyophilized (freeze-dried) drugs, or a combination of liquid and dry in a multiple chamber syringe.

We have developed a proprietary safety needle device that is adaptable to a wide variety of pre-filled syringes. This device provides intuitive, one-handed activation. Additionally, the device is designed for easy integration into pharmaceutical manufacturing. Our device can be applied to the pre-filled syringe after filling and before final packaging. This minimizes capital investment and speeds integration.

In July 2002, we entered into a Development and License Agreement (the "TAP Agreement") with TAP Pharmaceutical Products Inc. (a joint venture between Abbott Laboratories and Takeda Chemical Industries, Ltd.), whereby TAP acquired the right to attach our proprietary safety needle device to their pre-filled syringes. The TAP Agreement has an effective date of January 1, 2002. Under the TAP Agreement, we have and will receive reimbursement for research and development expenses, payments related to the achievement of certain development and regulatory milestones, and on-going royalty payments based upon the number of pre-filled syringes manufactured with our proprietary safety needle device. The TAP Agreement is for a minimum period of three years.

TAP is attaching our proprietary safety needle device to pre-filled syringes of Lupron Depot® (leuprolide acetate for depot suspension), the first pharmaceutical product available with our pre-filled syringe safety needle device and the first product in its class to offer an integral safety needle device on pre-filled syringes. TAP has branded this integral safety needle device LuproLoc™. TAP initiated the U.S. market launch of Lupron Depot® with LuproLoc™ in January 2003, after receiving FDA approval as the result of filings with both the FDA's Center for Drug Evaluation and Research ("CDER") and its Center for Devices and Radiological Health ("CDRH"). Pharmaceutical products sold in pre-filled syringes represent a multi-billion dollar worldwide market. The total U.S. market for pre-filled syringes is estimated to be in excess of $100 million annually.

Safety Blood Collection (Phlebotomy) Devices

The present method for drawing large amounts of blood from patients for blood tests involves insertion of a needle, which is attached to a barrel, into a blood vessel. Blood is then obtained by way of vacuum pressure, most often into a small evacuated tube-like container inserted into the barrel. After blood is drawn, the needle is manually removed from the patient. While the healthcare worker continues attending to the patient, the collection tube, barrel and needle are often placed on a tray, table or otherwise set aside. Afterward, the needle is usually unscrewed from the barrel and discarded into a sharps container, while the barrel is often used again with another patient (increasing the risk of cross contamination).

We have developed a family of safety blood collection products that combine a unique, one-piece injection molded barrel with an integral safety needle device. Since the blood collection barrel is integral to the needle assembly, our safety phlebotomy device ensures that a new barrel is used for each patient. Our product offers easy, one-handed activation and has been highly rated in market acceptance studies.

Our safety blood collection product line is manufactured and marketed by Kendall, a business unit of Tyco Healthcare. In April 2002, we entered into a Second Development and License Agreement with Kendall (the "2nd Kendall Agreement") relating to blood collection needles and blood collection needle/holder combinations. Under the terms of the agreement, we receive reimbursement for research and development expenses, payments related to the achievement of certain regulatory and sales milestones, and on-going royalty payments on all product sales.

Kendall initiated its U.S. market launch of the Monoject Magellan™ safety blood collection product line in January 2004. This product line competes in the $130 million U.S. blood collection needle market.

Safety Angiographic Needles

Angiographic needles are used to provide vascular access for the introduction of guidewires or other devices during diagnostic or therapeutic procedures, primarily in the fields of cardiology and radiology. Approximately 10 million angiography procedures are performed each year worldwide.

We have entered into a License Agreement (the "Merit Agreement") with Merit Medical Systems, Inc. relating to the manufacture and marketing of safety needle devices for angiographic guidewire introducers. Merit is a leading manufacturer and marketer of proprietary disposable products used in cardiology and radiology procedures. We received an upfront license fee payment of $100,000 in January 2001, which is being recognized ratably by us over the estimated five-year life of the Merit Agreement. Under the terms of the Merit Agreement, we will receive ongoing royalties on net product sales and began receiving minimum royalty payments in 2002.

Merit initiated its U.S. market launch of a safety angiographic needle based upon our proprietary safety needle technology in November 2002. Merit designed and developed the product, and is marketing it under the Majestik™ Shielded Needle brand name. The Majestik™ Shielded Needle is intuitive and easy-to-use. After using the introducer needle, the clinician simply presses a button to mechanically extend a safety shield over the needle. After the safety device is locked around the needle, the entire unit is then discarded into an approved sharps container. The Majestik™ Shielded Needle competes in the estimated $17 million U.S. introducer needle market.

Safety Long Specialty Needles

We have a significant program underway for developing safety long specialty needles based upon our SecureLoc™ technology. These needles are used across a wide range of medical disciplines, including anesthesiology, oncology, radiology, urology, and cardiology. Initial markets of interest include epidural, spinal, introducer needles, soft tissue and bone biopsy, and others. Together long specialty needles represent a combined market opportunity well in excess of $200 million annually in the U.S.

Due to their length, these specialty needles present unique challenges for developing an effective safety system that does not interfere with clinical technique. We have developed and filed patents for SecureLoc™, an innovative safety needle technology that we believe effectively addresses these problems. SecureLoc™ is an integral safety needle device that automatically senses the end of the needle as it advances down the needle shaft and instantly locks out to fully encapsulate the needle tip. We are currently engaged in active discussions with potential corporate partners for several specialty long needle product applications of the SecureLoc™ technology.

In August 2003, we entered into a License Agreement (the "BD Agreement") with BD relating to the manufacture and marketing of safety-engineered spinal and epidural needles and certain other specialty needles sold by BD. Under the terms of the agreement, we will receive reimbursement for certain research and development expenses, payments related to the achievement of certain regulatory and commercialization milestones, and on-going royalty payments on all product sales.

Safety Catheter Introducers

Catheter introducers are devices that insert catheters into veins or other areas of the body using a catheter insertion needle to allow blood or other fluids to be removed from or delivered into the patient's body. Peripheral IV catheter use has problems similar to those faced in drawing blood. Inserting a catheter involves a percutaneous (*i.e.,* through the skin) needlestick followed by threading the catheter over the needle into a patient's vein or artery. This method can be unsafe in two respects. First, when the needle is pulled out of the catheter, there is often a discharge of blood that could contaminate the healthcare worker. Second, inadvertent needlesticks can occur when the needle is withdrawn from the catheter, because, in some instances, the needle is temporarily left exposed while the healthcare worker tends to the patient.

We have developed proprietary safety needle products for catheter insertion, which provide passive needle protection in an intuitive design that is integral to the catheter introducer. These products are also based upon our SecureLoc™ technology. Clinicians would be able to use our passive safety catheter introducers without modification to their current technique and still have effective protection. Our device also minimizes the issue of blood splatter or loss of control, as is the case with some of the existing technologies. This device will compete in the $255 million U.S. IV catheter market. We are currently engaged in active licensing discussions on this product line.

Industry

Market

Healthcare is one of the largest industries in the world and grows larger each year. Healthcare worker safety is and will remain a high priority, high profile issue. Healthcare workers in the U.S. use about 6 billion needles and suffer an estimated 800,000 injuries from accidental needlesticks and other sharps annually. Diseases that can be acquired from such accidents include HIV/AIDS, HBV, HCV, diphtheria, gonorrhea, typhus, herpes simplex virus, malaria, syphilis and tuberculosis. Recent federal and state legislation in conjunction with increased awareness of these statistics is projected to spur significant growth in the safety needle and syringe market, as sales are converted from the traditional disposable needle and syringe market. The current U.S. market for disposable medical needles is in excess of $1.4 billion and growing.

User efficiency and cost effective solutions are being sought with increasing demand. Our products target this market segment. Non-safety products today compete primarily on price. Although our strategy includes being priced competitively with other safety devices, we also seek to compete on the basis of healthcare worker safety, ease of use, reduced cost of disposal, patient comfort, and compliance with Occupational Safety and Health Administration ("OSHA") regulations. We believe that when all indirect costs (needle disposal, testing, labor savings and costs, treatment and workers compensation expense) are

considered, our products will compete effectively both with "traditional" products and with the safety products of our competitors.

Accidental Needlestick Injuries

Needles for hypodermic syringes, phlebotomy sets, intravenous catheters, safety steel needles and specialty medical needles are necessary to inject drugs and other fluids into the body and for drawing blood and other fluids from the body. Hypodermic needles are used for the injection of drugs. Phlebotomy sets are used for the drawing of blood. Catheters, butterfly needles and specialty needles are used for access to patient vessels. There is an increasing awareness of the potential danger of infections and illnesses to healthcare workers that result from accidental needlesticks and of the need for safer needle devices to reduce the number of such accidents.

It is estimated that at least 1,000 healthcare workers annually contract serious infections from accidental needlestick and sharps injuries in the U.S. Estimates also suggest that safety needle devices may prevent more than 80% of all needlestick injuries. Testing and treatment of needlestick injuries costs the U.S. healthcare system between $750 million and $1 billion each year. The average cost of treating a needlestick injury not resulting in the transmission of a disease is between $450 and $800 per incident, which only considers the direct costs associated with HBV, HCV and HIV screens and employee health time. According to the American Hospital Association, a single case of serious blood-borne pathogen infection can cost more than $1 million in expenses for follow-up testing, lost work time and disability payments. Even if no infection occurs as a result of the injury, the average cost of treating a high-risk exposure is estimated to be about $3,000 per needlestick. According to the CDC, the 1998 infection rate following a single needlestick injury with a contaminated needle or other sharp was between 6% and 30% for HBV, 0.5% and 2% for HCV, and about 0.3% for HIV. 85% of the healthcare workers infected with HCV become chronic carriers of the virus. Treatment of HCV is very expensive, averaging $1,700 per month. Treatment for HIV is also expensive, with costs averaging up to $6,000 per month. Accidental needlesticks are the cause of 86% of all occupationally acquired cases of HIV/AIDS.

While we expect recent government regulations to dramatically increase conversions to safety products in the future, the greatest obstacle to conversion in certain product categories may be adequate supply and availability of well-designed and cost-efficient safety products. We believe that pressure is increasing from the government and private sectors for the healthcare industry to develop medical devices that will provide a safer working environment for healthcare and related workers and patients. Our products are intended to address the demand for medical devices that reduce the risk of accidental exposure to blood-borne diseases.

Legislative Response

National safety regulations have highlighted the demand for safety medical devices. The Needlestick Safety and Prevention Act was signed into federal law in November 2000, and became effective in April 2001. Twenty-six U.S. states have passed safety legislation requiring the use of safety needle products. OSHA also issued a national directive in November 1999 requiring use of safety medical devices, then revised the order in November of 2000 to comply with the Needlestick Safety and Prevention Act. This order requires healthcare employers to review new safety products and mandates their use by employees. Various government agencies now monitor hospitals and clinics for compliance. We believe these developments will positively affect our ability to commercialize our products.

Our Strategy

Our primary objective is to be the leader and innovator in disposable medical safety sharps products, with an initial focus on safety medical needles. We are seeking to accomplish this objective by capturing significant market share of targeted product segments, broadening existing product lines, developing new products and seeking additional market opportunities.

Our business model is to enter into licensing, OEM supply, or distribution agreements for our products, rather than engage in direct sales of products to end-users on our own. OEM supply or distribution arrangements are our preferred business relationship for targeted specialty products. Out-licensing agreements are pursued for high volume product opportunities where efficient and low cost manufacturing is unfeasible at a contract manufacturer, or when a large capital investment is required to scale-up manufacturing.

Marketing and Sales

Because we focus on the design, development, manufacture, OEM supply and license of cost-effective, innovative safety healthcare products, we are not engaged in the sale of our products directly to end-users. For our licensed products, our current marketing efforts primarily focus upon identifying market leaders in the pharmaceutical and medical device industries who are highly qualified to sell and distribute our products after manufacture, incorporate our safety applications in their existing products, or some combination of the foregoing.

For products that we supply on an OEM private label basis or market under our own SHPI label, such as LiftLoc® Safety Infusion Set, we provide significant sales and marketing support to our corporate partners and qualified distributors. This support includes development and supply of marketing materials, active lead generation through participation in trade shows, outbound telemarketing and sales presentations, in-service participation and customer service support.

Manufacturing and Facilities

Products being developed under OEM supply or distribution agreements are manufactured under our authority and supervision by a qualified contract manufacturer. In 2002, we began producing our LiftLoc® Safety Infusion Set and Patient Comfort Pad™ at an ISO 9002 qualified contract manufacturer. Products subject to licensing agreements are manufactured by our corporate partners. The materials used to produce our products are generally widely available. We do not anticipate difficulty in obtaining such materials.

In 2003, we were certified to ISO 9001:94, ISO 13485:96 and EN 46001:96 international quality systems standards by our registrar, Orion Registrar, Inc. Certification to these international quality systems standards allows us to apply for CE Marking required for product distribution in Europe and to seek product registrations for our manufactured products in other international markets. We have also been certified to CMDCAS ("Canadian Medical Device Conformity Assessment System"), which will allow us to market our manufactured products in Canada.

Our facilities include 15,574 square feet of leased space. Our primary use of the space is for offices. However, our facility also includes designated laboratory space for the development and testing of product prototypes, and a dedicated machine shop to support our product development activities. In 2002, we established a controlled warehouse, customer service and pick, pack and ship operation at our facility to support sales of LiftLoc® Safety Infusion Set.

Patents and Proprietary Rights

Our policy is to seek patent protection for all developments, inventions and improvements that are patentable and which have potential value to us and to protect as trade secrets other confidential and proprietary information. We intend to vigorously defend our intellectual property rights to the extent our resources permit.

We have 22 U.S. patents relating to our safety medical needle technologies. We have over 90 U.S. and international patents and patent applications pending. The patents referred to above first begin to expire in 2013. We filed 18 U.S. and international patent applications during 2003.

Our future success may depend upon the strength of our intellectual property. We believe that our patents and patent applications are or will be valid and enforceable. There is no assurance, however, that if such patents are challenged this belief will prove correct. In addition, patent applications filed in foreign countries and patents granted in such countries are subject to laws, rules and procedures, which differ from those in the U.S. Patent protection in such countries may be different from patent protection provided by U.S. laws and may not be as favorable to us.

We are not aware of any patent infringement claims against us directly. In December 2002, BD filed a lawsuit against Tyco Healthcare Group LP ("Tyco Healthcare"), asserting that the Monoject Magellan™ safety products infringe upon a BD patent. See Item 3. "Legal Proceedings." In our agreement with Kendall we agreed to indemnify Kendall for all costs associated with any claims, liabilities, suits or judgments arising out of Kendall's use of the patent rights and technical information transferred to them under the Agreement. Based on information obtained during the fourth quarter of 2003 related to costs incurred by Kendall, we have recorded a liability of $1,300,000 as of December 31, 2003, which amount is our estimate of the portion of costs associated with BD's suit against Tyco Healthcare that Tyco Healthcare will withhold against the royalties due SHPI through 2005. Additional litigation to enforce patents, to protect proprietary information, or to defend us against alleged infringement of the rights of others may occur. Such litigation would be costly, could divert our resources from other planned activities, and could have a material adverse effect on our results of operations and financial condition.

Research and Development

We have devoted a substantial portion of our efforts to designing and developing healthcare products. To date, research and development expenditures have resulted in our ownership of, or right to, in excess of 90 patents and patent applications worldwide and the creation of 20 highly differentiated, patented safety needle technologies. We spent $2,595,022 in 2003 and $2,468,347 in 2002 on research and development activities. Customer sponsored research activities relating to the development of new products, services or techniques or the improvement of existing products, services or techniques for which we earned revenues were $59,880 in 2003 and $636,425 in 2002. We plan to continue research and development on our current products under development and new products. There is no assurance that our ongoing research and development activities will prove effective.

Government Regulation

Product Approvals

We are regulated by the FDA, pursuant to various statutes, including the Federal Food, Drug and Cosmetic ("FD&C") Act, as amended and supplemented by the Medical Device Amendments of 1976 (the "1976 Amendments") and the Safe Medical Devices Act of 1990. Although our focus in the past has been on the design and development of devices, we anticipate that as we engage in more OEM manufacturing, we will become increasingly active in pursuing regulatory approvals. We have submitted and received FDA clearance for our LiftLoc® Safety Infusion Set. In addition, our strategic partners have received FDA clearances for Monoject Magellan™ Safety Syringe Needle, Monoject Magellan™ Safety Blood Collection Device, LuproLoc™ Pre-filled Syringe Safety Needle, and Majestik™ Shielded Angiographic Needle. We plan to submit additional 510(k) applications for safety needle devices based upon the SecureLoc™ technology during 2004 and 2005.

Pursuant to the 1976 Amendments, the FDA classifies medical devices intended for use with humans into three classes, Class I, Class II and Class III. The controls applied to the different classifications are those the FDA believes are necessary to provide reasonable assurance that a device is safe and effective. Many Class I devices have been exempted from pre-market notification requirements by the FDA. These products can be adequately regulated by the same types of controls the FDA has used on devices since the passage of the FD&C Act in 1938. These "general controls" include provisions related to labeling, producer registration, defect notification, records and reports and good manufacturing practices

("GMP"). The GMP regulation has been recently replaced by a more comprehensive Quality System Regulation ("QSR"). QSRs include implementation of quality assurance programs, formalized product development procedures, written manufacturing specifications and processing procedures, written distribution procedures and record keeping requirements. Class II devices are products for which the general controls of Class I devices are deemed not sufficient to assure the safety and effectiveness of the device and thus require special controls. Special controls for Class II devices include performance standards, post-market surveillance, patient registries and the use of FDA guidelines. Standards may include both design and performance requirements. Class III devices have the most restrictive controls and require pre-market approval by the FDA. Generally, Class III devices are limited to life-sustaining, life-supporting or implantable devices. None of our currently proposed products are believed to be to be Class III products. The FDA has further established three tiers or levels of scientific review – Tier 1, Tier 2, and Tier 3 within each class. Submissions for Tier 1 devices receive limited review while submissions for Tier 2 and 3 devices receive more comprehensive reviews.

Section 510(k) of the FD&C Act requires individuals or companies manufacturing medical devices intended for use with humans to file a notice with the FDA at least 90 days before introducing a product not exempted from notification requirements into the marketplace. The notice (a "510(k) Notification") must state the class in which the device is classified and the actions taken to comply with performance standards or pre-market approval which may be needed if the device is a Class II or Class III device, respectively. If a company states the device is unclassified, it must explain the basis for that determination.

In some cases obtaining pre-market approval for Class III devices can take several years. Product clearance pursuant to a 510(k) Notification can be obtained in much less time. The average time for 510(k) clearance for safety devices is currently 90 days. In general, clearance of a 510(k) Notification for a Class II device may be obtained if we can establish that the new device is "substantially equivalent" to another device of that Class already on the market. This requires the new device to have the same intended use as a legally marketed predicate device and have the same technological characteristics as the predicate device. If the technological characteristics are different, the new device can still be found to be "substantially equivalent" if information submitted by the applicant (including clinical data if requested) supports a finding that the new device is as safe and effective and does not raise questions of safety or efficacy that are different from the predicate device.

We expect our safety medical needle products to be categorized as Class II devices. We also expect that these products will not require pre-market approval applications but will be eligible for marketing clearance through the 510(k) Notification procedure based upon their substantial equivalence to previously marketed devices.

Although the 510(k) Notification clearance process is ordinarily simpler and faster than the pre-market approval application process, there can be no assurance that we will obtain 510(k) Notification clearance to market our products, that our products will be classified as set forth above, or that, in order to obtain 510(k) Notification clearance, we will not be required to submit additional data or meet additional FDA requirements which could substantially delay sales and add to our expenses. Moreover, any 510(k) Notification clearance, if obtained, may be subject to conditions on the marketing or manufacturing of the related products, which could impede our ability to market or manufacture such products.

In addition to the requirements described above, the FD&C Act requires that all medical device manufacturers and distributors register with the FDA annually and provide the FDA with a list of those medical devices that they distribute commercially. The FD&C Act also requires that all manufacturers of medical devices comply with labeling requirements and manufacture devices in accordance with QSRs. QSRs require that companies manufacture their products and maintain their documents in a prescribed manner with respect to manufacturing, testing, and quality control. The FDA's Medical Device Reporting regulation requires that companies provide information to the FDA on death or serious injuries alleged to have been associated with the use of their products, as well as product malfunctions that would likely cause or contribute to death or serious injury if the malfunction were to recur. The FDA further requires that

certain medical devices not cleared with the FDA for marketing in the U.S. meet specific requirements before they are exported. We are registered as a manufacturer with the FDA.

The FDA inspects medical device manufacturers and distributors, and has broad authority to order recalls of medical devices, to seize non-complying medical devices, to enjoin and/or impose civil penalties on manufacturers and distributors marketing non-complying medical devices, and to criminally prosecute violators. Noncompliance with FDA regulations could have a material adverse effect on our company.

In addition to the laws and regulations described above, we are subject to government regulations applicable to all businesses, including, among others, regulations related to occupational health and safety, workers' benefits and environmental protection.

Safety Product Mandates

Safety regulations and legislation have also increased the demand for and exposure of safety medical devices. The Needlestick Safety and Prevention Act became effective in April 2001 and orders specific revisions to OSHA's blood-borne pathogens standard. This legislation requires healthcare employers to review new safety products and mandates their use by employees. The revised standard directs all healthcare facilities and employers to select safety needle devices as they become available.

Twenty-six U.S. states have passed safety legislation requiring use of safety needle products. OSHA also issued a national directive in November 1999 requiring use of safety medical devices. In November 2000, the CDC and OSHA issued safety alerts urging healthcare workers to use safety devices having engineered controls.

Foreign Regulation

Distribution and sales of our products in countries other than the U.S. is subject to regulations in those countries. In December of 2003, we received certification to ISO 9001:94, ISO 13485:96 and EN46001:96 international quality systems standards. Following ISO certification we were granted a CE Mark for our LiftLoc® Safety Infusion Set product line. The granting of the CE mark enables us to distribute products in Europe and to seek product registrations in other international markets. We have also been certified to CMDCAS ("Canadian Medical Device Conformity Assessment System"), which certification allows us to market products in Canada

Competition

The healthcare products market is highly competitive. Many of our competitors have longer operating histories, are substantially larger and are better financed and better situated in the market than we are. Our major competitors are identified below.

The leading suppliers of syringe needles and syringes with needles are BD and Kendall. Terumo Medical Corporation ("Terumo") holds a minor U.S. market share. B. Braun Medical ("B. Braun") is a leader in Europe and Asia, while Terumo is a leader in Japan and the Pacific Rim. In addition to the major companies mentioned above, other developers of safety medical needles include Med-Design Corporation, ICU Medical, Inc., Now Medical Technologies, Retractable Technologies, Inc., Medi-Hut Co., Inc., Medisys Technologies, Inc., and Smiths Medical.

Competitive suppliers of safety Huber needle products with an integral safety feature or mechanism include Now Medical, Smiths Medical, Horizon Medical Products, Inc., B. Braun, and Churchill Medical Ltd. We believe our LiftLoc® Safety Infusion Set provides significant advantages versus competitive safety Huber needle products on the market.

Leading suppliers in the blood collection (phlebotomy) needle market are BD, Kendall and Terumo.

The specialty needle market includes a wide variety of needles including Huber, spinal, epidural, biopsy, dental, dialysis, plasma aphaeresis, blood donor collection sets, guidewire introducer, PICC introducer, Veress and opthalmic needles. Numerous companies compete within the various markets associated with each of these needles. These companies include Cardinal Health, Arrow, Bard, B. Braun, Kendall, Cook, Inc., BD, Horizon Medical Products, Boston Scientific, Guidant, ICU Medical, Inc., Merit, Medtronic, Manan Medical Products, Hart Enterprises, Baxter International, Inc., Johnson & Johnson, Medamicus, Needle Tech, Terumo, Daum, U.S. Biopsy, Kimberly Clark Corporation, and Abbott Laboratories.

The leading suppliers in the IV catheter market are BD and Medex. Other suppliers of IV catheters with minor positions in this market include B. Braun and Terumo.

Conventional needle products have competed primarily on the basis of price. However, we believe the safety needle market offers substantial opportunities for premium priced products. We expect to compete on the basis of healthcare worker safety, ease of use, patient comfort, added product features and compliance with state, federal and OSHA regulations. We believe our products will perform well based on product design features and provide attractive margins for our partners and us at a reasonable cost to the end user.

Company Background

Specialized Health Products, Inc. ("SHP"), a Utah corporation, was incorporated in November 1993. On July 28, 1995, SHP became a wholly owned subsidiary of SHPI, a Delaware corporation, through a merger with a subsidiary of SHPI (the "Acquisition"). On that date SHP changed its name to "Specialized Health Products International, Inc ("SHPI")." The persons serving as officers and directors of SHP immediately prior to the consummation of the Acquisition were elected to the same offices with SHPI and retained their positions as directors and officers of SHP. In addition, the outstanding securities of SHP became outstanding securities of SHPI.

We restructured our management team and board of directors in November 2001 following a private placement of preferred stock to Galen Partners III, L.P., Galen Partners International III, L.P., Galen Employee Fund III, L.P. (collectively, "Galen Partners"), and other accredited investors. In conjunction with the investment, we recruited a new president and CEO and appointed five new members to our board of directors. Our leadership team is highly experienced in both the healthcare and medical safety product sectors. See Item 9 "Directors, Executive Officers, Promoters and Control Persons."

Seasonality of Business

Sales of our products are not subject to seasonal variations.

Backlog

There is no backlog of unfilled orders of our products.

Employees

As of March 22, 2004, we employed 21 people, 11 of which are engineers. All but four of our employees are actively engaged in our research, product development, or sales and marketing efforts.

Our employees are not represented by any labor union, and we believe our relations with employees are good.

Item 2. Description of Property

Our principal offices are located at 585 West 500 South, Bountiful, Utah, under the terms of a lease with an unaffiliated lessor, which expires on May 31, 2006, subject to our right to extend the lease term for an additional three years. The offices and laboratories comprise 15,574 square feet of space. We believe that our current office space will be adequate to meet the needs of current and expected growth for the foreseeable future. We may, however, require additional warehousing or manufacturing facilities in the future depending upon the volume of products sold and the manufacturing arrangements we develop.

Item 3. Legal Proceedings

In December 2002, BD filed a lawsuit against Tyco Healthcare in the United States Court of the District of Delaware, asserting that Tyco Healthcare's Monoject Magellan™ safety products infringe upon BD's U.S. Patent No. 5,348,544 ('544 Patent), titled "Single-Handedly Actuable Safety Shield for Needles." BD is seeking injunctive relief as well as damages, including attorneys' fees and costs, in an unspecified amount. Tyco Healthcare responded in court filings that the Monoject Magellan™ safety products do not infringe the '544 Patent. Moreover, Tyco Healthcare asserted in court filings that the '544 patent is invalid and unenforceable. A trial date has been scheduled for October 2004.

Under a Development and License Agreement executed between Tyco Healthcare and us related to the Monoject Magellan™ safety products, Tyco Healthcare is exercising its right to withhold up to fifty percent (50%) of royalties due as an offset against litigation expenses related to BD's lawsuit discussed above. This right continues during the period in which such litigation is pending. If, as a result of judgment in the litigation or settlement with BD, Tyco Healthcare is required to pay royalty and/or other monies to BD, Tyco Healthcare may thereafter deduct from the amount of royalties due us on unit sales of products alleged to infringe, an amount which is the lesser of all royalties and/or other monies paid by Tyco Healthcare to BD, or fifty percent (50%) of all royalty payments otherwise payable to us.

Based on information obtained during the fourth quarter of 2003 related to costs incurred by Kendall, we have recorded a liability of $1,300,000 at December 31, 2003, which amount is our estimate of the portion of costs associated with BD's suit against Tyco Healthcare that Tyco Healthcare will withhold against the royalties due SHPI through 2005. Additional litigation to enforce patents, to protect proprietary information, or to defend us against alleged infringement of the rights of others may occur. Such litigation would be costly, could divert our resources from other planned activities, and could have a material adverse effect on our results of operations and financial condition.

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

No matters were submitted to a vote of security holders during the fourth quarter of 2003, either through the solicitation of proxies or otherwise.

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PART II

Item 5. Market for Common Equity and Related Stockholder Matters

Dividend Policy

To date, we have not paid dividends on our common stock. The payment of dividends on the common stock, if any, is at the discretion of the board and will depend upon our earnings, if any, our capital requirements and financial condition, and other relevant factors. See Item 6. "Management's Discussion and Analysis or Plan of Operation." We do not intend to declare any dividends in the foreseeable future, but instead intend to retain all earnings, if any, for use in our operations.

Share Price History

Our common stock is traded in the over-the-counter market in what is commonly referred to as the "Electronic" or "OTC Bulletin Board" or the "OTCBB" under the trading symbol "SHPI." The following table sets forth the high and low bid information of our common stock for the periods indicated. The price information contained in the table was obtained from Bloomberg. Note that the over-the-counter market quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission, and that the quotations may not necessarily represent actual transactions in the common stock.

Quarter Ended	High	Low
2002		
March 31	$1.73	$1.25
June 30	$1.43	$1.05
September 30	$1.05	$0.60
December 31	$1.03	$0.65
2003		
March 31	$0.90	$0.61
June 30	$0.75	$0.60
September 30	$1.01	$0.64
December 31	$0.99	$0.80

Holders of Record

At March 22, 2004, there were approximately 310 holders of record of our common stock. The number of holders of record was calculated by reference to our stock transfer agent's books.

Issuance of Securities

None.

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

The following discussion and analysis provides information which management believes is relevant to an assessment and understanding of our consolidated results of operations and financial condition. The discussion should be read in conjunction with the consolidated financial statements and notes thereto.

Overview

We design, develop, manufacture, and license cost-effective, innovative safety healthcare products designed to minimize the risk of accidental needlesticks, which are a leading cause of the spread of blood-borne diseases such as HIV/AIDS and the hepatitis B and C viruses. We have 20 highly differentiated, patented safety needle technologies that apply to virtually all medical needles used today. We manufacture and market certain products, including LiftLoc® Safety Infusion Set, under our own label. Other products are supplied to third parties on an OEM basis or licensed to leading manufacturers and marketers in the disposable medical products industry.

Financial Position

We had $2,405,626 in cash and cash equivalents as of December 31, 2003, a decrease of $3,101,954 from December 31, 2002. Working capital as of December 31, 2003 was $1,506,455 as compared to $4,719,110 at December 31, 2002. These decreases were primarily due to the net cash used to fund operations during 2003.

Product Agreements

License Agreements

Kendall

In November 1999, we entered into a Development and License Agreement with The Kendall Company, a division of Tyco Healthcare Group LP, relating to the production of a line of safety medical needle products, including six syringe products and five other safety needle products. The Kendall Agreement became effective in March 2000. In April 2000, we received $1,464,956 under the Kendall Agreement. We received an additional $1,000,000 in November 2002 in exchange for assigning to Kendall the FlexLoc® and ReLoc™ trademarks and two related U.S. patents and their progeny for a technology. Both of these payments are being recognized ratably over the life of the Kendall Agreement. The assignment of the patent rights to Kendall provides for the Company's retention of an exclusive, royalty-free license in a number of strategic product areas. The Kendall Agreement also provides for us to receive development fees and ongoing royalties, including a $500,000 advance royalty payment that was also received in November 2002.

In April 2002, we entered into a Second Development and License Agreement with Kendall relating to blood collection needles and blood collection needle/holder combinations. Under the terms of the agreement, we receive reimbursement for research and development expenses, payments related to the achievement of certain regulatory and sales milestones, and on-going royalty payments on all product sales.

Merit Medical

In January 2001, we entered into a License Agreement with Merit Medical Systems, Inc. relating to the manufacture and marketing of safety needle devices for angiographic guidewire introducers. We received an upfront license fee payment of $100,000 in January 2001, which is being recognized ratably over the estimated five-year life of the Merit Agreement. Under the terms of the Merit Agreement, we receive ongoing royalties on net product sales, and began receiving minimum royalty payments in 2002.

TAP Pharmaceutical Products

In July 2002, we entered into a Development and License Agreement with TAP Pharmaceutical Products Inc. whereby TAP acquired the right to attach our proprietary safety needle device to TAP's pre-filled syringes. The TAP Agreement has an effective date of January 1, 2002. Under the TAP Agreement, we receive reimbursement for research and development expenses, payments related to the achievement of certain development and regulatory milestones, and on-going royalty payments based upon the number of

pre-filled syringes manufactured with our proprietary safety needle device. The TAP Agreement is for a minimum period of three years.

Becton, Dickinson and Company

In August 2003, we entered into a License Agreement with Becton, Dickinson and Company relating to the manufacture and marketing of safety needle devices for spinal and epidural needles and certain other specialty needles sold by BD. Under the terms of the agreement, we receive reimbursement for certain research and development expenses, payments related to the achievement of certain regulatory and commercialization milestones, and on-going royalty payments on all product sales.

Distribution Agreements

Bard Access Systems

In September 2001, we entered into a Distribution Agreement with Bard Access Systems, Inc. whereby Bard acquired the non-exclusive right to promote, market, distribute and sell LiftLoc® Safety Infusion Set, which we manufacture, to hospitals and group purchasing organizations. The Bard Agreement excludes alternate site locations. Under the terms of the agreement, we sell finished product to Bard for marketing under Bard's private label. The Bard Agreement is for a two-year period from the initial date of product launch, and automatically renews for successive one-year terms unless terminated by either party in writing not less than 180 days prior to the expiration of the initial term or any renewal term.

Physician Sales & Service

In July 2002, we entered into a Distribution Agreement with Physician Sales and Service, Inc. whereby PSS acquired the non-exclusive right to distribute and sell LiftLoc® Safety Infusion Set. Under the terms of the agreement, PSS purchases SHPI branded product from us for resale to PSS's end-user customers. The PSS Agreement is for a one-year period, which automatically renews for successive one-year terms unless terminated by either party in writing not less than 45 days prior to the expiration of the initial term or any renewal term.

Medline Industries

In August 2002, we entered into a Distribution Agreement with Medline Industries, Inc. whereby Medline acquired the non-exclusive right to distribute and sell LiftLoc® Safety Infusion Set. Under the terms of the agreement, Medline purchases SHPI branded product from us for resale to Medline's end-user customers. The Medline Agreement is for a one-year period, which automatically renews for successive one-year terms unless terminated by either party in writing not less than 45 days prior to the expiration of the initial term or any renewal term.

Cardinal Health

In August 2002, we entered into a Distribution Agreement with Cardinal Health, formerly named Allegiance Healthcare Corporation, whereby Cardinal acquired the non-exclusive right to distribute and sell LiftLoc® Safety Infusion Set. Under the terms of the agreement, Cardinal purchases SHPI branded product from us for resale to Cardinal's end-user customers. The Cardinal Agreement shall continue until 90 days after written notice of termination is received by either party.

ExelInt International

In May 2003, we entered into a Distribution Agreement with ExelInt International, Company whereby Exel acquired the non-exclusive right to promote, market, distribute and sell LiftLoc® Safety Infusion Set. Under the terms of the agreement, we sell finished product to Exel for marketing under Exel's private label. Exel is subject to minimum purchase requirements. The Exel Agreement is for a five-

year period and automatically renews for successive five-year terms unless terminated by either party in writing not less than 180 days prior to the expiration of the initial term or any renewal term.

Other LiftLoc® Distribution Agreements

During 2003, we entered into Distribution Agreements with Medical Specialties Distributors, Inc., Briggs Corporation, Omni Medical Supply, Inc., Wolf Medical Supply, Inc. and Henry Schein, Inc., whereby each company acquired the non-exclusive right to distribute and sell LiftLoc® Safety Infusion Set. Under the terms of these agreements, each company purchases SHPI branded product from us for resale to their end-user customers. Each of the agreements is for a one-year term and shall be renewed automatically for additional, consecutive one-year terms unless terminated by either party in writing not less than 45 days prior to the expiration of the initial term or any renewal term.

In December 2003, we entered into a Distribution Agreement with Biometrix Ltd. whereby Biometrix acquired the non-exclusive right to distribute and sell LiftLoc® Safety Infusion Set in Israel. Under the terms of the agreement, Biometrix purchases SHPI branded product from us for resale to their end-user customers. The agreement is for a three-year term and shall be renewed automatically for additional, consecutive one-year terms unless terminated by either party in writing not less than 45 days prior to the expiration of the initial term or any renewal term.

In February 2004, we entered into a Distribution Agreement with Medical Mart Supplies Ltd. whereby Medical Mart acquired the non-exclusive right to distribute and sell LiftLoc® Safety Infusion Set in Canada. Under the terms of the agreement, Medical Mart purchases SHPI branded product from us for resale to their end-user customers. The agreement runs through December 2005 and shall be renewed automatically for additional, consecutive one-year terms unless terminated by either party in writing not less than 90 days prior to the expiration of the initial term or any renewal term.

In connection with these product agreements, all product introductions are scheduled and controlled by our distribution and license partners. There is no assurance that products will be launched as anticipated, that effective sales and marketing efforts will be maintained, or that we will realize future revenues in excess of any minimum purchase/royalty commitment from these agreements.

We plan to focus our research and development activities on the further development of additional products based upon our intellectual property portfolio and unique safety needle technologies. We plan to focus our business development efforts on continuing discussions and negotiations with third parties to generate revenues through additional OEM manufacturing, distribution and product licensing relationships.

Critical Accounting Policies

Revenue Recognition

Pursuant to Staff Accounting Bulletin ("SAB") No. 101, "Revenue Recognition in Financial Statements," we recognize license revenue when the following criteria have been met: (1) persuasive evidence of an arrangement exists, (2) delivery has occurred or services have been rendered, (3) the price is fixed or determinable and (4) collectibility is reasonably assured.

We have received upfront fees totaling $1,080,000 in 2003 and $230,000 in 2002. These upfront payments are being recognized ratably over the life of the respective agreements.

Product revenues are recognized upon the shipment date of the product, and transfer of both title and risk of loss to the customer.

Royalty revenue is recognized when the related products are sold or upon our fulfillment of any future obligation under the related agreements. Revenue from development agreements is recognized as the services are performed in accordance with the stated terms of the agreements.

Long-Lived Assets

We regularly evaluate whether events or circumstances have occurred that indicate the carrying value of our long-lived assets may not be recoverable. When factors indicate the asset may not be recoverable, we compare the related undiscounted future net cash flows to the carrying value of the asset to determine if impairment exists. If the expected future net cash flows are less than the carrying value, an impairment charge is recognized based on the fair value of the asset. No such impairments were recorded during the years ended December 31, 2003 and 2002.

Stock Based Compensation

We have chosen to account for stock options granted to employees and directors under the recognition and measurement principles of APB Opinion 25 instead of the fair value recognition provisions of SFAS No. 123, "Accounting for Stock Based Compensation", as amended by SFAS No. 148.

Years Ended December 31, 2003 and 2002

During the year ended December 31, 2003, we had total operating revenue of $3,606,574, compared with total operating revenue of $1,630,948 for the year ended December 31, 2002. During 2003, we recognized $2,768,570 in product sales and royalties revenue, $778,124 in technology fees and licensing revenue, and $59,880 in development fee revenue. Cost of goods sold combined with costs incurred to generate development fee revenue in 2003 was $582,575. During 2002, we recognized $487,623 in product sales and royalties revenue, $506,900 in technology fees and licensing revenue and $636,425 in development fee revenue. Costs of goods sold and costs incurred to generate development fee revenue in 2002 were $295,921. The substantial growth in product sales and royalties revenue in 2003 reflects a full year of sales for products introduced into the market in late 2002. The decrease in development fee revenue in 2003 versus 2002 reflects the cessation of development stage work for products introduced into the market in late 2002. We will look to our product agreements, sales of our own branded products through distributors, and additional development and strategic arrangements for future revenue growth.

Research and development ("R&D") expenses in 2003 were $2,595,022 compared to $2,468,347 in 2002. The increase was primarily due to costs incurred in continued development work on the SecureLoc™ technology and the hiring additional of R&D personnel.

Sales and marketing ("S&M") expenses in 2003 were $1,203,310 compared to $437,256 in 2002. The increase was primarily due to the expansion of our sales and marketing staff and travel expenses related to our in-market support of LiftLoc® Safety Infusion Set.

General and administrative ("G&A") expenses in 2003 were $1,139,699 compared to $1,079,927 in 2002, an increase of $59,772. An increase of $61,000 in insurance costs primarily accounts for the total increase in G&A expenses.

Based on information obtained during the fourth quarter of 2003 related to costs incurred by Kendall, we have recorded a liability of $1,300,000, which amount is our estimate of the portions of costs associated with BD's suit against Tyco Healthcare that Tyco Healthcare will withhold against the royalties due SHPI through 2005. The balance remaining at December 31, 2003, is $1,291,365.

Operating expenses in 2003, including the patent litigation expense, were $6,238,031 compared to $3,985,530 in 2002, an increase of $2,252,501. Increased sales and marketing expenses related to our investment in building and developing a distribution network for the LiftLoc® Safety Infusion Set product

line accounted for $766,054 of the total increase in operating expenses. Actual and accrued expenses related to patent litigation accounted for $1,300,000 of the increase.

Other income was $94,910 in 2003 compared to $36,112 in 2002. The change was primarily due to interest earned on higher cash balances during 2003.

Our net loss from operations in 2003 was $3,119,122, compared to $2,614,391 (not including preferred stock dividends) in 2002. The primary factor contributing to the increased loss was the increase in sales and marketing expenses and patent litigation expense, offset in part by the substantial revenue growth achieved in 2003.

Our basic and diluted net loss per share for the year ended December 31, 2003 was ($0.17) per share. This compares to a net loss per share of ($0.33) for the year ended December 31, 2002, of which a loss of ($.18) per share is attributable to the beneficial conversion feature resulting from the sales of Series A preferred stock.

The Series A Preferred Stock Purchase Agreement (the "Series A Agreement") entered into in November 2001 provided that the investors had the right, but not the obligation to acquire additional shares of Series A Preferred Stock at $.458 per share ($5,000,000 total) during the 12 months following the initial closing date of November 7, 2001. In September 2002, Galen Partners exercised their option to purchase the additional shares to which they held rights. Under the terms of the Series A Agreement, the options to purchase held by the remaining qualified investors would expire in thirty days if not exercised. All of those holding options to purchase exercised some or all of their rights, purchasing an additional 10,944,339 shares of Series A Preferred stock. We realized net proceeds of $5,002,957 from the transaction. A non-cash beneficial conversion charge of $3,281,564 was recognized related to this transaction. This amount has been treated as a preferred stock dividend in the 2002 financial statements.

Liquidity and Capital Resources

To date, we have financed our operations principally through private placements of equity securities, the sale of products, technology and patents, advanced royalties, development fees, technology and license fees and proceeds from the exercise of common stock rights. We used net cash for operating activities of $2,845,885 during 2003, compared to net cash used of $2,568,832 for 2002. In addition, during 2003, $256,069 was used for the purchases of intangible assets and property and equipment, compared to $279,952 during 2002. No financing activities were entered into in 2003. Net cash of $5,002,957 was provided from the placement of preferred stock in 2002. As of December 31, 2003, our working capital was $1,506,455 and our current liabilities were $1,993,557.

Our working capital requirements for the foreseeable future will vary based upon a number of factors, including the costs to complete development work, the cost of bringing safety medical needle technologies and other products to commercial viability, the timing of the market launches of new safety needle products and the level of sales of our current products. As of December 31, 2003, we had accounts payable and accrued liabilities totaling $547,940. We also had a current portion of accrued patent litigation expense of $650,000 and current deferred revenue of $795,616, neither of which will require the use of cash. At December 31, 2003, we had cash and cash equivalents of $2,405,626. This cash, along with cash generated from the sale of products, development fees and royalties and $1,000,000 of committed funding from several major stockholders, is expected to provide sufficient cash for us to execute our business plan in 2004. If we are not able to reduce our operating losses, our liquidity will be adversely affected and we may be required to seek additional sources of financing to fund operations. We may not be able to obtain adequate financing when needed or upon satisfactory terms. Failure to raise capital when needed could prevent us from achieving our long-term business objectives.

As of March 22, 2004, we had granted stock options that were exercisable for 6,685,690 shares of common stock at exercise prices ranging from $1.00 to $2.00 per share and issued warrants that are

exercisable for 580,000 shares of common stock exercise prices of $0.02 and $2.00 per share. The exercise of all such stock options and warrants would result in an equity infusion of $9,276,751. A portion of the stock options and warrants are out of the money, certain options are not yet exercisable, and there can be no assurance that any of the stock options or warrants will be exercised.

Recent Accounting Pronouncements

On January 17, 2003, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation No. 46, "Consolidation of Variable Interest Entities – an Interpretation of ARB No. 51" ("FIN 46"). FIN 46 clarifies the application of Accounting Research Bulletin No. 51, "Consolidated Financial Statements," to certain entities in which equity investors do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 is applicable immediate for variable interest entities created after January 31, 2003. For variable interest entities created prior to February 1, 2003, the provisions of FIN 46 are applicable to the Company no later than January 1, 2004. The adoption of FIN 46 is not expected to have a material effect on our financial condition or results of operations.

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity" ("SFAS 150"). SFAS 150 establishes standards on the classification and measurement of certain financial instruments with characteristics of both liabilities and equity. The provisions of SFAS 150 are effective for fiscal periods beginning after December 15, 2004. The adoption of SFAS 150 is not expected to have a material effect on our financial condition or results of operations.

Contractual Obligations

Our contractual obligations as of December 31, 2003 were as follows:

		Payments Due by Year		
Obligation	**Total**	**2004**	**2005**	**Thereafter**
Operating leases	$ 621,804	$ 253,908	$ 260,397	$ 107,499

We lease office space under a non-cancellable operating lease.

Inflation

We do not expect the impact of inflation on operations to be significant.

Risk Factors

In addition to the risks set forth above, we are subject to certain other risk factors due to the industry in which we compete and the nature of our operations. These risk factors include the following:

We have a history of losses and may never become profitable.

We have accumulated deficits totaling $36,809,073 since inception in November 1993. With the exception of the second quarter of 1999, all quarters have had operating losses. Among other things, our ability to achieve profitability is dependent on:

- Successful marketing of our products by our distribution partners and licensees;
- For products that are not subject to distribution or license arrangements, our ability to enter into OEM manufacturing or license arrangements on commercially advantageous terms; and

- Our ability to develop additional safety medical products.

There can be no assurance that we will become profitable.

Our success is dependent on sales generated by our distribution and licensing partners.

We have entered into licensing arrangements with Kendall, TAP, Merit and BD. In addition, we have entered into a private label distribution agreement with Bard and Exel, and distribution agreements for our branded products with Cardinal Health, Medline, PSS, and other specialty distributors. You should consider the following in assessing the value of these agreements and our financial prospects:

- We are reliant on our business partners for substantially all of our product revenues;
- Our product revenues will depend, in part, on the marketing ability, marketing plans and credit-worthiness of our business partners;
- The ability of our business partners to sell our products will depend on competitive factors and the resources such parties commit to the sale of our products. The extent to which our partners commit their resources to the sale of our products is entirely within their control. In addition, our partners are not obligated to pursue the development and commercialization of our products;
- We are dependent on our business partners with respect to release dates for the products under contract;
- Our licensed products and products subject to private label distribution agreements will be marketed under our business partners' labels and goodwill associated with use of the products may inure to the benefit of our business partners rather than to us;
- We have limited sales and marketing capabilities, and those resources are deployed in support of our distributors' efforts. At this time, we do not intend to build a direct sales and marketing infrastructure for commercial sales of products;
- Our distribution and licensing arrangements provide us with only limited protection from changes in manufacturing costs and raw materials costs;
- We may be limited in our ability to negotiate with new business partners upon any renewals of agreements;
- The Kendall Agreement can be terminated upon 15 days written notice;
- BD has filed a lawsuit against Tyco Healthcare asserting that the Monoject Magellan™ safety products infringe upon a BD patent. BD is seeking injunctive relief as well as damages, including attorneys' fees and costs, in an unspecified amount. Under a Development and License Agreement, Tyco Healthcare has the right to withhold up to fifty percent (50%) of royalties due us as an offset against litigation expenses related to charges of infringement by a third party for the manufacture, use or sale of licensed product. This right continues during the period in which such litigation is pending. If, as a result of judgment in the litigation or settlement with BD, Tyco Healthcare is required to pay royalty and/or other monies to BD, Tyco Healthcare may thereafter deduct from the amount of royalties due us on unit sales of products alleged to infringe, an amount which is the lesser of all royalties and/or other monies paid by Tyco Healthcare to BD, or fifty percent (50%) of all royalty payments otherwise payable to us. Based on information obtained during the fourth quarter of 2003 related to costs incurred by Kendall, we have recorded a liability of $1,300,000 as of December 31, 2003, which amount is our estimate of the portion of costs associated with BD's suit against Kendall that Kendall will charge against the royalties due SHPI through 2005;

- Because our licensing arrangements are generally expected to provide our business partners with exclusivity with respect to the products to be marketed by those partners, our success will be highly dependent on the results obtained by our partners and the diligence with which our partners seek to develop, market and sell our products; and

- Our distribution and licensing arrangements do not provide for substantial minimum product royalties in the event our partners do not seek to develop, market or sell our products.

If our distribution and licensing partners are not successful in their efforts to develop, market and sell our products, it may result in the discontinuance of our business due to lack of revenue. These and other factors create uncertainty concerning our ability to generate future revenues and future profits.

In 2003, over fifty percent of our revenues were generated under agreements with two of our corporate partners.

The significant amount of revenues we received in 2003 under these arrangements presents additional risks to our commercial success. If arrangements with either of these partners were terminated or if there is a decline in revenues under either of these arrangements it could have a material adverse effect on us and our revenues and could require us to significantly curtail or even cease operations. In accessing the value of these arrangements you should consider the fact that one of these arrangements may be terminated on fifteen days notice and the other arrangement is subject to annual renewal. In addition, these arrangements are subject to the marketing ability, marketing plans and credit-worthiness of these business partners and the other factors identified in the prior risk factor. There can be no assurance that one or both of these arrangements will not be terminated or that our business partners will be successful in their marketing and sale of the products that are subject to these arrangements.

We are dependent upon our licensing partners or contract manufacturers to manufacture our products.

Under our licensing arrangements, we are primarily relying on licensees to arrange for the commercial manufacture of products. LiftLoc® Safety Infusion Set is manufactured at a contract manufacturer under our authority and supervision. Contracting with third parties or relying on licensees to manufacture products presents the following risks:

- Delays in the manufacture of products could have a material adverse effect on the marketing of the products;

- The manufacturers may not comply with requirements imposed by the FDA or other governmental agencies;

- We may have to share intellectual property rights to improvements in the manufacturing processes or new manufacturing processes for products;

- In those instances where we may seek third-party manufacturers for new products, we may not be able to locate acceptable manufacturers or enter into favorable long-term agreements with them; and

- We may not be able to find substitute manufacturers, if necessary.

Any of these factors could delay commercialization of products and adversely affect the sale of the products and license or joint venture revenues.

Possible Need for Additional Funding.

At December 31, 2003, we had cash and cash equivalents of $2,405,626. This cash, along with anticipated cash generated from the sale of products, development fees and royalties and $1,000,000 of committed long-term funding from several major stockholders, is expected to provide sufficient cash for us to execute our business plan in 2004. If we are not able to reduce our operating losses, our liquidity will be

adversely affected and we may be required to seek additional sources of financing to fund operations. If we are not able to reduce our operating losses, we may be required to seek additional sources of financing to fund operations. We may not be able to obtain adequate financing when needed or upon satisfactory terms. Failure to raise capital when needed could prevent us from achieving our business objectives and may require us to significantly curtail or even cease operations.

Our medical devices must be cleared or approved by the FDA before they can be sold in the U.S.

Our ability to receive revenue from our products is subject to obtaining proper regulatory approvals. Moreover, obtaining FDA approval or clearance to market a product can be a lengthy and costly process, which, in some cases, involves extensive clinical studies. While we or our partners have received FDA clearance for our safety syringe needle, safety Huber needle products, safety angiographic needle, pre-filled syringe safety needle, and blood collection devices, we or our distribution partners or licensees may not be able to obtain the necessary FDA authorizations to allow marketing of our other products in a timely fashion, or at all.

Once the necessary FDA approvals or clearances are obtained, later problems with the product could cause the FDA to suspend or revoke the approvals or clearances. Also, once the FDA provides clearance to market our products, our distribution partners or licensees are subject to continuing requirements governing, among other things, the claims that can be made with respect to the products and manufacturing processes. Failing to comply with the FDA's requirements can result in issuance of FDA Warning Letters, FDA refusal to approve or clear products, revocation or withdrawal of approvals previously granted, product seizures, injunctions, recalls, operating restrictions, limitations on continued marketing and civil and criminal penalties.

Our manufacturing activities require us to comply with ongoing FDA requirements for submission of post market information. In addition, we are required to adhere to requirements pertaining to the FDA's current QSR. The current QSR requirements govern the methods, facilities and controls used for the manufacture, testing, design, packaging, labeling and storage of medical devices.

Our failure or the failure of our distribution partners or licensees to comply with the FDA and other applicable regulations could cause our business to be harmed significantly.

There are negative pricing pressures on safety products.

Prices for our safety products may be higher than for competing conventional products that are not designed to provide the safety protection afforded by our products. Our prices, however, are expected to be competitive with those of competing safety products. Continuing pressure from third-party payers to reduce costs in the healthcare industry, as well as increasing competition from safety products made by other companies, could adversely affect our selling prices. Reductions in selling prices could adversely affect our operating margins if we cannot achieve corresponding reductions in manufacturing costs.

Our business could be adversely affected by changes in safety medical product technology.

Our products are in various stages of production, pre-production, development and research. There is no assurance that development of superior products by competitors or changes in technology will not eliminate the need for our products. The introduction of competing products using different technology could adversely affect our attempts to develop and market our products.

Our products may not be accepted by the market.

The use of safety medical products, including our products, is relatively new. The market may not accept our products. Their acceptance will depend in large part on our ability to demonstrate the operational advantages, safety, efficacy, and cost-effectiveness of our products in comparison with competing products and our ability to distribute our products through major medical products companies or distributors. Our products may not achieve market acceptance and major medical products companies or distributors may not sell our products.

Our long-term success is dependent on the success of our research and development efforts.

Many of our safety medical needle technologies and products are still in various stages of pre-production, development and research. We are also exploring additional product applications for our technologies. The continued development of our products and development of additional applications and new products is important to our long-term success. There can be no assurance that our technologies or products will be developed or, if developed, that they will be successful.

Our success is dependent on our patents and proprietary rights.

Our future success depends in part on our ability to protect our intellectual property and maintain the proprietary nature of our technologies through a combination of patents and other intellectual property arrangements. The protection provided by our patents and patent applications, if issued, may not be broad enough to prevent competitors from introducing similar products. In addition, our patents, if challenged, may not be upheld by the courts of any jurisdiction. Patent infringement litigation, either to enforce our patents or to defend us from infringement suits, would be expensive and, if it occurs, could divert our resources from other planned uses. Any adverse outcome in such litigation could have a material adverse effect on our ability to market, sell or license the related products. Patent applications filed in foreign countries and patents in such countries are subject to laws and procedures that differ from those in the U.S. Patent protection in such countries may be different from patent protection under U.S. laws and may not be as favorable to us. Some of our international patent prosecution efforts are funded by third parties. The failure of the funding parties to pay for the international patent prosecution costs would materially affect our ability to prosecute these patents. We also attempt to protect our proprietary information through the use of confidentiality agreements and by limiting access to our facilities. There can be no assurance that our program of patents, confidentiality agreements and restricted access to our facilities will be sufficient to protect our proprietary technology.

We may not have adequate resources to manage anticipated growth.

We may not be equipped to successfully manage any future periods of rapid growth or expansion, which could be expected to place a significant strain on our managerial, operating, financial and other resources. Our future performance will depend, in part, on our ability to manage growth effectively, which will require us to:

- Improve existing and implement management information systems, operating, administrative, financial and accounting systems and controls;
- Maintain close coordination among engineering, accounting, finance, marketing, sales and operations; and
- Retain and train additional management, technical and marketing personnel.

There is intense competition for management, technical and marketing personnel in our business. Our failure to attract and retain additional key employees could have a material adverse effect on our ability to continue as a going concern.

We are dependent on Management and Technical Personnel.

Our success depends upon the skills, experience and efforts of our management, and technical personnel (the "working team"). Should the services of one or more members of our present working team become unavailable for any reason, our business could be adversely affected. The employment agreements that we have in place with the working team allow members of the working team to terminate their employment at any time. There is no assurance that we will be able to retain the existing working team or attract new employees of the caliber needed to achieve our objectives.

Because we are significantly smaller than the majority of our competitors, we may lack the resources needed to capture market share.

We are engaged in a highly competitive business and will compete directly with companies that have longer operating histories, more experience, substantially greater financial resources, greater size, more substantial research and development and marketing organizations, established distribution channels and are better situated in the market than us. Our competitors and potential competitors include Arrow, Baxter International, B. Braun, Becton, Dickinson and Company, Boston Scientific, Churchill Medical Ltd., Cook, Inc., Horizon Medical Products, ICU Medical, Inc., Johnson & Johnson, Kendall, Manan Medical Products, Medamicus, Med-Design Corporation, Medi-Hut Co., Inc., Medisys Technologies, Inc., NMT Group PLC, Now Medical Technologies, Smiths Medical, Retractable Technologies, Inc., Terumo, and several others identified in Item 1 "Description of Business-Competition". Our competitors may use their economic strength to influence the market to continue to buy their existing products. Our competitors may also be potential strategic partners with respect to various products as are, for example, Kendall, Bard and Merit. We do not have an established customer base and are likely to encounter a high degree of competition in developing a customer base. One or more of these competitors could use their resources to improve their current products or develop new products that may compete more effectively with our products. New competitors may emerge and may develop products that compete with our products. No assurance can be given that we will be successful in competing in this industry.

Potential product liability relating to failure of our safety products.

The sale of safety medical devices entails an inherent risk of liability in the event of product failure or claim of harm caused by product operation. There can be no assurance that we will not be subject to such claims, that any claim will be successfully defended or, if we are found liable, that the claim will not exceed the limits of our insurance. Our current insurance coverage is in the amount of $1 million per occurrence and $2 million in aggregate. We also have an umbrella policy in the amount of $4 million. In some cases, we have indemnification arrangements in place with strategic partners who are selling our products under their label or distributing our branded products. There is no assurance that we will maintain product liability insurance in the future, that such insurance will be available, or that we will not be subject to product liability claims in excess of our insurance coverage.

Uncertainties in the healthcare industry create uncertainties regarding medical safety products.

The healthcare industry is subject to changing political, economic and regulatory influences that may affect the procurement practices and operations of healthcare facilities. During the past several years, the healthcare industry has been subject to increased government regulation of reimbursement rates and capital expenditures. Among other things, third-party payers are increasingly attempting to contain healthcare costs by limiting both coverage and reimbursement levels for healthcare products and procedures. Because prices of our products may exceed the price of conventional products, the cost control policies of third-party payers, including government agencies, may adversely affect use of our products.

Limitations on director liability.

Our Certificate of Incorporation provides, as permitted by Delaware law, that our directors are not personally liable to the company or its stockholders for monetary damages for any action or failure to take any action, with specified exceptions. These provisions may discourage stockholders from bringing suit against a director for breach of duty and may reduce the likelihood of derivative litigation brought by stockholders on behalf of the company against a director. In addition, our Certificate of Incorporation and Bylaws provide for mandatory indemnification of directors and officers to the fullest extent permitted by Delaware law and we have entered into contracts with our directors and officers providing for such indemnification.

Anti-takeover provisions of certificate of incorporation and bylaws may discourage non-negotiated takeover of our company.

Our Certificate of Incorporation provides for the division of the board of directors into three classes substantially equal in number. At each annual meeting of stockholders one class of directors is to be

elected for a three-year term. Amendments to this provision must be approved by a two-thirds vote of all the outstanding stock entitled to vote; the number of directors may be changed by a majority of the entire board of directors or by a two-thirds vote of the outstanding stock entitled to vote. Meetings of stockholders may be called only by the board of directors, our CEO, or our president. Stockholder action may not be taken by written consent. These provisions could have the effect of (i) discouraging attempts at non-negotiated takeovers that may provide for stockholders to receive a premium price for their stock, or (ii) delaying or preventing a change of control, which some stockholders may believe is in their interest.

Our common stock price may continue to be volatile.

Market prices of securities of medical technology companies are highly volatile from time to time. The trading price of our common stock may be significantly affected by factors such as the announcement of new product or technical innovations by us or our competitors, proposed changes in the regulatory environment, or by other factors that may or may not relate directly to us. Sales of substantial amounts of common stock (including stock which may be issued upon exercise of warrants or stock options), or the perception that such sales may occur, could adversely affect the trading price of our common stock.

We have outstanding 21,861,369 Shares of Common Stock whose holders have been granted registration rights.

In October 2001, the Company entered into an Investor Rights Agreement with the purchasers of the Company's Series A Preferred Stock. These shares are being automatically converted into 21,861,369 shares of our common stock. Holders of these shares have been granted demand and piggy-back registration rights with respect to these shares. In addition, in March 22, 2004, the Company entered into an agreement whereby several major stockholders agreed to make up to $1,000,000 in funding available to the Company under the terms of a convertible note. As partial consideration for this commitment, the Company issued to these stockholders warrants to acquire 80,000 shares of the Company's common stock. The Company has also granted demand and piggy-back registration rights with respect to the common stock underlying these warrants and the common stock into which the $1,000,000 convertible promissory note, if issued, may be convertible. Sales of this common stock in the public market could materially and adversely affect the market price of the common stock.

We do not anticipate paying dividends in the foreseeable future.

We have never paid dividends on our common stock. The payment of dividends, if any, on the common stock in the future is at the discretion of the board of directors and will depend upon our earnings, if any, capital requirements, financial condition and other relevant factors. The board of directors does not intend to declare any dividends on our common stock in the foreseeable future.

Our common stock is subject to dilution.

As of December 31, 2003, there were 17,831,479 shares of our common stock issued and outstanding. On this date we also had outstanding 21,861,369 shares of Series A Preferred Stock, which is convertible into the same number of shares of common stock. The Series A Preferred Stock automatically converted into common stock because the average closing share price of our common stock, as reported on the OTC Bulletin Board, exceeded $1.374 per share for twenty consecutive trading days between January 26, 2004 and February 23, 2004. After the Series A Preferred Stock certificates are returned and the shares of common stock are issued upon conversion of the preferred stock, we will have 39,692,848 shares of common stock outstanding. This amount does not include an additional aggregate of 7,185,690 additional shares of our common stock that are issuable pursuant to stock options granted under our stock option plans and warrant agreements.

No assurance of a liquid public market for our common stock.

There can be no assurance as to the depth or liquidity of any market for our common stock or the prices at which holders may be able to sell their shares. As a result, an investment in our common stock may not be totally liquid, and investors may not be able to liquidate their investment readily or at all when they need or desire to sell.

Applicability of low priced stock risk disclosure requirements may adversely affect the prices at which our common stock trades.

Our common stock may be considered a low priced security under rules promulgated under the Securities Exchange Act of 1934 (the "Exchange Act"). Under these rules, broker-dealers participating in transactions in low priced securities must first deliver a risk disclosure document which describes the risks associated with such stocks, the broker-dealer's duties, the customer's rights and remedies, and certain market and other information, and make a suitability determination approving the customer for low priced stock transactions based on the customer's financial situation, investment experience and objectives. Broker-dealers must also disclose these restrictions in writing to the customer, obtain specific written consent of the customer, and provide monthly account statements to the customer. With these restrictions, the likely effect of designation as a low priced stock will be to decrease the willingness of broker-dealers to make a market for the stock, to decrease the liquidity of the stock and to increase the transaction cost of sales and purchases of such stock compared to other securities.

Item 7. Financial Statements

See index to consolidated financial statements and consolidated financial statement schedules beginning on page F-1 hereof.

Item 8. Changes In and Disagreements With Accountants on Accounting and Financial Disclosure

None.

Item 8A. Controls and Procedures

We have evaluated, with the participation of our Chief Executive Officer and Chief Financial Officer, the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2003, pursuant to Exchange Act Rule 13a-15. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective in timely alerting them to material information relating to that which is required to be included in our periodic SEC filings. There have been no significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation.

PART III

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

Set forth below is certain information concerning each of our directors and executive officers as of March 22, 2004.

Name	Age	Position	With the Company Since
Jeffrey M. Soinski	42	President, Chief Executive Officer and Director	2001
Guy J. Jordan, Ph.D. (1) (2) (3)	55	Chairman of the Board	2001
Donald D. Solomon, Ph.D.	53	Vice President, Chief Operating Officer, Chief Technical Officer and Director	2000
Paul S. Evans	41	Vice President, Business Development, General Counsel and Secretary	2000
Keith L. Merrell	58	Controller, Acting Chief Financial Officer and Treasurer	2000
David W. Jahns (2)	38	Director, Chairman of Compensation Committee	2001
Stuart A. Randle (1) (3)	44	Director, Chairman of Nominating Committee	2001
Stephen I. Shapiro (2)	59	Director	2001
Robert R. Walker (1) (3)	73	Director, Chairman of Audit Committee	1994

(1) Member of Audit Committee.
(2) Member of Compensation Committee.
(3) Member of Nominating Committee.

Jeffrey M. Soinski. Mr. Soinski is our President, Chief Executive Officer and a director. His term as a director expires at the 2005 annual meeting of stockholders. Mr. Soinski brings over 20 years of general management, business development and marketing experience to our company, including several years as the President and Chief Executive Officer of ViroTex Corporation ("ViroTex"), a venture-backed pharmaceutical company focused on the development and commercialization of proprietary drug delivery systems. Mr. Soinski was with ViroTex from 1992 through 1999. He merged ViroTex into Atrix Laboratories, Inc. (Nasdaq: ATRX) in 1998, and continued working with Atrix on a transitional basis through 1999. From 2000 through 2001, Mr. Soinski was the Managing Partner and Chief Executive Officer of Mad Dogs & Englishmen, a marketing communications firm with offices in New York and San Francisco. Mr. Soinski has a BA degree from Dartmouth College.

Guy J. Jordan, Ph.D. Dr. Jordan is our Chairman of the board. His term as a director expires at the 2005 annual meeting of stockholders. Dr. Jordan brings a wealth of senior management healthcare experience to our company, with a strong focus in the areas of vascular disease and oncology. Dr. Jordan recently retired as Group President for C.R. Bard, Inc. with global operating responsibility for their oncology businesses, geographic responsibility for Canada, Australia, Latin America and Asia Pacific, and functional responsibility for all of Bard's research and development. Prior to joining C.R. Bard in 1986, Dr. Jordan held senior product development positions at American Cyanamid. Dr. Jordan has a Ph.D. degree from Georgetown University and an MBA from Fairleigh Dickinson University.

Donald D. Solomon, Ph.D. Dr. Solomon is Chief Operating Officer, Chief Technology Officer, a Vice President and a director. His term as a director expires at the 2004 annual meeting of stockholders. Dr. Solomon joined us in October 2000 and has served as a director since March 2001. He has over 24 years of medical product experience in research, product development, engineering and manufacturing. Prior to joining our company, Dr. Solomon was the Vice President of Research and Development at Johnson & Johnson Medical – Vascular Access from 1997 to 2000. Prior to that Dr. Solomon spent 14 years at Becton Dickinson ("BD"), and held positions as Worldwide Director of R&D for BD Pharmaceutical Systems Division based in France, and Director of R&D for Biocompatible Polymer Development at the BD Infusion Therapy Division. Dr. Solomon holds 38 patents and is the author of 52 scientific publications. He received Masters and Ph.D. degrees from Case Institute of Technology at Case Western Reserve University.

Paul S. Evans. Mr. Evans is our Vice President, Business Development, General Counsel and corporate Secretary. He joined us in June 2000. Mr. Evans manages our intellectual property portfolio and corporate legal matters, and is extensively involved in business development efforts. Mr. Evans brings a wide range of intellectual property and corporate legal experience to us, having previously served as Vice President, General Counsel for an R&D company (1994 to 2000), and as a patent attorney with the law firm of Snow, Christensen & Martineau. Prior to earning his law degree, Mr. Evans worked as a Project/Design Engineer for Morton International (now Autoliv). He holds BS and JD degrees from the University of Utah.

Keith L. Merrell. Mr. Merrell is our Controller, Acting Chief Financial Officer and Treasurer. He joined us in July 2000. Mr. Merrell draws on 29 years of accounting experience to manage all of our accounting functions and to interface with our independent public accountants. He spent two years in the field of public accounting, and served as Chief Financial Officer or Controller of four companies prior to his joining us. His business career also includes extensive experience in management, sales and marketing, and consulting. He served as Vice President – Western Operations for Michelex, an injection molding company with corporate headquarters in New York, from 1998 to 2000. From 1991 to 1998 he served as Director of Finance for The Duplication Group, planning, implementing and bringing online the first CD manufacturing facility in the intermountain area. He graduated from Arizona State University with a BS degree in Accounting.

David W. Jahns. Mr. Jahns serves as one of our directors. His term as a director expires at the 2006 annual meeting of stockholders. Mr. Jahns is a General Partner and principal of Galen Partners. Since joining Galen in 1993, Mr. Jahns has been responsible for making and managing investments in several of the firm's portfolio companies. He is an experienced board member and currently serves on the boards of DAOU Systems, Inc. and several of Galen's privately held portfolio companies. Prior to joining Galen, Mr. Jahns worked in the Corporate Finance Division at Smith Barney, where he worked on a variety of corporate finance and merger and acquisition related transactions, and assisted in the marketing of public offerings. Mr. Jahns has an MBA degree from the J. L. Kellogg Graduate School of Management at Northwestern University and a BA degree from Colgate University.

Stuart A. Randle. Mr. Randle serves as one of our directors. His term as a director expires at the 2004 annual meeting of stockholders. Mr. Randle is a highly experienced healthcare executive with over 20 years of operating successes. From 1998 to 2001, Mr. Randle was the President and CEO of ACT Medical, Inc., a leading company providing outsourcing services to the medical device, biotech and diagnostic industries. He merged ACT Medical, Inc. with MedSource Technologies in 2001. From 1996 through 1998, Mr. Randle was President, Northeast Region, for Allegiance Corporation, a $5 billion medical products distribution and manufacturing company. He is also the past President, New England Region, for Baxter Healthcare Corporation. Mr. Randle has an MBA degree from the J. L. Kellogg Graduate School of Management at Northwestern University and a BS degree from Cornell University.

Stephen I. Shapiro. Mr. Shapiro serves as one of our directors. His term as a director expires at the 2005 annual meeting of stockholders. Mr. Shapiro has over 30 years of relevant medical device and equipment industry experience, with special expertise in a wide variety of healthcare markets, particularly

high-volume sterile disposables, critical care instruments and cardiovascular devices. Mr. Shapiro began his career at Union Carbide Clinical Diagnostics and Becton Dickinson, where he was Director of Advanced R&D and New Business Development. In 1982, he joined The Wilkerson Group, a leading management consultancy to pharmaceutical, medical device, and diagnostic companies. Mr. Shapiro was Managing Director and a principal of The Wilkerson Group at the time of its acquisition by IBM in 1996. In 1999, Mr. Shapiro left The Wilkerson Group (now IBM Healthcare Consulting) to focus on sourcing and evaluating investments for two premier healthcare venture capital firms, including Galen Partners. He currently serves on the board of Novoste Corporation and Closure Medical Corporation. Mr. Shapiro has a BS degree from the Massachusetts Institute of Technology and an MS degree in biomedical engineering from the University of California, Berkley.

Robert R. Walker. Mr. Walker serves as one of our directors. His term as a director expires at the 2006 annual meeting of stockholders. Since 1992, Mr. Walker has been principally self-employed as a consultant in the healthcare industry primarily in the area of start-up medical device companies. From 1976 to 1992, Mr. Walker was employed by IHC Affiliated Services Division of Intermountain Healthcare, a regional hospital company. He retired as President of IHC Affiliated Services in 1992. He is also a former Chairman of the board of AmeriNet, Inc., a national group purchasing organization for hospitals, clinics, detox/drug centers, emergency, nursing homes, private laboratories, psychiatric centers, rehabilitation facilities, surgical centers and other institutions. Mr. Walker is a member of the American Hospital Association and the Hospital Financial Management Association. He has a BS degree in Business Administration from the University of Utah.

Our executive officers are elected by the board on an annual basis and serve at the discretion of the board.

The Company has adopted a Code of Ethics that applies to our principal executive officer, principal financial officer, principal accounting officer and other senior financial officers. Our Code of Ethics is posted on the Company's Web site.

Board Committees

We have a standing Audit Committee established in accordance with section 3(a)(58)(A) of the Exchange Act, a Compensation Committee and a Nominating Committee.

The Audit Committee

The Company's Audit Committee held three meetings during 2003. The function of the Audit Committee as detailed in the Audit Committee Charter is to provide assistance to the Board in fulfilling their responsibility to the stockholders, potential stockholders, and investment community relating to corporate accounting, reporting practices of the Company and the quality and integrity of the financial reports of the Company. In so doing, it is the responsibility of the Audit Committee to maintain free and open means of communication between the directors, the independent auditors and Company management. The Company believes that the members of the Audit Committee are independent as defined by Rule 4200(a) of NASD's listing standards. The members of the Audit Committee are Guy J. Jordan, Stuart A. Randle and Robert R. Walker. Mr. Walker, Chairman of our Audit Committee, serves as our financial expert on that committee.

The Compensation Committee

The Company's Compensation Committee held one meeting during 2003. The Compensation Committee administers the Company's stock option plan, establishes a general compensation policy for the Company and, except as prohibited by applicable law, may take any and all actions that the Board could take relating to the compensation of employees, directors and other parties. The members of the Compensation Committee are David W. Jahns, Guy J. Jordan, and Stephen I. Shapiro. David W. Jahns is Chairman of our Compensation Committee.

The Nominating Committee

The Nominating Committee was formed in January 2004. As a result, it held no meetings in 2003. The Nominating Committee's Charter and Policies are available on the Company's website, which is located at www.shpi.com. The Company believes that the members of the Nominating Committee are independent as defined by Rule 4200(a) of NASD's listing standards. The members of the Nominating Committee are Guy J. Jordan, Stuart A. Randle and Robert R Walker. Stuart A. Randle is Chairman of our Nominating Committee.

The Nominating Committee has held one meeting during 2004 to date in which it recommended the nomination of Messrs. Randle and Solomon for reelection to the Board. The function of the Nominating Committee, as detailed in the Nominating Committee's Charter, is to recommend to the Board the slate of director nominees for election to the Board and to identify and recommend candidates to fill vacancies occurring between annual stockholder meetings. It is the policy of the Nominating Committee to consider candidates recommended by security holders, directors, officers and other sources, including, but not limited to, third-party search firms. Security holders of the Company may submit recommendations for candidates for the Board. All recommendations shall be submitted to Paul Evans at SHPI, Inc, 585 West 500 South, Bountiful, Utah 84010 (telephone: 801-298-3360, email: pevans@shpi.com). Such submissions should include the name, contact information, a brief description of the candidate's business experience and such other information as the person submitting the recommendation believes is relevant to the evaluation of the candidate. Paul Evans will then pass all such recommendations on to the Nominating Committee for consideration. For candidates to be considered for election at the next annual meeting stockholders, the recommendation must be received by the Company no later than 120 calendar days prior to the date that the Company's proxy statement is released to security holders in connection with such meeting.

The Nominating Committee has not established any fixed minimum qualifications in order to consider a proposed candidate for election to the Board. However, the Nominating Committee has a strong preference for candidates with prior board of director experience with public companies. The Nominating Committee will also consider such other factors as it deems appropriate to assist in developing a board and committees that are diverse in nature and comprised of experienced and seasoned advisors. These factors include judgment, skill, diversity (including factors such as race, gender or experience), integrity, experience with businesses and other organizations of comparable size, the interplay of the candidate's experience with the experience of other Board members, and the extent to which the candidate would be a desirable addition to the Board and any committees of the Board.

The Nominating Committee will evaluate whether an incumbent director should be nominated for re-election to the Board or any committee of the Board upon expiration of such director's term using the same factors as described above for other Board candidates and the committee will also take into account the incumbent director's performance as a Board member. Failure of any incumbent director to attend at least seventy-five percent (75%) of the Board meetings held in any calendar year will be viewed negatively by the Nominating Committee in evaluating the performance of such director.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act requires our executive officers, directors and persons who beneficially own more than 10% of our common stock to file initial reports of ownership and reports of changes in ownership with the SEC. Such persons are required by SEC regulations to furnish us with copies of all Section 16(a) forms filed by such persons.

Based solely on our review of forms furnished to us and representations from reporting persons, we believe that all filing requirements applicable to our executive officers, directors and more than 10% stockholders were complied with during 2003.

Item 10. Executive Compensation

Incorporated by reference to the Company's definitive proxy statement, which the Company intends to file with the Securities and Exchange Commission within 120 days after the close of its fiscal year.

Item 11. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of March 22, 2004, for: (i) each person who is known by us to beneficially own more than five percent of our common stock, (ii) each of our directors, (iii) each of our Named Executive Officers, and (iv) all directors and executive officers as a group. On March 22, 2003 the Company had 39,782,848 shares of Common Stock outstanding. This figure includes the 21,861,369 shares of Series A Preferred stock that were converted into Common Stock on a one-for-one basis in the first quarter of 2004.

Name and Address of Beneficial Owner(1)	Shares Beneficially Owned(2)	Percentage of Total(2)	Position
Jeffrey M. Soinski (3)	1,521,980	3.68	President, CEO and Director
Guy J. Jordan, Ph.D. (4)	322,220	*	Chairman of the Board
Donald D. Solomon, Ph.D. (5)	600,259	1.49	Vice President, COO, CTO and Director
Paul S. Evans (6)	444,253	1.10	Vice President, Business Development, General Counsel, and Secretary
Keith L. Merrell (7)	168,715	*	Controller, Acting CFO and Treasurer
David W. Jahns (8)	80,542	*	Director
Stuart A. Randle (9)	77,765	*	Director
Stephen I. Shapiro (10)	146,045	*	Director
Robert R. Walker (11)	187,542	*	Director
Executive Officers and Directors as a Group (9 persons)	3,361,779	7.79	
Galen Partners III, L.P. and affiliates (12)	15,336,413	38.5	

* Less than 1%.

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(1) Except where otherwise indicated, the address of the beneficial owner is deemed to be the same address as the company.

(2) Beneficial ownership is determined in accordance with SEC rules and generally includes holding voting and investment power with respect to the securities. Shares of common stock subject to options or warrants currently exercisable, or exercisable within 60 days, are deemed outstanding for computing

the percentage of the total number of shares beneficially owned by the designated person, but are not deemed outstanding for computing the percentage for any other person.

(3) Includes 11,586 shares of common stock purchased through our 401(k) plan and options to acquire 1,510,394 shares of common stock. Does not include options to acquire 978,020 shares of common stock that vest 60 days beyond March 22, 2004.

(4) Includes options to acquire 322,220 shares of common stock. Does not include options to acquire 77,780 shares of common stock that vest 60 days beyond March 22, 2004.

(5) Includes 10,000 shares of common stock, 65,666 shares of Series A Preferred Stock that is immediately convertible into the same number of shares of common stock, 62,101 shares of common stock purchased through our 401(k) plan and options to acquire 462,492 shares of common stock. Does not include options to acquire 237,508 shares of common stock that vest 60 days beyond March 22, 2004.

(6) Includes 61,000 shares of common stock, 41,609 shares of common stock purchased through our 401(k) plan and options to acquire 341,644 shares of common stock. Does not include options to acquire 158,356 shares of common stock that vest 60 days beyond March 22, 2004.

(7) Includes 36,000 shares of common stock, 36,953 shares of common stock purchased through our 401(k) plan and options to acquire 95,762 shares of common stock. Does not include options to acquire 84,238 shares of common stock that vest 60 days beyond March 22, 2004.

(8) Includes options to acquire 80,542 shares of common stock. Does not include options to acquire 19,548 shares of common stock that vest 60 days beyond March 22, 2004. Does not include shares held by Galen Partners III, L.P. David Jahns is a member of Claudius, L.L.C., a Delaware limited liability company, and a general partner of Galen Partners III, L.P. and Galen Partners International III, L.P. See note (12) below.

(9) Includes options to acquire 77,765 shares of common stock. Does not include options to acquire 72,235 shares of common stock that vest 60 days beyond March 22, 2004.

(10) Includes 65,503 shares of Series A Preferred Stock that is immediately convertible into the same number of shares of common stock and options to acquire 80,542 shares of common stock. Does not include options to acquire 19,458 shares of common stock that vest 60 days beyond March 22, 2004.

(11) Includes stock options to purchase 124,542 shares of common stock and 63,000 shares of common stock that Mr. Walker is deemed to beneficially own through a trust. Does not include options to acquire 69,458 shares of common stock that vest 60 days beyond March 22, 2004.

(12) Information regarding Galen Partners III, L.P. and its affiliates is derived from the Form 4 filed by Galen Partners III, L.P. with the Securities and Exchange Commission on September 9 and September 26, 2002. Shares owned represent 13,937,735 shares of Series A Preferred Stock held of record by Galen Partners III, L.P., 1,261,605 shares of Series A Preferred Stock held of record by Galen Partners International III, L.P., and 57,073 shares of Series A Preferred Stock held of record by Galen Employee Fund III, L.P. Also includes warrants to purchase 80,000 shares of common stock. William R. Grant, Bruce F. Wesson, L. John Wilkerson, David W. Jahns, Srini Conjeevaram, and Zubeen Shroff are all natural persons and are the members of Claudius, L.L.C., a Delaware limited liability company, the general partner of Galen Partners III, L.P. and Galen Partners International III, L.P. Bruce F. Wesson is the President of Wesson Enterprises, Inc., a Delaware corporation, which is the general partner of Galen Employee Fund III, L.P.

Series A Preferred Stock

At December 31, 2003 we had issued and outstanding 21,861,369 shares of Series A Preferred Stock. Galen Partners III, L.P. and affiliates own 15,256,413 of these shares as described in the above table, which comprises 69.78% of the outstanding Series A Preferred Stock. No other stockholder owned more than 5% of the outstanding Series A Preferred Stock. The Series A Preferred Stock automatically converted into common stock if the average closing share price of our common stock, as reported on the OTC Bulletin Board, exceeds $1.374 for at least twenty consecutive trading days. Between January 26, 2004 and February 23, 2004 the Company's common stock closed each trading day at $1.39 per share or more. On February 23, 2004, the closing price was $1.48 per share. As a result, all of the Series A Preferred Stock was converted into common stock on a one-for-one basis. After the Series A Preferred Stock certificates are returned and the shares of common stock are issued upon conversion of the preferred

stock, 39,692,848 shares of common stock will be issued and outstanding. This does not include common stock issuable upon the exercise of outstanding stock options and warrants.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table sets forth certain information with respect to equity securities of the Company that are authorized for issuance as of the year ended December 31, 2003.

Equity Compensation Plan Information

	Number of securities to be issued upon exercise of outstanding options, warrants and rights (1)	Weighted average exercise price of outstanding options, warrants and rights (1)	Number of securities remaining available for future issuance (1)
Equity compensation plans approved by security holders	7,265,690	$1.28	814,310
Equity compensation plans not approved by security holders	0		0
Total	7,265,690	$1.28	814,310

(1) All of the securities referenced in the table are shares of our common stock. Does not include common stock issuable under the Specialized Health Product International, Inc. 2004 Employee Stock Purchase Plan, which was adopted in January 2004.

Item 12. Certain Relationships and Related Transactions

On November 7, 2001, our stockholders approved the issuance to Galen Partners and other accredited and sophisticated investors of a total of 10,917,030 shares of Series A Preferred Stock for an aggregate purchase price of $5 million, or $.458 per share. Galen Partners purchased their shares for $3,500,000 and the other investors purchased their shares in exchange for the cancellation of $1,500,000 of debt.

In September and November 2002, Galen Partners and other accredited and sophisticated investors exercised rights to acquire an additional 10,944,339 shares of Series A Preferred Stock for an aggregate net purchase price of $5,002,957, or $.458 per share. The Series A Preferred Stock is in the process of being converted into common stock on a one-for-one basis, as discussed in Item 11.

On March 22, 2004, we entered into an agreement with Galen Partners III, L.P., Galen Partners International III, L.P., and Galen Employee Fund III, L.P. (collectively, "Galen Partners") whereby Galen Partners agrees to purchase a convertible promissory note ("Note") in the aggregate principal amount of $1,000,000 upon our request made at any time between March 31, 2004 and March 31, 2005. The Note has a term of three years and bears interest at the rate of 12% per annum, with accrued interest to be paid July 1 and January 1 of each year the Note remains outstanding. The entire outstanding principal amount due on the Note may, at Galen Partner's option, be converted into fully paid and nonassessable shares of our common stock. The conversion price will be 110% of the average closing share price for our common stock as reported on NASDAQ or the OTC Bulletin Board for the twenty (20) consecutive trading days prior to the date of the issuance of the Note. As consideration for entering into this purchase agreement, Galen Partners will receive a warrant that provides them the right, but not the obligation, to purchase

80,000 shares of our common stock at an exercise price of $0.02 per share. The warrant shall expire and be no longer exercisable after 5:00 p.m., Eastern Time, on March 22, 2007. Further, we are obligated to pay up to $10,000 in legal fees incurred by Galen Partners related to this transaction.

Item 13. Exhibits and Reports on Form 8-K

Exhibits

Listed on page 39 hereof.

Reports on Form 8-K

On November 13, 2003, we filed a current report on Form 8-K reporting under Item 5 information relating to our third quarter financial results.

Item 14. Principal Accountant Fees and Services

Audit Fees

The aggregate fees billed for professional services rendered by our principal accountant for the audit of our financial statements, review of financial statements included in our quarterly reports and other fees that are normally provided by the accountant in connection with statutory and regulatory filings or engagements for the fiscal years ended December 31, 2003 and 2002 were $76,855 and $74,070, respectively.

Audit Related Fees

The aggregate fees billed for assurance and related services by our principal accountant that are reasonably related to the performance of the audit or review of our financial statements, other than those previously reported in this Item 14, for the fiscal years ended December 31, 2003 and 2002 were $0 and $0, respectively.

Tax Fees

The aggregate fees billed for professional services rendered by our principal accountant for tax compliance, tax advice and tax planning for the fiscal years ended December 31, 2003 and 2002 were $9,500 and $9,500, respectively.

All Other Fees

The aggregate fees billed for products and services provided by the principal accountant, other than those previously reported in this Item 14, for the fiscal years ended December 31, 2003 and 2002 were $0 and $0, respectively.

Audit Committee

Our audit committee is comprised of three independent directors. It is the Company's policy that the Audit Committee pre-approves all audit, tax and related services. All of the services described above in this Item 14 were approved in advance by our Audit Committee. No items were approved by the audit committee pursuant to paragraph (c)(7)(i)(C) of Rule 2-01 of Regulation S-X.

SIGNATURES

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

SPECIALIZED HEALTH PRODUCTS INTERNATIONAL, INC.
(Registrant)

Date: March 23, 2004

By /s/ Jeffrey M. Soinski
Jeffrey M. Soinski
President, Chief Executive Officer and Director

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Jeffrey M. Soinski Jeffrey M. Soinski	President, Chief Executive Officer and Director (Principal Executive Officer)	March 23, 2004
/s/ Keith L. Merrell Keith L. Merrell	Controller, Acting Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	March 23, 2004
/s/ Guy J. Jordan, Ph.D. Guy J. Jordan, Ph.D.	Chairman of the Board	March 23, 2004
/s/ Donald D. Solomon, Ph.D. Donald D. Solomon, Ph.D.	Director, Vice President, COO and CTO	March 23, 2004
/s/ David W. Jahns David W. Jahns	Director	March 23, 2004
/s/ Stuart A. Randle Stuart A. Randle	Director	March 23, 2004
/s/ Stephen I. Shapiro Steve I. Shapiro	Director	March 23, 2004
/s/ Robert R. Walker Robert R. Walker	Director	March 23, 2004

EXHIBIT INDEX

EXHIBIT NO.	DESCRIPTION OF EXHIBIT
3(i).1	Restated Certificate of Incorporation of the Company (Incorporated by reference to Exhibit 3(i).1 of the Company's Form 10-QSB, dated September 30, 2001).
3(i).2	Certificate of Designations, Preferences and Limitations of Series A Preferred Stock, dated November 6, 2001 (Incorporated by reference to Exhibit 3(i).2 of the Company's Form 10-QSB, dated September 30, 2001).
3(i).3	Articles of Incorporation of Specialized Health Products, Inc. ("SHP") (Incorporated by reference to Exhibit 3(i).2 of the Company's Registration Statement on Form S-1 filed December 11, 1995 (File No. 33-901014)).
3(i).4	Articles of Amendment of SHP (Incorporated by reference to Exhibit 3(i).3 of the Company's Registration Statement on Form S-1 filed December 11, 1995 (File No. 33-901014)).
3(ii).1	Second Amended and Restated Bylaws of the Company (Incorporated by reference to Exhibit 3(ii).1 of the Company's Form 10-KSB, dated December 31, 2002)..
3(ii).2	Bylaws of SHP (Incorporated by reference to Exhibit 3(ii).2 of the Company's Registration Statement on Form S-1 filed December 11, 1995 (File No. 33-901014)).
10.1	Employment Agreement with Jeffrey M. Soinski, dated November 8, 2001 (Incorporated by reference to Exhibit 10.1 of the Company's Form 10-QSB, dated September 30, 2001).
10.2	Employment Agreement with Donald D. Solomon, Ph.D. (Incorporated by reference to Exhibit 10.2 of the Company's Form 10-KSB, dated December 31, 2001).
10.3	Employment Agreement with Mr. Paul S. Evans. (Incorporated by reference to Exhibit 10.2 of the Company's Form 10-KSB, dated December 31, 2001).
10.4	Form of Indemnity Agreement with Executive Officers and Directors (Incorporated by reference to Exhibit 10.4 of the Company's Form 10-KSB, dated December 31, 2000).
10.5	Employment Agreement with Mr. Larry Sheldon (Incorporated by reference to Exhibit 10.5 of the Company's Form 10-KSB, dated December 31, 2002).
10.6	Development and License Agreement, effective date of March 29, 2000, by and among Safety Syringe Corporation, a wholly owned subsidiary of the Company and The Kendall Company (Incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, dated March 29, 2000).
10.7	License Agreement by and among Merit Medical Systems, Inc. and Safety Syringe Corporation (Incorporated by reference to Exhibit 10.7 of the Company's Form 10-KSB, dated December 31, 2000).
10.8	Specialized Health Products International, Inc. 1998 Stock Option Plan (Incorporated by reference to Appendix A to the Company's Amended Proxy Statement filed October 1, 1998).
10.9	Specialized Health Products International, Inc. 2000 Stock Option Plan (Incorporated by reference to Exhibit 10.7 of the Company's Quarterly Report on Form 10-QSB, dated June 30, 2000).
10.10	Specialized Health Products International, Inc. 2001 Stock Option Plan (Incorporated by reference to Exhibit 10.9 of the Company's Quarterly Report on Form 10-QSB, dated September 30, 2001).
10.11	Series A Stock Purchase Agreement, dated October 5, 2001, by and between the Company and the investors identified therein (Incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, dated November 7, 2001).

EXHIBIT NO.	DESCRIPTION OF EXHIBIT
10.12	Investors' Rights Agreement, dated October 5, 2001, by and between the Company and the investors identified therein (Incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K, dated November 7, 2001).
10.13	Distribution Agreement, dated September 17, 2001, by and between the Company and Bard Access Systems, Inc. (certain portions of the agreement were omitted from the exhibit pursuant to a request for confidential treatment) (Incorporated by reference to Exhibit 10.12 of the Company's Current Report on Form 8-K, dated November 7, 2001).
10.14	Second Development and License Agreement, effective date of April 12, 2002, by and among Safety Syringe Corporation, a wholly owned subsidiary of the Company and Tyco Healthcare Group LP. (Incorporated by reference to Exhibit 10.13 of the Company's Quarterly Report on Form 10-QSB, dated June 30, 2001).
10.15	Development and License Agreement, effective as of January 1, 2002, by and among Safety Syringe Corporation and TAP Pharmaceutical Products, Inc. (Incorporated by reference to Exhibit 10.14 of the Company's Quarterly Report on Form 10-QSB, dated June 30, 2001).
10.16	OEM Supply and Distribution Agreement, effective as of May 21, 2003, by and between Specialized Health Products, Inc., a wholly owned subsidiary of the Company and ExelInt International, Company. (Incorporated by reference to Exhibit 10.16 of the Company's Quarterly Report on Form 10-QSB, dated June 30, 2002).
10.17	License Agreement, effective August 8, 2003, by and between Specialized Health Products, Inc. and Becton, Dickinson and Company. (Incorporated by reference to Exhibit 10.17 of the Company's Quarterly Report on Form 10-QSB, dated June 30, 2002).
10.18	Specialized Health Products International, Inc. 2004 Employee Stock Purchase Plan.
10.19	Purchase Agreement, dated March 22, 2004, by and between Specialized Health Products International, Inc. and Galen Partners III, L.P., Galen Partners International III, L.P. and Galen Employee Fund III, L.P.
10.20	Amendment No. 1 to Investors' Rights Agreement, effective date of March 22, 2004, by and between the Company and the Initiating Holders as identified on the signature page.
21.1	Schedule of subsidiaries (Incorporated by reference to Exhibit 21.1 of the Company's Form 10-KSB, dated December 31, 2000).
23.1	Consent of Independent Public Accountants
31.1	Certification by Jeffrey M. Soinski under Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification by Keith L. Merrell under Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Jeffrey M. Soinski pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Keith L. Merrell pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

SPECIALIZED HEALTH PRODUCTS INTERNATIONAL, INC. AND SUBSIDIARIES

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT AUDITORS

To the Board of Directors and Stockholders of
Specialized Health Products International, Inc.:

In our opinion, the accompanying consolidated balance sheet and the related consolidated statements of operations, of stockholders' equity and of cash flows present fairly, in all material respects, the financial position of Specialized Health Products International, Inc., and its subsidiaries at December 31, 2003 and the results of their operations and their cash flows for each of the years in the two year period ended December 31, 2003 and 2002 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with auditing standards generally accepted in the United States of America, which require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

Salt Lake City, Utah
March 22, 2004

SPECIALIZED HEALTH PRODUCTS INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEET

	December 31, 2003
Assets	
Current assets:	
Cash and cash equivalents	$ 2,405,626
Accounts receivable, net of an allowance of zero	727,615
Inventory	199,044
Prepaid expenses and other	167,727
Total current assets	3,500,012
Property and equipment, net:	
Research and development machinery and equipment	359,525
Office furniture and fixtures	158,085
Computer equipment and software	200,177
Leasehold improvements	139,350
Molds	201,090
Manufacturing equipment	69,326
Construction in process	33,993
	1,161,546
Less accumulated depreciation and amortization	(833,968)
Total property and equipment, net	327,578
Other assets	27,000
Intangible assets, net	235,585
	$ 4,090,175

See accompanying notes to consolidated financial statements.

SPECIALIZED HEALTH PRODUCTS INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEET (Continued)

	December 31, 2003
Liabilities and Stockholders' Equity	
Current liabilities:	
Accounts payable	$ 229,122
Accrued liabilities	318,819
Accrual for patent litigation expenses, current portion	650,000
Deferred revenue	795,616
Total current liabilities	1,993,557
Accrual for patent litigation expenses, net of current portion	641,365
Deferred revenue, net of current portion	371,349
Deferred rent	11,929
Total liabilities	3,018,200
Commitments and contingencies (Note 4)	
Stockholders' equity:	
Series A preferred stock, $.001 par value; 30,000,000 shares authorized, 21,861,369 shares issued and outstanding at December 31, 2003 (liquidation preference of $11,422,917 at December 31, 2003)	21,861
Common stock, $.02 par value; 70,000,000 shares authorized, 17,831,479 shares issued and outstanding at December 31, 2003	356,630
Additional paid-in capital (common and preferred)	37,502,557
Accumulated deficit	(36,809,073)
Total stockholders' equity	1,071,975
Total liabilities and stockholders' equity	$ 4,090,175

See accompanying notes to consolidated financial statements.

SPECIALIZED HEALTH PRODUCTS INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years ended December 31	
	2003	2002
Revenue:		
Product sales and royalties	$ 2,768,570	$ 487,623
Technology fees and licensing revenues	778,124	506,900
Development fees and related services	59,880	636,425
	3,606,574	1,630,948
Cost of revenue	582,575	295,921
Gross profit	3,023,999	1,335,027
Operating expenses:		
Research and development	2,595,022	2,468,347
Sales and marketing	1,203,310	437,256
General and administrative	1,139,699	1,079,927
Patent litigation expense	1,300,000	-
Total operating expenses	6,238,031	3,985,530
Loss from operations	(3,214,032)	(2,650,503)
Other income (expense):		
Interest income	93,158	39,086
Interest expense	-	(4,897)
Other income (expense), net	1,752	1,923
Other income (expense), net	94,910	36,112
Net loss	(3,119,122)	(2,614,391)
Less preferred stock deemed dividend related to beneficial conversion feature	-	(3,281,564)
Net loss applicable to common shares	$ (3,119,122)	$ (5,895,955)
Basic and diluted net loss per common share	$ (.17)	$ (.33)
Basic and diluted weighted average number of common shares outstanding	17,831,479	17,921,479

See accompanying notes to consolidated financial statements.

SPECIALIZED HEALTH PRODUCTS INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

	Series A Preferred Stock		Common Stock		Additional Paid-in	Deferred Compensation	Accumulated
	Shares	Amount	Shares	Amount	Capital	Expense	Deficit
BALANCE as of December 31, 2001	10,917,030	$ 10,917	17,921,479	$ 358,430	$ 29,227,180	$ (19,073)	$(27,793,996)
Issuance of preferred stock for cash, net of expenses	10,944,339	10,944	-	-	4,992,013	-	-
Amortization of deferred compensation expense	-	-	-	-	-	19,073	-
Preferred stock dividend related to beneficial conversion feature	-	-	-	-	3,281,564	-	(3,281,564)
Net loss	-	-	-	-	-	-	(2,614,391)
BALANCE as of December 31, 2002	21,861,369	21,861	17,921,479	358,430	37,500,757	-	(33,689,951)
Cancellation of shares	-	-	(90,000)	(1,800)	1,800	-	-
Net loss	-	-	-	-	-	-	(3,119,122)
BALANCE as of December 31, 2003	21,861,369	$ 21,861	17,831,479	$ 356,630	$ 37,502,557	-	$(36,809,073)

See accompanying notes to consolidated financial statements.

SPECIALIZED HEALTH PRODUCTS INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31, 2003	2002
Cash flows from operating activities:		
Net loss	$ (3,119,122)	$ (2,614,391)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	135,342	54,886
Amortization of deferred compensation	-	19,073
Changes in operating assets and liabilities:		
Accounts receivable	(484,680)	(142,385)
Notes receivable, net	-	2,132
Inventory	194,844	(393,888)
Prepaid expenses and other	125,289	(244,023)
Accounts payable	28,448	108,134
Accrued liabilities	3,522	(245,389)
Accrual for patent litigation expenses	1,291,365	-
Deferred revenue	(1,019,026)	887,325
Deferred rent	(1,867)	(18,306)
Net cash used in operating activities	(2,845,885)	(2,586,832)
Cash flows from investing activities:		
Purchase of intangible assets	(95,865)	(158,218)
Purchase of property and equipment	(160,204)	(121,734)
Net cash used in investing activities	(256,069)	(279,952)
Cash flows from financing activities:		
Net proceeds from issuance of preferred stock	-	5,002,957
Net cash provided by financing activities	-	5,002,957
Net increase (decrease) in cash	(3,101,954)	2,136,173
Cash and cash equivalents at beginning of year	5,507,580	3,371,407
Cash and cash equivalents at end of year	$ 2,405,626	$ 5,507,580
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ -	$ 4,897

See accompanying notes to consolidated financial statements.

SPECIALIZED HEALTH PRODUCTS INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(1) NATURE OF OPERATIONS

History and Nature of Operations

Specialized Health Products, Inc. ("SHP"), a Utah corporation, was incorporated in November 1993. On July 28, 1995, SHP became a wholly owned subsidiary of SHPI, a Delaware corporation, through a merger with a subsidiary of SHPI (the "Acquisition"). On that date SHP changed its name to "Specialized Health Products International, Inc. ("SHPI" or the "Company"). The persons serving as officers and directors of SHP immediately prior to the consummation of the Acquisition were elected to the same offices with SHPI and retained their positions as directors and officers of SHP. In addition, the outstanding securities of SHP became outstanding securities of SHPI.

SHPI designs, develops, manufactures, and licenses safety healthcare products that minimize the risk of accidental needle sticks. The Company has 20 highly differentiated, patented safety needle technologies. These technologies apply to the following: syringe, pre-filled syringe, IV catheter, guidewire introducer, PICC introducer, blood collection, epidural, spinal, Huber, biopsy, and other specialty needles. The Company operates in one business segment.

The Company's business model is to enter into licensing, original equipment manufacturing ("OEM") supply, or distribution agreements for its products, rather than engage in direct sales of products to end-users on its own. SHPI has entered into product agreements relating to specific technologies and product lines with The Kendall Company ("Kendall"), a division of Tyco Healthcare Group LP, Bard Access Systems, Inc. ("Bard"), TAP Pharmaceutical Products Inc. ("TAP"), Merit Medical Systems, Inc. ("Merit") and Exelint International Co. ("Exel"). SHPI has distribution agreements in place with Cardinal Health, Medline Industries, Inc. ("Medline"), Physician Sales and Service, Inc. ("PSS"), Medical Specialties Distributors, Inc., Omni Medical Supply, Inc., Briggs Corporation, Henry Schein, Inc., Wolf Medical Supply, Inc., Biometrix Ltd. and Medical Mart Supplies Ltd. for products marketed under the SHPI label.

The Company's working capital requirements for the foreseeable future will vary based upon a number of factors, including the costs to complete development work, the cost of bringing safety medical needle technologies and other products to commercial viability, the timing of the market launches of new safety needle products and the level of sales of our current products. As of December 31, 2003, the Company had accounts payable and accrued liabilities totaling $547,941. The Company also had the current portion of accrued litigation expenses of $650,000 and current deferred revenue of $795,616, neither of which will require the use of cash. At December 31, 2003, the Company had cash and cash equivalents of $2,405,626.

The Company believes existing cash, along with cash generated from the sale of products, development fees and royalties and $1,000,000 of committed funding from several major stockholders (Note 9) will provide sufficient cash for the Company to execute its business plan in 2004

(2) SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

The consolidated financial statements include the accounts of SHPI and its wholly-owned subsidiaries. All material intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that effect the reported amounts of

assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from these estimates.

Concentrations of Credit Risk

The Company's distribution and license agreements are primarily with partners operating in the United States. At December 31, 2003, one partner accounted for approximately 56% of the accounts receivable balance. For the years ended December 31, 2003 and 2002, two partners accounted for approximately 55% and 82% of total revenues, respectively.

The Company is currently utilizing a single contract manufacturer to produce its LiftLoc® Safety Infusion Set.

Cash and Cash Equivalents

The Company considers all certificates of deposit with an original maturity date of three months or less to be cash equivalents. Cash and cash equivalents are deposited with financial institutions located in Salt Lake City, UT and at times may exceed insured depository limits.

Inventory

Inventory is valued at the lower of cost or market. Cost is determined using a method that approximates costs determined using the first-in first-out ("FIFO") basis. At December 31, 2003, inventory is comprised of the following:

	12/31/2003
Raw materials	$ 123,060
Work in process	4,318
Finished goods	81,666
Less: Allowance for obsolescence and shrinkage	(10,000)
Total	$ 199,044

Property and Equipment

Property and equipment are stated at cost. Manufacturing equipment is depreciated using the straight-line method over seven years or the units-of-production method, whichever is greater. Leasehold improvements are amortized using the straight-line method over the shorter of the lease term or the estimated useful life of the asset. All other property and equipment are depreciated using the straight-line method based on the estimated five-year useful life of the related assets, except for computer equipment and software, which have a useful life of three years.

Maintenance and repairs are charged to expense as incurred and costs of improvements and betterments are capitalized. Upon disposal or sale, the related asset costs and accumulated depreciation or amortization are removed from the accounts and resulting gains or losses are reflected in current operations.

Long-Lived Assets

The Company regularly evaluates whether events or circumstances have occurred that indicate the carrying value of its long-lived assets may not be recoverable. When factors indicate the asset may not be recoverable, the Company compares the related undiscounted future net cash flows to the carrying value of the asset to determine if impairment exists. If the expected future net cash flows are less than the carrying value, an impairment charge is recognized based on the fair value of the asset. No such impairments were recorded during the years ended December 31, 2003 and 2002.

Other Assets

Other assets consist of a building security lease deposit for the Company's headquarters building.

Intangible Assets

Intangible assets consist of outside legal patent costs which have been capitalized and are being amortized over 17 years. Accumulated amortization at December 31, 2003 was $18,498. The following summarizes amortization on the asset valuation at December 31, 2003, that will be recorded over the next five years:

Year Ending December 31	Amortization Expense
2004	$ 16,648
2005	16,648
2006	16,648
2007	16,648
2008	16,648
	$ 83,240

Stock Options

The Company accounts for stock options granted using Accounting Principles Board APB Opinion No. 25. Accordingly, no compensation cost has been recognized for its fixed stock option plans. Had compensation cost for the Company's stock-based compensation plans (See Note 5) been determined based on the fair value at the grant dates for awards under those plans consistent with Statement of Financial Accounting Standards ("SFAS") No. 123, the Company's net loss and net loss per common share would have changed to the pro forma amounts indicated below:

		Years Ended December 31, 2003	2002
Net loss applicable to common stockholders, as reported		$ (3,119,122)	$ (5,895,955)
Total compensation cost determined under fair value based method for all awards		(1,199,150)	(1,384,435)
Pro forma net loss applicable to common stockholders		$ (4,318,272)	$ (7,280,390)
Basic and diluted net loss per common share:	As reported	$ (.17)	$ (.33)
	Pro forma	(.24)	(.41)

Revenue Recognition

Pursuant to Staff Accounting Bulletin ("SAB") No. 101, "Revenue Recognition in Financial Statements", the Company recognizes license revenue when the following criteria has been met: (a) persuasive evidence of an arrangement exists, (b) delivery has occurred or services have been rendered, (c) the price is fixed or determinable, and (d) collectibility is reasonably assured.

The Company has received upfront fees totaling $1,080,000 in 2003 and $230,000 in 2002. These upfront payments are being recognized ratably over the life of the respective agreements.

Product revenues are recognized upon the shipment date of the product, and transfer of both title and risk of loss to the customer.

Royalty revenue is recognized when the related products are sold or upon the Company's fulfillment of any future obligation under the related agreements. Revenue from development agreements is recognized as the services are performed, in accordance with the terms of the agreements.

Research and Development Costs

Research and development costs are expensed as incurred.

Income Taxes

The Company recognizes a liability or asset for net operating loss carry forwards and the deferred tax consequences of temporary differences between the tax bases of assets and liabilities and their reported amounts in the consolidated financial statements that will result in taxable or deductible amounts in future years when the reported amounts of the assets and liabilities are recovered or settled. A valuation allowance is established when necessary to reduce deferred tax assets to the amount expected to be realized.

Fair Value of Financial Instruments

The book values of the Company's financial instruments approximate their fair values. The estimated fair values have been determined using appropriate market information and valuation methodologies.

Recent Accounting Pronouncements

On January 17, 2003, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation No. 46, "Consolidation of Variable Interest Entities – an Interpretation of ARB No. 51" ("Fin 46"). FIN 46 clarifies the application of Accounting Research Bulletin No. 51, "Consolidated Financial Statements," to certain entities in which equity investors do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 is applicable immediate for variable interest entities created after January 31, 2003. For variable interest entities created prior to February 1, 2003, the provisions of FIN 46 are applicable to the Company no later than January 1, 2004. The adoption of FIN 46 is not expected to have a material effect on the Company's financial condition or results of operations.

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity" ("SFAS 150"). SFAS 150 establishes standards on the classification and measurement of certain financial instruments with characteristics of both liabilities and equity. The provisions of SFAS 150 are effective for the Company for fiscal periods beginning after December 15, 2004. The adoption of SFAS 150 is not expected to have a material effect on the Company's financial condition or results of operations.

Basic and Diluted Net Loss Per Common Share

As a result of the Company incurring net losses for the years ended December 31, 2003 and 2002, the basic and diluted net loss per common share for the years are based on the weighted average number of common shares outstanding. Stock options and warrants prior to conversion are not included in the calculation of diluted net loss per common share for the year because their inclusion would be antidilutive, thereby reducing the net loss per common share. Options and warrants to purchase 7,185,690 and 7,347,500 shares

of common stock at exercise prices ranging from $0.02 to $2.00 per share were outstanding at December 31, 2003 and 2002, respectively.

Additionally, as of December 31, 2003 and 2002, there were 21,861,369 shares of Series A Preferred Stock outstanding, which are convertible into common stock on a one-for-one basis. Such shares were also not included in the computation of diluted earnings per share for the respective years then ended because their inclusion would be antidilutive.

(3) DISTRIBUTION AND LICENSE AGREEMENTS

License Agreements

Kendall

In November 1999, the Company entered into a Development and License Agreement (the "Kendall Agreement") with The Kendall Company ("Kendall"), a division of Tyco Healthcare Group LP ("Tyco Healthcare"), relating to the production of a line of safety medical needle products, including six syringe products and five other safety needle products. The Kendall Agreement became effective in March 2000. In April 2000, the Company received $1,464,956 under the Kendall Agreement. The Company received an additional $1,000,000 in November 2002 in exchange for assigning to Kendall the FlexLoc® and ReLoc™ trademarks and two related U.S. patents and their progeny for a technology. Both of these payments are being recognized ratably over the life of the Kendall Agreement. The assignment of the patent rights to Kendall provides for the Company's retention of an exclusive, royalty-free license in a number of strategic product areas. The Kendall Agreement also provides for the Company to receive development fees and ongoing royalties, including a $500,000 advance royalty payment that was also received in November 2002.

In April 2002, the Company entered into a Second Development and License Agreement with Kendall (the "2nd Kendall Agreement") relating to blood collection needles and blood collection needle/holder combinations. Under the terms of the agreement, the Company receives reimbursement for research and development expenses, payments related to the achievement of certain regulatory and sales milestones, and on-going royalty payments on all product sales.

Merit Medical

In January 2001, the Company entered into a License Agreement (the "Merit Agreement") with Merit Medical Systems, Inc. ("Merit") relating to the manufacture and marketing of safety needle devices for angiographic guidewire introducers. The Company received an upfront license fee payment of $100,000 in January 2001, which is being recognized ratably by the Company over the estimated five-year life of the Merit Agreement. Under the terms of the Merit Agreement, the Company receives ongoing royalties on net product sales. The Company began receiving minimum royalty payments in 2002.

TAP Pharmaceutical Products

In July 2002, the Company entered into a Development and License Agreement (the "TAP Agreement") with TAP Pharmaceutical Products Inc. ("TAP," a joint venture between Abbott Laboratories and Takeda Chemical Industries, Ltd.), whereby TAP acquired the right to attach the Company's proprietary safety needle device to TAP's pre-filled syringes. The TAP Agreement has an effective date of January 1, 2002. Under the TAP Agreement, the Company receives reimbursement for research and development expenses, payments related to the achievement of certain development and regulatory milestones, and on-going royalty payments based upon the number of pre-filled syringes manufactured with the Company's proprietary safety needle device. The TAP Agreement is for a minimum period of three years.

Becton, Dickinson and Company

In August 2003, the Company entered into a License Agreement (the "BD Agreement") with Becton, Dickinson and Company ("BD") relating to the manufacture and marketing of safety needle devices for spinal and epidural needles and certain radiology and biopsy needles. Under the terms of the agreement, the Company receives reimbursement for certain research and development expenses, payments related to the achievement of certain regulatory and commercialization milestones, and on-going royalty payments on all product sales.

Distribution Agreements

Bard Access Systems

In September 2001, the Company entered into a Distribution Agreement (the "Bard Agreement") with Bard Access Systems, Inc. ("Bard") whereby Bard acquired the non-exclusive right to promote, market, distribute and sell LiftLoc® Safety Infusion Set, which the Company manufactures, to hospitals and group purchasing organizations. The Bard Agreement excludes alternate site locations. Under the terms of the agreement, the Company sells finished product to Bard for marketing under Bard's private label. The Bard Agreement is for a two-year period from the initial date of product launch, and automatically renews for successive one-year terms unless terminated by either party in writing not less than 180 days prior to the expiration of the initial term or any renewal term.

Physician Sales & Service

In July 2002, the Company entered into a Distribution Agreement (the "PSS Agreement") with Physician Sales and Service, Inc. ("PSS") whereby PSS acquired the non-exclusive right to distribute and sell LiftLoc® Safety Infusion Set. Under the terms of the agreement, PSS purchases SHPI branded product from the Company for resale to PSS's end-user customers. The PSS Agreement is for a one-year period, which automatically renews for successive one-year terms unless terminated by either party in writing not less than 45 days prior to the expiration of the initial term or any renewal term.

Medline Industries

In August 2002, the Company entered into a Distribution Agreement (the "Medline Agreement") with Medline Industries, Inc. ("Medline") whereby Medline acquired the non-exclusive right to distribute and sell LiftLoc® Safety Infusion Set. Under the terms of the agreement, Medline purchases SHPI branded product from the Company for resale to Medline's end-user customers. The Medline Agreement is for a one-year period, which automatically renews for successive one-year terms unless terminated by either party in writing not less than 45 days prior to the expiration of the initial term or any renewal term.

Cardinal Health

In August 2002, the Company entered into a Distribution Agreement (the "Cardinal Agreement") with Cardinal Health ("Cardinal"), formerly named Allegiance Healthcare, whereby Cardinal acquired the non-exclusive right to distribute and sell LiftLoc® Safety Infusion Set. Under the terms of the agreement, Cardinal purchases SHPI branded product from the Company for resale to Cardinal's end-user customers. The Cardinal Agreement shall continue until 90 days after written notice of termination is received by either party.

ExelInt International

In May 2003, the Company entered into a Distribution Agreement (the "Exel Agreement") with ExelInt International, Company ("Exel") whereby Exel acquired the non-exclusive right to promote, market, distribute and sell LiftLoc® Safety Infusion Set. Under the terms of the agreement, the Company sells finished product to Exel for marketing under Exel's private label. Exel is subject to minimum

purchase requirements. The Exel Agreement is for a five-year period and automatically renews for successive five-year terms unless terminated by either party in writing not less than 180 days prior to the expiration of the initial term or any renewal term.

Other LiftLoc® Distribution Agreements

In April, May and September 2003, the Company entered into Distribution Agreements with Medical Specialties Distributors, Inc., Briggs Corporation, Omni Medical Supply, Inc., Wolf Medical Supply, Inc. and Henry Schein, Inc. whereby each company acquired the non-exclusive right to distribute and sell LiftLoc® Safety Infusion Set. Under terms of these agreements, each distributor purchases SHPI branded product from the Company for resale to their end-user customers. Each of the agreements is for a one-year term and shall be renewed automatically for additional, consecutive one-year terms unless terminated by either party in writing not less than 45 days prior to the expiration of the initial term or any renewal term.

In December 2003, the Company entered into a Distribution Agreement with Biometrix Ltd. whereby Biometrix acquired the non-exclusive right to distribute and sell LiftLoc® Safety Infusion Setin Israel. Under the terms of the agreement, Biometrix purchases SHPI branded product from the Company for resale to their end-user customers within Israel. The agreement is for a three-year term and shall be renewed automatically for additional, consecutive one-year terms unless terminated by either party in writing not less than 45 days prior to the expiration of the initial term or any renewal term.

In February 2004, the Company entered into a Distribution Agreement with Medical Mart Supplies Ltd. whereby Medical Mart acquired the non-exclusive right to distribute and sell LiftLoc® Safety Infusion Set in Canada. Under the terms of the agreement, Medical Mart purchases SHPI branded product from the Company for resale to their end-user customers. The agreement runs through December 2005 and shall be renewed automatically for additional, consecutive one-year terms unless terminated by either party in writing not less than 90 days prior to the expiration of the initial term or any renewal term.

(4) COMMITMENTS AND CONTINGENCIES

Lease Obligations

The Company leases office space under a non-cancelable operating lease. The following summarizes future minimum lease payments under the operating lease at December 31, 2003:

Year Ending December 31	Minimum Lease Payments
2004	$ 253,908
2005	260,397
2006	107,499
	$ 621,804

Rental expense for the years ended December 31, 2003, and 2002 totaled approximately $244,800 and $268,500, respectively.

Employment and Indemnity Agreements

The Company has entered into employment agreements with five members of senior management. While each differs as to salary, bonus and stock options, each of the agreements provides for health and life insurance coverages, vacation, and severance benefits if the officers are terminated for reasons other than disability, death, or for cause.

In January 2003, the Company approved a 2003 Executive Officer Bonus Plan. Under the plan, executive officers eligible for bonuses during 2003 include the CEO, COO, VP of Sales and Marketing and VP of Business Development. Plan participants will earn 20% of their annual salary based upon 100% achievement of the overall revenue goal outlined in the approved budget plan. Also, plan participants will be eligible to receive incremental bonus payments for performing beyond the budget plan. The amount of incremental payments, if earned, will be based upon the recommendation of the Compensation Committee and approved by the board of directors. The maximum base bonus that could be paid under this plan is $160,200. In January 2004, the board of directors approved total payments of $105,729 under the plan. In connection with this plan, the Company also adopted an Employee Bonus Plan for employees other than the Named Executive Officers to reward specific individual or team achievements during 2003. The total approved for this plan was $75,000. During 2003 and in February 2004, payments of $61,000 were made against this plan.

In February 2004, the board of directors approved a 2004 Executive Officer Bonus Plan. Under the plan executive officers eligible for bonuses during 2004 include the CEO, COO, and VP of Business Development and General Counsel. Plan participants will earn up to 20% of their annual salary based upon achievement of certain revenue, net income, and cash flow goals. Also, plan participants will be eligible to receive incremental bonus payments for performing beyond the goals. The amount of incremental payments, if earned, will be based upon the recommendation of the Compensation Committee and approved by the board of directors. The maximum base bonus that could be paid under this plan is $126,750. The board has also approved $75,000 for a 2004 Employee Bonus Plan to be administered in the same manner as the 2003 plan.

SHPI has entered into indemnity agreements (the "Indemnity Agreements") with each of its executive officers and directors pursuant to which the Company has agreed to indemnify the officers and directors to the fullest extent permitted by law for any event or occurrence related to the service of the indemnitee for SHPI as an officer or director that takes place prior to or after the execution of the Indemnity Agreement. The Indemnity Agreements obligate the Company to reimburse or advance expenses relating to any proceeding arising out of an indemnifiable event. Under the Indemnity Agreements, SHPI's officers and directors are presumed to have met the relevant standards of conduct required by Delaware law for indemnification. Should the Indemnity Agreements be held to be unenforceable, indemnification of these officers and directors may be provided by SHPI in certain cases at the Company's discretion.

Litigation

In December 2002, Becton Dickinson filed a lawsuit against Tyco Healthcare in the United States Court of the District of Delaware, asserting that Tyco Healthcare's Monoject Magellan™ safety products infringe upon BD's U.S. Patent No. 5,348,544 ('544 Patent), titled "Single-Handedly Actuable Safety Shield for Needles." BD is seeking injunctive relief as well as damages, including attorneys' fees and costs, in an unspecified amount. Tyco Healthcare responded in court filings that the Monoject Magellan™ safety products do not infringe the '544 Patent. Moreover, Tyco Healthcare asserted in court filings that the '544 patent is invalid and unenforceable. A trial date has been scheduled for October 2004.

Under a Development and License Agreement executed between Tyco Healthcare and the Company related to the Monoject Magellan™ safety products, Tyco Healthcare is exercising its right to withhold up to fifty percent (50%) of royalties due as an offset against litigation expenses related to BD's lawsuit. This right continues during the period in which such litigation is pending. If, as a result of judgment in the litigation or settlement with BD, Tyco Healthcare is required to pay royalty and/or other monies to BD, Tyco Healthcare may thereafter deduct from the amount of royalties due the Company on unit sales of products alleged to infringe, an amount which is the lesser of all royalties and/or other monies paid by Tyco Healthcare to BD, or fifty percent (50%) of all royalty payments otherwise payable to the Company.

Based on information obtained during the fourth quarter of 2003 related to costs incurred by Kendall, the Company has recorded a liability of $1,300,000 as of December 31, 2003, which amount is its estimate of the portion of costs associated with BD's suit against Tyco Healthcare that Tyco Healthcare will withhold against the royalties due the Company through 2005. At December 31, 2003, the balance remaining is $1,291,365. Additional litigation to enforce patents, to protect proprietary information, or to defend the Company against alleged infringement of the rights of others may occur. Such litigation would be costly, could divert the Company's resources from other planned activities, and could have a material adverse effect on the Company's results of operations and financial condition.

(5) STOCK OPTIONS

Effective November 2001, the Company's Board of Directors and stockholders approved the adoption of the Specialized Health Products International, Inc. 2001 Stock Option plan. The plan permits the Company to grant non-qualified stock options and incentive stock options to acquire common stock. The total number of shares authorized for the plan may be allocated by the board between non-qualified stock options and incentive stock options from time to time, subject to certain requirements of the Internal Revenue Code of 1986, as amended. The option exercise price per share under the plan may not be less than the fair market value on the date on which the option is granted. A total of 5,000,000 shares are available for issuance under the plan. The options are exercisable for a period not to exceed 10 years (or five years when the optionee is a 10 percent stockholder) from the date of grant. At December 31, 2003, options to acquire an aggregate of 4,672,690 shares of common stock at exercise prices ranging from $1.00 to $2.00 were outstanding under the 2001 Stock Option plan.

Effective June 2000, adoption of the Specialized Health Products International, Inc. 2000 Stock Option plan was approved by the Company's Board of Directors. The plan is administered by the Board of Directors. The plan provides for the issuance of up to 2,500,000 shares of common stock to directors, officers, employees and consultants. The exercise price of the options granted will be the greater of $1.00 per share or the fair market value (or 110 percent of such fair market value when the optionee is a ten percent stockholder) of the underlying common stock on the date of grant. The options are exercisable for a period not to exceed 10 years (or five years when the optionee is a 10 percent stockholder) from the date of grant.

Effective August 1998, adoption of the Specialized Health Products International, Inc. 1998 Stock Option Plan was approved by the Company's Board of Directors. The plan is administered by the Board of Directors. The plan provides for the issuance of up to 2,000,000 shares of common stock to directors, officers, employees and consultants. The exercise prices of the options granted may not be less than the greater of $2.00 per share or the fair market value (or 110 percent of such fair market value when the optionee is a 10 percent stockholder) of the underlying common stock on the date of grant. The options are exercisable for a period not to exceed 10 years (or five years when the optionee is a 10 percent stockholder) from the date of grant.

As of December 31, 2003, options to acquire an aggregate of 2,013,000 shares of common stock at exercise prices ranging from $1.00 to $2.00 were outstanding under the 2000 and 1998 stock option plans.

A summary of the status of the Company's option plans as of December 31, 2003 and 2002, and changes during the years then ended is presented below:

	2003		2002	
	Shares	Wtd. Avg. Exercise Prices	Shares	Wtd. Avg. Exercise Prices
Outstanding at beginning of year	6,547,500	$ 1.26	6,057,500	$ 1.27
Granted	473,000	1.00	500,000	1.00
Exercised	-		-	
Forfeited	(334,810)	1.41	(10,000)	2.62
Outstanding at end of year	6,685,690	1.24	6,547,500	1.26
Exercisable at end of year	3,749,822	1.31	2,595,768	1.40
Weighted average fair value of options granted	$ 0.69		$ 0.55	

The following table summarizes information about stock options outstanding at December 31, 2003:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding as of December 31, 2003	Wtd. Avg. Remaining Contractual Life	Wtd. Avg. Exercise Price	Number Exercisable as of December 31, 2003	Wtd. Avg. Exercise Price
$ 1.0000	989,000	9.26 years	$ .18	141,000	$ .05
1.1250	114,000	6.45	.02	114,000	.04
1.1900	4,572,690	7.87	.85	2,518,165	.88
1.2500	251,000	6.67	.05	251,000	.09
1.4375	4,000	6.88	.00	4,000	.00
1.5100	100,000	7.99	.02	66,667	.02
1.5625	100,000	6.73	.02	100,000	.03
1.6250	50,000	6.52	.01	50,000	.02
2.0000	505,000	6.91	.09	505,000	.18
$1.00 to 2.0000	6,685,690		$ 1.24	3,749,832	$ 1.31

The fair value of each option granted is estimated on the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions used for grants in 2003 and 2002: average risk-free interest rate ranging from 4.23 to 4.71 were used for 2003, with a rate of 2.5 being used for 2002; expected lives of 10 years; expected dividend yields of zero percent in each year; expected volatility of 81and 63 percent, respectively.

In calculating the pro forma net loss and pro forma basic and diluted net loss per share, the Company has also considered the effect of 500,000 common stock warrants issued to a director and officer and an employee of the Company during 1998. The issuance of the warrants was accounted for in accordance with APB No. 25. For disclosure purposes under SFAS No. 123, the fair value of each warrant granted was estimated on the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions used: risk-free interest rate of 6.0 percent; expected lives of 2 years; expected dividend yield of zero; expected volatility of 68 percent.

The following summarizes all warrant activity for the Company for the years ended December 31, 2003, and 2002.

	2003		2002	
	Shares	Wtd. Avg. Exercise Prices	Shares	Wtd. Avg. Exercise Prices
Outstanding at beginning of the year	800,000	$ 1.72	1,050,000	$ 1.85
Granted	-	-	-	-
Exercised	-	-	-	-
Forfeited	(300,000)	1.25	(250,000)	2.00
Outstanding at end of the year	500,000	$ 2.00	800,000	$ 1.72
Exercisable at end of the year	500,000		800,000	

(6) CAPITAL TRANSACTIONS

The Series A Preferred Stock Purchase Agreement entered into in November 2001 provided that the investors had the right, but not the obligation, to acquire additional shares of Series A Preferred Stock at $.458 per share ($5,000,000 total) during the 12 months following the initial closing date of November 7, 2001. In September 2001, Galen Partners exercised their option to purchase the additional shares to which they held rights. Under terms of the agreement, the options to purchase held by the remaining qualified investors would expire in thirty days if not exercised. All of those holding options to purchase exercised some or all of their rights, purchasing an additional 10,944,339 shares of Series A Preferred stock. The Company realized net proceeds of $5,002,957 from the transaction. A non-cash beneficial conversion charge of $3,281,564 was recognized related to this transaction, as the conversion price was less than the market price of the Company's common stock on the date of exercise. This amount has been treated as a deemed preferred stock dividend in the 2002 financial statements.

The holders of Series A Preferred Stock are entitled to receive dividends at the rate of eight percent per share per annum, payable semi-annually, when, if and as declared by the board of directors out of any assets legally available therefore. The right to dividends on the Series A Preferred Stock is not cumulative, and the holders of Series A Preferred Stock have no right to any accrued or future dividend payment by reason of the fact that dividends on such shares are not declared or paid in any prior year. As of December 31, 2003, no dividends had been declared or paid. No dividend shall be declared and paid on the Common Stock of the Company unless a dividend is also concurrently being declared and paid on the Series A Preferred Stock and no dividend shall be paid on the Common Stock at a rate greater than the rate at which dividends are paid on the Series A Preferred Stock.

Upon liquidation, dissolution or winding up of the Company, either voluntary or involuntary, the holders of Series A Preferred Stock shall be entitled to receive, prior and in preference to any distribution of any of the assets of the Company to the holders of common stock, an amount equal to at least $.458 per outstanding share of Series A Preferred Stock, plus an amount equal to eight percent annual compounded return on $.458 per outstanding share of Series A Preferred Stock from the date of the initial purchase of such shares less any dividends previously paid on such shares ($11,422,917 at December 31, 2003).

The holder of each share of Series A Preferred Stock has the right to one vote for each share of common stock into which the Series A Preferred Stock could then be converted (with fractional shares being rounded to the nearest whole share). The preferred stockholders have full voting rights and powers equal to the voting rights and powers of the common stockholders.

Each share of Series A Preferred Stock shall be convertible at the option of the holder thereof, at any time after the date of issuance of such share, into the equivalent number of common shares. In addition, each

share of Series A Preferred Stock shall automatically be converted into the equivalent number of shares of common stock at any time 66 2/3% of the Series A Preferred Stock has been converted by the holders into common stock. Each share of Series A Preferred Stock shall automatically be converted into the equivalent number of shares of common stock if, after the second anniversary of the original issue date, the Company's average closing share price per common stock for at least 20 consecutive trading days exceeds three times the conversion price.

(7) INCOME TAXES

The Company recognized no income tax benefit for the years ended December 31, 2003 and 2002 from its net operating losses. Significant components of the Company's net deferred income tax assets as of December 31, 2003 are as follows:

	2003
Deferred income tax assets:	
Net operating loss carryforwards	$ 8,988,466
Non cash compensation expense	206,894
Accrued liabilities	539,314
Intangible assets	104,093
Research and experimentation tax credits/carryforwards	501,764
Deferred revenue	435,278
Depreciation	28,392
Total gross deferred income tax asset	10,804,201
Less valuation allowance	(10,804,201)
Net deferred income taxes	$ -

The net change in the valuation allowance for the years ended December 31, 2003 and 2002 was an increase of $1,343,824 and $1,295,194, respectively.

SFAS 109 requires that a valuation allowance be provided if it is more likely than not that some portion or all of a deferred tax asset will not be realized. The Company's ability to realize the benefit of its deferred tax asset, because the Company has a history of operating losses, will depend on the generation of future taxable income. The Company has recorded a full valuation allowance as of December 31, 2003.

At December 31, 2003, the Company had total tax net operating losses ("NOLs") of $24,097,763 and Research and Experimentation tax credits of $501,764 that can be carried forward to reduce federal income taxes, if any. Approximately $19,000 of NOLs expired in 2003. As defined in Section 382 of the Internal Revenue Code, the Company has undergone a greater than 50 percent ownership change as a result of the financing initiatives taken in 2001 and 2002. Consequently, there are limitations on the amount of the Company's tax net operating loss carryforwards available to offset future taxable income in any one year. The maximum amount of carryforwards available in a given year is limited to the product of the Company's value on the date of ownership change and the federal long-term tax-exempt rate, plus any limited carryforwards not utilized in prior years.

(8) EMPLOYEE BENEFIT PLAN

Employees who are 21 years of age are eligible for participation in the Specialized Health Products International, Inc. 401(k) Plan and may elect to make contributions to the plan. The Company matches 100 percent of such contributions up to five percent of the individual participant's compensation. The Company's contribution to the plan was approximately $106,300 and $67,700 for the years ended December 31, 2003 and 2002, respectively.

(9) SUBSEQUENT EVENTS

At December 31, 2003 the Company had issued and outstanding 21,861,369 shares of Series A Preferred Stock. The Series A Preferred Stock automatically converts into common stock if the average closing share price of the Company's common stock, as reported on the OTC Bulletin Board, exceeds $1.374 for at least twenty consecutive trading days. Between January 26, 2004 and February 23, 2004, the Company's common stock closed each trading day at $1.39 per share or more. On February 23, 2004, the closing price was $1.48 per share. As a result, all of the Series A Preferred Stock will automatically be converted into common stock of the Company on a one-for-one basis. On February 24, 2004, the Company sent notice of the conversion to its Series A Preferred Stock holders.

Immediately prior to the conversion, the Company had outstanding 17,831,479 shares of common stock and 21,861,369 shares of Series A Preferred Stock. After the Series A Preferred Stock certificates are returned and the shares of common stock are issued upon conversion of the preferred stock, the Company will have 39,692,848 shares of common stock outstanding. This does not include common stock issuable upon the exercise of outstanding stock options and warrants.

On March 22, 2004, the Company entered into an agreement with Galen Partners III, L.P., Galen Partners International III, L.P., and Galen Employee Fund III, L.P. (collectively, "Galen Partners") whereby Galen Partners agrees to purchase a convertible promissory note ("Note") in the aggregate principal amount of $1,000,000 upon the request of the Company made at any time between March 31, 2004 and March 31, 2005. The Note has a term of three years and bears interest at the rate of 12% per annum, with accrued interest to be paid July 1 and January 1 of each year the Note remains outstanding. The entire outstanding principal amount due on the Note may, at Galen Partner's option, be converted into fully paid and nonassessable shares of common stock of the Company. The conversion price will be 110% of the Company's average closing share price for common stock as reported on NASDAQ or the OTC Bulletin Board for the twenty (20) consecutive trading days prior to the date of the issuance of the Note. As consideration for this purchase agreement, Galen Partners will receive a warrant that provides them the right, but not the obligation, to purchase 80,000 shares of common stock of the Company at an exercise price of $0.02 per share. The warrant shall expire and be no longer exercisable after 5:00 p.m., Eastern Time, on March 22, 2007. Further, the Company is obligated to pay up to $10,000 in legal fees incurred by Galen Partners related to this transaction.

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Exhibit 31.1

I, Jeffrey M. Soinski, as Chief Executive Officer of the Company, certify that:

1. I have reviewed this report on Form 10-KSB of Specialized Health Products International, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the small business issuer as of, and for, the periods presented in this report;

4. The small business issuer's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) for the small business issuer and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the small business issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the small business issuer's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the small business issuer's internal control over financial reporting that occurred during the small business issuer's most recent fiscal quarter (the small business issuer's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the small business issuer's internal control over financial reporting; and

5. The small business issuer's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the small business issuer's auditors and the audit committee of small business issuer's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the small business issuer's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the small business issuer's internal control over financial reporting.

Date: March 23, 2004

/s/ Jeffrey M. Soinski
Jeffrey M. Soinski
President, Chief Executive Officer, Director

Exhibit 31.2

I, Keith L. Merrell, as acting Chief Financial Officer of the Company, certify that:

1. I have reviewed this report on Form 10-KSB of Specialized Health Products International, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the small business issuer as of, and for, the periods presented in this report;

4. The small business issuer's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) for the small business issuer and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the small business issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the small business issuer's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation, and

   d. Disclosed in this report any change in the small business issuer's internal control over financial reporting that occurred during the small business issuer's most recent fiscal quarter (the small business issuer's fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the small business issuer's internal control over financial reporting; and

5. The small business issuer's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting,, to the small business issuer's auditors and the audit committee of small business issuer's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the small business issuer's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the small business issuer's internal control over financial reporting.

Date: March 23, 2004

/s/ Keith L. Merrell
Keith L. Merrell
Acting Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Specialized Health Products International, Inc. (the "Company") on Form 10-KSB for the period ending December 31, 2003 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jeffrey M. Soinski, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Jeffrey M. Soinski
Chief Executive Officer
March 23, 2004

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Specialized Health Products International, Inc. (the "Company") on Form 10-KSB for the period ending December 31, 2003 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Keith L. Merrell, Acting Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Keith L. Merrell
Acting Chief Financial Officer
March 23, 2004

SPECIALIZED HEALTH PRODUCTS INTERNATIONAL, INC.
585 West 500 South
Bountiful, Utah 84010

NOTICE OF ANNUAL MEETING OF STOCKHOLDERS
April 28, 2004

NOTICE is hereby given that the Annual Meeting of Stockholders of Specialized Health Products International, Inc. (the "Company") will be held at the Grand America Hotel located at 555 South Main Street, Salt Lake City, Utah 84101, at 9:00 a.m. MDT on April 28, 2004, for the following purposes:

1. To elect two members of the Board of Directors; and

2. To transact such other business as may properly come before such meeting or any adjournments thereof.

The record date for the meeting is the close of business on March 15, 2004 and only the holders of voting securities of the Company on that date will be entitled to vote at such meeting or any adjournment thereof.

By order of the Board of Directors

/s/ Paul S. Evans
Secretary

March 31, 2004

Please Return Your Signed Proxy

PLEASE COMPLETE AND PROMPTLY RETURN YOUR PROXY IN THE ENCLOSED ENVELOPE. THIS WILL NOT PREVENT YOU FROM VOTING IN PERSON AT THE MEETING. IT WILL, HOWEVER, HELP ASSURE A QUORUM AND AVOID ADDED PROXY SOLICITATION COSTS.

PROXY STATEMENT

SPECIALIZED HEALTH PRODUCTS INTERNATIONAL, INC.
585 West 500 South
Bountiful, Utah 84010

ANNUAL MEETING OF STOCKHOLDERS

To Be Held April 28, 2004

INTRODUCTION

This Proxy Statement is being furnished to holders of Specialized Health Products International, Inc. (the "Company") common stock (the "Common Stock" or the "Shares"), par value $0.02 per share, in connection with the solicitation of proxies by the Company for use at the Annual Meeting of Stockholders of the Company (the "Annual Meeting") to be held at the Grand America Hotel located at 555 South Main Street, Salt Lake City, Utah 84101, at 9:00 a.m. MDT on April 28, 2004, and at any adjournment(s) or postponement(s) thereof. This Proxy Statement, the enclosed Notice and the enclosed form of proxy are being first mailed to stockholders of the Company on or about March 31, 2004.

VOTING AT THE ANNUAL MEETING

The Board of Directors of the Company (the "Board") has fixed the close of business on March 15, 2004, as the record date (the "Record Date") for the determination of stockholders entitled to notice of and to vote at the Annual Meeting. As of the Record Date, there were outstanding approximately 39,782,848 shares of Common Stock held by approximately 310 holders of record. This figure includes the 21,861,369 shares of Series A Preferred stock that were converted into Common Stock on a one-for-one basis in the first quarter of 2004. On the Record Date there were no Shares of the Company's stock held as treasury stock by the Company. Holders of record of the Company's Shares on the Record Date are entitled to cast one vote per Share, exercisable in person or by properly executed proxy, with respect to each matter to be considered by them at the Annual Meeting. The presence, in person or by properly executed proxy, of the holders of a majority of the outstanding Shares is necessary to constitute a quorum at the Annual Meeting.

The Shares will be voted in accordance with the instructions indicated in a properly executed proxy. If no instructions are indicated, such Shares will be voted as recommended by the Board. If any other matters are properly presented to the Annual Meeting for action, the person(s) named in the enclosed form(s) of proxy and acting thereunder will have discretion to vote on such matters in accordance with their best judgment. Broker non-votes and abstentions are not treated as votes cast for purposes of any of the matters to be voted on at the meeting. A stockholder who has given a proxy may revoke it by voting in person at the meeting, or by giving written notice of revocation or a later-dated proxy to the Secretary of the Company at any time before the closing of the polls at the meeting. Any written notice revoking a proxy should be sent to Specialized Health Products International, Inc., 585 West 500 South, Bountiful, Utah 84010, Attention: Mr. Paul S. Evans, Secretary.

At the Company's annual meeting, stockholders will act upon the matters outlined in the accompanying notice of meeting, including the election of two directors by the holders of Common Stock. The affirmative vote of a plurality of the votes cast at the meeting by the holders of the Common Stock is required to elect the Common Director. The Board recommends that holders of the Shares vote FOR the approval of election of the directors proposed by the Board.

MATTERS TO BE CONSIDERED AT THE ANNUAL MEETING

1. Election of Directors

Board of Directors

The Company's Board is divided into three classes. One class of directors is elected at each annual meeting of stockholders for a three-year term. Each year a different class of directors is elected on a rotating basis. The terms of Stuart A. Randle and Donald D. Solomon expire in 2004. The terms of Jeffrey M. Soinski, Guy J. Jordan and Stephen I. Shapiro expire in 2005. The terms of David W. Jahns and Robert W. Walker expire in 2006. No other person has acted as a director of the Company during 2003. The number of directors comprising the Board of Directors is seven.

At this meeting Stuart A. Randle and Donald D. Solomon have been nominated by the Board for election to the class whose term expires at the 2007 annual meeting.

Unless otherwise specified, proxy votes will be cast for the election of the nominee as a director. If the nominee should be unavailable for election, the Board may designate a substitute nominee. It is intended that proxy votes will be cast for the election of such substitute nominee. Stockholder nominations of persons for election as directors are subject to the notice requirements described under the caption "Other Matters" appearing later in this proxy statement. The affirmative vote of a plurality of the votes cast at the meeting by the holders of the Shares is required to elect each director.

The following pages contain information concerning the nominee and the directors whose terms of office will continue after the meeting. Unless the context otherwise requires, all references in this Proxy to the "Company" shall mean Specialized Health Products International, Inc. ("SHPI") and its subsidiaries, Specialized Health Products, Inc. and its other subsidiaries, on a consolidated basis and, where the context so requires, shall include its predecessors.

THE BOARD RECOMMENDS A VOTE FOR THE ELECTION AS DIRECTOR OF THE NOMINEES NAMED HEREIN.

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Set forth below is certain information concerning each of our directors and executive officers as of March 22, 2004.

Name	Age	Position	With the Company Since
Jeffrey M. Soinski	42	President, Chief Executive Officer and Director	2001
Guy J. Jordan, Ph.D. (1) (2) (3)	55	Chairman of the Board	2001
Donald D. Solomon, Ph.D.	53	Vice President, Chief Operating Officer, Chief Technical Officer and Director	2000
Paul S. Evans	41	Vice President, Business Development, General Counsel and Secretary	2000
Keith L. Merrell	58	Controller, Acting Chief Financial Officer and Treasurer	2000
David W. Jahns (2)	38	Director, Chairman of Compensation Committee	2001
Stuart A. Randle (1) (3)	44	Director, Chairman of Nominating Committee	2001
Stephen I. Shapiro (2)	59	Director	2001
Robert R. Walker (1) (3)	73	Director, Chairman of Audit Committee	1994

(1) Member of Audit Committee.
(2) Member of Compensation Committee.
(3) Member of Nominating Committee.

Jeffrey M. Soinski. Mr. Soinski is our President, Chief Executive Officer and a director. His term as a director expires at the 2005 annual meeting of stockholders. Mr. Soinski brings over 20 years of general management, business development and marketing experience to our company, including several years as the President and Chief Executive Officer of ViroTex Corporation ("ViroTex"), a venture-backed pharmaceutical company focused on the development and commercialization of proprietary drug delivery systems. Mr. Soinski was with ViroTex from 1992 through 1999. He merged ViroTex into Atrix Laboratories, Inc. (Nasdaq: ATRX) in 1998, and continued working with Atrix on a transitional basis through 1999. From 2000 through 2001, Mr. Soinski was the Managing Partner and Chief Executive Officer of Mad Dogs & Englishmen, a marketing communications firm with offices in New York and San Francisco. Mr. Soinski has a BA degree from Dartmouth College.

Guy J. Jordan, Ph.D. Dr. Jordan is our Chairman of the board. His term as a director expires at the 2005 annual meeting of stockholders. Dr. Jordan brings a wealth of senior management healthcare experience to our company, with a strong focus in the areas of vascular disease and oncology. Dr. Jordan recently retired as Group President for C.R. Bard, Inc. with global operating responsibility for their oncology businesses, geographic responsibility for Canada, Australia, Latin America and Asia Pacific, and functional responsibility for all of Bard's research and development. Prior to joining C.R. Bard in 1986, Dr. Jordan held senior product development positions at American Cyanamid. Dr. Jordan has a Ph.D. degree from Georgetown University and an MBA from Fairleigh Dickinson University.

Donald D. Solomon, Ph.D. Dr. Solomon is Chief Operating Officer, Chief Technology Officer, a Vice President and a director. His term as a director expires at the 2004 annual meeting of stockholders. Dr. Solomon joined us in October 2000 and has served as a director since March 2001. He has over 24 years of medical product experience in research, product development, engineering and manufacturing. Prior to joining our company, Dr. Solomon was the Vice President of Research and Development at Johnson & Johnson Medical – Vascular Access from 1997 to 2000. Prior to that Dr. Solomon spent 14 years at Becton Dickinson ("BD"), and held positions as Worldwide Director of R&D for BD Pharmaceutical Systems Division based in France, and Director of R&D for Biocompatible Polymer Development at the BD Infusion Therapy Division. Dr. Solomon holds 38 patents and is the

author of 52 scientific publications. He received Masters and Ph.D. degrees from Case Institute of Technology at Case Western Reserve University.

Paul S. Evans. Mr. Evans is our Vice President, Business Development, General Counsel and corporate Secretary. He joined us in June 2000. Mr. Evans manages our intellectual property portfolio and corporate legal matters, and is extensively involved in business development efforts. Mr. Evans brings a wide range of intellectual property and corporate legal experience to us, having previously served as Vice President, General Counsel for an R&D company (1994 to 2000), and as a patent attorney with the law firm of Snow, Christensen & Martineau. Prior to earning his law degree, Mr. Evans worked as a Project/Design Engineer for Morton International (now Autoliv). He holds BS and JD degrees from the University of Utah.

Keith L. Merrell. Mr. Merrell is our Controller, Acting Chief Financial Officer and Treasurer. He joined us in July 2000. Mr. Merrell draws on 29 years of accounting experience to manage all of our accounting functions and to interface with our independent public accountants. He spent two years in the field of public accounting, and served as Chief Financial Officer or Controller of four companies prior to his joining us. His business career also includes extensive experience in management, sales and marketing, and consulting. He served as Vice President – Western Operations for Michelex, an injection molding company with corporate headquarters in New York, from 1998 to 2000. From 1991 to 1998 he served as Director of Finance for The Duplication Group, planning, implementing and bringing online the first CD manufacturing facility in the intermountain area. He graduated from Arizona State University with a BS degree in Accounting.

David W. Jahns. Mr. Jahns serves as one of our directors. His term as a director expires at the 2006 annual meeting of stockholders. Mr. Jahns is a General Partner and principal of Galen Partners. Since joining Galen in 1993, Mr. Jahns has been responsible for making and managing investments in several of the firm's portfolio companies. He is an experienced board member and currently serves on the boards of DAOU Systems, Inc. and several of Galen's privately held portfolio companies. Prior to joining Galen, Mr. Jahns worked in the Corporate Finance Division at Smith Barney, where he worked on a variety of corporate finance and merger and acquisition related transactions, and assisted in the marketing of public offerings. Mr. Jahns has an MBA degree from the J. L. Kellogg Graduate School of Management at Northwestern University and a BA degree from Colgate University.

Stuart A. Randle. Mr. Randle serves as one of our directors. His term as a director expires at the 2004 annual meeting of stockholders. Mr. Randle is a highly experienced healthcare executive with over 20 years of operating successes. From 1998 to 2001, Mr. Randle was the President and CEO of ACT Medical, Inc., a leading company providing outsourcing services to the medical device, biotech and diagnostic industries. He merged ACT Medical, Inc. with MedSource Technologies in 2001. From 1996 through 1998, Mr. Randle was President, Northeast Region, for Allegiance Corporation, a $5 billion medical products distribution and manufacturing company. He is also the past President, New England Region, for Baxter Healthcare Corporation. Mr. Randle has an MBA degree from the J. L. Kellogg Graduate School of Management at Northwestern University and a BS degree from Cornell University.

Stephen I. Shapiro. Mr. Shapiro serves as one of our directors. His term as a director expires at the 2005 annual meeting of stockholders. Mr. Shapiro has over 30 years of relevant medical device and equipment industry experience, with special expertise in a wide variety of healthcare markets, particularly high-volume sterile disposables, critical care instruments and cardiovascular devices. Mr. Shapiro began his career at Union Carbide Clinical Diagnostics and Becton Dickinson, where he was Director of Advanced R&D and New Business Development. In 1982, he joined The Wilkerson Group, a leading management consultancy to pharmaceutical, medical device, and diagnostic companies. Mr. Shapiro was Managing Director and a principal of The Wilkerson Group at the time of its acquisition by IBM in 1996. In 1999, Mr. Shapiro left The Wilkerson Group (now IBM Healthcare Consulting) to focus on sourcing and evaluating investments for two premier healthcare venture capital firms, including Galen Partners. He currently serves on the board of Novoste Corporation and Closure Medical Corporation. Mr. Shapiro has a BS degree from the Massachusetts Institute of Technology and an MS degree in biomedical engineering from the University of California, Berkley.

Robert R. Walker. Mr. Walker serves as one of our directors. His term as a director expires at the 2006 annual meeting of stockholders. Since 1992, Mr. Walker has been principally self-employed as a consultant in the healthcare industry primarily in the area of start-up medical device companies. From 1976 to 1992, Mr. Walker was

employed by IHC Affiliated Services Division of Intermountain Healthcare, a regional hospital company. He retired as President of IHC Affiliated Services in 1992. He is also a former Chairman of the board of AmeriNet, Inc., a national group purchasing organization for hospitals, clinics, detox/drug centers, emergency, nursing homes, private laboratories, psychiatric centers, rehabilitation facilities, surgical centers and other institutions. Mr. Walker is a member of the American Hospital Association and the Hospital Financial Management Association. He has a BS degree in Business Administration from the University of Utah.

Our executive officers are elected by the board on an annual basis and serve at the discretion of the board.

The Company has adopted a Code of Ethics that applies to our principal executive officer, principal financial officer, principal accounting officer and other senior financial officers. Our Code of Ethics is posted on the Company's Web site.

Board Committees

The Board has a standing Audit Committee, Compensation Committee, and Nominating Committee.

The Audit Committee

The Company's Audit Committee held three meetings during 2003. The function of the Audit Committee as detailed in the Audit Committee Charter is to provide assistance to the Board in fulfilling their responsibility to the stockholders, potential shareholders, and investment community relating to corporate accounting, reporting practices of the Company and the quality and integrity of the financial reports of the Company. In so doing, it is the responsibility of the Audit Committee to maintain free and open means of communication between the directors, the independent auditors and Company management. The Company believes that the members of the Audit Committee are independent as defined by Rule 4200(a) of NASD's listing standards. The members of the Audit Committee are Guy J. Jordan, Stuart A. Randle and Robert R. Walker. Mr. Walker, Chairman of our Audit Committee, serves as our financial expert on that committee.

The Compensation Committee

The Company's Compensation Committee held one meeting during 2003. The Compensation Committee administers the Company's stock option plan, establishes a general compensation policy for the Company and, except as prohibited by applicable law, may take any and all actions that the Board could take relating to the compensation of employees, directors and other parties. The members of the Compensation Committee are David W. Jahns, Guy J. Jordan, and Stephen I. Shapiro. David W. Jahns is Chairman of our Compensation Committee.

The Nominating Committee

The Nominating Committee was formed in January 2004. As a result, it held no meetings in 2003. The Nominating Committee's Charter and Policies are available on the Company's website, which is located at www.shpi.com. The Company believes that the members of the Nominating Committee are independent as defined by Rule 4200(a) of NASD's listing standards. The members of the Nominating Committee are Guy J. Jordan, Stuart A. Randle and Robert R Walker. Stuart A. Randle is Chairman of our Nominating Committee.

The Nominating Committee has held one meeting during 2004 to date in which it recommended the nomination of Messrs. Randle and Solomon for reelection to the Board. The function of the Nominating Committee, as detailed in the Nominating Committee's Charter, is to recommend to the Board the slate of director nominees for election to the Board and to identify and recommend candidates to fill vacancies occurring between annual shareholder meetings. It is the policy of the Nominating Committee to consider candidates recommended by security holders, directors, officers and other sources, including, but not limited to, third-party search firms. Security holders of the Company may submit recommendations for candidates for the Board. All recommendations shall be submitted to Paul Evans at SHPI, Inc, 585 West 500 South, Bountiful, Utah 84010 (telephone: 801-298-3360, email: pevans@shpi.com). Such submissions should include the name, contact information, a brief description of the candidate's business experience and such other information as the person submitting the recommendation believes is relevant to the evaluation of the candidate. Paul Evans will then pass all such recommendations on to the

Nominating Committee for consideration. For candidates to be considered for election at the next annual meeting stockholders, the recommendation must be received by the Company no later than 120 calendar days prior to the date that the Company's proxy statement is released to security holders in connection with such meeting.

The Nominating Committee has not established any fixed minimum qualifications in order to consider a proposed candidate for election to the Board. However, the Nominating Committee has a strong preference for candidates with prior board of director experience with public companies. The Nominating Committee will also consider such other factors as it deems appropriate to assist in developing a board and committees that are diverse in nature and comprised of experienced and seasoned advisors. These factors include judgment, skill, diversity (including factors such as race, gender or experience), integrity, experience with businesses and other organizations of comparable size, the interplay of the candidate's experience with the experience of other Board members, and the extent to which the candidate would be a desirable addition to the Board and any committees of the Board.

The Nominating Committee will evaluate whether an incumbent director should be nominated for re-election to the Board or any committee of the Board upon expiration of such director's term using the same factors as described above for other Board candidates and the committee will also take into account the incumbent director's performance as a Board member. Failure of any incumbent director to attend at least seventy-five percent (75%) of the Board meetings held in any calendar year will be viewed negatively by the Nominating Committee in evaluating the performance of such director.

Board Meetings, Directors' Attendance and Security Holder Communications

The Board held nine meetings during 2003. There were no actions taken by unanimous consent during 2003. No incumbent director attended fewer than 75 percent of the Board meetings held or fewer than 75 percent of the committee meetings held by committees on which an incumbent director served during 2003. The Company's policy is to encourage, but not require, Board members to attend annual stockholder meetings. Four of our Board members attended the 2003 annual stockholders meeting.

Security holders who would like to send communications to the Board may do so by submitting such communications to Paul Evans at SHPI, Inc, 585 West 500 South, Bountiful, Utah 84010 (telephone: 801-298-3360, email: pevans@shpi.com). The Board suggests, but does not require, that such submissions include the name and contact information of the security holder making the submission and a description of the matter that is the subject of the communication. Paul Evans will then pass such information on to the Board for review.

Certain Relationships And Related Transactions

On November 7, 2001, our stockholders approved the issuance to Galen Partners and other accredited and sophisticated investors of a total of 10,917,030 shares of Series A Preferred Stock for an aggregate purchase price of $5 million, or $.458 per share. Galen Partners purchased their shares for $3,500,000 and the other investors purchased their shares in exchange for the cancellation of $1,500,000 of debt.

In September and November 2002, Galen Partners and other accredited and sophisticated investors exercised rights to acquire an additional 10,944,339 shares of Series A Preferred Stock for an aggregate net purchase price of $5,002,957, or $.458 per share. The Series A Preferred Stock automatically converted into Common Stock in the first quarter of 2004 as a result of the average closing share price of our Common Stock, as reported on the OTC Bulletin Board, exceeding $1.374 for twenty consecutive trading days.

On March 22, 2004, the Company entered into an agreement with Galen Partners III, L.P., Galen Partners International III, L.P., and Galen Employee Fund III, L.P. (collectively, "Galen Partners") whereby Galen Partners agreed to purchase a convertible promissory note ("Note") in the aggregate principal amount of $1,000,000 upon the request of the Company made at any time between March 31, 2004 and March 31, 2005. The Note has a term of three years and bears interest at the rate of 12% per annum, with accrued interest to be paid July 1 and January 1 of each year the Note remains outstanding. The entire outstanding principal amount due on the Note may, at Galen Partners' option, be converted into fully paid and nonassessable shares of common stock of the Company. The conversion price will be 110% of the Company's average closing share price for common stock as reported on NASDAQ or the OTC Bulletin Board for the twenty (20) consecutive trading days prior to the date of the issuance

of the Note. As consideration for this purchase agreement, Galen Partners will receive a warrant that provides them the right, but not the obligation, to purchase 80,000 shares of common stock of the Company at an exercise price of $0.02 per share. The warrant shall expire and be no longer exercisable after 5:00 p.m., Eastern Time, on March 22, 2007. Further, the Company is obligated to pay up to $10,000 in legal fees incurred by Galen Partners related to this transaction.

Security Ownership of Management and Certain Beneficial Owners

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of March 22, 2004, for: (i) each person who is known by us to beneficially own more than five percent of our common stock, (ii) each of our directors, (iii) each of our Named Executive Officers, and (iv) all directors and executive officers as a group. On March 22, 2003 the Company had 39,782,848 shares of Common Stock outstanding. This figure includes the 21,861,369 shares of Series A Preferred stock that were converted into Common Stock on a one-for-one basis in the first quarter of 2004.

Name and Address of Beneficial Owner(1)	Shares Beneficially Owned(2)	Percentage of Total(2)	Position
Jeffrey M. Soinski (3)	1,521,980	3.68	President, CEO and Director
Guy J. Jordan, Ph.D. (4)	322,220	*	Chairman of the Board
Donald D. Solomon, Ph.D. (5)	600,259	1.49	Vice President, COO, CTO and Director
Paul S. Evans (6)	444,253	1.10	Vice President, Business Development, General Counsel, and Secretary
Keith L. Merrell (7)	168,715	*	Controller, Acting CFO and Treasurer
David W. Jahns (8)	80,542	*	Director
Stuart A. Randle (9)	77,765	*	Director
Stephen I. Shapiro (10)	146,045	*	Director
Robert R. Walker (11)	187,542	*	Director
Executive Officers and Directors as a Group (9 persons)	3,361,779	7.79	
Galen Partners III, L.P. and affiliates (12)	15,336,413	38.5	

* Less than 1%.

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(1) Except where otherwise indicated, the address of the beneficial owner is deemed to be the same address as the company.

(2) Beneficial ownership is determined in accordance with SEC rules and generally includes holding voting and investment power with respect to the securities. Shares of common stock subject to options or warrants currently exercisable, or exercisable within 60 days, are deemed outstanding for computing the percentage of the total number of shares beneficially owned by the designated person, but are not deemed outstanding for computing the percentage for any other person.

(3) Includes 11,586 shares of common stock purchased through our 401(k) plan and options to acquire 1,510,394 shares of common stock. Does not include options to acquire 978,020 shares of common stock that vest 60 days beyond March 22, 2004.
(4) Includes options to acquire 322,220 shares of common stock. Does not include options to acquire 77,780 shares of common stock that vest 60 days beyond March 22, 2004.
(5) Includes 10,000 shares of common stock, 65,666 shares of Series A Preferred Stock that is immediately convertible into the same number of shares of common stock, 62,101 shares of common stock purchased through our 401(k) plan and options to acquire 462,492 shares of common stock. Does not include options to acquire 237,508 shares of common stock that vest 60 days beyond March 22, 2004.
(6) Includes 61,000 shares of common stock, 41,609 shares of common stock purchased through our 401(k) plan and options to acquire 341,644 shares of common stock. Does not include options to acquire 158,356 shares of common stock that vest 60 days beyond March 22, 2004.
(7) Includes 36,000 shares of common stock, 36,953 shares of common stock purchased through our 401(k) plan and options to acquire 95,762 shares of common stock. Does not include options to acquire 84,238 shares of common stock that vest 60 days beyond March 22, 2004.
(8) Includes options to acquire 80,542 shares of common stock. Does not include options to acquire 19,548 shares of common stock that vest 60 days beyond March 22, 2004. Does not include shares held by Galen Partners III, L.P. David Jahns is a member of Claudius, L.L.C., a Delaware limited liability company, and a general partner of Galen Partners III, L.P. and Galen Partners International III, L.P. See note (12) below.
(9) Includes options to acquire 77,765 shares of common stock. Does not include options to acquire 72,235 shares of common stock that vest 60 days beyond March 22, 2004.
(10) Includes 65,503 shares of Series A Preferred Stock that is immediately convertible into the same number of shares of common stock and options to acquire 80,542 shares of common stock. Does not include options to acquire 19,458 shares of common stock that vest 60 days beyond March 22, 2004.
(11) Includes stock options to purchase 124,542 shares of common stock and 63,000 shares of common stock that Mr. Walker is deemed to beneficially own through a trust. Does not include options to acquire 69,458 shares of common stock that vest 60 days beyond March 22, 2004.
(12) Information regarding Galen Partners III, L.P. and its affiliates is derived from the Form 4 filed by Galen Partners III, L.P. with the Securities and Exchange Commission on September 9 and September 26, 2002. Shares owned represent 13,937,735 shares of Series A Preferred Stock held of record by Galen Partners III, L.P., 1,261,605 shares of Series A Preferred Stock held of record by Galen Partners International III, L.P., and 57,073 shares of Series A Preferred Stock held of record by Galen Employee Fund III, L.P. Also includes warrants to purchase 80,000 shares of common stock. William R. Grant, Bruce F. Wesson, L. John Wilkerson, David W. Jahns, Srini Conjeevaram, and Zubeen Shroff are all natural persons and are the members of Claudius, L.L.C., a Delaware limited liability company, the general partner of Galen Partners III, L.P. and Galen Partners International III, L.P. Bruce F. Wesson is the President of Wesson Enterprises, Inc., a Delaware corporation, which is the general partner of Galen Employee Fund III, L.P.

Section 16(a) Beneficial Ownership Reporting Compliance

The members of the Board, the executive officers of the Company and persons who hold more than ten percent of the Company's Common Stock are subject to reporting requirements of Section 16(a) of the Securities Exchange Act of 1934, which require them to file reports with respect to their ownership of and transaction in the Company's securities, and furnish the Company copies of all such reports they file. Based upon the copies of those reports furnished to the Company, and written representations that no other reports were required to be filed, the Company believes that all reporting requirements under Section 16(a) for the fiscal year ended December 31, 2003, were met in a timely manner by its executive officers, Board members and greater than ten percent stockholders.

Executive Compensation

Summary Compensation Table. The following table provides certain information regarding compensation paid by the company to the Named Executive Officers.

SUMMARY COMPENSATION TABLE

Name and Principal Position	Year	Annual Compensation Salary ($)	Bonus ($)	Other Annual Compensation($) (1)	Awards Restricted Stock Awards ($)	Stock Options/ SAR(#)	Payouts LTIP Payouts($)	All Other Compensation ($) (3)
Jeffrey M. Soinski	2001	14,615(2)	---	---	---	2,500,000	---	---
President, CEO & Director	2002	240,000	43,200(4)	11,000	---	---	---	610
	2003	246,312	41,873(5)	12,000	---	---		658
Donald D. Solomon, Ph.D.	2001	165,000	---	8,250	---	600,000	---	273
VP, CTO, COO &	2002	190,000	34,200(4)	9,500	---	---	---	1,081
Director	2003	195,312	33,203(5)	9,766	---	---	---	1,754
Paul S. Evans , VP of	2001	165,000	---	7,219	28,125	400,000	---	460
Business Development,	2002	175,000	31,500(4)	---	---	---	---	579
General Counsel & Secretary	2003	180,312	30,653(5)	8,550	---	---	---	627
Keith L. Merrell	2001	90,000	---	4,500	---	55,000	---	410
Acting CFO, Controller &	2002	102,000	3,000	5,100	---	---	---	456
Treasurer	2003	105,168	5,000(5)	5,258	---	75,000	---	504
Larry D. Sheldon (7)	2002	21,923(6)	---	---	---	500,000	---	---
VP, Sales and Marketing	2003	180,312	---	8,839	---	---	---	925

(1) These amounts represent payments by us into our 401(k) retirement plan for the benefit of the Named Executive Officer.
(2) Mr. Soinski joined SHPI in November 2001. Salary represents partial year from the date of his employment.
(3) Represents amounts paid by us for life insurance on the lives of Mr. Soinski, Dr. Solomon, Mr. Evans, Mr. Sheldon and Mr. Merrell with insurance proceeds payable to the beneficiary designated by them.
(4) Bonuses accrued and expensed in 2002; paid in 2003.
(5) Bonuses accrued and expensed in 2003; paid in 2004.
(6) Mr. Sheldon joined SHPI in November 2002. Salary represents partial year from the date of his employment.
(7) Mr. Sheldon resigned from the Company effective February 13, 2004.

Option Grants in Fiscal Year 2003

The following table sets forth certain information with respect to stock options grants during the year ended December 31, 2003 to Named Executive Officers.

OPTION/SAR GRANTS IN LAST FISCAL YEAR
(Individual Grants)

Name	Number of Securities Underlying Options/SAR Granted (#) (1)	Percent of Total Options/SAR Granted to Employees in Fiscal Year	Exercise or Base Price ($/Share)	Expiration Date
Keith L. Merrell	75,000	20%	$1.00	12/04/2013

(1) These options were granted pursuant to our 2000 Stock Option Plan.

Compensation of Directors

No cash fees or other consideration were paid to our employee directors for service on the Board during 2003. We did not provide cash compensation to non-employee directors in 2003. In November 2001, we granted stock options, which vest over a three-year period, to our non-employee directors as compensation for service on the Board. During 2002 and 2003 we made no other agreements regarding compensation of non-employee directors.

All directors are entitled to reimbursement for reasonable out-of-pocket travel related expenses incurred in the performance of their duties as Board members.

During 2004, non-executive Board members will each receive $2,500 per in-person Board meeting attended, $500 per telephonic Board meeting participated in, $500 per committee meeting attended, and $2,500 per additional in-person meeting scheduled by the Board and requiring director attendance.

Employment and Indemnity Agreements

We have entered into an employment agreement with Mr. Jeffrey Soinski. The employment agreement provides that (i) Mr. Soinski receive a beginning base salary of $240,000 per year in addition to performance based bonuses; (ii) Mr. Soinski receive stock options to acquire 2.5 million shares of our Common Stock at market value on the date of grant which stock options vest over a four-year period; (iii) Mr. Soinski is entitled to vacation pay, health insurance and life insurance; (iv) Mr. Soinski's employment contract may be terminated at any time by us; (v) if the employment of Mr. Soinski is terminated by reason of disability, death or for cause, his salary and benefits (except as otherwise required by law) will terminate as of the date of termination; (vi) if Mr. Soinski is terminated for reasons other than disability, death or for cause, then Mr. Soinski's salary and medical benefits will continue for a period of 18 months from the date of termination and his other benefits will cease as of the date of termination.

We have entered into an employment agreement with Donald Solomon, Ph.D. The employment agreement provides that (i) Dr. Solomon receive a beginning base salary of $190,000 per year in addition to performance based bonuses; (ii) Dr. Solomon receive stock options to acquire 600,000 shares of our Common Stock at market value on the date of grant which stock options vest over a four-year period; (iii) Dr. Solomon is entitled to vacation pay, health insurance and life insurance; (iv) Dr. Solomon's employment contract may be terminated at any time by us; (v) if the employment of Dr. Solomon is terminated by reason of disability, death or for cause, his salary and benefits (except as otherwise required by law) will terminate as of the date of termination; (vi) if Dr. Solomon is terminated for reasons other than disability, death or for cause, then Dr. Solomon's salary and medical benefits will continue for a period of 12 months from the date of termination and his other benefits will cease as of the date of termination.

We have entered into an employment agreement with Mr. Paul Evans. The employment agreement provides that (i) Mr. Evans receive a beginning base salary of $175,000 per year in addition to performance based bonuses; (ii) Mr. Evans receive stock options to acquire 400,000 shares of our Common Stock at market value on the date of grant which stock options vest over a four-year period; (iii) Mr. Evans is entitled to vacation pay, health insurance and life insurance; (iv) Mr. Evans' employment contract may be terminated at any time by us; (v) if the employment of Mr. Evans is terminated by reason of disability, death or for cause, his salary and benefits (except as otherwise required by law) will terminate as of the date of termination; (vi) if Mr. Evans is terminated for reasons other than disability, death or for cause, then Mr. Evans' salary and medical benefits will continue for a period of 12 months from the date of termination and his other benefits will cease as of the date of termination.

We have entered into an employment agreement with Mr. Keith Merrell. The employment agreement provides that (i) Mr. Merrell receive a beginning base salary of $102,000 per year in addition to performance based bonuses; (ii) Mr. Merrell receive stock options to acquire 55,000 shares of our Common Stock at market value on the date of grant which stock options vest over a four-year period; (iii) Mr. Merrell is entitled to vacation pay and health insurance; (iv) Mr. Merrell's employment contract may be terminated at any time by us; (v) if the employment of Mr. Merrell is terminated by reason of disability, death or for cause, his salary and benefits (except as otherwise required by law) will terminate as of the date of termination; (vi) if Mr. Merrell is terminated for reasons other than disability, death or for cause, then Mr. Merrell's salary and medical benefits will continue for a period of 3 months from the date of termination and his other benefits will cease as of the date of termination.

In January 2003, the Board approved a 2003 Executive Officer Bonus Plan. Under the plan executive officers eligible for bonuses during 2003 include the CEO, COO, VP of Sales and Marketing and VP of Business Development and General Counsel. Plan participants will earn 20% of their annual salary based upon 100% achievement of the overall revenue goal outlined in our approved budget plan. Also, plan participants will be eligible to receive incremental bonus payments for performing beyond the budget plan. The amount of incremental payments, if earned, will be based upon the recommendation of the Compensation Committee and approved by the

Board. The maximum base bonus that could be paid under this plan is $160,200. In January 2004, the Board approved payment of $105,729 under this plan. In connection with this plan, we also adopted an Employee Bonus Plan for employees other than the Named Executive Officers to reward specific individual or team achievements during 2003. Of the $75,000 maximum authorized, $61,000 was approved for payment.

In February 2004, the Board approved a 2004 Executive Officer Bonus Plan. Under the plan executive officers eligible for bonuses during 2004 include the CEO, COO, and VP of Business Development and General Counsel. Plan participants will earn up to 20% of their annual salary based upon achievement of certain revenue, net income, and cash flow goals. Also, plan participants will be eligible to receive incremental bonus payments for performing beyond the goals. The amount of incremental payments, if earned, will be based upon the recommendation of the Compensation Committee and approved by the Board. The maximum base bonus that could be paid under this plan is $126,750.

We have entered into indemnity agreements (the "Indemnity Agreements") with each of our executive officers and directors pursuant to which we have agreed to indemnify the officers and directors to the fullest extent permitted by law for any event or occurrence related to the service of the indemnitee for us as an officer or director that takes place prior to or after the execution of the Indemnity Agreement. The Indemnity Agreements obligate us to reimburse or advance expenses relating to any proceeding arising out of an indemnifiable event. Under the Indemnity Agreements, our officers and directors are presumed to have met the relevant standards of conduct required by Delaware law for indemnification. Should the Indemnity Agreements be held to be unenforceable, indemnification of these officers and directors may be provided by us in certain cases at our discretion.

401(k) Retirement Plan

Effective in 1996, we adopted a 401(k) retirement plan whereby we contribute up to five percent of payroll compensation to the plan, matching employee contributions to the plan on a dollar for dollar basis up to the maximum five percent contribution.

Accrued Vacation Pay

Our current policy allows all employs to carry over maximum days of vacation pay from year to year equivalent to a one-year accrual at the rate earned.

Indemnification for Securities Act Liabilities

Delaware law authorizes, and our Bylaws and Indemnity Agreements provide for, indemnification of our directors and officers against claims, liabilities, amounts paid in settlement and expenses in a variety of circumstances. Indemnification for liabilities arising under the Act may be permitted for our directors, officers and controlling persons pursuant to the foregoing or otherwise. However, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Exchange Act of 1934 and is, therefore, unenforceable.

Stock Options and Warrants

In November 2001, our stockholders approved the adoption of the Specialized Health Products International, Inc. 2001 Stock Option Plan (the "2001 Option Plan"). The 2001 Option Plan permits us to grant "non-qualified stock options" and "incentive stock options" to acquire our Common Stock. The total number of shares authorized for the Option Plan may be allocated by the Board between the non-qualified stock options and the incentive stock options from time to time, subject to certain requirements of the Internal Revenue Code of 1986, as amended. The option exercise price per share under the Option Plan may not be less than the fair market value of a share of Common Stock on the date on which the option is granted. A total of 5,000,000 shares are allocated to the Option Plan. As of December 31, 2003, options to acquire an aggregate of 4,672,690 shares of Common Stock at exercise prices ranging from $1.00 to $2.00 were outstanding under the Option Plan.

We have also issued stock options under stock options plans that preceded the 2001 Option Plan ("Prior Plans"). As of December 31, 2003, options to acquire an aggregate of 2,013,000 shares of Common Stock at exercise prices ranging from $1.00 to $2.00 were outstanding under Prior Plans.

In addition to the stock options detailed above, we have outstanding warrants to buy 500,000 shares of Common Stock at an exercise price of $2.00.

Compensation Committee Interlocks and Insider Participation

None of our executive officers serve on our Compensation Committee or in a like capacity in any other entity.

2. Other Matters

Discretionary Authority

At the time of mailing of this proxy statement, the Board was not aware of any other matters, which might be presented at the meeting. If any matter not described in this Proxy Statement should properly be presented, the persons named in the accompanying proxy form will vote such proxy in accordance with their judgment.

Independent Public Accountants

The Company retained PricewaterhouseCoopers LLP ("PWC") as its independent auditor for the current year. PWC has acted as the Company's independent auditor since 2002. The Company expects representatives of PWC to be present at the Company's 2003 Annual Meeting of Stockholders. PWC will have the opportunity to make a statement at the annual meeting if it desires to do so and it is expected that representatives of PWC will be available to respond to appropriate questions if called upon to do so.

Report of the Audit Committee of the Board Of Directors

The Company's Board has adopted a written charter for the Audit Committee, which is included as Annex A hereto.

The Audit Committee hereby reports as follows:

1. The Audit Committee has reviewed and discussed the audited financial statements with the Company's management.

2. The Audit Committee has discussed with PWC, the Company's independent accountants, the matters required to be discussed by SAS 61 (Communication with Audit Committees).

3. The Audit Committee has received the written disclosures and the letter from PWC required by Independence Standards Board Standard No. 1 (Independence Discussions with Audit Committees), and has discussed with PWC their independence.

4. Based on the review and discussion referred to in paragraphs (1) through (3) above, the Audit Committee recommended to the Board, and the Board has approved, that the audited financial statements be included in the Company's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2002, for filing with the Securities and Exchange Commission.

Guy J. Jordan
Stuart A. Randle
Robert R. Walker

Changes in Accountants

In July 2002, the Company retained PWC as its independent auditor. Prior to the engagement of PWC, Arthur Andersen LLP ("AA") had acted as the Company's independent auditor. The Company's Board of Directors made the decision to change auditors due to the cessation of business by AA.

The reports on the financial statements of the Company for each of the two past fiscal years did not contain any adverse opinion or disclaimer of opinion and were not modified as to uncertainty, audit scope, or accounting principles.

During the Company's two most recent fiscal years, there were no disagreements with AA on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements(s), if not resolved to the satisfaction of AA, would have caused AA to make a reference to the subject matter of the disagreements(s) in connection with its report; nor has AA ever presented a written report, or otherwise communicated in writing to the Company or its Board of Directors the existence of any "disagreement" or "reportable event" within the meaning of Item 304 of Regulation S-B.

Audit Fees

The aggregate fees billed for professional services rendered by our principal accountant for the audit of our financial statements, review of financial statements included in our quarterly reports and other fees that are normally provided by the accountant in connection with statutory and regulatory filings or engagements for the fiscal years ended December 31, 2003 and 2002 were $76,855 and $74,070, respectively.

Audit Related Fees

The aggregate fees billed for assurance and related services by our principal accountant that are reasonably related to the performance of the audit or review of our financial statements, other than those previously reported above under "Audit Fees," for the fiscal years ended December 31, 2003 and 2002 were $0 and $0, respectively.

Tax Fees

The aggregate fees billed for professional services rendered by our principal accountant for tax compliance, tax advice and tax planning for the fiscal years ended December 31, 2003 and 2002 were $9,500 and $9,500, respectively.

All Other Fees

The aggregate fees billed for products and services provided by the principal accountant, other than those reported above, for the fiscal years ended December 31, 2003 and 2002 were $0 and $0, respectively.

Audit Committee

It is the Company's policy that the Audit Committee pre-approves all audit, tax and related services. All of the services described under the prior four headings were approved in advance by our Audit Committee. No items were approved by the audit committee pursuant to paragraph (c)(7)(i)(C) of Rule 2-01 of Regulation S-X. The Audit Committee has considered whether the provision of the services performed by our principal accountant is compatible with maintaining the principal accountant's independence.

Financial Information Systems Design and Implementation Fees

The aggregate fees billed by PWC for professional services rendered in connection with Company's financial information system and related design and implementation fees was $0.

Notice Requirements

Any stockholder who desires to have a proposal included in the Company's proxy soliciting material relating to the Company's 2005 annual meeting of stockholders should send to the Secretary of the Company a signed notice of intent. This notice, including the text of the proposal, must be received no later than February 15, 2005.

Annual Report

This Proxy Statement has been preceded or accompanied by an Annual Report. Stockholders are referred to such reports for financial and other information about the activities of the Company, but such report is not to be deemed a part of the proxy soliciting material.

Expenses and Methods of Solicitation

The expenses of soliciting proxies will be paid by the Company. In addition to the use of the mails, proxies may be solicited personally, or by telephone or other means of communications, by directors, officers and employees of the Company and its subsidiaries, who will not receive additional compensation therefor. Arrangements will also be made with brokerage firms and other custodians, nominees and fiduciaries for the forwarding of proxy solicitation material to certain beneficial owners of the Company's Common Stock, and the Company will reimburse such forwarding parties for reasonable expenses incurred by them.

By order of the Board of Directors,

By /s/ Paul S. Evans
Paul S. Evans, Secretary

APPENDIX A

SPECIALIZED HEALTH PRODUCTS INTERNATIONAL, INC.

AUDIT COMMITTEE CHARTER

ORGANIZATION

There shall be a committee of the board of directors of Specialized Health Products International, Inc. (the "Company") to be known as the Audit Committee. The Audit Committee shall be composed of directors who are independent of the management of the Company and are free of any relationship that, in the opinion of the board of directors (the "Board"), would interfere with their exercise of independent judgment as a committee member.

STATEMENT OF POLICY

The Audit Committee shall provide assistance to the board of directors in fulfilling their responsibility to the shareholders, potential shareholders, creditors and other stakeholders relating to corporate accounting, reporting practices of the Company and the quality and integrity of the financial reports of the Company. In so doing, it is the responsibility of the Audit Committee to maintain free and open means of communication between the directors, the independent auditors and Company management.

COMPOSITION

The Audit Committee shall be comprised of three or more directors as determined by the Board, each of whom shall be independent directors. All members of the Audit Committee shall have a working familiarity with basic finance and accounting practices, and at least one member of the Audit Committee shall have accounting or related financial management expertise.

The members of the Audit Committee shall be appointed by the Board at the annual organizational meeting of the Board or until their successors shall be duly qualified and appointed. Unless a chair is appointed by the full Board, the members of the Audit Committee may designate a chair by majority vote of the full Audit Committee membership.

MEETINGS

The Audit Committee shall meet at least two times annually, or more frequently as circumstances dictate. As part of its responsibility to foster open communication, the Audit Committee or its members are expected to meet for discussions with Company management frequently. There will be at least two formal meetings with Company management in the presence of the independent auditors. The Audit Committee will hold separate executive sessions to discuss any matters that the Audit Committee believes should be discussed privately.

RESPONSIBILITIES

In carrying out its responsibilities, the Audit Committee's policies and procedures will remain flexible, in order to best react to changing conditions and to ensure that the corporate accounting and reporting practices of the Company are in accordance with all requirements and are of the highest quality.

In carrying out these responsibilities, the Audit Committee will:

1. Develop an effective Audit Committee charter approved by the Board. Update this charter at least annually or as business developments may dictate.

2. Influence the overall Company "tone" for quality financial reporting, sound business risk controls, and ethical behavior.

3. Review and recommend to the Board the Audit Committee's choice of independent auditors and the level of fees for audits of the financial statements of the Company. Recommend dismissal when necessary. Maintain an active dialog with the independent auditors to identify and disclose any relationship or services that may impact the objectivity and independence of the auditors.

4. Meet with the independent auditors and financial management of the Company to review the scope of the proposed audit for the current year and the audit procedures to be utilized, and at the conclusion thereof review the results of such audit, including any comments or recommendations of the independent auditors.

5. Emphasize the adequacy of internal controls to identify any payments, transactions, or procedures that might be deemed illegal or otherwise improper. Review the Company's policy statements to enforce adherence to its code of conduct.

6. Monitor the integrity and quality of annual and interim financial reporting to shareholders with management and the independent auditors to determine that the independent auditors are satisfied with the disclosure and content of the financial statements to be presented to the shareholders. Review changes in accounting principles and concur as to their appropriateness.

   The Audit Committee on a regular basis should also monitor the integrity and quality of internal financial and operating information used by management in its decision making processes.

7. Provide sufficient opportunity for the independent auditors to meet with the members of the Audit Committee without members of management present. Among the items to be discussed in these meetings are the independent auditors' evaluation of the Company's financial and accounting personnel, and the cooperation that the independent auditors received during the course of the audit.

8. Consider and review with the independent auditors:

   (a) Any significant findings in the independent auditors SAS 71 interim financial statement review prior to the Company's filing of its Form 10-QSB.

   (b) The adequacy of the Company's internal controls including computerized information system controls and security.

   (c) Any significant findings and recommendations of the independent auditors together with management's responses thereto.

9. Monitor compliance with the Company code of conduct and regulatory requirements, and review and assess conflicts of interest and related-party transactions.

10. Evaluate and make recommendations regarding management initiatives affecting the financing of the Company and related matters.

11. Assess independent auditor performance.

12. Assess Audit Committee performance.

13. Review and approve required stock exchange certifications, if any, and proxy statement disclosure.

14. Provide a report of the Audit Committee's findings that result from its financial reporting oversight responsibilities including representation that the Audit Committee has:

    a. discussed with the independent auditors the matters required to be discussed by Statement on Auditing Standards No. 61, Communication with Audit Committees, as amended,

b. received and reviewed the written disclosures and the letter from the independent auditors required by Independence Discussions with Audit Committees, as amended, by the Independence Standards Board,

c. discussed with the auditors the auditors' independence.

This report from the Audit Committee is to be included in proxy statements filed by the Company.

15. Conduct an annual quality discussion with the independent auditors wherein the independent auditors discuss their judgment about the quality, not just the acceptability, of the Company's accounting principles as applied in it financial reporting.

16. Ensure that the independent auditors review interim financial statements and conduct a quality discussion with the independent auditors before the Company files its Form 10-Q or 10-QSB.

PROXY CARD FOR ANNUAL MEETING OF STOCKHOLDERS OF SPECIALIZED HEALTH PRODUCTS INTERNATIONAL, INC

This Proxy is Solicited on Behalf of the Board Of Directors. The undersigned hereby appoints Jeffrey M. Soinski as Proxy, with the power to appoint his substitute and hereby authorize them to represent and to vote, as designated below, all voting shares of stock of Specialized Health Products International, Inc. held of record by the undersigned on March 15, 2004, at the annual meeting of stockholders to be held on April 28, 2004, or any adjournment thereof.

1. Election of Nominee Director

☐ FOR Stuart A. Randle ☐ WITHHOLD AUTHORITY to vote for Stuart A. Randle

☐ FOR Donald D. Solomon ☐ WITHHOLD AUTHORITY to vote for Donald D. Solomon

2. In their discretion, the Proxy is authorized to vote upon such other business as may properly come before the meeting.

This proxy when properly executed will be voted in the manner directed herein by the undersigned stockholder(s). If no directions are made, this proxy will be voted for the above Proposals.

Please sign below. When shares are held by joint tenants, both should sign. When signing as attorney, executor, administrator, trustee or guardian, please give full title as such. If a corporation, please sign in full corporation name by President or other authorized officer. If a partnership, please sign in partnership name by authorized person.

Dated: _____, 2004

_____
(signature)

_____
(signature if held jointly)

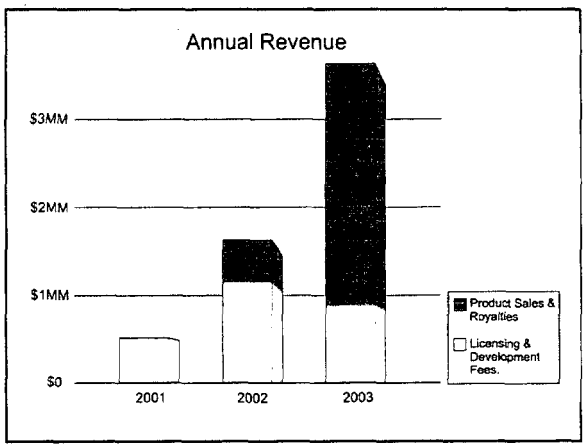
Please mark, sign, date and return the proxy card promptly using the enclosed envelope or proxy cards may be sent by facsimile to Colonial Stock Transfer at (801) 355-6505 or directly to the Company at (801) 298-1759.

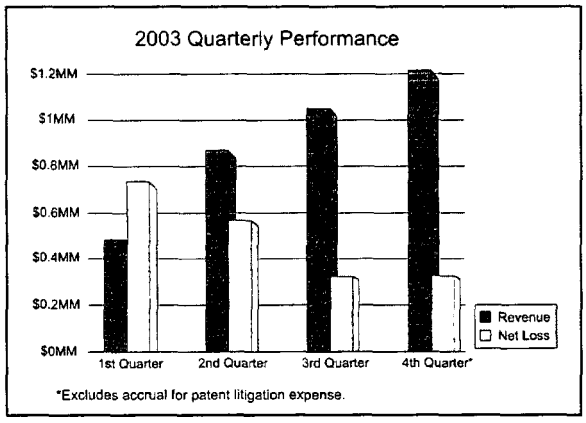
_____
(print name of stockholder(s))

March 31, 2004

Dear Stockholders,

2003 was a year of significant growth for SHPI. We more than doubled our revenue to $3.6 million in 2003, based largely upon the strength of our LiftLoc® Safety Infusion Set product line, our first manufactured product, and the Monoject Magellan™ safety syringe product line marketed by Kendall, a business unit of Tyco Healthcare. We expanded our marketed product portfolio with the launch of LuproLoc™ by TAP Pharmaceutical Products early in 2003 and the Monoject Magellan™ safety blood collection product line by Kendall earlier this year. We built our infrastructure with the achievement of ISO certification and a CE Mark for LiftLoc® to pave the way for the international launch of our manufactured products. We established a foundation for future growth with the filing of 16 additional U.S. and foreign patent applications for SecureLoc™, our second major platform technology, and the completion of our first major product agreement on this technology with BD (Becton, Dickinson and Company). We carefully managed our expenses to significantly reduce our net loss in 2003, and bring the company closer to sustainable profitability.





As highlighted in my letter to the stockholders at this time last year, we began 2003 with the objective of dramatically improving our operating results to bring us closer to our goal of becoming a successful operating company with multiple product lines and strategic relationships. As discussed above and illustrated in the graphs to the right, we built upon the positive momentum started in 2002 with the launch of our first marketed products to take our company to the next level in 2003, and establish a platform for continued growth in 2004.

The year, however, has not been without challenges. In December 2002, BD filed a lawsuit against Tyco Healthcare asserting that Tyco Healthcare's Monoject Magellan™ safety products infringe upon one of BD's U.S. patents. Tyco Healthcare responded in court filings that the Monoject Magellan™ safety products

SHPI
WWW.SHPI.COM
SPECIALIZED HEALTH PRODUCTS INTERNATIONAL, INC.
585 WEST 500 SOUTH
BOUNTIFUL, UT 84010
T: 801.298.3360
F: 801.298.1759

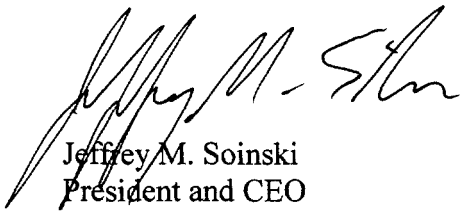
do not infringe the BD patent, and that the BD patent is invalid and unenforceable. A trial date has been scheduled for October 2004. Under our agreement with Tyco Healthcare, Tyco is exercising its right to withhold up to fifty percent of royalties due as an offset against litigation expenses related to this lawsuit. During fourth quarter 2003, we recorded a liability for patent litigation expense of $1.3 million. This amount is our estimate of the portion of costs associated with this pending litigation that Tyco Healthcare will withhold against royalties due us through 2005. After accounting for this charge, our reported net loss for 2003 was $3.1 million, an improvement of $2.8 million or 47% as compared to the reported net loss for 2002. Excluding the accrual for patent litigation expense, our net loss for 2003 would have been $1.8 million or ($0.10) per diluted share.

We ended 2003 with current assets of $3.5 million, including cash and cash equivalents of $2.4 million. We believe that this cash, along with cash generated from the sale of products, development fees and royalties will be sufficient to execute our business plan in 2004.

As we look to 2004, we expect to deliver continued steady revenue growth, without significantly increasing operating expense prior to the accrual for patent litigation expense in 2003. We expect to maintain strong blended gross margins from sales of our high-margin OEM products combined with 100% gross margin royalty revenue from our licensed products. Without material adverse events, which we do not anticipate at this time, we expect to significantly reduce our net loss in 2004 to achieve sustainable profitability by the fourth quarter of this year.

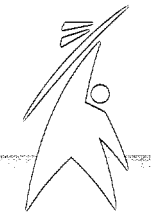
Thank you for your continued interest and support. I look forward to reporting our progress to you throughout the year as we complete our transition to a successful operating company.

Sincerely yours,



Jeffrey M. Soinski
President and CEO

This letter contains forward-looking statements within the meaning of the Securities Act of 1933 and the Securities Exchange Act of 1934, as amended. Such statements are subject to risks and uncertainties that could cause actual results to vary materially from those projected in the forward-looking statements. The Company may experience significant fluctuations in future operating results due to a number of economic conditions, risks in product and technology development, the effect of the Company's accounting policies and other risk factors detailed in the Company's SEC filings. These factors and others could cause operating results to vary significantly from those in prior periods and those projected in forward-looking statements. Additional information with respect to these and other factors, which could materially affect the Company and its operations, are included on certain forms the Company files with the Securities and Exchange Commission.



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T: 801.298.3360 • F: 801.298.1759 • WWW.SHPI.COM

NASDAQ OTCBB: SHPI