VITAL SIGNS INC
Form 10-K
December 14, 2004

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SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

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

FOR THE FISCAL YEAR ENDED SEPTEMBER 30, 2004.

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

FOR THE TRANSITION PERIOD FROM TO
COMMISSION FILE NUMBER 0-18793

VITAL SIGNS, INC.
(Exact name of registrant as specified in its charter)

New Jersey	11-2279807
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

20 Campus Road, Totowa, New Jersey 07512; (973) 790-1330
(Address and telephone number, including area code, of registrant's principal executive office)

Securities registered pursuant to Section 12(b) of the Act:
None

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

Title of each class
Common Stock, no par value

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

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

Indicate by checkmark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act) [X] Yes [_] No

Aggregate market value of voting stock held by non-affiliates as of December 9, 2004 was approximately $541,933,413.

Number of shares of Common Stock outstanding as of December 9, 2004: 14,156,004

Documents incorporated by reference: None.

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PART 1

Item 1. Business

Introduction

Vital Signs, Inc. was initially incorporated in New York in 1972 and reincorporated in New Jersey in 1988. Unless otherwise indicated, references in this Annual Report to "Vital Signs, Inc.", "Vital Signs", "Company", "we", "us" and "our" refer to Vital Signs, Inc., and its consolidated subsidiaries. Vital Signs' principal executive offices are located at 20 Campus Road, Totowa, New Jersey 07512; its telephone number at that location is (973) 790-1330.

Vital Signs designs, manufactures and markets medical products for the anesthesia, respiratory, critical care, neonatal, sleep therapy and emergency markets. A number of single-patient use products are increasing their share of the medical products market primarily because of their cost advantages and improved patient care features, including reducing the potential of transmitting infections from one patient to another. With the acquisition of Breas Medical AB ("Breas") from 1997 to 2002, National Sleep Technologies, Inc. in 2000 (see below), and the merger of HSI Medical Services Corporation in 2002, we have expanded our focus into the sleep therapy and personal ventilation markets.

We pioneered the development and introduction of a variety of single-patient use products. In 1975, we commenced the marketing of clear, non-conductive anesthesia breathing circuits. The first clear plastic, single-use air-filled cushion facemask for anesthesia delivery and resuscitation was launched by us in 1981. We were the first organization to introduce a single-patient use manual resuscitator in 1984. The first single-patient use laryngoscope system for use in the anesthesia and critical care arenas was developed and launched by us in 1988. We have also developed a general anesthesia kit, which can combine over 20 disposable items in one convenient, cost-effective package. The first single-patient use infant resuscitation circuit with an adjustable pressure limiting valve, used to protect the infant's lung from injury due to over pressurization.

We offer products and services for the sleep disorder/personal ventilation markets, which builds upon our airway management expertise. Our products are used in the treatment of obstructive sleep apnea, a condition caused by the narrowing of the airway, usually the result of the soft tissue in the rear of the throat collapsing during sleep. We operate a number of sleep diagnosis centers which test for the presence of sleep apnea, and tailor specific products for individual patients.

We also deliver regulatory compliance services to FDA regulated companies, primarily to pharmaceutical, medical device, diagnostic and biotechnology companies.

Acquisitions--1999 to Present

Through several transactions from 1997 to 1999, we acquired 53% of Breas Medical, AB ("Breas"), a manufacturer of CPAP (continuous positive airway pressure) machines and personal ventilators, based in Sweden. In May 2001 we purchased another 41%. At that time substantially all of the minority interest was held by Breas' management. In April of 2002 we purchased the remaining minority shares, bringing our ownership to 100%.

In June 1998 and May 1999, we purchased $10.4 million of common stock and convertible preferred stock of National Sleep Technologies, Inc. ("NST"). NST provides sleep diagnostic testing services in the United States through free standing labs and, through contracts with hospitals, in hospital facilities, for patients suspected of suffering from sleep disorders, such as obstructive sleep apnea. In 2000, we converted our investment in the preferred stock of NST into common stock and assumed control of NST. On January 1, 2002, NST merged with HSI Medical Services, Inc., ("HSI"), a subsidiary of the Johns Hopkins Health System. In this merger, we received a controlling interest in the merged entity, known as Sleep Services of America, Inc. ("SSA"). We held a 70% and a 68% equity interest in SSA, for both September 30, 2004 and 2003, respectively.

On March 28, 2002 we acquired Stelex Inc. ("Stelex"), a company engaged in pharmaceutical technology services, through the merger of our wholly owned subsidiary, The Validation Group ("TVG"), and Stelex Inc. The surviving entity is known as Stelex-TVG ("Stelex"). TVG had been engaged in process validation for pharmaceutical companies. The merger enabled us to move into the technology services area through the sale of dedicated software and the customization of this software.

For additional information regarding our products, see "Business--Products" and for additional information regarding the accounting treatment of the Breas, SSA and Stelex transactions, see "Management's Discussion and Analysis of Financial Condition and Results of Operations--Overview."

Forward-Looking Statements

This Annual Report on Form 10-K contains, and from time to time we expect to make, certain forward-looking statements regarding our business, financial condition and results of operations. The forward-looking statements are typically identified by the words "anticipates", "believes", "expects", "intends", "forecasts", "plans", "future", "strategy", or words of similar import. In connection with the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 (the "Reform Act"), we intend to caution investors that there are important factors that could cause our actual results to differ materially from those projected in our forward-looking statements, whether written or oral, made herein or that may be made from time to time by or on behalf of us. Investors are cautioned that such forward-looking statements are only predictions and that actual events or results may differ materially from such statements. We undertake no obligation to publicly release the results of any revisions to our forward-looking statements to reflect subsequent events or circumstances or to reflect the occurrence of unanticipated

events.

We wish to ensure that any forward-looking statements are accompanied by meaningful cautionary statements in order to comply with the terms of the safe harbor provided by the Reform Act. Accordingly, we have set forth in Exhibit 99.1 to this Annual Report on Form 10-K a list of important factors, certain of which are outside of management's control, that could cause our actual results to differ materially from those expressed in forward-looking statements or predictions made herein and from time to time by us. Reference is made to such Exhibit 99.1 for a list of such risk factors.

Acquisition Strategy

Historically, we have made both product and business acquisitions. Although no assurances can be given with respect to future acquisitions, our acquisition strategy is focused upon the following principal objectives: (i) identification and acquisition of companies and/or products in the anesthesia, respiratory/critical care, emergency, homecare, sleep/ventilation and pharmaceutical technology services markets with the goal of expanding our product line and improving our market share positions, (ii) expansion to international markets, and (iii) acquiring unique technologies with research and development capabilities. Such acquisitions may consume substantial amounts of capital, both to fund the purchase price and to fund the working capital needs of acquired companies and acquired product lines.

Principal Products and Services

Our primary products and services fall into four categories:

- anesthesia;
- respiratory/critical care;
- sleep/personal ventilation (referred to as "sleep"); and
- pharmaceutical technology services.

We believe that our broad range of product offerings represents a competitive advantage over suppliers with more limited product offerings. We continue to supplement our existing products and services with new offerings designed to meet the needs of health care professionals. For example, in response to reports of allergic reactions to medical devices containing latex, we manufacture a number of latex-free products. As a leading provider of single-patient use airway management products for the anesthesia and respiratory/critical care markets, we have developed a reputation with physicians for providing quality products. We believe that brand recognition helps drive demand for our products.

We have leveraged our airway management expertise by providing products and services for the high growth sleep/personal ventilation and sleep services markets. We offer products for the treatment of obstructive sleep apnea and operate approximately 60 sleep diagnosis centers which test the need for sleep apnea products.

Our principal products and services are described below:

Anesthesia Products

Anesthesia Breathing Circuits. We offer a wide variety of single-patient use anesthesia breathing circuits, which are used to ventilate and carry oxygen and anesthesia to a patient while under general anesthesia during surgery. Breathing circuits connect the patient to the anesthesia machine and to various patient monitors. The traditional system is referred to as a "circuit" because it is comprised of two tubes, one carrying inspiratory gases to a patient and the other carrying expiratory gases away from the patient. Each breathing circuit consists of flexible hoses, a breathing bag, and a "Y" and elbow attachment. Since the breathing circuit needs of hospitals vary significantly, we offer a large variety of circuits designed to be compatible with anesthesia equipment manufactured by numerous other companies. Technological advances in the areas of gas sampling, temperature monitoring, humidification and bacterial/viral filtration have provided us with opportunities to expand our breathing circuit offerings.

Face Masks. In 1981, Vital Signs introduced the first clear plastic air-filled cushion facemask for single patient anesthesia and respiratory use. We believe that the soft air-filled cushion facemask provides a better seal on most patients than other facemasks, thus improving the delivery of anesthetic gases and oxygen to the patient. A clear facemask also permits the clinician to better observe certain patient problems, such as life-threatening aspiration, while the patient is anesthetized. We offer various sizes and types of facemasks. We anticipate that the usage of single-patient use face masks in surgical procedures internationally will continue to expand as single-patient use products become increasingly accepted in international hospitals.

General Anesthesia Systems (GAS'TM'). We assemble and market General Anesthesia Systems (generically considered customized anesthesia kits), which can include more than 20 products, such as air-filled cushion facemasks, breathing circuits, blood pressure cuffs and temperature monitoring probes. In marketing our GAS'TM' kits, our sales representatives use detailed questionnaires to assist each customer in determining the particular products the hospital desires in its anesthesia kits. We then assemble GAS'TM' kits to meet the hospital's specific needs.

Limb-O'TM'. In the first quarter of Fiscal 2001, we introduced Limb-O'TM', a single limb breathing circuit used for general anesthesia, transport and/or critical care situations. The single limb incorporates a patented technology with a septum to separate inspiratory and expiratory gases. It competes with the traditional two limb system and is an alternative to the tube within a tube circuit.

PAX'TM'. In the first quarter of Fiscal 2001, we introduced a pharyngeal airway (PAX), a single use airway device promoted as an alternative to the LMA (laryngeal mask airway) device. The PAX 'TM' is used for airway management during general anesthesia procedures, and with just one size, can accommodate all adults over 90 pounds

INFUSABLE'r' Disposable Pressure Infusor. Invasive pressure monitoring has been used since the early 1970's as a means of monitoring blood and other fluid pressures of patients in certain critical care situations. The monitoring process involves inserting a catheter into the artery of the patient, connecting the catheter to a transducer (a device which converts the pressure impulse from the patient's blood into an electrical signal), and transmitting the electrical signal to a monitoring screen. The monitoring process uses a fluid filled

conduit to connect the catheter to the transducer. The fluid generally is a saline solution forced into the system by a pressure infusor. Our INFUSABLE'r' disposable pressure infusor consists of an inflatable bladder, a bulb to pump air into the bladder and a patented pressure gauge. The Infusable'r' also has a mesh netting into which a package of sterile fluid or "solution bag" is placed. The fluid is connected to the monitoring system and the pressure on the solution bag is set at a pressure level designed to maintain the pressure required by the monitoring system. The Infusable'r' is also designed to deliver blood or fluids to a patient at a rapid rate usually under trauma conditions.

Vital View'TM' Single-Patient Use Fiberoptic Laryngoscope System. This disposable system is designed to assist the anesthesiologist in correctly placing an endotracheal tube within the trachea of the patient. Our Vital View'TM' system has single-patient use blades which we believe offers several advantages over traditional reusable metal blade laryngoscope systems, including lowering the risk to both the patient and physician of infection associated with reusable metal blades and handles. In addition, we believe that hospital capital outlays for stocking emergency crash carts can be reduced by purchasing the Vital View'TM'. system rather than a reusable fiberoptic system.

Thomas Medical Products

Thomas Medical Products, Inc. ("TMP"), a wholly-owned subsidiary of Vital Signs, Inc., is an original equipment manufacturer ("OEM") and contract development organization which relies upon its scientific, technical, engineering, manufacturing and QA/Regulatory expertise in the disposable medical device area. TMP manufactures devices which provide access primarily to the vascular system by medical professionals and include products such as introducers, sheaths, dilators, hemostasis valves and catheters. TMP's products are sold primarily to other healthcare product providers to be used in their products or as part of kits, or as a finished product. TMP is included in the anesthesia business segment in Note 20 to the Notes to the Consolidated Financial Statements.

Respiratory and Critical Care Products

Gas-Lyte'r' and Quick-ABG'r'. We offer a broad line of disposable arterial blood gas ("ABG") syringes and collection systems. Blood gas syringes are used to collect arterial blood for blood gas analyses routinely performed in hospitals on patients suspected of having metabolic, respiratory or other cardiopulmonary difficulties. The blood gas sample is processed through a blood gas analyzer. Blood gas analyzers are manufactured by a wide range of manufacturers. We offer our ABG products in both standard configurations and in kits that are customized to meet a specific hospital's needs, and function with their blood gas analyzers.

Code Blue II'TM'. Vital Signs was the first to offer single-patient use manual resuscitators. Manual resuscitators are ventilation devices which are squeezed by hand to force oxygen into a patient's lungs. They are used throughout the hospital in a variety of settings. For example, patients on a ventilator require the use of a resuscitator prior to tracheal suctioning

procedures. Another use is in providing oxygen while transporting the patient between the operating room and other critical care units. In addition, resuscitators are typically placed strategically throughout the hospital to provide assistance to patients who have stopped breathing and require resuscitation. Code Blue II'TM' resuscitators are sold in different sizes for infants, children and adults. These resuscitators alleviate certain problems involved in mouth-to-mouth emergency resuscitation, including the risk to both the rescuer and the individual of transmitting infections. We believe that most reusable manual resuscitators are costly to sterilize and require re-assembly, which may result in errors that compromise proper function. In contrast, Code Blue II'TM' resuscitators are relatively inexpensive and are delivered fully assembled.

Babysafe'TM' and Hyper Inflation Systems. We offer both Babysafe'TM' and traditional hyperinflation systems used for infant resuscitation, a specialized line of infant hyperinflation products (BabySafe'TM' hyperinflation systems), used in labor and delivery rooms and in neonatal intensive care units, where controlling the spread of infection is particularly critical. BabySafe'TM' offers the ability to adjust and limit the level of pressure that can be delivered during resuscitation. Oxygen can be delivered without the risk of barotrauma. These systems are available in a variety of configurations and sizes to meet the needs of infants.

CleenCuff'TM' and CUFF-ABLE'r' Blood Pressure Cuffs. We manufacture and sell single patient use blood pressure cuffs which are wrapped around the arm or thigh of a patient to obtain a blood pressure reading. Our single-patient use blood pressure cuffs provide hospitals with an alternative to traditional reusable blood pressure cuffs that can become contaminated by touch, with blood and other body fluids. While all patients admitted to hospitals are candidates for their own dedicated blood pressure cuff, we believe that to date the primary market for disposable cuffs has been for cases where infection control is a high priority. Our cuffs are sold in a variety of sizes (including neonatal) and are adaptable to all manual and electronic blood pressure monitors that utilize blood pressure cuffs.

Continuous Positive Airway Pressure ("CPAP") Systems. Our facemask CPAP systems provide a less invasive and more comfortable way of providing oxygen to certain patients than conventional ventilator-based systems. Our facemask CPAP systems eliminate the need to insert an endotracheal tube into the patient's trachea and then attach the patient to a ventilator. Mask CPAP systems are now being used successfully in the pre-hospital setting to treat patients with cardiogenic pulmonary edema. The system consists of a compact flow generator connected to an air filled cushion facemask. The facemask is attached to a single patient use PEEP (positive end expiratory pressure) valve designed to maintain positive airway pressure in the lungs, thus allowing for more oxygen to diffuse into the patient's blood system.

Misty Ox'r' Respiratory Products. The MistyOx'r'line consists of two respiratory product lines that deliver hydration to a patient, and is comprised of a nebulizer which delivers medium to high flow and high concentrations of oxygen to patients, and the addition of a regulated heater to the nebulizer. These products may be used by infants, children and adults in many areas of the hospital, including emergency, recovery and critical care.

ACTAR'r' and ACTAR D-Fib'TM' CPR Training Manikins. We manufacture a line of patented cardiopulmonary resuscitation ("CPR") training manikins. The ACTAR'r'manikin was re-designed in Fiscal 2000 to meet changing market demands. The new Actar D-Fib incorporates additional functionality to meet the updated requirements of the American Heart Association and the Red Cross. New features include jaw thrust, abdominal thrust and anatomical landmarks for proper defibrillation training. While maintaining the necessary features and anatomical landmarks for CPR practices, our training manikins are far smaller and less expensive than full size manikins typically used for CPR training. The smaller size and affordable pricing enable each person in a CPR training class to practice with his or her own manikin, rather than sharing a single demonstration model.

Broselow/Hinkle'TM' Pediatric Emergency System and the Broselow-Luten System. The Broselow/Hinkle'TM' Pediatric Emergency System and the Broselow-Luten System are a part of our "Color Coding Kids" product line. These are the products of extensive clinical efforts by James Broselow, M.D., Dr. Robert Luten, M.D., and Alan Hinkle, M.D. to enable emergency care providers to determine the proper dose of medication and appropriate equipment size for infants in emergency situations. This system takes advantage of the direct correlation between a pediatric patient's body length and the proper size of emergency supplies and correct drug dosages. This patented system, licensed to Vital Signs, consists of: a tape measure having eight color zones, a corresponding series of color-coded single-patient use emergency kits or modules and a nylon organizer bag custom-designed to hold all the supplies needed in either a trauma, cardiac or respiratory pediatric emergency. During the 2004 fiscal year we, with the direct assistance and input of Dr. Broselow and Dr. Hinkle, began to develop additional products in the Broselow/Luten System. The newest product, which was introduced in the fourth quarter of the 2004 fiscal year, is an easy reference, spiral-bound, color-coded booklet entitled the Pediatric Resuscitation Medication Pocket Guide. With these systems, emergency room and EMS personnel can be confident that all the supplies necessary to manage a pediatric emergency are readily identified, available and organized in a manner that minimizes reaction time.

Sleep/Personal Ventilation Products

We have designed our sleep products to deliver airflow to patients undergoing therapy for the treatment of obstructive sleep apnea with the objective of increasing patient comfort and acceptance of the treatment. Continuous positive airway pressure is a common method for treating obstructive sleep apnea. We have manufactured and distributed continuous positive airway pressure systems for more than a decade for other respiratory applications and actively entered the sleep apnea market in 1997 through our interest in Breas Medical AB, a European manufacturer of personal ventilators for obstructive sleep apnea and long term ventilation. To date, most of our sales of these devices have been overseas. We received FDA clearance for our first home care continuous positive airway pressure product in August 2000. We have designed our ventilation systems to produce and deliver gases to a patient requiring ventilation or oxygen therapy in both hospitals and the home. In addition, we provide diagnostic and therapeutic services through our Sleep Services of America subsidiary, which was created in January 2002 when we merged our National Sleep Technologies subsidiary with the sleep diagnostic business of The Johns Hopkins Health Systems Corporation.

Our principal products and service offerings in this category are set forth below. Other than the Breas PV10'TM', Breas PV10i, and the Breas HA50'TM', all of the products below are currently sold only outside of the U.S. We provide our sleep diagnostic services exclusively in the U.S.

Sleep Products

- CPAP Flow Generators are electromechanical devices which deliver continuous positive airway pressure through a nasal mask to a patient suffering from obstructive sleep apnea in order to keep the patient's airway open during sleep. Given the importance of patient compliance in treating obstructive sleep apnea, we have designed our products to be easy to use, lightweight, small and quiet, making them relatively unobtrusive at the bedside. The Breas PV10'TM' is a high-end standard CPAP device meeting normal needs for obstructive Sleep apnea treatment.

- In October 2003, we received FDA clearance for the Breas PV10i'TM' CPAP system for sale in the United States for obstructive sleep apnea. The PV10i is a self-adjusting Continuous Positive Airway Pressure (CPAP) device that uses a highly advanced, patented technique to respond to changes in an individual's breathing patterns. The device can adjust treatment pressure appropriately, as patient needs change, before apneic events occur. Traditional, constant CPAP devices must be set to a maximum pressure that is usually higher than is required throughout the night creating discomfort for the user. With the PV10i'TM', the mean treatment pressure is lower. Clinical studies have demonstrated that

patients prefer the lower pressure provided by the PV10i'TM' to other devices available in the marketplace.

- Bi-Level CPAP such as our Breas PV101'TM' are electromechanical devices which deliver two levels of continuous positive airway pressure to a patient. It is used to treat more severe Obstructive Sleep Apnea and is comfortable for the user.

- Humidification Systems are heated humidifiers for use with continuous positive airway pressure or ventilation devices. Our Breas Humidification system, HA 50'TM', is a heated humidifier constituting an important factor in the function of the respiratory system.

- Sleep Disorder Home Screening Devices are home-use systems for screening for sleep disorders, including obstructive sleep apnea. Our Breas SC20'TM' is a lightweight screening system for measuring and recording physiological data during sleep. The system can record oxygen saturation, airflow, pulse, breathing effort, snoring, limb movement and body position. The data is downloaded to a personal computer where our analysis software provides an indication of the presence of sleep apnea and other associated disorders.

- Sleep Diagnostic Services. We provide diagnostic and therapeutic services through our Sleep Services of America ("SSA") subsidiary. As of September 30, 2004, this business operated approximately 60 sleep centers in 6 states and Washington, D.C., principally in the eastern

U.S. SSA is duly accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) in Ambulatory and Homecare. SSA also has 11 laboratories accredited by the AASM with applications submitted or pending for several others At these facilities, which typically accommodate two patients per night, we conduct sleep studies to determine whether the patients referred to us suffer from sleep disorders. If a patient is determined to suffer from sleep apnea, we can offer follow-up diagnostic and monitoring services to the patient and may, under certain circumstances, be in a position to sell our sleep products to the patient. A sleep study is the process of recording various measurements used to identify different sleep stages and classify various sleep problems. During sleep testing, the activities that occur in a patient's body during sleep--brain waves, muscle movements, eye movements, breathing through the mouth and nose, snoring, heart rate, and leg movements--are monitored by small electrodes and sensors applied to the patient. These functions can be normal while the individual is awake, but abnormal during sleep. All of this information is transmitted from the equipment being worn to a special recorder, which saves these measurements for technicians to analyze. The referring physician receives a sleep report which includes a physician interpretation of the data and a diagnosis of the sleep-related problem, if any.

Ventilation Products

Ventilators are electromechanical devices used to assist a patient with respiratory problems. We have designed our systems for use in a clinical setting or at home for life support ventilation.

PV102'TM' Bi-Level Ventilator. The PV102'TM' is an advanced bi-level ventilator device which allows separate pressure levels for inspiratory and expiratory phases of each individual breath. Ventilation can be matched to the patient's own breathing pattern by setting levels which promote more comfortable and more natural respiratory support. It can also be operated from an external battery, so that it can be used during transportation and traveling.

PV403'TM' Mixed Lifesupport Ventilator. The PV403'TM' ventilator supports the ventilation needs of patients suffering from respiratory insufficiency diseases. Patients benefiting from the PV403'TM' may suffer from neuromuscular (Duchene's), or other restrictive or obstructed diseases. The PV403'TM' is an advanced mixed homecare ventilator which can provide volume and pressure ventilation. It has various settings that make it very flexible to a broad band of applications. It has both internal and external battery capability and is well suited to be used in transport and traveling.

Pharmaceutical Technology Services

We deliver technology services to FDA regulated companies primarily in the pharmaceutical sector. In addition, we also provide services from time to time to medical device, diagnostic and biotechnology companies. We advise clients by helping them establish and monitor processes designed to satisfy their regulatory

requirements set forth by the FDA. Our focus has been in the areas of development and validation of systems and processes used in the manufacturing, information technology and infrastructure, research and development, laboratory and quality assurance departments of our clients. In addition, we have developed and currently market proprietary software products that we use in conjunction with our services to help clients comply with FDA regulations.

In the 2004 fiscal year we have expanded our offering to include Sarbanes Oxley section 404 compliance services in the area of information technology compliance. These services, targeted at life sciences market, are designed to help our clients bring their information systems into compliance with internal controls requirements stipulated by well-known controls and governance frameworks.

As of September 30, 2004 our staff consisted of 102 professionals and our range of consulting services includes computer systems validation, IT governance, process validation, equipment qualification, development and implementation of quality control programs, regulatory auditing, development of software for regulated environments, and customized training programs.

Market Data

The following table sets forth, for each of the past three fiscal years, the dollar amount and approximate percentage of total net revenue represented by our four business segments: anesthesia, respiratory/critical care, sleep and our pharmaceutical technology services:

	Year Ended September 30,					
	2004		2003		2002	
	Amount	%	Amount	%	Amount	%
	(Dollars in millions)					
Anesthesia	$ 82.8	45.0	$ 76.0	41.7	$ 71.8	41.3
Respiratory/Critical Care	42.1	22.9	45.8	25.2	46.8	26.9
Sleep	44.0	23.9	45.6	25.0	39.6	22.8
Pharmaceutical Technology Services	15.1	8.2	18.1	9.9	14.2	8.1
Rebate allowance adjustment (1)	--	--	(3.3)	(1.8)	--	--
Other (2)	--	--	--	--	1.6	.9
Total	$184.0	100%	$182.2	100%	$174.0	100%

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(1) Reflects an adjustment made during the second quarter of fiscal 2003. See "Management's Discussion and Analysis of Financial Condition and Results of Operations--Critical Accounting Principles and Estimates".

(2) "Other" relates primarily to one-time licensing revenue recorded in the first quarter of fiscal 2002 in the anesthesia business segment. Income from continuing operations related to this one-time licensing revenue was $1,439,000 before taxes ($953,000 after taxes).

For additional information regarding these segments, see Note 20 to the Consolidated Financial Statements.

Sales, Marketing and Customers

U.S. Sales

We sell our anesthesia and respiratory/critical care products to hospitals and surgery centers in the U.S. through our own sales force, which is led by our Vice President of Sales. As of September 30, 2004, our U.S. sales force consisted of 57 sales representatives and six regional sales managers.

We market our anesthesia and respiratory/critical care products primarily to hospitals and other health care providers. While we utilize national distributors to deliver a portion of our anesthesia and respiratory/critical care products in the U.S., the end-user hospitals and other health care providers determine the channel through which they receive our products, either directly from us or through a distributor of their choice. See Note 19 to the Consolidated Financial Statements.

Many of our customers are members of Group Purchasing Organizations ("GPO's"). GPO's provide their members access to discounted prices on products by negotiating discounts with manufacturers like us. GPO's act as agents to facilitate better pricing for their members. We have agreements with several leading group purchasing organizations, including AmeriNet, Broadlane, Consorta, Healthsouth, Healthtrust, MedAssets (HSCA), Novation, and Premier. Our strategy is to more fully penetrate our existing Group Purchasing Agreements and secure additional agreements. GPO's do not themselves make purchases, carry inventory or physically handle products. GPO's provide access to discounted prices for their members by negotiating a group price for their member hospitals and health care providers. No sales are made to GPO's; therefore there is no revenue recognition. Revenue is recognized upon the sale of goods, to either the end user or via a sale to a distributor.

In July 2003, we were awarded a three-year competitively bid dual-source supply agreement with the group purchasing division of Premier, Inc., Chicago, IL. The agreement, effective August 1, 2003, includes our anesthesia

breathing systems and breathing bags, face masks, filters and HCH (Hygroscopic Condensed Humidifier), airways and gas sampling lines. Premier is a leading healthcare alliance, collectively owned by more than 200 independent hospitals and healthcare systems in the United States, which are affiliated with nearly

1,500 hospitals and other healthcare sites, offering group purchasing supply chain and performance improvement services to nearly 1,500 member not for profit hospitals.

Also in July 2003, we were awarded two three-year dual-source supply agreements with AmeriNet, St. Louis, MO. The new agreements include our anesthesia breathing systems, facemasks, arterial blood gas kits, disposable resuscitators, filters, HCH (Hygroscopic Condenser Humidifiers) and gas sampling lines. AmeriNet represents more than 18,500 member facilities, including hospitals, integrated delivery networks, long-term care facilities, surgery centers, clinics, home care and emergency services.

Again in July 2003, we were awarded a supply agreement with Novation, the supply chain management company based in Irving, TX. This is Vital Signs' first supply agreement with Novation. The agreement, effective June 1, 2003 for three years with the option of Novation to extend for up to an additional two years includes Vital Signs' HEPA filters, bacterial/viral filters, pulmonary function filters and related accessories. Novation serves the purchasing needs of more than 2,300 VHA Inc. and UHC (University HealthSystem Consortium) members, made up of community-based hospitals and academic medical centers. Novation agreements are also available to HealthCare Purchasing Partners International (HPPI) which serves more than 5,400 members and clients.

As new products that can be sold by our U.S. sales force are developed, we educate and train our sales force in the need, use, application and advantages of our products. We also hold quarterly training sessions for all of our sales people and conduct additional training, as we deem appropriate.

As of September 30, 2004, the sales and marketing department of our subsidiary, Sleep Services of America (SSA), consisted of four (4) field personnel, a director of marketing communications and a Vice President of Sales. The primary focus of this team is to increase the patient volumes of existing accounts and negotiate contracts with new and existing sleep centers. SSA seeks to differentiate itself from many of its competitors by providing clients a range of marketing options from direct marketing to an al la carte selection of services. In addition, SSA seeks to increase the number of laboratory beds, improve the utilization of existing beds, increase sleep educational and disease awareness programs directed toward physicians and by provide comprehensive high quality service offerings to the communities that they serve.

As of September 30, 2004, our Stelex subsidiary had a team of seven sales account managers, one sales manager, two marketing support personnel, and one director of business development for our pharmaceutical technology services. Our pharmaceutical technology services sales team is responsible for obtaining new business in the continental U.S. and Puerto Rico. Our regulatory consulting team calls on pharmaceutical and medical device companies regarding compliance with FDA regulations. As of September 30, 2004, we also employed two sales people to promote the video technology developed in the vioWorks'TM' division of our Stelex subsidiary. Our vioWorks'TM' sales team sells online meetings, presentation and multi-media conferencing via the Internet primarily to pharmaceutical and medical device companies which are seeking to train their sales forces and service organizations.

International Sales

For fiscal 2004, 2003 and 2002, international sales of $46.6 million, $45.3 million and $38.3 million, respectively, accounted for approximately 25%, 25% and 22%, respectively, of our revenue. Our products are sold in over 55 countries worldwide. International net sales for our anesthesia and respiratory/critical care products for fiscal 2004, 2003 and 2002 were $19.7 million, $18.8 million, and $15.9 million, respectively. We sell our anesthesia and respiratory/critical care products in European and other international

markets primarily through a strategic alliance with Rusch GmbH, a manufacturer of medical devices. In October 2002, we entered an exclusive multi-year strategic alliance and distribution agreement with Rusch International, to distribute Vital Signs anesthesia, respiratory and critical care products in those countries where Rusch has a direct sales force in the healthcare market. Rusch represents us in 10 countries. We view this alliance as an alternative to our historic approach of relying upon local distributors to sell anesthesia and respiratory/critical care products in foreign countries. However, during the 2004 fiscal year, Rusch's parent company announced its purchase of Hudson-RCI, a competitor of ours in a number of respiratory and anesthesia products. We have been meeting with Rusch to re-

assess the relationship in light of this acquisition. In the United Kingdom, we have a sales manager and a direct sales force, which, as of September 30, 2004, consisted of five people.

Our sleep/personal ventilation products are sold internationally through Breas' direct sales force, which calls on home health care distributors in France, Germany, Scandinavia, Spain and the United Kingdom, and through an independent distribution network in other countries. As of September 30, 2004, the Breas direct sales force consisted of 38 people. International net sales for Breas for fiscal 2004, 2003, and 2002 were $26.9 million, $26.5 million, and $22.7 million, respectively.

Marketing

Our marketing staffworks closely with our sales forces, collects and analyzes customer responses to new and existing products, participates in our product development program and assists in product training. In addition, our marketing staff develops and helps implement various internal and external promotional activities.

Research and Development

We believe that product development and innovation is an essential part of our overall success. As of September 30, 2004 we employed 41 engineers, scientists and technicians who are principally engaged in research and development activities. We supplement their efforts with outside consultants from time to time. The principal focus of our research and development activities in fiscal 2004 was the development of a new generation of sleep and ventilation products at our Breas subsidiary. Our other focus is to develop product solutions for health care problems, specifically in the areas of anesthesia, respiratory/critical care and sleep.

We incorporate technical, manufacturing, operations, sales and marketing, and clinical expertise within our research and development processes. Our research and development staff works with health care providers to develop an in-depth understanding of, and to be responsive to, product applications and clinical needs, and works with our sales and marketing teams to better understand industry trends. We believe that we are often able to reduce the costs associated with new product development by utilizing our in-house

manufacturing capabilities to rapidly produce quantities of prototype products suitable for trial use and sale.

We expect to continue to rely principally on our internal staff to perform research and development in our primary areas of expertise. Our research and development expenses aggregated $7,036,000, $5,871,000 and $6,615,000 for fiscal 2004, 2003 and 2002, respectively.

Product Liability Exposure

We are exposed to potential product liability resulting from the use of our products. We presently maintain primary and umbrella product liability insurance coverage of $20,000,000 in the aggregate. Our product liability policy generally protects us against claims of bodily injury or property damage arising out of any products manufactured, sold or distributed by us. If a judgment in a product liability suit were entered against us or we entered into a settlement agreement in excess of a policy limit or outside the scope of coverage, including for example, punitive damages, our profitability and financial condition may be impacted significantly. We cannot assure you that our current level of insurance will be sufficient to cover product liability claims or that such coverage will remain available to us on satisfactory terms, if at all. See Note 15 to the Consolidated Financial Statements for additional information on the limits of our product liability coverage.

Manufacturing and Quality Control

We manufacture almost all of our products. Our manufacturing processes and systems have allowed us to provide quality products, to react quickly to changes in demand and to generate manufacturing efficiencies. We purchase resins, our primary raw material used in a variety of our anesthesia and respiratory products, in bulk. We believe that these capabilities allow us to contain costs, control quality and maintain security of proprietary processes. For certain products, our manufacturing function consists principally of assembling and packaging components that we purchase from others. We continually evaluate our manufacturing processes, with the objective of increasing automation, streamlining production and enhancing efficiency in order to achieve cost savings and improve quality.

We manufacture anesthesia breathing circuits, filters, blood pressure cuffs, pressure infusors, arterial blood gas syringes, heated humidification circuits, nebulizers, manual resuscitators, introducers, sleep therapy products and ventilators. We perform tube extrusion, injection molding, radio frequency welding, product assembly, product testing, packaging and distribution. In some instances, plastic components incorporated in certain products are molded to our specifications by outside custom injection molders who utilize molds that are designed and, in most instances, owned by us. Our suppliers typically are presented with written specifications to assure that components are manufactured in conformity with our design.

As many of our products are utilized within the operating rooms and critical care units of hospitals, we conduct quality control testing in all of

our facilities. Our quality systems are designed to meet the FDA's Quality Systems Regulation. We are required to maintain records of all raw materials received and used in the manufacturing process along with complete histories of all devices manufactured. In order to distribute in Europe, our Quality Systems have been certified to be in compliance with ISO 9001, EN46001 and ISO 13485 standards.

Significant Suppliers

In 1980, we acquired the rights to our air-filled cushion anesthesia facemask through a collaboration arrangement with Respironics, Inc. ("Respironics"). Facemasks are used in a variety of our anesthesia circuits and manual resuscitators and are sold individually to customers. We purchase our facemasks from Respironics, a single source which manufactures the facemask in the People's Republic of China. Our supply agreement with Respironics requires Respironics to supply air-filled cushion facemasks of various specifications to us on an exclusive basis for anesthesia purposes, and obligates us to purchase all of our anesthesia facemasks from Respironics as long as Respironics is the low cost supplier. We have had a series of supply agreements with Respironics for many years. The current supply agreement with Respironics was renewed in 1999 to extend its term until 2006, with an additional option to further extend the term of the agreement through 2011, providing us with a secure supplier relationship on this key product.

If the supply of facemasks from Respironics should be interrupted for any reason, we would seek to find alternative suppliers of facemasks. In such event, we may experience disruption in our business. No assurance can be given that, in the event of such an interruption or cessation, we could, in fact, maintain our required supply of facemasks in a quantity and at a cost that would not have a material adverse effect on our business and operating results. Our policy is to maintain a stock of facemasks in the United States to lessen the impact of any temporary production or supply disruption.

Sales Backlog

Our objective is to ship all orders within relatively short time frames; therefore, backlog is not significant to our business.

Competition

The markets in which we do business are highly competitive. The principal bases for competition in our markets include product features, price, quality, customer service, performance, market reputation, breadth of product offerings and effectiveness of sales and marketing. We believe that our products compete favorably with respect to these factors.

We compete on a product-by-product basis with various companies, many of which have greater financial and marketing resources, broader product lines or both. Our primary competitors in each of our product and service categories are the following entities and their affiliates.

Product/Service Category	Primary Competitors
Anesthesia:	Baxter International Inc. King Systems Corporation Medline SIMS Portex, Inc.
Respiratory/Critical Care:	Cardinal Health Inc. Ambu International A/S Critikon, Inc./General Electric Medical Services Fisher & Paykel Healthcare Corporation Limited Teleflex Kimberly-Clark Corporation Tyco International, Inc.
Sleep/Personal Ventilation:	Fisher & Paykel Healthcare Corporation Limited Resmed, Inc. Respironics, Inc. Tyco International, Inc. Sleep centers maintained by hospitals and various local
Pharmaceutical Technology Services:	Day & Zimmerman Taratec The Washington Group Numerous national and regional companies.

Regulation

Medical Device Regulation

As a manufacturer of medical devices, we are subject to regulation by, among other governmental entities, the FDA and the corresponding agencies of the states and foreign countries in which we sell our products. We must comply with a variety of regulations, including the Quality System Regulations of the FDA, and are subject to periodic inspections by the FDA and applicable state and foreign agencies. Enforcement of the Quality System Regulations has increased significantly in recent years, and the FDA has publicly stated that compliance will be more strictly scrutinized. If the FDA believes that its regulations have not been fulfilled, it may invoke extensive enforcement powers. Noncompliance with applicable requirements can result in, among other things, warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure to receive pre-market clearances or approvals, withdrawal of approvals and criminal prosecution. The FDA also has the authority to require recall, repair, replacement or refund of the cost of any device manufactured or distributed by us.

Medical devices are classified by the FDA into three classes that determine the degree of regulatory control to which the manufacturer of the device is subject, Class I being the least stringent and Class III being the most stringent. Class I devices are subject to general controls, including reporting certain types of device-related events to the FDA, labeling and adherence to the Quality System Regulations. Class II devices are generally subject to general and special controls including Section 510(k) clearance, performance standards, postmarket surveillance, patient registries and FDA guidelines. Class III devices are those which must receive pre-market approval by the FDA to ensure their safety and efficacy; such devices include life-sustaining, life-supporting and certain implantable devices, or new devices which have not been found to be substantially equivalent to legally marketed Class I or

Class II devices. The pre-market approval process may take several years and requires the submission of extensive performance and clinical information.

We believe that most of our products are either Class I or Class II products. However, some of the devices manufactured by our Thomas Medical Products subsidiary are Class III devices which are used for arterial closure following angiography, angioplasty or stenting. Also some of our products in development for use by patients with congestive heart failure may be classified as Class III and, therefore, may be subject to the time-consuming and expensive pre-market approval process. Many new medical devices, including most of our products, and some modifications to existing medical devices, are subject to a pre-market notification process pursuant to Section 510(k) of the Federal Food, Drug, and Cosmetic Act. Furthermore, current FDA enforcement policy prohibits the marketing of approved or cleared medical devices for unapproved or uncleared uses. We cannot assure investors that we will be able to identify each circumstance in which compliance with the pre-market notification process is required.

After clearance or approval is given, the FDA or foreign regulatory agencies may withdraw clearances or approvals or require us to change the device or its manufacturing process or labeling, to supply additional proof of its safety and effectiveness or to recall, repair, replace or refund the cost of the medical device. The process of obtaining clearances or approvals to market products can be costly and time consuming and can delay the marketing and sale of our products.

Federal, state and foreign regulations regarding the manufacture and sale of medical devices are subject to change. In the future, we cannot predict what impact, if any, such changes might have on our business.

International sales of medical devices are subject to foreign government regulations, which vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA approval, and the requirements may differ significantly.

The European Union has adopted legislation, in the form of directives to be implemented in each member state, concerning the regulation of medical devices within the European Union. The directives include, among others, the Medical Device Directive that establishes standards for regulating the design, manufacture, clinical trials, labeling, and adverse event reporting for medical devices. Under the Medical Device Directive, a Competent Authority is nominated by the government of each member state to monitor and ensure compliance with the Directive. The Competent Authority of each member state then nominates a Notified Body to oversee the conformity assessment procedures set forth in the Directive, under which manufacturers demonstrate that their devices comply with the requirements of the Directive and are entitled to bear the "CE" marking. "CE" is an abbreviation for Conformite Europeene, or European Conformity, and the CE marking, when placed on a product, indicates compliance with the requirements of the applicable directive. Medical devices properly bearing the CE marking may be commercially distributed throughout the European Union. We

have approval to affix the CE marking on all our major product lines. As new products are introduced, we intend to take steps to gain approval for CE marking. While no additional premarket approvals in individual European Union countries are required prior to marketing of a device bearing the CE mark, practical complications with respect to marketing introduction may occur. For example, differences among countries have arisen with regard to labeling requirements. Failure to maintain the CE mark will preclude us from selling our products in the European Union.

Canada requires device manufacturers to obtain licenses for their products. To obtain these licenses, the manufacturer's quality systems must be audited by a Canadian approved third party and the manufacturer must obtain a certification to CAN/CSA ISO-13485-98. Failure to obtain and retain these licenses would preclude us from selling our products into Canada.

A new Quality Systems Standard, ISO 13485-2003, has been adopted and all medical device companies must transition to this standard and be third party certified to it by 2006 in order to continue CE Marking of products and to continue to obtain Canadian licenses. Failure to receive re-certification to this standard by March 2006 would preclude us from selling our products in the European Union and Canada.

Additionally, some of the services we provide in our Sleep business segment are subject to additional regulation from various state and local regulatory authorities. There has been a trend developing in the State to require the licensing of technical personnel to perform diagnostic testing procedures. Licensed personnel are more highly compensated than unlicensed personnel.

Health Care Regulation

As a provider of sleep diagnostic services, we are subject to regulation by U.S. federal and state authorities aimed at combating fraud and abuse in the health care industry. The federal government has enacted statutes and corresponding regulations addressing, among other things, kickbacks, self-referral, the submission of false claims for reimbursement and the failure to follow physician prescriptions. Many states have enacted similar statutes. The federal laws apply in any case where we may provide a product or service that is reimbursable under the Medicare or Medicaid programs, or where we are requesting reimbursement from Medicare or Medicaid.

The federal government is authorized to impose criminal, civil and administrative penalties on a health care provider who files a false claim for reimbursement from Medicare or Medicaid. Even where a claim has not been submitted to Medicare or Medicaid, criminal penalties may be imposed against the provider if the government can show that the claims constitute mail fraud or wire fraud. The government has increasingly been applying penalties in a broadening range of circumstances, for example, in instances where reimbursement has been made or sought for medically unnecessary services or for services that fall below clinical standards for quality care.

The federal anti-kickback law prohibits the offering, solicitation, payment

or receipt of anything of value which is intended to induce the referral of Medicare or Medicaid patients, or to induce the ordering of items or services that are reimbursable under those programs. The federal anti-kickback law has been interpreted to apply where one purpose of an arrangement is to induce referrals--it need not be the primary purpose of the arrangement. Arrangements that meet certain so-called "safe harbors" are deemed not to violate the federal anti-kickback law; but the failure of a particular arrangement to meet a safe harbor also does not necessarily mean that such an arrangement is illegal per se.

The federal self-referral law, commonly referred to as the Stark Law, prohibits a physician from referring a patient to another health care provider for certain designated health products and services reimbursable by Medicare or Medicaid including durable medical equipment--if the referring physician has a financial relationship with that provider. "Financial relationship" has been broadly defined in the applicable regulations to include both direct and indirect relationships, and includes both ownership interests and compensation as forms of financial relationships. As with the federal anti-kickback law's safe harbors, the Stark Law and its regulations exclude certain arrangements from the general prohibition, provided that specific criteria applicable to each arrangement are met.

Our ability to sell our Breas products in our sleep centers is restricted by strict federal regulations which prohibit us from diverging from a physician's prescription. If a physician prescribes a continuous positive airway pressure product other than a Breas product for a patient at one of our sleep centers, we are prohibited by federal regulations from substituting a Breas product.

The penalties for violating these federal laws include criminal sanctions and fines including treble damages and civil and administrative penalties, which may include, but not be limited to, exclusion from the Medicare and Medicaid programs, and the requirement to repay to the federal government any reimbursement the provider has received in violation of the law.

Many states have enacted laws similar to the federal fraud and abuse laws. There is a great degree of variability among these states in terms of the applicability and requirements of each of their laws. For instance, some states' laws are applicable only to services or products reimbursable under Medicaid, while others' apply to all health care services regardless of the source of payment. By way of further example, some states do not prohibit referrals to a provider with which the referring physician has a financial relationship, but only require that the patient be informed of the relationship before the referral is made.

Privacy Regulation

Certain of our business activities require that we collect and/or use information about individuals and their medical conditions. As a result, we are subject to regulations by both U.S. and foreign authorities intended to protect the privacy of those individuals by requiring that we maintain the confidentiality of their information.

In 1996, the U.S. Congress enacted the Health Insurance Portability and Accountability Act, which mandated, among other things, the promulgation of regulations to address the privacy of health information and to reduce many of the costs and administrative burdens of the health care industry. These regulations have been developed by the U.S. Department of Health and Human Services, and address three general areas: standardization of electronic

transactions, security of health information systems, and privacy of protected health information. Collectively, these regulations are intended to establish federal standards concerning the use, disclosure and protection of health information which, by its nature, can be linked to specific individuals. In addition to limited access to protected health information of our employees, our SSA subsidiary collects protected health information of its clients.

In addition, the Health Insurance Portability and Accountability Act calls for civil and criminal fines and penalties for the improper use and disclosure of individually identifiable health information. The regulations continue to evolve as the U.S. Department of Health and Human Services continues to receive public comment and revise certain of the regulations, most notably those addressing privacy. There is no meaningful history of enforcement efforts by the federal government at this time. It is therefore not possible to ascertain the likelihood of enforcement efforts in connection with the Health Insurance Portability and Accountability Act regulations or the potential fines and penalties that may result from the violation thereof.

Foreign governments are increasingly addressing concerns related to the privacy of information collected about their citizens with laws and regulations designed to protect the confidentiality of such information.

In addition, we are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, environmental protection and fire hazard control. We cannot assure investors that we will not be required to incur significant expenses to comply with such laws and regulations in the future.

Third Party Reimbursement

The cost of medical care in the U.S. and many other countries is funded substantially by government and private insurance programs. Although we do not generally receive payment for our products or services directly from these payors other than in connection with our sleep diagnostic services, our continued success is dependent upon the ability of patients, hospitals and home care distributors to obtain adequate reimbursement for our products and sleep services. In most major markets, our products are purchased primarily by hospitals, which are generally either government funded or which invoice third-party payors directly, or otherwise invoice patients, who then seek reimbursement from third-party payors. Other than our direct to hospital sales and our sleep diagnostic services and any resulting sales of continuous positive airway pressure equipment, our remaining sales are to distributors and manufacturers of other medical products, who then sell to these customers. When we provide sleep diagnostic services in our own sleep centers, patients are generally covered by private insurance. In those instances, the patient is responsible for his/her co-payment portion of the fee and we invoice the patient's insurance company for the balance. In hospitals, we contract with the hospital on a "fee for service" basis and the hospital assumes the risk of billing.

In the U.S., third-party payors include Medicare, Medicaid and private health insurance providers. These payors may deny reimbursement if they determine that a device has not received appropriate FDA clearance, is not used

in accordance with approved applications, or is experimental, medically unnecessary or inappropriate. Third-party payors are also increasingly challenging prices charged for medical products and services, and certain private insurers have initiated reimbursement systems designed to reduce health care costs. The trend towards managed health care and the growth of health maintenance organizations, which control and significantly influence the purchase of health care services and products, as well as ongoing legislative proposals to reform health care, may all result in lower prices for our products and services. We cannot assure you that our products and services will be considered cost-effective by third-party payors, that reimbursement will be available or continue to be available, or that payors' reimbursement policies will not adversely affect our ability to sell our products and services on a profitable basis, if at all.

Intellectual Property

We primarily rely upon trade secrets and continuing technological innovations to develop and maintain our competitive position. However, where appropriate, we seek patent protection for inventions that we believe give our products a competitive advantage. When deemed appropriate, we have enforced and plan to continue to enforce and defend our patent rights. In an effort to protect our trade secrets, we require certain employees, consultants and advisors to execute proprietary information and invention assignment agreements upon commencement of employment or consulting relationships with us.

Some of our patents relate to significant technologies that are utilized in our anesthesia, respiratory/critical care and sleep therapy product lines. Our ongoing success depends in part on our ability to maintain our patents,

obtain new patents, and develop new products and applications without infringing the patent and other proprietary rights of third parties. There has been substantial litigation involving the intellectual property rights of medical device manufacturers. We have been involved in several such proceedings, often at significant expense to us. We cannot assure you that any of our patents will not be circumvented or challenged, that the rights granted by our patents will provide competitive advantages or that any of our pending or future patent applications will be issued with claims of the scope that we seek, if at all. If challenged, we cannot assure you that our patents will be held valid or enforceable. We cannot assure you that our products or proprietary rights do not infringe the rights of third parties. If an infringement were established, we could be required to pay damages, enter into royalty or licensing agreements on onerous terms and/or be enjoined from making, using or selling the infringing product. Any of these outcomes could have a material adverse effect on our business. We may decide not to introduce a product in the United States or a foreign country based upon the potential risk of patent infringement litigation.

Employees

As of September 30, 2004, we had 1,128 full-time employees and 28 part-time employees. We believe that our relations with our employees are good. None of our employees are members of unions, although certain employees outside of the

U.S. have statutory benefits comparable to collective bargaining agreements. Our full-time employees by department as of September 30, 2004 were:

Manufacturing and quality control	605
Sales and marketing	112
Sleep center technical personnel	147
Regulatory consultants	102
Research and development	41
Administration	121
Total	1,128

Item 2. Properties

We believe that our properties are adequate for our current needs. In addition, we believe that adequate space can be obtained to meet our foreseeable business needs. The following chart identifies the principal properties which we own or lease.

The properties listed below relate to the anesthesia and respiratory/critical care business segments, except for the Molnlyke, Sweden and Glen Burnie, Maryland properties which relate to our sleep segment, and Bensalem, Pennsylvania which relates to our pharmaceutical technology services business segment.

Location	
Totowa, New Jersey* (executive offices, principal manufacturing and warehouse facilities)	1
Englewood, Colorado* (manufacturing, warehouse and office space)	
Burnsville, Minnesota (manufacturing, warehouse and office space)	
Molnlyke, Sweden* (Breas--manufacturing, warehouse and office space)	
Malvern, Pennsylvania (Thomas Medical--manufacturing, warehouse and office space)	
Bensalem, Pennsylvania (Stelex--office space)	
Glen Burnie, Maryland (Sleep Services of America--office space)	
Littlehampton, United Kingdom (Vital Signs, Ltd--warehouse and office space)	

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* We own this facility.

Item 3. Legal Proceedings

(a) On December 8, 1999, a complaint was filed against us on behalf of the former shareholders of our Vital Pharma subsidiary alleging breach of contract for failure to pay earnout payments allegedly due under the stock purchase agreement executed in connection with our purchase of Vital Pharma in December 1995. In August 2000,

the court ordered the plaintiffs to submit their claims to binding arbitration and stayed all other proceedings pending the outcome of the arbitration. The arbitration hearing commenced on January 26, 2004. The presentation of testimony of both the plaintiff's direct case and the defendant's case is essentially completed. There may be additional testimony presented should the arbitrator permit plaintiffs to present a rebuttal. The arbitrator has not set a schedule for post-arbitration briefs or other submissions. It is likely that a decision may be rendered by the arbitrator during the second quarter of fiscal 2005. Plaintiff's have claimed damages in the pre-interest amount of approximately $7.5 million. We have recorded a reserve in an amount not exceeding plaintiffs' claim.

(b) A first amended complaint was filed against the Company's Vital Pharma subsidiary on September 8, 2003 in the U.S. District Court for the Northern District of California related to the packaging services it provides to Lifecore Biomedical, Inc. ("Lifecore") for a product designed to prevent adhesions in certain surgical procedures sold under the brand name "Intergel" by Ethicon, Inc. (a subsidiary of Johnson and Johnson). The complaint also names Lifecore and Ethicon, Inc. as defendants. On January 28, 2004 this same plaintiff filed a similar action in California state court. On October 21, 2004 plaintiff voluntarily dismissed the state court action without prejudice.

Following the service of the complaints described in the preceding paragraph, Vital Pharma became a defendant in 37 matters filed in state court in Florida related to the Intergel product. Vital Pharma has been served with complaints in most of these filed actions, but has not yet been served in all of them. Additional claims may be filed. Each of the complaints assert multiple theories of negligence and product liability claims against the defendants for injuries allegedly sustained through the use of Intergel during surgery.

Lifecore was the manufacturer of the product, which had been approved by the FDA for reducing post-surgical adhesions. Vital Pharma packaged the product for Lifecore pursuant to a written agreement. The agreement contained mutual indemnification provisions, pursuant to which Lifecore and Vital Pharma agreed to indemnify each other in the event either had breached their contractual obligations.

Vital Pharma has notified Lifecore of Lifecore's obligations to defend and indemnify Vital Pharma for these claims. Our insurance carrier has been funding the defense of each of the pending actions. We believe that we have meritorious defenses to these actions. Additionally, except for our responsibility for payment of the insured retention amounts under our product liability policy, we believe that the coverage under the primary and umbrella insurance policies, supplemented by Lifecore's indemnification obligation, provide for adequate coverage for the claims. Also, in light of the early stages of the proceedings we cannot quantify the exposure, if any, to us. In light of the foregoing factors we have not established a reserve for these matters.

(c) We are also involved in other legal proceedings arising in the ordinary course of business. We cannot predict the outcome of our legal proceedings with certainty. However, based upon our review of pending legal proceedings, we do not believe the ultimate disposition of our pending legal proceedings will be material to our financial condition. Predictions regarding the impact of pending legal proceedings constitute forward-looking statements. The actual results and impact of such proceedings could differ materially from the impact anticipated, primarily as a result of uncertainties involved in the proof of facts in legal proceedings.

Item 4. Submission of Matter to a Vote of Securities Holders

Not Applicable

Item 4A. Executive Officers of the Registrant

The Company's executive officers are as follows:

Name	Age*	Positions With the Company
Terry D. Wall	63	President, Chief Executive Officer and Director
Barry Wicker	64	Executive Vice President--Sales and Director
Joseph J. Thomas ** ...	69	President, Thomas Medical Products, Inc. and Director
Alex Chanin	36	Chief Information Officer
Richard Gordon	49	Executive Vice President--Global Operations

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* As of September 30, 2004.

** Mr. Thomas resigned from his position on October 1, 2004

Terry D. Wall founded the Company in 1972 and has been President, Chief Executive Officer and a director of the Company since that time. He has also invested in and serves on the board of directors of certain healthcare businesses'. He received a Bachelor of Science degree in 1963 from the University of Maryland and a Master of Business Administration degree from Pace University in 1975. For the foreseeable future, the Company will remain dependent upon the efforts of Mr. Wall. The Company does not maintain key man life insurance on Mr. Wall's life.

Barry Wicker has served as a director and an Executive Vice President of the Company since 1985 (with primary responsibility for sales and marketing). Mr. Wicker joined the Company in 1978 as National Sales Manager and became Vice President--Sales in 1981. Prior to joining the Company, he held various marketing and sales positions with The Foregger Co. over a 20 year period.

Joseph J. Thomas has served as a director of the Company and President of Thomas Medical Products, Inc. ("TMP") since the Company acquired TMP on October 1, 1992. Prior to the acquisition of TMP, Mr. Thomas was President of TMP from 1990--1992. Mr. Thomas was President and General Manager of Access Devices, Inc., (a catheter manufacturer) from 1982 to 1989 and has held various research and development positions with various companies including Johnson & Johnson. On October 1, 2004 Mr. Thomas resigned his positions as Director and President of Thomas Medical Products, Inc.

Richard Gordon has served as Executive Vice President of Global Operations since January 2004. Mr. Gordon joined the Company in 1982 as Controller and became Vice President for Operations in 1991. Mr. Gordon holds a Bachelor of Business Administration from Baruch College of the City University of New York.

Alex Chanin has served as Chief Information Officer for the Company since January 2004. He has served as President of the Company's Stelex, Inc. Subsidiary from 2003 to 2004 and Vice President of Stelex, Inc. from April 2002 to 2003. Mr. Chanin was one of the founding partners (in 1991) of Stelex prior to the Company's acquisition of Stelex. Mr. Chanin holds Bachelor of Science degrees in Computer Science and Electrical Engineering from Drexel University and a Masters of Science in Computer Engineering from Princeton University.

Each of the Company's executive officers serves as such at the pleasure of the Board.

PART II

Item 5. Market for the Registrant's Common Equity and Related Stockholder Matters

Our Common Stock (the "Common Stock") is traded in the over-the-counter market and quoted on the National Market System of the National Association of Securities Dealers Automated Quotation System ("NASDAQ") under the symbol "VITL". The following table sets forth the high and low closing sales prices of the Common Stock on the NASDAQ National Market System, and the cash dividends declared per share of Common Stock, for the periods indicated:

	High	Low	Dividend Per Share
Fiscal Year Ended September 30, 2003:			
Quarter ended December 31, 2002:	$31.90	$27.69	$.04
Quarter ended March 31, 2003:	30.64	25.53	.05
Quarter ended June 30, 2003:	29.91	21.95	.05
Quarter ended September 30, 2003:	32.94	21.84	.05
Fiscal Year Ended September 30, 2004:			
Quarter ended December 31, 2003:	$34.08	$29.01	$.06
Quarter ended March 31, 2004:	35.75	30.00	.06
Quarter ended June 30, 2004:	34.00	26.70	.06
Quarter ended September 30, 2004:	33.72	27.65	.06

As of September 30, 2004, there were approximately 343 holders of record of the Common Stock. This number of record holders does not represent the actual number of beneficial owners of shares of our Common Stock because shares are

frequently held in "street name" by securities dealers and others for the benefit of individual owners who have the right to vote their shares.

During fiscal 2004, the Company declared and paid cash dividends of $.24 per share. We expect to continue to pay dividends on our Common Stock. However, the declaration of dividends is subject to the discretion of our Board of Directors and will depend upon various factors, including our financial condition, capital requirements, loan agreement restrictions and earnings, as well as such other factors as our board may deem relevant.

The following table gives information about the Company's Common Stock that may be issued upon the exercise of options, warrants and rights under all of the Company's existing equity compensation plans as of September 30, 2004, including the Company's Investment Plan, as amended and restated as of May 30, 2001, 1991 Director Stock Option Plan and 1990 Employee Stock Option Plan, as amended and restated as of December 1, 1997, and the 2002 Stock Incentive Plan. No warrants or rights are outstanding under the foregoing plans.

Plan Category	(a) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	(b) Weighted Average Exercise Price of Outstanding Options, Warrants and Rights	N Rem Fu Equi (E Ref
Equity Compensation Plans Approved by Shareholders	349,329	$26.85	
Equity Compensation Plans Not Approved by Shareholders	165,900	$25.14	
Total:	554,529		

In addition to options granted pursuant to Company benefit plans, the Company, in fiscal 2004 has granted 55,400 stock options to employees independent of any such plans. As such, these options represent contractual commitments by the Company to the individual involved.

The following table provides information about purchases made by the Company of its common stock during the quarter ended September 30, 2004:

	(c)(1) Total Number of	(d)(1)

Period	(a) Total Number of Shares Purchased	(b) Average Price Paid Per Share	Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Dollar Amount That May Yet be Purchased Under the Plans or Programs
7/1/2004-7/31/2004 ...	--	$ --	--	$9,786,708
8/1/2004-8/31/2004 ...	--	$ --	--	$9,786,708
9/1/2004-9/30/2004 ...	16,200	$32.34	16,200	$9,262,207
Total	16,200	$32.34	16,200	$9,262,207

In May 2003, our Board of Directors authorized the expenditure of up to $20 million for the repurchase of Vital Signs' stock. During the year ended September 30, 2004, we repurchased 274,6000 shares for $8.1 million at an average price of $29.66. Any purchases under Vital Signs' stock repurchase program may be made from time-to-time in the open market, through block trades or otherwise. Depending on market conditions and other factors, these purchases may be commenced or suspended at any time or from time-to-time without prior notice.

Item 6. Selected Financial Data

The selected financial data as of and for each of the five years ended September 30, 2004 has been derived from consolidated financial statements that have been audited by Goldstein Golub Kessler LLP, independent certified public accountants. The information set forth below is not necessarily indicative of the results of future operations and should be read in conjunction with our consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" appearing elsewhere in this annual report.

Acquisitions occurring during the past five years, including National Sleep Technologies, Now Sleep Services of America (acquired in June 2000), Breas Medical AB (acquired from June 1997 through April 2002), HSI Medical Services, Inc. (acquired in January 2002), and Stelex (acquired in April 2002) have been accounted for as purchases and, accordingly, are only reflected herein for dates and periods on and after the respective dates noted above.

In September 2002, our Board of Directors adopted a formal plan to sell our Vital Pharma, Inc. subsidiary. Accordingly, we have classified the Vital Pharma business as a discontinued operation. As such, the results of Vital Pharma have not been included in any of the five years presented in the Selected Financial Data schedule set forth below. See Note 2 to the Company's Consolidated Financial Statements. On October 30, 2003, the Company sold its Vital Pharma subsidiary to Pro-Clinical, Inc. No further gain or loss was recorded on the sale. See Note 2 to the Consolidated Financial Statements.

For additional information regarding the NST, Breas, HSI and Stelex acquisitions, see "Management's Discussion and Analysis of Financial Condition and Results of Operations--Overview."

SELECTED FINANCIAL DATA

Income Statement Data:

	Year Ended Septe		
	2004	2003	2002
	(In thousands except p		
Net revenue	$183,991	$182,163	$174,018
Cost of goods sold and services performed	91,374	91,608	86,803
Gross profit	92,617	90,555	87,215
Operating expenses:			
Selling, general and administrative	50,115	51,338	44,216
Research and development	7,036	5,871	6,615
Restructuring charge	539	--	--
Impairment and other charges (credit) (Notes 13)	--	133	(3,428
Goodwill amortization	--	--	--
Other expense (income) net (Notes 1 and 12)	612	717	305
Total operating expenses	58,302	58,059	47,708
Operating income	34,315	32,496	39,507
Other expense (income):			
Interest income	(824)	(654)	(638
Interest expense	26	910	179
Loss on equity investments (Notes 1)	--	--	--
Total other (income) expense	(798)	256	(459
Income from continuing operations before provision for income taxes and minority interest	35,113	32,240	39,966
Provision for income taxes	12,498	12,802	13,225
Income from continuing operations before minority interest	22,615	19,438	26,741
Minority interest	447	248	241
Income from continuing operations(a)	$ 22,168	$ 19,190	$ 26,500
Earnings from continuing operations per common share:			
Basic	$ 1.73	$ 1.49	$ 2.05
Diluted	$ 1.72	$ 1.48	$ 2.03
Basic weighted average number of shares outstanding	12,793	12,905	12,896
Diluted weighted average number of shares outstanding	12,907	12,985	13,036

(a) See our consolidated financial statements for a disclosure of the operating

results and of the discontinued operations of Vital Pharma.

Balance Sheet and Other Data:

	September 30,		
	2004	2003	2002
	(In thousands except per		
Working capital:	$113,241	$ 98,469	$ 86,600
Total assets	235,676	223,078	205,077
Long-term debt, excluding current installments	--	--	1,560
Cash dividends ($0.24 per share in fiscal 2004, $0.19 per share in fiscal 2000-2002)	3,096	2,486	2,070
Total shareholders' equity	216,223	202,222	187,815

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

The following discussion and analysis of our financial condition and results of operations should be read together with the "Selected Consolidated Financial Data" and our financial statements and the related notes appearing elsewhere in this Annual Report. This discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. The actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including but not limited to those described in Exhibit 99.1 to this Annual Report.

Overview

We are a leading designer, manufacturer and marketer of medical products. Many of our products are single-patient use airway products. Our products address the anesthesia and respiratory/critical care markets as well as the sleep/personal ventilation markets and the pharmaceutical technology services market. See Note 20 to the Company's consolidated financial statements for segment information.

In fiscal 2003, we classified our Vital Pharma business as a discontinued operation. Accordingly, the results of Vital Pharma are not included in continuing operations in this "Management's Discussion and Analysis of Financial Condition and Results of Operations." On October 30, 2003, we sold our Vital Pharma subsidiary to Pro-Clinical, Inc. No further gain or loss was recorded on the sale.

Our net revenue was derived from four business segments as follows during the periods indicated:

Products and services	Fiscal Years Ended September 30, 2004	2003	2002
	(In thousands)		
Anesthesia	$ 82,792	$ 75,949	$ 71,823
Respiratory/critical care	42,078	45,829	46,753
Sleep	44,053	45,580	39,628
Pharmaceutical technology services	15,068	18,105	14,175
Rebate allowance adjustment (1)	--	(3,300)	--
Other (2)	--	--	1,639
Total	$183,991	$182,163	$174,018

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(1) Reflects an adjustment made during the second quarter of fiscal 2003. See "Management's Discussion and Analysis of Financial Condition and Results of Operations -- "Critical Accounting Principles and Estimates." This rebate adjustment relates to our anesthesia and respiratory/critical care segment.

(2) "Other" relates primarily to one-time licensing revenue relating to our anesthesia segment recorded in the first quarter of fiscal 2002. See "Management's Discussion and Analysis of Financial Condition and Results of Operations--Critical Accounting Principles and Estimates".

The percentage of our net revenue derived from each of our product lines was as follows during the periods indicated:

Products and services	Fiscal Years Ended September 30, 2004	2003	2002
Anesthesia	45.0%	41.7%	41.3%
Respiratory/critical care	22.9	25.2	26.9
Sleep	23.9	25.0	22.8
Pharmaceutical technology services	8.2	9.9	8.1
Rebate allowance adjustment	--	(1.8)	--
Other	--	--	0.9
Total	100%	100%	100.0%

We sell our products in over 55 countries worldwide. In the U.S., we sell most of our anesthesia and respiratory/critical care products primarily to hospitals using our direct sales force and certain major health care distributors. Outside of the U.S., most of our anesthesia and respiratory/critical care sales have been made through a strategic alliance agreement with a medical device manufacturer and distributor, Rusch GmbH. Our sleep/ventilation products are sold primarily outside of the U.S. through our direct sales force and country-specific distributors.

We compensate our direct sales force principally though salary and commission payments, included in selling, general and administrative expenses. Sales to distributors are made at our established price. When the distributor provides us with documentation verifying that the product has been shipped to an end-user that is entitled to a price lower than our established price, we owe the distributor a rebate equal to the difference between our established price and the lower price to which that end-user is entitled. The allowance for rebates is recorded at the time the Company records the revenue for the product sold to the distributor. We record this sales rebate allowance as a reduction of gross revenue.

Recent Acquisitions

As part of our strategic plan to expand significantly into the obstructive sleep apnea field, we acquired our interests in our Breas Medical AB and Sleep Services of America subsidiaries through a series of transactions over a period of several years:

Breas Medical AB:

- During the period from November 1997 through May 1, 2000, we acquired a 53% ownership stake in Breas for $15.2 million.
- On May 2, 2001, we purchased an additional 41% of Breas from two minority shareholders, for an initial payment of $3.7 million, with an earnout based on a formula of sales and profits.
- The final earnout payment to the two minority shareholders for the additional 41%, totaling $6.5 million, was made in April 2002.
- Our final purchase, amounting to $1.7 million, for the remaining 6% of the minority interest in Breas, was completed in April 2002.
- The total purchase price for Breas was approximately $27 million.

Sleep Services of America:

- In June 1998 through May 1999, we purchased $10.4 million of common stock and convertible preferred stock of National Sleep Technologies, a company engaged in the operation of diagnostic sleep centers.

- In June 2000, we converted our preferred stock into common stock of National Sleep Technologies; at that point, we owned 84% of the common stock.

- On January 1, 2002, our National Sleep Technologies business was merged with HSI Medical Services Corporation, a subsidiary of The Johns Hopkins Health System Corporation, to form Sleep Services of America. No cash was contributed at that time. Instead, we received a 62% equity interest in Sleep Services of America. An affiliate of Johns Hopkins Health System Corporation received a 29% equity interest in Sleep Services of America and the other minority shareholders of National Sleep Technologies received a 9% interest in Sleep Services of America.

- Subsequent to the merger, we paid $775,000 to certain of the minority shareholders to increase our ownership to 70%, and reduce the minority ownership to 1%.

- The portion of Sleep Services of America not owned by us is recorded as a minority interest. See "Results of Operations" for fiscal 2004 and 2003 revenue and operating income information.

Stelex-TVG:

On March 28, 2002, we acquired Stelex Inc. for $13.3 million in cash. Stelex was a private company which, like our subsidiary, The Validation Group, Inc., was engaged in regulatory compliance counseling. We structured the transaction as a merger of Stelex into The Validation Group, renamed the surviving corporation Stelex--The Validation Group, Inc. and accounted for the transaction as a purchase. The subsidiary now operates under the name Stelex, Inc.

Critical Accounting Principles and Estimates

We have identified the following critical accounting principles that affect the more significant judgments and estimates used in the preparation of our consolidated financial statements. The preparation of our consolidated financial statements in conformity with generally accepted accounting principles requires us to make estimates and judgments that affect our reported amounts of assets and liabilities, revenues and expenses, and related disclosures of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, including those related to asset impairment, revenue recognition, allowance for doubtful accounts, and contingencies and litigation. We state these accounting policies in the notes to our consolidated financial statements and at relevant places in this discussion and analysis. These estimates are based on the information that is currently available to us and on various other assumptions that we believe to be reasonable under the circumstances. Actual results could vary from these estimates under different assumptions or conditions.

We believe that the following critical accounting principles affect the more significant judgments and estimates used in the preparation of our consolidated financial statements:

- Through September 30, 2001, we amortized goodwill and intangibles on a straight-line basis over their estimated lives. Upon our adoption of SFAS No. 142 on October 1, 2001, we ceased amortizing goodwill and we perform an annual impairment analysis based upon discounted cash flows to assess the recoverability of the goodwill, in accordance with the provisions of SFAS No. 142. We completed this impairment test during the three month period ended March 31, 2004 and found no impairment. If we are required to record impairment charges in the future, it

would have an adverse impact on our results of operations and financial condition. Goodwill amounted to $69,506,000 at September 30, 2003 and 2004.

- We maintain an allowance for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments, which results in bad debt expense. Our allowance for doubtful accounts was $563,000 at September 30, 2004 and $919,000 at September 30, 2003. We determine the adequacy of this allowance by evaluating individual customer receivables, considering the customer's financial condition and credit history and analyzing current economic conditions. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required.

- Our sales to U.S. distributors are made at our established distributor price. Since the end-user (i.e., a hospital) is typically entitled, on a case by case basis, to a price lower than our established distributor price, the distributor is then due a rebate--the difference between the established price and the lower

price to which the end-user is entitled--when shipment is made to the end user. In order to properly reflect our sales to distributors, we record the gross sale (at our established price), less the amount of the expected rebate, to arrive at the net sale. This net sale is the amount we expect to receive in cash from the distributor on the sale.

On a monthly basis, each distributor provides us with documentation of shipments to particular end-users and computes a rebate claim on such shipments. Once the distributor has provided us with this claim, the distributor will deduct the computed rebate from its net remittance.

The amount of the estimated rebate that has not yet been taken by the distributor through the reduction of a payment is included in the allowance for rebates, which reduces the accounts receivable on our balance sheet. This allowance is calculated by adding (1) the amount of rebates claimed by the distributors through documentation but not yet reimbursed and (2) an estimate by the Company of the amount of future rebates due on any inventory that the distributors are holding at the end of each period.

For several years, we utilized an historical moving average calculation (comparing rebates to sales to distributors) in order to estimate the amount of rebate expense that should be recorded against gross sales in each period. Based upon a review conducted in connection with the filing of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2003, the Company concluded that the required allowance calculated as described in the previous paragraph was greater than previously calculated by means of the historical moving average calculation. As a result of this review of the rebate allowance, we recorded an additional allowance for rebates of

$3,300,000 in the second quarter of fiscal 2003. We have continued to monitor the recorded allowance for rebates, as well as the payments made against this estimate, and believe we are now providing a better estimate of the ultimate rebate our distributors are entitled to than the estimate arrived at through utilization of the historical moving average calculation.

The allowance for rebates was $8,162,000 and $6,156,000 at September 30, 2004 and September 30, 2003, respectively. Rebate expense was $47,809,000 and $44,439,000 for the fiscal years ended September 30, 2004 and 2003, respectively

- We are subject to various claims and legal actions in the ordinary course of our business. These matters frequently arise in disputes regarding the rights to intellectual property, where it is difficult to assess the likelihood of success and even more difficult to assess the probable ranges of recovery. Although we currently are not aware of any legal proceeding that is reasonably likely to have a material adverse effect on our financial position and results of operations, if we become aware of any such claims against us, we will evaluate the probability of an adverse outcome and provide accruals for such contingencies as necessary.

- We have established an allowance for inventory obsolescence. The allowance was determined by performing an aging analysis of the inventory; based upon this allowance, inventory is stated at the lower of cost (first in, first out method) or its net realizable value. In the fourth quarter of fiscal 2004, the Company wrote-off certain inventory amounting to $939,000. Our inventory allowance for obsolescence was $1,150,000 at September 30, 2004 and $981,000 at September 30, 2003.

Accounting Principles. For information regarding new accounting principles, see Note 1 of our notes to consolidated financial statements.

Results of Operations

The following table sets forth, for the periods indicated, certain statement of income data as a percentage of our revenue.

	Fiscal Years Ended September 30,		
Consolidated Statement of Operations Data:	2004	2003	2002
Net revenue	100.0%	100.0%	100.0%
Gross profit	50.3	49.7	50.1
Operating expenses	31.7	31.9	27.4

Income from continuing operations	12.0	10.5	15.2
Net income	12.0	7.8	14.4

Comparison of Results for the Year Ended September 30, 2004 to the Year Ended September 30, 2003

Net Revenue. Total net revenue increased 1.0%, from $182.2 million for the year ended September 30, 2003 to $184.0 million for the year ended September 30, 2004. Of the 1.0% increase, (a 0.9% decrease excluding favorable foreign exchange rates). Of our total revenues, $137.4 million (or 74.7%) were derived from domestic sales and $46.6 million (or 25.3%) were derived from international sales. Domestic revenues increased 0.4%, from $136.9 million for the year ended September 30, 2003 to $137.4 million for the year ended September 30, 2004. The 0.4% increase resulted from a 9.0% increase in our Anesthesia segment which offset declines in our Respiratory/Critical Care, Sleep and Pharmaceutical Technology Services segments. International revenues increased 2.8% (a 4.6% decrease excluding foreign exchange), from $45.3 million for the year ended September 30, 2003 to $46.6 million for the year ended September 30, 2004, principally from favorable foreign exchange rates. Following are the net revenues by business segment for the year ended September 30, 2004 compared to the year ended September 30, 2003.

REVENUE BY BUSINESS SEGMENT

	For the Year Ended September 30,		Percent
	2004	2003	Change
Anesthesia	$ 82,791	$ 75,949	9.0%
Respiratory/Critical Care	42,079	45,829	(8.2%)
Sleep	44,053	45,580	(3.4%)
Pharmaceutical Technology Services	15,068	18,105	(16.8%)
Rebate allowance adjustment	--	(3,300)	N/A
	$183,991	$182,163	1.0%

The rebate allowance of $3.3 million relates to our anesthesia and respiratory/critical care segments. Refer to Footnotes 1 and 18 of the Notes to Consolidated Financial Statements for a description of the rebate allowance.

Sales of anesthesia products increased 9.0% from $75.9 million for the year ended September 30, 2003 to $82.8 million for the year ended September 30, 2004. This increase was due to volume growth in anesthesia circuits, including our Limb-O'TM', our patented anesthesia circuit, sales of which increased 70.5% to $8.2 million, a 12.0% increase in sales of traditional anesthesia circuits to $25.0 million and volume increases in our Thomas Medical Products subsidiary. Domestic sales of anesthesia products increased 8.7%, from $69.8 million to $75.9 million. International sales of anesthesia products increased 12.4%, from $6.1 million to $6.9 million, principally from the European distribution agreement with Rusch.

Sales of respiratory/critical care products decreased 8.2%, from $45.8 million for the year ended September 30, 2003 to $42.1 million for the year ended September 30, 2004. Domestic sales declined 11.6%, from $33.2 million to $29.3 million, resulting from increased competition within the segment.

International sales of respiratory/critical care products increased 0.8% from $12.7 million for the year ended September 30, 2003 to $12.8

million for the year ended September 30, 2004, reflecting higher sales volumes through our distributor arrangement in Europe with Rusch.

Our sleep segment revenues decreased 3.3% (a decrease of 10.2% excluding favorable foreign exchange), from $45.6 million for the year ended September 30, 2003 to $44.0 million for the year ended September 30, 2004. Sleep Services of America's revenues decreased 5.8% from $18.2 million for the year ended September 30, 2003 to $17.1 million for the year ended September 30, 2004. SSA has closed 14 sleep labs that had not returned the appropriate margins; however it has opened 9 new sleep labs in fiscal 2004. In the continuing sleep labs, revenue has increased 16.1%. Pre-tax margins in our SSA business improved to 14.3% for the year ended September 30, 2004, as compared to 7.4% in the comparable period last year. Revenues at our Breas subsidiary decreased 1.7% (a decrease of 12.8% excluding favorable foreign exchange) from $27.4 million for the year ended September 30, 2003 to $26.9 million for the year ended September 30, 2004, resulting from increased competition in our ventilator product line and from discontinuing certain OEM products as a result of the increased focus on our own manufactured products

Service revenues in the Pharmaceutical Technology Services segment decreased 16.8%, from $18.1 million for the year ended September 30, 2003 to $15.1 million for the year ended September 30, 2004. Our larger pharmaceutical customers have reduced their external resource usage with regards to 21 CFR Part 11 FDA regulatory compliance needs. Revenues trends in the Pharmaceutical Technology Services segment have leveled off to approximately $3.7 million in each of the last five quarters.

Cost of Goods Sold and Services Performed. Cost of goods sold and services performed decreased 0.2% from $91.6 million for the year ended September 30, 2003 to $91.4 million for the year ended September 30, 2004.

Cost of goods sold increased $1.5 million, or 2.1%, from $71.9 million for the year ended September 30, 2003 to $73.4 million for the year ended September 30, 2004. The increase resulted primarily from sales volume increases in our anesthesia and respiratory/critical care segments. Increases due to inventory adjustments (due in part to the closing of our California plant) were offset by the planned reduction of costs at our New Jersey, Colorado, and Minnesota facilities of approximately $900,000.

Cost of services performed decreased 9.1%, from $19.7 million for the year ended September 30, 2003 to $17.9 million for the year ended September 30, 2004, resulting primarily from reduced sales volumes in our Pharmaceutical Technology Services segment and at Sleep Services of America, our sleep diagnostics company, where the business has closed 14 sleep labs that had not returned the appropriate margins.

Gross Profit. Our gross profit increased 2.3%; from $90.6 million for the year ended September 30, 2003 to $92.6 million for the year ended September 30,

2004. Our overall gross profit margin was 50.3% for the year ended September 30, 2004 and 49.7% for the year ended September 30, 2003.Gross profit information related to our four segments was:

	Fiscal Year Ended September 30,	
	2004	2003
Anesthesia	54.4%	53.8%
Respiratory/CriticalCare	51.8%	54.3%
Sleep	45.3%	43.7%
Pharmaceutical Technology Services	38.6%	45.2%
Total	50.3%	49.7%

Gross profit improvements in our anesthesia segments resulted from sales volume increases at Thomas Medical Products and cost improvement projects at our New Jersey plant. The declines in